

**REQUIREMENTS FOR A PATIENT SELF
MONITORING SERVICE FOR ORAL
ANTICOAGULATION**

Bridget Coleman

Centre for Health Informatics and Multiprofessional Education

University College London

Highgate Hill

London N19 5LW

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This thesis describes research conducted at The Centre for Health Informatics and Multiprofessional Education, University College London between 2007 and 2010 under the supervision of Professor Dipak Kalra, Professor David Ingram, Jeannette Murphy and Dr. Jacqueline Nicholls. I certify that the research described is original and that any parts of the work that have been conducted collaboratively are clearly indicated. I also certify that I have written all the text herein and have clearly indicated any suitable citation any part of this dissertation that has already appeared in publication.

ABSTRACT

Self-care is considered a means of meeting the challenge of providing care to patients with long-term conditions. However this has not achieved widespread penetration in the UK, the reasons for which are unclear.

This research examined one area of self-care in depth - self-monitoring of oral anticoagulation therapy. The aim was to derive the requirements for an anticoagulation patient self-monitoring service from an analysis of the drivers for, the benefits of, the barriers to, and the challenges of establishing this service from the perspectives of key stakeholders – patients, healthcare professionals and healthcare managers.

Qualitative and quantitative techniques - interviews, semi-structured questionnaire survey and focus groups – were used to gain an in-depth understanding of their views. From triangulated results, the candidate requirements for an anticoagulation self-monitoring service were derived, presented in Donabedian's framework: structure, process and outcome. Most of these requirements were then validated through a pilot self-monitoring service.

All stakeholder groups supported anticoagulation self-monitoring. However, financial, clinical and legal barriers were identified.

53% of surveyed patients were willing to undertake self-monitoring. However, only 17% of respondents felt able to purchase a coagulometer, a significant barrier. Lack of confidence in the ability to self-test was also demonstrated.

Healthcare staff welcomed self-monitoring as a way to increase capacity and support evolution in the healthcare landscape. There were concerns about affordability to all stakeholders, the potential for increased clinical risk through sharing care with patients, and a fear of litigation compounded by a lack of clarity in the medicolegal position.

Patient education and support were essential requirements, to prepare the patient, and on an ongoing basis. Primary care professionals felt expert support was essential for them to deliver this service.

A definitive set of service requirements is proposed, and the implications of this research for other long term conditions discussed.

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CHAPTER ONE: INTRODUCTION

1.1. The case for patient self-care

Providing care for people with long-term conditions is one of the greatest challenges facing healthcare providers. This is a large and growing group. Around 15 million people in England – almost a third of the population - suffer from a long-term condition, and it is predicted that this number will rise by 23% over the next 25 years.¹

This predicted increase is largely due to people living longer. However, the rising incidence of some long-term conditions amongst younger people, related in part to lifestyle and obesity (e.g. diabetes), is a contributory factor. Because of increasingly sophisticated treatments, more illnesses are, in effect, becoming long-term conditions (e.g. HIV). The expected growth in this health burden will, therefore, be due to a larger number of people with one (or more) long-term conditions, but also partly due to the greater complexity of the care delivery and treatment of each condition.

Not least of the challenges facing the National Health Service (NHS) is the financial one. It was estimated in 2008 that the treatment and care of those with those with long-term conditions accounts for 69% of the primary and acute care budget in England.¹ A consequence of an ageing population is the changing balance between the number of persons working and the number of those who are in retirement, decreasing the number of people contributing financially to healthcare provision for an increasing number of those no longer working.

The challenge of providing care to those with a long-term condition has prompted healthcare providers to re-assess how services are designed and delivered. The NHS has focused on altering the ‘delivery system’, targeting the level of care according to need. Supporting those with long-term conditions can be conceptualised as a three-level delivery system: case management, disease management and supporting self-care.² This builds on what is known as the Kaiser Permanente chronic disease management triangle and is shown below.

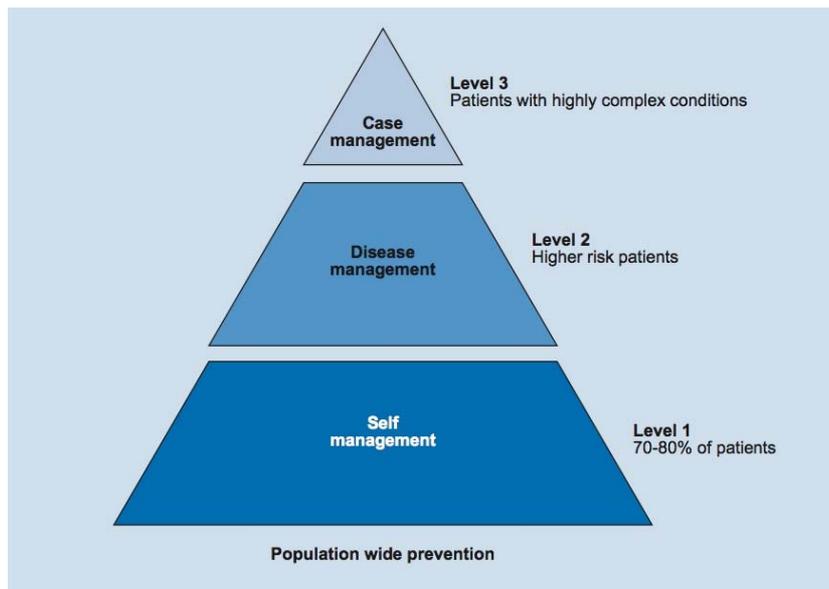


Figure 1: Kaiser Permanente Chronic Disease Management Triangle³

Level 3 of this model, case management, focuses attention on those high intensity users of the service for whom a lead case manager in the community will be nominated to better co-ordinate health and social care services, to anticipate and hopefully to prevent disease escalation.

Level 2 involves the alignment of multi-professional teams through National Service Frameworks to provide optimally effective care to patients needing regular health professional involvement, that follows evidence based guidelines and efficient care pathways.

Level 1, embracing patient self-care or self-management, is perhaps the most innovative, and involves “helping individuals and their carers to develop the knowledge, skills and confidence to care for themselves and their condition effectively”. This level of the triangle has the potential to make the greatest difference to chronic condition management, as it covers 70-80% of the long-term condition population (as estimated by the Department of Health³). Even small increases in the number of people self-caring could therefore have a huge impact on the demand for (and cost of) healthcare services. It is also, arguably, the least well developed level thus far, and might require significant learning and innovation in order to identify optimal ways to foster good quality and well-accepted self-care services.

Self-care has been enshrined in health policy in the UK since the 1999 White Paper *Saving lives: our healthier nation*,⁴ which set out the then newly elected Labour government's public health strategy. This was swiftly followed by the establishment of the Expert Patients Programme (EPP), which was largely based on the work of Kate Lorig, head of the Chronic Disease Self-Management Program in California. By 2005, self-care was a major component of British health policy.⁵

Aside from the predicted benefit of reduced use of health services, self-care may also bring benefits to the patient. These include improved quality of life and well-being, increased life expectancy and greater independence and symptom control.⁵ For example, diabetes self-management has been shown to improve glycaemic control and dietary habits.⁶

However, despite being enshrined in government policy, and the benefits it may bring to healthcare providers and patients, services to support patient self-care are not widespread. The reasons for this are not clear and warrant further investigation. Focusing on one area of self-care in depth - patient self-monitoring of oral anticoagulation therapy – this research will investigate why its rate of adoption remains low in the UK, despite it being technically feasible for many years. It will aim to identify the drivers for, the benefits of, the barriers to, and the challenges of establishing and delivering an oral anticoagulation patient self-monitoring service from a multi-stakeholder perspective. From these perspectives, a set of requirements of a service designed to support patient self-monitoring of oral anticoagulation will be derived. Finally, a patient self-testing pilot will be developed, implemented and evaluated to test these requirements.

The focus of the research will be to identify the factors that will ensure the quality and the acceptability of oral anticoagulation patient self-monitoring to the key stakeholders. Although any emerging issues will be discussed in the thesis, a detailed examination of the legal issues and the cost-effectiveness of an oral anticoagulation patient self-monitoring service is beyond the scope of this investigation.

It is not clear if an identical set of drivers, benefits, barriers and challenges will be applicable to other long-term conditions. Many of these conditions will require some form of daily treatment; will require the frequent monitoring of one or more physiological parameters to maintain stability and optimal functional capability; may require the monitoring of other parameters to detect complications; may be influenced by lifestyle behaviours as well as by treatments; and will have outcomes that are influenced by the quality of care provided. The configuration of self-monitoring services might plausibly have some common features. The research therefore proposes to examine these issues for one condition in detail, and then to discuss if some of the findings may be generalised to other conditions.

1.2. The case for patient self-monitoring of oral anticoagulation

Some long-term conditions (e.g. atrial fibrillation) require the person to take lifelong oral anticoagulation therapy (OAT), usually warfarin. Managing oral anticoagulation entails many of the facets of managing a long-term condition as mentioned above. Treatment is often lifelong. Patients need to adjust their diet and lifestyle to minimise the risk of adverse effects from treatment. There is normally some input from healthcare professionals, and this is often focused on patient education – for example, monitoring of disease indicators and skills development – and ongoing support.

Warfarin's narrow therapeutic range and unpredictable patient response means that a fixed dose cannot be given to every patient and clinical expertise is needed to titrate the dose to response. Because of this narrow range, treatment monitoring by measurement of the patient's International Normalised Ratio (INR) from a small sample of blood is mandatory. INR monitoring is usually done by a healthcare professional. However, self-monitoring of oral anticoagulation treatment – where the patient measures their own blood INR on a small hand-held machine – is an alternative model of care for patients taking OAT. After measuring their INR, the patient can either seek dosing advice from a healthcare professional or they can decide on the appropriate dose of warfarin on the basis of personal experience, or supported by written or computerised guidance.

In Germany, this model of monitoring has been better adopted, with 160,000 patients self-monitoring their oral anticoagulation as of 2010.⁷ However, the UK has not widely embraced this model of care.

On the face of it, the lack of interest in OAT patient self-monitoring in the UK is surprising. In addition to the widespread interest in promoting general patient self-care, there are other, more specific drivers for patient self-monitoring of OAT: the technology to facilitate patient self-monitoring is available; published evidence is available to support its safety; there is widespread support for shared decision-making and there are models of successful self-care for other long-term conditions. Thus, one would expect the NHS to pursue a model of care whereby patients assume responsibility for testing their INR.

Research is needed to investigate how this form of monitoring may be more widely adopted and to specify the requirements for a patient self-monitoring service which would be acceptable to patients, clinicians and managers. Until the drivers for, the benefits of, the barriers to, and challenges of, setting up an OAT patient self-monitoring service are established, including its factors influencing acceptability to patients and healthcare professionals, it is difficult to find the best way of migrating from the current model of care (where clinicians carry out the monitoring) to a self-monitoring service where patients take responsibility for self-testing and perhaps self-management (i.e. adjusting their dosage).

1.3. A framework for specifying a patient self-monitoring service

The requirements for a patient self-monitoring service need to be formally organised. A framework to specify a patient self-monitoring service, that accommodates the perspectives and needs of the major stakeholders, is required at the outset for a number of reasons:

- i. To support the design of the service
- ii. To specify the processes that will support implementation of the service
- iii. To establish the measures used to assess the quality of the service
- iv. To cultivate a shared view of the service across these stakeholder groups
- v. To define and connect components of the service

As a successful patient self-monitoring service for anticoagulation will need to be of demonstrably high quality as well as empowering patients, the quest for a high quality service lies at the heart of specifying this framework.

The goal of the NHS in adopting the three level Kaiser Permanente Triangle is to improve the quality of care for patients with long-term conditions. (Although reduced cost is probably an additional desired outcome, this is not presented as a driver behind its strategy to enhance self-care.) However, quality is multi-dimensional and defining it is problematic. Although stressing the goal of improving quality, the Department of Health does not define what it means by quality in either the *NHS Improvement Plan* or in the report *Supporting People with Long Term Conditions*. There is no single, universally accepted definition and, in an effort to elucidate the concept, experts have developed broad conceptual frameworks to describe it in a systematic way.

1.3.1. Conceptual frameworks for describing quality

In 1998, the Institute of Medicine (IOM) in the USA launched an initiative to assess and improve the nation's quality of healthcare with the formation of the Committee on Quality of Health Care in America. Its seminal report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, outlined a strategy to improve the quality of care over ten years.⁸

This report defines the following six broad aims for improvement earmarked for 21st century health care systems:

- i. Safety
- ii. Effectiveness
- iii. Patient centeredness
- iv. Timeliness
- v. Efficiency
- vi. Equity

The chasm in the title of the report refers to the one that exists between the current and future healthcare system, and the framework described in the report is a set of recommendations aimed at bridging this gap to build a stronger healthcare system.

These aims describe the major quality categories for describing a good health service, but could they be applied to describe a specific clinical service? Considering these aims from the perspective of oral anticoagulation patient self-monitoring, five of these six quality considerations can be readily mapped to this service:

Safety: optimising the time each patient spends within the therapeutic range, to maximise the benefits of anticoagulation and to minimise the risks of treatment.

Effectiveness: ensuring that care is based on systematically acquired evidence and will result in better outcomes than alternative models

Patient centeredness: ensuring that the service meets the needs of patients

Efficiency: ensuring that the service is cost effective compared with current service models.

Equity: enabling all patients to take advantage of self-monitoring if their clinical situation permits, regardless of cultural background or financial circumstance.

The remaining aim – timeliness, defined in the report as relating to patient waiting times – is not readily applicable. A successful patient self-monitoring service will eliminate the need to wait for a service to be provided. This quality aim is therefore not directly applicable to this research, except to note that it can be met.

In 2002, the Nuffield Trust commissioned an appraisal of the quality agenda in the NHS in the UK as set out by the Labour Government in their policy documents.⁹ As part of this appraisal, a conceptual framework was developed to provide a basis for the evaluation. This framework comprises of four levels, described in Table 1.

	Functional level of healthcare system	Generic function
TIER 1	National	Policy formulation and infrastructure
TIER 2	Regional	Performance monitoring and management
TIER 3	Institutional	Operations management
TIER 4	Individual	Clinical service provision and individual accountability

Table 1: Conceptual model for the NHS Quality Agenda

A patient self-monitoring service maps to Tier 4 of this model. The authors of this report do not single out specific quality characteristics of this tier that might be used in this research. They do, however, review definitional models of quality and conclude proposing a set of six domains that closely resemble the IOM six aims quoted above:

- i. Access
- ii. Effectiveness
- iii. Equity
- iv. Responsiveness and patient centeredness
- v. Safety
- vi. System capacity

On an international level, the Organisation for Economic Co-operation and Development (OECD) has set out a conceptual framework for their Health Care Quality Indicator (HCQI) project.¹⁰ The aim of the HCQI project was to develop a set of indicators for comparing the quality of health care across the 23 participating OECD countries, including UK, USA, Canada and Australia. To do this, a conceptual framework outlining the dimensions of quality to be measured, was developed from quality indicators already developed in member countries. This framework is shown in Figure 2.

From the perspective of patient self-monitoring, the closest corresponding healthcare need in the HQI model is “Living with illness or disability”. The three quality dimensions of healthcare performance: effectiveness, safety and patient-centeredness, map to three of the six IOM domains.

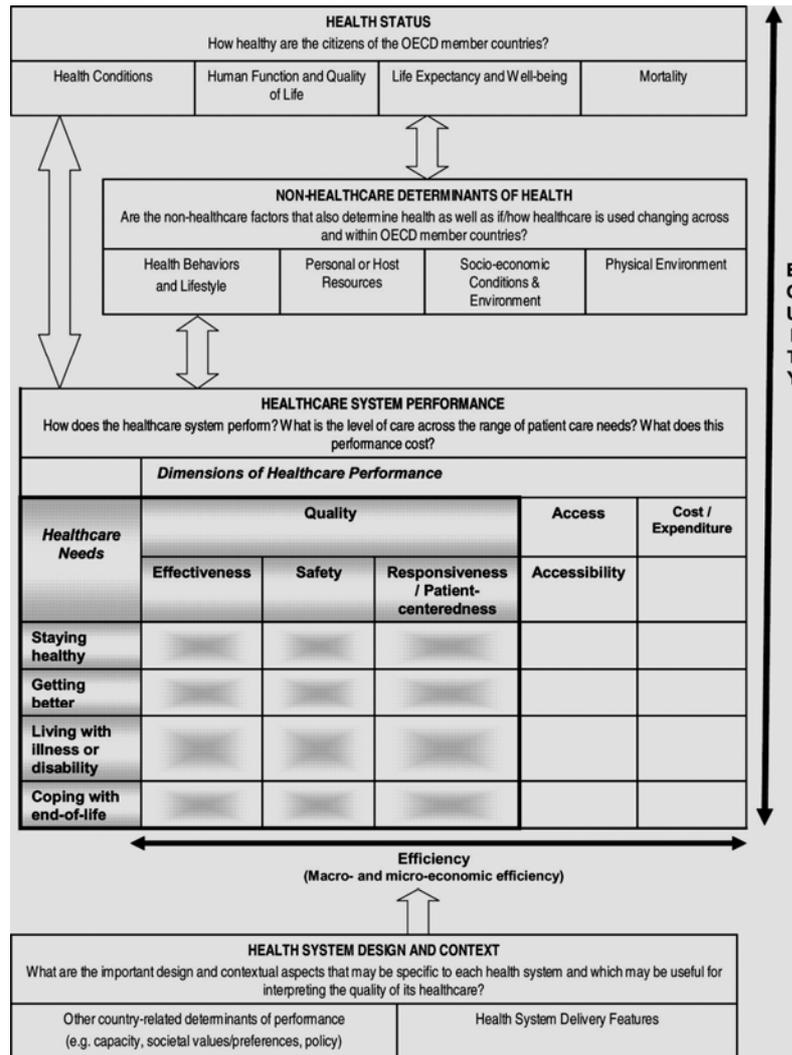


Figure 2: Conceptual framework for the OECD HQI project

In conclusion, the quality domains in the conceptual model for the NHS quality agenda and the OECD framework are largely based on those used by the IOM. Although these aims were informative on quality, they were unlikely to map fully to the envisaged anticoagulant self-monitoring service, and would have been less useful to categorise and connect these service requirements. Two of the domains – timeliness and effectiveness – were likely to be redundant categories. Establishing a self-monitoring service eliminates the need to wait in clinic, and thus obviates the need to formally measure timeliness. And although, the effectiveness of the service is considered, in terms of its evidence base, when establishing a service, it is less helpful in assessing a service once it is operational. Additionally, if the IOM framework was used, some of the service categories could have conceivably straddled multiple categories.

1.3.2. Using Donabedian's framework to specify a patient self-monitoring service

All of these quality frameworks - the NHS Quality Agenda, the IOM's *Crossing the Quality Chasm* and the OECD's Health Care Quality Indicator (HCQI) project - are explicitly underpinned by the use of the Donabedian triad, which is widely used in healthcare research to measure the quality of services. Avedis Donabedian, regarded as the father of assessing quality, developed the structure-process-outcomes triad¹¹ that classifies measures of quality into three broad categories:

- i. Structure – measuring service elements
- ii. Process – measuring service activities
- iii. Outcome – measuring health and system status

Each component has a direct influence on the next: for example in anticoagulation monitoring, clinicians (structure) monitoring OAT effectively (process) will result in good INR control (outcome). Donabedian's triad was adopted in this research as a framework to define the requirements of a service model for OAT patient self-monitoring for the following reasons.

