Towards an integrated web-based service for the management of patients requiring oral anticoagulation in Ireland

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Declaration

I declare that the work described in this dissertation is, except where otherwise stated entirely my own work, and has not been submitted as an exercise for a degree at this or any other university

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Summary

Oral anticoagulation is a necessary treatment for people at increased risk of potentially fatal blood clots. Regular blood monitoring with an INR is required to prevent adverse events. A low INR or too little medication places the patient at increased risk of thrombosis; a high INR or too much medication places the patient at risk of bleeding. Monitoring can occur in hospital-based clinics, GP surgeries or in the patient's home.

Anticoagulation monitoring in a systematic manner leads to improved patient outcomes. The location in which this monitoring occurs is immaterial; the attention to detail is not. Anticoagulation clinics are struggling to cope with increasing patient numbers. Any further increase is likely to result in compromised safety and quality of care for all patients. In view of this, a different way of delivering a high quality, safe, cost effective and convenient service to all patients is urgently required.

There is a large body of evidence confirming the effectiveness of other models of care such as near patient testing in the GP surgery and patient self-testing. This raised the possibility of monitoring all patients using a coordinated web-based approach thus providing consistent quality of care in the hospital, the community and in the home. Web-based computerized decision support software would allow expert supervision of all patients on anticoagulation without the need for hospital visits

The aim of this research was to see if this model of anticoagulation monitoring was acceptable to all stakeholders and to examine the barriers to implementation of such a system. A series of non-structured interviews and focus groups, a patient questionnaire and an extensive literature review were the research methods employed.

An integrated web-based system will be a reality in the coming months. The adoption of a national strategy in respect to these management systems presents a unique opportunity to develop a national, web-based anticoagulation management system.

Abbreviations

ACCP	American College of Chest Physicians
BCSH	British Committee for Standards in Haematology
CAD	Computer Assisted/Aided Dosing
CDSS	Computerised Decision Support Systems
DOH	Department of Health
DoHC	Department of Health and Children
DVT	Deep Vein Thrombosis
HSE	Health Service Executive
INR	International Normalised Ratio
ISI	International Sensitivity Index
NEQAS	National External Quality Assurance Scheme
NPSA	National Patient Safety Agency
NPT	Near Patient Testing
OAT	Oral Anticoagulant Therapy
PE	Pulmonary Embolism
POCM	Point of Care Meter
POCT	Point of Care Testing
PSM	Patient Self-Management
PST	Patient Self-Testing
PT	Prothrombin Time
TTR	Time in Therapeutic Range
VTE	Venous thromboembolism

Table of Contents

Table of Contents (cont)

List of Figures

Chapter 1 Introduction

1.1 Introduction

Oral anticoagulation with vitamin K antagonists is the treatment of choice for people at increased risk of potentially fatal blood clots. Warfarin was first prescribed, as an oral anticoagulant, more than 50 years ago. It remains the most widely used oral anticoagulant in the world and the only one licensed for use in Ireland. (MIMS 2008). Warfarin is a vitamin K antagonist. For the purposes of this dissertation the terms oral anticoagulant, vitamin K antagonist and warfarin are interchangeable.

An estimated 2% of the population require anticoagulation with warfarin. Indications for its use include the treatment and prevention of deep vein thrombosis (clot in deep veins of legs) and pulmonary embolism (clot in lung, which can be fatal) and the prevention of thrombosis associated with mechanical heart valves.

The most common indication however is the treatment of atrial fibrillation, a cardiac condition characterised by an irregular heartbeat. The indications for this therapy are increasing at a rate of 10% per year as the evidence for its effectiveness in preventing stroke in patients with atrial fibrillation continues to mount. No accurate Irish data are available on the number of patients currently receiving oral anticoagulation. Patient numbers are set to increase further as only one quarter to one half of patients who would benefit are currently receiving it. (Connolly 2000)

One of the major issues associated with the use of oral anticoagulant therapy (OAT) relates to the substantial inter and intra-individual biological variability in patient response to treatment. This is dependant on genetic factors, drug absorption, pharmacological interactions and dietary components. Additionally, these medications have a narrow therapeutic index making the management of oral anticoagulant therapy particularly challenging.

Such management requires regular blood monitoring to ensure correct dosage. Monitoring occurs by means of a blood test known as an INR (International Normalised Ratio). A low INR or too little medication places the patient at increased risk of thrombosis; A high INR or too much medication places the patient at risk of bleeding. Monitoring can occur in hospital-based clinics, GP surgeries or in the patient's home.

The frequency of monitoring varies from every three days to every twelve weeks with most patients requiring testing on a fortnightly basis. Monitoring ensures that patients are within a given therapeutic range and experience the benefits associated with warfarin therapy whilst minimising the risks. This causes enormous inconvenience to patients and their service providers but is a prerequisite for safe and effective care.

According to the National Patient Safety Agency (NPSA) in the United Kingdom, warfarin is one of the medications most commonly associated with fatal medication errors in primary care. In secondary care, warfarin is one of the ten drugs most frequently associated with dispensing errors. Resultant claims prompted the inclusion of anticoagulants as a high-risk medication in the Department of Health report, 'Making Medication Practice Safer' (Department of Health 2004). This report identified high-risk behaviours and made recommendations on the implementation of additional safety measures in the United Kingdom.

1.2 Motivation

Monitoring in specialised anticoagulation clinics by dedicated staff improves control and reduces complications. Anticoagulation monitoring in a systematic manner leads to improved patient outcomes. The location in which this monitoring occurs is immaterial; the attention to detail is not.

Anticoagulation clinics are struggling to cope with increasing patient numbers. Any further increase is likely to result in compromised safety and quality of care for all patients. In view of this, a different way of delivering a high quality, safe, cost effective and convenient service to all patients is urgently required.

The numbers of patients requiring treatment is similar to the numbers of patients requiring treatment for diabetes. The HSE have recognized the need for a new model of care to cater for the increasing number of patients with Diabetes. The recent publication of A Practical Guide to Integrated Type 2 Diabetes Care (Harkins 2008) copper fastens this commitment. Our aging population requires a more pro-active model of care, with inbuilt flexibility to deal with the diverse demands of persons at different stages of their disease. This is true of all chronic diseases and not just diabetes. The Transformation programme reiterates the development of integrated care across primary, secondary and community care. (HSE 2006)

The author proposes that a similar system would be ideally suited to anticoagulation management. This would lead to a reduction in the number of patients needing hospital monitoring and increase the amount of time available to staff to see new and complex patients. The monitoring of anticoagulant medications with appropriate dose adjustment can occur in hospital-based clinics, in primary care or in the patient's home in an integrated manner.

1.3 Research Question

The research questions asked were if an integrated web-based model of anticoagulation monitoring was acceptable to all stakeholders, and what, if any were the barriers to the implementation of such a system. An assessment of the status of both the hospital and community clinics was conducted in order to answer the research questions in more detail.

The aim of assessment were therefore

- To obtain demographic information on patients attending hospital and community based clinics
- To ascertain patient preference with respect to anticoagulation monitoring
- To identify potential barriers which might hamper the success of the proposed model of care

1.4 Methods

In order to answer the research question posed in this thesis, three distinct bodies of work were undertaken.

Firstly, a series of non-structured interviews and focus groups explored the attitudes, perceived obstacles and receptiveness of stakeholders in the hospital and in the community to the implementation of a novel model of care.

Secondly, a questionnaire was administered to patient groups attending the hospital based clinic and the community clinics recording demographics, attitudes, and preferred model of care.

Finally, an extensive literature search examined the evidence for an integrated model of care in other jurisdictions to determine its generalisaility and possible utility in the Irish setting.

1.5 Contribution

The Irish situation is not unique. Hospital based anticoagulation clinics have reached capacity and the current models of care are unsustainable for a variety of reasons. General practitioners are ideally placed to provide an anticoagulation monitoring service, which has been traditionally provided in the hospital. Furthermore, patients are seeking patient orientated models of care.

The background work and literature review undertaken here are applicable to all healthcare providers managing oral anticoagulation. The principle of integrated care may serve as a future model for anticoagulation management in Ireland.

Ultimately findings from this thesis may support the creation of a centralised, web-based, national anticoagulation management system for all patients in primary, community, secondary and tertiary care.

1.6 Thesis Outline

Chapter 2 presents an introduction to oral anticoagulant therapy. It examines the difficulties involved in the monitoring of OAT. It also details the monitoring and safety aspects that form the hub of any anticoagulant service. The models of delivering anticoagulation services and the evidence supporting each model are critically appraised. The development of the warfarin services in St James's Hospital and the South Inner City Partnership is outlined. Much of the terminology used throughout this thesis is introduced in chapter 2.

'State of the art' as it applies to an integrated model of care for patients receiving oral anticoagulation is discussed in chapter 3. Chapter 3 will present the evidence for integrated models of care and appraises models of care in other countries.

The research methodology is presented in chapter 4 and the results are analysed in chapter 5. Chapter 6 discusses the limitations and possible solutions and finally, chapter 7 concludes this piece of work.

Chapter 2 Background

2.1 Introduction

Warfarin is the oral anticoagulant of choice in most countries. The problems associated with the administration and monitoring of anticoagulants were alluded to in chapter one. .This chapter provides a detailed history and rationale for the use of anticoagulant therapy in order for the reader to gain a broader understanding of the complex issues involved in the prescription of these medicines. Much of the terminology used in this dissertation is introduced in this chapter. The development of the hospital and community anticoagulation clinics is outlined. Evidence from the literature for current practices is included as appropriate.

2.1.1 Terminology

Thinning of the blood in order to prevent excessive or abnormal clotting is termed anticoagulation. This is broadly achievable by two methods. The first is by administration of parenteral agents by injection. The second is with enteral or oral anticoagulant therapy. Warfarin is the most commonly prescribed oral anticoagulant worldwide. It is a member of the coumadin family of oral anticoagulants, which also includes acenocoumarol and dicoumarol. All of these medications have a similar mode of action. They work by antagonising the effect of Vitamin K. and are also referred to as Vitamin K antagonists (VKA). The terms oral anticoagulant, oral anticoagulant therapy (OAT), vitamin K antagonist (VKA) and warfarin are used interchangeably in this dissertation. The next section describes the discovery of warfarin.

2.2 Background

2.2.1 Historical perspective

Oral anticoagulation originated with the discovery of the agent responsible for "sweet clover disease" in cattle on the prairies of North America in the 1920s. Cattle were dying of uncontrollable bleeding. This bleeding was due to ingestion of mouldy sweet clover hay. Spoiling of sweet clover hay held in damp storage by bacteria converted the natural coumarin into a potent anticoagulant. In 1939, Karl Paul Link identified this anticoagulant substance as dicoumarol (Campbell and Link 1941, Link 1959).

Link's group subsequently synthesized more than 150 anticoagulant compounds. Analog number 42 was particularly active and was given the name *warfarin*, from the initials of the ***W****isconsin* ***A****lumni* ***R****esearch* ***F****oundation*, which funded the research. Warfarin was found to be a potent rat poison which was its indication for use when patented in 1948. It had been suggested that dicoumarol and warfarin could be used as anticoagulants in humans but an antidote was required. In the early 40's it was shown that Vitamin K could reverse the bleeding properties of these agents. At this time these agents were trialled in humans and their clinical potential began to be realised.

Warfarin was first used as an anticoagulant almost 60 years ago. In 1953, President Eisenhower was treated with compound 42 after suffering a coronary thrombosis. This enabled "rat poison" to gain acceptance as an oral anticoagulant. Despite a large amount of investment in technology and drug development, warfarin still remains the oral anticoagulant of choice worldwide and is the only oral anticoagulant licensed for use in Ireland. The next section will examines why patients require therapy with these agents.

2.3 Indications for Use

Warfarin is indicated for the long-term treatment and prevention of thromboembolism. This primarily relates to the treatment and prevention of deep vein thrombosis and pulmonary emboli collectively known as venous thromboembolic disease (VTE) and to the secondary prevention of thromboembolic events in patients with mechanical heart valves.

The numbers of patients requiring anticoagulation for these indications has remained stable, however the number of patients attending anticoagulation clinics has increased exponentially. The reason for the dramatic increase is due to warfarin's efficacy in preventing stroke in patients with atrial fibrillation. This will be discussed in the following section.

2.3.1 Stroke prevention in patients with atrial fibrillation

The indications for use and demographics of patients using these medications changed dramatically in the early 1990's. Around this time there was overwhelming evidence from randomised controlled clinical trials that dose adjusted warfarin was effective in preventing strokes in patients with an irregular heartbeat known as atrial fibrillation.

This effect was most dramatic in patients over the age of 75 and there appeared to be no upper age limit at which the effect was lost. Despite clear evidence from clinical trials and strong support from more than fifteen years of clinical guidelines only half of the patients in whom oral anticoagulation is indicated with no clear contraindication are estimated to have received therapy.

It is currently estimated that more than half of patients with atrial fibrillation remain unidentified and less than half of those identified are receiving treatment (Connock 2007). With the number of stroke events expected to rise

to “epidemic” level secondary to atrial fibrillation in an increasingly aged population, there are significant financial implications. An economic analysis suggested that almost 1% of National Health Service expenditure in 2000 was related to atrial fibrillation and its related outcomes (Fuller 2005).

Atrial fibrillation affects more than 5% of the population over 65 years of age and 10% of the population over 75 years. By 2030 one in four of the Irish population will be over 65. (Central Statistics Office 2006) This has significant implications for health service provision. Atrial fibrillation is well recognised to increase the risk of embolic stroke, particularly in the elderly; anticoagulation with warfarin substantially reduces this risk. This was confirmed in a meta-analysis of 16 trials of anti-thrombotic therapy (Hart 1999).

There is overwhelming, grade A, level 1 evidence for the use of warfarin in preventing stroke in patients with atrial fibrillation. Oral anticoagulant therapy remains severely under-prescribed. (Sudlow 1998, Samsa 2000, Connolly 2000). Part of the explanation relates to the biological properties of this class of drugs and will be discussed next.

2.4 Mechanism of Action

The coumarins or vitamin K antagonists have been the mainstay of oral anticoagulation for over sixty years. Warfarin is the most commonly prescribed of all of these compounds. The clinical effectiveness of oral anticoagulant therapy is undisputed.

The main reasons for the lack of use of this highly effective therapy are obvious when one understands the mechanism of action, monitoring and biological effects of this class of drugs. The following section will examine this in more detail.

Vitamin K is a necessary co-factor involved in the synthesis of clotting factors in the liver. Warfarin partially blocks or “antagonises” this process, which thins the blood and causes an anticoagulant effect. Under-anticoagulation can result in thrombosis which can be life threatening. Over-anticoagulation can result in haemorrhage, which can also be fatal (Baglin 2006). Warfarin has a narrow therapeutic window and requires regular blood monitoring to ensure the optimum anticoagulant effect.

Unlike other medications, there is considerable variability in dose response amongst patients. This inter-individual dose variation is due to genetic and other factors and is one of the reasons why blood monitoring is so important (Ansell 2008). This is particularly true at the initiation of warfarin therapy. Most adverse events occur within the first three months of therapy and this is reflected in the increased requirement for blood testing at initiation of treatment.

More drug interactions have been reported for warfarin than for any other commercial drug. The only common side effect of anticoagulant therapy is haemorrhage (bleeding). Intracranial haemorrhage is the only complication of anticoagulation that regularly produces deficits more severe than the strokes that such therapy is intended to prevent. The risk of bleeding is directly related to the intensity of anticoagulation (Palereti 1996).

2.5. Monitoring of Anticoagulant Effect

2.5.1 Internationalised Normalised Ratio (INR)

Recognition of the haemorrhagic side effects of warfarin led to the development of the prothrombin time test for monitoring anticoagulant activity. A sample of blood is collected in a tube containing anticoagulant. Thromboplastin and a source of calcium are added to the blood sample. This causes the patients blood sample to clot. The time it takes for the blood to clot is measured in seconds and is referred to as the prothrombin time or PT.

It was recognised that different batches and manufacturers of this biologically obtained thromboplastin led to different prothrombin time measurements on the same venous sample. This meant that the prothrombin time was unreliable and not comparable with previous results. It also explained the wide variability in bleeding among patients with similar prothrombin times. Standardisation provided the solution. .

The thromboplastin or tissue factor was sourced from a wide variety of animal species and tissues. Thromboplastins varied widely in their responsiveness to a reduction in the vitamin K dependent clotting factors. The responsiveness of a thromboplastin can be measured by assessing its International Sensitivity Index (ISI). Each manufacturer gives an ISI (International Sensitivity Index) for any tissue factor (thromboplastin) they make. The ISI value indicates how the particular batch of tissue factor compares to an internationally standardised sample. The ISI is usually between 1.0 and 1.4.

A calibration model, suggested by Kirkwood in 1982, is now used to standardise reporting by converting the PT ratio measured with the local thromboplastin into an INR as follows

$$\mathbf{INR} = \left(\text{Patient PT/ Mean Normal PT}\right)^{\mathbf{ISI}}$$

The INR is more accurate with sensitive thromboplastin reagents with lower ISI values. This INR result is in use all over the world to monitor the warfarin effect. A person not taking warfarin should have an INR of 1.0. The therapeutic range for most patients on warfarin is an INR of between 2.0 and 3.0.

2.5.2 Quality Assurance

Oral anticoagulant monitoring has traditionally been hospital based, in part because of the need for laboratory measurement of the INR. The difficulties associated with INR measurement have been discussed in the previous section. There were wide variations in readings from different hospital laboratories. It is not surprising that there was a large amount of resistance to measuring the INR outside the hospital setting.

All laboratory tests are subject to stringent quality procedures and protocols. This involves both internal checks of the analyser and reagents used to measure the INR in a process referred to as internal quality control. All laboratories are also encouraged to participate in external quality assurance schemes such as National External Quality Assurance Scheme (NEQAS), (Murray 2004). Participation in these schemes ensures that the same result is obtained from the same sample in different laboratories and is an effective way of checking that the laboratory is getting the "right" result.

Despite major concerns about the performance of INR testing outside the hospital laboratory, it was clear that in the face of a rapidly expanding number of anticoagulated patients, that some degree of decentralisation was desirable. The solution came in the form of near patient testing using point of care meters.

2.5.3 Point of Care Meters (POCM)

Near patient testing (NPT) or point of care testing (POCT) is defined as the performance of a diagnostic test outside a laboratory setting. Point of care meters (POCM) are not new modalities in the management of chronic illness. Patients with diabetes have checked their blood sugars used portable glucometers for years.

A similar system was devised for measuring the INR. A portable coagulometer measures the INR of whole blood obtained by a finger prick. A strip is inserted

into the monitor. The strip contains thromboplastin that is activated when a drop of blood is placed on the strip. An INR value is displayed within one minute of placing the blood sample onto the test strip. Internal quality control measures prevent an INR from being displayed if certain conditions are not met.

The manufacturers have addressed the initial concerns. Additional safety features and internal quality controls are inbuilt on the latest models. Extensive external quality comparisons with laboratory testing demonstrate excellent correlation. While small differences in the INR result may appear, it is their effect on clinical management that is important and none of the reports indicate significant differences in clinical management associated with the use of POCM. (Shiach 2002)

Despite initial concerns, INR results obtained using portable coagulometers give accurate, reliable, valid and reproducible results, (Hobbs 1997, Shiach 2002, Poller 2003, Murray 2004, and Bereznicki 2007). Continuous collaboration between laboratories and primary care is essential if Point of Care testing is to be safely and effectively utilised.

2.6 Safety and Quality of Care

The primary focus of quality is this context is to ensure that anticoagulated patients spend the maximum amount of time within the desired therapeutic range. Over anticoagulation increases the risk of life threatening bleeding and under anticoagulation increases the risk of thrombosis. The quality of the monitoring service is the primary determinant of adverse events. Safety aspects and measuring the quality of an anticoagulant service will be discussed in the next section.

2.6.1 National Patient Safety Agency (NPSA)

The National Patient Safety Authority (NPSA) reported 480 cases of harm or near harm associated with anticoagulants in the UK between 1990 and 2002. There were 120 deaths in the same period, 93 of which were due to Warfarin. In primary care, anticoagulants are one of the classes of medicines most commonly associated with fatal medication errors. It is no surprise to hear that the National Health Service (NHS) litigation authority have reported that anticoagulants are one of the ten drugs most commonly involved in claims against the NHS (Department of Health, United Kingdom, 2004).

There is a direct relationship between adverse events and the quality of anticoagulation monitoring. A risk assessment of all aspects of anticoagulant therapy was undertaken to identify specific areas which were thought to contribute to the high incidence of harm. (**Appendix 4)** On the basis of this work, the NPSA suggested some safer practice solutions. These are outlined in full in **Appendix 5** and can be found at http://www.npsa.nhs.uk.

The recommendations are numerous and relevant but recurring themes are improved education, documentation and communication. Regular monitoring of specific safety indicators is required and this information is readily captured by all computer dosing software. A brief discussion on safety indicators is necessary.

