

**STRATEGIC IMPLEMENTATION OF AN
ANTICOAGULATION MANAGEMENT SERVICE IN A
COMMUNITY-BASED PHARMACY SETTING**

By

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ABSTRACT

The drug warfarin is used for the prevention or treatment of arterial and venous thrombosis. Managing this drug is challenging due to its narrow therapeutic window, as well as, ongoing, time-consuming, laboratory blood tests to avoid potentially life-threatening complications. The introduction of point-of-care testing technology has given pharmacists an opportunity to provide an alternative and more effective solution. Through a collaborative effort, pharmacists can provide a service involving on-site INR blood tests and disease management.

External forces, such as health reform due to rising costs, increase utilization of prescriptions, and a growing demand for better health services from an aging population, allows pharmacists to take a leadership role in primary health care. This timing has never been better for community pharmacists to offer anticoagulation services.

Business leaders must decide what level of involvement is best for their organization. Three differentiated anticoagulation management strategies exist, depending on the firm's internal capabilities.

Keywords: Anticoagulation, Coaguchek S, Community Pharmacy, INR, International Normalized Ratio, Pharmacists, Pharmacist-managed Anticoagulation Service, Warfarin

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TABLE OF CONTENTS

Approval	ii
Abstract	iii
Acknowledgements	iv
Table of Contents	vi
List of Figures	viii
List of Tables	ix
Glossary	x
Introduction	1
1.1 Background.....	3
1.2 Antithrombotic Therapy	4
1.2.1 Warfarin Underutilized.....	5
1.2.2 Narrow Therapeutic Window	6
1.3 Anticoagulation Monitoring	7
1.3.1 Usual Care – Low Cost Strategy	7
1.3.2 International Normalized Ratio (INR).....	9
1.3.3 New Point-of-care Testing Technology – Self-Monitoring In Canada	11
1.4 Alternative Strategies to Anticoagulation Management	12
2 External analysis	15
2.1.1 Supplier Bargaining Power – Very Low to High Power	17
2.1.2 Buyer Power – High	23
2.1.3 Threats of Substitutes – High	31
2.1.4 Threat of Entry – Moderate to High	46
2.1.5 Government– High Bargaining Power	51
2.2 Key Success Factors	59
2.2.1 Rivals in the Retail Pharmacy Industry	60
2.2.2 Rivalry	62
2.2.3 Key Success Factors and Rivalry Intensity	67
2.3 Opportunities	69
2.4 Threats	73
2.4.1 Physician Acceptance.....	73
2.4.2 Patient Acceptance	76
2.5 Recommended Anticoagulation Strategy	77
3 Internal Analysis	80
3.1 Management Preferences	80
3.2 Organization Analysis	82
3.2.1 Organization Structure	82
3.2.2 Organization Systems	86
3.2.3 Organizational Culture	92

3.3	Resource Analysis.....	94
3.3.1	Human Resource.....	94
3.3.2	Equipment and Facility.....	100
3.3.3	Marketing Plan	101
3.4	Market Potential.....	109
3.5	Summary of Internal Analysis	115
4	Recommendations.....	118
4.1	Key messages for Decision-makers	119
	Bibliography.....	122
	Work Cited and Consulted.....	122
	Internet Sources.....	127

LIST OF FIGURES

Figure 1:	Warfarin's Narrow Therapeutic Window	6
Figure 2:	Sample of Altering Warfarin Dosage to Achieve INR of 2.0 to 3.0	9
Figure 3:	Traditional Lab Service Value Chain	11
Figure 4:	Summary of Porter Five Forces on Pharmacy-managed Anticoagulation Service	16
Figure 5:	Warfarin percent Prescription share in 2003 by Brand	23
Figure 6:	Anticoagulation Service Matrix	47
Figure 7:	Retail Pharmacies in Canada 2006	60
Figure 8:	Competitive Analysis of Other Key Activities.....	77
Figure 9:	Pharmacy On-site INR Testing and Anticoagulation Management	79
Figure 10:	Patient-Centered Anticoagulation Care.....	84
Figure 11:	Organizational Chart	85
Figure 12:	Overview of Patient-specific Pharmacist Care Plan – Anticoagulation Therapy	87
Figure 13:	Pharmacy Owners' Response to Pharmacy Shortage.....	94
Figure 14:	Technology-enhanced Dispensary Activities	100
Figure 15:	Five-year Financial Outlook.....	113
Figure 16:	Combined Patient Self-management and Pharmacist-driven Anticoagulation Service	115

LIST OF TABLES

Table 1:	Alternative Strategies to Anticoagulation Therapy in Pharmacy	14
Table 2:	Point-Of-Care Devices	21
Table 3:	Coaguchek S® Pricing Schedule.....	38
Table 4:	Fixed Costs 5-year Forecast	39
Table 5:	Break-even Analysis.....	39
Table 6:	Forecast Sale of Coaguchek S®	40
Table 7:	Competitive Strategies vs. Retail Pharmacy Format.....	51
Table 8:	Emerging Anticoagulants	52
Table 9:	Evolution of Today's Pharmacy	63
Table 10:	Competitive Analysis of Pharmacy Services	65
Table 11:	Key Success Factors for Anticoagulation Management.....	68
Table 12:	Opportunities with Point-of-care Technology.....	72
Table 13:	Profile of the Average Retail Pharmacy	82
Table 14:	Pharmacy Workload Analysis	97
Table 15:	Pharmacist Adjusted Hours	98
Table 16:	Anticoagulation Workload	99
Table 17:	Equipment and Facility Costs.....	101
Table 18:	Anticoagulation Service	102
Table 19:	Pharmaceutical Services & Fees	105
Table 20:	Fixed Costs per Pharmacy Store Location	107
Table 21:	Anticoagulation Management Variable Costs.....	107
Table 22:	Break-even Analysis.....	108
Table 23:	Warfarin Prescriptions and Sales.....	110
Table 24:	Anticoagulation Management Service - Setup Costs	111
Table 25:	Coaguchek S Pricing Schedule.....	113
Table 26:	Five-Year Coaguchek S® Sales Forecast.....	114
Table 27:	Summary of Internal Requirements.....	116

GLOSSARY

Anticoagulants	drugs that make the blood less likely to form harmful clots in the blood vessels by slowing or inhibiting the process of coagulation (clotting).
Atrial Fibrillation (AF)	a condition where the upper part of the heart (atrium) beats faster than the rest of the heart. This leads to poor cardiac output.
Antithrombotic Therapy	an agent that prevents or interferes with the formation of blood clots.
Coagulation	a process involving a cascade of events that stops the process of bleeding in order to prevent significant blood loss from trauma or injury to the blood vessel.
Collaborative Agreement	an agreement between the pharmacist and physician where the physician delegates management authority to the pharmacist in a formal contractual arrangement. The agreement can include ordering laboratory tests, assessing patients, initiating and modifying drug therapy, monitoring patients and administering drugs.
Deep Vein Thrombosis (DVT)	a harmful blood clot in a vein of the body, most commonly in the lower limbs, involving the superficial large veins, veins of the large calf, and deep veins above the knee.
Embolus	usually a small blood clot that has broken away from a thrombus and forms an obstruction in the bloodstream. An embolus usually forms in the heart and in the arteries that take blood to the brain.
International Normalized Ratio (INR)	a standardized system to measure the blood coagulation effects of warfarin.
Myocardial Infarction (MI)	a myocardial infarction is the clinical term for a heart attack. A heart attack is the death of heart muscle from the sudden blockage of a vessel supplying blood to the heart.
Narrow Therapeutic Window (or Index)	a relatively low margin between safety and toxicity.

Notice of Compliance (NOC)	a notification from Health Canada indicating that a pharmaceutical company has complied with the <i>Food and Drug Regulations</i> . Notices of Compliance are issued to a pharmaceutical company following the satisfactory review of a drug submission.
Phase I clinical trials	scientists test a new drug or treatment (“the study drug”) in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
Phase II clinical trials	the study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.
Phase III clinical trials	the study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
Stroke	the death of brain tissue resulting from the sudden lack of blood flow and insufficient oxygen to the brain. This is due to either a blockage (ischemic stroke) or a rupture of a blood vessel in the brain (hemorrhagic stroke).
Study Phase	clinical trials of a new drug or treatment that are described as phase I, II, or III, based on the type of questions that the study is seeking to answer.
Thrombosis	a blood clot formation which can impede blood flow and oxygen delivery to a major organ, potentially causing damage and death to cells.
Thrombocytopenia	any disorder in which there are not enough platelets in the blood. Platelets are cells in the blood that help blood to clot. This condition is sometimes associated with abnormal bleeding.
Thrombophilia	the potential to develop blood clotting in the veins or arteries. This condition may be present at birth (congenital or inherited), or may occur as a result of another condition (acquired).
Warfarin	an oral anticoagulant agent used to treat thromboembolic disease.

INTRODUCTION

The purpose of this paper is to discuss the strategic implementation of an anticoagulation service in community pharmacy. The paper will highlight the opportunities, challenges, requirements, and gap-closing solutions which community pharmacists may face in launching this initiative. A thorough industry analysis of the anticoagulant market will serve as part of the external analysis; follow by identifying key success factors and internal capabilities that are necessary to determine the market attractiveness and feasibility of this initiative. This project will serve as a blueprint for retail pharmacies that wish to take a differentiated strategy approach to their business, and transform their dispensary services to include pharmaceutical care services. No specific attention is placed on any particular retail format; however, the paper recognizes there are unique competitive advantages within each pharmacy retailer and, in some situations, make general strategic assumptions. Many of the internal capabilities of each format are difficult to ascertain due to the nature of this paper.

Reforms in the Canadian health care system continue to change the retail pharmacy landscape. Pharmacists' expanded scope of practice, and primary health care roles and responsibilities continue to be a topic of discussion by various stakeholders: governments, professional associations, academia, the pharmaceutical industry, and other healthcare organizations. According to the Romanow "Commission on the Future of Health Care in Canada", there is a move towards a health management approach by "linking medication management to primary health care."¹ People with chronic diseases should have access to a range of health care providers such as physicians, nurses, dietitians, and pharmacists, working together to monitor and manage their health. To this end, pharmacists can play a key role on the primary

¹ Romanow RJ, November 2002, Health Care Renewal: Building on Values. Commission on the Future of Health Care in Canada, Final Report, Chapter 9; p189-210.

health care team, consulting with physicians and patients, monitoring patients' medication use, providing better information on prescription drugs, and, in some cases, prescribing certain drugs under specific conditions.

This expanded role of pharmacists coupled with an ever increasing competitive retail environment places pharmacists in a vulnerable position. Currently, there is no consistent compensatory model for disease management driven by the profession. Pharmacists, however, must take proactive steps and prepare for change through the integration of prescription drugs and chronic disease state management. In time, those that plan and prepare for change will likely survive. Today, those pharmacy business leaders that struggle to gain and sustain market share, explore differentiation strategies that emphasize value more than price to gain a competitive advantage. The increasing entrance of box store retailers, offering a "one-stop-shop" concept and a low-cost strategy approach to their value proposition, is significantly impacting the retail pharmacy market. Community pharmacy's role in anticoagulation monitoring service may be one solution to counter the competitive environment.

Anticoagulation management is traditionally the physician's role. However, this role may not be the ideal arrangement, given that there are significant concerns with the system of warfarin management²: limited warfarin dosing expertise, sub-therapeutic warfarin dosing³, warfarin under prescribed,⁴ and inefficient laboratory monitoring and follow-up. Pharmacists may be well-positioned to take on this initiative. Several practice models have been used in the US, Australia, and Europe. This paper will examine three potential anticoagulation management strategies: (1) patient point-of-care self-monitoring; (2) community-based pharmacy onsite point-of-care testing;

² Ansell J, Buttaro ML, Thomas OV, et al. Consensus guidelines for coordinated outpatient oral anticoagulation therapy management. *Ann Pharmacother* 1997;31:604-615

³ Schaufele MK, Marcielio MA, Burke DT. Dosing practices of physicians for anticoagulation with warfarin during inpatient rehabilitation. *Am J Phys Med Rehabil* 2000 Jan-Feb;79(1):69-74

⁴ Wenger NK, Scheidt S, Weber MA. Anticoagulation at elderly age: the challenge to do better. *Am J Geriatr Cardiol* 2003 May-Jun;12(3):152-152.

and (3) pharmacist-managed anticoagulation service. From these three, a strategy will be selected that meets the following criteria: improved patient clinical outcomes, expanded scope of the pharmacy profession, and increased direct and indirect economic benefits to the community pharmacy.

1.1 Background

Oral anticoagulants, such as warfarin, are effective for the prevention and treatment of venous and arterial thrombosis in a variety of health conditions.⁵ For these prescription medications to be safe and effective, regular monitoring is required. In most patients, conventional monitoring involves travel to a blood-test center to withdraw blood samples to be sent to a laboratory for analysis. To ensure the patient's blood coagulation levels are optimized, the international normalized ratio (INR) is measured. The INR results are returned to the patient's doctor within 24 to 48 hrs for interpretation.⁶ Medication dosage changes may be required from the test results in which the patient is contacted and a new prescription is issued. Regular blood tests and dosage changes are ongoing until the anticoagulant therapy is in the therapeutic range. This process could take several months. From the patient's perspective, this may impact their quality of life, and as result, be a contributing factor to poor adherence to their medication regimen and inconsistent monitoring.

Due to the continuing sustained increase in the number of patients receiving oral anticoagulation therapy, recent advances in technology have enabled patients and health care professionals to better monitor anticoagulation therapy through the use of portable point-of-care INR testing devices for self-monitoring and point-of-care testing.⁷ In December 2003, Roche

⁵ Anderson DR, Cox JL, MacLellan E, Martell C, Monette K, Morash T, Wilson S J. A Pilot Study Evaluating the Feasibility of Monitoring Oral Anticoagulant Therapy with Point-of-Care Testing in a Community Pharmacy. *CJHP* 2004; 57: 158-164.

⁶ Anderson DR et al, 2004.

⁷ Fitzmaurice DA, McCahon D, Murray ET. Point of care testing for INR monitoring : where are we now ? *British Journal of Haematology* 2004;127:373-378.

Diagnostics announced the launch of a portable self-testing coagulation monitoring system, CoaguCheck S monitor, in the province of Quebec. It has been recognized for many years that coagulation self-monitoring and point-of-care testing has been largely accepted and practiced in other countries such as Europe, Australia and the US. Several clinical studies support various point-of-care practice models which facilitate the patients' involvement in anticoagulation management, improvement of patient health outcomes, and enhanced quality of life.

With the recent availability of a point-of-care testing technology, pharmacists are not only in a position to simplify oral anticoagulation management in both the physician's office and the patient's home, but also further expand their scope of practice and create a business case for disease state management and medication management in the retail pharmacy market.

1.2 Antithrombotic Therapy

Warfarin is a prescription medication in Canada that is widely used since the 1950's.⁸ In 2005, 3,876,000 prescriptions were dispensed: an increase of 7.3 percent from 2004, with an average compounded rate of 11 percent from 2001 to 2005.⁹ Specifically, the drug's common indications of use include:

- Deep Vein Thrombosis (DVT) – blood clots in the leg veins
- Pulmonary Embolism (PE) – blood clots in the lungs
- Patients with congenital risk factors
- Cerebral Vascular Accident (CVA) or Stroke – caused by clot formation in the brain
- Patients who are at high risk for blood clot formation due to:
 - Atrial fibrillation (AF)
 - heart valve replacement surgery

⁸ Hirsh J, Dalen JE, Andersen DR, Poller L, Bussey H, Ansel J, et al. Oral anticoagulants: mechanism of action, clinical effectiveness, optimal therapeutic range. *Chest* 2001;119:8S-21S.

⁹ IMS, 2005 Pharmaceutical Industry Review.

- Post myocardial infarction (heart attack)
- Recent stroke
- Recent heart bypass surgery
- Severe congestive heart failure
- Thrombophilia – tendency to clot
- Peripheral occlusive artery disease

Warfarin is used in 67 percent of patients with DVT and PE¹⁰, 20 percent of patients with stroke¹¹, 40 percent in patients with AF¹², and 100 percent in patients with mechanical heart valves.¹³

1.2.1 Warfarin Underutilized

Warfarin's main indications for life-long use are heart valve replacement, atrial fibrillation, and multiple blood clots. Several clinical studies conclusively demonstrate that long-term anticoagulation therapy can reduce the risk for stroke by 68 percent per year in patients with non-valvular atrial fibrillation, and even higher in patients with valvular atrial fibrillation.¹⁴ However, a large body of evidence conclude that anticoagulation treatment is under-used in patients with atrial fibrillation despite proven efficacy.¹⁵ The benefit of warfarin is not entirely

¹⁰ Stein PD, Beemath A, Olson RE, Trends in the incidence of pulmonary embolism and deep venous thrombosis in hospitalized patients, *Am J Cardiol.* 2005 Jun 15;95(12):1525-6., Abstract, NCBI PubMed

¹¹ Heart and Stroke Foundation of Canada, Stroke statistics 2002, Web: <http://ww2.heartandstroke.ca/Page.asp?PageID=33&ArticleID=428&Src=stroke&From=SubCategory>.

¹² J. Sztajzel, H. Stalder, Atrial Fibrillation, *PrimaryCare* 2003; 3:695-699, p. 699

¹³ Heart and Stroke Foundation of Canada, 2003, *The Growing Burden of Heart Disease and Stroke*, p.43 fig.2-27, fig.2-28

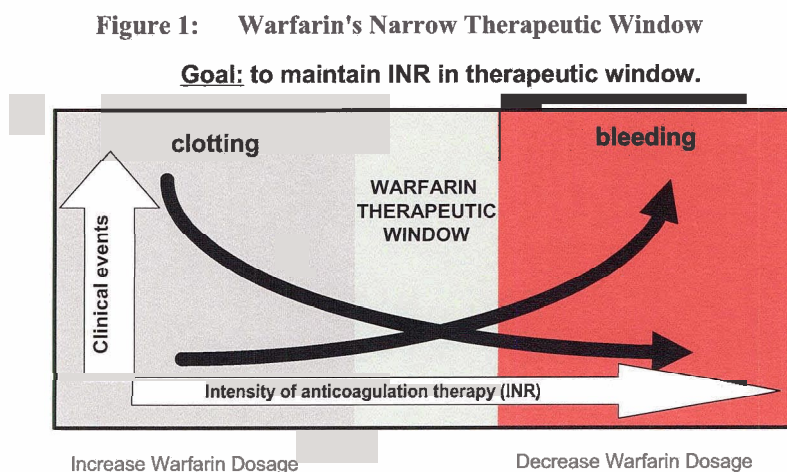
¹⁴ Bungard TJ, Ghali Wa, Teo KK, McAlister FA, Tsuyuki RT. Why do patients with atrial fibrillation not receive warfarin? *Arch Intern Med.* 2000 Jan 10;160(1):41-6.

¹⁵ Carlsson J, Miketic S, Dees S, Haun A, Cuneo A, Tebbe U. Stroke prevention practice in patients with atrial fibrillation and pacemaker therapy: Evidence for under-use of anticoagulation. *The European Society of Cardiology* (2000) 2, 115-118

realized because anticoagulation therapy is either not chosen or not done well¹⁶. This underutilization occurs in rural communities, community and tertiary hospitals, and nursing home and long-term care facilities. Other studies state that only 15 to 44 percent of cases of atrial fibrillation are treated with warfarin, and that the underutilization of warfarin has been identified to be patient-, physician-, and health care system-related barriers. To improve anticoagulation management, a number of studies suggest that patient self-monitoring of oral anticoagulation leads to a 1/3 reduction in deaths, leading to better therapeutic outcomes. This is possibly due to more frequent testing by the patient.

1.2.2 Narrow Therapeutic Window

The level of anticoagulation must be maintained within a narrow therapeutic window¹⁷. If not adequately monitored, falling outside the range, could lead to thromboembolic or clotting events such as a stroke or pulmonary embolism, while excessive anticoagulation could place the patient at risk of haemorrhaging or bleeding. (See figure 1). Increasing or decreasing the dosage of warfarin will be necessary, depending on the INR values.



¹⁶ Buckingham TA, Hatala R, Anticoagulants for atrial fibrillation: why is the treatment rate so low?, Clin Cardio, Vol 25, 2002, p.447-454.

¹⁷ European Atrial Fibrillation Trial Study Group. Secondary prevention in non-rheumatic atrial fibrillation after transient ischaemic attack or minor stroke. Lancet 1993;342:1255-62.

“Warfarin has been shown to prevent 20 strokes for every bleeding episode associated with its use”.¹⁸ Consequently, regular warfarin dosage changes and blood tests are critical in helping the patient stay healthier and live longer. The prescribing dosage adjustments must avoid hemorrhagic complications while balancing thrombosis (clotting) suppression.

Furthermore, the management of warfarin therapy is comprehensive and complicated by many other factors including medication interactions, therapy in elderly patients, acute and chronic diseases, diet and nutrition, and inter- and intra-individual variability in responding to warfarin.¹⁹ For this reason, once a patient is prescribed warfarin medication therapy, time-intensive routine laboratory testing is necessary and significantly impacts a patient’s quality of life.²⁰ For most indications, the warfarin dose is adjusted to maintain the patient’s INR at 2 to 3.²¹ However, only 33 percent to 63 percent of the time, patients are in this optimal range, which suggests a better model for anticoagulation management is necessary.²²

1.3 Anticoagulation Monitoring

According to Roche, there are about 600,000 anticoagulation patients in Canada, with 42,000 new cases each year (+7 percent). Based on these values, greater than 11 million INR tests are performed in a lab each year.

1.3.1 Usual Care – Low Cost Strategy

Laboratory services are covered by the Medical Service Plan (MSP) in BC and are influenced by governmental budgetary constraints. Subsequently, private laboratories take a low

¹⁸ <http://www.aafp.org/afp/990201ap/635.html>

¹⁹ Bringing the benefits of anticoagulation management services to the community. CPJ/RPC; March/April 2006, volume 139, No 2.

²⁰ Lane D, Lip GY. Anti-thrombotic therapy for atrial fibrillation and patient’s preferences for treatment. Ageing. 2005;34:1-3.

²¹ www.aafp.org/afp/9909201ap/635.html.

²² McCall KL, MacLaughlin EJ. Ximelagatran: a new era in oral anticoagulation. J Pharm Technol 2003;19:222-8.

cost strategy approach to their business. This is also illustrated by the following variables that constitute the firm's strategic fit:

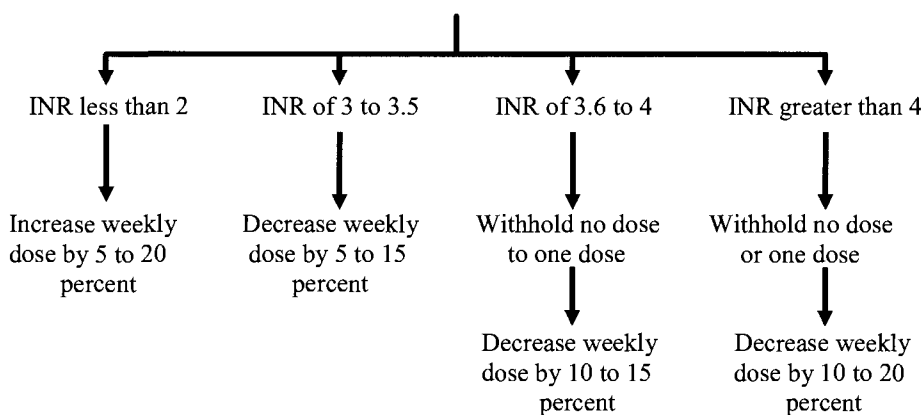
- **R&D costs** – since blood tests are funded by the provincial government, minimal or no funds are invested into innovation.
- **Product strategy** –lab tests are simple and don't require on-going innovation. Patients will not perceive any added-value by innovating blood tests. In fact, costs are seamless to the patient. Patients are queued through the lab in first-come-first-serve (i.e. work-in-progress) basis. They pick a number to secure their place in line for the next available lab technician.
- **Centralization** – lab tests are centralized and limited to most major urban centres. Patients in rural communities have difficulty accessing labs, and must travel great distances or to hospital centres for lab tests.
- **Labour** – facilities are set up to accommodate high turnover, and therefore, the skill sets are based on a mass production model. Highly skilled employees are not required for this level of performance. A simple venous puncture is required and a sample is sent off for analysis by a lab technician.
- **Decision-making** – a protocol and guidelines for INR testing outlines the lab process, which minimizes autonomy in the decision-making process.
- **Marketing** – there is no or very minimal investment in marketing lab services as INR tests are requisitioned by the physician. This is similar to a push-strategy.
- **Risk Level** – To keep costs low, the labs risk profile is low.

1.3.2 International Normalized Ratio (INR)

When a person on anticoagulation medication has a laboratory blood test, the INR value is calculated from the results. This INR value allows the doctor to determine how the medication is working and whether the warfarin dose is appropriate for the patient. Adjusting the dosage of the medication helps keep the INR value of the blood in the optimal range. Often, several dosage changes are required over a 3 to 6 month period.

When patients are initiated on warfarin, INR monitoring should be performed on a daily basis until the INR is within the therapeutic range for at least two consecutive days. INR laboratory blood tests are then generally performed two to three times per week for one to two weeks or until stable. As the INR target value is reached and maintained, the time between tests can be lengthened, however, the maximum period between laboratory tests should be no more than 4 to 5 weeks.²³ If adjustments to the dosage are necessary, INR monitoring is performed more often until stabilization of the new state is achieved. For example, when an interacting drug is prescribed or discontinued or the dosage is modified. Below is an example of an algorithm for establishing percentage change in weekly warfarin dosage to achieve an INR of 2 to 3.

Figure 2: Sample of Altering Warfarin Dosage to Achieve INR of 2.0 to 3.0



²³ <http://www.tigc.org/eguidelines>

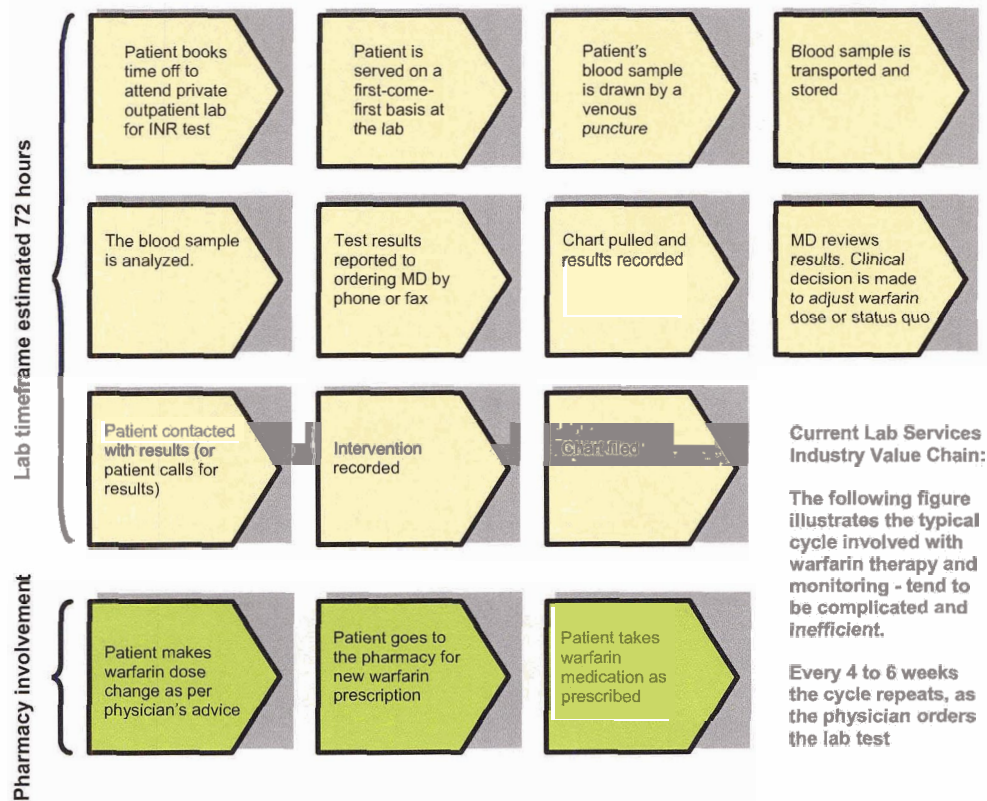
The duration of anticoagulation therapy varies depending on the patient's medical condition and risk factors. This timeframe ranges anywhere from 3 months to life-long treatment. Warfarin therapy is often started with 5 to 10 milligrams (mg) tablets once daily; it generally requires 5-7 days of treatment to obtain a stable INR and anticoagulation effect. The warfarin dosage changes are based on the frequent INR lab values – once stabilized, the dose adjustments are increased or decreased by 10 to 20 percent, accordingly, to maintain a desired INR range.