Firstly, this framework would not only guide the development of, but would also provide a framework to evaluate the patient self-monitoring service.

Secondly, it was felt that a framework based on Donabedian's triad would be dynamic and adaptive to change, providing scope for fine-tuning if necessary – for example, the addition of sub-classes.

Thirdly, there was evidence of its use in defining the characteristics of other service models. As an example, Canadian researchers have used this framework to develop a service model of primary health care (PHC) rehabilitation for arthritis.¹² Using Donabedian's triad as a framework for their literature review, they described the best practice approaches for PHC rehabilitation and from this, and from interviews with key informants (healthcare professionals who had a role in caring for this group of patients), developed a conceptual model for the delivery of PHC rehabilitation services for those with arthritis.

Finally, the author was familiar with the model, having used it to define the quality standards for a community pharmacy-led anticoagulation monitoring service.¹³

The elements of this triad – structure, process and outcome –are described in Table 2, with some examples of how these elements might be applied to specifying OAT patient self-monitoring.

Element	Description	Examples
Structure	Resources required to deliver the service. Include healthcare staff, patients and carers and organisational resources.	<ul style="list-style-type: none"> - Healthcare staff supporting patient self-monitoring - Patients undertaking self-monitoring - The coagulometers used by patients to measure the INR
Process	Activities undertaken to provide care to patients	<ul style="list-style-type: none"> - Management of an OAT patient self-monitoring service - Educating self-monitoring patients - Referral procedures when patients become unstable
Outcome	Desired states resulting from the care process. Can be sub-divided into technical and interpersonal outcomes	<ul style="list-style-type: none"> - Self-monitoring patients achieved good therapeutic control - Patients are satisfied with the service - The service is cost-effective

Table 2: Description of Donabedian's framework and its application to OAT patient self-monitoring

The success of this framework for presenting the requirements for the OAT patient self-monitoring service will be discussed in Chapter 9.

1.4. Setting the scene - a personal history

I set out on this journey at the start of 2006. As a pharmacist working in a hospital-based anticoagulation service, my interest was to understand the long-term future of this service and the steps the Trust needed to take to ensure it was responsive to changing patient expectations, government initiatives and technological innovations. My starting point was to explore the area of patient self-monitoring, which, though not currently provided by the Trust, fits in with the direction of travel of the Anticoagulation Monitoring and Stroke Prevention Service. I reviewed the literature on patient self-monitoring of oral anticoagulation and then broadened my reading to include government policy documents on patient self-care, along with literature on self-care initiatives for a range of chronic conditions.

My initial plan was to set up a pilot patient self-monitoring project at the Trust, which would provide a basis for redesigning our service to support patients who elect to self-monitor. It quickly became clear that this would be more difficult than it first appeared. Self-monitoring for those on OAT poses issues which have not been highlighted or addressed for other chronic conditions. A service which caters for OAT patient self-monitoring would necessarily entail changes in clinical roles, relationships between clinicians and patients, and methods of organising workflows. Although there was a body of evidence to demonstrate the safety of an oral anticoagulation patient self-monitoring service, there was very little in the literature to help in the redesign of service delivery. I realised that in order to derive the requirements for an oral anticoagulation patient self-monitoring service, empirical research exploring the perspectives of the key stakeholders was needed.

1.5. Explanation of terms used in this thesis

It was felt that it was important from the outset to define the key terms and abbreviations used in this thesis. These are as follows.

Oral anticoagulant treatment (OAT). A group of drugs which slow down the rate of blood clotting by antagonising vitamin K. The most common OAT used in the UK is warfarin.

International normalised ratio (INR). A test that measures how long it takes blood to clot. It is used to monitor warfarin treatment.

Patient self-monitoring. An all-embracing term suggesting that the patient measures their INR with a portable device. When self-monitoring, the patient can then either self-test or self-manage.

Patient self-testing (PST). The patient measures their INR, but the dose is decided by a healthcare professional.

Patient self-management (PSM). Analogous to diabetic self-care, PSM involves the patient measuring their INR at a convenient location, then interpreting the result, and altering their warfarin dose as appropriate.

Near-patient testing (NPT). Diagnostic testing performed near, or at, point of care. Also known as **point-of-care testing (POCT)**.

National Health Service (NHS). The publicly funded healthcare system in the UK, which provides treatment free at the point of care.

General practitioner (GP). A primary-care physician whose practice covers a variety of medical problems in patients of all ages.

Primary Care Trust (PCT). Organisation within the NHS that commissions primary, community and secondary care from providers.

1.6. Content of this thesis

The chapters in this thesis are set out in Table 3: Thesis chapters and a description of their content, along with a brief description of the contents of each chapter.

	Chapter heading	Description
1	Introduction	Introduces the subject area, and the need for the research to be undertaken.
2	Background	Provides the context for the research and defines the research problem.
3	Literature review	Summarises and critically evaluates the relevant bodies of literature, to identify where gaps exist and provide justification for the research.
4	Materials and methods	Sets out the aims and objectives of the research. Defines the methodological approach taken, instruments used and the environment in which the research was conducted.
5	Patients' perspectives of self-monitoring of oral anticoagulation	Describes how patients' perspectives were evaluated and analysed, and presents the results.
6	Healthcare personnel's perspectives of patient self-monitoring of oral anticoagulation	Describes how the views of those delivering and commissioning oral anticoagulant monitoring were evaluated and analysed, and presents the results.
7	A validation of a set of candidate requirements for an OAT patient self-monitoring service	Describes how a PST pilot service was developed, implemented and evaluated to validate a set of candidate service requirements derived from the empirical work.
8	Requirements for an oral anticoagulation patient self-monitoring service	Presents the validated requirements as an OAT patient self-monitoring service blueprint.
9	Discussion	Summarises the key findings from the empirical work undertaken, describes any limitations and makes recommendations for future work.
10	Conclusion	Provides a final short summary of the key messages from the thesis

Table 3: Thesis chapters and a description of their content

The next chapter sets out the context for this investigation and defines the research problem.

CHAPTER TWO: BACKGROUND

The last chapter set out the case for patient self-care, with a focus on patient self-monitoring of oral anticoagulation.

This chapter takes a closer look at patient self-monitoring of OAT. It will consider the clinical management issues relating to OAT, and how the challenges of monitoring treatment, and technological, economic and Governmental policy drivers have led to the development of alternative models of service delivery, including patient self-monitoring.

2.1. An overview of the Clinical Management Issues Relating to Oral Anticoagulant Treatment

2.1.1. Introduction

Oral anticoagulants have been the mainstay of prevention and treatment of thromboembolic disease for over 50 years. This class of drugs acts by slowing down the blood clotting process, preventing clots from forming.¹⁴ The most commonly used oral anticoagulant in the UK, and worldwide, is warfarin. Other less commonly prescribed oral anticoagulants include phenindione and nicoumalone (acenocoumarol).

Oral anticoagulant treatment (OAT) is used to reduce the risk of thromboembolism in a wide variety of clinical conditions. Since the first clinical use of these agents in the 1950s, indications for therapy have been subject to changes in medical knowledge and attitudes. An overview of current indications, as recommended by the British Committee for Standards in Haematology, is shown in Table 4.¹⁵

Pulmonary embolus
Proximal deep vein thrombosis
Calf vein thrombosis
Recurrence of venous thromboembolism
Symptomatic inherited thrombophilia
Antiphospholipid syndrome
Non-rheumatic atrial fibrillation
Atrial fibrillation due to rheumatic heart disease, congenital heart disease and thyrotoxicosis
Cardioversion
Mural thrombus
Cardiomyopathy
Mechanical prosthetic heart valve – aortic
Mechanical prosthetic heart valve – mitral
Bioprosthetic heart valve
Arterial grafts
Coronary artery thrombosis

Table 4: British Committee for Standards in Haematology: Indications for oral anticoagulation

2.1.2. The challenges of OAT monitoring

The management of patients on long term OAT poses clinical challenges for healthcare providers.

Although warfarin is a highly effective drug, it has a narrow therapeutic range - i.e. there is a relatively small margin between efficacy and toxicity - and there is huge variation in response to a given dose both between individuals and within the same individual. This means that a fixed dose cannot be given to every patient and, instead, the dose must be titrated to response, to achieve a balance between the risk of stroke or venous thrombosis (under-treatment) and risk of bleeding (over-treatment).

Adverse effects associated with warfarin are listed in Table 5.

Haemorrhage
Hypersensitivity
Rash
Alopecia
Diarrhoea
Skin and soft tissue necrosis
Cholestatic liver damage
Priapism
Nausea and vomiting
Pancreatitis

Table 5: Adverse affects associated with warfarin¹⁶

Bleeding is the most serious complication of treatment. Although numerous studies have demonstrated that the risk of bleeding is directly related to the INR, determining the true incidence of bleeding complications associated with OAT has been difficult. Definitions of the occurrence and severity of bleeding have differed between studies, and there has been a lack of consistency in anticoagulant initiation doses used.

A review of bleeding complications associated with oral anticoagulant treatment reported bleeding rates of 0 – 4.8% for fatal bleeding and 2.4 to 8.1% for major bleeding.¹⁷ In another review of observational studies, the average annual rates of fatal and major bleeding were 0.8% and 4.9% respectively.¹⁸ A meta-analysis of 33 studies involving patients receiving OAT for the treatment of venous thromboembolism with more than six months of follow-up reported a rate of fatal major bleeding as 13.4%.¹⁹

Although rare, patients can demonstrate a resistance to warfarin and may require doses 5 – 20 times greater than usual achieve a therapeutic effect.²⁰ An ongoing study is attempting to define the genetic and environmental factors that determine variability in response to warfarin.²¹ The proposed outcome would be the development of an algorithm, accounting for genetic and environmental factors, which would help clinicians to better individualise anticoagulant therapy.

Variations in vitamin K availability – for example, as a result of low vitamin K diet or malabsorption - can also cause individuals to respond differently to OAT. However, the most common cause of inter-individual variation in response is due to pharmacokinetic differences, particularly the extent of plasma protein binding of warfarin and variations in liver enzyme activity.²² This is explained further below.

Warfarin has complex pharmacokinetics, which complicate its management. It is completely and rapidly absorbed from the GI tract. However, there are considerable variations in the rate and extent of absorption between different commercially available tablets.²³ Although warfarin reaches a peak concentration in the blood stream within one hour, there is a marked delay in it exerting its effect. This is because whilst oral anticoagulants inhibit the synthesis of clotting factors in the liver, they have no effect until existing clotting factors are catabolised, a process that can take several days to complete.²⁴ As the effects of a single dose of warfarin are not observed until some time after that dose is ingested, dose titration can be problematic.

Many other factors can affect a patient's response to warfarin, including interacting drugs, diet, concurrent diseases and age.

Warfarin is very highly bound to plasma proteins – up to 99.5%. When other drugs are introduced which are also highly bound to plasma proteins – for example non-steroidal anti-inflammatory drugs (e.g. ibuprofen, aspirin) – these drugs can compete for the binding sites and displace warfarin, making more warfarin available in the circulation, resulting in an increase in the INR.

Warfarin is extensively metabolised in the liver by the enzyme cytochrome P450C9.²⁵ Metabolism is very important for removing drugs from the body. If this process did not occur, warfarin would not be removed and its effects would persist for a very long time. However, certain drugs can “induce” cytochrome P450 by enhancing its rate of synthesis or reducing its rate of degradation. Conversely, other agents can “inhibit” cytochrome P450. Therefore when warfarin is administered with drugs that either induce or inhibit this enzyme, its effects can be reduced or enhanced respectively.

Alcohol consumption also affects anticoagulant control. Whilst a regular modest intake is unlikely to cause any problems, acute excessive intake enhances the effect of warfarin. Conversely, regular heavy drinking reduces the effects of warfarin.

Oral anticoagulants act by antagonising the effect of vitamin K, which plays a crucial role in the formation of clotting factors. Therefore, any changes to dietary vitamin K content are likely to affect its action. Foods that are high in vitamin K, including broccoli, spinach, liver and cabbage, can reduce or negate the effects of warfarin. Nutritional supplements containing vitamin K can also reduce the effect of warfarin.

Concurrent disease also affects response to warfarin. Congestive cardiac failure, hyperthyroidism, cholestasis and renal impairment may all increase its effects.²⁶

Finally, individuals demonstrate increasing sensitivity to warfarin with age, and a reduced dose may be required.²⁵

Therefore, monitoring treatment by regular measurement of the patient's International Normalised Ratio (INR) from a small sample of blood is mandatory.

2.1.3. Monitoring oral anticoagulant treatment

The INR is a measurement of how long it takes for the blood to clot, and each patient's treatment plan states the INR at which they should be maintained. A healthy person who is not taking warfarin should have an INR of around 1.0. The target INR for those on warfarin is most commonly 2.5 or 3.5 depending on the indication. The British Committee for Standards in Haematology makes recommendations on these target INRs¹⁵, and some of the common indications and target INRs are shown in Table 6. It should be noted though that these target INRs are only recommendations, and they may be tailored to the patient; for example, the target may be reduced if the patient has frequent nosebleeds.

Indication	Target INR
Pulmonary embolus	2.5
Deep vein thrombosis	2.5
Recurrence of venous thromboembolism whilst taking warfarin	3.5
Symptomatic inherited thrombophilia	2.5
Antiphospholipid syndrome	2.5
Atrial fibrillation	2.5
Mechanical prosthetic heart valve - aortic	2.5 or 3.0
Mechanical prosthetic heart valve - mitral	3.0 or 3.5

Table 6: British Committee for Standards in Haematology: Recommended target INRs for common indications for oral anticoagulation¹⁵

2.2. Current model for monitoring oral anticoagulation

In the UK the need for frequent monitoring and close patient follow-up has been met by dedicated anticoagulant clinics. Despite policy initiatives to foster shared care with patients, the predominant model of care for patients receiving warfarin is still a paternalistic one.

In a paternalistic model the clinician holds the knowledge and decides on the treatment choice. Characteristically, there is little or no discussion of alternative options with the patient complying with this clinician-directed standard, assuming a largely passive role. It is assumed that the clinician will make the best treatment decision for the patient without involving them in the decision making process. This is in stark contrast to a more contemporary, collaborative model, where decision-making is shared, grounded in the expertise and experience of both patient and clinician.²⁷

The monitoring process for OAT is summarised in Figure 3. The patient attends an anticoagulation monitoring service at an outpatient hospital clinic, where the INR is measured using capillary or venous citrated blood samples. Dosing recommendations are made by a healthcare professional - doctors, nurses, and pharmacists - and the patient is given a date for the next appointment.

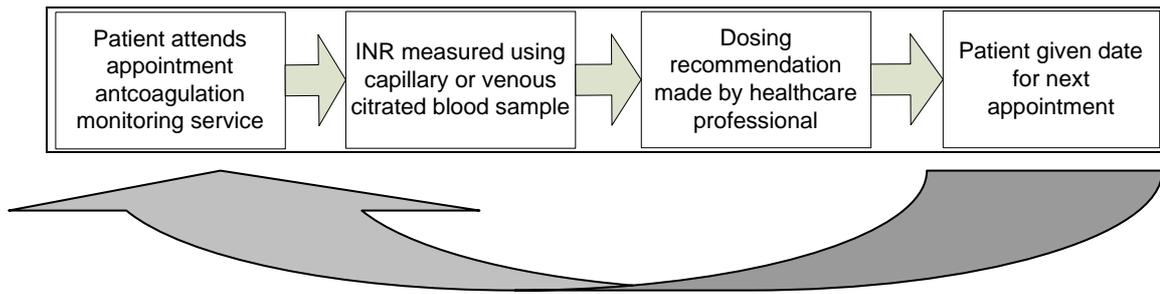


Figure 3: The general process for anticoagulation monitoring

How frequently a patient attends clinic for anticoagulation monitoring depends on the stability of their INR blood result – i.e. if their INR is within their target range a longer time interval to their next appointment is acceptable. Time intervals between clinic appointments range from one to twelve weeks.

The challenge of providing anticoagulation monitoring services in secondary care, both in terms of meeting demand and organisationally, is considerable. It has been estimated just under a million people in the UK are taking warfarin, and this number is predicted to increase still further.²⁸ The main driver behind the increase in the number of patients prescribed warfarin is published trial data proving the effectiveness of the drug in preventing stroke in those with atrial fibrillation (AF).

Atrial fibrillation is associated with an increased risk of thrombotic stroke and increased mortality. The substantially increased use of warfarin in the 1990s was predicated on robust evidence for the use of adjusted dose warfarin to reduce the risk of stroke. A pooled analysis of five randomised controlled trials (RCTs) demonstrated a stroke risk reduction of 68%, compared to aspirin, when warfarin was used.²⁹

AF is predominantly a disease of the elderly; its prevalence increases from 0.5% in those 50 – 59 years, to approximately 9% in those aged over 70 years.³⁰ With an increasingly elderly population, the need for warfarin for stroke prevention increases.

In a UK survey conducted in 2005 nearly three quarters of anticoagulant clinics surveyed stated that their patient numbers had increased by up to 25% in the preceding two years.³¹ Eighty-six per cent of the clinics expected demand to increase still further over the next year, and 17% of clinics surveyed were considering limiting the number of new patients to cope with the increase in demand.

In addition to burgeoning numbers, from an organisational point of view, traditional management of OAT is far from ideal. OAT management is a distributed service: patients are not necessarily hospitalised at the start of therapy, and the planning, implementation and monitoring of care take place at different places and at different times. Patients on OAT frequently have concurrent diseases, again managed by different people at different places, and it is easy for care to become fragmented, leading to sub-optimal care.³²

A consequence of fragmentation of care is fragmentation of knowledge amongst the different healthcare professionals caring for that patient. Potentially, this may lead to an individual clinician having a relatively narrow understanding about a patient's total health care. Good communication is a vital component of any anticoagulation monitoring service, and breakdowns in communication can occur.

Distributed care also raises questions as to where liability rests when things go wrong.

2.3. Drivers for the development of INR monitoring services in primary care

These two issues – the need to increase INR monitoring capacity and the existing fragmented care - have raised questions about how, and where, warfarin monitoring should be undertaken. Consequently, new models of service delivery have been developed.

Increasingly, INR monitoring clinics are being held in primary care. Two factors have made this a feasible option; reforms in the National Health Service (NHS) financial system and the development of reliable & portable near patient testing (NPT) devices. These factors will now be considered.

2.3.1. Reforms in the NHS financial system

Payment by Results (PbR), which was fully implemented in England in 2008/9, has been a key driver in NHS financial system reform, and has also been instrumental in commissioning of anticoagulant monitoring services in primary care. Under PbR, hospitals are paid a fixed price for each treatment carried out. The Department of Health has drawn up a list of procedures, each with its own Healthcare Resource Groups (HRG) code. The price of each HRG procedure or treatment is fixed in relation to a national tariff, based on its average cost across the NHS.