2.6.2 Time in Therapeutic Range (TTR)

Monitoring of the effect of warfarin is required to ensure that the risk of bleeding is kept to a minimum but that excessive clotting is prevented. This is achieved by adjusting the dose of warfarin to keep the INR between two predefined measurements (Target Range) The amount of time the INR is between these two values is the Time in Therapeutic Range (TTR)

The relationship between the intensity of treatment and the risk of adverse events has been evaluated by examining the frequency of adverse events as a function of the TTR. A strong relationship exists between the TTR and bleeding and thromboembolic events. It is widely accepted that the percentage of time for which the patients INR is in range can be consistently improved by the use of computerised assisted dosing. Improved time in range has been shown to correlate with patient outcome.

2.6.3 Frequency of Monitoring

Clinical studies show that there is a clear relation between adequate control of anticoagulation and a lower incidence of bleeding and thrombotic complications in patients on oral anticoagulation. (Levine 1998, Cannegieter 1995). Evidence suggests that more frequent monitoring may improve the time in therapeutic range (TTR). As TTR is a surrogate marker for safety, more time in the therapeutic range has been associated with fewer adverse events.

There is still no definite recommendation on the optimum frequency of monitoring. Patients who were tested weekly in the context of clinical trials were found in range up to 90% of the time but similar results were achieved with fortnightly testing (Ansell 2000). 50-60% of patients can be expected to remain in range if monitoring of the INR occurs monthly. (Oral Anticoagulation Monitoring Study Group 2001).

Time in range of greater than 60% is recommended by the British Committee of Standards in Haematology (BCSH) and so monthly testing would seem to be the minimum requirement for all patients and this is supported by guidelines published by the American College of Chest Physician (ACCP) that suggest monitoring should occur at an interval of no less than 4 weeks (Ansell 2008).

Frequency of monitoring is an important safety indicator but increased frequency of testing has huge implications for anticoagulation services. In 1998 the British Committee for Standards in Haematology (BCSH) recommended not less than six weekly testing in patients with prosthetic heart valves and not less than every twelve weeks in other patients. Obviously more frequent testing entails more hospital visits which cannot be accommodated in many clinics at present given that they are operating at capacity. Inevitably quality will suffer and an alternative model of care is urgently required.

2.6.4 Bleeding and Thrombotic Events

All anticoagulants cause bleeding. The bleeding risk is directly related to INR value and the time in therapeutic range. In a 1996 study, the bleeding rate doubled as the INR increased from 2.0-2.9 to 3.0-4.4, quadrupled between 4.5 -6.0 and was multiplied by five when the INR was above 7.0 (Palereti 1996). The incidence of bleeding and thrombotic episodes is a marker of the quality of anticoagulant control and should be recorded by all anticoagulation services. The rates of major bleeding in patients on oral anticoagulant therapy are reported as 1 - 3 % with thrombotic complications occurring in 1 - 6%. The incidence of these complications is a marker of the quality of a service. It is higher in practices with no dedicated physician/health professional than in formalised anticoagulant monitoring services (AMS) using decision support and computer assisted dosing. Indeed the widespread adoption of computer assisted dosing in AMS has had a dramatic effect on patient outcome.

2.6.5 Computer Assisted Dosing (CAD)

Factors that improved control of anticoagulation in the 80's were the adoption of guidelines on the indications for anticoagulation and defining the intensity of anticoagulation required using a target INR for each patient. The introduction

of computerised decision support systems (CDSS) for computer assisted dosing (CAD) of oral anticoagulant therapy has further improved control.

Much of routine but important medical activity requires compulsive attention to protocol rather than intellectual brilliance. Anticoagulation management systems are examples of where this attention to detail can result in improved patient outcomes. Computer Assisted Dosing (CAD) in anticoagulation management has been shown to improve safety. CAD is effective in both hospital and primary care settings. The success is not dependant on the person managing the dosing as long as they are appropriately trained; the person can be a physician, nurse or pharmacist. The evidence for its effectiveness in anticoagulation management is so convincing that one could argue that not using a CDSS in current practice may be negligent.

CDSS were initially used in the hospital setting but were found to give equivalent improvements in quality of management when used in primary care, Indeed Galloway (1995) and Fitzmaurice (1998) recognized that with the increasing pressure on hospital clinics more patients would require monitoring in primary care and CDSS systems were necessary to ensure uniform high quality care for all.

The NPSA has recommended CDSS to assist in the auditing monitoring and reporting of safety indicators in all anticoagulation clinics. They are in widespread use in hospital anticoagulation clinics in Ireland, but are seldom used in the community due to associated cost

Dawn AC (4S Dawn Clinical Software, Milnthorpe, Cumbria, UK) is one of the most widely used computer assisted dosage programme used internationally. It is also used in Ireland, having been used in St James Hospital for the last four years. DAWN AC was initially used in a randomised trial to compare computer assisted dosing to usual care and was shown to improve INR control (Poller 1998).

The effectiveness of the DAWN anticoagulation system has been validated by a large multicentre trial involving 13,000 patients. The use of these programs by nurses resulted in an increased time in range and a reduction in clinical events compared to manual dosing by physicians (Poller 2008). The authors do advise caution when choosing a computer assisted dosing program. Programs are of variable reliability and one cannot assume that they are all the same. PARMA 5 and DAWN AC were the programs used in the multi-centre study. All other programs need to be clinically validated before being introduced into hospital and community clinics. A similar conclusion was reached ten years ago when CDSS was initially introduced into clinical practice (Fitzmaurice 1998).

In summary, the quality of anticoagulation monitoring depends on a number of factors. The models of care in use in Ireland will be discussed in the upcoming sections. Evidence for their effectiveness and applicability will be discussed where appropriate.

2.7 Models of Care

Model of care in Ireland are often geographically determined. These are often referred to as 'historical' models of care but they remain current practice for many patients in Ireland.

2.7.1 Venous Blood Sampling in General Practice

Patients attend their General Practitioner/ Practice nurse for an INR test. The GP contacts the patient on receipt of the result and advises on the dose of warfarin and date of next test. There is an inevitable delay in reporting results due to varying working hours in hospital laboratories and general practices. This can cause potential problems for patients particularly those who have high INR readings. A large amount of patients are monitored in this way. This method of monitoring has been associated with reduced time in therapeutic range and more bleeding and thrombotic complications, than monitoring in a specialised anticoagulation monitoring service (AMS).

2.7.2 Venous Blood Sampling in Hospital Clinic

Patients attended the hospital for an INR. In the past patients tended to wait many hours for the result. Prescription of warfarin was the responsibility of the most junior doctors with the least amount of experience. Not surprisingly anticoagulation was often poorly controlled. Monitoring was extremely inefficient, costly and of poor quality. It was disliked by both junior doctors and patients (Doble 1987) and became unsustainable as the number of patients on oral anticoagulants rose exponentially.

Patients in the current system do not wait for the INR result. Dosing instructions are recorded in the "yellow" warfarin book and posted to the patient. Any changes in dose are telephoned to the patient. This is the model of care most commonly practiced in hospitals in Ireland and the United Kingdom. It is usually nurse-led and uses a computerised decision support system to assist in dosing. This also facilitates audit and the collection of data on safety indicators. Standard operating procedures and regular staff training and competency assessment are mandatory component of the system. The result is a high quality, efficient and safe AMS and is the standard by which all services are currently measured.

2.7.3 Near Patient Testing in General Practice/Community Clinic

Patients attend their GP/practice nurse for INR testing using a point of care device known as a coagulometer. This provides an accurate, precise and reliable INR result in one minute. The patient is instructed on their dose by the GP or practice nurse. A return appointment is made depending on the stability of the INR. Many practices in Ireland are using this model of care. The remoteness of many GP surgeries and patients from hospital laboratories and clinics has prompted many practices to invest in a portable coagulometer and test-strips. This is an extremely efficient model- of care as it allows testing and dosing at the same visit. It removes the need for follow up phone calls and potential confusion over dosing instructions. (Daly 2003, Galloway 1995, Murray 2004)

In the UK many practices have decision support software to assist in patient management. Patient outcomes are equivalent to hospital outcomes. This model of care is widespread in the UK and is often referred to as the Birmingham model as a large amount of the initial research was conducted in the Department of General Practice at the University of Birmingham by Fitzmaurice and Hobbs. The essential components of the system are near patient testing, dedicated staff and CDSS. This complete model of care is not in use in primary care in Ireland due to the high cost of decision support software. (Fitzmaurice 1998, Hobbs 1997) Web based versions of the software may be less expensive due to less costly maintenance, upgrade and installation compared to older versions. The possibility of purchasing an individual licence has less financial implications for a practice than installation of a completely new software system.

The widespread adoption of near patient testing and CDSS in primary care would solve the current problems facing hospital clinics and most likely result in improved patient outcome. However, this model of care would not meet the needs of all patients. There are a number of patients who find attendance at any anticoagulation clinic to be a huge inconvenience. These patients are often younger but not necessarily so. They have full time jobs, often travel a lot with work or for other reasons, have young families and generally lead very busy lives. These patients are ideally suited to patient self testing.

2.7.4 Patient Self-Testing

Patient self-testing refers to the patient using a portable point of care device to test their INR at home with a healthcare professional interpreting the result. The patient performs the INR test at home using a coagulometer. The patient communicates the result to their GP or Consultant who advises on the dose and timing of the next test.

Meta-analysis of 14 randomised trials suggested that self monitoring of oral anticoagulation leads to a significant one- third reduction in death from all causes. Thromboembolism was reduced by 55% and major haemorrhage was also decreased (Heneghan 2006).

This model of care is only available to a select few patients in Ireland due the costs involved and the lack of an organized structure in which to manage these patients. Early studies in this area demonstrated superiority of this model to “usual care”. Usual care is taken to mean general practitioner or specialist without decision support software or point of care devices and applies to certain patients currently managed in the Irish setting. The standard of care in all countries varies depending on the organisational structure involved.

Usual care in the hospital setting in Ireland would be considered excellent as measured by benchmarking and other performance indicators. St James Hospital participates in a benchmarking scheme and consistently performs in the top 25 % of participating centers. (Dawn AC; 4S Information Systems, Milnthorpe, Cumbria, UK) Indeed the anticoagulation clinic performed second out of over 100 centers in Europe in the most recent Benchmarking report (**Appendix 8)** For this reason patient self testing would be unlikely to be superior in terms of time in therapeutic range but it should not be inferior. The aim of decentralization is delivery of high quality care in a setting that suits the patient’s needs. An inferior model of care is not an option.

2.7.5 Patient Self-Management

This model is similar to patient self testing except the patient adjusts his or her warfarin dose according to a patient specific predetermined algorithm. Testing is usually performed weekly unless more frequent testing is required. This is not a novel model of care. Diabetic patients have been successfully managing their blood sugars this way for years. What is more surprising is that more patients are not managed in this way. Less than 0.5% of patients in the UK perform self-management.

A successful self monitoring program is in operation in Germany since 1992. This success is mainly attributable to a structured education program for patients and an effective cost reimbursement system operated by health insurance companies. It is doubtful if any patient self-management program would succeed in the absence of these critical factors. There are over 150,000 patients performing self management at present and it is estimated that 50-60 % of patients in Germany are suitable candidates compared to 20-30% in countries like the Netherlands and the UK (Taborski 1999). There is currently no evidence for this model of care in the Irish setting.

More recently McCahon (2007) addressed the issue of whether participation in a clinical trial in itself improves outcome and if trial results are comparable to routine practice. The **S**elf **M**anagement of **A**nticoagulation **R**andomised **T**rial **(SMART)** showed that therapeutic control and adverse event rate for patient self-management was equivalent to routine UK care. It suggested that self-management was three times more expensive. The authors were very keen to see if this was the case outside the trial setting.

Therapeutic control and adverse events were similar pre and post SMART trial. Mean testing frequency was less frequent post trial. This was mainly dictated by patient preference indicating that patients will test less frequently than two-weekly when given the choice.

This information is important as many of the previous trials in the area involved weekly testing. Patient self-management is more costly than routine care even outside of a trial setting (£193 v £118). This difference in cost must be balanced against the increased autonomy and control PSM offers and the reduced workload in busy anticoagulation clinics.

Many clinics cannot take on any more patients if numbers continue to increase (Anticoagulation Clinic Survey 2004). This also means the quality of care for existing patients suffers and there is less time to manage difficult complex patients, less time is available for new patient education as clinics are full.

The importance of an appropriate management structure for patient self-testing and patient self-management patients were highlighted by this study and are one of the reasons why such a program is unavailable in Ireland outside of a trial setting. Only 33% of patients in the self-management arm continued after completion of the trial. Lack of a clinical supervisor was the main reason stated.

Quality assurance is also a concern as many patients did not participate after the completion of the trial. This reflects real life and so safety measures should be in place before a self-management program is undertaken. Recent guidelines for self testing recommend a number of measures which will be discussed at the end of this chapter (Ansell 2004, Fitzmaurice 2005).

2.8 Current Clinic Workflow

By now the reader has an excellent understanding of the issues involved in the management of oral anticoagulant therapy and the determinants of a quality service. Much of the previous information relates to anticoagulation management in general. Specific features of the research population warrant special mention. The clinic settings in which the research was conducted will be described in detail in the upcoming section.

2.8.1 St James's Hospital Anticoagulation Clinic

In 2002 the warfarin clinic in St James's was operating without a predefined protocol. There was no computer assisted dosing system and no audit trail. Patient turnaround time was unacceptable at more than 3 hours per visit. There was no lead clinician with responsibility for the anticoagulant service. The service was not patient orientated. The indication for warfarin and duration of therapy were not available for many patients due to documentation issues. There was no formal education program for patients nor was there formal training and education for nursing staff. No facilities existed for patient self-testing or patient self-management. These issues were universal to all hospital based anticoagulant clinics in Ireland at the time.

The National Centre for Hereditary Coagulation Disorders (NCHCD) is based at St James's Hospital and is the reference centre for coagulation disorders in Ireland Patients with inherited bleeding disorders and thrombotic problems are managed by the service which provides a twenty-four our on call service. It is ideally placed to improve the anticoagulation service in the hospital

The National Centre for Hereditary Coagulation Disorders assumed responsibility for the anticoagulation service in 2001. Standard operating procedures were introduced. The DAWN AC computerised decision support software system was purchased for computer assisted dosing at the clinic. This software also facilitated audit and clinic management capabilities including scheduling, monitoring of non attendance and completion of therapy. A new referral system was implemented in the hospital. All patients had a defined therapeutic range and indication for warfarin. This information was entered onto the computerised decision support system at the start of treatment.

A strict appointment system was introduced. The clinic started at 8am with appointments every 15 minutes until 12.30. Waiting times were reduced from more than three hours to 15 minutes or less. Patients attended for a venous blood test and left again provided they had no clinical problems; otherwise

they were directed to the nurses. The blood samples were transferred to the laboratory via a vacuum transport system. The INR was calculated and the INR result was downloaded to the computer software program at the clinic.

The warfarin dose was calculated and stored on DAWN AC. This information together with the date and time of the next appointment was recorded in the anticoagulation book (Yellow Book). The patient was contacted by phone if they required a dose change. Otherwise the yellow anticoagulation book was posted to the patient.

This resulted in a dramatic improvement in the quality of the service with most patients spending less than 15 minutes attending the hospital clinic. An audit was carried out post-implementation of the postal system. Overall 99% of patients were satisfied with the service received with 97% being very satisfied.

The demands on the service have increased exponentially in the last four years. Last year there were 25,807 attendances at the clinic. Twenty-five patients can be safely bled every hour. The phlebotomy service operates from 8am until 12.30pm with 100 appointment slots per day. The maximum number of patient encounters, allowing for weekends and public holidays and assuming that every appointment is filled are 25,000 per year. The system has reached capacity. Expansion is not the solution. Change is not an option but a necessity.

Decentralisation of the service is the only solution. Patients could be managed in the home and in the community reducing demand on the hospital clinic. This would allow the hospital clinic to concentrate on the education and monitoring of new patients. These patients have a high risk of bleeding, particularly in the first three months and require intensive monitoring and education. This is becoming increasingly difficult within the confines of the current system. Decentralisation of the service would allow hospital staff more time to devote to complex patients.

Half of the patients attending the hospital service would be suitable for monitoring in the community. Many are elderly with other medical problems and attend their GP regularly. The community setting is ideal for monitoring more stable long term patients. The other potential method of transferring patients to the community would be by incorporating the community intervention team. This group of health professionals could call to the patients' home, perform an INR test and administer the dose the patient. This would be an option for a minority of patients but would greatly enhance the community service. It would be ideally suited to patients recently discharged from hospital or with reduced mobility

A substantial number of patients attending the clinic wish to monitor their INR at home (self-testing); currently only thirteen or 1% of patients perform self-testing at home. It is suggested that 30% of patients in a similar cohort in the UK are suitable for self-testing. Between 350 and 450 patients in St James's anticoagulation clinics could self test with a reduction in the demand on the service; The cost of the meters and strips and a method of managing these patients has prevented this to date.

Computer assisted dosing and warfarin dosing algorithms are in use at the clinic. When a patient has a high or low INR a dose adjustment is made and the patient returns for repeat testing. The clinics are often fully booked with no appointment times available and so the patient is accommodated in the next available slot. This deviation from the protocol is not consistent with best practice and is not acceptable from a safety point of view this. The increasing demand being placed on the service cannot continue and an innovative solution is required.

2.8.2 South Inner City Partnership Community Anticoagulation clinic

The South Inner City Partnership (SICP) in Primary Care was established in 1998. Prior to this, there had been much discussion about the local needs of the inner city community. This concern intensified with the closure of the local Adelaide and Meath hospitals and prompted a proactive group of inner city GPs to begin discussions with the Health Board. Although the initial focus of the SICP was on the closure of the hospitals, the partnership evolved and has very strong links with St James's Hospital. Currently there are sixty-three GPs from 30 practices participating in the SICP.

The SICP runs community anticoagulation clinics in five GP practices. A warfarin Liaison Nurse is employed by SICP and manages the clinics at four sites. A practice nurse operates the clinic at the fifth site. All sites are within a five-mile radius of St James's hospital. These clinics use point of care testing (CoaguChek® XS) which provides a result within one minute. The clinics operate to a very high standard adhering to strict protocols but do not use computer assisted dosing and have limited audit capability.

This innovative service was the first of its kind to use an inter-referral system. GPs in the SICP can refer patients to one of these clinics for anticoagulation monitoring. This inter-referral system is ideally suited to anticoagulation management. Clinic GPs become highly skilled in anticoagulation management due to the increased volume of patients. The anticoagulation nurse is proficient at dosing as well as having a large amount of technical expertise and a wealth of experience. This partnership is ideally positioned to participate in an integrated model of care.

2.9 An Integrated Model of Care

We pride ourselves on being a patient centered service. Local circumstances vary enormously so the process of decentralization from hospital clinics will require significant modification according to local needs and resources. GPs are under-resourced to cope with this additional burden.

We were in a unique situation in that the South Inner City Partnership (SICP) were running a point of care warfarin clinic with a trained anticoagulation nurse using similar protocols to our hospital based clinic. They were participating in both internal and external quality assurance schemes and were extremely motivated. What's more a significant number of patients attending the hospital clinic were patients of many of the practices forming the SICP.

The proof of concept of near-patient testing in the community is nothing new. A study by Caroline Shiach (2002) is worthy of mention. This randomised trial looked at patients transferred from a hospital clinic to the community. The most interesting finding in this study related to patient satisfaction data. The questionnaire indicated that most patients had been very satisfied with their previous hospital service with 12 % finding it inconvenient. Areas surveyed included privacy and comfort, the waiting area, the staff, access to information and medical staff. There were no adverse comments in relation to any of the above areas in the community clinic and an overwhelming ninety eight per cent of patients expressed a preference for the community clinic.

The study used an older version of the CoaguChek® device available in Ireland and the DAWN AC Version 6 dosing software. These results demonstrate the equal success of an anticoagulant service based in the community compared to a long established hospital clinic. The high level of satisfaction expressed by staff and patients alike is encouraging. This model would facilitate transfer of patients to the community without any compromise in the quality of care.

Surveys of the anticoagulation service in St James's are equally positive and are quoted as a reason for continuing with a hospital based service. The location of the clinic may not be the deciding factor. Satisfaction is more likely to be due to the quality of the service. Patient satisfaction survey conducted after the introduction of community anticoagulation monitoring in the SICP produced very similar results. Patients were very satisfied with the clinic and all expressed a preference for community monitoring over attending the hospital clinic.

2.9.1. Proposed Solution

It would appear that a combination of a hospital clinic, community monitoring and patient self-testing are all required for successful decentralisation of the hospital-based service. No single model of care meets the needs of all patients and individual patients may require different models of care at different times depending on circumstance. This model needs to be able to cope with increased demand, it needs to be dynamic while always maintaining a quality service based on international best practice.