If there are unexpected fluctuations of the INR when the patient is generally stabilized, a thorough investigation is necessary. Often it is related to one or more causes such as a change in diet, missed warfarin dose or other related compliance issues, use of alcohol consumption, and/or self-medications. Regular testing is required along with dosage adjustments until the patient's INR levels are restored to therapeutic levels.

Once therapeutic levels have been achieved, regular INR laboratory testing is a continual disruption to daily living, compounded by the associated dietary and lifestyle changes, concomitant medication requirements, regular physician and pharmacy visits, and warfarin therapy changes over the long-term. Proper patient education of their anticoagulation therapy is required to improve patient outcomes and avoid potential complications and adverse events.²⁴ Traditional low-cost lab-based anticoagulation monitoring is complicated and an inefficient process as illustrated in figure 3.

²⁴ McLachlan, Spindler, Fois, Krass, Chen, and Bajorek, A Community pharmacy based anticoagulant management service, Australia. August 2005.

Figure 3: Traditional Lab Service Value Chain



This course of action is repeatedly long, difficult, uncomfortable and costly. While patients currently do not pay for the direct cost of care (i.e. doctor visits, blood sampling and INR analysis), there are a number of indirect costs that are overlooked such as parking, taxi fares, transportation of caregiver (i.e. if patient is not mobile), and absenteeism. Frequently, the patient's doctor may fail to call the patient back if test results are acceptable, leaving the patient unaware about their health status and subsequently having to contact their physician for more information.

1.3.3 New Point-of-care Testing Technology – Self-Monitoring In Canada

Roche Diagnostics' recent launch of the CoaguChek S®, a portable device for monitoring INR blood levels, has revolutionized the monitoring of oral anticoagulation therapy. The use of

point-of-care monitoring has many advantages including decreased turnaround time, decreased use of resources, decreased risk of errors from handling and labelling lab specimens, decreased loss of blood, and improved patient satisfaction.²⁵ Point-of-care testing can also improve outcomes as it encourages rapid and frequent testing which can result in timelier warfarin dosage changes.

1.4 Alternative Strategies to Anticoagulation Management

While warfarin therapy has been shown to be efficacious in preventing clotting disorders, many patients remain under-treated.²⁶ This suboptimal therapy highlights the need for alternative strategies and a need for change in the current health care system. According to a 2004 Canadian survey, anticoagulation services in community and hospital pharmacies were uncommon and limited to tertiary care centres and a few primary and secondary hospitals.²⁷ The level of expertise at these sites showed pharmacists to have from none to full certification according to the survey.

There have been many clinical studies in Europe, Australia and the US which explore various models of anticoagulation management, from patient self-monitoring to pharmacist involved anticoagulation services in private physician clinics, university-affiliated clinics, health maintenance organizations and community pharmacies.²⁸ The models vary with the level of delivery from one-on-one, comprehensive pharmacist consultations to centralized telephone-based monitoring services. One particular study suggests patient self-monitoring and management improves the quality of oral anticoagulation therapy.²⁹ These patients' health outcomes show

²⁵ Reiss RA, Haas CE, Griffis DL, Porter B, Tara MA. Point-of-Care Versus Laboratory Monitoring of Patients Receiving Different Anticoagulant Therapies. *Pharmacotherapy* 2002.

²⁶ Bungard TJ, Hamilton P, Tymchak W, Bringing the benefits of anticoagulation management services to the community. *CPJ/RPC* March/April 2006; 139

²⁷ Leong WA, Anticoagulation: Opportunities for community pharmacists. *Pharmacy Practice*. Nov 2004. Continuing Education Supplement.

²⁸ Wilson SJ, Wells PS, Kovacs MJ, et al. Comparing the quality of oral anticoagulant management by anticoagulation clinics and by family physicians: a randomized controlled trial. *CMAJ* 2003;169:293-8.

²⁹ Alonso-coello P, Garcia-Alamino JM, Glasziou P, Heneghan C, Meats E, Perera R. Self-monitoring of oral anticoagulation: a systematic review and meta-analysis. *The Lancet* 2006; 367:404-411.

fewer thromboembolic events and lower mortality than those who self-monitor alone. The study further suggests self-monitoring is not appropriate for all patients, and that education by a health professional is an essential component to self-monitoring.

In Canada, studies at the University of Alberta, in collaboration with Alberta Capital Health, suggest the use of the existing provincial health care infrastructure, specifically community pharmacist, to offer anticoagulation management services. The researchers used a physician-supervised, pharmacist-managed anticoagulation service which systematically evaluated and monitored patients on warfarin therapy.³⁰ Pharmacists provide ongoing patient education and served as a resource for patients. They also provided warfarin dosage changes under a collaborative agreement with the physician. These non-randomized studies compared usual care vs. pharmacist-managed anticoagulation clinics.

With the advent of INR point-of-care testing, pharmacists working in community pharmacies can become certified and offer INR testing and anticoagulation management in-store. Table 1 is a summary of the various differentiated strategies to improve anticoagulant control, which can be potentially adopted in a community pharmacy setting.³¹

³⁰ Bungard TJ. et al.

³¹ Semchu R. Community pharmacists managing warfarin therapy. Cdn Pharm J 2002;(Oct):14-5.

Table 1: Alternative Strategies to Anticoagulation Therapy in Pharmacy

LEVELS:	USUAL CARE	LEVEL 1	LEVEL 2	LEVEL 3
Levels	Traditional Care	Distribution Center & Training Center	INR Testing Center	Anticoagulation Clinic
Description	Physician managed anticoagulation	Promote the sale of CoaguChek S® for patient self-testing	Perform on-site coagulation in Pharmacy	Manage & direct anticoagulation
Certification	N/A	Yes (including yearly quality assurance)	Yes (including yearly quality assurance)	Yes (including yearly quality assurance)
Physician Role	Physician prescribing	Physician prescribing	Physician prescribing	Pharmacist prescribing via collaborative agreement with physician
INR Test	INR test performed by outpatient private lab	Patient self-administered INR test at home	On-site INR testing at pharmacy	On-site testing at pharmacy
Pharmacist Role	Basic medication counselling + Dispense warfarin	Basic medication counselling + Dispense warfarin	Basic medication counselling + Dispense warfarin	Comprehensive counselling + Co-prescribing + Dispense warfarin
Technician Role	Dispensing and technical duties only	Training and technical duties only	Testing and technical duties only	Testing and technical duties only
Other Related Services	N/A	Promotional and educational materials	Additional add-value services	Case Management + additional added-value services
Setup Costs	N/A	\$	\$\$\$	\$\$\$\$
INR = International Normalized Ratio				

The bottom-line utilizing the skills and attributes of community pharmacies an alternative, more effective and efficient pharmacist-based differentiated strategy should be considered for monitoring INR and warfarin therapy. This paper will develop a differentiated strategy to compete with the current lab-based cost strategy. The following section will examine the external forces such as the opportunities and threats that may exist in formulating this strategy.

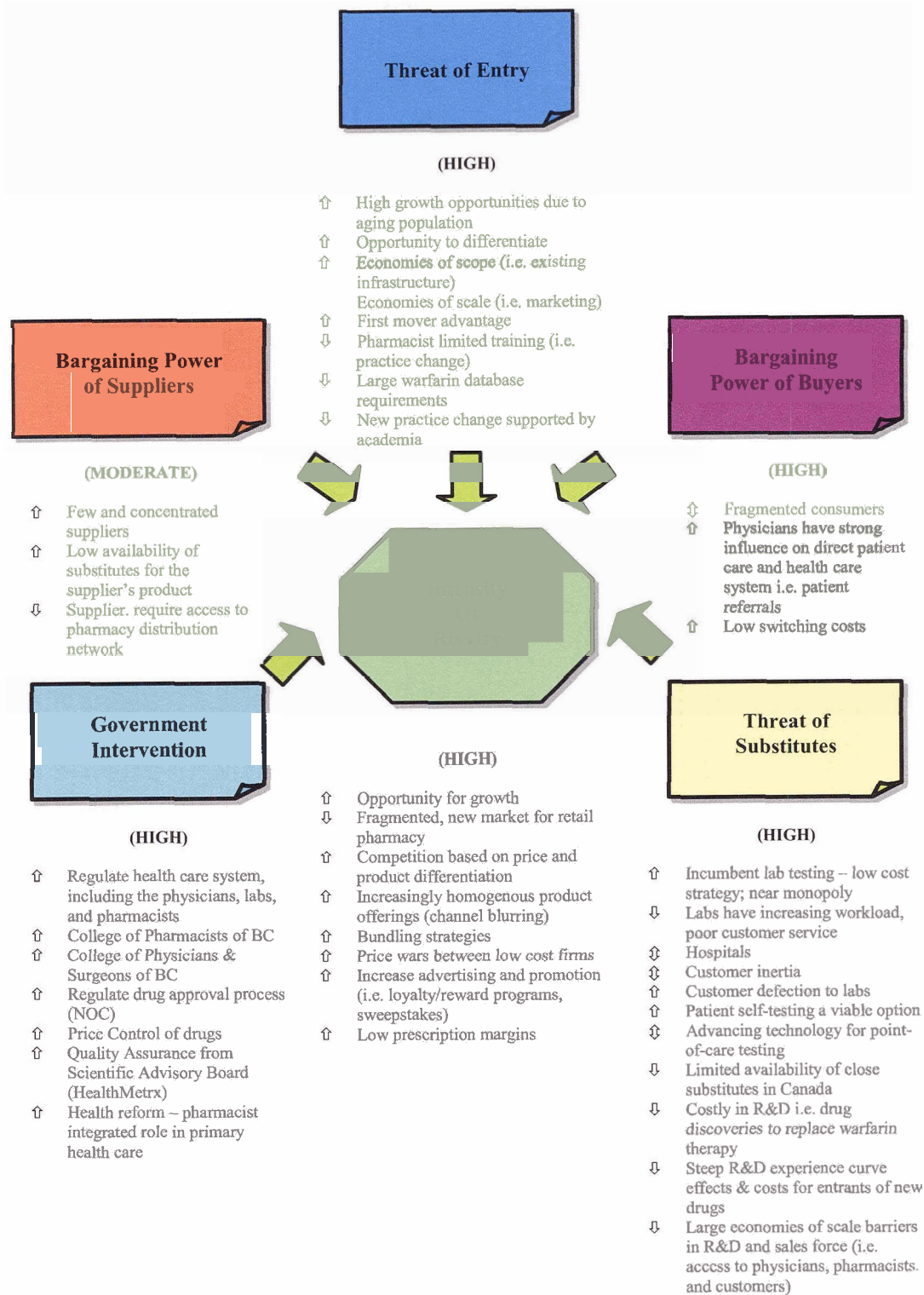
2 EXTERNAL ANALYSIS

For community pharmacy to be successful in offering an anticoagulation management service, an external analysis of the anticoagulation market from the perspective of pharmacy is necessary to understand the threats and opportunities that shape this industry. Intense competition, governmental influences, and consumer preferences are examples of external factors that impact this analysis and will determine community pharmacy's strategy that will exploit the opportunities and negate the threats. A step-wise approach to this analysis involves Michael Porter's Five Forces framework.

Porter's framework examines the primary forces that determine the competitiveness within an industry and describes how those forces are related. These forces – supplier power; threats and substitutes, rivalry among firms in the industry, threat of entry; and buyer power – have varying degrees of influence on the profitability of the pharmacy industry.³² In addition, the framework is used to evaluate the attractiveness of the market. Once each force is analyzed, key success factors (KSFs) can be identified – the critical assets and competencies that are necessary to compete successfully. Figure 3 provides an overview of the forces involved in the anticoagulant market.

³² Aaker DA. 2001. Developing Business Strategies. 6th Edition.

Figure 4: Summary of Porter Five Forces on Pharmacy-managed Anticoagulation Service



(Adapted from Bukszar (2006) with permission)

2.1.1 Supplier Bargaining Power – Very Low to High Power

Suppliers for the retail pharmacy industry, specifically the oral anticoagulation market, consist of: (1) diagnostic health care companies; (2) pharmaceutical companies; and (3) physicians. The supplier power ranges from very low to high.

2.1.1.1 Diagnostic Health Care Companies – Medium Buying Power

There are five main suppliers that represent the retail diagnostic health care industry: Roche Diagnostics, Bayer Diagnostics, Abbott Laboratories, Lifescan Canada, and BD Consumer Healthcare. All of these suppliers currently sell point-of-care diagnostic equipment for the diabetes market. Roche Diagnostics, however, is the only supplier in Canada to sell home-testing point-of-care diagnostic equipment for the anticoagulation market. As a result, the focus will be on this particular supplier.

Roche is a multinational healthcare organization, employing an estimated 65,000 employees in 150 countries and is headquartered in Basel, Switzerland.³³ The company's core business is in pharmaceuticals and diagnostics. It is a global leader in the diagnostic market and in pharmaceuticals for cancer, virology and transplantation. It also has alliances and R&D arrangements with several partners, including majority ownership interests in the biotechnology research company, Genentech, and multinational pharmaceutical manufacturer, Chugai Pharmaceutical Company, Ltd.

Roche Diagnostics Canada provides patient care through the development of innovative, cost-effective and reliable diagnostic systems for the *in vitro* market, for patient self-monitoring and for the research industry. The company has over 50 years of R&D in clinical chemistry, automated diagnostic systems and immunochemistry and, therefore, is a pioneer in laboratory

³³ www.roche-diagnostics.com

diagnostics. With respect to the community-based pharmacy practice setting, Roche Diagnostics is known for its diabetes care division, featuring product lines such as Aviva® and Compact Plus® self-monitoring blood glucose devices. These home monitoring devices are sold in pharmacies to patients with diabetes who require regular blood glucose monitoring.

Roche Diagnostic's recent launch of the only point-of-care monitor, Coaguchek S® , for anticoagulation management in the Canadian market has given the company high bargaining power since there are currently no substitutes. Retail pharmacies have no alternative but to use Roche Diagnostic's equipment and consumables for delivering an anticoagulation monitoring service to their clients. Until new entrants offer alternatives, Roche Diagnostics' niche product line has a significant share and control of the point-of-care anticoagulation market as well as first mover advantage. Subsequently, the company is in a position to slowly penetrate the market with a price skimming strategy. They are able to charge higher prices and maximize profits. They also have access to a marketing network of physicians from their pharmaceutical and diagnostic sales divisions.

Despite being the only anticoagulation point-of-care product in Canada, Roche Diagnostics' product launch faces a number of challenges. First, its distribution channel is limited to community pharmacies. Not all pharmacies are prepared to invest in the new technology due to internal circumstances (i.e. pharmacist labour shortage, pharmacy layout, cost-focused strategy) or external forces (i.e. low patient and physician acceptance). For example, the combination of high fixed costs and low consumer adoption rate may deter those pharmacies that are risk averse from investing in the initiative. The costs of the units are high and the inventory turnover is low compared to other similar markets such as the diabetes industry. Furthermore, Roche has invested a considerable amount of sunk cost into the Canadian market. Pharmacies seeking to differentiate their businesses may consider other areas other than anticoagulation due to high opportunity costs and limited internal capabilities.

New entrants may enter the market in the near future. These entries will be based on the attractiveness of the small Canadian market and opportunities to extract economic rent from the industry. In addition, advancing technologies at lower costs from competitors will impact the incumbent Coagucheck S. The new entries may approach with a low cost strategy (i.e. lower cost of monitor and consumables) and price penetration approach to acquire market share, or a differentiated strategy (i.e. improved functionality, faster results, smaller unit, and greater memory storage) with a price point equal to or possibly greater than Roche Diagnostics. A third option may consist of a bundled approach combining additional resources to assist the patient (i.e. patient call center, supplemental educational materials) and access to health care professionals via educational programs and push programs as observable in the highly competitive diabetes market. Currently in the US, there are just a few diagnostic companies that sell point-of-care devices for home testing and community pharmacies. (See table 2.) It is likely that these companies will enter the Canadian market at some point in time, but they will be up against a number of barriers:

- High initial investment and fixed costs.
- Governmental and other regulatory bodies' approval of devices for sale in Canada.
- Cost advantages for Roche due to the experience and learning curve effects and economies of scale with marketing and sales force.
- Brand loyalty of customers, pharmacists and other health care professionals.
- Distribution channels are controlled by Roche due to first mover advantage of networks with community pharmacists, physicians and specialists, and service contracts and warranties are established with pharmacies.

- Limited resources, such as qualified expert staff, are necessary to enter the market. These companies may enter through a wholesaler distributor with limited knowledge of the anticoagulation market.

Overall in this area, new product entries would not be considered threats to the pharmacy industry. In fact, the new products may lower the supplier bargaining power as more options will become available to the consumer and pharmacy retailer.

Table 2: Point-Of-Care Devices³⁴

Description	INRatio	ProTime	CoaguChek S®
Manufacturer	HemoSense	International Technidyne Corporation	Roche Diagnostics
Handheld / size / weight incl. bat.	No / 40 cu. in. / 325g (Light-weight and small size)	No / 95 cu. in. / 758g (Heavy-weight and large size)	No / 60 cu. in. / 455g (moderately-heavy and medium size)
OBC for measuring channel	No	No	No
Electronic Quality Control	No need for separate device to check electronic controls – performs electronic system self-test automatically	Built in quality control	Requires separate device to check electronic controls
Sample dosing	Top dosing only – high risk of instrument contamination and loss of sample	Outside dosing – low risk of instrument contamination	Top dosing only – high risk of instrument contamination and loss of sample
Volume of blood sample	15 ul	27 ul	10 ul
INR range	0.7 -7.5	1.0 – 7.0	1.2 -8.0
Market approach/ target group	Pro and Consumer	Pro and Consumer	Pro and Consumer
Estimated price	\$1,595.00	\$ 1,695.00 USD	\$1,265.00
Messaging/ positioning	Ease of use and quick for both pros and consumers / OBC	Ease of use and quick for both pros and consumers / OBC	Reliable, ease of use and accurate for pros and consumers
Test time	Less than 2 minutes	4-5 minutes	1 minute
Other features	Built-in port for printing / electronic communication, no reagent preparation	No calibration or reagent preparation required.	Only INR test unit available in Canada
Test Strips	No refrigeration required – can be stored at room temperature until expiry date (12 months) No need to warm up test strips	Refrigeration of strips recommended. Strips expire in 30 days at room temperature Test strips must be at room temperature before use.	Refrigeration of strips recommended. Strips expire in 60 days at room temperature Test strips must be at room temperature before use.

In summary, considering all these factors, Roche diagnostics has medium bargaining power.

³⁴ www.hansonmedicalsyste.ms.com

Key success factor: Pharmacies considering an anticoagulation management service may seek early collaboration and partnership from the manufacturer as both parties have a vested interest in the success of the program such as sustained growth and market penetration. Historically, most pharmacies have taken this approach with the diagnostic industry for the diabetes market. Hence, they create a partnership with the supplier whereby there is a win-win approach to cost-sharing and risk-sharing initiatives.

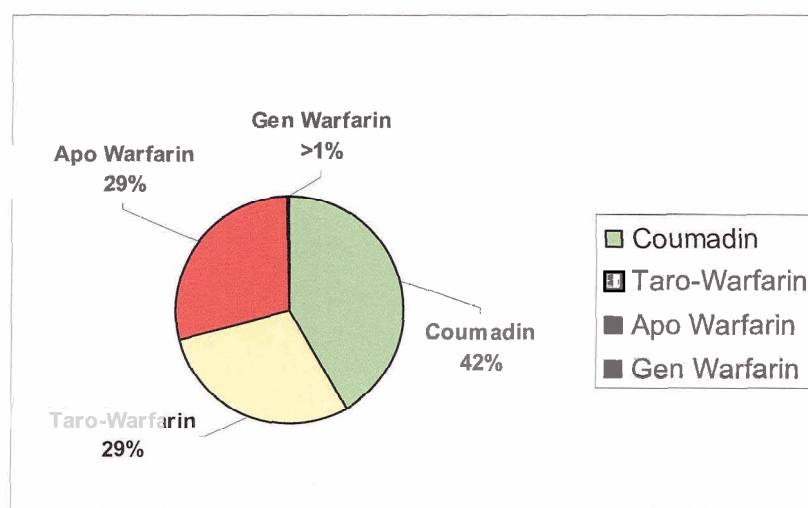
2.1.1.2 Pharmaceutical Companies – Low Bargaining Power

Since warfarin is off patent, it is produced by several generic pharmaceutical firms such as Apotex, Taro Pharmaceuticals, Genpharm and Novopharm. The competing generic brands are bioequivalent (i.e. homogeneous), and easily interchangeable (i.e. low switching costs), with identical drug-benefit status on the BC provincial formulary. As a result, rivalry in the generic pharmaceutical industry is intense. These firms strive for a competitive advantage over their competitors. The figure below is an illustration of the market share of the various firms in 2003, including the original version of warfarin, Coumadin®, produced by Bristol Myer Squibb.³⁵

For all the aforementioned reasons – low switching costs, intense rivalry, homogenous product, and supplier concentration – these generic pharmaceutical firms have low bargaining power.

³⁵ Skinner BJ, Canada's Drug Price Paradox. The Unexpected Losses Caused by Government Interference in Pharmaceutical Markets. February 2005. Fraser Institute Digital Publication

Figure 5: Warfarin percent Prescription share in 2003 by Brand



2.1.2 Buyer Power – High

Buyers are consumers and physicians in the anticoagulation market. Consumers are patients who require warfarin therapy and INR monitoring. Physicians are indirect buyers who have significant influence on their patients' warfarin medication and on-going blood tests.

2.1.2.1 Consumer Profile

Buyers in the oral anticoagulation market are consumers who require anticoagulation monitoring and oral anticoagulant therapy with warfarin to manage their risk of clotting. Reviewing the consumer profile, including the ability to influence pricing and demands on service, the degree of consumer bargaining power can be determined, and key success factors to support the implementation of a pharmacy anticoagulation program can be identified. The consumer's view on warfarin prescription purchases, lab testing and monitoring and patient care are also important in supporting this initiative.

Active and Aging Population

These consumers are prescription shoppers because they require warfarin therapy and possibly a number of other prescription medications to manage their clotting condition. Patient demographics suggest that the majority who are on anticoagulation therapy are generally older individuals; for example, atrial fibrillation is one of the three most common cardiac diseases in the elderly population.³⁶ The prevalence of atrial fibrillation increases three times in those greater than 80 compared to patients less than 65 years old (Mairs et al.1996). Approximately 10 percent of patients over 75 years of age have atrial fibrillation along with the presence of other risk factors and medical conditions.³⁷ This aging population is the reason the number of drug therapies are growing.

Drug expenditures in Canada are growing at a five-year growth rate of over 12 percent (12.8 percent).³⁸ In 2004, Canadians filled an average of 12 prescriptions per person. Canadians aged 80 and over filled the greatest number of prescriptions, averaging 42 per person, while those aged 60 to 79 filled 22 prescriptions per capita. To this end, pharmacies are in a position to capitalize on managing this aging population segment with their pharmaceutical expertise to improve patient care (reduce adverse events and drug interactions) and reduce cost to the health care system (i.e. cost avoidance such as reduction of emergency visits and improvement in efficiency of physician's time).

Today's mature adults, 55 and older, are living longer, have higher levels of education and are wealthier. This population demographic is increasingly more ambulatory and more active longer into their later years. Additionally, less than 1 percent of the 55 and older age group are living in nursing homes.

³⁶ Mair FS, Crowley TS, Bundred PE. Prevalence, aetiology and management of heart disease in general practice. *Br J Gen Pract* 46, 77-79. 1996

³⁷ Health Canada. The changing face of heart disease and stroke in Canada 2000

³⁸ Canadian Institute for Health Information. National Health Expenditure Trends 1975-2004 Report. 2004.

Demanding Service and Knowledgeable about Products

Consumer behaviour has a major influence on a pharmacy's corporate strategy. A large number of pharmacy patients are significantly concerned about their health care needs, the prescription medications that they purchase and the professional services that they receive.³⁹ Consumers have purchasing choice since they can locate a pharmacy in shopping malls, clinics, department stores, warehouse clubs and grocery stores. Across Canada, pharmacies are attempting to address the growing incidence of age-related conditions. Continuing efforts and resources are allocated toward developing age-related pharmacy programs to retain or capture this population group. Despite the low degree of buying power on prescriptions, these consumers have influence on pharmacy service levels. Additionally, consumers are very knowledgeable of prescription products (i.e. side effects, dosage, indications of use). A significant amount of information is available to consumers through media and the Internet. Approximately 80 percent of adults, who are online, search for health information.⁴⁰ This has helped create a more actively involved patient who seeks more information and treatment options. They want increased product breadth in front-store over the counter (OTC) and health and beauty aid (HABA) products as well as increased shelf presence of alternative and preventative medicines. This demand will shape and expand the future role of the pharmacist.

Price Sensitive

Consumers have increased bargaining power as they have the alternative of going to the lab to have their INR levels measured at no out-of-pocket expense. They have influence on the market due to several variables: high switching costs, price sensitivity, and receptiveness to new technology.

³⁹ Engel JF, Blackwell RD, Miniard PW. Consumer Behavior. Forth Worth, Tex: Dryden Press; 1993

⁴⁰ Bisanz, C. (2005). CACDS. Pharmacy in Canada: The Retail Scene.

The anticoagulation market consists mostly of seniors who have a finite income and are typically price sensitive. Generally, seniors are the high end users of prescriptions, and the government subsidizes their drugs. When faced with the exorbitant cost of purchasing a portable INR device, they may not be ready to pay out-of-pocket. The high switching cost is a barrier to this group. Alternatively, a differentiated service consisting of private and personalized on-site INR testing, bundled with a pharmacist providing pharmaceutical care services at a reasonable out-of-pocket cost, may be perceived as valuable to this group. The use of incentives and added-valued programs can move consumer purchase decisions away from price.