When PbR was first introduced, a hospital anticoagulation monitoring service was considered expensive, costing the commissioning Primary Care Trust (PCT) £207 for a first appointment and £110 for each subsequent visit (June 2007). This made primary care monitoring financially attractive to PCTs. However, the hospital tariff price for anticoagulation monitoring service has fallen significantly over the last three years, challenging the economic basis for the shift to primary care monitoring.

2.3.2. The technology supporting monitoring INR in primary care

Point-of-care testing (POCT), or near-patient testing (NPT), is “diagnostic testing performed at or near the point of patient care”.³³ The development of portable, accurate, affordable NPT devices – coagulometers - for measuring INR has meant that it is no longer necessary to bring the patient to the hospital for anticoagulation monitoring.

Coagulometers are small lightweight devices that use freeze-dried thromboplastin reagents incorporated in strips or cuvettes. When a drop of fresh capillary blood is applied to a pre-warmed reaction chamber, the thromboplastin starts to aid formation of a blood clot. The instrument then detects the formation of the clot. The clotting time, the time from the beginning of the reaction to clot detection, is then converted to an INR by a microprocessor.³⁴

Lucas³⁵ established the validity of measuring prothrombin time from a whole-blood capillary blood sample, kick-starting the development of NPT machines for monitoring oral anticoagulation. The prototype machine, the Protime Monitor 1000, was launched in the late 1980s, and was swiftly followed by other models based on the same technology, the models evolving as they acquired additional functionalities.³⁶ The Biotrak 512 coagulometer™ (Ciba) evolved from the Protime™ machine, and was launched for patient use in Germany in 1991. Roche launched CoaguChek™ in Germany in 1993, and the following year bought the Biotrak machine which they marketed as CoaguChek Plus™.

However, the development of reliable NPT coagulometers has not only made monitoring by healthcare professionals outside of the hospital setting possible. It is now also feasible for patients to use them in their own homes to monitor their INR.

2.4. Patient self-monitoring of oral anticoagulation: a brief history

Patient self-monitoring of anticoagulation, where the patient measures his or her own INR on a NPT coagulometer, has been feasible since the 1980s. The evolution of research evidence relating to patient self-monitoring of oral anticoagulation is summarised in Table 7.

In 1974, Israeli patients with mechanical heart valves were trained to manage their OAT based on INR measured by the lab, which still therefore required patients to attend the hospital. No further reports of patient self-monitoring were published until the mid-1980s when, with the emergence of near patient testing technology, a case report of a young German student taking the initiative to monitor her OAT was published.³⁷

The first published data indicating that both patient self-testing and self-management are feasible models of anticoagulation emerged from the USA in the late 1980s. White³⁸ demonstrated concordance between home measured and laboratory INRs, and that the anticoagulation control achieved by those self-testing was better compared with those receiving standard anticoagulation clinic care. In the same year, Jack Ansell published a study demonstrating that patients could make safe dose adjustments based on home-measured INRs.³⁹ Ansell and colleagues then followed up this work with a larger scale case-control study.⁴⁰

However, much of the supporting evidence has emerged from Germany. Angelika Bernardo provided the impetus towards the large-scale use of PSM in Germany. Her descriptive study followed up 600 patients over 6 years (1986 – 1992), and provided 205 patient-years of PSM follow-up.⁴¹ In the same year the results of the first randomised controlled trial (RCT) to demonstrate that PSM of OAT produces at least as good control of anticoagulation, as measured by the time spent by the patient at a therapeutic INR, as “conventional” care became available.⁴² Other RCTs emerged from Germany⁴³ and Holland^{44;45} supporting these results.

The first UK patient started self-testing in 1994, with the first UK controlled study published in 2001.⁴⁶ Since 2002, the INR test strips have been prescribable by general practitioners (GPs) i.e. patients can obtain a supply of these strips at no charge or at minimal charge (depending upon their income).

	Israel	Germany	USA	UK
1974	First published paper on PSM using lab-measured INRs			
1985		A student takes the initiative to manage her own INR after purchasing a NPT machine		
1989			White et al publish the seminal PST study, demonstrating that PST leads to significantly better control	
1989			Seminal PSM pilot study published by Jack Ansell & colleagues	
1994				First UK patient starts self-monitoring
1995			Ansell et al follow up their pilot study with a retrospective matched case-control study. Demonstrated feasibility of this approach.	
1996		Six year retrospective analysis of PSM published by Bernado et al. Leads to large-scale adoption of PSM in Germany		
		First prospective RCT comparing PSM by Horskotte & colleagues showing modest improvement in control with PSM compared with routine care (published only as abstract in 1996 - fuller publication in 1998)		
2001				First prospective RCT from UK comparing PSM with routine care showing improvement in control with PSM.
2002				Strips become prescribable by GPs

Table 7: Milestones in the evolution of anticoagulant patient self-management

2.5. Patient self-monitoring of oral anticoagulation – an international perspective

As of June 2011, patients in 55 countries are self-monitoring their oral anticoagulation treatment.⁴⁷ But, this is uncommon in the UK, with an estimated 20,000 of approximately 1 million patients self-monitoring, representing just 2% of this population.

Reimbursement of the costs of testing strips, meters and patient education varies from country to country, and may have an impact on the uptake of patient self-monitoring. The key differences between the UK and the two countries where there has been greater uptake of patient self-monitoring – USA and Germany - are summarised in Table 8.

	UK	Germany	USA
Health system funding	Publicly funded by taxation	Contributory state health insurance plans	Private health insurance plans. Government health insurance (Medicare™) for less well off.
Reimbursement of machines	X	√	√ ^a
Reimbursement of consumables	√	√	√ ^a
Reimbursement of training	X	√	√ ^a
National training program	X	√	X
Encouragement to self-test from start of treatment	X	√	X
Strong patient advocacy movement	X	√	X

a = via Medicare™

Table 8: Key differences in OAT patient self-monitoring in the UK, USA and Germany

2.5.1. Patient self-monitoring in the USA

Although many Americans have health insurance through their employers, Medicare™, a government sponsored health insurance program, pays some medical benefits on behalf of qualified disabled and elderly people. Coverage is available under Medicare™ for prescription drugs, wheelchairs, and for the cost of certain medical supplies. In July 2002, Medicare™ started to cover the cost of both NPT devices and consumables for patients self-testing.³⁴ For reimbursement by Medicare™, the following conditions needed to be met:

- i. The machine and home testing must be prescribed by the patient's doctor
- ii. Patient must have a mechanical heart valve. (Some private insurers may cover other indications)
- iii. Patient must have been anticoagulated for at least 3 months
- iv. Patient must have undergone an educational programme before use
- v. Use of the device is limited to once a week

The patient does not purchase the machine or supplies directly. The physician or Independent Diagnostic Testing Facility (IDTF) purchases them, and is then reimbursed by Medicare™. The physician (or IDTF) is also paid a one-off fee for training the patient on how to use the device, and for reviewing and interpreting the INRs the patient measures.

In March 2008 the Centers for Medicare™ & Medicaid™ Services (CMS) expanded Medicare™ coverage for self-testing to those taking oral anticoagulants for atrial fibrillation and venous thromboembolism.⁴⁸ This has resulted in a sharp increase in uptake of patient self-monitoring in the USA.⁷ Under the new Medicare™ B policy, the patient portion of costs for self-testing is expected to be about \$30 a month (based on a national average) for the use of the coagulometer meter and test strips, and about \$35 for the initial training. Patients with supplemental insurance coverage could potentially have little or no out-of-pocket expenses.

There is no national training scheme in the USA.

2.5.2. Patient self-monitoring in Germany

Although enthusiasm for patient self-monitoring is growing in the USA, no other country has achieved the level of OAT self-monitoring uptake seen in Germany. It has over 20 years of experience with patient self-monitoring, and currently approximately 160,000 German patients are using the CoaguChek™ machine, by far the largest market.⁷ If eligible for self-monitoring, patients are encouraged to self-test as soon as warfarin is initiated. They then graduate to self-management if appropriate.

Insurance companies heavily influence the German health system. Most Germans receive health care coverage through state health insurance plans, funded by contributions. Employers subsidise these contributions for those on low earnings. Germans can opt to pay for private insurance instead of the state insurance plan.⁴⁹

The Association of Self-Management of Anticoagulation (ASA) has established nationally approved training centres across Germany to train both healthcare professionals and patients. The patient receives a certificate of competency when they have completed this training, which is required for them to obtain a NPT machine. Patients are then reimbursed for the first machine that they purchase and for consumables thereafter.

The system of rehabilitation following valve replacement surgery may have a part to play in the rapid uptake of patient self-monitoring of OAT in Germany.³⁷ Patients are provided with 4 – 6 weeks of mandatory inpatient rehabilitation which offers an excellent opportunity for the necessary education. The strong voice of the ASA may be another contributory factor.

2.5.3. Patient self-monitoring in the UK

Healthcare in the UK is publicly funded by the National Health Service (NHS) which provides the majority of healthcare in the UK. NHS services are largely free at the point of delivery, paid for by taxes. Although private health care has continued parallel to the NHS, paid for largely by private insurance, it is used only by a small percentage of the population and, unlike Germany and the USA, insurance companies do not currently play a large role in the British Health Care System. However, this may change in the future. *Equity and excellence: Liberating the NHS*, the White Paper setting out the Government's long-term vision for the future of the NHS, envisages increasing roles for the medical insurance industry.⁵⁰ Patients need to buy their own machines (and quality control solutions if required). Testing strips for available machines have been prescribable by the patient's GP since 2002.

However, matters are not always that straightforward. Anticoagulation Europe, a patient advocacy group for warfarinised patients, has received reports of GPs refusing to supply test strips. There appears to be an element of buck-passing; while GPs were blaming Primary Care Trusts (PCTs), the PCTs would say that it was the GP's decision leaving the patient firmly in the middle.

There is no established approved national syllabus for educating those who wish to self-monitor their OAT, or a national training scheme. This is discussed further in 3.12.1. In addition, the cost and effort associated with preparing this group of patients to assume a greater role in their OAT are not reflected in the current funding model within our internal commissioning market for healthcare services.

2.6. Drivers for OAT patient self-monitoring

For the purposes of this thesis, a driver is considered to be factor that allows, or provides impetus for, uptake of patient self-monitoring of OAT. Despite the patchy uptake in the UK, there are OAT monitoring-specific drivers in place that may facilitate the adoption of OAT patient self-monitoring. These are the availability of portable, reliable NPT machines that allow the patient to monitor their INR at home, and the financial incentives available to practitioners to support self-monitoring patients. These will now be described.

2.6.1. Near patient testing (NPT) coagulometers for patient self-monitoring

As of October 2011, there were three NPT coagulometers suitable for patient use on the UK market; CoaguChek™ XS (Roche Diagnostics), INRatio (Hemosense, distributed in UK by Sysmex UK) and the ProTime 3 machine (ITC, distributed in UK by Instrumentation Laboratory Ltd). Some key features are summarised in Table 9.

Machine	Manufacturer	MHRA* evaluation	Published evidence	Testing strips available on prescription	Cost of machine – October 2011 (£)
CoaguChek™ XS	Roche Diagnostics	Yes	+++	Yes	299**
INRatio	Allere	Yes	+	Yes	399
ProTime	ITC	Yes	++	Yes	840

* MHRA = Medicines and Healthcare Products Regulatory Agency

** Promotional price until 31st December, 2011

Table 9: NPT coagulometers currently on UK market

Home coagulation monitoring is a growing and highly profitable market. Roche dominates the global market. Its CoaguChek™ machine has been extensively used in published clinical trials, and has gone through many iterations with the launch of the CoaguChek™ XS machine in May 2006. The CoaguChek™ XS machine was one of Roche's biggest sellers in 2010, generating global sales of 330 million Swiss francs (approximately £264 million) and demonstrating a 19% year-on-year growth.⁵¹ Expansion in Medicare™ coverage for home coagulation testing, as described earlier, was a key factor contributing to this growth.

UK consensus guidelines, produced by the British Society for Haematology, recommend that NPT coagulometers should be thoroughly evaluated prior to use.⁵² However, the NHS decommissioned the organisation responsible for assessing these devices - the Centre for Evidence-based Purchasing (formerly the Medicines and Healthcare Products Regulatory Agency's (MHRA) Device Evaluation Service) - in 2011. Therefore, at the time of writing this thesis it was not known which body would be undertaking these evaluations in future.

2.6.2. Financial drivers for OAT patient self-monitoring

Supporting patients who are self-testing may qualify general practitioners for extra payment. Since March 2006, anticoagulation monitoring has been one of the national enhanced services (NES) under the new GP contract.⁵³ These are services that were negotiated into the General Medical Services (GMS) contract as a key tool to help Primary Care Trusts (PCTs) reduce demand on secondary care, and are commissioned to meet local need to national specifications and benchmark pricing. Under the terms of the Department of Health's national specification for this service, providers would be responsible for sampling, testing and dosing patients according to locally agreed protocols approved by the PCT.

There are financial rewards for practices choosing to offer an anticoagulation monitoring NES, the magnitude of which is dependent on the level of service offered. An illustration of the remuneration for provision of anticoagulation monitoring service levels is provided in Table 10.

Level	Responsibility	Summary	Payment (per patient per year)
Level 1	Prescribing	Practice prescribing following laboratory sampling, testing and dosing.	£10.63
Level 2	Dosing & prescribing	Practice dosing and prescribing following appropriate external sampling and testing.	£116.34
Level 3	Sample, dosing & prescribing	Practice sampling, dosing and prescribing with laboratory testing.	£126.30
Level 4	Sampling, testing, dosing & prescribing.	Practice sampling, testing, dosing and prescribing.	£144.79

Table 10: Service agreement for anticoagulant monitoring 2011-12: financial details. NHS Hertfordshire NHS Trust⁵⁴

Practices offering a level 4 service agree to offer a comprehensive package with near patient testing and dosing by practice staff, for which they can command over £140 per year per warfarinised patient. Feasibly, the patient could undertake the INR measurement. The challenge is to identify why this change has not yet widely occurred, and how it might be enabled.

Thus, patient self-monitoring of oral anticoagulation is the latest stage in the evolution of OAT monitoring services, driven largely by a need to increase to build capacity and reduce fragmentation of care, and the availability of reliable NPT devices has made this model of care possible. However, patient self-monitoring of oral anticoagulation forms part of the broader agenda of self-management of long-term conditions, for which there are other, more general, drivers. These will now be considered.

2.7. Drivers for patient self-management of long-term conditions

2.7.1. Societal drivers

There has been a paradigm shift in how the patient-clinician relationship is conceptualised. A paternalistic approach to healthcare, as described earlier, is not acceptable to many patients who are better educated, and have greater access to health information through the mass media and the Internet.⁵⁵

Self-management, described in more detail in the next chapter, is one, but not the only, way in which patients can play a more active role. A number of ways of increasing patient involvement in their healthcare have been developed and evaluated.⁵⁶ These include the following:

- Improving health literacy (e.g. providing health information tailored to an individual's needs) to improve patients' confidence and ability to be involved in decisions
- Involving patients in shared decision-making, where they patients are involved as active partners to clarify medical options and choose treatments.
- Providing patient coaching to empower patients to participate in making treatment decisions
- Providing patients with decision aids to increase their level of involvement in treatment decisions

2.7.2. National Health Service policy drivers

As described in the last chapter, the NHS direction of travel supports the redesign of clinical services that involve the patient taking more responsibility for their care.

Since the founding of the NHS in 1948, the focus has been on elective care – for example, reducing waiting lists and increasing productivity. However, by 2030, the incidence of long-term conditions is expected to double.⁵ A long-term medical condition is usually incurable and, whilst usually not immediately life-threatening, can have a considerable impact on the patient. In addition to the health & economic burdens, they may experience disruption to daily life, social exclusion and reduced mobility, and are more likely to be unemployed and reduced educational achievements.^{5;57}

2.8. The research problem

There is a need to meet the challenges of providing services to monitor oral anticoagulation, and patient self-monitoring presents an alternative method of service delivery. It is in keeping with societal and policy drivers for patient self-management, and the technology exists to make it possible.

However, it is unclear how an oral anticoagulation monitoring service model would be redesigned to successfully incorporate patient self-monitoring. Successful OAT patient self-monitoring models exist elsewhere, but although OAT self-monitoring is well established in Germany, and gaining in momentum in the USA, it is unclear if these models are transferable to other countries. The lack of uptake in the UK suggests that existing established models are not directly transferable, and there is insufficient detail to allow the requirements of a service model that encourages OAT patient self-monitoring to be defined.

To define the requirements of this new service model, it is necessary to have an understanding of the drivers for, the benefits of, the barriers to, and the challenges of establishing and delivering an oral anticoagulation patient self-monitoring service from the perspectives of the key stakeholders. The challenge of this research is to better understand what these drivers, benefits, barriers and challenges are.

Some of these factors may be derived from the published literature on patient self-monitoring of oral anticoagulation. Lessons may be also learnt from experiences in self-management of other long-term conditions – for example, diabetes – where this model of care is more established. The next chapter takes a critical look at this literature, and describes how it was identified and analysed.

CHAPTER THREE: LITERATURE REVIEW

The last chapter proposed patient self-monitoring of oral anticoagulation as a way of redesigning services to meet the challenges of OAT monitoring, and some drivers for this model of service delivery were described. However, for a successful scalable adoption, it is also necessary to understand the benefits of, the barriers to, and the challenges of this model of care.

These elements were synthesised below into a diagrammatic representation (Figure 4), which helped to structure the literature review and subsequent method of investigation.