The success of community anticoagulation services depends to a large extent on the sharing of hospital resources and active involvement of the hospital (Sheehan 2000). High quality staff training is mandatory and should include continuing medical education as well as staff feedback and brainstorming which should be provided by hospital. Fast track clinics should be arranged for the referral of poorly controlled, complicated and difficult cases back to the hospital. Computerised decision support software should be validated and used initially in the hospital setting prior to use in Community. Consultants should be available to provide specialist advice and a 24 hour on-call service

Recent guidelines for patient self-testing made a number of recommendations. One of the most critical components was the identification of a suitable supervisor as was mentioned earlier. The lack of a suitable supervisor was one of the main reasons stated for discontinuation of PST and PSM outside the trial setting. Protocols and procedures should be clearly

defined. A standard dosing algorithm should be in operation and patients must participate in both internal and external quality assurance schemes. The patient should be reviewed at six monthly intervals in person and must complete a defined education programme as well as continuing education in order to be eligible for patient self-testing.

If a patient agrees to all of the above then a standard contract is signed for the safety of the supervisor and the patient and the reader is directed to ***Appendix 6*** for an example of the standard operating procedures and contract required.

The Active involvement of the hospital anticoagulation clinic in the design and implementation of this integrated model is essential. The expertise of the National Centre for Hereditary Coagulation Disorders in the management of patients with coagulation disorders and the anticoagulation service is ideally placed to provide the links between all the stakeholders involved in this process.

One important component of the service is lacking. In order to facilitate communication between patients, nurses, doctors in all of these areas a shared database is essential. The difference is that this shared database will be web-based. This project is not a pilot but instead represents the full deployment of a new service delivery model. If successful the proposal will be expanded to include all warfarinised patients in Ireland. The web-based nature of this model of care mean it will be possible to manage patients remotely and is crucial to the success of this project.

The advantages of a web-based solution are numerous and include a real time integrated service ideally suited to the management of chronic illness, equitable access to care regardless of geography, improved use of resources and access to expert care by linking small centres with centres of excellence. There are disadvantages which mainly centre around cost and security.

In this dissertation I hope to show that by cooperation and collaboration with our colleagues in general practice, industry and the Health Service Executive that we can and will deliver an integrated web based anticoagulation service which can meet the needs of all patients. It will be based on the newest technologies, will be capable of evolving and diversifying depending on patient and service need but will always maintain the highest standards of care as per best international practice. Chapter three looks at the state of the art in terms of web-based anticoagulation monitoring.

Chapter 3 State-of-the-Art

3.1 Literature Review

The literature review was initially very broad to get a good overview on the area of oral anticoagulation. Much of this literature has been discussed in chapter 2.
The initial database search was conducted in PubMed. The titles of all articles were examined for content. The relevant abstracts were read and if suitable the full article was obtained. EMBASE (Excerpta Medica Database) and MEDLINE (Index Medicus online) were also searched and any relevant references not obtained in PubMed were retrieved and examined for appropriate content. Google and Google Scholar were the search engines used for grey literature and for unpublished work: This included general information on integrated care and research methodologies as well as commercial information related to software companies of CDSS in anticoagulation and manufacturers of prothrombin time and INR monitors. A hand search of journals and reference text books from libraries and the workplace also yielded many useful articles.

Websites of patient groups were accessed for available information and links. Websites of organizations involved in the production of guidelines in the area were also accessed for available information. References from all relevant articles were examined and the article retrieved if appropriate. Time lines were crucial in terms of developments in the area and the available literature. The literature search extended as far back as 1948 when warfarin was discovered.

The literature review process was ongoing throughout the entire year using the key search term
MeSH terms used were “anticoagulants”, “warfarin” OR “vitamin K antagonists” AND “Computerised Decision Support Systems” OR “CDSS” AND “Models of Care” AND “patient self testing” AND “patient self management” AND “INR” and “Point-Of-Care” AND “Integrated care” AND “web-based” OR Internet

3.2 The Need for Change

Health care costs are rising exponentially and developed countries are finding it increasingly difficult if not impossible to deliver high quality appropriate care for an aging population with a high prevalence of chronic disease. Governments, communities and health professionals the world over are looking for new and innovative ways of delivering quality health care services as traditional models struggle.

Ireland is no exception. In 2008, there was a 7.5% increase in spending on health to over €16.1 billion but the system as it stands is unable to cope. Brendan Drumm, Chief Executive Officer of the HSE, has stated that the solution to the challenges we face is not simply more of the same and bigger budgets. (HSE Dec 2006). This particularly applies to the area of anticoagulant monitoring. The number of patients on warfarin has increased exponentially in the last ten years and is placing an enormous strain on hospital anticoagulant services. Our current system has reached capacity; Change is no longer an option it is a necessity. (Drumm 2006)

This problem is not unique to Ireland and is mirrored in all developed countries. People are living longer and populations are increasing with an unsustainable rise in the cost of healthcare. One possible solution involves a concept known as “Integrated Care”. The next section will examine the integrated care model in more detail.

3.3 Integrated Care

3.3.1 Definitions

To integrate means the bringing together or merging of elements or components that were formerly separate. Integration is at the heart of all systems theory and therefore, central to organisational structure. Health systems and health care institutions are among the most complex and interdependent entities known to society (Charns 1993). The division, decentralisation and specialisation that ensue in complex organisations such as the health service often interfere with efficiency and quality goals.

Without integration at various levels, all aspects of health care performance suffer. Patients suffer, services suffer, quality deteriorates and costs increase. The onus is on all health care providers to deliver high quality, patient centered and cost effective services. This is not possible in the current Irish healthcare system due to chronic under-funding of primary, community and continuing care; the current system is dysfunctional, fragmented, expensive and inefficient. Integrated care is the key.

Grone and Garcia-Barbero (2001) define health care integration as the bringing together of inputs, delivery, management and organisation of services as a means of improving access, quality, user satisfaction and efficiency. Brown and McCool (1992) suggest that integration allows for greater efficiency and effectiveness, less duplication and waste, more flexible service provision and better co-ordination and continuity. These are core requirements of the proposed integrated model of anticoagulation services.

Kodner and Spreeuwenberg's (2002) perspective on integrated care is more patient centered and more appropriate to healthcare. The goal of the models and methods they described was to enhance the quality of care and quality of life, consumer satisfaction and system efficiency for patients with complex, long-term problems cutting across multiple services, providers and settings. This is also directly applicable to the anticoagulation domain as has been discussed in chapter 2.

This definition of integrated care takes the personal circumstances and wishes of each individual patient into account. The authors offer some suggestions on how to apply these concepts. They provide a list of methods and tools that may help to overcome the barriers of implementing integrated care.

Funding is the rate limiting step for most integrated care initiatives and funding in healthcare comes from many different sources. The pooling of funds and introduction of prepaid capitation may help in implementing an integrated care strategy. This will be the defining factor in the proposed integrated anticoagulation system.

The mode of service delivery and management has a major impact on a number of critical variables in integrated care. Joint systems for training, centralized information, multidisciplinary/ interdisciplinary working, around-the-clock coverage and integrated information systems improve service access, availability, continuity and coordination of care, quality and cost outcomes.

Finally, shared clinical records, common decision support tools including practice guidelines and protocols, a shared understanding of the patient's needs not to mention ongoing communication and feedback are essential quality ingredients from a clinical perspective. Anticoagulation monitoring is ideally suited to an integrated approach

3.3.2 Integrated care model in Diabetes

This concept of integrated care is not new. The Professor of the Department of General Practice at the University of Birmingham, (Hobbs 1997) noted the inherent similarities between INR monitoring and glucose estimation using point of care meters. He stated that there was no reason why practice-based anticoagulation clinics could not become as routine a practice as practice-based diabetic clinics.

Indeed as much as 2% of the population may be eligible for treatment with oral anticoagulation, similar in scale to diabetes. The Health Service Executive has recently published a document entitled A Practical Guide to Integrated Type II Diabetes Care. They state that the current model of disorganized care is not acceptable in the management of Diabetes mellitus and have formalised arrangements with primary, secondary and tertiary care.

The management of Diabetes and the management of oral anticoagulant therapy (OAT) have many features in common

- Point-of-care devices are available for monitoring both conditions.
- Both conditions are associated with severe complications, which can be fatal or cause chronic disability.
- These complications are more common in patients with poor control, poor compliance or both.
- Good control results in better outcomes with huge cost savings to the health service.
- Continuity of care results in better outcomes.
- Organised care results in improved patient outcomes.
- Primary care is the optimal site for service delivery
- Patient self management ensures optimal care in motivated patients
- Education is crucial and needs to be reiterated regularly

A similar formalised monitoring arrangement between primary, secondary and tertiary care would be extremely effective for the monitoring of oral anticoagulation. The ultimate aim of this dissertation is to show that such a

strategy is equally applicable to oral anticoagulation therapy by identifying the factors that contribute to a anticoagulant monitoring service in all patient populations so that they can be incorporated into an integrated web-based model of care.

Several models of care will need to be available to patients receiving warfarin. These will include traditional warfarin clinics for new and complex patients, community based monitoring in GP surgery or nursing home settings as well as patient self-testing. It is crucial that these services are developed in partnership to deliver the highest level of care to each patient. In the past this tended to be a hospital-based service irrespective of patient wishes or needs. Now, the focus is on providing a patient centered service.

3.4 Cost Analysis

There is very little research into the cost implications of devolving anticoagulant management into the community. The available research may not apply to the Irish health service due to differences in reimbursement, enormous variation in the cost and availability of acute care and services.

One study performed in Birmingham is relevant as it compares the quality of care in a nurse led primary care setting using near patient testing and CDSS to hospital care (Non nurse-led). It showed that the community based model of care was more expensive and will probably always remain more expensive in terms of actual cost. The potential reductions in high-cost adverse events, such as stroke or major bleeding necessitating hospital admission, were not considered and so the real benefits in terms of cost savings were grossly underestimated.

Improved time in therapeutic range reduces the complications associated with oral anticoagulant therapy. Management of anticoagulation in the setting described above improves time in therapeutic range. Accurate reporting of

bleeding and thrombotic complications is required to determine the true cost of anticoagulation monitoring (Parry 2000).

Another point worth considering in relation to economic analysis is how to compensate for time. One can measure the cost of a hospital bed and the cost of care but it is difficult to determine the cost of a patient's time. This applies to all patients and is especially true in to-days hectic environment. People value their time whether they are working or not.

The cost implications of frequent testing are significant. In the Irish setting assuming a test strip cost of four euro; this amounts to over two hundred Euros annually, excluding lancets and quality control measures. At present, this is not refundable under the GMS or drugs repayments scheme.

The most recent American College of Chest Physicians (ACCP) guidelines recommend a test frequency of four weeks in stable patients (Ansell 2008). This reduces the cost to approximately fifty euro per year for test strips. In the author's opinion optimal test frequency probably lies somewhere in between two and four weekly. There is always concern about the translation of research and clinical trials into practice and a reduced frequency of testing would ensure that the costs of self-monitoring do not become prohibitive without compromising on the quality of care

Cost effectiveness analysis exists in many countries. Extrapolation of this analysis to Ireland is not always useful due to differences in insurance reimbursement schemes and health economics in different countries. The cost effectiveness of patient self-management is accepted in Germany. Health insurance companies reimburse patients as it is cheaper than hospital based monitoring.

In the UK, it has been shown to be more expensive than usual care and less than 0.5 % of patients self manage. Patients tended to be younger or have busy working or social lives. It is clear that demand for patient self-testing and management reflects patient lifestyle, patient satisfaction with the current

service, patient motivation as well as patient preference. Reluctance to participate in a clinical trial as well as a high level of satisfaction with the current service are also contributing factors.

Knowledge of the population in question is mandatory, as it will give an indication of demand for patient self-testing and management prior to wide scale commissioning and implementation. The other area highlighted in all studies of patient self-testing and patient self-management studies is the significant contribution of the education program. This was one of the main research objectives of the present work.

Cost, reimbursement and careful patient selection are important in the successful implementation of a successful self testing programme. The value of education is underestimated in the success of these programmes. Indeed education itself improves clinical outcome. Improved outcomes in some clinical trials may have as much to do with patient education and empowerment, as improvement of time in therapeutic range. Patients participating in studies of self-monitoring receive a thorough education about their treatment and its side effects. The relative contribution of education to improved outcome is not clear.

Khan et al (2004) looked at the effect of an education program on an elderly cohort of patients in the north of England. A major outcome of this randomized study in unstable patients was that education alone resulted in similar improvements of time in therapeutic range, as education plus self-monitoring. Education alone for this group of patients represented an extremely cost effective initiative. Formal education programs delivered in a consistent way must form a major part of any integrated warfarin service as without this any service will be destined to fail

Patient education, patient selection and financial remuneration all contribute to a quality anticoagulation service. International models were examined looking for specific web-based management systems and successful adoption of these models into routine use.

3.5 International Web-based Solutions

In this final section the international web based solutions of various countries are reviewed and their applicability and relevance to the proposed domain are critically examined. In certain cases they represent pilot projects. Other centers are using them in daily management. By identifying the potential problems and pitfalls experienced by others valuable lessons can be learned. These lessons may prevent costly mistakes and facilitate the implementation of a web-based system.

3.5.1 Italy

The Federation of Centers for the Surveillance of Anticoagulant (FCSA) was established in Italy in 1989 to manage the increasing numbers of patients on oral anticoagulant therapy. It is a voluntary organisation without central funding which is struggling to cope with demand (Berrettini 1999) In 2005, 80,000 patients attended regular anticoagulant clinics. This only represented one tenth of the estimated population on OAT. The quality of care in anticoagulant clinics was superior to usual medical care. The problems encountered in the hospital based clinics included increasing numbers of patients with limited clinic space and staff

Testa et al (2006) reported a reorganization model to decentralize an anticoagulation clinic using telemedicine, whilst maintaining the same quality of care as measured by time in therapeutic range (TTR), thromboembolic and bleeding complications. Patient satisfaction levels were far superior to the hospital based model of care although TTR was inferior in the initial phase of the study. The results are not as important as the proof of concept. It represented a starting point to decentralise anticoagulation clinics. It forms the basis of an integrated web-based model of care.

Availability of new oral anti-thrombotic agents may reduce necessary investment in this area. The authors point out that strict clinical evaluation of

newer agents will be mandatory to assess disease progression on treatment, side effects as well as bleeding and thrombotic complications amongst patients attending general practitioners and medical specialists. It is imperative that such monitoring occur and a functioning system needs to be in place prior to the introduction of these newer oral anticoagulants (Testa et al 2006). This point is crucial in convincing hospital authorities and healthcare providers to continue to invest and develop anticoagulation services. Internet-based disease management programs have the potential to improve patient care.

3.5.2 United Kingdom

The City and Hackney Teaching Primary Care Trust is another model relevant to this work (Mason 2005). They had a similar number of patients to St James's Hospital. They hoped to increase the patient numbers attending primary care clinics and reduce numbers attending hospital based services. The overall aim was to provide an integrated anticoagulation monitoring service across primary and secondary care. It was pharmacy led and incorporated NPT and web-based CDSS and has a large number of similarities with the integrated model of care proposed in this dissertation. A pilot study was very successful but no recent published information is available in relation to this project and it has not been possible to contact the supervisors. This may be for one of two reasons; the pilot was successful and the system has been adopted into widespread use or the system is no longer in use.

Dawn AC confirmed that one centre in the UK is using the shared care facility of the Dawn AC Version 7. The DAWN AC package is in use or is about to be used in 130 centres worldwide. It is use across both primary and secondary care in one center in the United Kingdom. It is not used as part of an integrated service although the functionality exists (personal communication). The web-based functionality does not appear to be utilised in the UK setting. This may be due to the fact that most patients are monitored in the community by a GP with an interest in oral anticoagulant therapy. The existence of a

high-quality convenient service for patients may explain the low uptake of self-testing why a web-based management system is not required.

3.5.3 United States

In a study in Duke University, sixty patients were enrolled in an expert supervised home monitoring study which improved time in therapeutic range compared to the 'usual care' group managed in a specialised anticoagulation clinic. By providing continuous physician oversight without significantly increasing staffing time, "supervised self management" is theoretically an economically viable method of improving outcomes in anticoagulation management (O'Shea 2008).
This is very similar to the proposed integrated model of care. The main differences are the integration of the general practitioner as well as the community intervention team into the service.

Expert systems are ideally suited to anticoagulation management. The authors conclude that this is the first demonstration that patient access to an internet based expert system can improve therapeutic control in patients who require long term management for chronic disease. This system improved TTR while optimizing the use of health care provider and patient time. Staff will have more time to spend with complex patients. This will ensure that all patients receive a high standard of care

The supervised nature of this system may increase acceptance of home INR testing and lead to improved clinical outcomes as well as reducing the number of patients attending hospital based clinics. A lack of a clinical supervisor has been one of the reasons patients give for not self-testing and this also allows for management of patients remotely. This would have obvious advantages in the Irish setting.

3.5.4 Ireland

Increasing numbers of patients require anticoagulant therapy. One of the main objectives of the HSE is to decentralise hospital services and provide integrated services for patients. Diabetes services lend themselves to such a model of care. Anticoagulation services would also benefit from this approach. Many patients in Ireland are managed in the community by their GP.

There is only one study to date on patient self-testing in Ireland. This study assessed a web based model of care and is highly relevant to the integrated web-based model of care.

The study was carried out in University College Hospital Cork. It was a prospective randomised cross-over trial involving 163 patients in Ireland. The study used a novel approach to combine the advantages of an anticoagulation monitoring service with patient self-testing and using a web-based internet anticoagulation system (Coagcare®, Zycare, USA) to link patients with health care providers.

Using the CoaguChek XS® point of care testing device, (Roche, UK), patients obtained their INR measurement at home and entered it onto a web page. Patients with a therapeutic INR and no clinical issues were automatically provided with algorithm derived dosing instructions and the date of their next INR test. Patients with a non-therapeutic INR result were instructed to log on later that day. The system relied on a pharmacist (Health care professional) logging on at least twice per day. Those patients with INR results outside the therapeutic range or who had symptoms were dosed by the pharmacist. All patient results could be reviewed. Patients with extremely high or low INRs were discussed with the supervising physician.

This system was internet-based and is expert supervised. The patient or healthcare provider could access it at any location with an internet connection. This allowed increased flexibility for all concerned and avoids frequent hospital visits. Interim results have been presented in abstract form at the

annual scientific meeting of the Haematology Association of Ireland (Ryan 2007) and suggest this is a suitable alternative anticoagulation management system for many patients. The oldest patient using the system was 80 years of age and went on a cruise during the trial and the vast majority of patients have opted to continue using this system after completion of the trial.

This model of care is worthy of further research as it would solve many of the problems currently facing anticoagulation management services.

- Overcrowding
- Lack of staff
- Patient inconvenience
- Elderly patients
- Young patients
- Busy patients
- Community/ General Practice patients
- Immobile patients

3.5.5 New Zealand

Harper (2005) proposed a model of managing anticoagulation by using a web-based anticoagulant program which was accessible to GPs and patients performing self monitoring. They proposed a centralised, internet based, computerised anticoagulant monitoring system which could be used to mange all patients on anticoagulation in New Zealand. At that time there was no commercially available product that would facilitate this.

It would incorporate laboratory testing and near patient testing with a computer assisted dosing program. The main program and database would be located on a central server. Two models would be incorporated into the one system: clinician based management and patient self testing. It would operate similarly to commercially available products (Dawn AC Version 7®, Coagcare®).

Patient advantages include more control over their treatment and easier access to clinical help when needed. The knowledge that results are being supervised may encourage more patients to self test. Clinicians should see improvements in TTR and a reduction in complications due to the use of CAD. GPs would retain responsibility for their own patients. This should result in better control as GPs would have local immediate knowledge of interacting drugs and conditions in their patients.

Patients performing self testing would remain supervised by their GP rather than becoming isolated with little clinical support. This is similar to the Expert model proposed by O'Shea 2008. The Expert need not be a physician. It could equally be a nurse or pharmacist.

All information would be stored on a central database. This would allow immediate access to a patient's anticoagulant history in the event of an acute hospital admission. The Netherlands have had a central database for many years and not only does it improve safety through systematic audit but it also enables high quality clinical research to be published.

Computer assisted dosing improves anticoagulant control. Many smaller primary care practices could not afford to purchase such systems. A web-based version would mean that practices would not have to purchase software but might be able to pay per patient registered on such a system or per user license. This would standardize care across the country.

Web-based anticoagulation monitoring is not a new concept. Commercial computer software packages are widely available yet the literature is vague and often usually involves small numbers of patients or pilot studies. This discrepancy between the published data and proof of concept is concerning as it may imply problems occurred post implementation of the web-based systems. It may be that the implementation was successful and was not reported again.

Combined models of care have been used to manage self-testing and hospital patients but there is very little published on an integrated system of anticoagulation monitoring among hospital, community and self testing patients.
Important considerations for the self-testing component of the system include adequate funding, appropriate patient selection and structured education.