In addition, the waiting time, restrictive hours of operations, non-personalized and non-patient care aspects of labs services give pharmacies an opportunity to focus and fulfil some of the unmet needs of the patient. Because of warfarin's ability to cause internal bruising or hemorrhaging when the drug's INR levels are supra-optimal, having access to immediate and convenient readings is critical to the patient's health. Patients aware of this convenience may find on-site testing at a community pharmacy advantageous to their health.

Patients' receptiveness to new technology will vary for a number of reasons:

- Despite the CoaguChek S® device's consumer-friendly functionalities, individuals who may have limited dexterity, poor understanding of technology and/or poor visual acuity would not be selected for self-management.
- Research studies have compared patients who go to the lab and who use the point-of-care device. The results indicated that there was a high patient preference of 97 percent for point-of-care testing compared to the usual care of going to the lab⁴¹. Patients may prefer a finger-poke test versus venous (or capillary) puncture. The venous puncture draws a larger specimen

⁴¹ Ansell J, Hughes R. Evolving models of warfarin management: Anticoagulation clinics, patient self-monitoring, and patient self-management. *American Heart Journal* 1996; 32:1095-1100

sample which may cause scarring at the puncture site through time. Results using the point-of-care device are also virtually immediate, within 2 to 3 minutes.

Generally, factors affecting patient satisfaction can be broken down to the following key areas: patient's personal characteristics, situational factors and product and service quality. The goal is to identify those patient segments that have unmet needs under the usual care but who would find value and/or fulfilment under pharmacists-managed anticoagulation services. The pharmacy must be able to segment the senior market based on several variables: (1) discretionary income; (2) overall level of health; (3) overall level of activity; (4) amount of discretionary time; and (5) degree of social interaction with others.⁴² These patient preferences may be:

- Seeking convenience and flexibility (i.e. better operating hours, location, free parking, frequent traveller, busy lifestyle.(i.e.social, job and family activity)).
- Understanding the importance of proper warfarin dosing and monitoring and being motivated and actively engaged in their personal health. Interested consumers are more aware of health information, committed to their therapy and likely to collaborate with professionals to obtain good therapeutic outcomes.⁴³
- Seeking a better response time to their lab results – quick turnaround time in order to make warfarin regimen changes
- Initiating anticoagulation therapy for the first time and requiring additional support and resources (i.e. comfort with pharmacist involved in decision-making process).
- Patients who have extended medical coverage that will cover pharmacy care services.

⁴² Bone BF. Identifying mature segments. *J Serv Mark.* Winter 1991;5:47-60

⁴³ Holdford DA, 2003, Marketing for Pharmacists, American Pharmaceutical Association, p114.

- Those who are expected to take warfarin for long periods of time (i.e. atrial fibrillation).
- Those who are managed with high intensity therapy (i.e. patients with a mechanical heart valve).
- People who have had bleeding or clotting complications in the past and are concerned with the life-threatening complications associated with warfarin therapy.
- People who have a wide fluctuation in their response to warfarin.

Key Success Factor #1: Provide quality and reliable service that is personalized and patient-centred at a reasonable price. The pharmacist must be attentive to providing individualized attention and addressing the customer's specific requirements. Other service dimensions such as the appearance of the physical facilities, responsiveness (i.e. ability to provide prompt and timely service), courtesy (i.e. politeness, respect and friendliness of customer service) and credibility are additional considerations.

Key Success Factor #2: Build service loyalty through an effective marketing and advertising campaign that gives the consumer the perception that the product (INR test) and service (pharmaceutical care) are higher quality and more beneficial to their health than the usual care. When this is accomplished, the price or switching costs become less important.

2.1.2.2 Medical Community Bargaining Power – high

An indirect buyer, physicians have a strong influence on their patient's well-being. They prescribe medications to patients (buyers), who then have their medications dispensed by a pharmacy. They have influence on the patient's health, the type of medication that is prescribed and patient referrals to the community pharmacist and pharmacy. To this end, Physicians are able to identify and recommend patients to self-manage their own INR levels, seek pharmacist-managed anticoagulation services or maintain the usual customary care.

Influence on Patients

Physicians are the main decision-makers of their patients' health. As a result, physicians can identify, influence and refer patients to manage their warfarin levels. Similar to a lab requisition, a prescription is required should a physician recommend the patient to purchase the point-of-care device, Coaguchek S®, or have their INR levels managed by a community pharmacy. As the gatekeeper of the patient's health, the physician's level of acceptance will determine the success of the program.

Warfarin Under-utilized

There is reluctance by physicians to prescribe warfarin to elderly patients for atrial-fibrillation-related stroke even where there may be clear therapeutic benefits to the treatment.⁴⁴ Physicians have been known to restrict the use of warfarin in the elderly due to history of falls, a history of hemorrhagic stroke, and "presumed age-related" incompetence in anticoagulation control. One cross-sectional study revealed that only 62% of patients with no contraindications for warfarin therapy were actually taking the medication.⁴⁵ With age, the risk of stroke rises to a much greater extent than the risk of bleeding.⁴⁶

Physicians feel the use of warfarin has too many disruptions to the patient's quality of life due to ongoing dosage adjustments and laboratory monitoring. The main evidence-based anticoagulation contraindications in the elderly population include uncontrolled high blood pressure, bleeding disorders, thrombocytopenia (low platelet count) and non-compliance with drugs or INR monitoring.⁴⁷ Studies have shown pharmacist-managed anticoagulation clinics can

⁴⁴ Vasishtha S, Toor F, Johansen A, Hasan M, Stroke prevention in atrial fibrillation: physicians' attitudes to anticoagulation in older people, *Arch Gerontol Geriatr* Vol. 33, 2001, p.219-226.

⁴⁵ Pavlakovic, R. Geriatrics: Special pharmacotherapy considerations. *Pharmacy Practice Supplement*. Feb 2004.

⁴⁶ Pavlakovic et. al.

⁴⁷ Man-Son-Hing M, Laupacis A, Anticoagulated bleeding in older persons with atrial fibrillation: physicians' fears often unfounded, *Arch Intern Med*, Vol. 163, 2003, p.1580-1586.

improve therapeutic outcomes, however.⁴⁸ With this information, physicians may be more receptive to prescribe warfarin to these patients under the care of a pharmacist-managed anticoagulation program. Furthermore, a recent study in British Columbia illustrated that pharmacist-managed anticoagulation in the hospital setting not only saved the health care system money but also enhanced the care of the patient as compared to the usual physician care.⁴⁹

Physician Concerns

Historically, physicians have non-drug related issues with anticoagulation management services performed by pharmacists. They are reluctant to refer patients to have INR tests performed by community-based pharmacies for a number of reasons:

- **Threat to the medical profession** – Despite numerous international studies supporting the role pharmacists play in anticoagulation therapy, physicians view pharmacists as taking on the role of the physician in disease management.
- **Liability issues** – When London Drugs launched their INR program four years ago, the BC College of Physicians and Surgeons cautioned physicians not to participate in community-based pharmacy INR testing due to potential legal liabilities for the physician.
- **Technology issues** – although the Coaguchek S® is approved for home testing in Canada and in other countries, physicians do not believe the portable unit is accurate and reliable, especially when used to monitor a complicated drug with inherent risks and potential life-threatening consequences.

⁴⁸ Chiquette E, Arnato MG, Bussey HI. Comparison of an anticoagulation clinic with usual medical care: anticoagulation control, patient outcomes, and health care costs. *Arch Intern Med* 1998;158:1641-7.

⁴⁹ Regier DA, Sunderji R, Lynd LD, Gin K, Marra CA, Cost-effectiveness of self-managed versus physician-managed oral anticoagulation therapy. *CMAJ*, June 2006; 174(13): 1847-52

The physician is the gatekeeper to managing patients on warfarin therapy. Physician acceptance of an alternative anticoagulation service is critical to the success of the program. Physicians therefore, have high supplier bargaining power.

Key Success Factor: Physician support and referrals are critical to the success of the program. The pharmacist must demonstrate the value of the service to the physician. The pharmacist must have a strong rapport with the physician built on professional trust with the mutual purpose of benefiting the patient. A collaborative team approach is necessary and will allay many of the turf protection concerns. The service must be perceived as beneficial to the physician, saving them time to allow them to focus on more complicated patients and also saving them money.

2.1.3 Threats of Substitutes – High

A threat from substitutes exists if there are (1) alternative anticoagulation monitoring services and (2) alternative drug therapies.

2.1.3.1 Anticoagulation Monitoring Services

In Canada, the two commonly utilized methods of managing anticoagulation are through private labs or hospitals, including tertiary care units; both receive funding from the government. Other monitoring services include patient self-testing.

Private Labs

The private lab industry is dominated by only a few companies. According to the provincial government's assessment, BC's private and public lab costs and utilization rates are among the highest in the country. One study suggested that the province's per capita expenditures were 50 percent higher than the country's average and were increasing much more rapidly than

anywhere else in Canada.⁵⁰ Lab expenditures in 2002/2003 amounted to \$473 million, or 4 percent of the total provincial expenditures. Overall, the reviews indicated that the Canadian laboratory sector faces challenges from a fragmentation of management, poor system planning, inadequate cost control measures on expenditures and principal agency issues. The lab industry seeks to exploit opportunities to keep costs to a minimum by taking a cost-based strategy approach to its operation, particularly under these market conditions. Profits are generated by high turnover of tests, capitalizing on economies of scale.

Laboratory services are medically-based services that aid in monitoring diseases or assisting the medical community (i.e. physicians) in diagnosing a patient's illness or medical condition. Laboratory tests may be performed either on an inpatient or outpatient basis. Inpatient basis refers to tests performed in a public hospital under one of the BC province's six health authorities. These health authorities continue to undergo a number of health reform initiatives due to factors such as funding pressures, restructuring and issues of quality of patient care.⁵¹

Outpatient tests are performed by either public hospitals or private community labs. They are funded through the Medical Services Plan (MSP). Private labs are concentrated in two large firms, MDS Metro Laboratory Services (37 percent) and Biomedical Laboratories (23 percent), although a few small, independent physician-owned private lab services do exist.

MDS Metro Laboratory Services is a multinational health and life science company employing over 11,000 people worldwide. In the BC market, the company has substantial control of the lab testing market; it is BC's largest independent community laboratory network.⁵² They have significant power due to (1) technology advantages creating economies of scale opportunities with high volume tests; (2) extensive distribution network (i.e. 80 plus specimen

⁵⁰ Lillian Bayne & Associates. July 2003. BC Laboratory Services Review, www.health.gov.bc.ca/cpa/publications/lab_review.pdf

⁵¹ Lillian Bayne et. al.

⁵² http://www.mdsdx.com/MDS_Metro_Laboratories/

collection stations in most urban centres and close to medical clinics and hospitals); and (3) diversification into other business ventures (i.e. sterilization services, specialized analytical instruments, drug discovery, distribution of medical products, R&D, diagnostic assays).

BC Biomedical is owned by a group of pathologists and laboratory scientists who provide outpatient and inpatient services in the BC Fraser Valley. The company provides community lab services to over 1.5 million patients each year. It offers mobile community lab services for home- or institutional-bound patients and specimen transportation services. The company employs over 700 employees including pathologists.⁵³

With respect to INR monitoring, obtaining an INR blood test from a private lab is an inefficient process that is a continual disruption to a patient's quality of life (see to figure 3). While patients currently do not pay for the direct cost of care, there are a number of indirect costs that are overlooked such as parking, taxi fares, caregiver expenses (i.e. if patient is not mobile), and absenteeism (time off work). Despite all this, private labs constitute a significant threat to pharmacy-based anticoagulation services, since the private lab's INR fees are covered 100% by the Medical Service Plan. Those that cannot afford to participate in a fee-for-service program offered by a pharmacist will have no choice, but to go to a lab for their test.

Hospitals

Since the operations of the hospitals are publicly funded, the anticoagulation management costs are seamless to the consumer. A patient in the hospital setting is prescribed warfarin by the on-staff physician. Lab technicians within the hospital perform the INR blood tests and the results are noted on the patient's chart. The turnaround time for INR results is from a few hours to a day, depending on the workload and number of test requests from hospital staff members. Results are reviewed by the attending physician and warfarin dosages are revised as required based on the

⁵³ www.bcbio.com

INR levels. Once the patient is discharged from the hospital, their regular INR lab work is obtained at the private labs and monitored by their family physician.

Several of the anticoagulation management services in a hospital setting, such as St. Paul's Hospital and Burnaby General Hospital, are managed by a clinical pharmacist in a collaborative agreement with the prescribing physician. The clinical pharmacist will monitor and review the INR levels and make warfarin dosage changes as per the clinical practice guidelines. Once the patient is stabilized, they are discharged from the hospital and returned to the care of their family physician.

The potential to capture market share is limited as it is entrenched in the hospital's standard operating procedures and, in most incidences, their patients are under intensive care due to post-myocardial infarction, open heart surgery or valve replacement surgery and are in no position to seek alternative outpatient anticoagulation management services. Pharmacies offering anticoagulation management services should focus on outpatient care.

Patient Self-monitoring

Patient self-testing is a substitutable option. It consists of selling the point-of-care device, CoaguChek S®, to patients currently on warfarin therapy. At the pharmacy, this service is less complex and requires fewer resources than on-site INR testing and/or warfarin medication management. Presently, international guidelines for selecting suitable patients for self-testing recommend patients who are on long-term warfarin with artificial heart valve prosthesis, chronic atrial fibrillation, thrombophilia or post-myocardial infarction with impaired left ventricular pump function⁵⁴. These patients are likely to be on lifelong warfarin treatment, and therefore, may be

⁵⁴ Ansell J, Jacobson A, Levy Jonathan, Voller H, Hasenkam M, Guidelines for implementation of patient self-testing and patient self-management of oral anticoagulation. *International Journal of Cardiology* 2005;99:37-45.

more receptive to purchasing and using the Coaguchek S[®], especially for those who have busy lives and would like the freedom to manage their own schedule.

Several studies support those who live an independent and self-supporting life are capable of self-testing, provided they understand the concepts and potential risks associated with anticoagulation therapy. One study suggests patients' self-monitoring of oral anticoagulation treatment long-term is an effective strategy as fewer thrombotic and/or hemorrhagic events and deaths occurred versus management by a physician⁵⁵.

Advantages of Home Testing

The Coaguchek S[®] is a simple, convenient and safe device that helps patients to monitor their coagulation status at home rather than going to a lab. Those patients who are interested in purchasing a Coaguchek S[®] are likely to do so because of the following:

- It gives the patient more flexibility and independence in daily life. There is no need to travel to and from appointments or to interrupt a busy schedule. Avoiding long line-ups in the medical laboratory or at the hospital makes checking the INR levels more convenient and saves time for patients and caregivers.
- The patient is actively involved in his/her own health and treatment, and thus more compliant with drug therapy and testing.
- The home testing unit requires only a small sample of blood from a finger-poke, as compared to a venous puncture from the patient's arm when performed at the lab.
- The coagulation status can be regularly and frequently checked so that anticoagulant therapy can be adjusted when necessary.

⁵⁵ Regier DA, Sunderji R, Lynd LD, Gin K, Marra CA, Cost-effectiveness of self-managed versus physician-managed oral anticoagulation therapy. *CMAJ*, June 2006; 174(13): 1847-52

- Frequent testing takes less time and is essential as factors such as drugs, illness, nutritional intake, alcohol, travelling and stress may interfere with the coagulation status.
- Self-monitoring may encourage more frequent testing, which decreases the possibility of complications such as clots or bleedings. A patient who is anxious about his/her medical condition will want to be in control of his/her life.
- Individuals that travel regularly to a foreign country for an extended period may have difficulties getting their INR levels performed in the foreign country or the costs are exorbitant.
- Patients on chronic warfarin therapy, greater than 1 year to lifetime, are good candidates for home testing; for example: preventing recurrent myocardial infarction, chronic AF, valvular disease, and artificial heart value prosthesis.

Limitations

Although the Coaguchek S® is convenient and the first of its kind in Canada, there may be a number of challenges:

- **High switching costs** – Roche launched the product with a price skimming strategy. The Coaguchek S® is costly and is currently a non-benefit item on the provincial and federal healthcare formulary and limited coverage on thirty party insurance plans. Consequently, the patient bears the full cost of the unit. Moreover, the consumables are required i.e. test strips, control solutions, and lancets, which are also not covered. The current provincial health care system covers the cost of lab tests and as a result, the expense to the patient is transparent (i.e. free).

- **Duration of therapy** – due to the high cost of the Coaguchek S®, patients that are on short-term use of warfarin (3 months to 1 year) are less likely to purchase the unit and the associated consumables for home testing.
- **Distribution Channel (pharmacy)** – high patient interaction is required to educate and promote the product to a patient, despite a nominal training fee (to cover the pharmacist time) provided by the manufacturer. Extensive personal selling is necessary to encourage purchase. Only pharmacies with accredited training by Roche are licensed to sell the product; thus, accessibility is limited due to the few available sites.
- **High costs** – with the low adoption rate, pharmacies are wary of becoming certified sites. The costs of the units are high and the inventory turnover is extremely low. Pharmacies must weigh the opportunity costs in pursuing this type of initiative.
- **Distribution Channel (Physician)** – patients must receive a prescription from a physician in order to purchase the Coaguchek S. This process adds complexity to the distribution. Compounding this problem is the low physician acceptance. Since the unit is first of its kind in the Canadian market, physicians are not entirely confident with the accuracy of the unit, nor do not have the time to educate their patients on the value of the unit.

Bottom-line, the patient must choose between the high costs of the home monitoring program vs. the inconvenience of going to an outside lab. Unless Roche Diagnostics can lower the cost of the Coaguchek S®, the adoption rate may likely be low. The estimated market may be 3 to 5-percent of the BC market.

Forecast

To understand the economic benefits of investing in the sale of CoaguChek S® from the perspective of the community pharmacy, a brief overview of the costs and break-even analysis is illustrated below. The pricing schedule for home testing is outlined in table 3, including suggested retails and percentage profit margin.

Table 3: CoaguChek S® Pricing Schedule

Description	Cost	Retail Price	Sale per Patient	Gross Profit / Patient	% Gross Profit
Required Items					
CoaguCheck S Portable Unit	\$ 790.00	\$ 949.00	\$ 949.00	\$ 159.00	17%
Test Strips (12 per box)	\$ 65.00	\$ 89.00	\$ 178.00	\$ 113.00	63%
Lancets (50 per box)	\$ 5.99	\$ 7.99	\$ 7.99	\$ 2.00	25%
Total \$ Per Patient / Year	\$ 860.99	\$ 1,045.99	\$ 1,134.99	\$ 274.00	24%
Yearly Maintenance Service Fee					
Quality Assurance Service*	\$ 5.00	\$ 10.00	\$ 10.00	\$ 5.00	50%
Optional items**					
CoaguCheck S Control Solution (8/box)	\$ 25.00	\$ 29.99		\$ 4.99	17%
CoaguCheck QEC Electronic Control	\$ 338.00	\$ 399.00		\$ 61.00	15%

* suggested fee

**If patient chooses these items, they do not participate in the Quality Assurance Service above

Break-even analysis

A break-even analysis of the sale of the CoaguChek S® can be determined by calculating the yearly fix costs and variable costs. The fixed costs consist of training and marketing, which is typical of a pharmacy providing diabetes services and products. See table 4.

Table 4: Fixed Costs 5-year Forecast

Fixed Costs	1st Year Costs	2nd Year Costs	3rd Year Costs	4th Year Costs	5th Year Costs
Training Pharmacist	\$ 320.00	-	\$ 320.00	-	-
Training Pharmacy Technician	\$ 120.00	-	\$ 120.00	-	-
Marketing	\$ 1,500.00	\$ 1,000.00	\$ 1,000.00	\$ 1,000.00	\$ 1,000.00
Total Yearly Fix Costs	\$ 1,940.00	\$ 1,000.00	\$ 1,440.00	\$ 1,000.00	\$ 1,000.00

The break-even analysis provides a benchmark of expected sales volume to cover the cost of implementing the program. The estimated percentage of warfarin users that will purchase a Coaguchek S® is projected at 3-percent in the first year and increasing conservatively by 1-percent in subsequent years. Based on this information, pharmacies can review their warfarin client base and determine if their location is adequate for this service. See table 5 below:

Table 5: Break-even Analysis

Total Fix Cost / (Revenue per unit minus Variable Unit Cost)

Description	1st Year	2nd Year	3rd Year	4th Year	5th Year
# units sold to break-even	10	5	8	5	5
Average per month	0.9	0.5	0.6	0.5	0.5
Estimated percentage Patient-Self Testing	3%	4%	5%	6%	7%
Number of Warfarin Patient Required to break- even	350	135	156	90	77

The break-even analysis will give the pharmacy a better understanding of costs and retail prices. The cost and retail figures can be modified as needed to obtain a target profit margin as well. A sales forecast of can be determined once the retail price is established from the break-even analysis. Below in table 6, is an example of a pharmacy with a 250 warfarin client-base.

Table 6: Forecast Sale of Coaguchek S®

Description	1st Year	2nd Year	3rd Year	4th Year	5th Year
Estimated percentage Patient-Self Testing	3%	4%	5%	6%	7%
Pharmacy with 250 warfarin patients	8	10	13	15	18
Projected Units Sold / Pharmacy	8	10	13	15	18
Gross Revenues of Units Sold	\$ 1,480.00	\$ 1,850.00	\$ 2,405.00	\$ 2,775.00	\$ 3,330.00
Gross Revenues of Consumables		\$ 208.00	\$ 468.00	\$ 806.00	\$ 1,196.00
Total Revenues	\$ 1,480.00	\$ 2,058.00	\$ 2,873.00	\$ 3,581.00	\$ 4,526.00
Expenses	\$ 3,220.00	\$ 2,280.00	\$ 2,080.00	\$ 1,640.00	\$ 1,000.00
Gross Profits	\$ (1,740.00)	\$ (222.00)	\$ 793.00	\$ 1,941.00	\$ 3,526.00

A pharmacy with this warfarin client-base is estimated to dispense approximately 2,000 weekly prescriptions or over 100,000 prescriptions each year. This is typically a moderate to high-volume pharmacy and only selected banners, chains, and grocery formats are capable of performing at this level. In addition, other attributes are important in selling the Coaguchek S successfully:

- **Aging Demographics** – identify a site that serves a large growing community of seniors.
- **High Warfarin Users** – identify stores that have an existing large base-level of warfarin users. A specific threshold is required to be cost effective.
- **Pharmacists Support** – identify pharmacists who are willing to be trained and motivated to promote the sale of Coaguchek S® and target physicians in their community. Due to the non-benefit status of the Coaguchek S®, pharmacists will be required to fine tune their personal selling skills - a characteristic not too common with the profession.
- **Location** – identify stores that are close to tertiary hospitals that manage cardiovascular cases and INR patients.
- **Physician Support** – identify those stores with good physician support and willingness to refer their patients to self-manage their INR blood tests.

Resources such as marketing and employee training are major components of the strategy, and represent a large part of the set up costs. Other costs such as shelf allocation/schematic management and indirect costs are incremental, and are typically part of the internal operating structure of the organization.

Overall, the penetration of Coaguchek S® will be slow, unless Roche is able to reduce the upfront cost of the unit. The manufacturer must also consider offering pharmacy incentives, bundling additional services to the sale of the Coaguchek S® (i.e. patient incentives), directing marketing resources to warfarin patients and physicians (i.e. expand sales force and print advertising), as well as lobbying the provincial government for benefit status of the equipment and consumables.

Consumer Inertia

Despite the inconvenience and poor service levels, patients may routinely go to the private labs because they perceive no alternative, or they may feel that it is simply too much trouble to switch to a new service. Alternatively, there may be an issue of customer inertia—they do not have the initiative to change. In this situation, an effective marketing plan and good personal selling techniques from the pharmacist are critical components to the success of the anticoagulation program offered by the pharmacy. Featuring an in-store demonstration (i.e. in-store health event) or offering a free trial may raise their awareness of the pharmacy's service, making it easier for them to switch. In any event, it is important to recognize that customer inertia will be a barrier.

In addition, patients who use the pharmacist-driven anticoagulation service will eventually become stabilized on their warfarin therapy over the long-term. As this treatment becomes routine, patients can test less frequently as per the clinical practice guidelines (i.e. every 4 weeks). They may also become less compliant as they become more comfortable with the status

of their health and positive INR results. Consequently, vigilant follow up by the pharmacist or technician will be necessary. Tactics may include a reminder card in the mail, an email reminder, or simply a phone call 1-week prior to their next appointment. Also, a reminder note entered into the patient's prescription profile may also assist the pharmacist or technician to talk to the patient when they come to the pharmacy to pick up their warfarin prescription refill or other prescription medications. More importantly, the patient may periodically defect and return to the free service offered by the private labs. The hope is that the patient's defection rate is low, as the convenient and personalized service offered by the pharmacy is sufficient to keep the patient loyal. Adding to this is the fact that customer inertia is acute in the elderly. They are creatures of habit and may continue to use the pharmacy service, regardless of price.

To reduce the defection rate, the pharmacy must be able to assess the reasons why their clients are using alternative services. Evaluating the patient's satisfaction levels through either listening directly to their needs or having the patient complete a customer feedback/satisfaction survey are important steps that should be put in place in the early stages of the program launch. Understanding patient needs may identify a problem with the service level or some other problem associated with the program offering. The key is to offer outstanding and consistent customer service. A highly satisfied patient generally stays loyal longer. This can be done through establishing a strong rapport with the patient and building trust. Strong branding of the pharmacist as the expert in preventing life-threatening complications related to warfarin therapy (i.e. hemorrhaging or clotting) can create an emotional connection with the patient as well.

2.1.3.2 Limited Alternatives to Warfarin

Since warfarin is off-patent, it is inexpensive and not likely substitutable based on price alone. There are no current drugs on the market that are less costly than and as equally effective

as warfarin.⁵⁶ Over the past 50 years, warfarin has been the drug of choice or gold standard for a number of thromboembolic disorders (clotting disorders). An entire health care system infrastructure has been developed to manage this drug. Recognizing that potentially newer and better agents will enter the anticoagulation market at some time to replace warfarin therapy, the likelihood is low. With thousands of Canadians on warfarin therapy, this drug will not be easily driven from the market. Given the fact that warfarin management is the core activity of anticoagulation clinics (i.e. INR blood tests), its obsolescence will reshape the health care system.

Faced with the lack of anticoagulation blockbuster drugs in the marketplace, pharmaceutical companies are forced to focus their efforts on improving current treatments in order to improve sales.⁵⁷ For example, the combination use of clopidogrel and A.S.A. is an alternative to warfarin therapy. This is due to the problems associated with dosing, monitoring and adverse side effects of warfarin which place a burden on patients, health care professionals and the health care system.

Keeping abreast of potential new drugs in the pipeline and the changing landscape is important to pharmacy. Should a replacement therapy enter in the foreseeable future, there would be an anticipated lag time before a drug could obtain strong support from the medical community (i.e. distribution, sales and marketing, promotion and detailing of the drug). During this time, community pharmacies that are involved with anticoagulation services would be able to assess the seriousness of the threat, the drug's likelihood of success, and respond accordingly, giving sufficient time to prepare a contingency or exit plan if required.