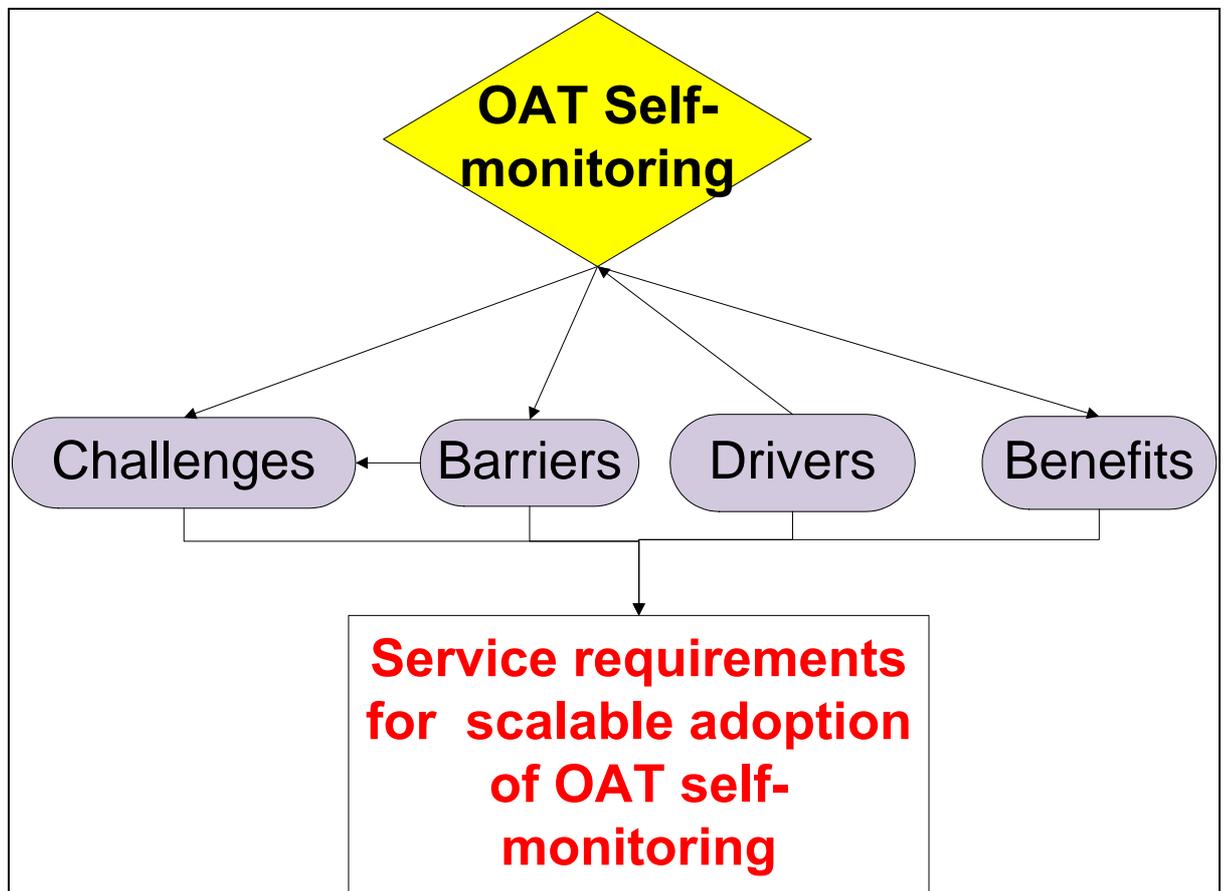


Figure 4. A conceptual framework for deriving the requirements for migration to an OAT self-monitoring service

Each element within this framework will now be defined.

- i. **Driver** – A factor that will allow, or provide impetus for, uptake of patient self-monitoring of OAT.
- ii. **Barrier** – A factor that may prevent or limit adoption of OAT patient self-monitoring
- iii. **Challenge** – A task that needs to be undertaken to enable successful adoption of OAT patient self-monitoring. May be derived from the barriers to OAT patient self-monitoring.
- iv. **Benefit** – An advantage that may arise from OAT patient self-monitoring
- v. **Scalable adoption of OAT patient self-monitoring** – The introduction of an OAT patient self-monitoring service that can be changed in size or scale with minimal effort
- vi. **Requirement** – A condition that needs to be met to enable successful adoption of OAT patient self-monitoring

The requirements will be identified from the drivers for, benefits of, barriers to, and challenges of OAT patient self-monitoring. The main drivers for OAT patient self-monitoring were discussed in the last chapter. This chapter will focus on identifying the benefits of, the barriers to, and the challenges of OAT patient self-monitoring service.

Some of these elements may be derived from published research. It was important to appraise the available literature not only to establish the strength of the evidence, but also to identify where gaps in knowledge existed. In a broader context, lessons may also be learnt from experiences in self-care of long-term conditions, especially those where dose adjustment is central to clinical care, and relevant literature from this domain was included.

As this research aims to establish these factors from a multi-stakeholder perspective, it was essential at an early stage to identify the key stakeholders, their role in OAT patient self-monitoring, and predict what their expectations might be, and the potential challenges they may face in establishing an OAT patient self-monitoring service (Table 11). This exercise served two purposes. Firstly, it informed the scope of the literature review. Secondly, as each of the elements in the conceptual framework (Figure 4) was to be considered from each stakeholder's perspective, it also informed the direction of the empirical work.

Stakeholder			
Patient / carer	Clinician (hospital or primary care)	Hospital manager	PCT commissioner
Role			
<ul style="list-style-type: none"> ➤ Assumes more responsibility for monitoring OAT by measuring INR at home + / - adjusting own dose of warfarin 	<ul style="list-style-type: none"> ➤ Provides initial patient education and ongoing support and review, including dosing advice for those self-testing ➤ Monitors the service to ensure that it is safe 	<ul style="list-style-type: none"> ➤ Manages the budget for OAT monitoring services 	<ul style="list-style-type: none"> ➤ Commissions OAT monitoring services both in primary and secondary care
Expectations			
<ul style="list-style-type: none"> ➤ Patient self-monitoring is integrated into everyday life ➤ INR control is good and there are no OAT-related adverse effects 	<ul style="list-style-type: none"> ➤ INR control is good and there are no OAT-related adverse effects ➤ Patients contact clinic at the appointed times for review and dosing advice ➤ Clinic capacity is increased 	<ul style="list-style-type: none"> ➤ OAT patient self-monitoring is cost-effective, and generates income for the organisation ➤ Clinic capacity is increased 	<ul style="list-style-type: none"> ➤ OAT patient self-monitoring is cost-effective compared with other methods of service delivery
Potential challenges			
<ul style="list-style-type: none"> ➤ Education provided prepares them for self-monitoring 	<ul style="list-style-type: none"> ➤ Patient selection criteria accurately predicts those who will be successful in self-monitoring ➤ Clinical staff will be able to support those who are self-monitoring ➤ Development of a patient self-monitoring service does not introduce new clinical risks 	<ul style="list-style-type: none"> ➤ Introduction of patient self-monitoring does not result in loss of revenue or extra cost for the organisation 	<ul style="list-style-type: none"> ➤ Introduction of patient self-monitoring is not a financial risk

Table 11: Key stakeholders in the development of an OAT patient self-monitoring service

The next section of this chapter describes the purpose and scope of the literature review, and how this review was conducted.

3.1. Purpose of the literature review

The purpose of this literature review was three-fold:

- i. To synthesise and interpret previous research on patient self-monitoring of OAT and patient self-management of other long-term conditions
- ii. To identify gaps in knowledge and understanding of patient self-monitoring of OAT
- iii. To guide the empirical work described in subsequent chapters

3.2. Scope of the literature review

The concept areas covered by this literature review are described in Table 12 below.

These concept areas were directly derived from the aim of the research, or were included to understand relevant context, informed by the author's own experience in developing innovative anticoagulation monitoring services in north London. The author contributed to establishing a hospital based anticoagulation service led by pharmacists and specialist nurses in 1998, and to establishing a community led service involving general practitioners and community pharmacists from 2001. These service developments involved consideration of several elements, including patient selection, education, cost-effectiveness and accountability, and these would be expected also to apply to developing a patient self-monitoring service. They also reflect the challenges that may face the key stakeholders, described in Table 11.

	Concept area	Derivation or rationale
1.	Safety of patient self-care	To provide context
2.	Safety of patient self-monitoring of OAT	
3.	Benefits of patient self-monitoring of OAT	Derived from aim of the research
4.	Barriers to patient self-monitoring of OAT	
5.	Patients' and healthcare professionals' views of self-care	
6.	Successful approaches to patient self-monitoring of OAT	
7.	Design of clinical service models	
8.	Patient selection for self-monitoring of OAT	Derived from author's experiences in developing anticoagulation monitoring services
9.	Educational support for patients wishing to self-monitor OAT	
10.	Educational support for healthcare professionals supporting patients self-monitoring OAT	
11.	Financial implications of patient self-monitoring of OAT	
12.	Accountability in patient self-monitoring of OAT	

Table 12: Derivation of concept areas for the literature review

3.3. Sources used for literature review

Material was initially identified and then reviewed periodically during the course of the research up to August 2011. Both qualitative and quantitative research were included. Material was confined to that published in the English language.

The sources used for the literature review are described below.

3.3.1. Published literature (print media)

Published literature on all core concepts was identified by searching the following computerised bibliographic databases;

Medline (Dialog Datastar, 1951 to present day)

Embase (Dialog Datastar, 1974 to present day)

CINAHL (Dialog Datastar, 1982 to present day)

Kings Fund database (Dialog Datastar, 1979 to present day)

MeSH terms were used if available, using Boolean operators to combine terms where desirable. Expert input from a medical librarian was sought to refine searches. The following search terms were used (all are MeSH terms unless stated):

<i>Anticoagulants; Warfarin; Oral anticoag\$ (non MeSH); Anticoagulant therapy (EMBASE only); Anticoagulant agent (EMBASE only); Coumadin (non MeSH)</i>
<i>Patient education; Patient education (free text search); Patient information (non MeSH); Consumer information (non-MeSH); Information dissemination; Information (non MeSH); Information needs; Needs assessment</i>
<i>Self care; Self administration; Self management (Kings Fund only); Self monitoring (EMBASE only)</i>
<i>Health knowledge attitudes practice; Attitude to health; Quality of life; Patient satisfaction; Patient acceptance of health care; Attitude of health personnel</i>
<i>Disease management; Chronic disease</i>
<i>Costs; Costs analysis; Cost (EMBASE); Cost utility analysis (EMBASE); Cost benefit analysis (EMBASE); Cost effectiveness analysis (EMBASE)</i>

Bibliographies of retrieved papers were hand-searched and relevant citations reviewed.

A citation search using ISI Web of Science citation index was performed for oral anticoagulant education using selected citations:⁵⁸⁻⁶¹

All searches were conducted until saturation was reached and nothing new of relevance was found.

3.3.2. Email discussion lists

JSIC Consumer Health Informatics email list archives

www.jiscmail.ac.uk/lists/CONSUMER-HEALTH-INFORMATICS.html

In December 2005, the author subscribed to this discussion list for developers/evaluators of computerised info for patients/public. The archive content prior to subscription was searched using the following search terms:

Anticoag\$; Warfarin; Chronic disease management; Self-management; Decision support; Electronic health record

3.3.3. Research registers

Research registers provide early access to information about early stage studies. This can be a useful indicator of present research priorities, and a pointer to future areas of research results

The National Research Register (NRR; www.nihr.ac.uk) is a database of ongoing and recently completed research projects funded by, or of interest to, the United Kingdom's National Health Service (NHS). Information is provided by NHS Trusts, national and regional funding programmes, universities and charities in England, Scotland and Wales. Unpublished anticoagulant-related research was identified from this database using the following search terms:

Anticoagulants; Self management; Self administration

3.3.4. Anticoagulation specialist websites

The following sites were checked for relevant information:

Anticoagulation forum (www.acforum.org)

Conceived in 1991, the Anticoagulation Forum is a network of anticoagulant clinics and promotes professional development and is committed to enhancing the quality of anticoagulation care. It currently has 3300 members representing over 1300 anticoagulation clinics throughout the world.

Anticoagulation Europe (www.anticoagulationeurope.org)

Anticoagulation Europe is a UK-based charity providing information and advice to communication and education on anticoagulation therapy.

Anticoagulation.org (www.anticoagulation.org.uk/main.html)

This website is produced by the University of Birmingham (UK) and is a source of information, links & references. It is aimed mainly at healthcare professionals.

ClotUK (www.clotuk.com)

CLOT - Clinical Leaders Of Thrombosis - is an anticoagulation and deep vein thrombosis special interest group for health care professionals in the UK. The site is designed as a resource for professionals in anticoagulant care.

Anticoagulation Specialist Association (ASA) (www.the-asa.org.uk)

This UK-based body acts as an “advocate for specialists working within the field of anticoagulation, and their patients to encourage and promote high standards of care within the speciality through evidence-based practice.”

ClotCare (www.clotcare.com)

ClotCare is aimed at both patients and healthcare professionals and aims to provide current information and expert insight on optimal use of oral anticoagulants. Its multidisciplinary editorial board are all from the US.

International Self-Monitoring Association for oral Anticoagulation (ISMAA)
(www.ismaa-int.org)

The ISMAA’s website is aimed at healthcare professionals who manage patients on oral anticoagulant therapy, with the aim of improving the quality of treatment through patient self-testing. Its executive committee is international and includes UK representation.

The International Self-Monitoring Association of oral Anticoagulated Patients (ISMAAP) (www.ismaap.org)

Representatives of National Associations of patients on oral anticoagulation therapy founded ISMAAP. The site acts as a resource to support patients on oral anticoagulation therapy and to motivate them to carry out self-monitoring. Its executive committee comprises mainly European patient members.

3.3.5. Other resources

Department of Health website (www.dh.gov.uk)

At the start of the literature review in December 2005, and periodically through the course of the research, relevant policy documents were identified by entering the following terms into the website's search engine:

Self care; Self management; Long term conditions; Chronic disease management

The Cochrane Collaboration (www.cochrane.org)

The Cochrane Collaboration produces and disseminates systematic reviews of healthcare interventions. Its major product is the Cochrane Database of Systematic Review, published in the Cochrane Library

(www.mrw.interscience.wiley.com/cochrane/cochrane_clsystrev_articles_fs.html)

At the start of the literature review in December 2005, and again towards the end of the research in July 2011, reviews of patient self-management were identified by searching The Cochrane Library's alphabetical index.

Health Technology Appraisals (NHS HTA) website (www.hta.org)

The HTA programme ensures that high quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most effective way for those who use, manage and provide care in the NHS. The National Coordinating Centre for HTA coordinates the HTA programme on behalf of the Department of Health's Research and Development Division. Every year the HTA programme commissions research, and the results of this research are published as reports in the HTA monograph series.

The HTA website was searched for relevant research by inputting the following terms into the website's search engine:

Anticoagulants; Self management

Google (www.google.com)

Throughout the course of the research, the search engine Google™ was used to search for information on topics that was difficult to search for using standard medical bibliographic databases (e.g. locus of control, patient pathways, history of discovery of warfarin)

Websites of manufacturers of near-patient testing coagulometers

The following websites were searched for product information and shareholders' reports:

www.protimetest.com

www.roche.com

www.hemosense.com

www.invernessmedical.com

The author also contacted representatives of Roche, Hemosense and Inverness Medical for additional information

Websites of professional bodies: BMA, RCGP, RPSGB, Royal College of Physicians, GMC and Royal College of Nursing

The following websites were searched for policies or position statements on patient self-management.

www.rcgp.org.uk

www.bma.org.uk

www.rpsgb.org

www.gmc-uk.org

www.rcn.org.uk

www.rcplondon.ac.uk

3.4. The growth and size of the literature

The literature supporting this thesis is diverse. It includes not only clinical data to support the safety of both general self-care of long-term conditions and oral anticoagulation, but also embraces organisational change, economic and medico-legal literature.

It is also a vast field of study: the volume of published literature to support self-care of long-term conditions and oral anticoagulation has grown hugely since the 1990s (Figure 5).

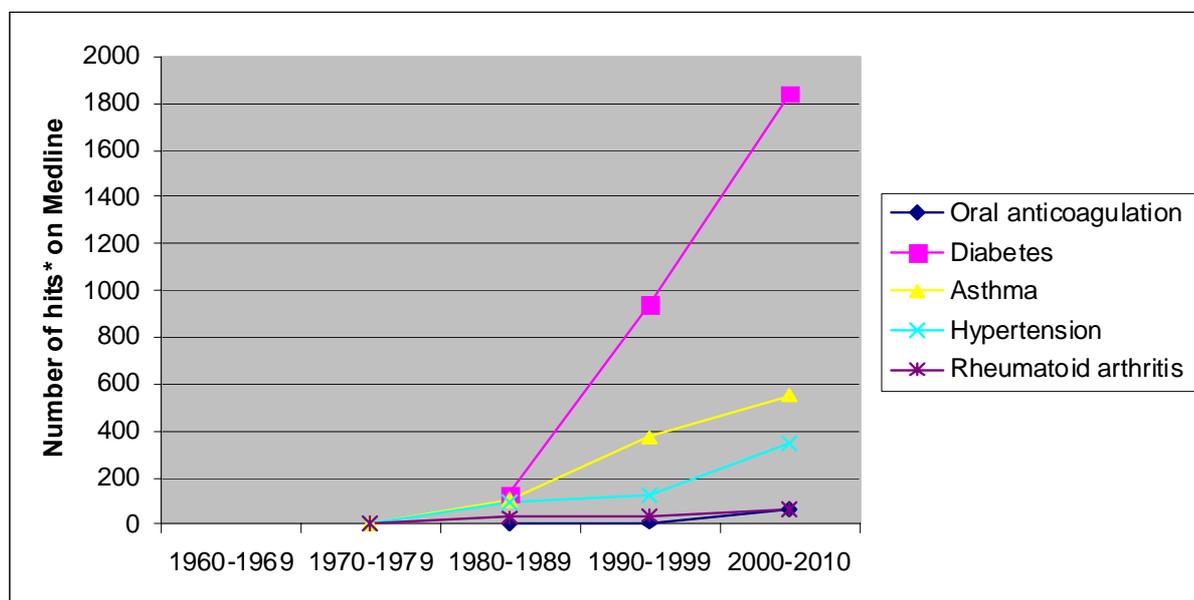


Figure 5: The growth of published self-care literature: 1960-2010

* Hits were papers with keywords “self-care” and therapeutic area (e.g. “asthma”)

This literature review examines the available evidence on patient self-monitoring of oral anticoagulation and also, in a broader sense, self-care of long-term conditions. Firstly, the evidence supporting patient self-monitoring will be critically reviewed. Then the benefits of, the barriers to, and challenges of introducing this model of care will be discussed.

3.5. Evidence for the safety of patient self-management of long-term conditions

3.5.1. Introduction

Historically, individuals and families have always taken care of their own health. With the growth of organised healthcare systems, affordable or free access to these services, and increasing sophistication of healthcare interventions, personal autonomy and responsibility for self-care has diminished in favour of professionally directed and delivered care.

One of the first times that the term ‘self-management’ appeared in print was in a book written by Thomas Creer on the rehabilitation of asthmatic children.⁶² Since the mid 1960s, Creer and his colleagues at the Children’s Asthma Research Institute in Denver had used this term to indicate that the patient was an active participant in treatment.⁶³ Randomised trials examining the effectiveness of self-management interventions started appearing from the late 1970s, with the publication of a trial exploring the effects of relaxation therapy and patient self-monitoring on the management of hypertension.⁶⁴

3.5.2. Describing self-management

The definition of self-management is problematic. There is a lack of consensus about its meaning, and that of the closely related concept of self-care. Self-management and self-care are defined as one entry in the glossary of the NHS Care Records Service, as how *“many people can learn to be active participants in their own health and social care, living with and managing their conditions/needs”*.⁶⁵

However, self-care can be thought of as an overarching concept; it embraces the spectrum of activities undertaken by a person to stay well or to manage a chronic illness, with or without support from a healthcare professional.⁶⁶ This care can be extended to children, family, friends and others in neighbourhoods and local communities.

Self-management can be thought of as a sub-category of self-care, and relates to the tasks that an individual must undertake to live well with one or more chronic conditions. Barlow & colleagues defined self-management as:

*“the individual’s ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition”*⁶⁷

Self-management will normally include some input from healthcare professionals, which is often focused on education, monitoring of disease indicators and skills development.

However, for self-management to be considered feasible it must result in disease control that is at least as good as conventional care. The evidence to support the clinical effectiveness of self-management of long-term conditions will now be considered.