The evidence also suggests that the number of patients suitable for self-testing is highly variable and may be a unique feature of each area. Self-testing requirements should be determined in each area. This will need to be examined as part of the research question

3.5.6 The Netherlands

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The concept of creating a network of anticoagulation clinics was initially developed in the Netherlands. The Dutch Federation of Thrombosis Centres was founded in 1971 and each centre was recognized and funded by central government. Clinics cover more than 90% of the country with a specialist nurse coordinating the entire service. The interrogation of this national database has produced much of the evidence on treatment and outcome measures in patients with thrombosis and much of the evidence in this dissertation.

A coordinated approach to the management of oral anticoagulation is in existence for years Telemedicine was first introduced into practice in 2001 in a project entitled Telemedicine Training/treatment Centres for Anticoagulation or TTCA. Reports at international meetings in 2005 indicated that 29% of all anticoagulation clinics were using this software with a predicted rise of 23% the following year. Most patients communicated with the clinic via telephone. Only 30% of patients were using the web-based facility but remote management of self testing patients was facilitated by this system and indeed patients from France, Germany, Spain and Poland availed of this service. (Jan Hoijtink 2005) The software providers are Portavita (www.portavita.nl). This company is involved in all aspects of electronic health records and is the main

anticoagulation management system provider in the Netherlands. It is in use in 63 clinics representing 340,000 patients. It is in use in a small number of clinics in Spain and was recently introduced in Germany to facilitate self-management programmes

Much of the research in oral anticoagulation is performed in the Netherlands and the standard of care in terms of anticoagulation monitoring are considered the highest in the world. It is not surprising that complication rates associated with OAT are extremely low. The model of care in the Netherlands is truly state of the art. The integrated model of care proposed by the author should base itself on the Dutch system as it is not a concept but a reality.

Chapter 4 Research

4.1 Introduction

This chapter discusses the research questions in more detail and details the various methodologies used to answer the questions.

The research question asked was

> Would an integrated web-based system of anticoagulation monitoring be acceptable to all users of the anticoagulation service in a hospital-based clinic, in the community and among self-testing patients?

We have already discussed the gaps in service provision, and that we are meeting some of our patients needs some of the time, but that we should strive to meet all of our patients needs all of the time. In order to solve this problem it was necessary to institute change. This type of research is known as action research. The research is the means by which the action can occur. In this case, the research aim is to improve practice and to solve problems within the current system. Carr and Kemmis (1986) saw action research as a means of improvement and advancement of practice. The author has divided the research into two broad areas. The methodology used in each area will be discussed separately.

4.2 Preliminary work

In order to answer the research questions all of the users of the current service were identified. Representation was sought to discuss service problems, plans for change and potential problems with implementation of a new anticoagulation monitoring system.

Focus groups and meetings formed a large part of the research. They were mainly unstructured meetings and discussions. Readiness for change is often more important than change itself and prior to conducting any quantitative research a large amount of qualitative research was needed.

All stakeholders potentially involved in the delivery of warfarin care were identified. These included:

- Hospital Consultants
- Clinical nurse specialists in the area of oral anticoagulant therapy
- Clinical nurse managers in the area of oral anticoagulant therapy
- General Practitioners
- Industry colleagues in the area of CDSS and POC
- Clerical staff involved in the day to day operations of a busy anticoagulant clinic
- Phlebotomy staff
- IT experts
- Patients

Various focus group interviews with stakeholders were conducted throughout the year. The main purpose of these interviews was to explore readiness for change, perception of change and assess barriers that would prevent the project going forward. The GP focus groups started with a presentation outlining the status of the anticoagulant service, the aims of the project and the perceived roles of all involved parties.

All General practitioners with patients attending our hospital based anti-coagulant clinic and all GPs who send venous INRs to the hospital laboratory, were identified from clinic and laboratory lists. The author identified those practices with more than ten patients attending the hospital based anticoagulant service and those sending more than ten INR samples per month to the main hospital laboratory.

Individual GPs and nurse practitioners were contacted by phone and administered a semi structured informal interview. (Appendix 8) A brief explanation of the web-based service and point-of-care testing was offered. GPs were asked about their willingness to participate in a web based anticoagulation management system and the advantages and disadvantages

of such a system. Reasons reported to prevent participation in such a system were documented.

4.3 Research Design

A structured, self-administered questionnaire was the research tool for the survey. The aim was to gather valid, reliable, unbiased and discriminatory data from a representative sample of respondents (McColl, 2005). The researcher was not involved in the administration of the questionnaire in order to reduce bias. Staff answered any questions in relation to the survey. The survey was anonymous.

4.4 Research Instrument

4.4.1 Question format

Evidence indicates that the wording and formatting of a questionnaire can have a major impact on the nature and quality of participant responses. (McColl, 2001) After discussion with colleagues and researchers in similar clinical fields the questionnaire was designed in 3 sections.

Section A was general. It contained pertinent demographic data and information as to the indication for and duration of treatment. An “Other” option was included in this section to accommodate any response that was not listed. Section B, the critical part of the survey and followed the general data. It consisted of closed questions and a section for comments. The final part of the questionnaire consisted of questions rated by Likert scales to assess patient satisfaction and knowledge.

The Likert scale component of the questionnaire was difficult to construct. Information from previous audits and questionnaires on this group of patients consistently showed very high satisfaction rates. Issues such as satisfaction with the service and the people providing the service as well as patient knowledge and education are central to any anticoagulant service. It was

important to ask these questions now in order to identify specific problem that might arise after changing to the new web-based solution.

The author used simple everyday language to avoid confusion. The questionnaire was short to facilitate completion. It consisted of a number of closed questions. They are easier to complete and makes it easier to code and analyse the data. Many patients included comments in the section provided; this allowed patients to express themselves freely.

4.4.2 Administering the questionnaire

The questionnaire was short making on site delivery or collective administration the most efficient way to administer it. This ensured a higher response rate, as fewer people refuse to participate. It is also a quick and cheap way of collecting data and saves on postage. There is personal contact with the study population. Participants can ask questions and find out more about the research if required.

While response rates tend to be high with this method of survey administration, additional measures used to increase response rates even further. (Boynton 2004)

- Notices in the clinic and waiting area informed patients about the study.
- A covering note attached to the front of each questionnaire ensured that patients understood the purpose of the study. It also guaranteed anonymity and thanked them for their participation.
- A person well known to all the participants distributed questionnaires. This person noted reasons for nonparticipation if stated. This person was not involved in any other part of the process, thus avoiding the potential for bias.
- All patients are potential stakeholders and there was no incentive for survey completion.

- The author attended. This was purely to ensure the smooth running of the clinic as other staff members were facilitating the delivery of the survey.

4.5 Sampling Methods

There are currently 1529 patients active on the St James Hospital Anticoagulation database. Approximately one hundred patients attend the clinic each day. The survey was conducted over a five-day period. A total number of 500 patients scheduled during the survey week were eligible and were representative of the population under study. It would be extremely disruptive to the workflow of the clinic to administer questionnaires to all patients on all days and a suitable sampling method was needed.

A systematic sampling method was used. The clinic flow was conducive to this method of sampling as it provided a suitable sampling frame. Five patients attend every fifteen minutes from 8am until 12.30 pm. The first and fourth patients in each appointment slot or interval were invited to participate. Patients were chosen according to the time they turned up at clinic. This was the most appropriate method of patient selection as non-attendees were not eligible. They were provided with a pen and were told when they had completed the survey to place it in the box provided.

4.6 Inclusion Criteria

All patients attending the anticoagulation clinic in St James's hospital during the last week in June were potential participants. All patients attending community-based clinics in the surrounding areas were eligible. No sampling method was required as the numbers were smaller and all patients were invited to participate. There were no predefined exclusion criteria apart from non-attendance at clinic. All patients must be literate to be eligible for warfarin therapy.

4.7 Ethical Considerations

Ethical approval was sought from the local research ethics committee. A letter was written to the chairperson of the Ethics committee outlining the study methodology and requesting permission it and to publish results as part fulfilment of an MSc thesis. **(Appendix 1)** A copy of the questionnaire was included. **(Appendix 2)** Approval was granted.

In addition, a submission was made to the patient advocacy committee for permission to complete the survey. This was also approved and the survey was carried out at the end of June. **(Appendix 3)** Consent was obtained from the GPs and nurses involved in the study. All stakeholders were informed about the research prior to any discussions.

4.8 Pilot Study

An audit of the anticoagulant service in question was conducted in 2004. The author reviewed the results of this audit with respect to the questions asked. Information poor questions and ambiguous questions were excluded. Questions more pertinent to this study were expanded.

A similar questionnaire had been conducted in a similar cohort of patients in another region. That initial survey was much longer and more time consuming. The data obtained was difficult to interpret and the researcher felt it would not add to the question posed in this research. Armed with this information the author modified the questionnaire in order to answer the research question

Finally, five patients on warfarin who attended the anticoagulant clinic were asked to complete the questionnaire and give feedback. There reported that no major changes needed but an extra section was included for comments as suggested by the patients.

4.9 Reliable Use of Research Instrument

A research instrument is said to be reliable if repeat measurements made by it under constant conditions give the same result. The fact that the survey occurred over five days and these results were analysed on a daily basis as well as collectively adds to the reliability of the research tool by serving as an internal consistency check. The research took place in two distinct settings: a hospital based anticoagulation clinic and a community based clinic. The research tool performed consistently in both locations. This served as an external consistency check.

4.10 Valid Use of Research Instrument

Validity is the ability of an instrument to measure what it is designed to measure. (Kumar 2005) The questions were factual. The free text part of the questionnaire was included to gain any extra information not covered by specific questions. Each part of the research instrument had a purpose. The Likert portion of the research tool was designed to rate the attitudes of patients to the service with respect to age, indication for anticoagulation and treatment preference and is a commonly used valid method of rating attitudes in qualitative research

4.11 Data Collection

The patient survey was conducted in the anticoagulant clinic during the last week in June. Two hundred surveys were handed out in total and 166 were completed and returned. This equates to an 83% response rate for hospital-based patients and amounts to 11.7 % of the total population attending the clinic.

All patients attending the community based anticoagulation service from 23rd June to the 7th July were asked to participate. Eighty patients completed the

questionnaire out of one hundred patients attended in total. This represented an 80% response rate.

4.12 Data Analysis

A coding system was applied to the raw data and all data was inserted into a Microsoft Excel spread sheet. Data analysis was performed separately for hospital based patients and community patients.

4.13 Limitations

One potential limitation was non participation on the part of hospital patients. Sampling methods used were designed to capture a representative sample of the entire clinic population.

Younger patients and working patients are overrepresented at early morning appointments. The sampling method was representative of the population but is likely to underestimate the numbers of patients interested in self-testing.

As with all questionnaires, there is a self-selecting bias. Not all patients return questionnaires. The attitudes and motivations of respondents may represent the extremes of opinions and be different from non-respondents. The results will be presented in chapter five. And further limitations will be discussed if relevant.

The limitations of the research were extrinsic to the methodology. The major strength of the research was the lack of exclusion criteria which make it generalisable. Further limitations will be discussed in chapter 6.

Chapter 5 Analysis

5.1 Introduction

The clinic statistics are presented initially to give the reader a sense of the volume of work at the anticoagulation clinic in St James's hospital and in the community anticoagulation clinic. The results of the patient surveys are discussed. Comparisons and further discussion will be included where relevant.

Finally, some of the comments and suggestions made by stakeholders have been included at the end of this chapter. A detailed discussion of the focus group sessions and the unstructured interviews was not included as part of this dissertation.

5.2 Clinic Statistics

5.2.1 Clinic Attendance

5.2.1.1 Hospital

25,289 return patients attended the warfarin clinic in St James's hospital in 2007. There were 357 new patients. By the end of July 2008, 237 new patients and 13085 return patients had attended the clinic. 1529 patients were registered on the anticoagulation management system. On average seven patients per day did not attend for their scheduled appointment. The average patient age was 68 years. The mean test interval was 18.24 days.

This information was obtained from patient registration data and from a biannual benchmarking report for each individual site produced by Dawn AC, our anticoagulation management system. Many of the graphs and tables for our site are included in Appendix 8. From a management and bench marking perspective this data is invaluable: Accurate, up-to-date and reliable statistics are readily available.

5.2.1.2 Community

There are five anticoagulation clinics in the South Inner City Partnership. A community anticoagulation nurse is employed to work in four of the clinics and to liaise with the practice nurse in the fifth clinic. For the purposes of this study, statistics from the four clinics managed by the community anticoagulation nurse are presented. There were 125 patients on oral anticoagulation who attended the four clinics, with a weekly attendance of 48 patients. The average patient age was 72.25 years. On average six patients per week failed to attend their scheduled appointment. Testing frequency was variable. There is no computerized anticoagulation management system at present making data retrieval significantly more time consuming than in the hospital setting.

5.2.2 Time in Therapeutic Range

Time in therapeutic range or TTR is a surrogate marker of the quality and safety of anticoagulation (Ansel 2008, Cannegieter 1995). A high quality service is provided by both models of care and is comparable to international best practice

5.2.2.1 Hospital

Seventy-five percent of all patients were in range as measured by the Rosendaal method (Rosendaal 1993). This method of finding time in range assumes the INR changes in a straight line evenly over time between the two results and is the most widely accepted and published method for determining the time in range. This is one of the advantages of using a computerized dosing system, as this information is readily determined.

5.2.2.2 Community

In order to determine the time in range for the community patients one must use a method known as point prevalence. Ninety-six patients were included for analysis. Sixty-three INR readings were in range. Time in therapeutic

range was 66%.This reading looks at a point in time. 153 of the previous 192 or 80% of INR results in the community were in range. Obviously, this method of determining time in therapeutic range is not directly comparable to the Rosendaal method used in the hospital and international studies. Nevertheless these results are in keeping with the requirements of good practice as stated by the British Committee for Standards in Haematology (BCSH 2005).

It is likely that the SICP anticoagulation clinic would perform extremely well in any benchmarking exercise. Installation of a computerised anticoagulation management and dosing system in the community is a prerequisite of the integrated care model and would result in the generation of a substantial amount of statistics and data. Participation in this scheme would allow direct comparison of the hospital and community clinics.

5.2.3 Extreme INR values

Extreme INR values are defined as an INR of greater than 5 or less than 1.3 and are associated with an increased risk of bleeding and thrombosis respectively. This is another method of determining how well an anticoagulation clinic is performing.

5.2.3.1 Hospital

Approximately 1.3% of all INR results from November 2007 to April 2008 were greater than 5.0 (169/12,732) or less than 1.3 (162/12,732).

5.2.3.2 Communityv

In contrast, none of the 192 INR results from patients attending the community clinic were greater than 5 or less than 1.3.

Anticoagulant control is more labile in the first three months of therapy and so hospital patients are more likely to have extreme values than stable community patients.

5.2.4 Bleeding or Thrombotic Complications

There were no bleeding or thrombotic complications recorded in patients attending the community clinic. A number of hospital patients had bleeding and thrombotic complications but the exact number was unavailable due to incomplete data collection. This is a failing on the part of the current system. An updated recording of adverse events is included on the newer version of the software and this information will be stored on all patients in the new integrated system.

5.2.5 Summary

Both the hospital and community anticoagulation clinics performed exceptionally well in terms of safety indicators. Regular monitoring of safety indicators for inpatient and outpatient/community anticoagulant services with reporting to appropriate clinical governance committees and risk management is one of the recommendations of the National Patient Safety Agency. An integrated web-based anticoagulation system will allow this data to be collected and collated for both hospital and community clinics.

5.3 Questionnaire Analysis

The results of the questionnaire are presented.

5.3.1 Demographic Data

5.3.1.1 Gender Distribution

470 return patients attended the clinic on the week of the survey. The survey was administered to two hundred patients in total. Overall, 166 patients participated in the hospital-based survey. This represented a response rate of 83%. Survey methodology, captive patient population and sampling methods all contributed to the high response rate in the author's opinion.

Some of the reasons for not responding included "no glasses" or "rushing to work". The male to female ratio was almost equal at 1.2:1 (90 male: 76 Female) and is representative of the overall demographics of the population in question**. (Figure 1)**

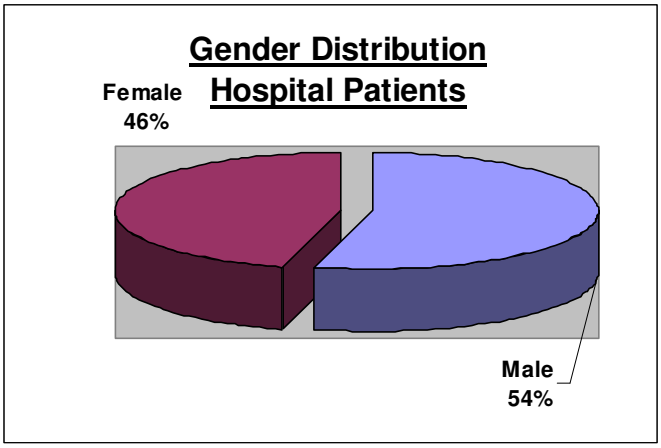

Figure 1: Gender distribution of Hospital Patients.

There were eighty participants in the community-based survey. Currently 125 patients attend the clinic, representing an overall response rate of 67%. The male to female ratio was 2:3 (41 male: 59 female). ***(Figure 2)***

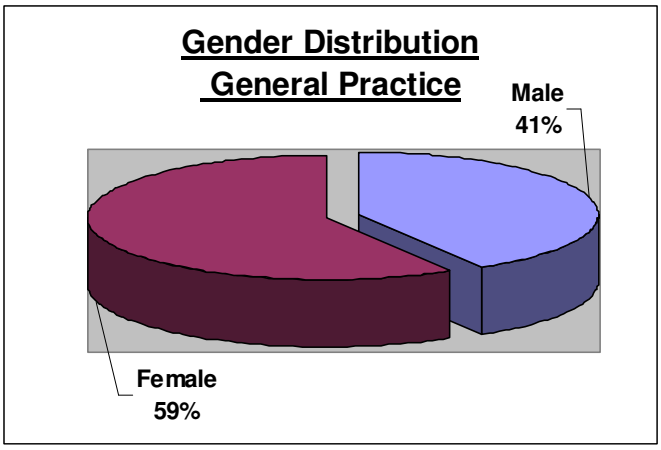

Figure 2: Gender Distribution of patients in General Practice

5.3.1.2 Age distribution of patients

Patients attending the hospital tended to be younger. Forty percent of hospital patients were under sixty compared to only ten percent of community patients. Only 44% of hospital patients were over seventy years of age. In contrast, 68% of patients attending the community clinic were over seventy years of age. **(Figure 3)**

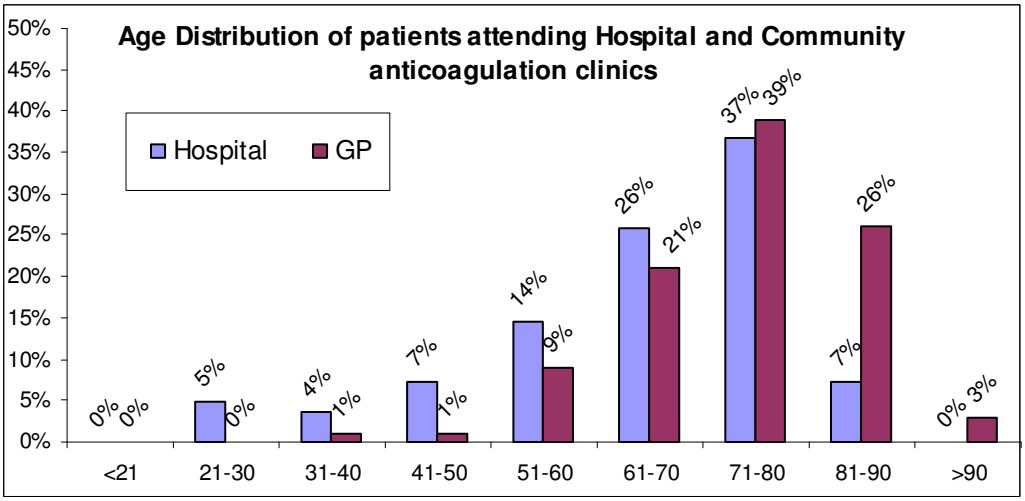

Figure 3: Age distribution of patients attending Hospital and Community anticoagulation clinics.

5.3.1.3 Indication for anticoagulation

The indications for anticoagulation in both hospital and community patients were similar and were consistent with international guidelines. **(Figure 4)** Atrial fibrillation was the most common indication for anticoagulation. Seventy four percent of patients in the community were on anticoagulation to treat or prevent stroke.