Regulation of drugs in Canada continues after they enter the marketplace. Under the Food and Drugs Act, there is ongoing post-marketing drug safety surveillance – monitoring for safety,

⁵⁶ O'Donnell M, Agnelli G, Weitz JI. Emerging therapies for stroke prevention in atrial fibrillation. *European Heart Journal Supplements* (2005) 7 (Supplement C), C19-C27 (http://eurheartjsupp.oxfordjournals.org/cgi/reprint/7/suppl_C/C19)

⁵⁷ Frost & Sullivan. US anticoagulant market, April 2006

efficacy and quality of new drugs – as they enter the marketplace of the general population.⁵⁸ This is the result of a string of serious side effects linked to widely used medications which has led to major changes to the drug review process. During this period, serious, adverse events may become more apparent within a larger population group. Side effects and adverse events may become less discrete, which ultimately can cause drugs to be pulled from the market.

2.1.3.3 High Investment and Fixed Costs

The pharmaceutical industry continues to invest in R&D through large phase III/IV clinical trials to acquire data in order to increase sales and to introduce line extensions of existing products. Rigorous efforts are placed on the new drug discovery phase. Clinical studies seek to find drug molecules that present lower bleed risk and superior results in clinical trials. This high-risk and -reward process will, in due course, identify new therapies that will replace warfarin, but with the recent events surrounding drug safety, the regulatory approval process may take much longer for drugs to enter the market. Pharmaceuticals that enter the market must not only be efficacious but have a better safety profile: no drug interactions, less risk of bleeding, and lower mortality rate. Other factors may include ease of administration, particularly in outpatient care where therapy is required for longer treatment periods (i.e. stroke or atrial fibrillation), less drug monitoring and predictable dose response.⁵⁹ Furthermore, non-drug capabilities, such as pharmaceutical companies with superior sales and marketing capabilities, can significantly impact warfarin's market share provided that the new product has a similar efficacy profile.

2.1.3.4 Drug Coverage

New substitutable pharmaceutical entrants will traditionally be more expensive compared to the off-patent warfarin pricing. Despite receiving NOC, cost-effective care and definite improvements in patients' quality of care will be major governmental considerations before a new

⁵⁸http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/access-therapeutic_acces-therapeutique_e.html#1

⁵⁹ Frost & Sullivan et. al 2006.

drug entrant is given provincial formulary approval. Canada has a fragmented drug coverage system across the country.⁶⁰ Each provincial drug plan varies in terms of individual qualifications, drug categories, co-payments and/or deductibles. Canada has a mix of private and public coverage, with the majority of drug coverage through employer-sponsored insurance plans. The combination of private and public plans will determine who has access to prescription medications and under what conditions, and how much to pay, with the balance being out-of-pocket expenses for the individual. Without full or partial benefit status, new drugs will have difficulty penetrating the prescription market as patients are reluctant to pay for their prescriptions if alternative, less costly drugs are still available.

Furthermore, the changing economic, financial and demographic landscape has caused Canadian private businesses to re-examine their post-retirement health care coverage. Government cost-shifting and budget reform has forced private companies to increase cost-sharing, reduce medical coverage and apply stricter eligibility requirements.⁶¹ A survey of Canadian companies revealed that 95 percent said the rising cost of health care was one of the top reasons for reducing post-retirement health care benefits. This pressure will have an impact on the elderly who have private insurance through their employers and will subsequently increase out-of-pocket medication and health service expenses.

2.1.3.5 Miscellaneous

Implantable cardiac defibrillators (ICDs) have been used to deliver an electric shock to halt atrial fibrillation in carefully selected patients. Although this is an alternative to warfarin, more research is still required.⁶²

⁶⁰ Romanow R. et al.

⁶¹ Hewitts Associates. Hewitt Survey: Changes in Retiree Health Care Coverage for Canadian Companies Imminent. March 7, 2006 Newsletter.

⁶² Mitchell AR. The role of pacemaker and defibrillator therapy for the treatment of atrial fibrillation. *Minerva Cardioangiologica* 2004;52:141-153

A new drug called idaprarinux, by Organon Sanofi-SntheLabo, and used in the management of atrial fibrillation is currently under clinical trials in the phase III AMADEUS study. Given subcutaneously once-weekly, idaprarinux is not as convenient as oral warfarin but does not require coagulation monitoring. Unlike warfarin, idaprarinux does not have an antidote, so reversal will be difficult in patients who require urgent medical or surgical intervention due to hemorrhaging. More clinical trials and post-marketing surveillance will be needed in the near future and will not likely supplant the first line choice of warfarin.

Although there may not be any clinical evidence using randomised-controlled studies on the use of herbal and/or complementary medicine in anticoagulation therapy, patients continue to seek and use these products. Patients taking this approach are placing their health at risk. More seriously, patients may disregard the use of warfarin therapy altogether (i.e. non-compliance) due to the side effect profile and inconvenience of regular lab tests.

2.1.4 Threat of Entry – Moderate to High

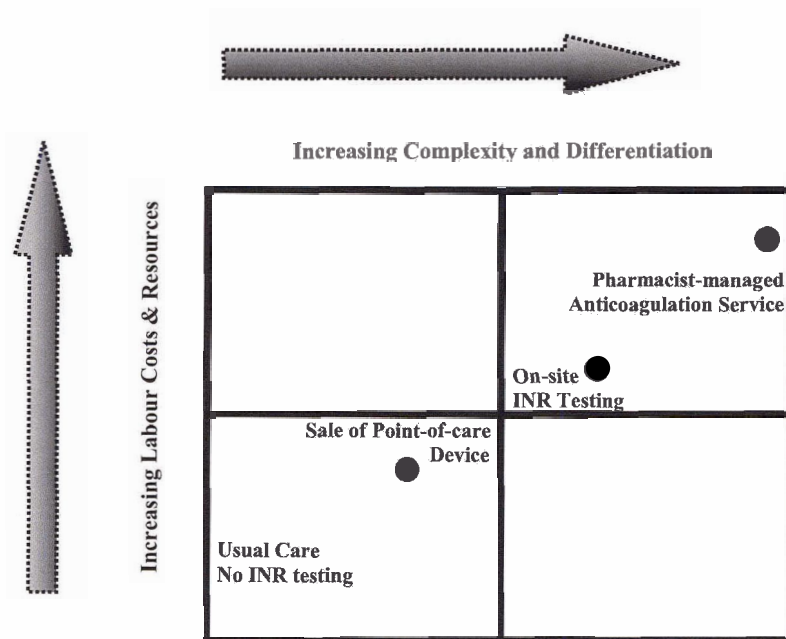
The field of anticoagulation management is fragmented and relatively new to the retail pharmacy industry. Only a few BC pharmacies have dedicated resources to pursue this new area of practice. The level of commitment from these firms varies. Most are involved in selling the Coaguchek S® device to their warfarin patients. The common entry strategies consist of:

1. **Level 1 Distribution and Training Center** – the sale of the point-of-care device, Coaguchek S®, to the patients. Resources can involve pharmacists and/or technicians.
2. **Level 2 INR Testing Center** – including Level 1, this level offers on-site testing for patients similar to a private lab. Resources can involve pharmacists and/or technicians.
3. **Level 3 Anticoagulation Center** – including Level 1 and 2, this level offers a comprehensive anticoagulation management service involving warfarin dosage adjustments, INR

interpretations, and disease state management. Level 3 is limited to pharmacists only and requires a collaborative agreement with a physician. The agreement delegates the pharmacist to provide medication management on behalf of the physician (i.e. initiation, continuation, and modification of warfarin therapy). For more details refer to table 1 in chapter 1.

As a pharmacy moves from option 1 to 3, the level of resources and financial investments increases. This is consistent with the level of complexity and differentiation involved when moving from a more product-based service of dispensing prescriptions (i.e. tangibility) to a near-pure service of patient care and medication management (i.e. intangibility). This is depicted in the anticoagulation service matrix below.

Figure 6: Anticoagulation Service Matrix



2.1.4.1 Economies of Scope

Entry into this market will vary between pharmacy formats because it requires certain internal capabilities and infrastructure changes. A highly skilled labour force (i.e. expertise in warfarin dosing) is necessary which will require high customer touch and individualized service. Those with a clinical background (i.e. hospital pharmacy experience and/or doctor of pharmacy degree) and experience in warfarin dosing are qualified to provide level 3 service. However, with extensive training, experiential learning, and using guidelines and protocols, pharmacists will be able to provide this service also. Furthermore, pharmacists graduating today are more familiar with this type of patient care philosophy. The Universities have changed their academic curriculum to focus more on pharmaceutical care activities (i.e. disease state management, developing therapeutic goals and care plan activities) – a process that is moving away from products to people. In time, more pharmacists will have the proper skill set to offer clinical services, including anticoagulation management services.

Although skilled labour is scarce at the moment, it is particularly challenging for those low-cost firms where dispensary services (i.e. high customer turnover, high prescription volume, low prices, limited customer service) is an essential element to their strategic fit. Banners and Chains, however, continue to differentiate their service levels by offering disease management programs (i.e. diabetes, asthma). They continue to invest in pharmacist and pharmacy technician training; and subsequently, these firms are familiar with pharmaceutical care and will be much better positioned to scale their services to level 2 or 3 in their stores. Further to this economy of scope is the existing infrastructure, as discussed in the next section.

Existing Infrastructure

An existing infrastructure, including internal capabilities such as marketing, and dedicated employees in the area of pharmacy operations and employee development give those firms a competitive advantage in launching an anticoagulation management strategy. These firms

generally have a corporate entity that is able to give direction and support on pharmacy-related programs. Firms such as chains, franchises, banners, and selected grocery pharmacies have this structure in place. Consequently, these firms are likely to lead the market with a program to capture either new market share or retain current market share from the low cost providers.

Those that aspire to roll out a complex anticoagulation program (top, right-hand quadrant in figure 6) must be able to tolerate the slow growth, and expect a longer term economic outlook than the norm. This is the norm for pharmacy organizations with a differentiated strategy. Building consumer interest will require investment in marketing (i.e. media, newsprint, in-store signage, and data mining) and personal selling by the pharmacist. Again, these infrastructures are in place for most of the large chains, banners and grocery chains, where they can capitalize on their economies of scale and scope.

Proper pharmacy design and workflow must be considered if offering level 2 and 3 options. A physical space that offers privacy (i.e. one-on-one consultations) and no interruptions is a necessary investment. Generally, the newer pharmacy layouts from various chains and banners have state-of-art counselling rooms, in anticipation of offering patient-focused services in the near future, while the older stores such as grocery and few independent formats, or those independent pharmacies in physician offices/clinics, are less likely to have adequate floor space. In these circumstances, expanding the pharmacy is necessary but barriers may exist due to adjacent competing departments (i.e. cosmetic department or book department in grocery store layouts) or expansion may lead to moving the entire pharmacy to a larger office space at exorbitant construction costs (i.e. medical clinics) and disruption to the pharmacy business. Overall, most pharmacies have an adequate layout for semi-private counselling.

The one-stop-shop concept is a natural fit for pharmacies that continue to offer a bundle of health services to combat the increasingly competitive environment. Patients are naturally

visiting the pharmacy for all their health and well-being needs. Extending INR laboratory testing and counselling to patients, while they are having their warfarin prescription filled, is an offering that is quick and convenient for the time-starved patient.

2.1.4.2 Warfarin Population

A threshold of warfarin patients is compulsory in order to create demand for the anticoagulation management service. Without a sufficient client-base, enrolment will be difficult and slow. Large urban centres where there is a large population of patients to draw anticoagulant clients are the most appropriate sites. Moreover, aging demographics is also important to the retailer, as warfarin is typically prescribed in the elderly population. A pharmacy that is located in a young developing community will have difficulties creating a number of clients to make the program viable. Overall, those stores in key urban areas with an aging and growing community are ideal for an anticoagulation program.

2.1.4.3 Entry Strategies

There are many deciding factors that contribute to entering the anticoagulation market. The likelihood of firms offering anticoagulation services is widely open to those that have a differentiated strategy and commitment to investing long-term resources to the program. Those firms with limited resources will likely participate at level 1 – the sale of Coaguchek S®. Minimal training (i.e. pharmacy technicians) is needed and no infrastructure changes are needed. The sale of these units is similar to the diabetes market, where blood glucose monitors are sold at all retail pharmacies. Due to these particular factors, the entry of level 1 will be much higher than the other levels.

Since the warfarin patient population continues to increase each year due to an aging population, the market will become increasingly attractive and the expectation of entry will likely increase. Firms will attempt to implement early in an attempt to capture the existing market share.

Once patients are familiar with the bundled anticoagulation service, they are likely to stay loyal to the store. To this end, entry to levels 2 and 3 will likely occur in larger urban centres where large volume pharmacies are located. Accordingly, based on the type of pharmacy competitor and the predictable strategy associated with each format, a competitor grid with entry strategies can be formulated. See Table 7 below. The field is more fragmented as the level of complexity increases.

Table 7: Competitive Strategies vs. Retail Pharmacy Format

Description	Chain / Banner / Franchise Stores	Independent Stores	Food	Mass
General Strategy	Differentiation Strategy	Differentiation Strategy	Low Cost or Differentiation Strategy	Low Cost Strategy
Level 1: Distribution Center & Training Center	Medium to High	Medium	Low to medium	Low
Level 2: INR Testing Center	Low to Medium	Low to Medium	Low	N/A
Level 3: Anticoagulation Clinic	Low to medium	Low	Fragmented and Low	N/A

2.1.5 Government– High Bargaining Power

Governments and professional regulatory bodies have significant bargaining power and influence on the health care industry. Their role in drug regulation, health reform, formulary coverage and patterns of professional practice will impact pharmacist-managed anticoagulation services.

2.1.5.1 Regulatory Approval

There are a number of emerging anticoagulants at various stages of the drug development process. It is estimated that the total revenue generated from new anticoagulants in international key markets is approximately \$10 billion by 2015, with unique oral anticoagulants contributing

70 percent of this estimate.⁶³ Biotechnology and genomics are bringing more and more advances to the forefront in drug discoveries. Table 3 is an example of potential anticoagulants presently in the drug pipeline; however, not all molecules are direct rivals to warfarin or impact INR monitoring services.

Table 8: Emerging Anticoagulants

Inhibitors of Coagulation Initiation	Inhibitors of coagulation propagation	Direct Thrombin Inhibitors
Nematode anticoagulant peptide (NAP)	Antibodies against factor IX/IXa	Recombinant hirudins (desirudin, lepirudin)
Tissue factor pathway inhibitor	Analogues of heparin (fonaparinux, idraparinux)	Bivalirudin
Active-site block factor VIIa	Direct factor Xa inhibitors	Argatroban
	Protein C derivatives	Dabigatran (oral)
	Soluble thrombomodulin	Ximelgatran (oral)*

(*recently withdrawn from the market due to severe liver toxicity)

The probability of these drugs receiving FDA approval in the United States, Notice of Compliance in Canada, and other regulatory approval to market these products is low. An ideal oral anticoagulant must have the following attributes:

- Direct and reversible mechanism of action
- Rapid onset/offset of action
- Wide safety and efficacy margin
- No food or drug interactions
- No dose titration
- No routine coagulation monitoring
- Effective safety profile (hemorrhaging)
- Patient convenience and ease to use
- Cost-effective

⁶³ www.leadingdiscovery.co.uk. Pipeline Insight: Antithrombotics and Antiplatelets Have Blockbuster Potential. Oct. 2005

According to IMS Canada, approximately less than 2 percent of proposed anticoagulant drugs make it to this final approval stage before they go to market. Health Canada assesses the risks and benefits of a new prescription drug before it reaches the Canadian market based on clinical trials and manufacturing guidelines.⁶⁴

Furthermore, the drug approval process is significantly slow. Among OECD countries, Canada's drug approval process is one of the longest. In 2000, the median approval time was 650 days due to the resource-taxing, complexity and technical intensity of the work that is required by Health Canada.⁶⁵ If a drug is successfully approved, there are other post-market surveillance issues to contend with.

The data from the clinical trials leading up to the approval process assess the risks and benefits of a new prescription drug before it reaches the market. The long-term side effect implications from the drug may not be evident until after thousands of prescriptions are dispensed and exposed to concomitant use with existing drugs and other therapeutic approaches in the current health care system. For example, AstraZeneca's new oral anticoagulant Exanta™ (melagatran/ximelagatran) was cited to be the first available alternative to warfarin.⁶⁶ It was touted as the first oral anticoagulant in 50 years to succeed warfarin as the gold standard. But in the interest of patient safety, on February 14, 2006 the company announced the withdrawal of this anticoagulant from the market and discontinued its clinical trials and any further development.⁶⁷ An updated report on adverse events identified serious liver injury, which led to the withdrawal of the anticoagulant. Bottom-line, new drugs may make a profound difference, but some new

⁶⁴ Romanow R. et. al.

⁶⁵ Rawson NSB. Issues in the Approval of, Access to, and Post-Marketing Follow-up of New Drugs in Canada: A Personal Viewpoint. *Pharmacoepidemiology and Drug Safety*. 2002. 11(4); 335-340.

⁶⁶ O'Donnell M, Agnelli G, Weitz JI. Emerging therapies for stroke prevention in atrial fibrillation. *European Heart Journal Supplements* (2005) 7 (Supplement C), C19-C27 (http://eurheartjsupp.oxfordjournals.org/cgi/reprint/7/suppl_C/C19)

⁶⁷ www.astrazeneca.com/pressrelease/5217.aspx Feb 2006

prescription drugs are not significantly more effective than older, less expensive drugs in terms of mortality rates, quality of life, and patient safety.

2.1.5.2 Health Reform

In Canada, a number of recent government commissions and reports have highlighted the need for reform of the current health care system, calling on an integrated approach to primary health care. Included in these findings is the changing role of health care professionals, including pharmacists, to better meet the needs of the general population. Canadians expect more focus on health promotion, wellness and disease prevention as important components to their health care system. This highlights the need for providers to collaborate in integrated teams and networks with an emphasis on meeting the patient's needs. Patients are taking a more proactive role in managing their health. This reform is also fuelled by rising drug expenditures in Canada. An estimated \$24.8 billion was spent in drug retailing in 2005, an increase of 11 percent from the previous year.⁶⁸ Cost-shifting of government-funded lab services to the private sector may become a reality in the long-term as the changing pharmacist roles may lead to better utilization of resources and provide patients better access to healthcare services.

Highlights from the Canadian Health Services Research Foundation suggest that pharmacists should play a significant role in primary health care.⁶⁹ Hypothetical models include:

- Pharmacists providing professional consultative services to a group of pharmacies, clinics or physicians' offices.
- In a clinic setting or a physician's office, pharmacists will be a vital member of the primary health care team.

⁶⁸ Canadian Pharmacist Association. June 2006. Blueprint for action for Pharmacy Profession in Canada. Background Paper.

⁶⁹ Canadian Pharmacist Association. et. al.

- In a community pharmacy practice setting, pharmacists will manage and direct primary health care clinics or primary health care practices.

This change to primary health care will be only a matter of time. Recently, significant changes have occurred for the province of Alberta. In May 2006 under the Health Professional Act, the Alberta government signed off this piece of legislation that expanded Alberta pharmacists' scope of practice to include prescribing. This practice change will mean improved patient care for the province.⁷⁰ This is a first in Canada and may lead to changes for other provinces. Also, in the province of Saskatchewan, there have been policy changes to permit pharmacies to offer in-store laboratory services. This recent change has allowed the profession to possibly negotiate a reimbursement fee schedule.

2.1.5.3 Benefit Status

Unlike blood glucose monitors for diabetes management, the anticoagulation point-of-care device is not covered on the provincial and federal healthcare formulary and has limited reimbursement on third party insurance plans. Consequently, the patient bears partial or full coverage of the unit. Moreover, the consumables, such as test strips, control solutions, and lancets, are also not covered. The current provincial health care system covers the cost of laboratory tests, and as a result, the cost is transparent (i.e. free) to the patient. In the end, the patient must weigh between the high costs of the home monitoring program or on-site testing at the pharmacy (i.e. a differentiated strategy) versus the inconvenience of going to an outside lab (low cost strategy).

The provincial government does not reimburse blood tests performed outside of a traditional lab or hospital, such as at community pharmacies. However, physicians are compensated for managing warfarin patients. A monthly fee is reimbursed to the physician for

⁷⁰ Wolfe K, Alberta wins expanded scope. *Pharmacy Post* July 2006;14 (7):1-15.

their time managing their warfarin patients. Those consumers who wish to have their INR tests and warfarin managed at the community pharmacy level must pay out of pocket. The expense, however, is tax-deductible. It will be a matter of time before INR testing or anticoagulation management services will also have benefit status.

Key Success Factor: the differentiated strategy must have significant value for the patient to make an out-of-pocket expense to buy the point-of-care device and consumables to self-manage their INR levels.

2.1.5.4 Professional Governing Bodies – High Bargaining Power

College of Pharmacists of BC

The College of Pharmacists of BC (CPBC) governs the professional practice and conduct of pharmacists and receives its authority from provincial pharmacy legislation.⁷¹ The CPBC's role is to ensure public safety and effective pharmacy care to help people achieve better health care. They do this by licensing and regulating pharmacists and their practice settings.

To launch an anticoagulation management service where pharmacists are either providing on-site INR testing or anticoagulation management services, the pharmacist's role and responsibilities must fall within the Framework of Professional Practice – a set of blue prints for good pharmacy practice – developed by the CPBC. The Framework of Professional Practice defines the:⁷²

- Main roles pharmacists perform;
- Broad functions that enable pharmacists to fulfil each role;
- Daily practice activities that contribute to each function;
- Indicators of good practice for each activity;

⁷¹ www.bcpharmacist.org.

⁷² <http://www.bcpharmacists.org/standards/pdf/FPP.pdf>

- Specifications for the knowledge and skills that pharmacists need.

Key success factor – The College has the authority to halt any pharmacy activity they deem unsafe to the general public. Proper protocols and standard operating procedures will be required before venturing into a comprehensive anticoagulation program in a community pharmacy practice setting. To ensure success, the pharmacy must work jointly with the CPBC and gain approval in the planning and developmental stages of the anticoagulation program. Pharmacists use the Framework of Professional Practice as a professional code of practice and as a guide to enhance the program and the professional development of the pharmacist.

College of Physicians and Surgeons of BC (CPSBC)

Very similar to the College of Pharmacists of BC, the role of the College of Physicians and Surgeons of British Columbia (CPSBC) is to protect the public by regulating the medical practice of licensed physicians. The CPSBC establishes and endorses the standards for the profession and monitors, assesses and, if required, disciplines its members.⁷³ In 2002, the CPSBC did not endorse the role pharmacists play in anticoagulation management.

The college strongly advised physicians that “such a referral would be considered an inappropriate delegation of a medical function” to pharmacists in non-hospital-based pharmacies (i.e. private community setting).⁷⁴ In the spring 2002 edition of the “College Quarterly”, produced by the CPSBC, the College expressed its concerns that the portable INR devices were inaccurate and not standardized and, as a result, physicians would potentially be making dosage changes based on inaccurate values, leaving the physician open to legal liability should a problem occur with the patient. The college also felt that “simple tests” should be properly accredited and standardized through a diagnostic accreditation program. The newsletter goes on to say:

⁷³ www.cpsbc.ca

⁷⁴ College Quarter. College of Physicians and Surgeons. Spring 2002, Issue 36; p1-7.

“Physicians are advised, therefore, not to use the facilities and the services of private pharmacies for diagnostic testing or management of patients on anticoagulants.”

The landscape has moderately changed since 2002. Today the CPSBC supports the collaborative role pharmacists play in a few areas. Most recently, the College established a collaborative agreement with pharmacists to prescribe the “morning after pill” or emergency contraceptive pill (ECP) to patients under specific guidelines.

As well, Roche Diagnostics has recently addressed many of the College’s concerns on quality issues with their portable INR device, CoaguChek S®. To ensure laboratory practice meets with the Scientific Advisory Board criteria, Roche developed a quality assurance program. Pharmacies that wish to offer on-site INR testing, must comply with the same standards held by private labs. Three times a year, they are required to submit test sample results to HealthMetrx, a company engaged in quality control tracking for multiple public and private laboratories across Canada. Those sites that fail to comply and who do not pass the quality assurance tests will have their licenses revoked. The purpose of the Q/A program is to validate: (1) quality of staff; (2) equipment; (3) testing procedures; and (4) quality of health care services. It ensures reliable results, quality service and legal protection in the event of a dispute. Additionally, laboratory practice standards are respected and promote credibility among physicians and patients.⁷⁵

Enlisting a few key opinion leaders, such as cardiologists and other related stakeholders, in supporting pharmacists-managed anticoagulation clinics and updated research papers on studies throughout Canada may dispel any issues the College may have.

Key success factors: Ensure the CPSBC endorses the pharmacist’s role in anticoagulation management. It would be a barrier to pharmacists interested in rolling out an anticoagulation program without the endorsement of the CPSBC, especially where a collaborative

⁷⁵ Roche Diagnostics Training Manual 2005.

agreement with a physician is necessary for pharmacist-managed anticoagulation services. Many physicians may first enquire of their College of the role pharmacists play in anticoagulation treatment.

2.2 Key Success Factors

Many key success factors (KSF) have been identified from the Porter Five Force analysis in the previous section. The main factors focus on the consumer, supplier, physician and professional colleges (pharmacist and physician). These key success factors are critical in developing a successful anticoagulation management program that also serves as a competitive advantage. The following illustrates the KSF in order of importance:

1. Gain consumer support by providing quality and reliable service that is personalized and patient-centred. This service consists of the following attributes:
 - a. Individualized patient care by a highly skilled medication expert
 - b. Convenience (location, accessible, hours of operation)
 - c. Enhanced patient knowledge of warfarin therapy and positive patient health outcomes

2. Gain endorsement from the medical community (physicians and Medical College) on the pharmacist's role in anticoagulation management by obtaining physician support and referrals.

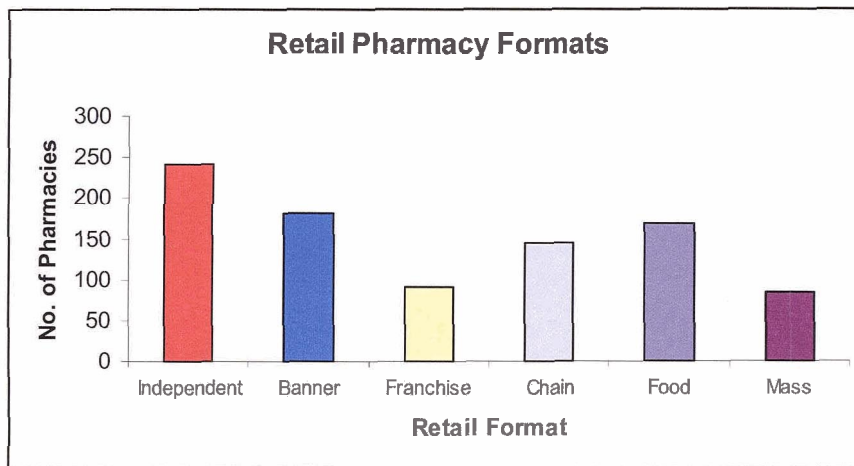
3. Gain approval and work jointly with the CPBC in planning and developing the anticoagulation program.