3.5.3. Evidence to support self-management intervention programmes

There is a small body of evidence to show that self-management of chronic disease may improve patients' quality of life and health, increase patient satisfaction & life expectancy and lead to less reliance on healthcare services.⁶⁸ However, the evidence is by no means unequivocal.

Three comprehensive reviews of self-management of long-term conditions have been published

Warsi⁶⁹ located 71 trials of self-management education, mostly in arthritis, asthma, diabetes and hypertension. The programs resulted only in a small to moderate overall effect. Also, there was evidence of publication bias which may overestimate the benefits of these programmes. Additionally, the author concluded that the methodology between studies was not consistent and was often sub-optimal.

Results were not consistent across all diseases. Whilst diabetic and asthmatic patients benefited from the education, this success was not reported with respect to those with hypertension & arthritis. Few researchers referenced behavioural science frameworks in developing these educational programmes.

Chodosh⁷⁰ conducted a meta-analysis of self-management programs for diabetes, hypertension and osteoarthritis and concluded that these programs had a beneficial effect for diabetes and hypertension, but not for osteoarthritis. The trials did not provide evidence about the essential elements of self-management programs, limiting the ability to design such programs. There was some evidence that the beneficial effects reported might have been in part achieved by increased adherence to prescribed medicines. The author also noted that publication bias was evident.

Newman⁷¹ adopted a more discursive approach. This review of 63 studies examining self-management interventions for asthma, diabetes and arthritis found that the content and intensity of the programmes differed substantially even within the three illnesses. The objectives of the interventions reflected the complexity of the issues that they were attempting to tackle. For example: for diabetes and asthma, there were clear strategies to achieve underlying control of the condition. However, strategies to deal with symptoms of pain and the consequences of disability in arthritis were more complex.

The Cochrane Collaboration, an independent international organisation that produces and disseminates systematic reviews of healthcare interventions, has published reviews of self-management of, chronic obstructive pulmonary disease (COPD)⁷², asthma⁷³ and non-insulin treated type II diabetes.⁷⁴ Its findings are summarised in Table 13.

Therapeutic area	Selection criteria	Number of trials	Main conclusions
Asthma	Randomised controlled trials (RCTs) of asthma self-management in adults > 16 years	15	Self-adjustment of medication using a written action plan is as effective as adjustment by a doctor Reducing the intensity of self-management education may reduce its effectiveness
COPD	Controlled trials of self-management education in those with COPD	9	Insufficient evidence to determine whether self-management of COPD is effective.
Type II DM (non insulin dependent)	RCTs comparing self-management of type II DM with usual care +/- or self-monitoring of urine glucose.	6	Self-monitoring of blood glucose might be effective at improving glycaemic control. Methodological quality of studies poor and well-designed RCT is needed

Table 13: Cochrane Reviews of self-management interventions in chronic disease

From the published evidence, it is difficult to draw firm conclusions as to the effectiveness and optimal content of programmes to support patient self-management of long-term conditions. There is evidence of publication bias, exaggerating the actual effect of these programmes, and methodological flaws. There may be a small to moderate beneficial effect derived from programmes to support patient self-management of asthma, diabetes and possibly hypertension, but there is no evidence of benefit in such programmes for either osteoarthritis or rheumatoid arthritis.

Therefore, patient self-management may be effective only for some long-term conditions, and these may be where goals are clearly defined and progress/attainment easily measured – i.e. blood glucose, systolic blood pressure. OAT patient self-monitoring, where keeping the INR within a defined range, is in keeping with these conditions. Conversely, the goals of arthritis are not so clearly defined, nor is progress easy to measure.

The next section will consider the evolution of patient self-monitoring of oral anticoagulation and the evidence supporting it.

3.6. Evidence for the safety of patient self-monitoring of oral anticoagulation

3.6.1. Assessing the safety of patient self-monitoring of oral anticoagulation

For patient self-monitoring of OAT to be considered feasible, it must be at least as safe as conventional care. Most studies have used the percentage of time in therapeutic range or the number of INR readings in therapeutic range as the primary endpoint. These are calculated as follows:

Time in therapeutic range (TTR): involves linear interpolation of the observed INR values to extrapolate daily INR values, then defining the TTR as the number of patient days spent in therapeutic range divided by the total number of patient days in the follow-up period

Percentage of time in therapeutic range: derived by dividing the number of INR values in therapeutic range by the number of INR tests (x100)

Of the two, time in therapeutic range is considered to be the outcome of choice.⁷⁵ The percentage of INR tests in therapeutic range, although far more simple to calculate, is more easily influenced by the frequency of monitoring, which might itself be subject to bias.

3.6.2. The safety of patient self-testing (PST)

From the available limited data, PST is at least as safe as usual control^{45;76;77} or better.^{38;78-80}

In the UK, the team at University College London has been instrumental in assessing the feasibility of PST in the UK. Their study showed that PST is a reliable method of anticoagulation monitoring, in that good correlation between laboratory values and those measured by the coagulometer was demonstrated.⁷⁶ Secondly, in terms of INR control, weekly PST was equivalent to usual care. However, dosing in the PST group was based on laboratory values and the median age of both study groups was lower than the average of their clinic population.

3.6.3. The safety of patient self-management (PSM)

More data are available to support the safety of PSM. INR control has been shown to be as good as usual care^{44;45;81} or better.^{40;43;46;82;83} In a handful of other studies, although INR control appeared to be better with PSM it was impossible to tell if this was statistically significant, either because the trial report was only available as an abstract^{42;78} or no statistical analysis was applied.⁸⁴ Although earlier studies used the percentage of INRs in therapeutic range as the primary endpoint,^{40;42;44;78;84} later studies,^{45;83;85} including those from the UK,^{46 86;49;81} used the preferred time in therapeutic range.

The Birmingham group, led by Professor David Fitzmaurice, has identified the need for robust data from the UK, and has led the way in this research in the UK. Their last (2005) study demonstrated that PSM results in similar INR control to routine care.⁴⁹

The seminal studies assessing the safety of patient self-monitoring or oral anticoagulation are summarised in Table 14.

Main author, year and country	Numbers analysed		Duration of study (months)	Description	Significance
	PST /PSM	Control			
White 1989, USA ³⁸	26	24	2	Comparison of home INR testing with management by specialist nurses in an anticoagulant clinic	The first published RCT to demonstrate that INR control achieved by self testing was as good as clinic care
Ansell, 1995, USA ⁴⁰	20	20	90	Retrospective cohort study of self-managing patients with matched control subjects monitored at an anticoagulation clinic.	The first published study to demonstrate that patients can safely self-manage their OAT .
Horskotte, 1998, Germany ⁴²	75	75	18	RCT comparing PSM with management by a home physician	The first published RCT to demonstrate that PSM produces INR control equal to conventional care
Sawicki, 1999, Germany ⁴³	82	83	6	RCT comparing PSM with management by family doctor	This study included a structured educational programme which has subsequently been used by other researchers.
Fitzmaurice, 2005, UK ⁴⁹	337	280	12	RCT comparing PSM with management by family doctor or hospital clinic.	This study (SMART study) is the largest published trial from the UK demonstrating the safety of PSM. The use of broad inclusion criteria demonstrated that PSM could be done by 'non-selected' patients

Table 14: Seminal studies assessing the safety of patient self-monitoring of oral anticoagulation

3.6.4. Comparing oral anticoagulation patient self-testing with self-management

In terms of INR control, there appear to be no advantages of patient self-management over self- testing. However, direct comparisons are few and make it difficult to draw firm conclusions.

Gadisseeur⁸⁷ compared PSM with PST; no significant difference in INR control was found between patients dosing themselves and those who are self-testing only.

Gardiner,⁸⁸ at University College London, has compared the safety of patient self-management and self-testing. Both groups measured their INR once every two weeks for 6 months; there were no significant difference between the time in therapeutic range for PSM (70%) or PST (72%).

3.6.5. Clinical outcomes data

Although INR control is an indicator of anticoagulant safety, it is a surrogate endpoint. Improved clinical outcomes are demonstrated by reductions in mortality and in thromboembolic and bleeding episodes, and few trials have these as the primary outcome measure.⁸⁹ This is because it is more difficult to demonstrate clinical effectiveness in terms of hard clinical endpoints as large numbers of patients and longer follow-up periods would be needed to power a study to demonstrate differences in incidence. If these data were available, the evidence would be far more robust.

However, meta-analyses have been conducted to determine if PSM and PST are better than standard care in terms of these definitive endpoints. The three largest, most recent ones will now be considered.

In 2006, a meta-analysis of 14 OAT patient self-monitoring trials (both PST and PSM) was conducted by a team at Centre for Evidence Based Medicine at Oxford and the Iberian Cochrane Centre in Barcelona.⁹⁰ Thromboembolic events were halved in those self-monitoring, probably due to the increased frequency of INR testing. However, there was not a compelling case for patient self-monitoring in terms of mortality and bleeding. Although there was a 36% reduction in death from all causes, this result was influenced by the single study that demonstrated a significant reduction. There was a non-significant (13%) reduction in major haemorrhage and although there was a significant reduction in minor haemorrhage, the results varied considerably.

When the patient self-testing trials were pooled, benefits in terms of clinical outcomes were minimal. There was no significant reduction in major bleeds and mortality and considerable variance in results in terms of minor haemorrhage. Although still significant, there was less impact on thromboembolic events compared with both patient self-management and self-testing trials.

This meta analysis was updated to form part of a Cochrane review in 2010.⁹¹ Although four additional controlled trials were identified, the outcomes were the same.

More recently (2011), the U.S. Department of Veterans Affairs (VA) Evidence-based Synthesis Program, in conjunction with the VA's Office of Quality and Performance, commissioned a review to determine whether OAT patient self-monitoring was more effective and safer than usual care.⁹² 22 trials were identified, four more than the Cochrane Review a year previous. Thromboembolic events were reduced by 42% in patients randomly assigned to PST or PSM. Although there was a significant 26% lower risk for death, this evidence was considered low strength because of inconsistency among studies. There was a non-significant reduction in major bleeding events.

This VA analysis included the largest PST study to date, THINRS, published in 2010.⁷⁷ THINRS randomly assigned 2,922 people receiving warfarin therapy for either mechanical heart valves or atrial fibrillation to PST or to receive care at a high-quality anticoagulation clinic. They were then followed up for an average of 3 years, giving the study sufficient power to yield hard endpoints in terms of strokes, bleeding and deaths. Although PST produced a small but significant improvement in INR control, the self-testing group reported more minor bleeding events and there was no significant difference in the time to the first major bleeding or thromboembolic event between the two groups (the primary endpoint).

In summary, patient self-monitoring results in fewer thromboembolic events than usual care, without causing bleeding. Although meta-analyses have demonstrated that patient self-monitoring reduces mortality, there is inconsistency amongst the studies reviewed. These benefits appear to be largely confined to patient self-

management. There is no evidence that patient self-testing has a positive effect on clinical events, reflected in outcome of these meta-analyses and THINRS study. David Matchar, the THINRS co-leader, remarked that any extra benefit of PST was “modest at best”.⁹³

3.6.6. Confounding factors

It is important to note that there are potential confounding factors that limit the generalisability of these trial results to a UK clinic population.

It is not entirely clear if the potential benefits of PST / PSM stem solely from the act of self-monitoring, or are modified by other factors. These factors include the education and training given to patients undertaking self-monitoring, increased frequency of testing, positive effects on compliance and greater patient empowerment.

Additionally, a randomised controlled trial (RCT) is the gold standard in terms of robustness of clinical evidence. Although it is not possible to totally blind the results of trials of OAT patient self-monitoring, it would be possible to blind the investigators to the results. As only one group of researchers has partially blinded their trial,⁴⁵ it is impossible to say that bias has been properly eliminated.

In the vast majority of self-monitoring trials, education and training have been given to patients randomised to the self-monitoring group to equip them with the necessary skills and knowledge to take responsibility for their own anticoagulation therapy. Generally, no such education has been provided for the control group, placing them at an immediate potential disadvantage.

Although there have been a few attempts to account for the effects of these educational programmes, no firm conclusions can be drawn from the results. Dutch researchers randomised 341 patients to four groups: weekly PST (trained patients); weekly PSM (trained patients); usual care (trained patients); usual care (untrained patients).⁴⁵ There were no significant differences in the time in therapeutic range between the four groups; education alone was at least as good as education plus self-monitoring.

Similarly, Khan⁸⁰ compared the effects of providing anticoagulation education, education plus weekly PST and usual care over a six-month period. Although education alone increased the percentage time in range from 61% to 70% (compared with the previous six-month's results), this result barely reached statistical significance ($p=0.05$) and greater benefits were derived from education plus PST (% time in range increased from 57% to 71%, $p<0.001$).

Although there is small body of published evidence examining the safety of anticoagulation patient self-monitoring, most of these studies originate from outside the UK, where the routine care that self-monitoring is being compared against may not be as good as that usually achieved in the UK. Therefore, generalisability and interpretation of this evidence in a British context is difficult.

Finally, as with trials evaluating self-management of long-term conditions, there is some suggestion of publication bias, which may lead to an overestimation of the benefits of patient self-monitoring

3.7. Patient benefits of self-monitoring of oral anticoagulation

From the limited body of evidence it appears then that patient self-monitoring is at least as safe as routine care, resulting in fewer thromboembolic events without causing bleeding, and may reduce mortality. However, the evidence is not compelling and raises the question that if there is no clear advantage in terms of clinical endpoints, are there other patient benefits that could augment the case for self-monitoring of OAT?

Four published studies, including one from the UK, have explored patient views of self-management of OAT: the results are mixed.

Sawicki⁴³ developed a 40-point structured questionnaire, with the assistance of a national self-help group, to assess the effect of an anticoagulation education program, which included self-management of OAT, on treatment-related quality of life. This questionnaire was used also in two subsequent studies to assess the impact of patient self-management and patient self-testing.^{44,45} The questionnaire included 5 treatment-related topics; general treatment satisfaction, self-efficacy, strained social network, daily hassles and distress.

All three of these OAT patient self-management studies reported benefits in terms of reduction in “daily hassles”. Daily hassles reflected minor, stressful events that were thought to add to the burden of having to cope with a long-term condition.

Improvements in distress and self-efficacy were also reported. The theory of self-efficacy proposes that people avoid activities that they perceive as more than they can manage.⁹⁴ Self-efficacy is important in self-management behaviour then, in both initiating and maintaining this behaviour.

Only one of the studies reported a reduction in the strain on the patient’s social network.

Gadisneur⁴⁵ examined the effects of both patient self-testing and self-management on quality of life. Patient self-testing conferred significant benefits in terms of self-efficacy. However, there was a trend towards an increased distress score, which may have been caused by an increase in patient awareness.

However, the reliability and validity of the questionnaire used in all three of these studies has been questioned, especially with respect to its low Cronbach alpha values. Also, patient numbers were small.

The sole published UK study examining this area is of limited value.⁸¹ It merely reported the five main themes arising from patient interviews: knowledge & management of condition & self-empowerment; increased anxiety & obsession with health; self-efficacy; relationship with health professionals; societal and economic cost.

3.8. Healthcare professionals' perspectives on OAT patient self-monitoring

From the patient perspective, self-monitoring appears at least as good as conventional management and may confer benefits such as a reduction in “daily hassles” and increased self-efficacy. However, for an OAT patient self-monitoring service to be successful, the support of the other key stakeholders – clinical staff, healthcare managers and commissioners - is essential.

No studies were found describing the views of healthcare managers or commissioners on self-monitoring of OAT.

One published study of the views of healthcare professionals on patient self-monitoring of oral anticoagulation was located. Wittkowsky⁹⁵ surveyed American anticoagulation practitioners to identify the main barriers to self-monitoring. The main barriers were financial ones, relating both to the cost of the machine and consumables. However, these conclusions should be considered with caution. The results are not representative, even from a US perspective, as the study did not address the use of self-testing by patients whose anticoagulation is not monitored by anticoagulation clinics, which is more often the case. Additionally, the UK patient will not usually pay for INR testing strips as they are available on prescription.

Although not supported by evidence, these authors did offer some thoughts on why PSM has been so successful in Germany, which are summarised below:

- Sufficient reimbursement for coagulometers & testing strips
- Physician ‘champions’ who have promoted self-management nationally
- Healthcare system provides resources for extensive patient training
- Marketing by coagulometer manufacturers

Whilst the published literature exploring the views of healthcare staff on self-management of long-term conditions is minimal, it may give an additional perspective on OAT patient self-monitoring. This evidence is now described.

3.9. Healthcare professionals' views of patient self-management of long-term conditions

One of the key challenges of self-management is changing the mindset of healthcare professionals. Traditionally, healthcare professionals are trained to treat acute illness and, to a much lesser extent, to manage long term conditions strategically – but still directing that management. A self-management model of care represents a new way of working with patients. Self-management requires changes in the traditional relationships and roles that health professionals assume with their patients.

Clinicians may be reluctant to relinquish control of management. Jones⁹⁶ reported that asthma nurses and GPs were not enthusiastic about asthma self-management plans. Both professional groups questioned their relevance and usefulness. Nurses felt that they were in the best position to provide the necessary education and monitoring that these patients needed. The group of GPs involved in the study agreed that these patients needed continuing education and dialogue and doubted patients' ability to self-manage.

Public Attitudes to Self Care, a 2005 survey commissioned by the Department of Health, found that engagement from healthcare professionals was essential.⁹⁷ Over half (55%) of patients surveyed said that they had not often received encouragement to self-care and a third said that they had never been encouraged to do so. A fifth of those questioned in this survey said that more advice and guidance from healthcare professionals would enable them to self-care better, and 13% said that more encouragement was important.

This supports the findings of a report compiled by the Kings Fund; support from healthcare professionals was found to be one of the key influences on compliance with self-management advice.⁶⁵

3.9.1. Views on patient self-management from healthcare professional bodies

Some of the main professional bodies have issued position statements on patient self-management.

General Medical Council

The update to the General Medical Council's 'Good Medical Practice' says that doctors should *'encourage patients and the public to take an interest in their health and to take action to improve and maintain it. This may include advising patients on the effects of their life choices on their health and well-being and the possible outcomes of their treatments'*.⁹⁸ It continues to ask that doctors support 'patients in caring for themselves to improve and maintain their health' and encourage *'patients who have knowledge about their condition to use this when making decisions about their care.'*

British Medical Association

The Patient Liaison Group and General Practitioners Committee of the British Medical Association (BMA) published a policy document for self-management of long-term conditions in 2007.⁹⁹ This document describes the BMA's aspiration to see self-care through self-management education become central to the patient involvement agenda. The BMA has also developed a web resource for GPs with information on the types of self-management education programmes available.¹⁰⁰

Royal College of General Practitioners

Self-care is a strategic element in the Royal College of General Practitioners' 2007 report 'The Future Direction of General Practice. A roadmap'.¹⁰¹

"Patients should be increasingly involved in planning health services, self-care, demand management, quality assessment, and in self-management and group education"

Royal Pharmaceutical Society of Great Britain (RPSGB)

The Royal Pharmaceutical Society of Great Britain has been pro-active in its recommendations to support self-care. In March 2006, it launched a strategy document aiming to maximise the potential of pharmacy in self-care.¹⁰² One of its key messages was to highlight the opportunities that exist for pharmacists to improve the care of long-term conditions, including delivery of high quality information, allowing more medicines to be purchased without a prescription (more "POM-to-P" switches) to enable self-treatment and offering point-of-care testing.