Patients diagnosed with acute venous thromboembolic disease (deep vein thrombosis or DVT and pulmonary embolism or PE) are managed in the hospital. These patients often require anticoagulation for six months to a year and are not referred to the community. On the other hand, patients with recurrent events require indefinite anticoagulation and similar numbers of patients attend the hospital and community clinics. (**Figure 4)**

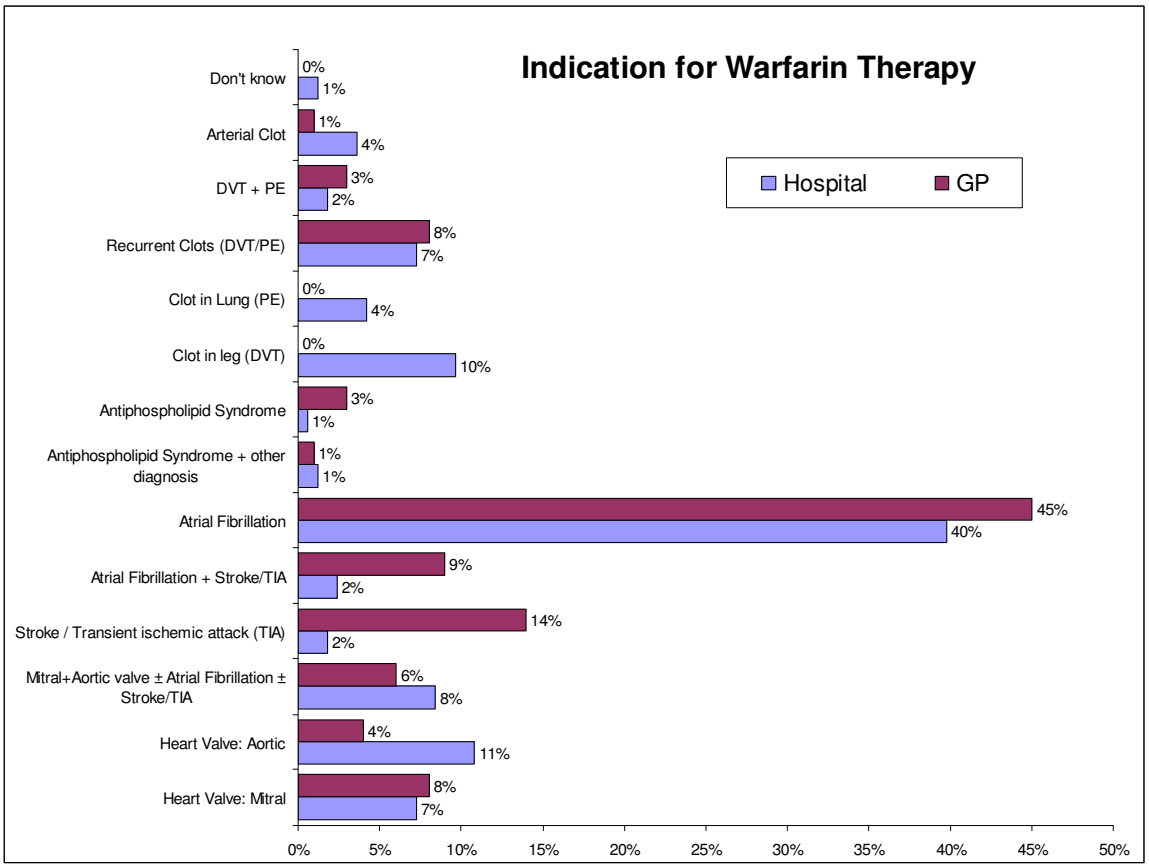

Figure 4: Indication for anticoagulation in hospital and community patients.

5.3.1.4 Duration of anticoagulation

The majority of patients in both the hospital and the community were on indefinite or lifelong anticoagulation. Similar proportions of patients are managed by both services. Fifteen per cent of hospital patients with acute venous thromboembolic disease required treatment for one year or less. This small group of patients is appropriately managed in the hospital setting as they require more intensive monitoring. ***(Figure 5 and figure 6)***

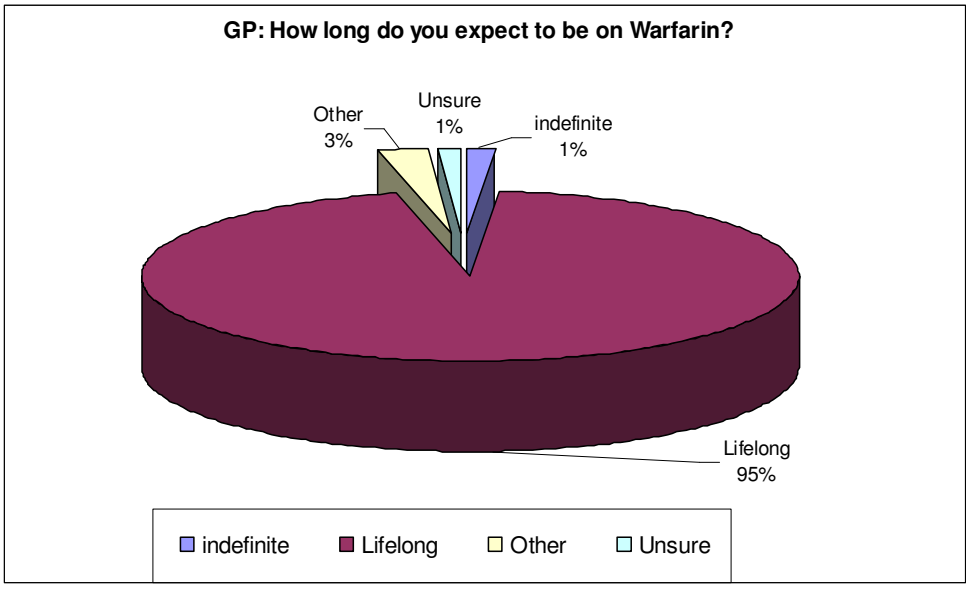

Figure 5: Expected duration of anticoagulation in community patients

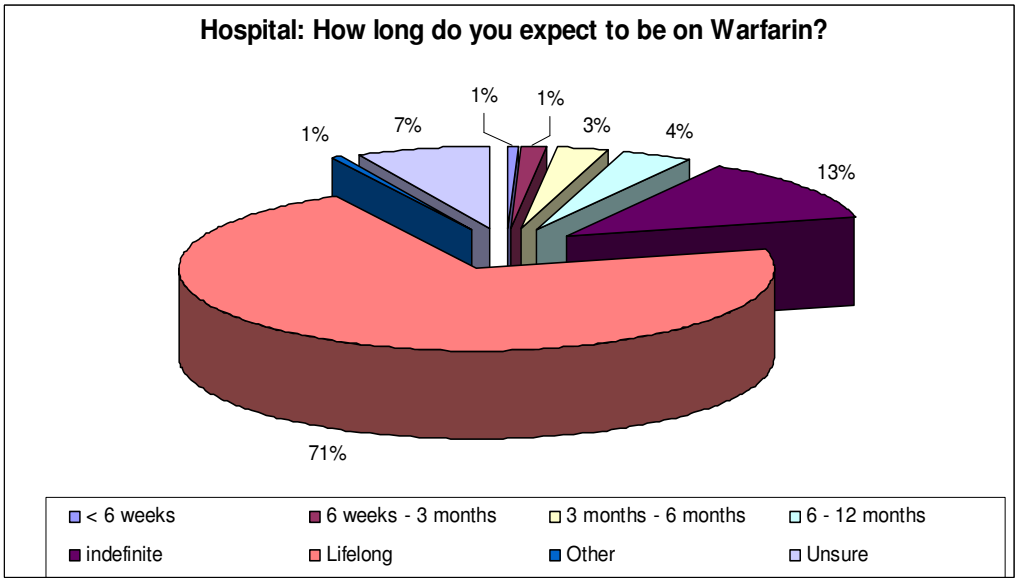

Figure 6: ***Expected duration of anticoagulation in hospital patients***

5.3.1.5 Distance from clinic

Ninety-two percent of hospital patients live within a ten-mile radius of the hospital with ninety-eight percent of patients living within twenty miles. **(Figure 7)**

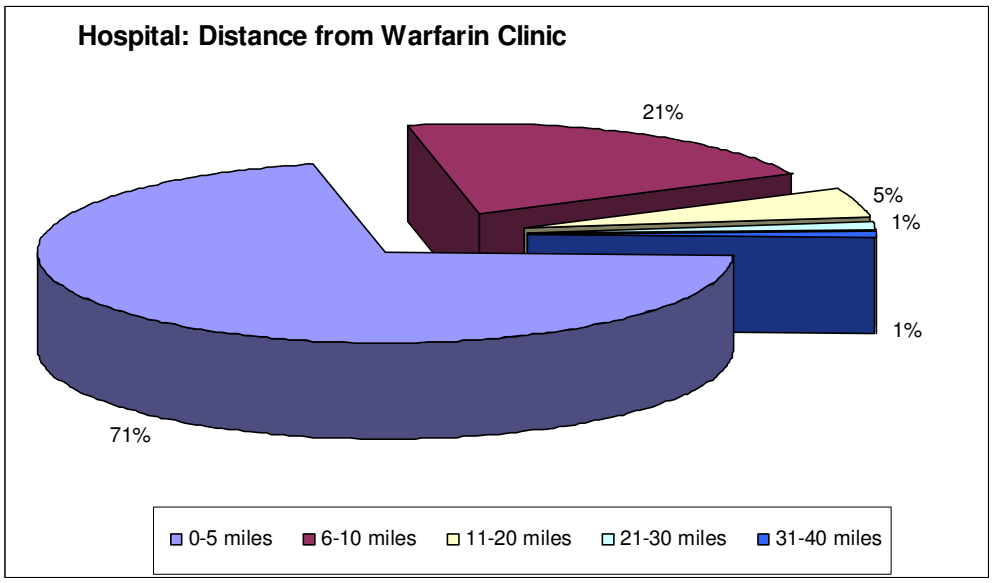

Figure 7*: *Distance from anticoagulation clinic: Hospital patients

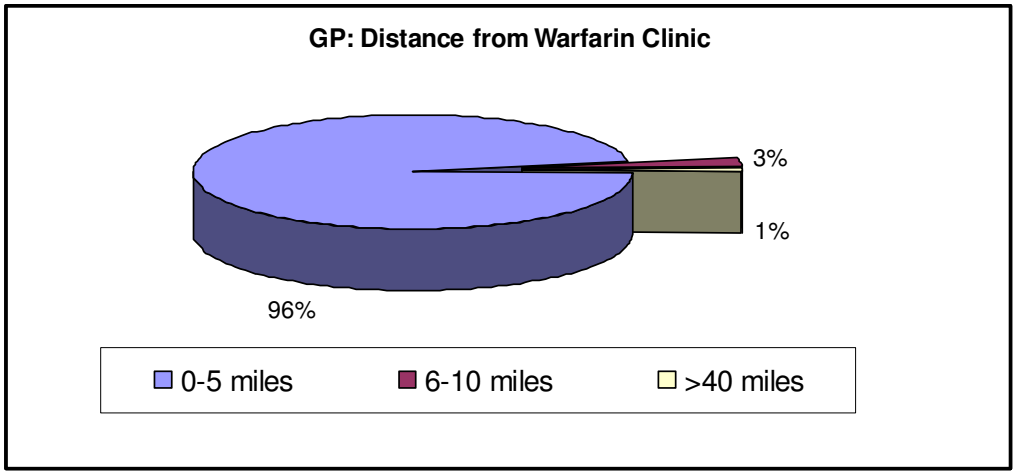

Figure 8: Distance from anticoagulation clinic. Community patients

Ninety six per cent of patients live within five miles of the community warfarin clinic with one patient a significant distance away (Figure 8). This patient prefers to travel to the community-based clinic.

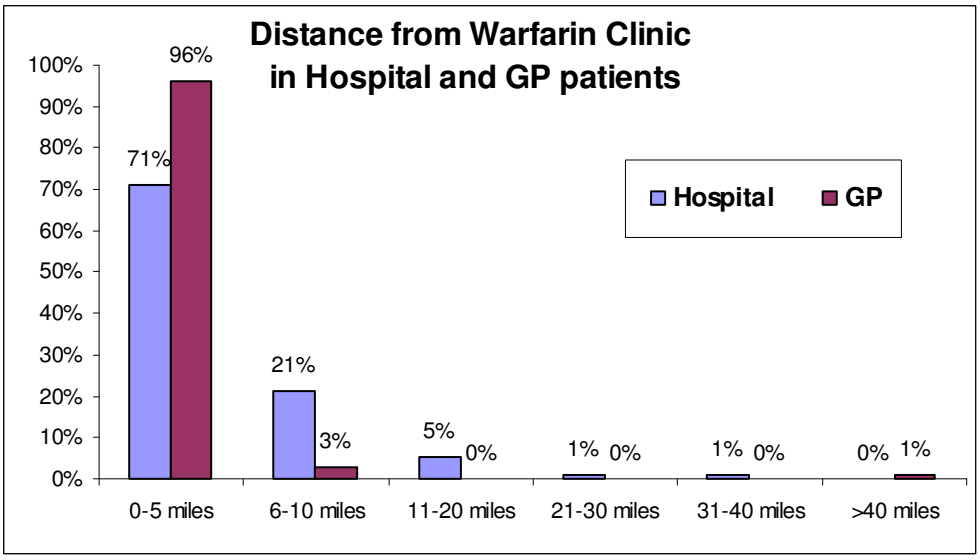

Figure 9: Distance from Warfarin Clinic in Hospital and GP Patients

Almost all patients (96%) live within ten miles of both the hospital and community clinic. **(Figure 9)** This may have implications for their preferred method of monitoring.

5.3.2 Preferred Model of Anticoagulation Monitoring

One of the main objectives of this research was to ascertain the preferred model of care of individual patients. The process of integrated care will have direct effects on patients and the delivery of care. It was important to involve patients in the process of integration from the outset. The success or failure of this project will ultimately depend on patient acceptance and readiness for change. In addition, results of this survey will be invaluable in targeting patient groups for each model of care. Different approaches and initiatives will be required depending on the cohort involved.

Question six asked patients in the hospital and community clinics to select their preferred method of anticoagulation monitoring from a list of three options, Hospital, GP or Home and to state any factors that influenced their choice.

Results are based on the model of care as well as the comparing the hospital with the community setting. All free text comments were examined in detail and were a rich source of information. They have been included in point format and will be discussed where appropriate.

5.3.2.1 Preferred model of care for hospital patients

One hundred and sixty-six hospital patients responded. **(Figure 10)**

- 102 patients stated they would like to continue attending the hospital
- 18 patients would like community monitoring by their general practitioner
- 48 patients would like to self-test

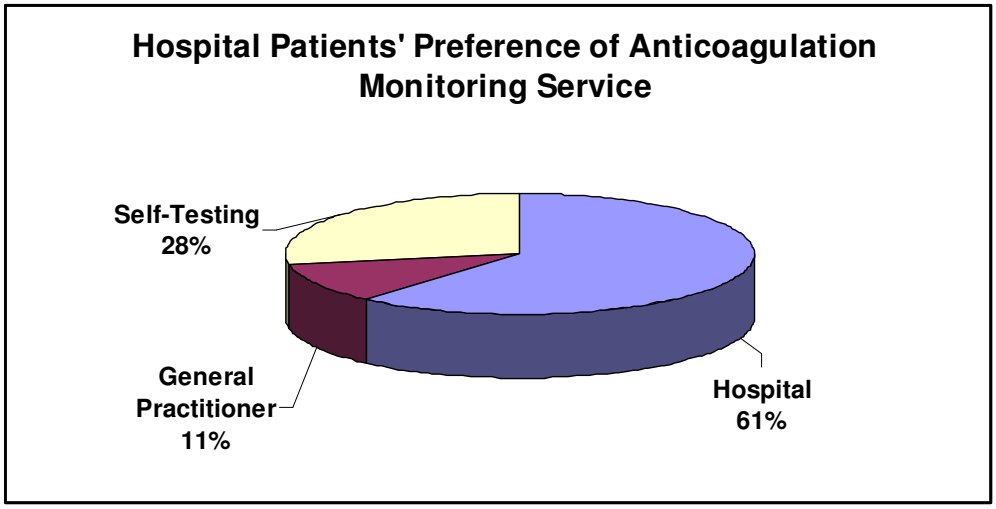

Figure 10: Preferred model of care in hospital patients

5.3.2.1 Preferred model of care for community patients

Eighty patients responded. ***(Figure 11)***

- 17 wished to test at home
- 63 would prefer to attend the community clinic
- NO patient wished to attend the hospital clinic

It is interesting that no patient attending the community clinic stated a preference for hospital monitoring. This research has confirmed that the patient demographic is very similar in terms of age, distance from the hospital

or clinic and indication for anticoagulation. There is no reason why patients from the hospital could not be managed in primary care. This preliminary research would suggest that once in the community they will not wish to return to the hospital setting (Shiach 2002).

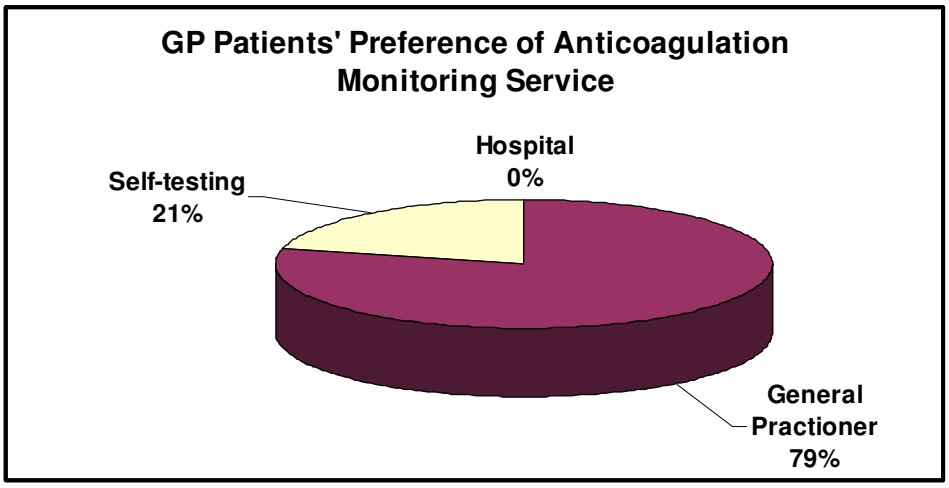

Figure 11: Preferred model of care among patients attending community anticoagulation clinic.

5.3.3 Hospital Monitoring

102 /166 patients stated they would prefer to attend the hospital-based service. Younger patients were less likely to want warfarin monitoring in hospital. Fifty one per cent of patients who stated they would like to continue attending the hospital clinic were over 70 years of age. ***(Figure 11)***

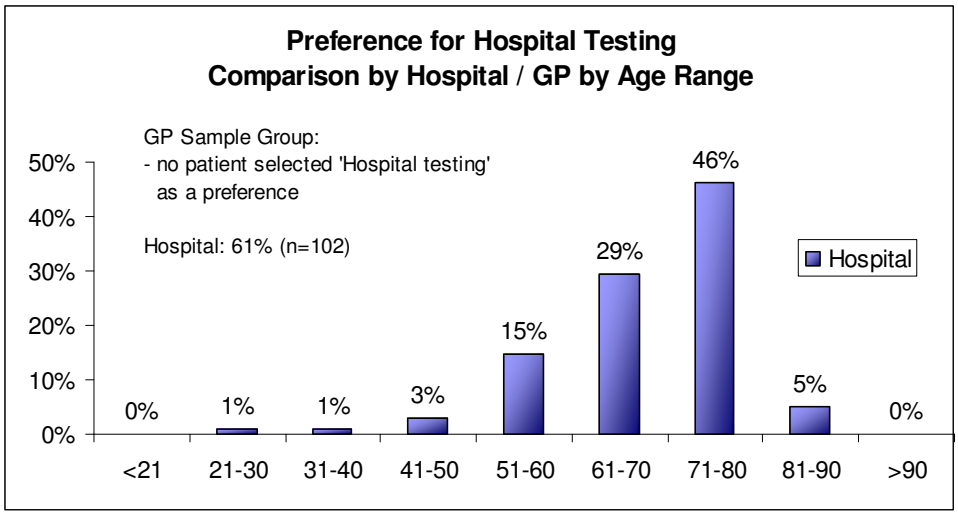

Figure 12: Age range of patients who would prefer to have hospital based anticoagulation monitoring

Reasons for choosing the hospital clinic as stated by patients included

- Distance from the hospital
- Trust in the hospital system*
- Safety of the hospital
- Speed
- Nurses and staff
- Friendly and efficiency
- “Gets me out of the house”
- Queuing at GP surgery*
- No designated appointment in GP
- Travel difficult as no public transport
- My doctor won’t take blood
- Referral to specialist coagulation clinic if required

5.3.4 Community Monitoring

Only 18 of the 166 (11%) patients attending the hospital-based clinic expressed a preference for anticoagulation monitoring in the community. Ninety-four per cent of these patients were over 60 years of age and at first glance, this may seem disappointing***. (Figure 13)***

Over 80% of these patients had atrial fibrillation or mechanical valves. These patients are ideally suited to community monitoring of oral anticoagulant therapy. The reasons for them choosing hospital over community based care might be related to the fact that the latter option is currently not available to most patients. Appropriate education will undoubtedly increase the number of patients requesting this service.