4. Build service loyalty and enhance value proposition through an effective marketing and advertising campaign.
5. Create a win-win partnership with supplier (i.e. Roche Diagnostics).

2.2.1 Rivals in the Retail Pharmacy Industry

In BC, there are over 3700 pharmacists and 900 pharmacies. The type of pharmacy format varies from independent community-based practice settings to institutional hospital practice settings.⁷⁶ The generally accepted competitor retail pharmacy formats are (1) chains; (2) banners; (3) food/mass/warehouse club retailers; (4) independent drugstores; and (5) franchises. See figure 6 for an illustration of the number of formats in the BC market.

Figure 7: Retail Pharmacies in Canada 2006⁷⁷



(Source: College of Pharmacists of BC)

2.2.1.1 Independent

An independent pharmacy is not associated with a corporate entity to run the banner, franchise or chain program. The name of the store is unique to that store, and the owner has

⁷⁶www.bcpharmacists.org.

⁷⁷www.bcpharmacists.org.

complete control over ordering, marketing strategies, store reputation and positioning. The owner may own more than one store; it is generally accepted that owning five or more stores under a single ownership constitutes a chain pharmacy.

2.2.1.2 Banner

Independent pharmacies are associated with a corporate entity and pay dues for the privilege to use a recognized banner name (i.e. Pharmasave, IDA, and Guardian Drugs). They participate in centralized buying, marketing and patient care programs. These banner pharmacies are independently owned, and the owners have a significant level of control in areas such as regional marketing and patient care programs. The owner may own five or more stores.

2.2.1.3 Franchise

The owner does not own the physical store or fixtures, and master leases are usually held by the franchisor. They have some level of autonomy in regional marketing, buying and in-store merchandising and patient care programs and services, as well as access to programs developed by their corporate office (i.e. Medicine Shoppe and Shoppers Drug Mart).

2.2.1.4 Chain

These pharmacies employ pharmacy managers who are salaried employees of a head office. All marketing, merchandising, buying, patient care programs and related value-added services are directed by a head office. An individual or corporation must own five or more stores to be considered a chain (i.e. London Drugs).

2.2.1.5 Food Stores

These pharmacies are departments within a supermarket outlet. They employ salaried pharmacy managers who follow the direction of head office for all marketing, merchandising, buying, and patient care programs (i.e. Loblaws, Save-On-Foods, and Thrifty Foods). These

organizations are either publicly or privately owned. Included are warehouse club stores. A warehouse club sells a limited selection of merchandise, generally in caselot and bulk sizes. Customers pay annual membership fees in order to shop in these no-frills format stores (i.e. Costco, Real Canadian Warehouse Club).

2.2.1.6 Mass Merchandisers

These pharmacies are departments within a mass merchandising outlet. They employ salaried pharmacy managers who follow the direction of head office for all marketing, merchandising, buying and patient care programs (i.e. Wal-Mart and Zellers). These large box stores have a low-cost strategy with an every day low price concept on their general merchandise and limited selection of food items. Many also feature a tire and oil change shop, optical center, one-hour photo processing lab and portrait studio. The companies are typically publicly traded on the stock exchange.

2.2.2 Rivalry

Currently, there are very few pharmacies offering anticoagulation management services at varying levels. The majority of those are selling the portable INR device, Coaguchek S®, to their patients. Because of this fragmented market and the competitive nature of the pharmacy retail industry, there are opportunities for pharmacies to consider offering a comprehensive anticoagulation management service to their patients. The following section will discuss the rivalry between retail pharmacies and the intensity of the rivalry.

2.2.2.1 Changing Landscape

The market for retail pharmacies has significantly changed over the past decade. According to IMS Health Canada, the growth of the Canadian retail pharmacy purchases continues to rise, fuelled by the introduction of newer high-priced prescription products, aging population, and consumer attitudes around health. This growth will increase traffic in the retail

pharmacy, as patients fill a larger number of prescriptions and seek additional drug and health information from the pharmacist. These are all strong indicators of a healthy market. Unfortunately, this growth creates more competition.

2.2.2.2 Entrance of Low Cost Firms

Historically, pharmacies were traditionally local, independent drugstores. Today, major chain drugstores, mass merchandisers and food store pharmacies clutter the landscape and are increasingly the dominant players in the retail pharmacy industry.⁷⁸ See Table 9 for a comparison. The price wars from mass merchandisers (i.e. “everyday low prices”) and food store pharmacies have caused rapid consolidation of small, independent drugstores. It is reported that the number of independent drugstores has dropped by 30 percent from 1994 to 2004.⁷⁹ This trend has prompted incumbent retailers to focus their attention to front store sales, and to differentiate their service levels.

Table 9: Evolution of Today’s Pharmacy

Yesterday’s Traditional “Drugstore” Less Rivalry	Today’s “Pharmacy” More Rivalry
Retail only source of prescriptions	One of many prescription choices
Independents, local community feel	Consolidation, corporate strength
Local druggist	Team of pharmacists, technicians, dietitians and nurses
Relationship Selling	Marketing, image, rewards programs, added value programs, drive-thru pharmacy
Smaller formats	Real estate focus, various retail formats (chain, grocery, warehouse club, mass merchandisers)
Limited over-the-counter/health & beauty aid selection	Channel blurring, new assortment of offerings i.e. groceries, expanded beauty care
Product distribution	Patient-centered care / medication management
Manual process	Automation, electronic billing

⁷⁸ Tenth Pharmacy Trends Report 2003.

⁷⁹ Mckesson Canada. Trends & Insights 2005.

Furthermore, the low cost strategies of Wal-Mart and big box food retailers offer an array of products and services that are homogeneous to several different channels. Adding to this intensity is the fact that consumers have choice. The low switching costs enable consumers to move from one business format to another with ease. As well, the convenient locations and diverse pharmacy formats (i.e. shopping malls, department stores, medical clinics, and food stores), extended store hours, and concentration of firms, particularly in major urban centres, increases the competitive intensity. This overabundance can be attributed to the strip mall concept where supermarket pharmacies are anchored with mass merchandisers and chain drugstores. This arrangement helps generate consumer traffic thus increasing sales for all stakeholders.

These low cost firms can stock a larger and broader inventory of HABA products and OTC drugs with which they can easily meet most demands. Their deep pockets allow them to exercise large volume buying incentives with suppliers – a competitive advantage over the smaller, independent drugstores. Wal-Mart, for example, uses its tremendous purchasing power and efficient supply chain to provide goods at a lower average price than most rivals. Moreover, the one-stop shopping concept attracts consumers to these destinations.

In response to the homogeneous services and programs offered by low cost pharmacies, chains and banner stores continue to maximize sales growth by building customer loyalty and increasing customer service and merchandising offerings. They are adopting tactics to increase basket size by improving front store layout, offering disease state management programs (i.e. smoking cessation and asthma programs), and expanding the breadth of product offerings such as cosmetic and natural health products, which require skilled labour to manage (i.e. cosmeticians, natural food advisors). See table 10 for a list of differentiated services.

Table 10: Competitive Analysis of Pharmacy Services

SERVICES	FOOD	BANNER	CHAIN	MASS	INDEPT
General Strategy	Low cost / Differentiated	Differentiated	Differentiated	Low Cost	Differentiated
In Store Health Events	+ /+++	+++	++	+	+ /++
Weekly Flyers	+++	++	++	+	- /+
Consumer Educational Materials	+++	+++	+++	+	++
Private Consultation Area	- /++	+++	+++	+	++
Online Prescription Refills	- / ++	-	++	- /++	-
Blister Packing Compliance Program	+++	+++	+++	+ /++	+++
Reward Programs	++ /+++	-	+	- /+++	-
Extended Hrs	++ /+++	++	++	++	++
Drive Thru	- /+	-	-	-	-
Website	Health tips and tools, online pharmacist & nutritionist	Health tips and tools	Health tips and tools	Limited	Limited
Added Value Programs	In-store Dietitians Diabetes Educators Community Health Events BC Nurses Line Baby Program Natural Food Advisors Smoking Cessation	“Heart Health Coaching” Program Walking Club BC Nurse Line Disease State Management Programs Community Health Events	Health Kiosks Diabetes Program INR Program Community Health Events Compliance programs BC Nurses Line Baby Program	Health magazine	Compounding Services Nursing Homes Disease State Management Internet Pharmacies Methadone Clinics Veterinary Medicine Home Care Services

2.2.2.3 Bundling

There continues to be a blending of retail formats with many grocery supermarkets featuring pharmacies and many drugstores selling convenience food items. Consequently, the retail channels are increasingly blurred. Adding a pharmacy to the grocery supermarket layout increases sales of health and beauty care by 15%-20% on sales growth in the 1st year⁸⁰. As well, adding a pharmacy improves total store traffic and customer loyalty. With these scalable effects, it is difficult for new entrants to compete. It also increases the rivalry intensity in the existing market. The overhead cost to place a pharmacy within a supermarket footprint is much less than building a drugstore. Other similar capabilities can be adopted such as adding financial or insurance services to the total store offerings (i.e. Credit Unions) or food franchises (i.e. coffee shops and fast food restaurants). Overall, the strategy is to create a “one-stop” shopping experience, increase traffic/sales, and retention of customers.

2.2.2.4 Government Budgetary Constraints

Due to the economic burden of rising health care costs, provincial and federal governments continue to place budgetary constraints on the price of drugs, and pharmacy dispensing fees; hence, the prescription margins continue to shrink in this industry forcing pharmacies to keep operating costs down and to explore revenue-generating alternative options.

2.2.2.5 Loyalty Cards and other Programs

Other non-price strategies include the increasing use of rewards/loyalty card programs. These cards offer bonus points, air miles, or discounts on in-store product purchases. These programs influence shopping behaviour as consumers continue to spend and accumulate the rewards from the card.

⁸⁰ Agnese, J. (2004). Standard and Poor's Industry Surveys. Supermarkets & Drugstores.

Firms offering reward programs have a better understanding of their current customers and are able to segment their shoppers into various levels and create targeted marketing programs that increase customer basket size, improve affinity and strengthen relationships⁸¹. Many of these programs offer on-line discounts and incentives as well. Firms that have this level of information on their customer spending and shopping behaviour have a competitive advantage. Furthermore, more firms continue to add more value to these loyalty cards by forming 3rd party alliances, such as credit card companies and insurance agencies.

Other types of programs that encourage consumers to shop include sweepstake programs. These pull strategies entice consumers to increase their shopping frequency by tying their purchase frequency to the number of entries into the sweepstake program. Overall, the use of these strategies signals a highly competitive industry where shoppers have buying power.

2.2.3 Key Success Factors and Rivalry Intensity

Using the key success factors, performance indicators can be developed to measure progress under each KSF and benchmarked against the industry competitors. See detail analysis in table 11 for a comparison of how each competitor format performs under these KSFs and the overall competitive intensity of this market. From this information, threats and opportunities can be established. The basic metrics used to rate the various competitors range from the lowest rating of (-) to the highest rating of (+++).

⁸¹ Chesak, J. 2004. Consumer Trend Insight. Frequent Doesn't Mean Loyal: Using segmentation Marketing to Build Shopper Loyalty.

Table 11: Key Success Factors for Anticoagulation Management

Description	Chain, Banner, Franchise	Indpt	Food	Mass	Private Lab	Hospital
Quality and reliable service that is personalized and patient-centred: <ul style="list-style-type: none"> ▪ Individualized service ▪ Highly skilled health professional ▪ Convenient location (free parking) ▪ Physical layout - private patient consultation area (selected pharmacies) ▪ Accessibility (hours of operation) 	+ / +++	+ / ++	+ / ++	+	-	+ / ++
Medical community support of INR testing/mgmt in Pharmacy	+	+ / ++	- / +	- / +	+++	+++
BC College of Pharmacists anticoagulation services	+++	+++	+++	+++	-	+++
Marketing Support <ul style="list-style-type: none"> ▪ Marketing & advertising resources 	+ / +++	+ / ++	+ / ++	+	- / +	-
Patient Self-Management	+	+	+	-	-	-
Collaboration with Roche Diagnostic	+++	+++	+++	+++	+	+ / ++

The performance indicators used to measure the key success factors consist of:

- Number of anticoagulation patients recruited (i.e. warfarin prescriptions/total prescriptions ratio, new warfarin patients);
- Revenues and expenses (i.e. warfarin sales, warfarin services / wage ratios);
- Physician feedback and number of referrals;
- Customer loyalty (i.e. customer satisfaction / feedback survey, repeat visits);
- Patient health outcomes (i.e. fewer thrombotic and hemorrhagic events);
- Number of patients in the desired therapeutic INR range;
- Increase market share;

The competitive intensity in the retail pharmacy industry is high due to the fact that products and services are becoming increasingly homogeneous, buyer switching costs are low, and the number of retail competitors is growing. However, as new entrants to the anticoagulation market, the competitive intensity is low. Furthermore, the monopolistic private labs (i.e. BC Biomedical and MDS Metro) do not view community pharmacy as a major threat to their industry. They have significant control of government contracts (i.e. government funding) and the distribution channels (i.e. physician referrals) to the clients. Those pharmacy retailers considering this market will be approaching it with a differentiated strategy.

2.3 Opportunities

Based on the analysis in Table 11, anticoagulation management service is a unique opportunity for those firms seeking a differentiated strategy to combat the intensely competitive pharmacy retail industry. Pharmacies have many attributes that make the market attractive:

- Pharmacists are highly skilled and are medication experts on warfarin therapy compared to the limited knowledge provided by laboratory technicians. Pharmacists are best suited to instruct patients on the complex issues of anticoagulation therapy such as drug-drug and drug-food interactions. With additional training, they will be able to assess the patients' lab values and recommend warfarin dosage adjustments. According to Ipsos-Reid, pharmacists are the leading source of information for Canadians when selecting an OTC product.⁸² Canadians are now turning to pharmacists as a source of health information and advice on dealing with minor illnesses. During their visit to the pharmacy, patients can ask the pharmacist for advice on OTC and prescription medications that may interfere with their warfarin medication. With advanced technology and better software, the pharmacist is able to

⁸² Ipsos-Reid. The Consumer Marketplace 1. Self-Medication: How Prevalent Is It? July/August 2001, Volume 16, No. 4

perform a drug-utilization review, including a drug interaction assessment that physicians can not.

- Pharmacists are more accessible and approachable, and the pharmacy is generally more conveniently located with extended hours of operation, including weekends, and with better access to parking.⁸³ Patients generally visit their pharmacy more often than any other health care professional, including the patients' family physicians.⁸⁴
- Pharmacists can provide individualized patient care with positive outcomes. The pharmacist-managed anticoagulation service increases frequency of testing, improves patient knowledge and patient satisfaction. There is an opportunity to create and enhance customer loyalty, increase store visits and shopping basket size.
- Pharmacies have internal marketing support to raise the awareness of their service, particularly those pharmacies with a corporate marketing department where they can exercise economies of scope (i.e. variety of marketing vehicles and services) and scale (i.e. lower pricing on print advertising).

In addition, other advantages that support the attractiveness of the market include:

- **Gold Standard:** Warfarin is the gold standard of therapy with no alternative therapy on the horizon. Significant R&D and marketing costs are necessary for global market development as well as high risk inherent in the drug development process (i.e. high barriers to entry).
- **Physician-Pharmacist Relationship:** Pharmacist-managed anticoagulation service improves communication and rapport with physicians and patients. This relationship may further enhance future programs and opportunities for pharmacy.

⁸³ Schulz R, Brushwood D, The pharmacist's role in patient care. *Am Pharm.* 1991; NS31: 42-8.

⁸⁴ McCurdy M. Oral Anticoagulation Monitoring in a Community Pharmacy. *American Pharmacy.* Oct.1993. NS33;10:61-70

- **Aging Demographics:** The aging population along with the prevalence of a sedentary lifestyle and obesity in Canada comes with an increase in chronic diseases such as cardiovascular diseases, including stroke, atrial fibrillation, and heart attacks. The proportion of the Canadian population over 65 years of age will double over the next decade compared to the total population, which will increase by just 20 percent.⁸⁵ About 5 percent of patients over age 65 have atrial fibrillation, and the incidence increases with age (i.e. an estimated 10 percent of patients over age 75 have atrial fibrillation).⁸⁶ These patients are at risk of a stroke between 4-15 percent per year. With the long-term use of warfarin, this risk is reduced by 65 percent.⁸⁷

- **Potential Market:** Warfarin therapy is underutilized based on its indication of use. For example, it is used in only 40 percent of patients with atrial fibrillation.⁸⁸ This suggests that the market is much greater for warfarin therapy. With this in mind, improved patient care using pharmacists-managed anticoagulation services may in fact increase warfarin utilization and better health outcomes.

- **Health Reform:** External forces, such as health reform due to rising costs, increase utilization of prescriptions, and a growing demand for better health services from an aging population, opens the door for pharmacists to take a leadership role in primary health care. Provincial-level legislative changes from Alberta has also expand the pharmacist's scope of practice to include prescribing privileges. This may set a precedence in other provinces in the near future. The timing has never been better for community pharmacists to offer anticoagulation services.

⁸⁵ Biem HJ, Semchuk W. Antithrombotic Therapy for Atrial fibrillation: Do Integrated Care Pathways Get Us There? The Canadian Association of Cardiac Rehabilitation Newsletter 2002.

⁸⁶ www.phac-aspc.gc.ca. Public Health Agency of Canada. The Changing face of heart disease and stroke in Canada 2000.

⁸⁷ Biem HJ et. al.

⁸⁸ The Medical Post, Many Canadians going without stroke therapy. Sept 19, 2000. Volume 36 issue 31.

- **New Technology:** With the introduction of convenient point-of-care testing, the sale of these devices and the availability of INR testing in pharmacies offer many possible opportunities. The advantages of point-of-care testing is illustrated in Table 12

Table 12: Opportunities with Point-of-care Technology

Description	Lab Testing	Patient Self-management	Pharmacist-Managed Anticoagulation
1. More frequent, easy and convenient		X	X
2. Quick results, leading to timely dosage adjustments		X	X
3. Enhance the patient's responsibility and knowledge of his/her own therapy		X	X
4. Better therapeutic outcomes		X	X
5. Revenue-generating opportunities		X	X
6. Expanding scope of pharmacy practice			X
7. Effective Monitor the patient's INR levels	X	X	X
8. Improve patient knowledge and subsequently reduce warfarin-related complications			X
9. Improve the quality of life for warfarin patients		X	X
10. Patients can shop while their results are reviewed by the pharmacist and physician, and have their prescription filled if required (i.e. one-stop shop concept).			X
11. Offer on-site testing outside of normal office hours i.e. evenings and weekends as retail pharmacies are open longer – some even 24/7.			X
12. Enhance the communication between the pharmacists and physicians			X

Overall, the market for warfarin therapy continues to grow, fuelled by aging demographics and the fact that there are no equivalent or more efficacious oral anticoagulant agents than warfarin for the prevention or treatment of venous or arterial thrombosis. In addition, life expectancy is increasing yearly, which leads to longevity of chronic diseases such as cardiovascular disease, atrial fibrillation and stroke. Strong research evidence supports warfarin therapy for stroke prevention in patients with atrial fibrillation. Consequently, more patients will

likely be prescribed warfarin and for a longer period. Pharmacists are in a position to take advantage of this attractive market, provided they are prepared for change and accept the roles and responsibilities that come with managing an anticoagulation service. This will be discussed in the next chapter.

2.4 Threats

Based on the Porter Five Force analysis, the two major threats to this market opportunity are: (1) physician acceptance of new role; and (2) patient acceptance to the high cost, differentiated service.

2.4.1 Physician Acceptance

The pharmacist and pharmacy must eliminate the asymmetrical information that the physician may have regarding warfarin therapy and alternative practice models. The successful implementation of an anticoagulation service relies on close collaboration between the pharmacist, patient and physician. A number of strategies are required to raise the physician awareness on (1) the collaborative role pharmacists play in improving patient health outcomes; (2) the clinical practice guidelines on the warfarin indications of use in the elderly; (3) the reliable and accurate use of INR point-of-care devices; and (4) the role patients and pharmacists play in self-management. Essentially, a strong marketing and promotional plan is necessary to gain support from the medical community.

2.4.1.1 Collaboration

Political support and alliances with the College of Pharmacists and BC, College of Physicians and Surgeons of BC, as well as the supplier (i.e. Roche Diagnostics), are key components to gaining support from the physicians. While moving away from this powerful intermediary and marketing directly to the patient is tempting, it would create barriers with the

patient's physician, particularly if a prescription is required for the anticoagulation service. A two-pronged approach of marketing to both physician and patient would be the best approach.

2.4.1.2 Effective Communication

Not all physicians will freely refer their patients to a pharmacy immediately, but they may observe the service levels and may even obtain feedback from peers. It is, therefore, important for the pharmacist to enlist support from a few physician opinion leaders to begin the process. These leaders are held in high regard and are viewed as subject matter experts amongst their peers. Having these opinion leaders support pharmacist-driven anticoagulation will alleviate significant concerns by the local community physician. Also, the ability to identify those physicians in the community who have had prior experience from other institutions in collaborating with pharmacists will be a competitive advantage to the pharmacy.

Regular and frequent communication between pharmacist and physician can help foster trust and confidence and ultimately support of the program. Communication regarding treatment plans is especially important in the initial phases as this helps to identify the physician's habits and medical preferences.⁸⁹ Letting the physician know that the pharmacist is interested in working cooperatively to achieve the physician's expectations or health outcomes and goals for their patient will help alleviate issues of "turf" protection. Periodic presentations to the local physician are important to sustain awareness, accountability and credibility of the program.

Cost avoidance or saving the physician time and money are also considerations when a pharmacist sees a patient for a one-on-one consultation on their warfarin therapy. This is especially the case for those patients with more complicated issues around their therapy. The

⁸⁹ Snella KA, Sachdev GP. Practice Insights. A Primer for Developing Pharmacist-managed Clinics in Outpatient Setting. *Pharmacotherapy* 2003;23(9):1153-1166).

physician in this example can defer their important drug-related patient telephone calls to the pharmacist.⁹⁰

2.4.1.3 Liability

Physicians that have concerns with patient liability or the quality of care provided by the pharmacist should be given an information package on the program. This package should include supporting documents and clinical studies on pharmacist-driven anticoagulation services, as well as consent forms, a scope of practice document which delineates what specific clinical services and expectations the pharmacy and pharmacists will provide, and which could include an overview of pharmacy's internal operating procedures if necessary. Patient testimonies and feedback from other stakeholders on the program may also be helpful.

2.4.1.4 Rural Communities

Areas such as rural communities in BC may also be ideal locations for community-based pharmacies to collaborate with physicians. Rural communities have a shortage of physicians and subsequently may require additional resources from other health care team members to assist in managing patients on oral anticoagulation therapy. In addition, efficient lab services may also be limited in rural a community, which raises the opportunity of point-of-care testing on-site at the community pharmacy level. Thus, physicians in these practice settings may be more receptive to pharmacists involved in coagulation management.

2.4.1.5 Supplier Involvement

Suppliers have influence and resources, such as an effective marketing and sales force, to inform and educate physicians on the role pharmacists play in anticoagulation management, as well as to market directly to the consumer. They have a close network relationship with

⁹⁰ Schumock GT, Butler MG, Meek PD, Vermeulen LC, Arondekar BV, Bauman JL. Evidence of the economic benefit of clinical services: 1996-2000. *Pharmacotherapy* 2003;23(1):113-32.

physicians through their regular office visits. During their routine drug detailing efforts at the physician's office, the sales force has an opportunity to raise the physician's awareness of the anticoagulation program options and new technology point-of-care technology that is available to patients. For example, Roche's two divisions, Roche Pharmaceuticals and Roche Diagnostics, could concentrate their efforts and target physician offices where pharmacies are set up for anticoagulation management. The supplier also has the ability to target physicians at various tradeshows and educational conferences where pharmacists may become actively involved. Hence, a strong partnership between Roche and pharmacy is vital to alleviate any concerns physicians may have.

Other marketing strategies may involve setting up an in-service at the physician's office where a pharmacist provides on-site INR testing on behalf of the physician's patients. This hands-on approach may allow the physician to experience and recognize the contribution from the pharmacist in managing their coagulation patients; furthermore, patients are able to experience the new service and technology that is available to them as well as provide immediate feedback on-site.

2.4.2 Patient Acceptance

To gain patient acceptance to the differentiated service, pharmacies must raise the perceived value versus the low-cost strategy offered by the private labs. This requires a comprehensive marketing plan with appropriate marketing mix – product strategy, effective promotional activities, the right price and ideal location to offer the service. Other marketing activities or inducements should be taken into consideration as well. See figure 7 for the various pharmacy formats and services that may influence purchasing decision.

Figure 8: Competitive Analysis of Other Key Activities

Description	Chain / Banner / Franchise Stores	Independent Stores	Food	Mass
Rewards Programs	-/+++	- /+	+++	-/+
In-store Pharmacy Clinic Programs	+++	++	+++	+
Disease State Management Programs	+++	++	+/+++	-/+
Website / Online Refills	-/++	-	+	+
Estimated Average Dispensing Fees	\$9.07	\$8.64	\$7.26	\$6.79
IT Support and Pharmacy Automation	+++	+	+ / ++	++
In-house Program & Professional Development Support Staff	+++	+	+/+++	+/++
Retail Operations Support Staff	+++	- /+	++/+++	++
Pharmacy Marketing Support	++/+++	+	+/+++	+/++
Location	++/+++	++	+++	+++
Human Resource Management	+/+++	+	+/+++	+/++

2.5 Recommended Anticoagulation Strategy

After reviewing the opportunities and threats from the external forces in BC, Level 1 is feasible, but is not the best choice. Patients may have difficulty justifying the high costs of participation in patient self-management at level 1. A combination of level 2 and 3 would be most appropriate (refer to table 1 in the first chapter for description of all 3 levels). This combination consists of:

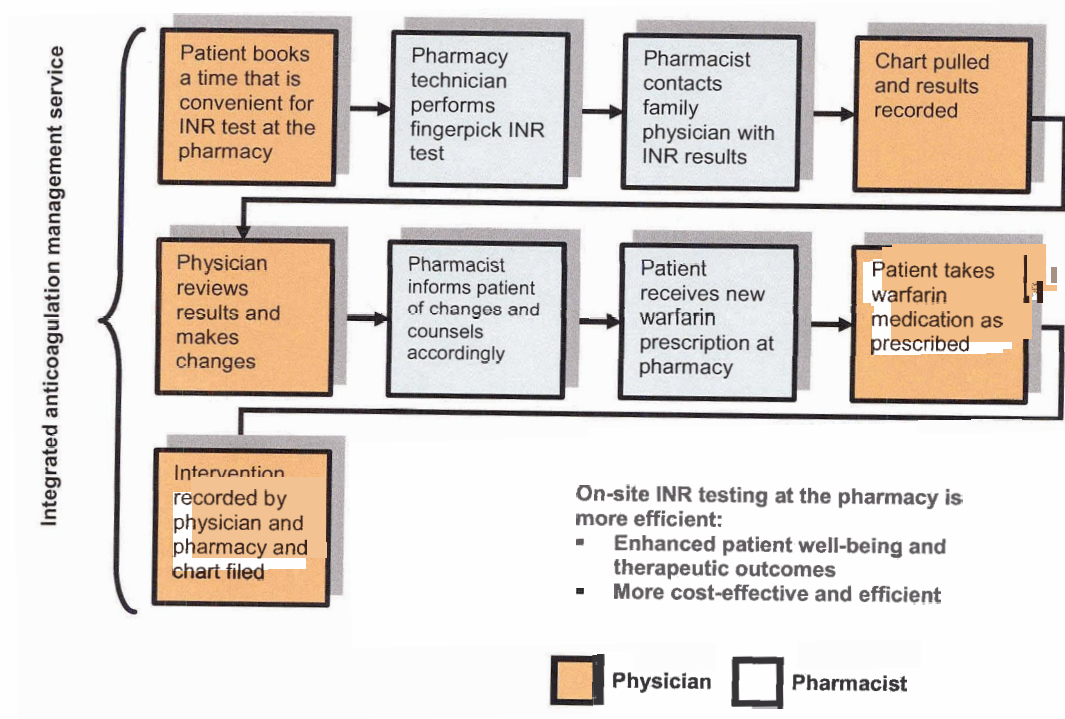
- On-site INR blood testing at the pharmacy. This will improve the quality of life for patients through quick on-site INR.
- Comprehensive counselling on warfarin therapy. This will improve patient knowledge and subsequently reduce warfarin-related complications.