Royal College of Nursing

As of September 2011, a policy or position statement relating to self-management of long-term conditions was not available from the Royal College of Nursing.

In summary, the support of healthcare professionals in enabling patient self-management is essential and this move away from the more traditional, paternalistic model of care is broadly embraced by most of the professional bodies. However, there may be a reluctance to relinquish control, which may be a barrier to overcome in establishing an OAT patient self-monitoring service. There may also be reluctance amongst patients to embrace patient self-monitoring, and the next section considers the potential patient-centred barriers.

3.10. Patient-centred barriers to self-management

There is little point in setting up an OAT self-monitoring service if patients are not willing to participate. Therefore, it is essential to establish the barriers that need to be overcome before introducing such a service.

3.10.1. Patient-centred barriers of patient self-monitoring of oral anticoagulation

Bungard¹⁰³ conducted a telephone survey of Canadian patients to assess their preferred method of OAT management. Only 24% of the 50 respondents chose PST or PSM (12% for each method) as their first choice of management. This survey was published only as a letter, which provides only limited detail on why the potential uptake of self-monitoring was so low. (This study was published after the empirical work with patients in this research was conducted)

Recruitment and attrition rates cited in published trials of patient self-monitoring programmes also provide some indication of the proportion of patients who would be willing and able to undertake self-testing. These data have been analysed in three systematic reviews and are summarised in Table 15.

Systematic review	Number of trials included in analysis	Averages from pooled trial data
Connock (2007) ²⁸ <u>All data</u>	12	33% of eligible patients agreed to participate 80% of those randomised to self-monitoring were successfully trained and able to self-monitor 87% of these continued to end of trial
<u>UK specific data</u>	2	24% eligible patients agreed to participate 70% of those randomised to self-monitoring were successfully trained and able to self-monitor 80% of these continued to end of trial (14% of total)
Heneghan (2006) ⁹⁰	8	62 % could or would <u>not</u> participate 78 % of those enrolled continued to end of trial
Garcia-Alamino (2010) ⁹¹	14	68 % could or would <u>not</u> participate 75 % of those enrolled continued to end of trial

Table 15: Average recruitment and attrition rates from pooled published trials of patient self-monitoring of oral anticoagulation

Analysis of UK-specific data suggests that an average 14% of those on oral anticoagulation would be willing and able to self-monitor their oral anticoagulation. An audit conducted at University College London suggests that, outside of trial conditions, 44% of eligible patients would choose to self-monitor from the start of treatment, with 86% of these patients successfully completing training (38% of the eligible patients).⁸⁶

The reasons for dropouts in OAT patient self-monitoring trials may give an indication of potential barriers to successfully implementing and sustaining a self-monitoring service. In common with published studies on self-management of long-term conditions, the study authors have not always stated the underlying reasons for attrition. However, the authors of the reviews cited in Table 15, and a retrospective analysis of attrition rates in OAT patient self-monitoring trials by Carl Heneghan's team at Oxford,¹⁰⁴ have attempted to understand the reasons behind drop-outs in these studies. These include the following:

- Problems with monitoring device
- Physical limitations
- Problems attending training
- Failing training
- Stopping OAT
- A preference for other method of monitoring
- Loss of confidence in self-monitoring
- Adverse events
- Moving out of the area
- Poor compliance

3.10.2. Patient-centred barriers of patient self-management of long-term conditions

Few studies have explored the potential barriers to patients self-managing long-term conditions.¹⁰⁵⁻¹⁰⁹ Emotional factors – for example, depression, anxiety and stress - can pose difficulties, as can physical factors such as fatigue and pain, both in terms of active involvement and in limiting the mobility needed to access self-management education programmes. Lack of family support, financial concerns, time constraints and lack of information or knowledge emerged as common problems. A barrier cited by patients in all studies was poor communication with physicians or physicians' poor attitudes to self-management.

To help assess the impact of recent initiatives and to inform care policy, the Department of Health commissioned MORI to survey the English public on their attitudes and behaviours on the following aspects of self care:

- i. Leading a healthy lifestyle (including diet, exercise and lifestyle choices)
- ii. Self care of minor ailments
- iii. Self care of long-term conditions
- iv. Self care of acute illness after discharge from hospital

Over 3000 people were surveyed in two stages between August 2004 and January 2005, and the results published in the document *Public Attitudes to Self Care - Baseline Survey*, previously discussed in 3.9. Among other topics, the survey explored overall attitudes to self-care, barriers and facilitators to self-care and knowledge & information.⁹⁷

The results were promising in that 82% of those surveyed who had a long-term condition claimed that they played an active role in caring for their condition. However, levels of self-care activity were not consistent across all demographic groups; younger people, those aged above 85 years, less affluent deprived groups and those from ethnic minorities were less active. 87% of those with a long-term condition stated that they were interested or very interested in taking a greater role in their management.

In summary, there may be potential significant patient-centred barriers to the introduction of patient self-monitoring of OAT, as evidenced by the low recruitment and high attrition rates in published clinical trials. However, these barriers have not been systematically studied. The long-term conditions literature suggests that emotional factors, co-morbidity and a lack of support from their clinician can be barriers to self-management.

In addition to overcoming these potential barriers, there may be clinical, financial and service challenges to be overcome when introducing a patient self-monitoring service. Earlier in this chapter, the generation of concept areas based on the author's experience of developing innovative anticoagulation monitoring services was described (Table 12). These concept areas were as follows:

- i. Patient selection
- ii. Patient education
- iii. Clinical staff education
- iv. Financial implication
- v. Accountability

These may also mirror the challenges facing key stakeholders in establishing an OAT patient self-monitoring service, and will now be discussed.

3.11. Patient Selection

Not everybody will be willing, or able, to monitor their oral anticoagulation. There are no clearly defined selection criteria for OAT patient self-monitoring and no reliable way to predict who will be suitable for PST or PSM. Most of the published trials used highly selected groups of patients; the inclusion and exclusion criteria for these studies are summarised in Table 16.

Study	Inclusion criteria	Exclusion criteria
Self-testing		
White, 1989, USA ³⁸	Ability to use a coagulometer Home telephone <150 miles from hospital Long-term treatment plan (> 8 weeks)	Previous treatment with warfarin Non-compliance Alcoholism Memory impairment
Beyth, 2000, USA ⁷⁹	Inpatients aged > 65 years Treatment plan of > 10 days	Treatment with warfarin in previous 6 months Did not speak English
Gardiner, 2004, UK ⁷⁶	Treated with warfarin for >8/12 Record of good compliance	None stated
Self-management		
Sawicki, Germany, 1999 ⁴³	Long-term treatment Willing to participate	None stated
Cromheecke, Holland, 2000 ⁴⁴	Long-term treatment Taken warfarin for >6/12	None stated
Sidhu, UK, 2001 ¹¹⁰	Mechanical heart valve Lifelong treatment	> 85 years Visual difficulties
Fitzmaurice, UK, 2002 ⁸¹	Long-term treatment Treated with warfarin for >6/12 Sufficient vision Manual dexterity Good control within last 12/12 (60% within 0.5 units of target) Compliant with treatment Physically well Not anxious Sufficient cognitive ability	None stated
Gadisseur, Holland, 2003 ⁴⁵	Long-term treatment Taken warfarin for >3/12	Antiphospholipid syndrome Life-threatening illness Life expectancy < 1 year Diminished understanding Physical limitations (e.g. dementia, tremors)
Sunderji, 2004, Canada ⁸⁵	Taken warfarin for >1/12 Clinicians then selected patients for inclusion based on an assessment of their competency, compliance and willingness	Mental incompetence Language barrier Hypercoagulable disorder Unable to attend training
Voller, Germany, 2004 ¹¹¹	Long-term treatment Capable of reading & writing German	Not stated
Fitzmaurice, UK, 2005 ⁴⁹	Long-term treatment Taken warfarin for >6/12	None stated
Koertke, Germany, 2005 ¹¹²	Willingness to perform PSM	Chronic alcoholism
Menendez-Jandula, Spain, 2005 ⁸³	Long-term treatment Taken warfarin for >3/12 Ambulatory	Severe mental or physical illness without caregiver Unable to understand Spanish

Table 16: Inclusion and exclusion criteria used in key studies of patient self-monitoring of oral anticoagulation

UK consensus guidelines, issued by the British Society for Haematology, state that the individual should be on long-term treatment (because it can take up to three months for the patient to become used to managing their treatment), and that previous INR stability is not a prerequisite to home testing as previously unstable patients may benefit from increased frequency of testing and greater autonomy.⁵²

International consensus guidelines, compiled by representatives from the USA, UK, Germany and Denmark, recommend that patient self-management should be considered as an option for those on long-term anticoagulation, irrespective of educational background and social status. However, the patient (or carer) must be able to understand the concept of OAT and its potential risks.³⁶ In Germany, the patient is deemed suitable for PSM if they have sufficient manual skills and eyesight, an indication for long-term anticoagulation and are willing and motivated to accept responsibility for self-management.¹¹³

The UK guideline considers previous non-adherence as a contraindication for patient self-testing or self-management. However, a history of non-adherence either in terms in attendance at the anticoagulant clinic or taking warfarin, is an area of contention. Medication adherence is a complex construct, a full consideration of which is outside the scope of this literature review. Non-adherence can be considered as the extent to which a patient's behaviour differs from that expected by the prescriber.¹¹⁴ In broad terms, non-adherence can be viewed as two types: intentional and non-intentional. Unintentional non-adherence is usually associated with financial, physical or cognitive barriers to using medication. For example; the patient wants to follow the treatment plan but is prevented from doing so because they cannot afford the prescription charges or cannot open the medication packaging or cannot understand the instructions. As the name suggests, intentional non-adherence results from the patient actively deciding not to take the medicine as recommended.

However, although not yet explored, it is possible that poor adherence with OAT or clinic attendance may be improved with self-management.

Through a review of the literature and patient interviews, researchers from the King's Fund have identified factors that determine the likelihood that a patient with a long-term condition will self-manage.⁶⁵ These findings are summarised in Table 17.

Factor	Comments
Length of time since diagnosis	Involvement in self-management is likely to fluctuate over time. It may increase but, equally, may also decrease.
Stage of life when diagnosed	For example, being a parent + / - in full-time employment will influence the time commitment to, and importance placed on, self-management
Severity of disease	Increasing severity of disease decreases confidence to self-manage
Age	Participants are more likely to be younger
Support services	Support from parents, healthcare professionals and peers may influence compliance with self-management advice. Healthcare services need to be flexible enough to support self-management
Gender	Women are more likely to participate in self-management.
Social class	Participants are more likely to be middle-class
Level of education	Participants are more likely to be better educated. Lack of basic literacy skills, or for those whom English is not their first language, may be less likely to self-manage well

Table 17: Factors affecting people’s ability to self-manage identified from a literature review conducted by the King’s Fund.

From this research, a young, female, middle class, well-educated patient is most likely to be motivated to manage her disease. This does not describe most of the patients attending the Whittington Anticoagulation & Stroke Prevention Service. Although the local population are relatively young compared to the rest of England, with more residents in the 20-44 year age group, patients attending the anticoagulant are, on average, considerably older than this. The local population is very mixed, both in terms of socio-economic status and ethnic origins. Within both Islington & Haringey there is considerable social and economic deprivation.¹¹⁵

3.12. Patient Education and Training

Once it has been decided that a patient is suitable for self-monitoring of OAT, they will have to be educated how to do so safely.

Deciding on the content of an educational programme for those wishing to self-monitor their oral anticoagulation will be challenging. There is no standardisation of training, no nationally endorsed programme for patients in the UK and the educational needs of anticoagulated patients, including those willing to undertake self-monitoring of OAT, are not known.

The next section will review the published work on educating those who are self-monitoring their oral anticoagulation.

3.12.1. Educating patients who are self-monitoring oral anticoagulation

Most of the work in educating patients self-monitoring their oral anticoagulation emerged from Germany in the late 1990's.

The first account of a training programme for patients undertaking self-management of OAT emerged from Angelika Bernardo's 1996 account of her 10-year experience in training patients in self-management of OAT.⁴¹ Nurses and physicians delivered an educational programme comprising three one-hour sessions to familiarise patients with the coagulometer and five hours of theory.

Stefan Morsdorf, another German physician, developed a training programme for patient self-management that gained only very limited popularity.⁵⁹ It was a very intensive course and, consequently, costly to deliver. A physician and "other qualified personnel" delivered a programme usually comprising four 1.5-hour theory sessions and between two and six 1.5-hour practical sessions using multimedia, video and flipcharts. Older participants needed significantly more theoretical sessions. Trainees undertook an examination, which is not described.

In the late 1990s, Peter Sawicki & colleagues developed their seminal program, which has achieved far greater popularity.⁴³ This programme takes the form of didactic teaching supplemented with practical dosing exercises, and a nurse and physician deliver it to groups of between three and six patients over three weekly sessions of 60 to 90 minutes.

The content of the programme is well-described and it has been adapted and used by many researchers,^{44;83;111} including the Birmingham group in the UK group who have adopted a “train the trainer” approach where trained healthcare professionals train patients.^{81;116;117} However, it is not clear how the Sawicki program was developed, and there was no attention paid to behavioural interventions to improve patients’ motivation and confidence.

The training programmes described in the literature share common elements. These are described below:

- Delivered to small groups of usually between 3 and 6 patients. This is distinct from traditional anticoagulant training which is delivered on a one-to-one basis.
- Where stated, delivered by a physician and / or nurse
- Involve more than one session of varying duration (1 – 3 hours)
- Theoretical content of course broadly similar

Although the content of the PSM education programmes are well described, none of them have formally established patient education needs.

It is unclear if a lower intensity of training is required for self-testing, compared with self-management. There is a very small body of literature describing educational programmes for patient self-testing of OAT. Where patients were provided with education, this is not described in any detail^{76;80} and other researchers provided instruction on how to use the coagulometer only.¹¹⁸⁻¹²⁰ A group of Italian researchers demonstrated that patient self-testing could produce acceptable INR control in the absence of specific education.¹²¹ However, this group of patients were highly selected in that they had to pass the Hodkinson Abbreviated Mental Test (AMT) – a measure of concentration and memory levels – to be included in the study.

UK consensus guidelines for PSM / PST of oral anticoagulation acknowledge that standardisation of training is a “*pressing requirement.*”⁶²

However, providing educational support is, in itself, not enough; assurance that patients can self-monitor safely is also necessary. A few of the programmes used a form of examination, including a simple examination of ten questions with one or two-word answers⁴⁶ and a multiple-choice performance test at six-months.¹²² Of particular interest, is the study by Voller, as this included an assessment of knowledge, using a questionnaire, before, during and after the training programme.¹¹¹ The percentage of correctly answered questions was twice as high directly after the end of training and remained at least 90% of this level 6 weeks after completing training.

Retention of knowledge was further assessed by Voller two years later.¹²³ Using a questionnaire to assess a training programme developed for users of the ProTime coagulometer, in addition to statistically significant improvements in knowledge immediately post-training, they determined that knowledge was retained at six months.

3.12.2. Self-management education and long-term conditions

Despite a growing body of literature, the optimal content of a patient educational programme to support self-management is still unclear, largely due to methodological issues associated with the published trials. The content of interventions has not been described in sufficient detail to allow a thorough understanding, small sample sizes and short follow-up periods have been used and there is very little information regarding the stage of disease at which the intervention should be implemented.

Behaviourally oriented programmes to support self-management produce better results than more didactic programs, particularly in diabetes.⁷¹ In addition to disease specific information and technical skills – in the case of anticoagulation patient self-monitoring, how to measure blood INR – patients also need other skills to enable them to self-manage. Problem-solving skills are essential; the patient needs to be able to both identify & solve problems related to their condition. Additionally they need to develop self-efficacy and build effective partnerships with clinicians.

3.13. Education and Training for Staff

The patient is not the only individual who may need education and support. Information and knowledge, and support from healthcare professionals are likely to be key factors in increasing uptake of patient self-management.¹²⁴ Healthcare professionals will require the skills to enable patient empowerment and facilitate effective self-management. Most professionals are skilled at managing patients' acute conditions, with treatment provided by clinicians and little contribution expected from the patient. However, they may not possess the communication skills that could improve patients' self-management.¹²⁵

There is currently very little evidence on how to educate healthcare professionals on how to support patients who wish to self-manage. Healthcare professionals may need training in skills such as group facilitation, goal setting, problem solving and cognitive behavioural techniques. Encouragingly, the new GP curriculum focuses on self-care.⁷⁴

3.14. Financial implications of patient self-monitoring of oral anticoagulant therapy

At this time (2011) of limited resources for healthcare, careful attention has to be paid to the cost of any new service development. Cost data are complex and there are no established standards for assessing the economics of point-of-care testing.¹²⁶ Test strips cost in the region of £2.50 to £2.70 per test and can be prescribed on the NHS. In 2010, the NHS in England spent over £2 million on INR testing strips prescribed on GP prescriptions.¹²⁷

The need for the patient to purchase the coagulometer adds further complexity, and it is unclear how willing, or able, UK patients are to buy a coagulometer.

Two UK analyses, described below, have assessed the financial implications of patient self-monitoring of OAT. There is also cost associated with training and assessing patients, and this was included in both analyses. Neither analyses support the cost-effectiveness of patient self-monitoring.

A cost-utility analysis was conducted alongside the SMART trial, the largest UK PSM trial.¹²⁸ Costs were estimated not only from a National Health Service perspective, but also from a wider societal perspective, accounting for costs borne by a random sub-sample of patients. This analysis not only factored in patients' time associated with clinic visits, but also considered activities that the patient had to forego to attend clinic appointments.

Costs of each model of care were estimated in two ways: the costs over 12 months to the NHS and the patient; and by a cost-effectiveness analysis using the outcome data generated by the SMART trial and results from quality of life questionnaires sent to study participants.

In terms of annual costs, patient self-management was more expensive than routine care, costing the NHS £417 per patient per year, compared with £122 for routine care. However, the mean costs to the patient were more in the control arm (£57) than in the PSM arm (£46).

Cost effectiveness was measured by the cost of monitoring per quality of life adjusted year – £ per QALY. The quality of life adjusted year is an internationally recognised method to measure the clinical effectiveness.¹²⁹ The QALY method uses health outcomes, including side effects, and quality of life measures to calculate how many extra months or years of life of a reasonable quality a person might gain as a result of treatment. The cost-effectiveness of a treatment is then assessed by considering how much the treatment costs per QALY. This is the cost of using the treatment to provide a year of the best quality of life available and is expressed as '£ per QALY'. The National Institute for Health and Clinical Excellence (NICE) is the body that makes recommendations to the NHS on medicines, treatments and

procedures, and it uses QALYs to measure the cost-effectiveness of these interventions. It considers interventions that cost more than £20,000-30,000 per QALY not to be cost effective.

Using this cost-effectiveness criterion applied by NICE, PSM did not fare well. At a cost-effectiveness threshold of £20,000 per QALY, PSM had a probability of only 30% of being cost-effective, and 46% at £30,000 per QALY.