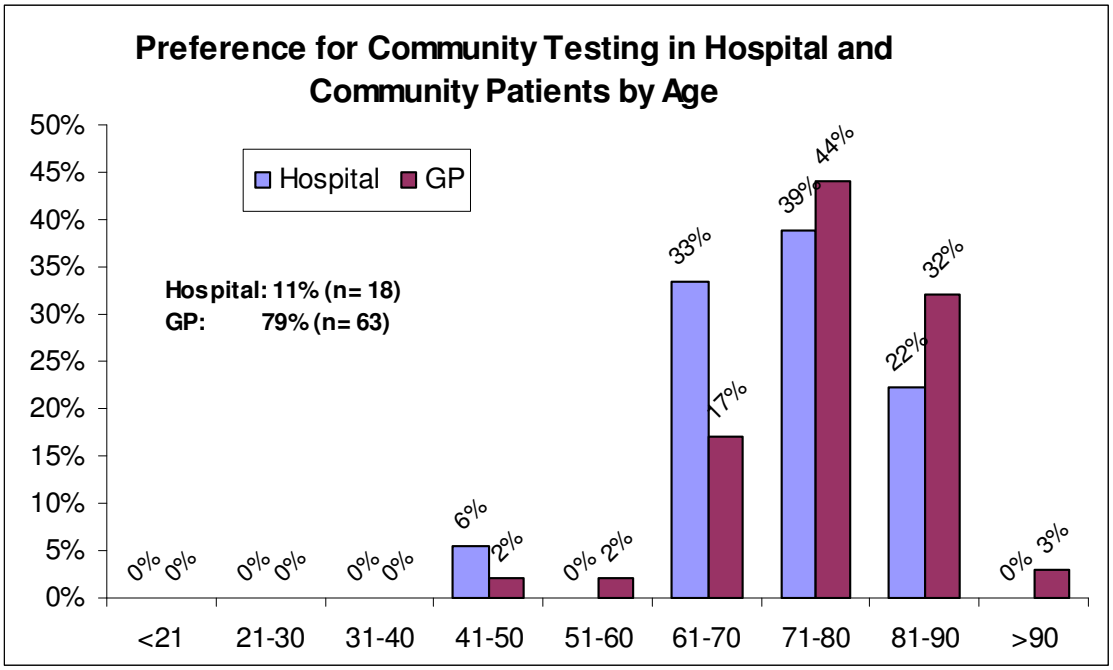

Figure 13: Preference for Community Monitoring in Hospital and Community Patients by Age

Education of staff and patients is required to encourage those patients who wish to attend their GP to do so and will be vital to the success of any integrated service. This will be discussed later when addressing limitations and future work.

5.3.5 Home Testing

Twenty-eight per cent (48/166) of hospital patients stated they would prefer to test at home. This is consistent with earlier studies conducted in the UK. It is lower than in countries such as Germany and the Netherlands where self-testing programs have been in place for many years. This is not surprising. Patients in these countries receive reimbursement for meters, strips and education through various health insurance and government funded schemes.

Patients who wished to test at home tended to be younger: 63% were less than 60 and 78% were less than 70. Advanced age was not a barrier to self-testing; 7% of patients wishing to test at home were over 80 years old. It is envisaged that the community intervention team would work as part of the proposed integrated service. Health professionals would call on patients and perform INR testing in the patients' home. This would allow patients with reduced mobility or access to benefit from home testing without the worry of using a coagulometer.

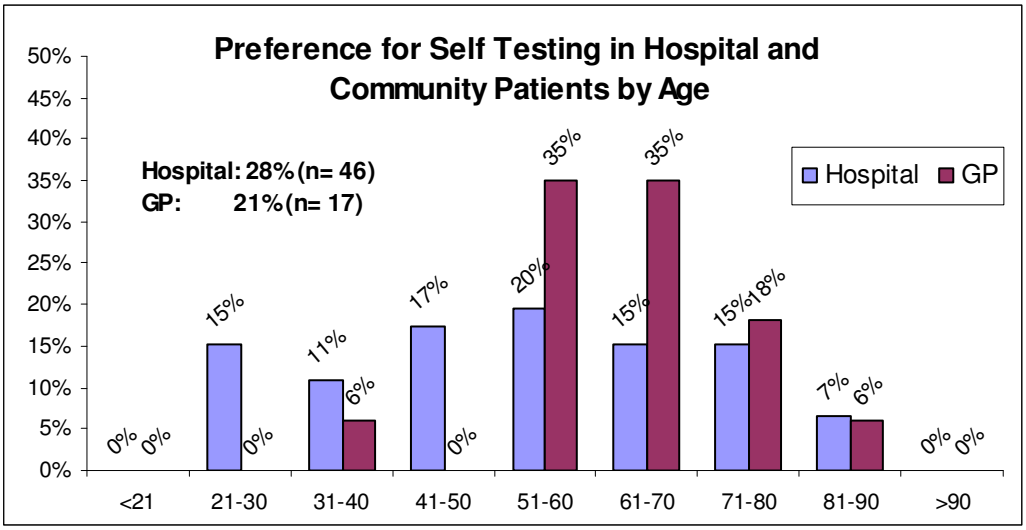

Figure 14: Preference for Self-Testing in Hospital and Community Patients by Age

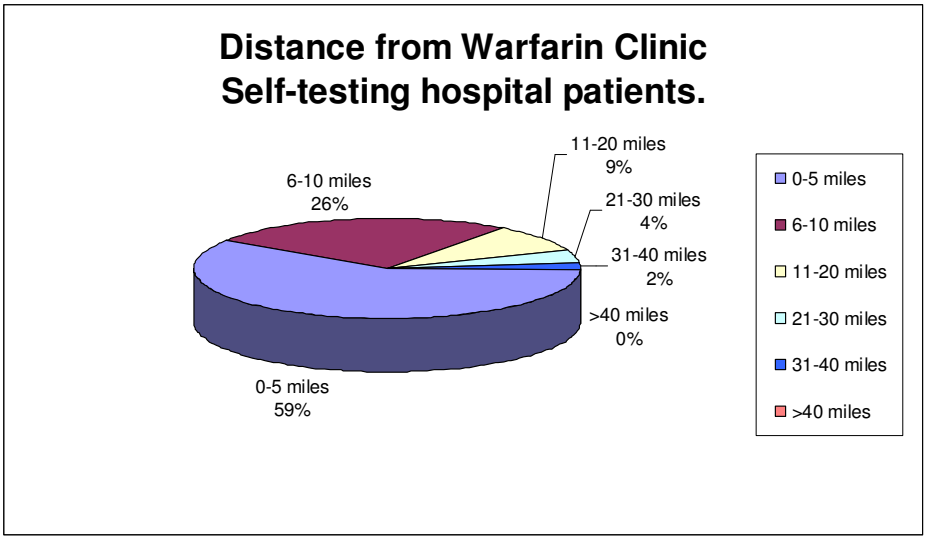

Figure 15: Distance from anticoagulation clinic among hospital patients who wished to test at home.

There was a tendency for patients who lived a greater distance from the hospital to select self-testing as the preferred method of monitoring. This was not statistically significant. (Figure 15) The majority (96%) of patients surveyed lived within ten miles of the hospital or their GP. Distance from the hospital or clinic did not have as dramatic an effect as one might have expected if this survey was conducted in a rural setting. One might argue this was a major limitation of the survey. However, it was also one of the reasons for conducting this research. The needs of this urban population are quite different and specific. Findings from surveys conducted in rural and other jurisdictions are equally inapplicable to our patient group.

There was concern that the demand for self-testing may be lower than expected because of the short distances involved. This was not the case and the numbers of patients requesting this model of care were consistent with other studies in similar patient groups.

Again, patients were asked to state any factors that influenced their decision to test at home. The most salient comments are listed below

- Convenience

- Freedom to travel
- Need to relieve pressure on hospital services
- Reliance on others. More Independence
- Need to arrange childcare for each visit
- Three young children and husband works nights
- Childcare and have to rearrange working day
- Would SAVE TIME
- Weekly checks so home testing would free up time
- Work
- Save on travel time
- Travel for work
- Time off work
- Concerned re employers

One can see a recurring theme: Work, Time, Travel and Childcare.

One elderly patient commented that his carer would be able to check his INR and his family would not have to bring him to the hospital. People of all ages can see the benefit of testing outside the hospital setting.

5.3.6 Patient Satisfaction with Anticoagulant Clinic

An overwhelming 97% of patients surveyed were totally satisfied with the warfarin clinic in the hospital. ***(Figure 16)***

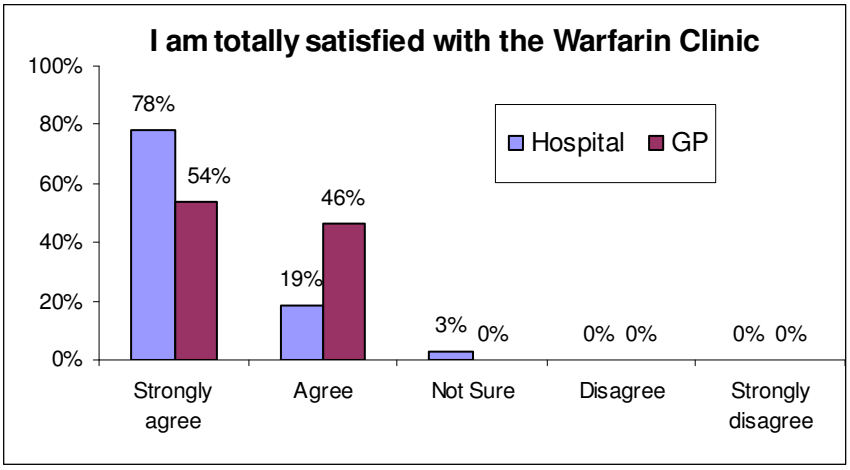

Figure 16: Satisfaction with warfarin clinic among patients.

An extremely high level of satisfaction with the staff at the clinic was also evident. Overall 99% of patients surveyed were very satisfied with the quality of care received from the nurses. ***(Figure 17)*** Two patients (1%) were not sure. This has been a consistent finding in previous audits of the service. Patients tend to be very satisfied with the quality of care, in both the hospital and community setting, but are also amenable to change.

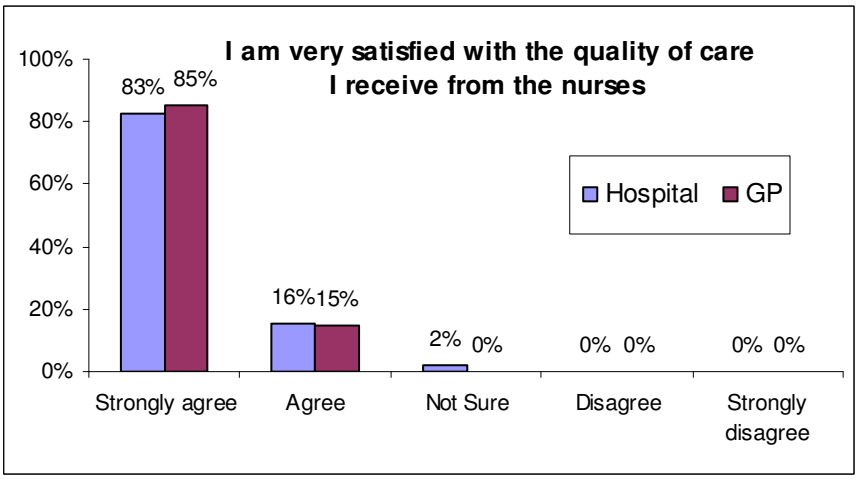

Figure 17: Patient Satisfaction with nursing staff

It is noteworthy that 17% of hospital patients stated that they would like more information about warfarin. Only 4% of community patients felt they needed more information. ***(Figure 17)*** Community patients see the nurse at every visit. This presents an invaluable opportunity to reiterate previous advice, re-educate and reassess patients. Education and communication improve

compliance and ultimately time in range and patient outcomes. This does not occur in the hospital setting due to the postal system and the high numbers of patients attending daily.

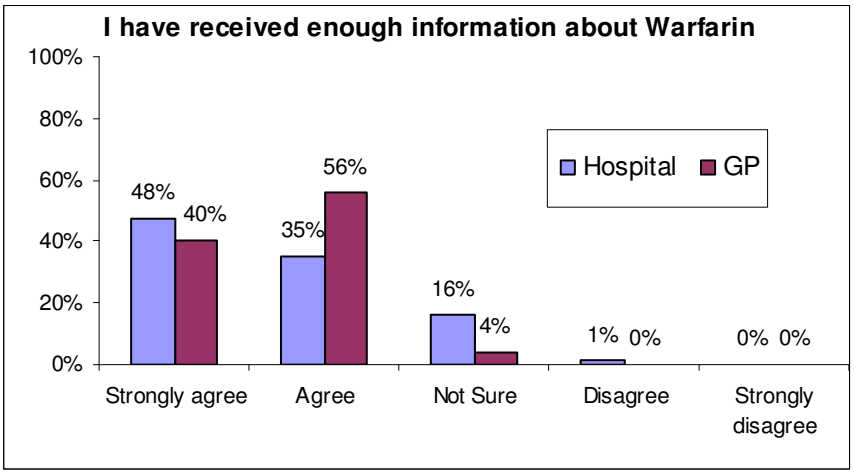

Figure 18: Adequacy of information on warfarin in patients

This also came across in the comments section of the questionnaire with many patients stating they would like to receive more written information on the food, medication and herbal supplement interactions of warfarin.

36% of patients were either unsure or were not aware of the risks and benefits associated with treatment with warfarin. ***(Figure 19)***

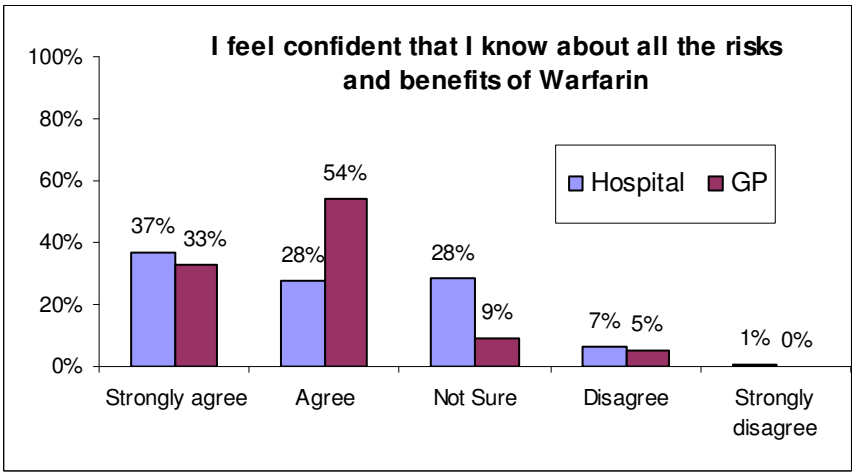

Figure 19: Knowledge of risks and benefits of warfarin

Continuing education on the multiple food and drug interactions of warfarin as well as reiteration of the risk of bleeding and thrombosis are extremely important and directly relate to patient safety. The community based anticoagulation clinic gives patients a chance to discuss their medication if required. This is not possible in the hospital-based clinic. This is obvious from ***figure 20.***

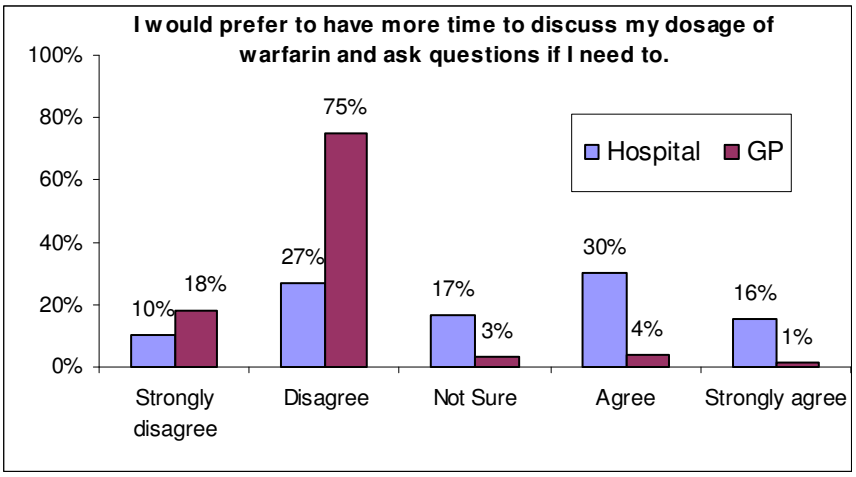

Figure 20: Adequate discussion time in hospital setting and community clinic.

Overall, there is a very high level of satisfaction with the care received in both the hospital and the community. Patients have a huge amount of confidence in the system to which they have become accustomed. This research has shown that the age, demographics and indications for long-term anticoagulation are similar in both patient groups. Increasing awareness of the availability of the community anticoagulation clinic among patients and healthcare professionals will facilitate management of patients in the community via a state of the art integrated web- based service.

Chapter 6 Limitations and future work

Integration of the anticoagulation service will require the transfer of patients from hospital-based clinics to their general practitioners, the community intervention team or to the home. This will involve changes for patients and for all staff involved in the delivery of this service. The problems and concerns of the main stakeholder groups will be discussed. Possible solutions and future work will be included where possible.

6.1 Information and communication technology ICT

Identification of suitable patients is a prerequisite for the success of an integrated system. This proved to be a major failing of the current anticoagulant management system. Currently all patients attending the anticoagulation clinic are registered to a hospital consultant. It is not possible to accurately search by GP. It was difficult to identify the exact number of patients registered to individual GP's or GP practices. There was no way of knowing if the patient was still attending the service or indeed if duplicate records existed on this GP list.

A data clean up will be part of the new upgrade and will assist in the identification of patients suitable for transfer to the South Inner City Partnership community anticoagulation service.

The anticoagulation management system in use at present in St James's Hospital is DAWN AC Version 6. (Dawn Clinical Software, 4S Information Systems Ltd, Milnthorpe, Cumbria, England). This system was in use by over 290 centers in fourteen countries worldwide. An upgraded web-based version has been available since late 2005. DAWN AC Version 7 is in use in 130 sites in various settings worldwide such as hospital clinics, nurse led clinics, primary care and pharmacy clinics. One hospital in the UK is using it across primary and secondary care but no one is using the Dawn AC system to integrate home testers although the functionality exists to support this. A

major teaching hospital in Dublin is in the process of installing Dawn AC Version 7 but has no plans as of yet to use it in the shared care setting.

There are other web-based dosing software systems in use for example Coagcare® (Zycare Inc, Chapel Hill, North Carolina, USA). This system is in use in a number of clinics in the US as well as a small number of sites in Europe. It was used in randomized clinical trials in Ireland (Ryan 2007). It operates on a web-browser and can manage hospital and home testing patients. It is extremely user friendly for both medical staff and patients.

Upgrading to a new web-based system will offer enhanced functionality as well as the possibility of shared care. None of these systems have been used to provide the complex integrated care solution required. Considerable IT support is needed for this project and is proving to be the rate-limiting step in the implementation of an integrated model of care.

Upgrading will necessitate the following, regardless of the software package selected.

6.1.1 Data cleanup and conversion process

This will meet two requirements

1. The provision of accurate, reliable information suitable for inclusion on the new database. It is important that redundant and duplicate data is not transferred to the new web-based system. This clean up process is mandatory.
2. Identification of suitable patients for self-testing and GP monitoring as well as those who would benefit from involvement of the community intervention team.

6.1.2 Web server and software

The technical requirements for a web-based solution are complicated. Currently none of the servers in St James's Hospital are accessible via the Internet. The IT architecture requires considerable security and support and is a major limitation to the implementation of an integrated model of care. Possible solutions may involve external hosting which will significantly increase cost.

The preferred option for GP access is through *Healthlink,* acting as a broker. *Healthlink* could manage the digital certification of GP's and provide a secure tunnel to the server/application in SJH. *Healthlink* are not in a position to provide access for patients.

There are two server/application platform options for the hospital which are currently being evaluated:

1. SJH host both the DAWN application and the Web Server and establish the necessary firewall security required
2. SJH host the DAWN application but use an externally hosted Web server.

Patient access cannot be accommodated within this framework. The most likely framework for patient access would be via the government Reach Programme, which facilitates citizen access to public services via the PPSN. No health application has been developed on Reach to date.

The following specification is provided by the company and is intended as an outline only.