- Case management and follow up. This will maintain patient's INR levels within the therapeutic range.
- Dosage recommendations without co-prescribing authority. This will enhance the communication and rapport between the pharmacists and physicians.

Until government policies and regulatory changes occur through health reform to significantly encourage a practice change, pharmacies will have fragmented prescribing authorities under a physician-pharmacist collaboration agreement. BC physicians may not, at this time, readily give pharmacists prescribing authority to provide dosage changes to their warfarin patients as indicated in level 3. Although the lack of prescriptive authority may be a barrier, pharmacists can still continue to develop a beneficial relationship with their patient and the physician. Pharmacists can continue to solve medication-related problems, set goals to enhance health outcomes, provide education and improve patients' quality of life. Therefore, a combination of on-site testing and a modified version of warfarin management may be the best strategic choice in this BC environment, with the expectation of a stepwise approach into level 3 in the future as the landscape changes. The experiential learning and tacit knowledge gained from this will also enable the pharmacy profession to transition their skill sets to other disease management programs.

A revised industry value chain of the anticoagulation service is illustrated in figure 8. The areas highlighted in green represent pharmacy integrating with the physician in orange. The overall alternative anticoagulation management model is more effective and efficient for all stakeholders involved. The traditional process may take 24 to 72 hours, depending on the availability of the physician to make the recommended dosage changes and to communicate this information back to the pharmacist. In the new model, the anticoagulation process can take 1 to 3 hours or less depending on the response time from the physician.

Figure 9: Pharmacy On-site INR Testing and Anticoagulation Management



The following chapter will focus on the internal issues – strengths and weaknesses – that pharmacies face. Any gaps in providing an anticoagulation service will need to be addressed in order to be competitive and successful.

3 INTERNAL ANALYSIS

The internal capabilities of the community pharmacy must be consistent with the pharmacy's strategy to succeed while addressing the external forces. The best option, as described in the previous chapter, is to offer on-site INR testing bundled with pharmacist-managed anticoagulation.

The next stage is to examine the internal requirements based on (1) management preferences; (2) organizational structure; and (3) resource requirements to determine if the strategy is feasible. If deficiencies exist, then gap-closing solutions are necessary.

3.1 Management Preferences

Senior management's decision criteria to support this differentiated strategy include improved customer satisfaction and retention, improved health outcomes, improved profitability (i.e. revenue-generating, increase prescription volume and other related store sales), expanding the scope of pharmacy practice and increasing or maintaining current market share. Store-level managers' typical activities are to maximize ROI. They are involved in setting plans, making store-level decisions, directing activities and organizing resources. Subsequently, there can be gaps with respect to goals and objectives between the two or more levels. In a more hierarchical organization (i.e. chains/grocery stores vs. independent pharmacies) this may be more evident, particularly when the pharmacy is a department within a large store. Therefore, there must be clear communication of the company's vision and strategic goals to help guide and motivate these managers through the change process. As well, store-level managers must be able to provide feedback and progress freely to senior managers and owners about issues and challenges they face with the program.

Due to a major practice change for those pharmacies with a product-focused strategy (i.e. prescription dispensary services), there may be store-level management resistance to change and to support for this differentiated program which involves personalized, customized services (i.e. intangible service). Store-level pharmacy managers may have difficulty overseeing their staff beyond traditional dispensary and merchandising roles, wherein they monitor and control prescription production, budgeting, scheduling, inventory management, and front store merchandising activities. These routine tasks are less complex and less difficult to solve. Furthermore, they are evaluated based on short-term profits. Anticoagulation management services require a long-term commitment which generates profits over the long-term.

In a more service-oriented strategy, store-level pharmacy managers will need to encourage employees to take on more responsibilities involving service leadership and mentoring. This new supervisory role may be more challenging for managers who are production focused, in which they are familiar with directing employees to accomplish dispensary tasks. To address these barriers, new performance indicators may need to be utilized to evaluate managers based on different metrics; for example, the number of repeat customers or recruitment of warfarin patients to the program.

Store-level pharmacy managers must be willing to evaluate their progress, have the initiative to continuously improve their practice site, and maintain a consistently high standard of practice (i.e. practice excellence). Ongoing training during work and free time will be necessary as clinical practice guidelines change periodically.

In addition, involving store-level pharmacy managers in the design and implementation of the program will help gain their support and alleviate fear of change. In many incidences, store-level pharmacy managers are directed to take on an initiative without appropriate knowledge and clear expectations of the disruptive workplace changes. Involving them in the

decision-making will give them a better understanding of the scope of the project and allow the firm to capitalize on their tacit knowledge in the area of operations, system design, and appropriate selection of employees who may be best suited for the anticoagulation program.

The anticoagulation program should have proper metrics in place such as operating performance measures to gauge the success or failure of the program (i.e. patient and physician satisfaction surveys, percentage of patients in warfarin therapeutic range). Examining industry benchmarks can also assist the pharmacy in measuring performance. See table 7 for an illustration.

Table 13: Profile of the Average Retail Pharmacy⁹¹

Description	Independent	Banner	Franchise	Chain	Food	Mass	Overall
Size of Dispensary	591	605	1,391	785	712	953	813
Size of front shop (sq.ft)	1,333	2,701	5,516	3,805	2,653	1,192	3085
Hours open (weekly)	54	63	84	71	77	70	67
Average Rx volume	37,000	51,500	83,500	64,300	35,200	46,100	55,000
Sales (\$ millions)	2.02	2.47	5.96	4.24	2.37	3.68	3.32
Net Profits	195,300	210,600	288,000	292,400	140,400	100,900	223,300
Dispensing Fee	\$9.48	\$9.32	\$9.57	\$9.40	\$6.25	\$6.49	\$9.16

Source: Trends & Insights 2005: Owners and Managers n=364 margin of error ± 4.9 percent, 19 times out of 20

3.2 Organization Analysis

3.2.1 Organization Structure

Infrastructure is a critical element of pharmacy practice and allows for efficient, cost-effective, high-quality patient services. This is supported by key components such as technology, workflow, effective use of technicians and pharmacists, and the development of policies and

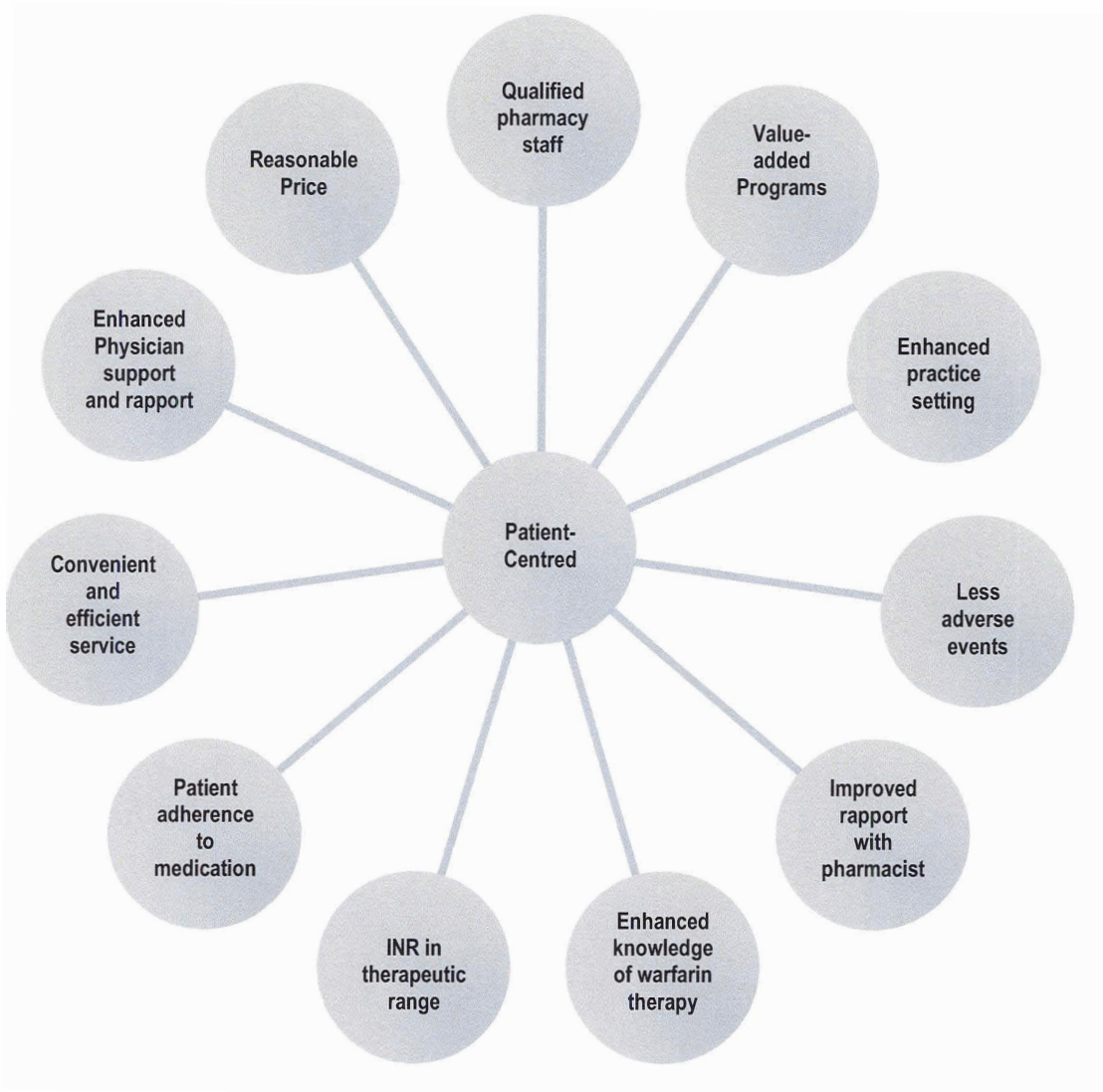
⁹¹ Mckesson Canada. Trends & Insights 2005

procedures which address all aspects of pharmacy operations. Introducing an anticoagulation management service will significantly change the way pharmacists practice.

The organization must have internal capabilities that focus on customer-facing activities that create a new value proposition for the customer. (See figure 9.) Pharmacists must be able to deliver these patient-centred core activities:

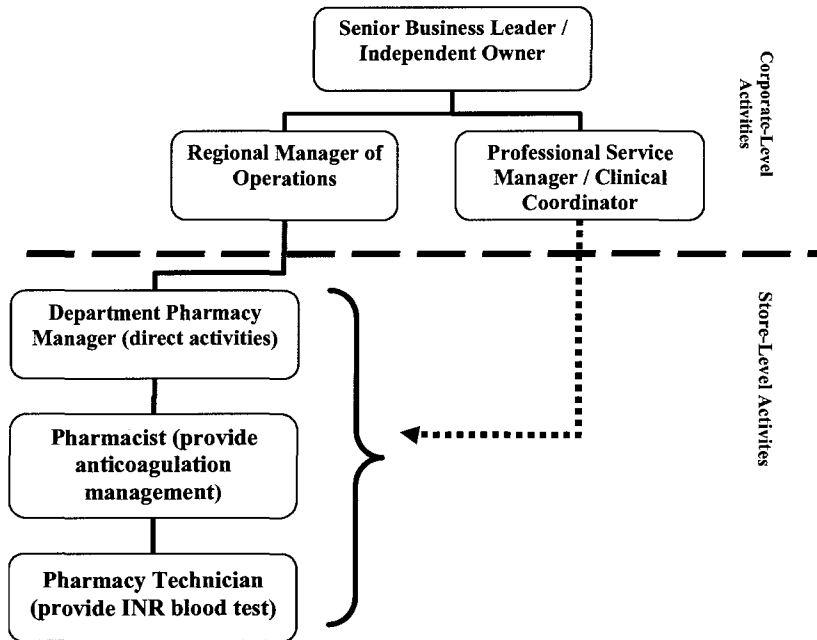
- Educating patients about the purpose of warfarin therapy and related principles of anticoagulation.
- Ensuring patients comply with the strict medication regimen.
- Assessing factors that influence warfarin therapy (i.e. diet, alcohol, and lifestyle).
- Communicating, documenting and sharing the patients' progress with other health care providers.
- Using point-of-care testing on-site and scheduling their next INR blood test.
- Following up with and managing those patients with critical INR levels.

Figure 10: Patient-Centered Anticoagulation Care



To implement and manage a community-based anticoagulation management service, the following is a typical organizational chart that would be sufficient to support the patient-care activities associated with the service. (See figure 10.)

Figure 11: Organizational Chart



Based on the above, the regional managers of operations, who are retail field specialists, ensure that all programs and corporate-driven activities are executed promptly and correctly. They are the key conduits between the retail stores and the corporate office and are responsible for coordinating and integrating activities throughout the pharmacy department. The manager of professional services or a clinical coordinator (or outside consultant) is responsible for program development, employee training and marketing. This individual works closely with all store-level team members to ensure that the program elements are appropriate and effective for the service and continues to receive feedback on improving the program. In an independent drugstore format, the organizational chart may be less hierarchical. And in many cases, the pharmacy manager would be responsible for the dual roles of both the regional manager and manager of professional services and obtains regular feedback and direction from the owner.

3.2.2 Organization Systems

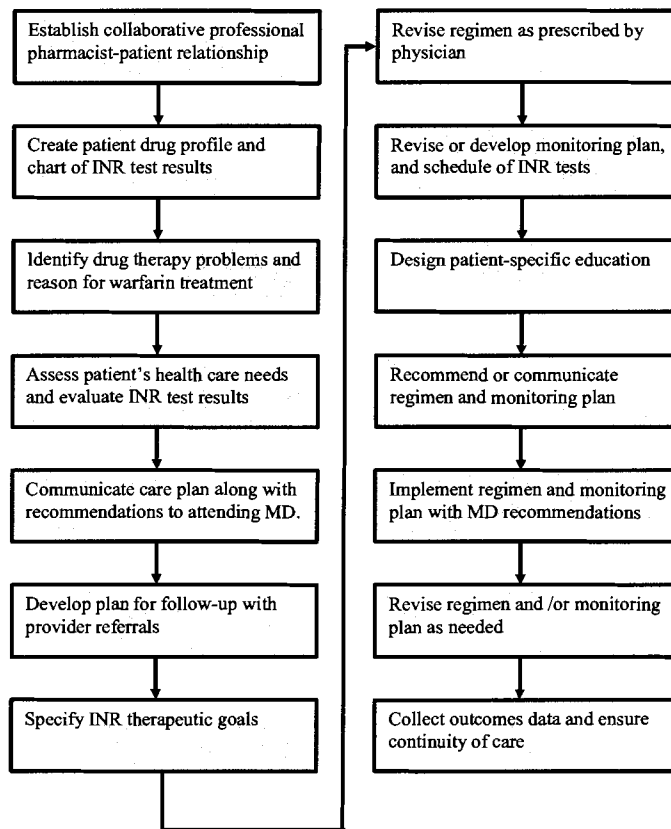
Implementing an anticoagulation management service will require changes to the organization's systems such as scope of practice, employee training and development and service levels.

3.2.2.1 Practice Change

One system change is documentation. Community pharmacists are not familiar with creating patient charts, recording patient INR records and other related activities. Documentation of patient care activities and care plans are a requirement in anticoagulation management. The documentation system enables pharmacists to systematically review the patient's health and drug treatment plan as well as record pharmacists' interventions, treatment failures, drug-related adverse events and follow up. These patient records may also be reviewed by a physician. Hence, a proper system must be put in place to ensure there is consistency in the documentation process to ensure quality care.

To ensure that pharmacists can deliver the above services, pharmacists will need to undergo advance training and be able to complete care plans for warfarin patients. See figure 11 for an illustration of the flow diagram of the tasks involved in developing patient care plans. With their new role, they will require an updated job description, including updated standard operating procedures that match the differentiated strategy.

Figure 12: Overview of Patient-specific Pharmacist Care Plan – Anticoagulation Therapy



3.2.2.2 Incentives and Compensation

Some organizations reward their employees with such as bonuses based on profits that result from dispensing prescriptions and front-store merchandising sales (i.e. OTC sales). To encourage pharmacists to adopt the new practice change and implement the anticoagulation program successfully, revisiting this compensation model may be necessary. Incentives linked to warfarin prescriptions, number of INR tests or the recruitment of warfarin patients may be a much better reward system.

3.2.2.3 Pharmacist Advanced Training

Pharmacist advanced training will be required since the level of competency and performance by the pharmacist will determine the level of quality of the anticoagulation service. Anticoagulation management requires complex cognitive problem-solving skills requiring professional judgement. In addition, case-based teaching through coaching and mentoring will aid the individual pharmacists in the early stages of their program to build confidence, enhance intrinsic motivation and promote self-esteem as they get started.⁹²

Training should include a base-level of knowledge (i.e. warfarin mechanism of action, pharmacokinetics, pharmacodynamics, dosage/schedule, indications of use, contraindications, interactions, adverse reactions), including physiology, pathophysiology of thromboembolic disorders, followed by practical applications (i.e. patient assessment and management, patient education). This training should be a combination of (1) instructional materials; (2) live continuing education programming with guided discussions/interactive lecture, including role playing or simulation; (3) the use of preceptors or mentors who are experts in the field; and (4) practice-based teaching or experiential learning on-site. The latter will require a restructuring of the work environment to create the time for training and learning. Pharmacists should also be able to assist in selecting the appropriate learning resources, where possible, to allow them to match their skills and preferences and be a part of the developmental stages; after all, they will be executing the program. Sources of anticoagulation training include:

- **Supplier** – Roche Diagnostics offers live basic and comprehensive workshops including Coaguchek S® portable device certification training.
- **Web-based Learning** – Online learning is flexible and can be learnt at the pace set by the individual pharmacist. An example of an on-line program is PHARMAlearn.com. This 6-

⁹² Holdford et. al.

hour program has been developed by the University of Alberta and is accredited for six continuing education units. Other online sites include an anticoagulation forum (www.acforum.org) consisting of a network of experienced pharmacists in anticoagulation services where pharmacists can share best practices and serve as an educational resource for ongoing continuing education.

- **Cross-border Training** – Since there are not many anticoagulation management courses available in Canada, in the US there are several live programming combined with self-study or web-based certificate training courses made available through the American Pharmaceutical Association (APhA), American Society of Health-system Pharmacists (ASHP), American College of Clinical Pharmacy (ACCP) and the National Community Pharmacists Association (NCPA).

Using a best practice model approach to anticoagulation management, the University of Alberta developed a comprehensive anticoagulation training program several years ago for their anticoagulation research project. This multi-stakeholder partnership project was initiated by the Epidemiology and Coordinating Research Centre at the Department of Medicine at the University of Alberta. It uses a physician-supervised, pharmacist-managed specialized anticoagulation management service and involved a combination of distance learning using web-based learning and readings, followed with intensive 3-day per week experiential training period, integrating theory into practice with case-based therapeutic discussions over a 4-week span. This was performed on-site at the University's anticoagulation clinic.

Training Costs

Many banners/chains and food pharmacies have yearly budgeted training costs that are reflected in the pharmacy's strategic business unit's overhead costs. Collaboration with various stakeholders, such as the suppliers and academia, may help offset some of the developmental

costs. Costs to consider when rolling out an anticoagulation program may consist of the following:

- **Instructional materials** – print and developmental costs.
- **Registration costs** – enrolling in educational programs.
- **Consulting costs** – If no in-house support staff member exists, then outsourcing talent will be a necessary expense. The use of a clinical pharmacist specializing in anticoagulation may be an appropriate choice for developing the guidelines, protocols and hands-on experiential training.
- **Opportunities costs** – costs that could be used for other store-level customer-facing activities (i.e. store-level prescription filling or patient counselling) or head office staff focusing on other professional development activities.
- **Travelling costs** – If no local training program exists, travel to or out of the city, province or country, particularly if the site is in rural BC, may be necessary.
- **Temporary staffing costs** – Pulling staff from the store to attend seminars and lectures will require replacement staff to fill regular retail duties.

3.2.2.4 Pharmacy Technician Training

To offset labour costs, pharmacy technicians play a key role in supporting the pharmacists expanding scope of practice. Technicians can be trained to provide INR testing using the Coaguchek S®. This arrangement will allow the pharmacists to focus their attention of medication management and patient consultations.

3.2.2.5 Quality of Service

Providing consistent quality service is difficult in the retail pharmacy practice, particularly if the service is offered at multiple sites. This is due to the different pharmacy staffs' skill sets, capabilities, attitudes, values and personalities. This is a significant weakness as the patient's perception and satisfaction of the anticoagulation service levels is dependent on the pharmacist's ability to deliver the program. The anticoagulation program requires the support of a patient-oriented organization that has a focus on service leadership and the investment in training and development of pharmacists and pharmacy technicians. In addition, the organization must have good hiring practices and retention strategies, because the foundation of good customer service is based on good employees.

The anticoagulation program is also a near-intangible service (i.e. combination of a patient consultation with a physical INR blood test), simultaneous in consumption and production (i.e. patient receives the service as it is produced) and heterogeneous (i.e. individualized service). This requires employees to be flexible and adaptive in making prompt, independent decisions to satisfy the unique needs of the patient within the clinical practice guidelines. This so called "employee empowerment" has many benefits:⁹³

- More individualized patient care.
- Greater ability to quickly resolve any adverse-related warfarin events (i.e. hemorrhaging).
- Pharmacists have greater ownership and responsibility in managing their warfarin patients.
- Increased loyalty to the pharmacy.

To ensure that a standard level of service is offered, the use of flow charts and service blueprints are effective in benchmarking the quality and efficiency of the program. These service

⁹³ Holdford DA. 2003, Marketing for Pharmacists. Published by the American Pharmaceutical Association. 2215 Constitution Avenue, NW, Washington, DC 20037-2985.

blueprints illustrate the service process from the perspective of all stakeholders – the patient, pharmacist, pharmacy technician and other support staff. The service process is broken down into components and allows the pharmacy to assess the various pieces, both external (i.e. customer) and internal (i.e. employee), which impact customer-facing activities.⁹⁴ It enables store-level managers to isolate service level problems and also assist in determining the roles and responsibilities.

3.2.3 Organizational Culture

3.2.3.1 Pharmacists

Since anticoagulation management is new to most community pharmacists, they may resist the practice change. Pharmacists' attitudes are a critical barrier to overcome that may be due to a number of reasons such as lack of comprehension, misconceptions, lack of motivation or simply fear of change.⁹⁵ Clearly defining their roles by collaborating with senior management and store-level managers can help dispel many misconceptions. Those that fear change may overcome this obstacle by taking additional training and setting goals and objectives at their own pace; for example, targeting three to five warfarin patients at a time. Despite the barriers, 66 percent of pharmacists agree they are interested in participating in a formal multidisciplinary primary health care team.⁹⁶

During the selection process for identifying sites for anticoagulation management services, the following employee attributes should be considered when attracting talented individuals to the program:

⁹⁴ Holdford et. al.

⁹⁵ American Pharmacists Association. A Practical Guide to Pharmaceutical Care. Second Edition. 2003. Published by the American Pharmacist Association. 2215 Constitution Avenue, N.W. Washington DC 20037-2985

⁹⁶ Mckesson Canada et. al.

- Pharmacists must be personally motivated to take on a new discipline of managing patients on warfarin therapy. They must also be willing to address internal operational challenges that may arise when launching a new program.
- Pharmacists must demonstrate initiative in providing direct patient care and patient problem-solving and exhibit a commitment to life-long learning in this area.
- Pharmacists must have strong leadership and communication skills – both verbal and written – and be willing to work in a team environment with referring physicians and other health care providers. Strong communication skills are not only necessary during their patient consultations but also marketing and explaining the benefits to patients, physicians and other related stakeholders.
- Pharmacists must be comfortable with this type of practice setting and level of patient contact; good interpersonal skills are necessary. They must also have a motivation to help patients and be effective at personal selling.
- The support of the physician cannot be overstated. Pharmacists must have a strong rapport with the medical community and convey the message that patients will not be disconnected from the physician’s care. They are a team working to improve the health status of their patient.

3.2.3.2 Warfarin Patients

Consumers purchasing the anticoagulation management service at the community pharmacy level will have a different perspective on the pharmacist’s role. Patients will be developing an ongoing relationship with the pharmacist and will have new expectations: private patient-pharmacist consultations, quick and efficient INR testing, improved patient knowledge of health status and medication information and personalized service.

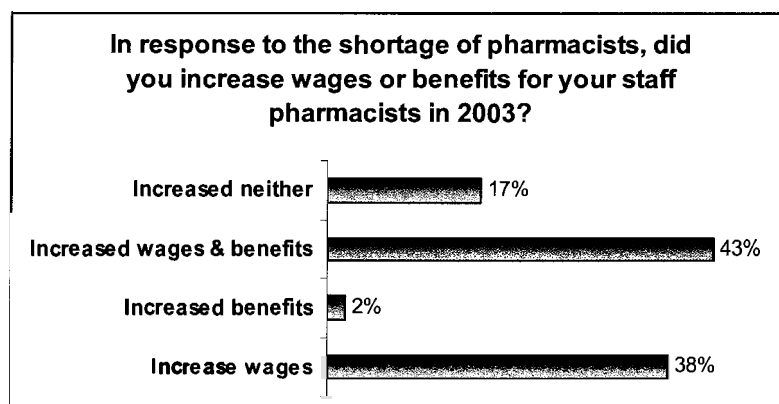
3.3 Resource Analysis

Resources that are required to operate an anticoagulation management program include (1) human capital, particularly pharmacists; (2) laboratory equipment and physical layout conducive to INR testing on-site; and (3) marketing plan.

3.3.1 Human Resource

In this highly competitive industry, price wars lead to lower economic profits. To remain competitive, operating costs need to be controlled or lowered. Labour costs are high due to the scarce supply of pharmacists.⁹⁷ Salaries, including signing bonuses and other incentives, continue to be negotiated regularly. With limited numbers of pharmacists available, service levels have a direct impact on sales. Pharmacies continue to increase staff wages and benefits each year to retain current staffing levels.⁹⁸ See figure 12 of a survey completed by a number of pharmacy owners.