In 2007, the NHS Health Technology Assessment (HTA) Programme commissioned the West Midlands HTA Collaboration to examine the cost-effectiveness of patient self-monitoring of anticoagulation treatment.²⁸ They estimated that wide adoption of PSM of OAT (one quarter of eligible patients, estimated at 0.6% of general population) would cost the NHS an additional £8 – 14.3 million per year. It is important to note that the cost of the machine was included in the costs to the NHS. By excluding this cost, the costs to the NHS are reduced considerably (by £4.6 – 6.8 million).

Aside from the cost of machines and testing strips, and that of training and assessing patients, the lack of adequate reimbursement may represent a barrier to potential uptake in the UK. Hospitals are paid for each outpatient clinic appointment, instead of receiving an *en bloc* payment as has been the case in the past. Therefore, the movement of patients away from the traditional outpatient setting could represent a substantial loss of revenue for the acute hospital Trust. It is quite feasible that whilst commissioners may embrace an OAT self-monitoring model, hospital managers may be opposed to patient self-testing.

There have also been published cost-effectiveness analyses from USA, Germany and Canada.¹³⁰⁻¹³² However, these are not transferable to the UK due to differences in the healthcare systems and estimation of costs.

In broader terms, although trials are ongoing, the current evidence base does not support the cost effectiveness of self-management of long-term conditions.¹³³ Consequently, as commissioners may not wish to fund a service with unproven cost-benefits, this may represent a barrier to the uptake of OAT patient self-monitoring. Part of this research will seek the views of commissioners to establish if this is the case.

3.15. Accountability in patient self-monitoring of oral anticoagulant therapy

Accountability sits at the heart of clinical governance, the framework for maintaining and improving the quality of healthcare in the NHS.¹³⁴ Accountability is a complex construct, and a comprehensive consideration of it is outside the scope of this literature review. However, in a broad context, accountability refers to individuals' responsibilities for a set of actions.¹³⁵

Traditionally, in paternalistic care models, accountability has focused on the clinician's competence and ethical and legal conduct. But the emergence of shared decision-making, with the patient playing an active role in their treatment decisions, challenges the clinician's ability to be wholly accountable for the care provided. UK law, predicated on the assumption that the clinician solely has the training and skills to make treatment choices, does not reflect this shifting relationship, and has been static for many years.¹³⁶

Thus, it is not clear where accountability for patients self-monitoring their OAT rests. From a legal liability perspective there are two key questions. Firstly, if something goes wrong is there a basis for legal action against the clinician? Secondly, by discharging more responsibility to the patient, has he / she taken on new risks of liability for the mistakes made by the patient? This is important to consider for the following reasons:

- As discussed above, the patient is taking over historically medical functions
- Patient self-monitoring of OAT is a new, innovative service. It represents a change from previous practice and medical advances are often imperfect when first applied.⁸
- Patient self-monitoring is an emerging method of monitoring OAT. As discussed earlier, its benefits remain to be conclusively proven.

As of October 2011, there had been no test cases associated with patient self-monitoring of OAT (similarly, there have been no cases associated with self-monitoring of blood glucose).

Accountability can also be considered in ethical terms. Empowering patients to self-monitor should not be viewed as a ‘responsibility dump’, and patients need support to preserve and develop their autonomy.¹³⁷ For this model of care to be ethical it should improve benefits, decrease harm and be equitable. Whilst patient self-monitoring is at least as safe as routine care and may reduce mortality and thromboembolic events without an increase in major bleeding, the evidence is not compelling. Although published trials do not suggest that patient self-monitoring of OAT causes excess harm, again, the evidence base is relatively small. Also, harm is not confined to mortality and bleeding events. Educational preparation is necessary for OAT patient self-monitoring, and there is a risk that this could invoke fear, depression, confusion and loss of confidence.

In terms of equity, patient access to self-management programmes for long-term conditions appears skewed in favour of higher socioeconomic groups.¹³⁸ There is, therefore, the risk of widening the gap between the ‘haves’ and the ‘have-nots’.

In summary, there is a lack of clarity as to where accountability sits with OAT patient self-monitoring, both in clinical and liability terms. Healthcare professionals’ views are required to establish if this is barrier to uptake of this model of care. In ethical terms, establishing an OAT patient self-monitoring service may present challenges. Patient participation in this model of care is predicated on their ability to purchase a coagulometer, which may exclude some of less affluent members of the clinic population.

3.16. Successful approaches to OAT patient self-monitoring

It is difficult to tease out the successful approaches to establishing and delivering an OAT patient self-monitoring service. In the last chapter, the position of self-monitoring in two countries that have achieved a greater uptake – Germany and USA – was contrasted with the UK. There are factors in these countries that may have facilitated this model of care, and these are listed below:

- i. Initiation of self-monitoring early in treatment
- ii. Nationally approved training scheme for both patients and healthcare professionals
- iii. Reimbursement to patient for coagulometers and consumables
- iv. Reimbursement to healthcare professionals for training and monitoring
- v. Strong advocacy

However, it is not known if these factors are transferable to the UK.

3.17. The information gap

In this chapter, the evidence supporting patient self-monitoring of OAT has been critically appraised, and any literature highlighting benefits, barriers, and challenges has been identified.

One of the aims of this literature review was to identify gaps in knowledge and understanding. What has been learnt and, more importantly, what is still to be understood is summarised in Table 18.

Topic area	What is known	What is not known
Benefits of OAT patient self-monitoring	In terms of INR control, OAT patient self-monitoring is at least as safe as standard management. It results in fewer deaths and thromboembolic events without causing any more bleeding It may increase patient self-efficacy and reduce “daily hassles”	Does OAT patient self-monitoring increase patient empowerment, increase satisfaction or reduce reliance on healthcare services. The benefits of OAT patient self-monitoring to healthcare staff and healthcare system.
Can lessons be learnt from patient self-management of long-term conditions?	Evidence from self-management of long-term conditions is equivocal. It may be more effective where the goals of treatment are clearly defined (e.g. blood glucose)	
Barriers to OAT patient self-monitoring	Published trials of PSM / PST of OAT have low recruitment and high attrition rates. Pooled trial data found that 68% of those eligible could or would not take part.	The reasons behind these rates have not been systematically documented. There are no prospective data to indicate the UK uptake of OAT patient self-monitoring outside of trial conditions
Can lessons be learnt from patient self-management of long-term conditions?	Barriers to self-management of long-term conditions include emotional factors, physical limitations, lack of support from family and clinicians, financial concerns and a lack of time and knowledge. There may be reluctance amongst clinicians to relinquish control. Clinicians’ poor attitude is a barrier to self-management.	
Successful approaches to OAT patient self-monitoring		Successful approaches to patient self-monitoring of OAT are not known
Can lessons be learnt from patient self-management of long-term conditions?	The support of healthcare staff is key to success in self-management of long-term conditions	
Challenges of OAT patient self-monitoring	OAT patient self-monitoring is unlikely to be cost effective	It is unclear how many patients would be prepared to buy a coagulometer There are no clearly defined patient selection criteria There is no standardised educational programme for those wishing to self-monitor OAT There is no evidence on how to educate healthcare professionals on how to support self-monitoring patients It is unclear where accountability lies if something goes wrong
Can lessons be learnt from patient self-management of long-term conditions?	A young, female, middle class, well-educated patient is most likely to be motivated to manage her disease	

Table 18: OAT patient self-monitoring – gaps in knowledge and understanding

3.18. The research problem

It is estimated that just under a million people in the UK take oral anticoagulation therapy.²⁸ The vast majority of patients are monitored through dedicated anticoagulant clinics, in primary or secondary care. With the development of coagulometers from the late 1980's, there has been growing interest in patients self-monitoring their INR. OAT patient self-monitoring appears to be a promising, innovative way of using available technology to reshape service delivery in the UK. It is in keeping with changing patient expectations; it has the potential to increase capacity; it is in line with Governmental policy; the technology is robust and there is published evidence to support its safety. Whilst there have been small pockets of interest in the UK, (the Birmingham primary care service, North Middlesex Hospital, and Barts and The London for example), there has not been widespread adoption of this form of service delivery.

My view is that we are unlikely to see widespread adoption of OAT patient self-monitoring until service providers have a clear understanding of the requirements of such a service. With clear requirements from the key stakeholders, providers would be in better position to design a service that would ensure that self-testing would gain the endorsement of patients, clinicians and managers.

In the absence of support from key stakeholders – patients, clinicians and healthcare managers - successful migration to a self-monitoring service is unlikely. The literature review has revealed that the views of key stakeholders – patients, clinicians and healthcare managers — have not been systematically studied. This leaves significant gaps in our knowledge of the requirements for an OAT service aimed at supporting patient self-monitoring. The focus of published work has been evaluating the safety of OAT patient self-monitoring, there has been very little work done on the how this type of shared care is perceived by patients, clinicians and service managers.

Therefore, there is a need to understand from patients, healthcare professionals and managers the drivers for, the benefits of, the barriers to, and challenges of, establishing an OAT patient self-monitoring service to derive these requirements. The next chapter describes the methodological approach taken to investigate the views of these stakeholder groups.

CHAPTER FOUR: MATERIALS AND METHODS

A review of the literature, described in the last chapter, established the following:

- That the drivers, benefits, barriers and challenges to adoption of patient self-monitoring of oral anticoagulation have not been well investigated, resulting in significant gaps in knowledge (Table 18)
- That the views of the key stakeholders in an oral anticoagulation patient self-monitoring service have not been systematically studied.

Therefore, the purpose of this research was to investigate key stakeholders' perspectives of the drivers, benefits, barriers and challenges to adoption of patient self-monitoring of oral anticoagulation. By involving these stakeholders, it was hoped to gain a more comprehensive understanding of the feasibility and impact of introducing a patient self-monitoring service, and to derive a set of requirements for a service model that encourages OAT patient self-monitoring.

The first part of this chapter will discuss the purpose and aims of this research and the methodological approach taken. Then, the design of the research, the methods used and the data analysis process will be given. Finally, the setting in which this research took place will be described.

4.1. Purpose and aims of the research

The purpose of this research was to establish the requirements of a service designed to support OAT patient self-monitoring.

The specific aims are as follows:

- i. To understand, from patients who are already self-testing, the key drivers, benefits and challenges
- ii. To explore the perspectives of different stakeholders (patients, clinicians, managers) on warfarin patient self-testing and self-management, including drivers, benefits, barriers and challenges
- iii. To define the requirements of a service model to support OAT patient self-monitoring

4.2. Methodological approach

A combination of qualitative and quantitative techniques was used for this research.

Qualitative research, traditionally used in social sciences, is used to gain an in-depth understanding of the meanings that people attach to their behaviour, how they interpret situations, and what their perspectives are on particular issues. The most common qualitative methods are interviews, unstructured or semi-structured surveys and focus groups. The resulting unstructured data – for example, interview transcripts, open-ended survey responses - are then usually analysed by categorisation.

By contrast, quantitative research ‘measures’. It refers to a systematic investigation, in which findings are expressed numerically to summarise and describe variables, and to examine the relationships among variables. Examples of quantitative research are randomised controlled trials and structured surveys.

The main focus of this research was to investigate key stakeholders’ perspectives of the drivers, barriers, benefits and challenges to adoption of patient self-monitoring of oral anticoagulation. As an in-depth understanding of the views of these key stakeholders was desired, a largely qualitative approach was adopted using interviews, semi-structured questionnaires and focus groups.

However, for the purposes of this investigation, an exclusively qualitative approach would not be sufficient. Quantitative analysis was desirable for two main reasons. Firstly to estimate the prevalence and strength of opinion – particularly of patients - uncovered through the qualitative studies. Secondly, it was desirable to see which patient characteristics – for example; age, duration of treatment with OAT - were associated with a willingness to self-monitor their OAT, and a qualitative quantitative analysis would test the relationship between variables with greater precision than a purely qualitative analysis. Therefore, a semi-structured questionnaire survey, which would yield data for quantitative analysis, was included.

Additionally, to ensure that self-testing was a safe option in the local patient population, a numerical analysis of INR control during the PST pilot was required, which is also a quantitative analysis.

In summary, qualitative methods were used to explore topics and identify and understand in detail the potential drivers, benefits, barriers and challenges, inevitably using small numbers of stakeholders. A quantitative analysis was applied to assess the prevalence and distribution of these viewpoints across a wider patient community, and also to assess the effectiveness and safety of a patient self-testing pilot study.

4.3. Research design

Redesigning an anticoagulation monitoring service model to embrace patient self-monitoring must result in high quality care, be acceptable to commissioners, service managers, patients, carers and staff, and have no adverse budgetary implications. To ensure that a redesigned service aimed at patients who self-monitor met their needs and at the same time identified and mitigated any potential risks to the health service, a set of requirements needed to be elaborated. Donabedian's triad of structure, process and outcome was used as a framework to analyse the requirements of a service model for patient self-monitoring of OAT, and this has been described in Chapter 1.

This research entailed eliciting from key stakeholders the drivers, benefits, barriers and challenges to warfarin patient self-testing and self-management were perceived to be. From these perspectives, the candidate requirements for a service that supports OAT patient self-monitoring were derived, in terms of the structure, process and desired outcomes. These candidate requirements were then tested by implementing and evaluating a PST pilot. The research design is summarised in Figure 6.

Patients' perspectives on self-monitoring of OAT were determined through three studies. Firstly, a small group of patients who were already self-monitoring their OAT were interviewed to provide an insight into the potential drivers, benefits and challenges to self-monitoring. Their views informed the next study; interviews conducted with a cohort of anticoagulated patients who were not self-monitoring to elicit their perspectives on OAT patient self-monitoring. These interviews were then used to develop an instrument to explore the perspectives of a larger group of patients on OAT patient self-monitoring, the final patient-centered study. The results of these three studies were then triangulated to produce a set of patient-centred candidate requirements for an OAT patient self-monitoring service

The perspectives of healthcare personnel – clinicians, commissioners and hospital managers - were gained through two focus group meetings. Through this exploration of the drivers, benefits, barriers and challenges of OAT patient self-monitoring, a second set of candidate requirements for an OAT patient self-monitoring service was derived, this time from a healthcare personnel point-of-view.

Lastly, these two sets of candidate requirements were combined and validated through a patient self-testing pilot. The safety and acceptability of this pilot service was evaluated through auditing the INR control of participants, and through the views of clinicians and patients.

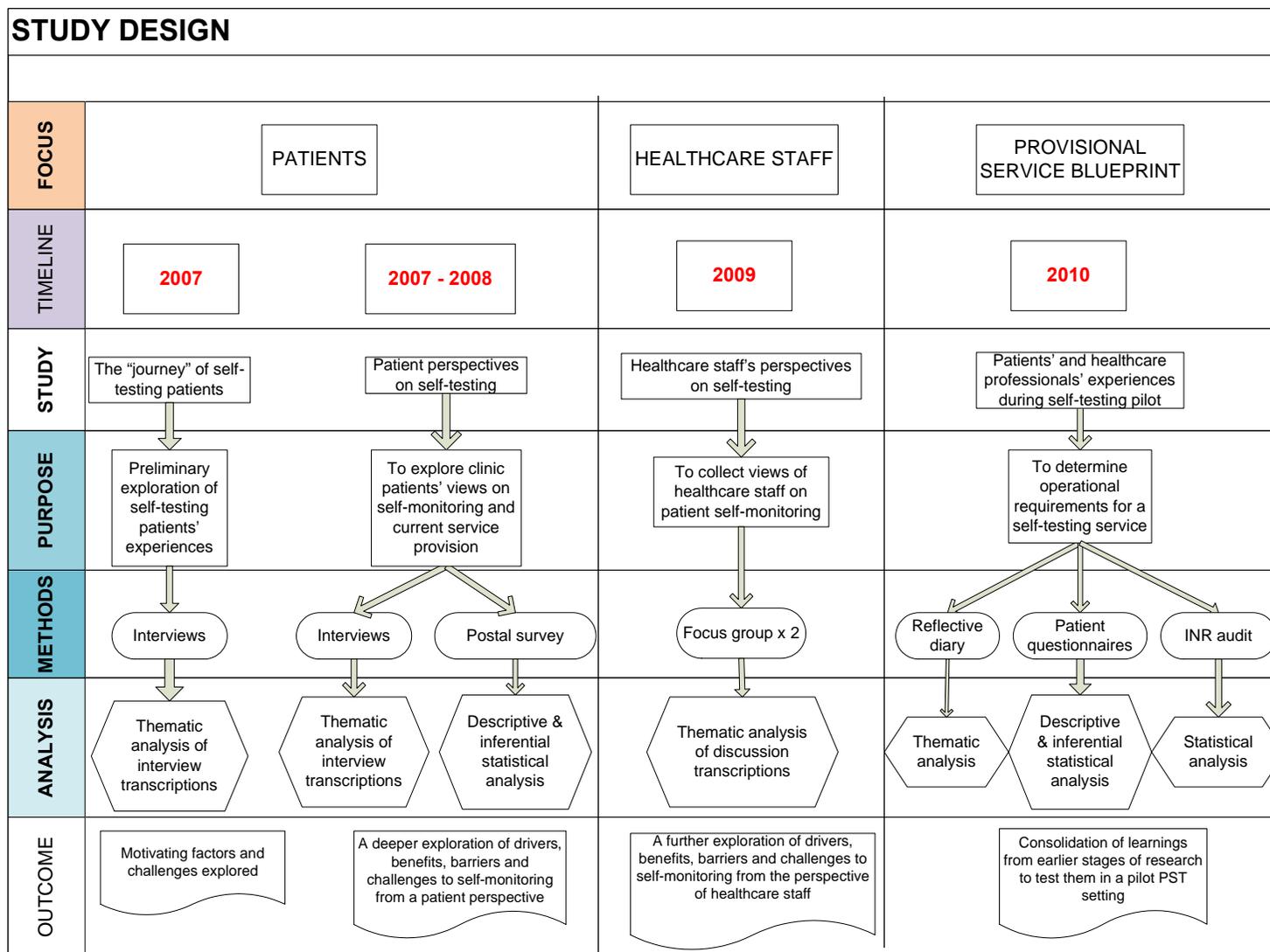


Figure 6: Research design for the investigation

In this investigation, the results from one study helped to develop and inform subsequent studies – for example, the patient interviews were used to develop and pilot the final patient questionnaire. But equally importantly, the results were complimentary - ‘hard data’ from the patient survey with patients’ views and experiences from both the survey narrative and the in-depth interviews.

The detailed method of each study is described in the relevant later chapter, along with the results obtained, and how these were then used to inform the subsequent studies. The next section discusses in general terms the methods used in this investigation .

4.4. Methods

There were three main stages to this research: eliciting patient views; exploring the perspectives of clinicians, healthcare hospital managers and commissioners; and testing a draft candidate service model requirements through a PST pilot. This research used patient questionnaires, one-to-one interviews and focus groups, which were applied across the main stakeholder groups:

Patients’ views assessed through	- interviews - questionnaires
Clinicians’ views assessed through	- focus groups - interviews
Healthcare managers’ views assessed through	- focus groups
Commissioners’ views assessed through	- focus groups

In addition, the following were undertaken during the PST pilot:

- i. Audit of INR results
- ii. Analysis of clinicians’ narrative in patients’ electronic health records.