- CLIENT SOFTWARE: Web browser; IE Version 6.0 and upward is recommended
- SERVER HARDWARE
    - Minimum 2Ghz Pentium IV
    - Recommended XEON processor 3.4Ghz with 2GB of memory
    - A 'Raid 5' disk system
- SERVER SOFTWARE

- Windows 2000 server and upwards (with Windows Scripting Host version 5.6 or higher)
- MDAC 2.8/ JET 4, SP8
- MS SQL Server Version 2000 Standard Edition or higher
- IIS as shipped with OS (version 5/6) with support for active server pages enabled

6.1.3 Staff retraining

- Mandatory part of the new web-based system
- Remote training provided for hospital staff and community anticoagulation nurse.
- Hospital staff to then train patients and GPs

6.1.4 Interfaces

- Currently Laboratory Information System (LIS) interface is in place
- HL7 interface will incur additional cost
- Patient Administration Systems (PAS) interface will be required

6.2 Quality Assurance

Quality is a prerequisite of all anticoagulation management systems regardless of location. This is also a major concern to users of an anticoagulant service. A comprehensive quality assurance programme with benchmarking will apply to all parts of the integrated care service. This will ensure the entire anticoagulant service achieves best international practice.

6.2.1 Internal Quality Control

Internal quality control is inbuilt into the CoaguChek® XS Systems. These devices are CE marked and have been independently validated.

6.2.2 External Quality Assurance.

Self-testing patients will have to sign a contract agreeing to participate in regular internal and external quality assurance schemes in order to meet the requirements for supervised self-testing. This contract will be standardised for all self-testing programs in the country **(Appendix 6)**.

The hospital laboratory and the community anticoagulation nurse participate in the National External Quality Assurance Scheme. (NEQAS, Sheffield) Point of Care meters in the hospital and home will also adhere to these requirements.

6.2.3 Benchmarking

Dawn AC currently offers a benchmarking service to all its users. This information is used to identify areas for improvement and provides a means of continuously monitoring progress in key areas. Performance indicators correlate with both the quality and safety of anticoagulation

A biannual report is produced which satisfies internal audit requirements and quality assurance principles. St James Hospital consistently performs extremely well and meets internationally accepted standards of a quality anticoagulation service.

An integrated service will allow benchmarking of our colleagues against the hospital clinic as well as against other users of the DAWN AC management system. Participation in the benchmarking exercise has the added benefit of easy production of meaningful statistics that are otherwise time-consuming to produce. ***(Appendix 8)***

6.3 Industry

Point of Care manufacturers are major stakeholders in this integrated model of care. Cooperation and collaboration in providing a high quality, cost effective product should be the goal. The CoaguChek® XS system is manufactured by Roche Diagnostics (Roche Diagnostics GmbH, Mannheim,

Germany) and is the only near patient testing system used for INR measurement in Ireland. The CoaguChek® XS is ideally suited to patient self-testing while the CoaguChek® XS Plus is manufactured specifically for healthcare professionals.

The CoaguChek® XS systems are CE marked. The Irish Medicines board has no inspection requirements with respect to these devices. The CoaguChek® XS has been critically evaluated in the United Kingdom. The purchasing and supply agency (PASA) under contract of the centre for evidence based purchasing, conducted an independent and objective evaluation in 2006. They found it to be accurate, reliable, easy to use and suitable for purpose as a near patient testing device. In light of this information, one would expect a significant number of patients in Ireland to be self-testing. This is not the case. Only one percent of patients on our database are currently self-testing. The barriers to widespread implementation of self-testing programmes are mainly financial

The CoaguChek® XS costs €588 excluding VAT and 24 test strips will cost €93.91 excluding VAT. There is no reimbursement to patients for any of these costs. Ireland is the only one of sixteen countries that contributes nothing towards the cost of near patient testing of oral anticoagulation. This currently prevents suitable patients from self-testing in Ireland. Representatives from Roche have had numerous discussions with the HSE in relation to reimbursement issues. Hopefully, this barrier will be removed to allow suitable patients to self-test rather than limiting it to those who can afford it.

An important requirement to enhance the safety of Point of care testing is an automated interface between the computer assisted dosing software and the coagulometer. This will enable automatic upload of the INR result and reduce the possibility of errors from manual entry of INR results. This will be a requirement of our integrated system and will require collaboration between CDSS manufacturers and point of care manufacturers.

6.4 Patients concerns

It became evident that patients had a number of concerns regarding the location and provision of care. The main purpose of the questionnaire was to identify appropriate target populations in the hospital setting suitable for community monitoring and self-testing. Patients were concerned that GPs would not be in a position to provide a similar service to the hospital clinic. Most patients are extremely satisfied with the hospital service. The appointment system is efficient and the clinic tends to run very smoothly. Earlier work has shown that patients are extremely satisfied with the community service once transferred and often are more satisfied. (Shiach 2002) An audit conducted post implementation of community testing in the South Inner City Partnership had similar findings.

Understandably, patients need assurances regarding the new integrated service. Education regarding the processes involved in the new integrated model of care including those items listed below will result in higher numbers of patients opting for community monitoring. The most pertinent issues according to the patients as identified in this research will be included in a specially designed information leaflet. This will be sent to all patients attending the warfarin clinic in St James's Hospital and the South Inner City Partnership.

It will include information on

- New integrated service involving hospital and GP
- Testing in the home, the GP surgery or the hospital
- Strict appointment times,
- Near patient testing using "finger-prick" testing rather than venous sample
- INR result in one minute
- "One stop shop" dosing there and then in the surgery
- No need to wait for yellow book in post
- Nurse led service
- Doctor on site in surgery if required

- Integrated with the hospital system
- Identical computerised dosing system
- Identical procedures, policies and protocols to hospital clinic
- Information leaflets on food, medications
- Information leaflets on dental work and endoscopy
- Alert cards
- Identical safety procedures in relation to testing and quality monitoring
- All INR results available in hospital for clinic or emergency room visits as part of electronic warfarin record
- Hospital consultant specialist input when needed at times of operations or procedures

6.5 GP Acceptance

This dissertation concentrated on two specific areas of the current anticoagulation system namely St James's Hospital and the SICP community anticoagulation clinic. A truly integrated service will require involvement of many more GP practices. Over half of the patients currently attending the hospital anticoagulation clinic would be suitable for monitoring in the community. All of the GPs contacted could see the advantages of an integrated model of warfarin management but were concerned regarding the funding of point of care meters and strips.

The other financial consideration relates to GP reimbursement for anticoagulation monitoring. In the NHS, with GPs as fund-holders, the costs of running a primary care clinic are less than the costs charged to GPs for hospital visits. Each patient on oral anticoagulation attracts a fee of up to £127.93. It is in the practices best interest to manage these patients.

However, in Ireland, GPs do not pay for patient hospital visits. There is no method of recouping the cost of the test strip or consultation under the current

GMS contract. Ideally, this sort of work would attract an STC payment (Special Type Consultation) for both public and private patients. A consultation for anticoagulation monitoring can take up to 15 minutes. A nurse could spend an entire morning managing an anticoagulation clinic and the practice receives no funding whatsoever for providing this service. One can see why general practitioners are skeptical about taking on such an initiative. This is the major barrier to the widespread adoption of an integrated service.

At present altruism is the only incentive to provide such a service. Successful implementation of integrated care between St James's Hospital and the South Inner City Partnership will prove to the Health Service Executive that this model of care is achievable in clinical practice with minimal use of resources once managed in a coordinated fashion.

The financial implications for general practice are substantial. Integration would allow the hospital service to assume responsibility for protocols, procedures, education, audit and quality assurance all of which have significant cost implications but are a mandatory requirement of the service Individual practice licenses for the computerized decision support software should also be included in the hospital anticoagulation clinic budget.

Possible incentives and solutions are proposed

- ***Purchase of GP and patient licenses for a computerised dosing and management system.*** This is the basis of the integrated web-based solution and will ensue that all patients receive the same high standard of care regardless of location. It is likely that any reimbursement of anticoagulation monitoring in the future will reflect the quality of care provided. Point of care testing with computer assisted dosing attracts the maximum fee per item in the UK. The success of the integrated model of care may well strengthen the case for reimbursement.

- **Creation of an electronic warfarin record.** This can be used by all service providers to ensure continuity of care.
- ***Redeployment of nursing staff to community clinics***. This is dependent on the reduction in present clinic numbers due to the provision of an integrated web-based service.
- ***Redeployment of existing resources*** including phlebotomy and laboratory staff to other areas such as quality assurance or point of care testing.
- ***Provision of coagulometers to patients*** with a substantial improvement in quality of life. Funding awarded by the Health Service Executive Innovation Fund 2008 will be used to purchase coagulometers. Patients may still have to pay for strips. This should cost a maximum of €93.91 ex VAT annually assuming a test frequency of once every two weeks. It is hoped that up to thirty percent of patients will be self-testing once the implementation is complete. Discounts may be possible once a significant number of patients are self-testing
- ***Education and training of patients and staff*** will be provided through the National Centre for Hereditary Coagulation Disorders. Collaboration and co-operation with our colleagues in Industry to ensure patients and staff are familiar with the point of care devices as well as the web-based software.
- ***Distribution of guidelines, policies and standard operating procedures*** for all practices involved in the integrated web-based model of care. These will be accessible electronically.
- ***Access to Consultant Haematologist and expert nursing staff in National Center for Hereditary Coagulation Disorders "24/7" for any queries***. This site is the reference center for coagulation disorders in Ireland and has considerable expertise in the area of oral anticoagulant therapy. Staff involved in all areas of oral anticoagulant therapy will be encouraged to attend the annual education meeting in St James's Hospital.

6.6 New oral anticoagulants

There are a number of oral direct thrombin inhibitors in development. The anticoagulant effect is mediated through thrombin inhibition and is not vitamin K dependent. INR monitoring is not required. These agents have a short half-life necessitating twice daily dosing which may cause problems with compliance. There is no antidote. The possibility that they will replace warfarin as the oral anticoagulant of choice worldwide has prompted an enormous amount of research and development in the area.

One might suggest that investment in the area of anticoagulant monitoring is a fruitless exercise but this is not the case and it may be more important than ever to have a high quality monitoring system and database in place.

All oral anticoagulants cause an increased risk of bleeding. There is usually a substantial difference between the results in clinical practice and those observed in controlled clinical trials due to careful patient selection. The true incidence of bleeding and thrombotic events is unknown. Ongoing prospective monitoring of these medications should be a mandatory requirement for all anticoagulation monitoring services. Concern has been raised over liver toxicity associated with these medications. Indeed, Ximelagatran, one of the first direct thrombin inhibitors was withdrawn from phase III trials due to abnormalities in liver function tests.

This raises another important issue with respect to post marketing surveillance of all new medications. Nimesulide or Aulin was withdrawn from the Irish market in May 2007 as it was linked to liver failure in nine patients three of whom died. This medication was on sale in Ireland since 1995. Concerns regarding liver toxicity were documented in the Lancet as early as 1999. Nimesulide was not licensed in the USA, Canada or Australia but was widely used in Europe.

The existence of an international database would facilitate monitoring of idiosyncratic reactions such as hepaotoxicity as well as bleeding and

thrombotic complications all oral anticoagulants. This could serve as an early warning system should any potential problem arise. Equally an international database would confirm the clinical efficacy of these agents for all indications in all patients.

Warfarin is the oral anticoagulant of choice world wide and is in use for almost sixty years. Despite all the problems associated with its use, it is unlikely to be replaced by new oral anticoagulants for the foreseeable future. The current hospital-based anticoagulation monitoring system has to change and safe and effective patient-centered community monitoring systems will need to be implemented so that requiring anticoagulation receive this extremely effective therapy.

Chapter 7 Conclusions

The aim of my research was to show that an integrated web-based anticoagulation service is a necessary and achievable model of care. This will amalgamate the existing hospital clinic and community clinics with an expanded self-testing programme and community intervention team. It will allow patients the same high standard of care regardless of location

An integrated web-based system involving St James's Hospital and the South Inner City Partnership will be a reality in the coming months. The procurement process for a web-based system is underway and security concerns are rate limiting at present. Significant progress has occurred in a short space of time. And the recent allocation of a project manager will identify and alleviate some of the concerns of stakeholders and facilitate coordination of the project.

Standard protocols are already in circulation to determine patient suitability and commence the education process. Staff training in near-patient testing and web-based anticoagulation software is ongoing. An educational campaign to be directed at all patients attending the hospital and community clinics is planned after the data clean-up process is complete.

The barriers to implementation are all surmountable. All stakeholders can see the benefits this system has to offer and are actively involved in implementation. There is a need for change. There is willingness for change. The technology exists. The aims of the research were to obtain demographic information, to ascertain patient preference and to identify potential barriers, which might hamper the success of the proposed integrated model of anticoagulation management.

These aims were achieved and additional unforeseen benefits were realised. The initial engagement process involving all the stakeholders was invaluable. This has prompted increased collaboration and discussion between the

hospital and community anticoagulation clinics and it is the author's opinion that this will greatly facilitate the progress of integration.

A substantial part of the health services / health policy research agenda in the past decade is based on the belief that demonstration of the efficacy of a practice or the willingness for change will lead to change. Experience has shown this belief to be naïve. Change is possible with the appropriate financial and practical support tools. Limited funding for this initiative was secured from the National Programme Management Office as part of the Health Service Executive Innovation Fund 2008. The remainder will come through the reallocation of existing resources. It is hoped that the success of the project will encourage further investment to facilitate a national thrombosis network. The merits of such a network are evident when one considers that complication rates from anticoagulant therapy are exceptionally low and the published research on these patients is high.

This research has provided important information on patient demographics and preference in terms of anticoagulation monitoring. It has highlighted the concerns and potential barriers that might prevent successful deployment of the system.

The majority of hospitals in Ireland are in the process of upgrading computerised anticoagulation management systems to new web-based versions. The adoption of a national strategy in respect to these management systems could ultimately result in the development of a thrombosis network as exists in the Netherlands. Not only will this result in uniform high quality anticoagulation monitoring for all patients but it will also provide accurate statistical data on patients receiving anticoagulation. This centralised national integrated web-based network will ultimately result in improved patient outcome.

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APPENDIX 1. Letter to Ethics Committee

Dr Ruth Gilmore
National Centre for Hereditary Coagulation Disorders
St James's Hospital
Dublin 8.

26th May 2008

Title: To conduct an audit of the anticoagulation clinic in St James's hospital.

Dear Ursula,
I am writing to seek permission to conduct an audit of the anticoagulation service in St James's hospital. This is required as part of any anticoagulant service and was last conducted in our clinic in 2005. I am seeking ethical approval as this audit will form part of my MSc dissertation in Health Informatics for the University of Dublin. My MSc is looking at different models of delivery of anticoagulant care in Ireland and is due for submission in September 2008.

Audit is an essential part of any service and indeed is included in the National Patient Safety Agency as one of the actions that can make anticoagulant therapy safer.

The anticoagulant clinic in St James's hospital is constantly striving to improve the service it provides to its 1500 patients. We aim to deliver a high quality service to all our patients. We realize that as clinic numbers continue to increase this is becoming increasingly difficult and we need to try and come up with innovative ways to deal with this problem.

With this in mind we are involved in an initiative which focuses on establishing a new model of delivering anticoagulation therapy in a Primary Care setting facilitating the measurement, monitoring and control of anticoagulation in the GPs surgery using a point of care device and an internet based expert dosing system. Suitable patients will be given the opportunity to attend their GP for INR monitoring. They will have all the benefits of the hospital based service in terms of protocols, procedures, advice and education without the need to attend the hospital itself.

Prior to any change we want to identify any problems within the current system so as to avoid repeating these errors in future models of care. We also want to see whether patients would be interested in such an approach.

The audit will be conducted in the last week of June and patients attending the clinic during the week will be invited to participate. It will be completely voluntary and all information will be anonymous and treated in confidence. The results will be analyzed using a standard statistics package and a report will be prepared for the hospital.

I have attached a copy of the questionnaire.

Should you require any further information please feel free to contact me?

Kind Regards

Dr Ruth Gilmore
rgilmore@stjames.ie

ST. JAMES'S HOSPITAL

James's Street, Dublin 8

APPENDIX 2. Patient Questionnaire.

Anticoagulation (Warfarin) Clinic

Patient Questionnaire

The staff at the anticoagulation clinic are committed to providing the best possible care to all patients who attend the clinic. In order to identify areas we might be able to improve, we would appreciate if you would take the time to complete the following questionnaire. The information you provide will be treated confidentially and is entirely anonymous. Participation is completely voluntary.

Completing the Questionnaire

For each question tick clearly inside one box using a black or blue pen.

Please do not write your name or address anywhere on the questionnaire

Your answers will be treated in confidence

Section A: This section asks some questions about you

1. Gender **Male** ☐ **Female** ☐

2. Your Age in years **≤ 20** ☐ **21-30** ☐ **31-40** ☐ **41-50** ☐ **51-60** ☐
61-70 ☐ **71-80** ☐ **81-90** ☐ **≥ 91** ☐

3. Why are you on warfarin?

Heart valve Mitral ☐ Aortic ☐

Clot in leg (Deep Vein Thrombosis/ DVT) ☐

Clot in lung (Pulmonary Embolus/PE) ☐

Recurrent clots (DVT/PE) ☐

Antiphospholipid syndrome ☐

Atrial Fibrillation (irregular heart beat) ☐

Stroke/ Transient ischemic attack (TIA) ☐

Arterial Clot ☐

Don't Know ☐

Other. If other, please specify: _____

4. How long do you expect to be on warfarin?

< 6 weeks ☐ 6 weeks - 3months ☐ 3 months - 6 months ☐

6-12 months ☐ Indefinite ☐ Lifelong ☐

Other ☐ Unsure ☐

If other, please specify:
_____

Section B: This section aims to identify how the current system suits your needs and which model of care best meets your needs.

5. How many miles do you travel to attend the warfarin clinic?

0-5 miles..... ☐
6-10 miles..... ☐
11-20 miles..... ☐
21-30 miles..... ☐
31-40 miles..... ☐
> 40 miles..... ☐

6. Listed below are three ways of providing Anticoagulation Monitoring. If you had a choice, which would you prefer (please tick only one answer)?

You can attend the hospital based warfarin clinic for blood testing and dosing …….. ☐

You can attend your GP for blood testing and dosing …….. ☐

You can check your INR at home using a portable meter and phone a nurse, doctor or pharmacist for your dose of Warfarin …… ☐

Please state any factors that influenced your choice above.

_____

_____

_____

Section C: In this section of the questionnaire you will read a number of statements about the care you currently receive at the warfarin clinic. For each statement tick the box of the answer that is closest to what you think. We are interested in your honest opinion, whether positive or negative

1. I am totally satisfied with the Warfarin clinic.

❑ Strongly agree ❑ Agree ❑ Not sure ❑ Disagree ❑ Strongly disagree

2. I find it easy to contact the warfarin clinic.

❑ Strongly agree ❑ Agree ❑ Not sure ❑ Disagree ❑ Strongly disagree

3. I have received enough information about Warfarin.

❑ Strongly agree ❑ Agree ❑ Not sure ❑ Disagree ❑ Strongly disagree

4. I would prefer to have more time to discuss my dosage of Warfarin and ask questions if I need to.

❑ Strongly agree ❑ Agree ❑ Not sure ❑ Disagree ❑ Strongly disagree

5. I feel confident that I know about all the risks and benefits of Warfarin.

❑ Strongly agree ❑ Agree ❑ Not sure ❑ Disagree ❑ Strongly disagree

6. I am very satisfied with the quality of care I receive from the Nurses.

❑ Strongly agree ❑ Agree ❑ Not sure ❑ Disagree ❑ Strongly disagree

We would welcome any suggestions you might have as to how the clinic could be changed to meet the needs of your lifestyle.

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

__

Thank you for taking the time to complete this questionnaire.

Please place it in the box provided.

APPENDIX 3. Patient Advocacy Committee Approval

Dr. Ruth Gilmore
NCHCD
St. James's Hospital
James's Street
Dublin 8

18th June 2008

RE: Anticoagulation (Warfarin) clinic Questionnaire.

Dear Dr. Gilmore

Thank you for your proposal received in my office on 30.05.08.

The following documents have been reviewed by the Patient Advocacy Committee:
- Proposed Survey
- Patient Advocacy Committee Survey Approval Form
- Questionnaire

Please note your proposed survey has been approved with no amendments to note. Furthermore you are now free to commence your study in your own time.

If I can be of any help to you during this time please do not hesitate to contact me.

Yours sincerely,

CAROL HICKEY
QUALITY MANAGER

APPENDIX 4. Risks identified from the NPSA Risk Assessment

1. Inadequate competencies and training of staff undertaking anticoagulant duties.

2. Failure to initiate anticoagulant therapy where indicated.

3. Poor documentation of reason and treatment plan at commencement of therapy.

4. Prescribed wrong dose or no dose of anticoagulant (especially loading doses).

5. Unconsidered co-prescribing and monitoring of interacting drugs.

6. Unsafe arrangements and communication at discharge from hospital including failure to adequately transfer duty of care to patient's general practitioner.