Figure 13: Pharmacy Owners' Response to Pharmacy Shortage



⁹⁷Human Resource Development Canada. (2001). A situational analysis of Human Resource Issue in the Pharmacy Profession in Canada. Prepared by Peartree Solutions Inc. July 2001.

⁹⁸ 2004 Trends & Insights Pharmacy Post

Pharmacists often face environmental and administrative challenges that limit their ability to carry out pharmacy care functions and other value-added services. These challenges include limited time, limited staffing and trouble-shooting health claims online from provincial and federal governments as well as other third party insurance carriers. Drug claim administrative responsibilities create bottlenecks in the workflow as excessive paperwork is required. Additionally, as the population ages and more people reach 65 years of age, they become eligible for provincial medical coverage, which adds more time to managing these types of claims.

Historically, the short supply of pharmacists has placed significant pressure on staff morale. The exceedingly long hours and excessive number of prescriptions have left staff with limited time to counsel their patients. Most businesses prefer to operate longer hours to generate more revenue since incremental operating expenses are relatively small with the extended store hours. However, according to the Canadian Association of Chain Drug Stores, there has been a shift to reduce hours due to the shortage of professional staffing – 28 percent of drug store chains and 78 percent of grocery chains / mass merchandisers reduced their retail hours over the past year.

The environment of high prescription growth, strategic expansion, low supply of pharmacists, aging population, expanded role of the profession and low profitability forces pharmacists to work quicker, longer and harder to serve their patients. To address the resource issues, careful attention to the following is necessary: (1) the use of pharmacy technicians and reallocation of existing labour; and (2) the use of technology.

3.3.1.1 Pharmacy technicians

Pharmacy technicians play a role in transforming the pharmacy into an INR testing center. Their current responsibilities will need to adapt as the pharmacist's role changes. Their skills and competencies will have to be redefined and redeveloped to bridge the areas that can

help support the pharmacist and the anticoagulation program. Technical and administrative roles of a pharmacist will need to be transferred to a technician in order to give the pharmacist more time to focus on patient care functions. Pharmacists spend a major amount of time and effort on the details of dispensing.⁹⁹ Computer entry often takes a significant portion of the pharmacists' time, which could otherwise be redirected to patient care. Breaking down the work activities into smaller pieces will allow the pharmacy to take an inventory of tasks and determine which are better suited for the pharmacist or for the pharmacy technician. Working together with corporate management and store level staff members is an important part of the process, as it requires teamwork to evaluate the tasks with open discussion and feedback. New roles and responsibilities can be developed following this exercise. Table 8 illustrates the transfer of duties between pharmacist and technician.

⁹⁹ Zellmer WA. Unresolved issues in pharmacy. *Am J Health-Syst Pharm* 2005; 62:2005;62:262.

Table 14: Pharmacy Workload Analysis

	Current Relative Contribution (%)		Optimal Relative Contribution (%)	
	Pharmacist	Technician	Pharmacist	Technician
Medication Distribution Activities				
Procurement / drug inventory mgmt	75%	25%	35%	65%
Receive Rx / refill requests	75%	25%	15%	85%
Obtain refill authorization	70%	30%	25%	75%
Obtain / update patient information	50%	50%	25%	75%
Review Rx for completeness	90%	10%	60%	40%
Clarify Rx for processing	95%	5%	55%	45%
Enter Rx into computer	85%	15%	25%	75%
Assess DUR	95%	5%	75%	25%
Select product from shelf	60%	40%	10%	90%
Compound product / formulation if required	60%	40%	10%	90%
Prepare medication for dispensing	30%	70%	5%	95%
Label medication	30%	70%	5%	95%
Dispense medication to patient	80%	20%	60%	40%
Added-value pharmacy programs	70%	30%	10%	90%
Administrative / Operational Activities				
Process reimbursement / charges	70%	30%	10%	90%
Prepare 3 rd party reports / records	90%	10%	10%	90%
Reconciliation of 3 rd party records	85%	15%	10%	90%
DSD	60%	40%	5%	95%
Supervise / train new staff	100%	0%	75%	25%
Handle customer complaints / problems	100%	0%	50%	50%
Answer the telephone	70%	30%	20%	80%
Total Relative Contributions	1540%	560%	595%	1505%
Net Relative Contributions	73%	27%	28%	72%

Based on the calculations in the above table, staff hours can be allocated accordingly. In a typical pharmacy setting, the number of FTE pharmacist shifts, Monday to Friday, is four per day; three per day on Saturday and two per day on Sunday. This accumulates to 208 pharmacist-hours per week. Approximately, an average of 60 percent of the hours is allocated to distribution tasks and 30 percent to administrative / operational activities. The balance is used for breaks and other miscellaneous activities. Using the “current” and “optimal” net relative contributions, the change in hours made available for INR testing can be determined (i.e. 73 percent to 28 percent), then 45 percent is divided by the current net relative contribution (73 percent) to arrive at the net

decrease in contribution to non-patient care activity. This value is 115 hours. See calculations in table 9.

Table 15: Pharmacist Adjusted Hours

CURRENT STAFFING HOURS	
Pharmacist Hours Scheduled Per Week	208 hours
Current distribution staffing hours	
Average Percentage of Overall Time	60%
Estimated Hours	125 hours
Current administrative / operational staff hours	
Average Percentage of Overall Time	30%
Estimated Hours	62 hours
TOTAL	187 hours
NON-PATIENT CARE HOURS	
Current Net Relative Contribution (see Table 10)	73%
Desired Net Relative Contribution (see Table 10)	28%
Change in Net Relative Contribution (73% - 28%)	45%
Net Decrease in Contribution to Non-patient Care [(73% - 28%)/73%]	61%
Potential Hours Made Available for INR (61% x 187)	115 hours

The 115 pharmacist-hours or an average of 16 hours per day per week is now allocated to managing the INR program. Once the program is up and running, the workload can be adjusted as needed to ensure that the program is performing effectively. Once this optimal level is achieved, further efficiencies can be obtained by revising the workload and again integrating the role of the pharmacy technician. (See table 10). Note that wide sweeping changes are not recommended until the pharmacists and technicians are comfortable with their role changes,

based on the earlier work activity analysis. Moreover, there will be invariably busy and slow periods throughout the week which will require scheduling adjustments.

Table 16: Anticoagulation Workload

Anticoagulation Services	Pharmacists	Technician
Perform INR testing with POCT device	25%	75%
Review INR results	100%	0%
Medication Review / Medical History	100%	0%
Review disease information/care plan	100%	0%
Contact Physician to review results	100%	0%
Book next INR appointments and follow up	10%	90%
Total Relative Contributions	435%	165%
Net Relative Contributions	73%	28%

Based on the anticoagulation workload changes, approximately 84 hours (115hrs x 73 percent) can be allocated to the pharmacist and 32 hours (115hrs – 84hrs) to the pharmacy technician.

3.3.1.2 Technology

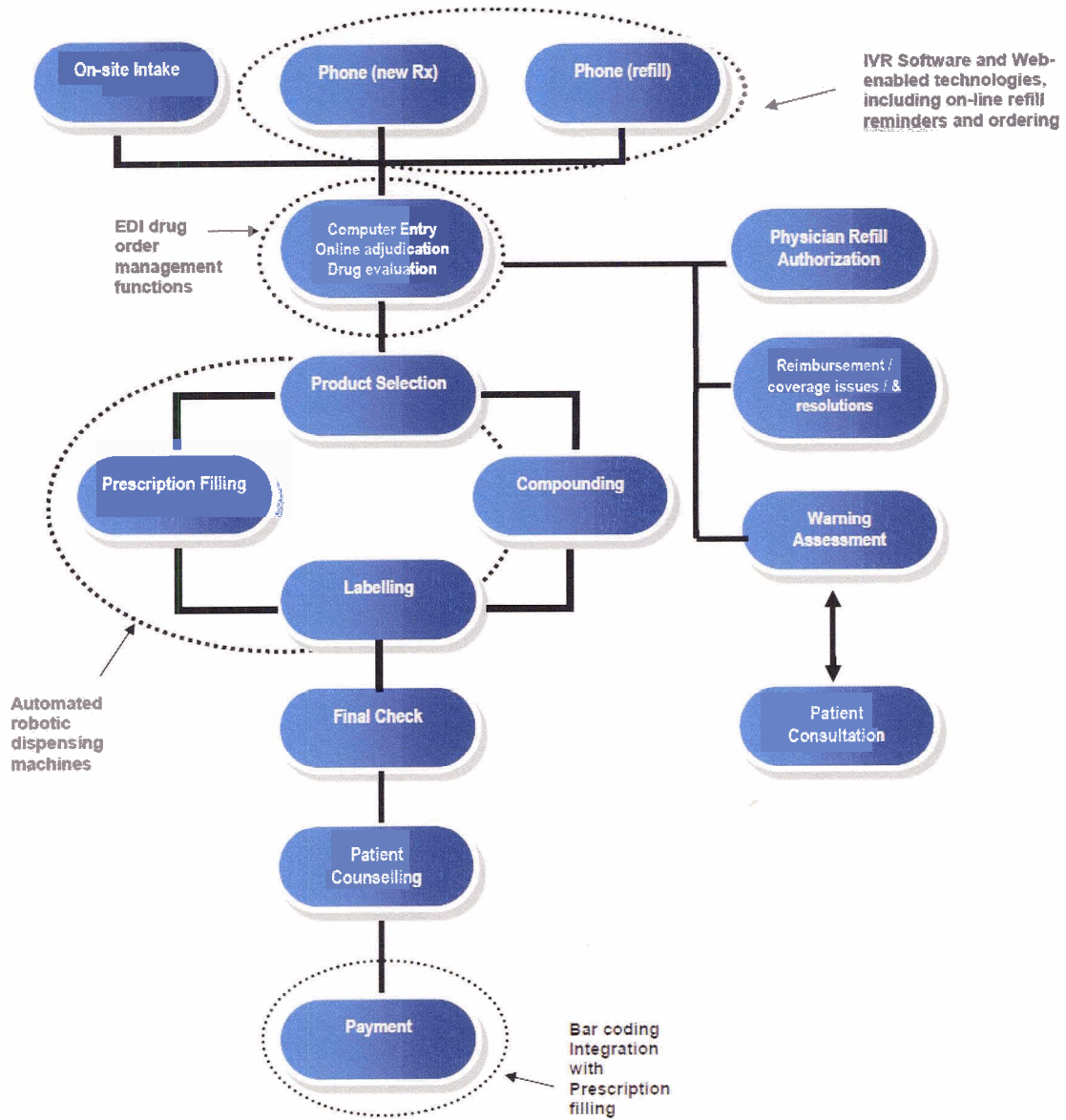
By improving the pharmacy’s primary dispensing activities, the pharmacist and pharmacy technician can focus their attention on value-added, patient-centered activities. The use of technology such as small pill counting devices (i.e. KL-15 or KL-25) or robotic prescription automation (i.e. Automed® or ScriptPro®) can augment dispensing efficiencies and address labour shortages. Figure 13 illustrates areas where technologies can:

- Improve working conditions and workflow.
- Improve productivity, and accuracy.
- Increase customer contact and service for better health outcomes.

Increase business profitability and growth.

Improve customer convenience and flexibility.

Figure 14: Technology-enhanced Dispensary Activities



3.3.2 Equipment and Facility

Offering on-site INR testing requires proper equipment. See table 11 for a list of items, including costs.

Table 17: Equipment and Facility Costs

Equipment	Price
CoaguCheck S Portable Unit	\$ 790.00
CoaguCheck EQC Electronic Control	\$ 338.00
Pharmacy Fixtures	\$ 2,500.00
Control Solutions	\$ 25.00
Promotional Kit Materials	N/C

In addition, a proper physical layout is necessary for on-site testing and subsequent patient-pharmacist consultations. There must be a balance between patient-care activities and merchandising activities. Fixtures such as table and chairs are the basic necessities for the program, including file cabinet for storing patient records. Most pharmacies have an existing counselling area or room that is designed for these types of patient-centred activities (see Marketing plan in next section) and only minor modifications may be required.

Other resource requirements include patient educational brochures, marketing materials such as in-store signage, pre-printed prescription pads and promotional brochures (see marketing plan in later section).

3.3.3 Marketing Plan

An effective marketing plan with the appropriate marketing mix is essential and one of the key success factors that must be fulfilled to be successful in launching an anticoagulation service. Investing resources into marketing is critical at this stage, especially in the introductory and growth phase of the product cycle. The marketing mix consists of product, promotion, price and place.

3.3.3.1 Product

The product is described as the range of tangible physical goods, services and information that is offered to a consumer.¹⁰⁰ The anticoagulation service is a combination of a tangible product (INR test) and an intangible service (pharmacist consultation and follow-up). The overall service can be broken into three primary components: (1) core product; (2) expected product; and (3) augmented product. The core product is the overall benefit that satisfies the underlying needs of the patient; in this case it is the patient's overall health status of his/her warfarin therapy. The expected product is the INR test results and the augmented product is the unexpected or differentiated service provided by the pharmacist consultation. (See table 12.)

Table 18: Anticoagulation Service

Total Product Concept	Description
Core Product	Warfarin Therapy: The management of warfarin therapy within the safe INR therapeutic range (i.e. no clotting or hemorrhaging).
Expected Product	INR Test: On-site 2 to 5-minute INR blood test using the point-of-care device.
Augmented Product	Consultation: 15 to 30-minute pharmacist consultation, involving assessment of the patient's health status, review of medications and any adherence issues, interpretation of INR results, development of a care plan, patient education and follow up with physician. Initial consultation will take more time, but subsequent visits will take less as patient's knowledge and understanding of warfarin therapy should improve.
Augmented Product	Follow-up: The pharmacist will follow up with the patient if any dosage changes are required. This follow up may take 2 to 5 minutes and may take place on-site following the consultation above or through a follow-up phone call.

3.3.3.2 Promotion

Promotion refers to communication in its various forms, such as advertising, direct marketing, public relations and media. The use of advertising can highlight the unique benefits of

¹⁰⁰ Holdford DA. 2003, Marketing for Pharmacists. Published by the American Pharmaceutical Association. 2215 Constitution Avenue, NW, Washington, DC 20037-2985.

the differentiated anticoagulation service and create customer awareness and interest leading to customer loyalty. A differentiated strategy highlights the value and benefits of the service rather than the price.

Pharmacies with an internal or corporate marketing department are able to use existing marketing vehicles such as store flyers, newspaper print ads, in-store posters and related signage, consumer newsletters and corporate magazines, company website and other media forms to reach the trade channels and the target consumers. Due to economies of scale, large pharmacy retailers can negotiate better advertising costs and in many cases the advertising expenditures may only be incremental if the pharmacy promotion is scaled onto an existing promotional vehicle. As well, the organization may have experience in promotional strategies, such as rewards programs, that can assist in inducing patients to utilize the anticoagulation service.

The traditional, product-oriented, pharmacy marketing model focused on selling merchandise featuring a special price through news print ads and merchandising flyers to attract customers to the pharmacy. This transactional marketing approach created immediate sales and short-term profits by driving customers to the store. The new approach is through relationship marketing by satisfying the customer's needs over a long time period. This encourages customer retention. It is estimated that increasing customer retention by 5 percent can increase profits by a low of 35 percent to a high of 95 percent.¹⁰¹

Promotion can take the form of personal selling by the pharmacist targeting various stakeholders in the local community. Some examples include:

- **Seniors' homes:** Target retirement homes, assisted living complexes or local community centres.

¹⁰¹ Mckesson Canada et. al.

- **Tertiary Hospitals:** Target pharmacists and physicians in heart failure and anticoagulation clinics in local hospitals. Those patients who are discharged from the hospital can be referred to the community pharmacy for outpatient monitoring; an example of seamless care.
- **Advocacy Groups & Associations:** Collaborate with the local Heart & Stroke Foundation branch.
- **Medial Clinics:** Target local physicians in the community or cardiology practices. Regular communication with physicians and specialists will build trust and confidence with the program. Providing an in-service or group presentation is an effective marketing tool to gain physician and patient support.
- **In-store Events:** Facilitating stroke awareness events or blood pressure programs in-store may raise awareness of the pharmacy's anticoagulation management program to targeted group of potential warfarin patients.

Promotions can also take the form of a demonstration to the patient. This can be done by personally inviting patients who are currently prescribed warfarin to an in-store demonstration or health event. The intangibility of this service makes it difficult to assess. By showcasing the value of the service, the patient receives first-hand experience and knowledge of the clinical service provided. This opportunity promotes the pharmacists' expertise and competence in providing a differentiated service compared to the lab services.

Because of the unique intangible characteristics of the anticoagulation service, one strategy is to make the service more tangible by providing the patient with documentation – a hardcopy assessment form of their health at each personalized consultation, as well as an invoice with a thorough listing of pharmacist interventions.

3.3.3.3 Price

Setting a reasonable price for the new service is one of the first steps to developing a marketing plan. Price signals quality. The higher the price is, the greater the perceived value. Other factors that may influence price and customer interest include: the degree of severity of the thromboembolic disease, the complexity of the associated therapies, and high number of medications. Wages, operating expenses and overhead costs are important considerations in setting a fee. Since the anticoagulation service is a differentiated product, bundling the offering (i.e. INR blood test and pharmacist consultation) de-emphasizes the focus on pricing. It also maintains the perceived value of the service and, in many cases, provides greater convenience for the patient (i.e. immediate INR test results with pharmacist consultation and recommended dosage changes).

In addition, a market survey conducted in 2005 indicated that fees charged for pharmaceutical services from several pharmacy retail formats ranged from \$18-\$43, depending on the type of program. See table 19 for a detailed illustration. Based on this information, the fees can serve as a benchmark for patient's willingness to pay for medical services offered by a pharmacist. The average consultation session was 32 minutes.¹⁰²

Table 19: Pharmaceutical Services & Fees

Description	Fee
Diabetes Management	\$18.59
Medication Management / Drug Utilization Review	\$27.17
Smoking Cessation	\$42.76

(n=489 pharmacists who provide special services Source: Trends & Insights 2005)

Usual Care

¹⁰² Mckesson Canada et. al.

Currently in the traditional model, MSP covers the laboratory fees for INR tests. It is seamless to the patient (i.e. perceived free). The fee schedule that is generally billed by the private labs is \$14.89. This fee typically covers the overhead costs (i.e. administration, technical and non-technical staff, infrastructure costs) and any professional activity that is deemed necessary (i.e. quality assurance, physician consultations etc...). However, the professional activity for INR is minimal and not a requirement as specified in the laboratory medicine payment schedule.

Break-even Analysis

To determine the price of the product offering and the break-even point, the estimated figures are calculated using fixed and variable cost described below. (See also tables 20, 21 and 22).

Fixed Costs:

- Training costs (Pharmacists / Pharmacy Technician)
- INR Test Equipment (CoaguChek S®)
- Quality Assurance / Maintenance Costs
- Advertising and Promotional Costs

Variable Costs:

- INR testing (i.e. test strips, lancets)
- Pharmacists' consultation
- Pharmacy Technician

Having this information will allow the firm to adjust accordingly to maximize profits (i.e. price skimming strategy) or set a target rate of return. In the analysis, a 2-percent yearly wage increase and 1-percent price increase on equipment and consumables has been included. Costs of fixtures and pharmacy layout have not been included, as many pharmacies currently have an existing counselling room or area that is designed specifically for these types of initiatives. These infrastructure costs are part of the organizations overhead costs. A clinical pharmacist has been added to the fixed costs. This individual will oversee the implementation of the program and

serve as a mentor to the practicing pharmacists during the initial phase. In some organizations, this fixed cost may be considered an overhead costs. In this example, the individual is treated as a consultant to the program.

Table 20: Fixed Costs per Pharmacy Store Location

Other Information	Figures
Yearly Wage increases	2%
Pharmacist wages	\$38
Pharmacy Technicians	\$15
Consumable Price Increase	1%

Description	Year 1	Year 2	Year 3	Year 4	Year 5
Training Costs:					
Pharmacist Training	\$ 1,960	\$ 310	\$ 316	\$ 323	\$ 329
Technician Training	\$ 120	\$ -	\$ 125	\$ -	\$ 127
Clinical Pharmacist	\$ 1,500	\$ 750	\$ -	\$ -	\$ -
Advertising & Promotions					
Newsprint ads	\$ 1,500	\$ 750	\$ 750	\$ -	\$ -
Posters / Brochures / Bag stuffers	\$ 500	\$ 250	\$ 100	\$ 100	\$ 100
Personal Selling (Wages & other related expenditures)	\$ 2,400	\$ 1,224	\$ -	\$ -	\$ -
Equipment					
CoaguCheck S Portable Unit	\$ 790	\$ -	\$ -	\$ -	\$ -
CoaguCheck EQC Electronic Control	\$ 338	\$ -	\$ -	\$ -	\$ -
Pharmacy Fixtures	\$ 2,500	\$ -	\$ -	\$ -	\$ -
Control Solutions	\$ 25	\$ 25	\$ 25	\$ 25	\$ 25
Quality Assurance Lab Requirements					
CoaguChek Teststrips	\$ 16	\$ 16	\$ 17	\$ 17	\$ 17
Wages	\$ 11	\$ 11	\$ 12	\$ 12	\$ 12
Total Set up Cost	\$ 11,661	\$ 3,337	\$ 1,344	\$ 476	\$ 610

Table 21: Anticoagulation Management Variable Costs

Description	Variable Costs	Retail Price	Margin
INR Test			
Test Strip	\$ 5.42	\$ -	
Lancet	\$ 0.12	\$ -	
Pharmacy Technician (Labour)	\$ 2.50	\$ -	
Pharmacist Consultation			
30 minute initial	\$ 17.50	\$ -	
15 minute	\$ 8.75	\$ -	
Initial visit: Bundled Consultation (30-minute)	\$ 25.54	\$ 30.00	15%
Regular visit: Bundled Consultations (15-minute)	\$ 16.79	\$ 25.00	33%

Table 22: Break-even Analysis

Break-even Volume Analysis = Fixed/(Retail-Cost)

Description	Year 1	Year 2	Year 3	Year 4	Year 5
Number of INR tests/Consultation to B/E	1,420	406	164	58	74
Estimated number of Patients Required to B/E*	79	23	9	3	4

*average yearly tests 18

Based on the break-even volume analysis and using an average retail price of \$25 per patient visit, an estimated number of patients can be determined. In the above illustration, approximately 79 patients must be recruited in the first year to break-even, based on the set up costs that have been presented. However, in the first year the set up costs are the greatest due to the initial investment of training and equipment costs. In subsequent years, the break-even volumes are much less and may be more accurately depicted and achievable.

According to the clinical practice guidelines, INR is monitored every 1-3 days during the initial phase until the INR results are in the therapeutic target for two consecutive INR values.¹⁰³ Once stable, INR tests may be performed less frequently (every 1- 4 weeks), depending on the stability of the results (i.e. two consecutive INR values within the therapeutic range). INR tests should be performed frequently (2-3 times a week) to ensure that it remains in the patient's target range if the patient is ill, if there are medication or dosage changes, or if there are significant diet change throughout the patients life. Based on this information, the number of tests can range from 15 to 20 tests per year and will vary each year for those on lifelong warfarin therapy. Also, the duration of therapy will vary depending on the type of medical indication. For example, patients with atrial fibrillation or valve replacement are on chronic warfarin therapy. For this reason, an average figure of 18 tests per year is used in the calculations.

¹⁰³ http://www.healthservices.gov.bc.ca/msp/protoguides/gps/warfarin_therapy.pdf

3.3.3.4 Place

The final marketing mix element is place. Place is the location and ease of access to the service. Providing on-site INR blood testing and patient care will require a proper pharmacy layout. The physical structure of the pharmacy including design and workflow are important factors to the overall service.

Sufficient space that is patient-oriented is mandatory so that the workflow process is smooth for both product-related functions (i.e. dispensing) and patient-related functions (i.e. INR testing and patient counselling). It must be conducive to private, one-on-one consultations between the pharmacist and patient, without any unnecessary interruptions and intrusions from other customers and staff. Additional pharmacy fixtures (storage for medical records and patient files) and displays (i.e. educational props and posters) may also be required. Other components to the anticoagulation service include lighting, cleanliness, and décor.

Many pharmacies have prepared for the expanding role of the pharmacists and have purposely designed a patient counselling area in their pharmacy with adequate privacy for one-on-one consultations. When selecting an appropriate pharmacy to provide the service, the location of the store is also an important consideration - close to a hospital or medical clinic with adequate parking.

3.4 Market Potential

The following is an estimated 5-year outlook of the project. The analysis is based on an existing pharmacy infrastructure (i.e. adequate pharmacy layout and associated fixtures in a best case scenario). According to the INR medical claims in BC, there were 925,212 INR claims in the 2004/2005 year. This estimates the market potential at \$23,130,300. Based on this figures and past yearly medical claims the annual average growth rate for INR tests is calculated to be at 7%,

according to the Medical Service Commission Payment Schedule.¹⁰⁴ Furthermore, there are approximately 600,000 warfarin patients in Canada. In BC this is estimated to be about 57,000. Yearly sales of warfarin prescriptions are indicated in table 23.

Table 23: Warfarin Prescriptions and Sales

YEAR DEC/04 Total Scripts	YEAR DEC/05 Total Scripts	YTD JNE/06 Total Scripts	YEAR DEC/04 Dollars	YEAR DEC/05 Dollars	YTD JNE/06 Dollars
359,000	387,000	215,000	\$ 8,551,000	\$ 9,113,000	\$ 4,914,000

(Source: IMS)

The following calculations are based on a growth phase of the service. The aforementioned INR growth rate of 7% will be used. Furthermore, the service is new and the anticipated competitive landscape is fragmented. An initial penetration rate of 5% of warfarin patients is used in the early phase of the program. Based on a number of studies in the US, the attrition rate (i.e. mortality rate) is less than 1% in pharmacist managed anticoagulation services.¹⁰⁵ However, for this program, an attrition rate of 10% will be used due to the different circumstances where patients are more likely to transition between pharmacist-managed anticoagulation clinics and the usual care (i.e. Lab).

Using the above information, a 5-year forecast can be calculated based on a pharmacy with 300 warfarin patients. This number of patients is estimated to generate approximately \$60,000 in yearly warfarin prescriptions and anticoagulation management fees. Only selected outlets with this large database can conceivably offer a comprehensive anticoagulation program. A client-base of this size is much higher than the average pharmacy and would be limited to those firms producing 2,000 to 2,500 prescriptions each week. However, those individual stores that do

¹⁰⁴ http://www.healthservices.gov.bc.ca/msp/paystats/FFS/ffs_manual.pdf

¹⁰⁵ Ansell J, Hirsh J, Dalen J, Bussey H, Anderson D, Poller L, et. al. Managing Oral Anticoagulation Therapy. Chest. 2001;119;22-38.

not have an adequate database of warfarin patients may consider centralizing the anticoagulation service to one location. By consolidating each store's respective warfarin patients, the break-even point can be achieved. This arrangement will enable the stores to actively participate in the full program by referring their warfarin clients to a central location within the same community. There are advantages to this arrangement: (1) it reduces overhead and training expenses; (2) it retains existing customers within the organization; and (3) it minimizes risk.

Table 24 illustrates the set up costs to implement the program, followed by the 5-year financial outlook in figure 15. The first year shows a loss due to the initial investment. However, in subsequent years there is a positive return.