7. Insufficient support and monitoring of warfarin therapy for the first 3 months and for vulnerable groups.

8. Inadequate safety checks at repeat prescribing and repeat dispensing in the community.

9. Confusion over anticoagulant management for dentistry, cardioversion, endoscopy and surgical procedures.

10. Potential confusion due to different strength tablets often presented in non-colour-coded packs.

11. The Yellow book (patient held information), in need of revision and translation into other languages.

12. Inflexible medicine presentation and arrangements in care homes to implement anticoagulant dose changes.

13. Inadequate quality assurance (QA) for near-patient testing equipment.

14. Inadequate audit of anticoagulant services and/or failure to act on identified risks.

APPENDIX 5. Recommendations Following NPSA Risk Assessment

Recommendations made by the British Committee for Standards in Haematology (2006) following NPSA (2006) risk assessment.

1. Identification of required competencies and training for staff responsible for anticoagulant care (see Skills for Health at http://www.dh.gov.uk/policyandguidance/humanresourcesandtraining/modernisingworkforceplanninghome.)

2. Regular monitoring of safety indicators for inpatient and outpatient/community anticoagulant services with reporting to appropriate clinical governance committees and risk management.

3. Improved guidelines for loading doses and management of anticoagulation for dental surgery, surgery, cardioversion and endoscopy.

4. Promotion of the use of computer dosing software for decision support and audit.

5. Potential greater use of nurses and pharmacists to provide anticoagulant care, especially for hospital inpatients and for improving links between inpatient and outpatient services.

6. Improved arrangements and communication when patients are discharged from hospital, including transfer of duty of care directly to general practitioner.

7. Improved safety checks when interacting medicines are prescribed.

8. Improved support and monitoring of patients in the first 3 months of warfarin therapy.

9. Clarification of safety checks for general practitioner prescribing of repeat prescriptions of anticoagulant drugs and for the pharmacy supplying the anticoagulant drugs.

10. Revision of design and content of the patient held record.

11. Dosing regimens should be consistent within anticoagulant services.

12. Local systems should be implemented to minimise the potential for confusion relating to anticoagulant dose and strength of tablets.

13. Review of procedures for supply and administration of anticoagulant drugs in care homes.

14. Improvement of the design of forms/software for prescribing, monitoring and administering anticoagulants.

15 Improvement of QA

APPENDIX 6. Consent Forms for Patient Self-Testing

Consent Form for Self-testing of INR

Medical Record No:	Date of Birth:
Patients Name:	
Address:	
Telephone number:	Consultant:

I_____ have undergone training and supervised practice of the Coaguchek XS Device. I have had opportunities to ask questions and I am fully aware of the procedure for phoning my INR results. I will fully participate in the Quality Assurance scheme.

SIGNED:
DATE:
WITNESS:
DATE:

Training and Support Team

APPENDIX6. Consent Forms for Self Testing

Appendix 1

TRAINING CHECKLIST FOR SELF-TESTING ANTICOAGULATION

Medical Record No:	Date of Birth:
Patients Name:	
Address:	
Telephone number:	Consultant:

PATIENT ATTENDANCE SESSION 1 _____

PATIENT ATTENDANCE SESSION 2 _____

LABORATORY COMPARISON SATISFACTORY _____

SIX SUPERVISED TESTS DONE _____

ONE UNSUPERVISED TEST SATISFACTORY _____

EXAM SCORE BETTER THAN OR EQUAL TO 7/10 _____

CONTACT NUMBERS FOR ANTI-COAGULATION CLINIC & ROCHE DIAGNOSTIC GIVEN TO PATIENT _____

TRAINERS SIGNATURE
TRAINERS NAME PRINT
DATE COMPLETED

Appendix 2

PATIENT SELF-TESTING COAGUCHEK TEST

Medical Record No:	Date of Birth:
Patients Name:	
Address:	
Telephone number:	Consultant:

How does Warfarin affect your blood? _____

What action does Vitamin K have? _____

What do you use to clean the Coaguchek? _____

What range must you keep your INR between? _____

Name 2 places you may bleed from if your INR is too high

1._____

2._____

Name a drug that may increase the effect of Warfarin _____

How long does it take before a dose of Warfarin has its full effect?

Where do you store the PT test strips? _____

If you eat more broccoli every day, will you need more or less Warfarin?

_____

What is the INR of someone who does not take Warfarin? _____

SCORE / 10

APPENDIX 7. Proforma for GP Interview

1. (a) Practice Name_____

   (b)Address_____

2. Estimated number of patients in your practice on Warfarin therapy? _____
3. Do you hold specific Warfarin clinics? _____
4. If yes on what day(s) do you hold such clinics. _____
5. How many patients per clinic do you see? _____
6. Who staffs the clinic? a Doctor? _____
   b Practice Nurse? _____
   c Doctor & Practice Nurse? _____
7. What are the current limitations of the service you provide?

8. Have you had previous experience with Point Of Care Testing (POCT) ie(CoaguChek XS) ? _____

9. (a) If YES would you be interested in expanding this service?

   _____

(b) If NO would you be interested in a pilot scheme to deliver anticoagulation services in the community. St James's would provide IT, training, laboratory and consultant support to facilitate patients returning to the community.

_____

Do you have any additional comments or observations on anticoagulation testing and how the Haematology department could best support your patient's needs?

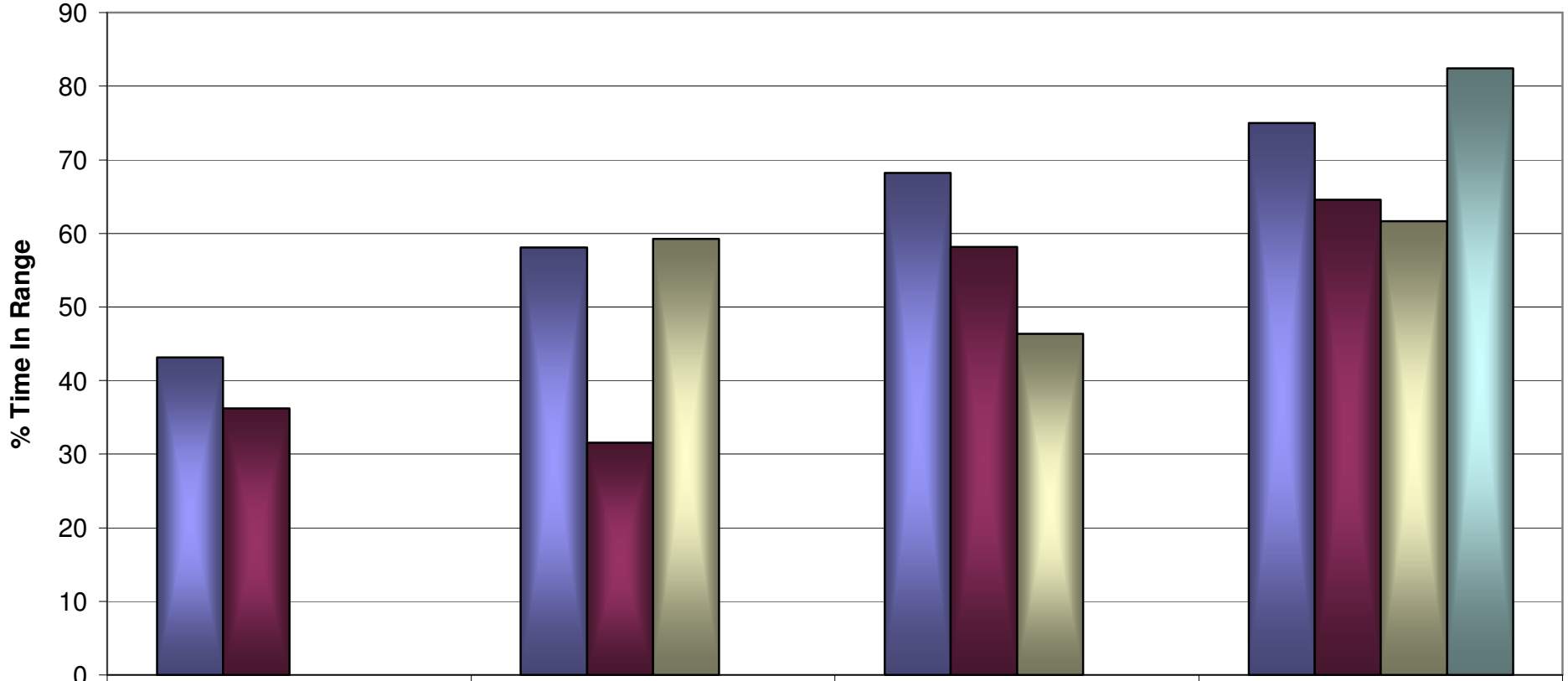
_____

DAWN AC BENCHMARKING

APPENDIX 8. BENCHMARKING REPORT Safety Indicators

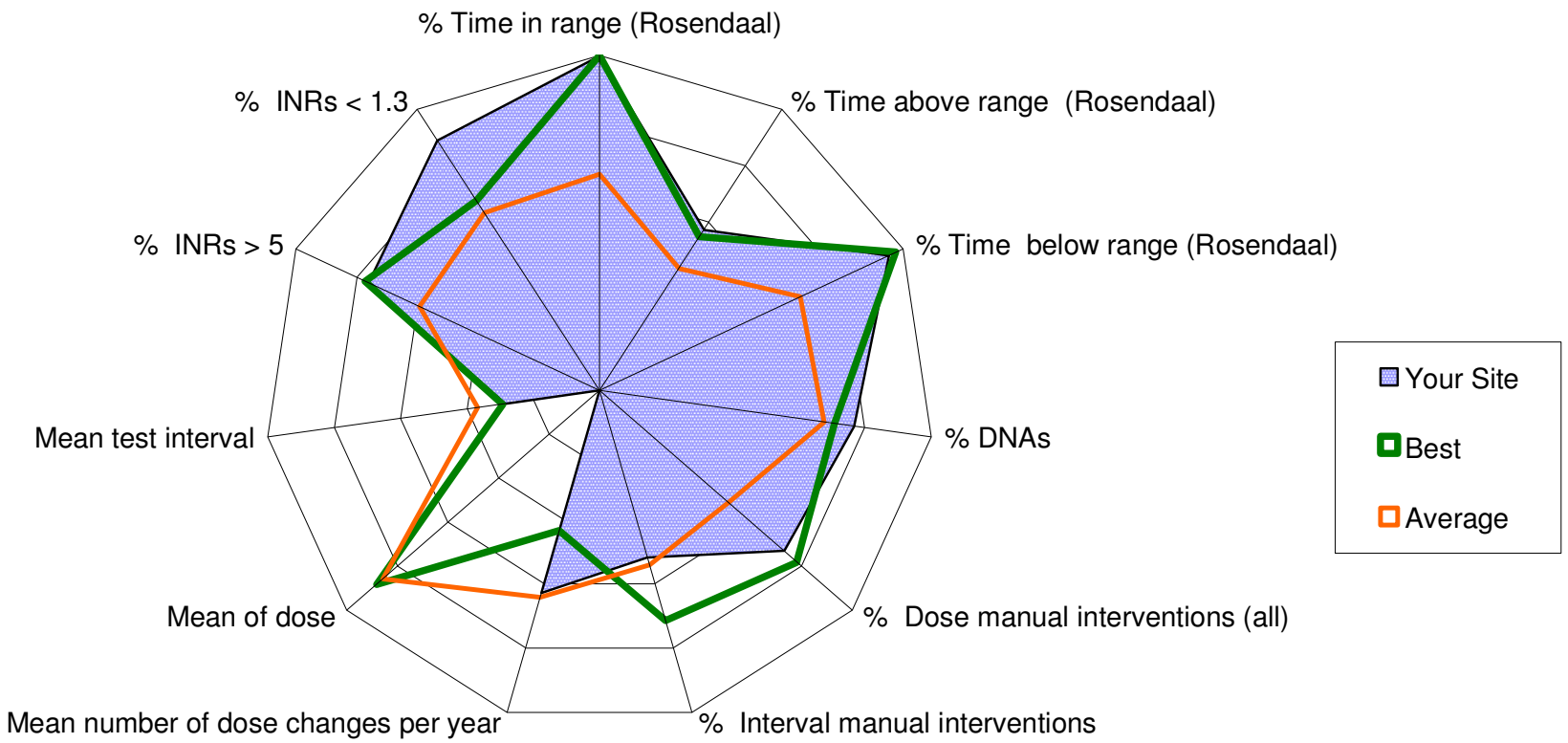
		Weeks Therapy			
	All	**1 - 3**	**4 - 9**	**10 - 21**	**22+**
Number of patients	1322	142	171	183	1172
Number of INRs	10191	375	567	693	8556
% Time in range (Rosendaal)	76.16	50.59	62.14	70.49	77.44
% Time above range (Rosendaal)	10.37	15.58	8.32	8.49	10.47
% Time below range (Rosendaal)	13.47	33.83	29.54	21.03	12.09
% Time in 2.0-4.4 (Rosendaal)	86.04	64.12	69.91	78.50	87.45
% Time in range (Duxbury)	74.05	45.20	62.36	67.37	75.14
Mean % Time in Range (Rosendaal)	74.81	50.29	59.47	68.15	76.97
SD % Time in Range (Rosendaal)	21.66	30.73	31.93	29.79	20.92
% INRs in range	64.92	43.36	54.21	60.43	66.93
% INRs above range	14.12	16.81	10.84	11.50	14.44
% INRs below range	20.95	39.82	34.95	28.07	18.63
% INRs within 0.5 units of target	64.92	43.36	54.21	60.43	66.93
% INRs within 0.75 units of target	79.60	61.36	68.41	75.61	81.45
% INRs > 5	0.71	1.18	0.75	0.61	0.69
% INRs < 1.3	1.45	7.67	2.80	2.76	0.99
% DNAs	6.90	9.60	5.64	5.92	6.94
Mean INR	2.45	2.32	2.30	2.34	2.47
SD INR	0.70	0.91	0.76	0.68	0.68
Mean of dose	33.52	32.62	33.81	36.96	33.26
SD of dose	17.70	15.54	16.63	19.30	17.69
Mean test interval	19.28	8.16	11.40	14.77	20.66
SD of test interval	16.69	6.37	6.49	9.70	17.54
Average patient age on cut off date	68.46	63.42	64.23	62.96	69.28
SD of patient age on cut off date	14.19	16.87	16.84	16.55	13.55
% Number of dose change increases	15.41	32.83	32.28	23.39	13.31
% Number of dose change decreases	13.55	35.86	14.93	12.28	13.05
% Number of all dose changes	28.97	68.69	47.20	35.67	26.36
Mean days between dose changes	64.70	21.29	24.59	39.95	74.46
Mean number of dose changes per year	5.64	17.15	14.84	9.14	4.90
% Dose manual interventions (all)	13.44	60.81	25.60	15.58	11.70
% Interval manual interventions	35.78	80.40	47.23	40.62	33.63

% Time In Range Comparison by Weeks into Therapy for April 2007 Run and Site 92



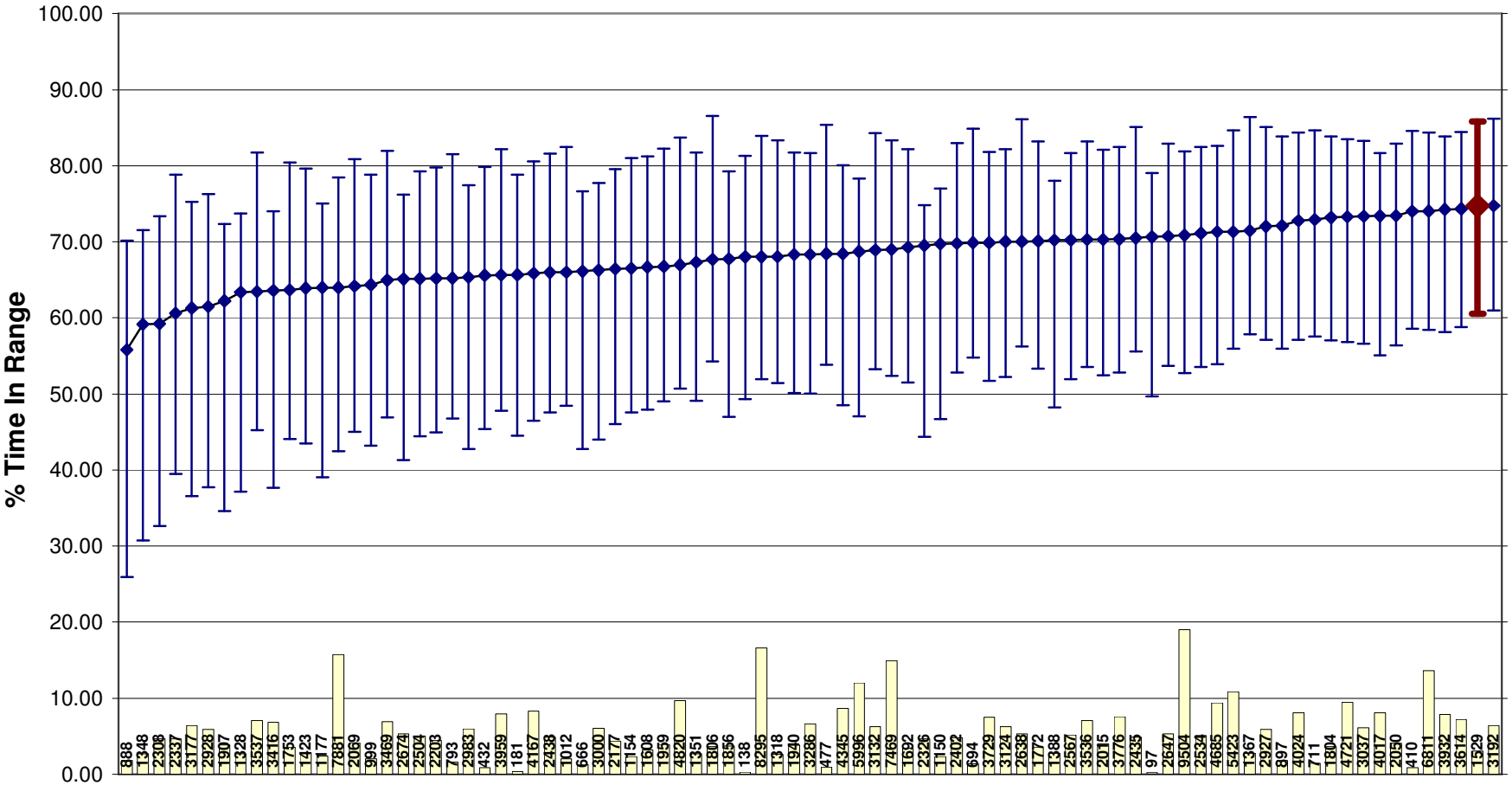
	1-3	4-9	10-21	22+
2.50	43.182	58.065	68.24	74.997
3.00	36.241	31.589	58.142	64.539
3.50	0	59.286	46.339	61.628
3.75	0	0	0	82.482

Multi-factor Comparison for April 2008 Run, Site 92 and All Ranges



This chart compares several measures for your site against the same measures for the 'best' site, i.e. the site with the highest time in range. The average across sites for each measure is also shown.
The further out the measure goes, the better it is.

% Time In Range Comparison for April 2008 Run, Site 92 and All Ranges



This chart shows the time in range for all sites in ascending order.
The bar below the line shows the time below range; the bar above the line shows the time above range.
Your site is highlighted in red. The numbers of patients for each site are shown at the bottom of the chart.

		Q2. Your age in years?		Q3. Why are you on Warfarin?		Q4. How long do you expect to be on Warfarin?	
	90	<21	0	Heart Valve: Mitral	12	< 6 weeks	1
	54%	%	0%	%	7%	%	1%
	76	21 - 30	8	Heart Valve: Aortic	18	6 weeks - 3 months	2
	46%	%	5%	%	11%	%	1%
es	166	31 - 40	6	Clot in leg (DVT)	16	3 months - 6 months	5
		%	4%	%	10%	%	3%
		41 - 50	12	Clot in Lung (PE)	7	6 - 12 months	6
		%	7%	%	4%	%	4%
		51 - 60	24	Recurrent Clots (DVT/PE)	12	indefinite	21
		%	14%	%	7%	%	13%
		61 - 70	43	Antiphospholipid Syndrome	1	Lifelong	117
		%	26%	%	1%	%	71%
		71 - 80	61	Atrial Fibrillation	66	Other	1
		%	37%	%	40%	%	1%
		81 - 90	12	Stroke / Transient ischemic attack (TIA)	3	Unsure	12
		%	7%	%	2%	%	7%
		> 90	0	Arterial Clot	6	Total Responses	165
		%	0%	%	4%		
		Total Responses	166	Don't know	2		
				%	1%		
				Mitral+Aortic valve ± Atrial Fibrillation ± Stroke/TIA	14		
				%	8%		
				DVT + PE	3		
				%	2%		
				Atrial Fibrillation + Stroke/TIA	4		
				%	2%		
				Antiphospholipid Syndrome + other diagnosis	2		
				%	1%		
				Total Responses	166		