Table 24: Anticoagulation Management Service - Setup Costs

Other Information	Figures
Yearly Wage increases	2%
Pharmacist wages	\$38
Pharmacy Technicians	\$15
Consumable Price Increase	1%

Description	Year 1	Year 2	Year 3	Year 4	Year 5
Training Costs:					
Pharmacist Training	\$ 1,960	\$ 310	\$ 316	\$ 323	\$ 329
Technician Training	\$ 120	\$ -	\$ 125	\$ -	\$ 127
Clinical Pharmacist	\$ 1,500	\$ 750	\$ -	\$ -	\$ -
Advertising & Promotions					
Newsprint ads	\$ 1,500	\$ 750	\$ 750	\$ -	\$ -
Posters / Brochures / Bag stuffers	\$ 500	\$ 250	\$ 100	\$ 100	\$ 100
Personal Selling (Wages & other related expenditures)	\$ 2,400	\$ 1,224	\$ -	\$ -	\$ -
Equipment					
CoaguCheck S Portable Unit	\$ 790	\$ -	\$ -	\$ -	\$ -
CoaguCheck EQC Electronic Control	\$ 338	\$ -	\$ -	\$ -	\$ -
Pharmacy Fixtures	\$ 2,500	\$ -	\$ -	\$ -	\$ -
Control Solutions	\$ 25	\$ 25	\$ 25	\$ 25	\$ 25
Quality Assurance Lab Requirements					
CoaguChek Teststrips	\$ 16	\$ 16	\$ 17	\$ 17	\$ 17
Wages	\$ 11	\$ 11	\$ 12	\$ 12	\$ 12
Total Set up Cost	\$ 11,661	\$ 3,337	\$ 1,344	\$ 476	\$ 610

There is a recognizable chance of competitors entering the market and offering a similar program. Therefore, the penetration rate in year 4 and 5 remains constant, since the competitor pricing structure is unknown. In the event, that a competitor enters the market with a price penetration or skimming approach, a revised pricing schedule will be necessary at that time. The former approach may be less likely by the competitor, as the anticoagulation management service is a small niche service. It would also be a very capital intensive strategy for the competitor to drop prices to simply drive customer traffic to the pharmacy. However, if the initiative creates consumer demand and continues to bring attractive margins, full service pharmacies will enter the market and offer a similar services. There are several options that can be taken at that time to respond to competitor prices:

- **Maintain price.** The pharmacy can keep the current pricing and carefully observe the market share and patient responses.
- **Maintain price and add value.** The incumbent pharmacy may wish to bundle the service by adding more value and maintain the current price position.
- **Reduce price.** The pharmacy can reduce the price, either at the break-even point or below cost (i.e. cost of the consumables only).
- **Increase price and improve quality.** This option may be difficult in a very competitive pharmacy industry. Patients currently have choice to go to the labs for free.

Figure 15: Five-year Financial Outlook

Description	Figures
Growth rate	7%
Cost per service	\$16.79
Retail price per patient	\$25.00
Number of tests per patient/year	18
Total Warfarin Patients	300
Attrition Rate	10%

At year 4, the growth rate is flat, due to the entrants of competitors

1 INR Testing and Anticoagulation Management Service

Description	1st Year	2nd Year	3rd Year	4th Year	5th Year
Penetration Rate	5%	7%	10%	10%	10%
# of Patients Recruited	15	22	32	30	30
Attrition*	0	2	3	3	3
Net # of Patients Recruited	15	20	29	27	27
Gross Revenues	\$ 6,750	\$ 9,212	\$ 13,095	\$ 12,150	\$ 12,150
Cost of Goods Sold	\$ 4,533	\$ 6,186	\$ 8,795	\$ 8,160	\$ 8,160
General Expenses	\$ 11,661	\$ 3,337	\$ 1,344	\$ 476	\$ 610
Gross Profits	\$ (9,444)	\$ (312)	\$ 2,956	\$ 3,514	\$ 3,380

*Attrition - refers to those patients who discontinue the use of the pharmacy anticoagulation management service

In the above model, there is an opportunity to self-select those patients who may benefit from self-monitoring their warfarin levels at home using the CoaguChek S. Earlier, this Level 1 service was briefly discussed as a feasible option. Adding it to the current program will generate additional revenue and offer patients more flexibility. A brief overview of the financials of this strategy is described below, including sales forecasts and break-even analysis. The pricing schedule for this strategy is also outlined in table 24, including suggested retails and profit margin.

Table 25: CoaguChek S Pricing Schedule

Required Items	Cost	Retail Price	Sale per Patient	Gross Profit / Patient	% Gross Profit
CoaguCheck S Portable Unit	\$ 790.00	\$ 949.00	\$ 949.00	\$ 159.00	17%
Test Strips (12 per box)	\$ 65.00	\$ 89.00	\$ 178.00	\$ 113.00	63%
Lancets (50 per box)	\$ 5.99	\$ 7.99	\$ 7.99	\$ 2.00	25%
Total \$ Per Patient / Year	\$ 860.99	\$ 1,045.99	\$ 1,134.99	\$ 274.00	24%
Yearly Maintenance Service Fee					
Quality Assurance Service	\$ 5.00	\$ 10.00	\$ 10.00	\$ 5.00	50%

Since employee training and other infrastructure costs have been accounted for, the overall expenditures to add this program is minimal. Using an estimated growth rate of 7-percent each year, a 5-year forecast of units sold can be calculated. See table 26.

Table 26: Five-Year Coaguchek S® Sales Forecast

Description	1st Year	2nd Year	3rd Year	4th Year	5th Year
Estimated percentage Patient-Self Testing	3%	4%	5%	6%	7%
Pharmacy with 300 warfarin patients	9	13	16	19	22
Projected Units Sold / Pharmacy	9	13	16	19	22
Gross Revenues of Units Sold	\$ 1,665.00	\$ 2,405.00	\$ 2,960.00	\$ 3,515.00	\$ 4,070.00
Gross Revenues of Consumables		\$ 234.00	\$ 572.00	\$ 988.00	\$ 1,482.00
Total Revenues	\$ 1,665.00	\$ 2,639.00	\$ 3,532.00	\$ 4,503.00	\$ 5,552.00
Expenses	\$ 3,220.00	\$ 2,280.00	\$ 2,080.00	\$ 1,640.00	\$ 1,000.00
Gross Profits	\$ (1,555.00)	\$ 359.00	\$ 1,452.00	\$ 2,863.00	\$ 4,552.00

By consolidating the two initiatives, this strategy portrays a much better 5-year financial outlook (see figure 16).

Figure 16: Combined Patient Self-management and Pharmacist-driven Anticoagulation Service

Description	Figures
Growth rate	7%
Cost per service	\$16.79
Retail price per patient	\$25.00
Number of tests per patient/year	18
Total Warfarin Patients	300
Attrition Rate	10%

At year 4, the growth rate is flat, due to the entrants of competitors

1 INR Testing and Anticoagulation Management Service

Description	1st Year	2nd Year	3rd Year	4th Year	5th Year
Penetration Rate	5%	7%	10%	10%	10%
# of Patients Recruited	15	22	32	30	30
Attrition*	0	2	3	3	3
Net # of Patients Recruited	15	20	29	27	27
Gross Revenues	\$ 6,750	\$ 9,212	\$ 13,095	\$ 12,150	\$ 12,150
Cost of Goods Sold	\$ 4,533	\$ 6,186	\$ 8,795	\$ 8,160	\$ 8,160
General Expenses	\$ 11,661	\$ 3,337	\$ 1,344	\$ 476	\$ 610
Gross Profits	\$ (9,444)	\$ (312)	\$ 2,956	\$ 3,514	\$ 3,380

*Attrition - refers to those patients who discontinue the use of the pharmacy anticoagulation management service

#2 Patient Self-Management

Description	1st Year	2nd Year	3rd Year	4th Year	5th Year
Projected Units Sold / Pharmacy	9	13	16	19	22
Gross Revenues of Units Sold	\$ 1,665	\$ 2,405	\$ 2,960	\$ 3,515	\$ 4,070
Gross Revenues of Consumables	\$	\$ 234	\$ 572	\$ 988	\$ 1,482
Total Revenues	\$ 1,665	\$ 2,639	\$ 3,532	\$ 4,503	\$ 5,552

Combination of Patient Self-management & Pharmacist-Managed Anticoagulation Service

Description	1st Year	2nd Year	3rd Year	4th Year	5th Year
Gross Revenues	\$ 8,415	\$ 11,851	\$ 16,627	\$ 16,653	\$ 17,702
Cost of Goods Sold	\$ 4,533	\$ 6,186	\$ 8,795	\$ 8,160	\$ 8,160
General Expenses	\$ 11,661	\$ 3,337	\$ 1,344	\$ 476	\$ 610
Gross Profits	\$ (7,779)	\$ 2,327	\$ 6,488	\$ 8,017	\$ 8,932

3.5 Summary of Internal Analysis

The internal requirements for launching an anticoagulation management service have been discussed throughout this last chapter, including areas of weakness that are common amongst most competitor formats. However, there are some salient differences between each

format as illustrated below in table 26. Selected formats may have greater capabilities and competencies than others and can support a differentiated anticoagulation program.

Table 27: Summary of Internal Requirements

Description	Chain / Banner / Franchise Stores	Independent Stores	Food	Mass
People and Skills: <ul style="list-style-type: none"> ▪ Clinically trained pharmacists ▪ Clerkship training sites ▪ Employee motivation ▪ Pharmacy continuing education 	+++	+++	+ / +++	+ / ++
IT Support / Automation	+++	+	+ / ++	+ / +++
Human Resource Support <ul style="list-style-type: none"> ▪ Labour relations ▪ Organizational Training and Performance 	+++	++	+ / +++	+ / ++
In-house program and professional development staff	+++	+	++	+
Field Specialists / District Managers/Regional managers of Operations	+++	- / +	+++	++
Service-focused Organization	++ / +++	+++	+ / +++	+ / ++
Facilities <ul style="list-style-type: none"> ▪ Convenient location ▪ Quality private patient area ▪ Enhanced store experience 	+++	++ / +++	+ / +++	+
Corporate Marketing Support <ul style="list-style-type: none"> ▪ Loyalty programs ▪ Media & community programs 	+ / +++	+	+ / +++	+

Organizations that have primary activities centred on pharmacy-related, customer-facing activities will have fewer difficulties in transitioning through a practice change. As well, organizations that have corporate resources in marketing, pharmacy program development, and organizational training and operational effectiveness, will have a competitive advantage in supporting an anticoagulation management service. Those firms must be cognizant that a pharmacist-driven anticoagulation service requires a long-term commitment. Once the program is offered, it is very challenging to remove the service, as many stakeholders are involved: patients, pharmacists, physicians and suppliers. Accordingly, only selected chains, banners and a few

grocery store pharmacy formats may be better positioned at store-level execution due to their internal capabilities, deep resources, and ongoing corporate-level support. As well, despite all the resources that are available to a particular pharmacy, without the market or demand, it can be costly to the organization. Pharmacy sites must have a high volume of warfarin patients to justify the investment. To reduce risk, firms may wish to cost-share the upfront investment between several stores in a certain region by engaging in a centralizing arrangement. The combined efforts of several stores may not only increase the warfarin patient population base, but also protect market share from competitors who may be considering an anticoagulation program in the neighbouring vicinity.

Firms should also be prepared to sell the Coaguchek S® device to those patients who would like flexibility. This full service approach brings credibility to the program by branding the pharmacists as experts in the anticoagulation field. Furthermore, creating a strong, long-lasting relationship with the patient is essential. Patients come to rely on the pharmacy, specifically the pharmacist, to trust them, and to feel comfortable consulting with them. They develop an emotional level of comfort that their health is under control with the help from their pharmacist.

4 RECOMMENDATIONS

The following section highlights the recommendations to key decision-makers who are strategically considering an anticoagulation management program in a community-based pharmacy practice setting. This differentiated strategy has revenue-generating opportunities, including potential incremental store sales and enhanced customer loyalty.

The changing health care landscape has redefined the role of pharmacists. Through an expanded scope of practice, community pharmacists have an opportunity to provide an alternative, safe and effective outpatient anticoagulation management service. Pharmacists are knowledgeable in drug therapy and are better suited to instruct patients on the complex issues of anticoagulation therapy than are the usual care providers. Using advanced technology, community pharmacists can successfully manage an anticoagulation clinic by providing INR blood tests on-site in 2 minutes, providing in-depth patient education, developing care plans, and recommending warfarin dosage changes, all at the point of care.

To be successful and remain competitive, the implementation of this alternative business model requires careful planning, internal resources, management support and appropriate organizational capabilities. Addressing the following key success factors is also critical to the business plan:

- **Patient Acceptance** – providing consistent, quality and reliable anticoagulation management service that is personalized and patient-centred.
- **Physician Support** – obtaining endorsements from the medical community on the pharmacist’s role in anticoagulation management.

- **Service loyalty** – building a sustainable and effective marketing and advertising plan to create customer loyalty.
- **Supplier Partnerships** – creating a win-win partnership with Roche Diagnostics.

4.1 Key messages for Decision-makers

Organizations considering this business opportunity must assess the competitive landscape of their local market, evaluate their internal capabilities and understand their corporate strategy before implementing a community pharmacist-driven anticoagulation management service. The organization must look at how the paradigm shift affects the structure and function of the business. Moreover, the following factors should be considered:

- Identify pharmacists who have a positive attitude and are motivated to take on a practice change in a team environment from a product-driven service to a patient-centered service. New roles and responsibilities will be required to delineate the new practice changes. In most cases, reallocating technical and administrative roles to pharmacy technicians will resolve many manpower issues.
- An effective marketing plan using the advantages of internal capabilities and resources of the organization can have large-scale effects and provide an advantage against competing pharmacies.
- Anticoagulation management services require a sustainable market. Establish a need for the services in the pharmacy's community (i.e. identify key pharmacy sites that have a growing elderly population). Ensure an adequate supply of warfarin patients exists in the pharmacy's current prescription database.

- Anticoagulation management services will reshape the way the organization does business. Create an infrastructure and organizational culture centered on service leadership and patient-centred care (i.e. physical structure, pharmacist and pharmacy technician training).
- Invest in developing the skills and knowledge of the pharmacists involved. Advanced training and credentialing may be required through a needs and knowledge assessment. Working collaboratively with the licensing and regulatory bodies is paramount.
- A pharmacist-driven anticoagulation management service is a long-term differentiated strategy that takes time, dedicated resources and ongoing commitment from senior management. Those that have short-term expectations may wish to reconsider implementing this type of program.
- Documentation of interventions and the development of care plans through regular monitoring of the patient's progress will create perceived value-added to the customer.
- Anticoagulation management is not easily scalable to other sites. Creating experiential knowledge from pharmacists is a long-term process. Once collected, this knowledge can be transferred to potentially new sites. These experienced pharmacists can serve as mentors and assist in building a client base at these new sites. Centralizing the sites may serve as an alternative strategy for those with limited resources.
- Workflow and pharmacy design changes are critical and necessary to implementing an effective anticoagulation management service.
- The skills and tacit knowledge created from implementing an anticoagulation management service may be scalable to expand the pharmacist role in other disease states.

- The combination of two business formats increases the likelihood of success (i.e. patient self-management and pharmacist-managed anticoagulation services).
- Health reform has paved the way for pharmacists to expand their scope of practice. Recent prescribing authority changes in Alberta will have a positive spill over in BC. This will further enhance the profile of anticoagulation management services and possibly economic support from government in the near future.
- Anticoagulation management services may be viewed as a patient retention strategy by many. The program can take on a relationship marketing approach that encourages frequent visits to the pharmacy and the potential to increase basket purchase and incremental sales. The target audience are generally seniors, who are likely to purchase a plethora of medications, thus increasing the pharmacy's prescription sales.

BIBLIOGRAPHY

Work Cited and Consulted

- Aaker DA. 2001. *Developing Business Strategies. 6th Edition.*
- Academic Reference Manual 2002. IMS Health Data.
- Adopted from Semchu R. Community pharmacists managing warfarin therapy. *Cdn Pharm J* 2002;(Oct):14-5.
- Alonso-coello P, Garcia-Alamino JM, Glasziou P, Heneghan C, Meats E, Perera R. Self-monitoring of oral anticoagulation: a systematic review and meta-analysis. *The Lancet* 2006; 367:404-411.
- American Pharmaceutical Association. *A Practical Guide to Pharmaceutical Care. Second Edition.* 2003. Published by the American Pharmaceutical Association 2215 Constitution Avenue, N.W. Washington DC 20037-2985.
- Anderson DR, Cox JL, MacLellan E, Martell C, Monette K, Morash T, Wilson S J. A Pilot Study Evaluating the Feasibility of Monitoring Oral Anticoagulant Therapy with Point-of-Care testing in a Community Pharmacy. *CJHP* 2004; 57: 158-164.
- Anderson DR, Cox JL, MacLellan E, Martell C, Monette K, Morash T, Wilson S J. A Pilot Study Evaluating the Feasibility of Monitoring Oral Anticoagulant Therapy with Point-of-Care testing in a Community Pharmacy. *CJHP* 2004; 57: 158-164.
- Ansell J, Buttaro ML, Thomas OV, et al. Consensus guidelines for coordinated outpatient oral anticoagulation therapy management. *Ann Pharmacother* 1997;31:604-615
- Ansell J, Hughes R. Evolving models of warfarin management: Anticoagulation clinics, patient self-monitoring, and patient self-management. *American Heart Journal* 1996; 32:1095-1100
- Ansell J, Jacobson A, Levy Jonathan, Voller H, Hasenkam M, Guidelines for implementation of patient self-testing and patient self-management of oral anticoagulation. *International Journal of Cardiology* 2005;99:37-45.
- Biem HJ, Semchuk W. Antithrombotic Therapy for Atrial fibrillation: Do Integrated Care Pathways Get Us There? *The Canadian Association of Cardiac Rehabilitation Newsletter* 2002.
- Bisanz, C. *Pharmacy in Canada: The Retail Scene.* CACDS 2005.

- Bone BF. Identifying mature segments. *J Serv Mark.* Winter 1991;5:47-60
- Buckingham TA, Hatala R, Anticoagulants for atrial fibrillation: why is the treatment rate so low? *Clin Cardio*, Vol 25, 2002, p.447-454.
- Bukszar, E (2006) EMBA Strategy Seminar Notes – Spring 2005. Vancouver: Simon Fraser University.
- Bungard TJ, Ghali Wa, Teo KK, McAlister FA, Tsuyuki RT. Why do patients with atrial fibrillation not receive warfarin? *Arch Intern Med.* 2000 Jan 10;160(1):41-6.
- Bungard TJ, Hamilton P, Tymchak W, Bringing the benefits of anticoagulation management services to the community. *CPJ/RPC* March/April 2006; 139.
- Canadian Institute for Health Information. National Health Expenditure Trends 1975-2004 Report. 2004.
- Canadian Pharmacist Association. Blueprint for action for Pharmacy Profession in Canada. Background Paper. June 2006
- Canadian Pharmacists Journal. Bringing the benefits of anticoagulation management services to the community. *CPJ/RPC*; March/April 2006, volume 139, No 2.
- Carlsson J, Miketic S, Dees S, Haun A, Cuneo A, Tebbe U. Stroke prevention practice in patients with atrial fibrillation and pacemaker therapy: Evidence for under-use of anticoagulation. *The European Society of Cardiology* (2000) 2, 115-118
- College Quarter. College of Physicians and Surgeons. Spring 2002, Issue 36; p1-7.
- Crossan M, Fry J, Killing P. *Strategic Analysis and Action* (6th Ed) Toronto: Pearson Prentice Hall. 2005.
- Engel JF, Blackwell RD, Miniard PW. *Consumer Behavior*. Forth Worth, Tex: Dryden Press; 1993
- European Atrial Fibrillation Trial Study Group. Secondary prevention in non-rheumatic atrial fibrillation after transient ischaemic attack or minor stroke. *Lancet* 1993;342:1255-62.
- Fitzmaurice DA, McCahon D, Murray ET. Point of care testing for INR monitoring : where are we now? *British Journal of Haematology* 2004;127:373-378.
- Health Canada. *The changing face of heart disease and stroke in Canada* 2000
- Heart and Stroke Foundation of Canada. *The Growing Burden of Heart Disease and Stroke*, 2003; p.43 fig.2-27, fig.2-28.
- Hewitts Associates. *Hewitt Survey: Changes in Retiree Health Care Coverage for Canadian Companies Imminent*. March 7, 2006 Newsletter.

- Hirsh J, Dalen JE, Andersen DR, Poller L, Bussey H, Ansel J, et al. Oral anticoagulants: mechanism of action, clinical effectiveness, optimal therapeutic range. *Chest* 2001;119:8S-21S.
- Holdford DA. *Marketing for Pharmacists*. Published by the American Pharmaceutical Association. 2215 Constitution Avenue, NW, Washington, DC 20037-2985. 2003
- Human Resource Development Canada. *A situational analysis of Human Resource Issue in the Pharmacy Profession in Canada*. Prepared by Peartree Solutions Inc. July 2001.
- IMS Canada. *Pharmaceutical Industry Review*. 2005
- Ipsos-Reid. *The Consumer Marketplace 1. Self-Medication: How Prevalent Is It?* July/August 2001, Volume 16, No. 4
- J. Sztajzel, H. Stalder, *Atrial Fibrillation*, *PrimaryCare* 2003; 3:695-699, p. 699
- Kotter, P, *Marketing Management*. Eleventh Edition. Copyright ©2003, 2000, 1997, 1994, 1991 by Person Education, Inc., Upper Saddle River, New Jersey, 07458.
- Lane D, Lip GY. Anti-thrombotic therapy for atrial fibrillation and patient's preferences for treatment. *Age Ageing*. 2005;34:1-3.
- Leong WA, *Anticoagulation: Opportunities for community pharmacists*. *Pharmacy Practice*. Nov 2004. Continuing Education Supplement.
- Lillan Bayne & Associates. *BC Laboratory Services Review*. July 2003.
- Mair FS, Crowley TS, Bundred PE. Prevalence, aetiology and management of heart disease in general practice. *Br J Gen Pract* 46, 77-79. 1996
- Man-Son-Hing M, Laupacis A, *Anticoagulated bleeding in older persons with atrial fibrillation: physicians' fears often unfounded*, *Arch Intern Med*, Vol. 163, 2003, p.1580-1586.
- McCall KL, MacLaughlin EJ. Ximelagatran: a new era in oral anticoagulation. *J Pharm Technol* 2003;19:222-8.
- McCurdy M. *Oral Anticoagulation Monitoring in a Community Pharmacy*. *American Pharmacy*. Oct.1993. NS33;10:61-70
- McKesson Canada. *Insights & Trends 2005*.
Retrieved July 23, 2006 from:
http://www.mckesson.ca/adocuments/news/documents/Trends_2005.pdf
- McLachlan, Spindler, Fois, Krass, Chen, and Bajorek, *A Community pharmacy based anticoagulant management service, Australia*. August 2005.
- Mitchell AR. *The role of pacemaker and defibrillator therapy for the treatment of atrial fibrillation*. *Minerva Cardioangiol* 2004;52:141-153

- O'Donnell M, Agnelli G, Weitz JI. Emerging therapies for stroke prevention in atrial fibrillation. *European Heart Journal Supplements* (2005) 7 (Supplement C), C19-C27 (http://eurheartjsupp.oxfordjournals.org/cgi/reprint/7/suppl_C/C19)
- Pavlakovic, R. Geriatrics: Special pharmacotherapy considerations. *Pharmacy Practice*. Supplement. Feb 2004.
- Porter ME, How Competitive Forces Shape Strategy. *Harvard Business Review*. March-April 1979.
- Rawson NSB. Issues in the Approval of, Access to, and Post-Marketing Follow-up of New Drugs in Canada: A Personal Viewpoint. *Pharmacoepidemiology and Drug Safety*. 2002. 11(4); 335-340.
- Regier DA, Sunderji R, Lynd LD, Gin K, Marra CA, Cost-effectiveness of self-managed versus physician-managed oral anticoagulation therapy. *CMAJ*, June 2006; 174(13): 1847-52
- Reiss RA, Haas CE, Griffis DL, Porter B, Tara MA. Point-of-Care Versus Laboratory Monitoring of Patients Receiving Different Anticoagulant Therapies. *Pharmacotherapy* 2002.
- Roche Diagnostics Training Manual 2005.
- Romanow R. Commission on the Future of Healthcare in Canada. *Building on Values: The Future of Healthcare in Canada*. 2002. National Library of Canada.
- Schaufele MK, Marcielio MA, Burke DT. Dosing practices of physicians for anticoagulation with warfarin during inpatient rehabilitation. *Am J Phys Med Rehabil* 2000 Jan-Feb;79(1):69-74
- Schulz R, Brushwood D, The pharmacist's role in patient care. *Am Pharm*. 1991; NS31: 42-8.
- Schumock GT, Butler MG, Meek PD, Vermeulen LC, Arondekar BV, Bauman JL. Evidence of the economic benefit of clinical services: 1996-2000. *Pharmacotherapy* 2003;23(1):113-32.
- Skinner BJ, Canada's Drug Price Paradox. *The Unexpected Losses Caused by Government Interference in Pharmaceutical Markets*. February 2005. Fraser Institute Digital Publication
- Snella KA, Sachdev GP. Practice Insights. A Primer for Developing Pharmacist-managed Clinics in Outpatient Setting. *Pharmacotherapy* 2003;23(9):1153-1166).
- Stein PD, Beemath A, Olson RE, Trends in the incidence of pulmonary embolism and deep venous thrombosis in hospitalized patients, *Am J Cardiol*. 2005 Jun 15;95(12):1525-6., Abstract, NCBI PubMed
- Tenth Pharmacy Trends Report 2003.

The Medical Post, Many Canadians going without stroke therapy. Sept 19, 2000. Volume 36 issue 31.

Frost & Sullivan, U.S. anticoagulant market, April 2006,

Vasishta S, Toor F, Johansen A, Hasan M, Stroke prevention in atrial fibrillation: physicians' attitudes to anticoagulation in older people, Arch Gerontol Geriatr Vol. 33, 2001, p.219-226.

Wenger NK, Scheidt S, Weber MA. Anticoagulation at elderly age: the challenge to do better. Am J Geriatr Cardiol 2003 May-Jun;12(3):152-152.

Wilson SJ, Wells PS, Kovacs MJ, et al. Comparing the quality of oral anticoagulant management by anticoagulation clinics and by family physicians: a randomized controlled trial. CMAJ 2003;169:293-8.

Wolfe K, Alberta wins expanded scope. Pharmacy Post July 2006;14 (7):1-15.

Zellmer WA. Unresolved issues in pharmacy. Am J Health-Syst Pharm 2005; 62:2005;62:262.

Internet Sources

<http://ww2.heartandstroke.ca>
<http://www.aafp.org>
www.aafp.org
www.astrazeneca.com
www.bcbio.com
www.bcpharmacist.org
www.cpsbc.ca
www.hansonmedicalsyste.ms.com
www.hc-sc.gc.ca
www.health.gov.bc.ca
www.healthservices.gov.bc.ca
www.ir.hemosense.com
www.leadingdiscovery.co.uk
www.mdsdx.com
www.medcompare.com
www.phac-aspc.gc.ca
www.roche-diagnostics.com
www.statcan.ca
www.tigc.org