This section discusses these methods, the reasons for their selection, their advantages, threats to validity and reliability and the steps taken to minimise potential biases.

Biases in the design, sampling and the process of a study can threaten its validity and reliability. Much of the debate over the quality and usefulness of qualitative research centres on the concepts of validity and, to a lesser extent, reliability.¹³⁹ Validity refers to whether a data collection instrument measures what it aims to measure and how credible the findings are. Reliability refers to the consistency of the measurement, or the extent to which an instrument measures the same way each time it is used under the same condition with the same subjects.

4.4.1. Interviews

Patient interviews were used three times in this research:

- i. In a preliminary exploration of self-testing patients' motivations for, and experiences of, undertaking OAT self-monitoring.
- ii. To pilot the patient questionnaire (the design of which was informed by the above exploration)
- iii. To elicit the views of staff managing the PST pilot

Interviews were used for the following reasons. Low literacy is not an issue, response rates are higher and inconsistencies and misinterpretations can be checked. But, importantly, they allow more detailed questions to be asked and complex issues can be probed more deeply, which allows a more in-depth understanding of the phenomenon being evaluated. The data yielded are often good and rich.

Reflective diaries were considered for recording clinic staff's experiences and perspectives during the PST pilot. Although these had the potential to produce rich data, this approach was rejected for two reasons. Firstly, there was a desire not to add to the staff's already heavy work burden associated with establishing and supporting a new service. Secondly, there was concern that the enthusiasm for recording entries would tail off over the six-month pilot period.

Instead, the author had regular – at least two-weekly – oral progress updates with staff supporting the service; for the purposes of methodological approach, these will be considered as interviews.

However, interviews are more time-consuming and can be subject to interviewer bias. Interviewers can, knowingly or unknowingly, influence the responses to questions by asking leading questions, or even by their tone of voice, threatening validity. Bias can also be introduced through the eagerness of the respondent to please the interviewer, or from a tendency by the interviewer to seek out answers that support preconceived notions. In an attempt to reduce bias, an interview guide was used for each interview. Care also had to be taken that probing did not become intrusive.

To increase reliability, two researchers analysed the interview results independently.

4.4.2. Focus groups

Two focus groups were convened to explore the perspectives of healthcare staff; one for clinicians and another for healthcare managers (including hospital managers and commissioners).

Focus groups are “unstructured interviews with small groups of people who interact with each other and the group leader”.¹³⁹ In addition to being a quick and convenient way to collect data from several people simultaneously, group dynamics are used to stimulate discussion. This interaction not only highlights respondents’ attitudes and framework of understanding, but also may encourage participants to raise their own questions and issues.

However, focus groups carry the risk of bias. The composition of the focus group has to be carefully considered or more vocal members may inhibit those who more retiring. Most the participants were known to the author and, to minimise bias, the groups were balanced as much as possible in terms of age, sex and seniority and a relaxed setting was aimed for to establish the right atmosphere.

There are also opportunities for interviewer bias. To minimise this, a discussion guide was used to ensure questions were posed consistently, and to maximise consistency between groups, the same interviewer interviewed both groups.

4.4.3. Analysis of clinicians' narrative in patients' electronic healthcare records

As discussed earlier, interviews were conducted with anticoagulant clinic staff supporting the PST pilot to gain an insight into their experiences and perspectives of this draft service model. Additionally, the electronic anticoagulant record of each patient participating in the pilot was reviewed, and narrative from clinic staff recorded. This was done for two reasons:

- i. To capture perspectives that staff omitted to convey during the interviews
- ii. To capture information on patient adverse events

4.4.4. Patient questionnaires

Patient questionnaires were used three times in this investigation. Firstly, to explore the perspectives of patients on long-term warfarin on self-testing and self-management. Then again, later in the investigation, they were used to explore both the expectations and experiences of those participating in the PST pilot. These uses will now be explained.

4.4.4.1 Patient questionnaires used to explore the perspectives of patients on long-term warfarin on self-testing and self-management

A semi-structured questionnaire was used to explore the perspectives of those on long-term OAT because it would allow a large number of people to be sampled and would yield unambiguous answers, allowing quantitative analysis. This would allow associations between patient characteristics and views of self-monitoring to be tested. This method of data collection is also relatively cheap.

Although interviews or focus groups would have allowed more in-depth probing, they were not felt to be suitable for this investigation as large patient numbers were involved, and a quantitative analysis was desired.

However, questionnaires have disadvantages. The main weakness is that the pre-coded responses may not accommodate all possible answers. This may force respondents to select pre-coded responses that do not fully represent their views, threatening validity. To try to mitigate this, although the questionnaire was largely structured, it also contained some optional questions requiring a free text response.

The wording of a questionnaire is fundamental to both the validity and reliability of a study. Extensive piloting of this questionnaire was undertaken to minimise these biases. This was to ensure that the questions were clear and unambiguous, and that questions yielding unusable data were eliminated.

Although a self-administered postal questionnaire eliminates interviewer bias, it is less suitable for complex issues, for those with low literacy levels and, unless resources are put into translating the questionnaire, for those speaking the default language (English, in this case). As the interviewer is not there to clarify questions and responses, the data are generally less reliable than face-to-face interviews.

Non-response is a major source of potential bias in postal questionnaires. Not only does it reduce the effective sample size, the characteristics of responders and non-responders may be different which may introduce bias into the results. Careful design and testing were undertaken in order to optimise the response rate. Other steps were also taken to increase the response rate, including sending a covering letter and a postal reminder.

The development of this questionnaire is described in Chapter 5.

4.4.4.2 Patient questionnaires used to explore the expectations and experiences of those participating in the PST pilot

A questionnaire was also used to explore both the expectations and the experiences of those participating in the PST pilot.

Focus groups or one-to-one interviews would have allowed in-depth probing, permitting a greater understanding of the perspectives of this patient cohort. However, they would have been time consuming, in terms of both conducting the interviews and their analysis. Also, although there is no consensus on the optimal way to measure patients' expectations,¹⁴⁰ the majority of published evaluations of patient expectations have used self-administered questionnaires.¹⁴¹ Therefore, questionnaires were used in this investigation to measure patients' expectations of PST.

Questionnaires are also routinely used to measure patient experiences, particularly whilst they are in hospital.¹⁴² Therefore, questionnaires were also used in this investigation to measure patients' experiences of PST.

In contrast to the earlier survey, less structured instruments were used. These have the advantage of accommodating more patients' views, increasing validity. As they were shorter questionnaires sent to a smaller group of people, it was felt patients would be more likely to complete them, and that it would be feasible to analyse them.

To ensure that the questions were clear and unambiguous, and to eliminate questions yielding unusable data, these questionnaires were sent to experts for comments before administering. Again, a covering letter was used.

The development of these instruments is described in the relevant chapter.

4.4.5. Audit of INR results

Audit is conducted to ensure that quality in healthcare is achieved and maintained.¹³⁹ For patient self-testing to be viable, INR control must be at least as good as that achieved by routine (clinic) management. Although this has been demonstrated under trial conditions, as has been discussed earlier (3.6), it was also important to determine that self-testing is safe for patients outside of trial conditions. Therefore, at the end of the pilot period, the INR results for each patient were audited.

The process of data analysis for each of these three research methods used – questionnaires, interviews and focus groups - will now be considered.

4.5 The plan for analysis of empirical data

Although questionnaires, interviews and focus groups tell us what participants said, they do not provide explanations. A meaning has to be attached to these data by sifting and interpreting them.

The overall aim of the analysis of the empirical data generated in these studies was to describe the drivers for, benefits of, barriers to, and challenges of, patient self-monitoring of oral anticoagulation. From this, it was hoped to derive a set of requirements for an OAT patient self-monitoring service. The data analysis process is summarised in

Figure 7.

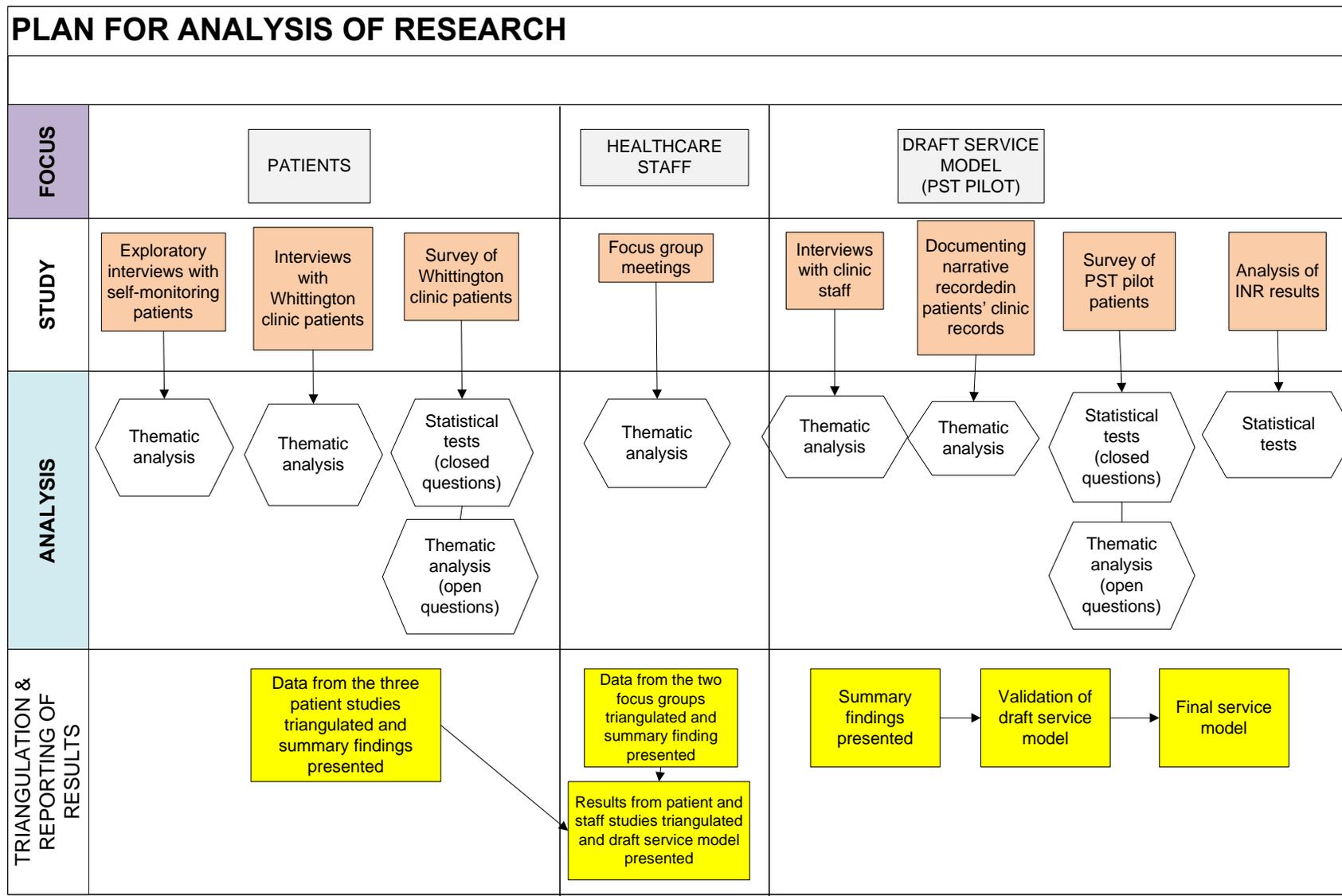


Figure 7: The data analysis plan for the investigation

4.5.1 Analysis of interview and focus group data

Thematic analysis was used to analyse the interview and focus group data. It is the most common type of qualitative analysis used in health care research.¹⁴³ This method was selected because it is of value in describing the important issues for a group of people.¹⁴⁴

An alternative method of data analysis would have been grounded theory. This is a process that results in a detailed account of the data, as opposed to describing themes. Practical constraints of time and funding meant that this type of analysis was not feasible. Grounded theory is an iterative approach: data are collected, analysed and coded, and then this cycle is repeated until the point of ‘saturation’ is reached, that is, no new constructs identified.¹⁴⁵ As this research was conducted within a deadline, it could not be guaranteed that saturation would happen.

However, although this was not a grounded theory research, a grounded theory approach was used. Open coding, a feature of grounded theory, is a line-by-line analysis to ‘open up’ the data, to generate as many themes as possible.¹⁴⁴ Although broad themes had already been defined from the research objectives – for example, the challenges and benefits of OAT patient self-monitoring – open coding was used to analyse the early data from the patient interviews to generate further themes. The iterative approach taken with grounded theory was adopted, in that the themes identified in earlier studies were verified in the later work.

4.5.2 Analysis of questionnaire data

A mixture of deductive and inductive analyses was applied to the questionnaires used to explore the perspectives of patients on long-term warfarin on self-testing and self-management. In induction, ideas are built from a set of observations which can be further tested. With deduction, there are general ideas to start with which are then tested.¹³⁹

Most of the questionnaire comprised questions for which there was a fixed response. Coding was mostly deductive in that previous knowledge and theory were used to construct the response categories. Descriptive statistics and bivariate analyses were then applied to pre-coded fixed questions. Descriptive statistics were used to summarise data; for example, the proportion of those willing to self-test. Bivariate analyses were used to determine the relationship between two variables; for example, if women were more likely to be willing to self-test than men. By contrast, inductive coding was used to categorise the responses to the open questions into themes.

The questionnaires used in the PST pilot comprised mostly open questions, the responses to which were categorised into themes. Descriptive statistics were applied to the few fixed-response questions.

4.5.3 Analysis of INR control from PST pilot

As described earlier, the PST pilot was evaluated by multiple methods: audit, patient questionnaires, unstructured interviews and document analysis. The analysis of questionnaires and interviews in this research has been described above.

The safety of the pilot service was evaluated by retrospective audit of the participants' INR results. Options for assessing the safety of anticoagulation control have been discussed previously (3.6.1). It was decided to use percentage time in therapeutic range (TIR) to assess INR control in this study, calculated using the method of linear interpolation described by Rosendaal et al.¹⁴⁶ Although it is more labour intensive to perform the calculations, it is subject to less bias and the relatively small patient numbers make it feasible.

However, this method is not without limitations. This calculation assumes a linear relationship between individual INR results, and the reality is that the INR will fluctuate between tests. In addition, small departures from the target range are treated exactly the same as larger deviations. Whilst the former will have little impact on event rates (i.e. thromboembolism / bleeding), the latter have a potentially greater impact. In an attempt to compensate for this, the proportion of tests above and below the therapeutic range were also recorded, as were the number of INRs <1.5 and >5.0, as the risk of thrombosis and bleeding are known to increase exponentially at these values.¹⁴⁷

Patients acted their own controls; INR values for the self-testing period were compared with the values recorded for the same set of patients in the six-months prior to the pilot. Inferential statistical tests were used to describe the differences between these two sets of values.

The narrative content recorded by anticoagulant clinic staff in the participants' electronic health record was analysed by thematic analysis. There are other techniques for analysing documents, including content analysis and semiotics.¹³⁹ Both of these techniques focus on the social and cultural context of the document, resulting in a highly structured and detailed report. As this part of the research was concerned largely with verifying themes that had emerged in the earlier studies, a thematic analysis was felt to be more suitable.

4.5.4 Triangulation of research data

Triangulation involves comparing the results from two or more methods of data collection (e.g. surveys and interviews) or from different data sources (e.g. patients and healthcare professionals).¹⁴⁵ This was carried out for the following reasons:

- i. It could offset any weaknesses of individual methods
- ii. It used the different perspectives to ensure that findings were as rich as possible.
- iii. It linked the qualitative and quantitative analysis

Triangulation of analysed data was conducted throughout this research:

- i. To compare and combine the results of the three patient studies
- ii. To compare and combine the results of the two focus groups
- iii. To compare and combine the results of the patient and healthcare professionals studies to produce a draft service model

Triangulated data are presented at the end of each relevant chapter. The draft service model – the candidate service requirements - is presented in a separate chapter. A framework based on the aims and objectives of the research, with each derived service requirement anchored to the relevant element of Donabedian’s triad, is used to present these results. Using the example of patients’ perspectives on the drivers for OAT patient self-monitoring, the template for this framework is shown below (Figure 8).

Drivers	Patient perspectives			Derived service requirement	Donabedian framework element
	Exploratory interviews with self-monitoring patients	Interviews with local anticoagulant clinic patients	Survey of with local anticoagulant clinic patients		
Convenience	Convenience cited as a major motivating factor for starting OAT self-monitoring	Convenience identified as a potential benefit	Patients were significantly more willing to self-monitor if clinic visits were disrupting their life	Self-monitoring service is acceptable to patients	Outcome
<i>Theme (i.e. driver 2) etc.</i>					

Figure 8: The framework for presenting triangulated research results

4.6 Materials

4.6.1 The setting: The Whittington Hospital

The Whittington Hospital employs over 2,000 staff and has 470 beds.¹⁴⁸ It is one of the teaching hospitals of University College London, providing clinical placements and training for doctors.

The Whittington is located in North London and predominantly serves the population of North Islington and West Haringey, which gives a combined total population of approximately 300,000. However, there may be significant under recording of population numbers in both Haringey and Islington due to the transient nature of the population and the large numbers of refugees and asylum seekers arriving in the area who have not yet registered in national statistics.

4.6.2 The research subjects

The local population is very mixed, both in terms of socio-economic status and ethnic origins. Within Islington and Haringey, there is considerable deprivation. Based on the borough average of the ward level scores for the DTLR (Department for Transport, Local Government and the Regions) Index of Multiple Deprivation 2000, which include a wide range of income, health and other deprivation indicators, both Islington and Haringey rank amongst the worst ten per cent nationally with very high average ward deprivation scores.¹⁴⁹ This has been proven to increase the risks of heart disease through smoking, hypertension, raised cholesterol, diabetes, physical inactivity and poor nutrition. Almost 17% (65,000) of those in Islington and Haringey have a limiting long-term illness.

30% of the population of Haringey and Islington are from ethnic minority groups, predominantly black Afro-Caribbean, Indian and Bangladeshi.¹⁵⁰ These figures are significant compared to a national (England and Wales) proportion of ethnic minorities of less than 9 %. This poses an increased specific health risk; deaths from heart disease are more common in people from the Indian subcontinent and deaths from stroke are more common in African and Caribbean people.

4.6.3 The service: The Whittington Hospital Anticoagulation Monitoring and Stroke Prevention Service

The Whittington Hospital has an Anticoagulation Monitoring and Stroke Prevention Service which provides INR monitoring, in the hospital or primary care setting, for those taking oral anticoagulants. Although the service offers traditional secondary care anticoagulation monitoring service as described above, it has been innovative in the development of other models of monitoring. The service's approach is a collaborative one; the Whittington service works closely with that at the North Middlesex Hospital and also with local PCTs to create a patient-centred, seamless service to their shared population.

At the time of starting this research, the next step in its development was establishing a patient self-monitoring service. This is the context and the setting in which this investigation takes place.

The Whittington Anticoagulation Monitoring & Stroke Prevention Service is managed by a full-time Anticoagulant Nurse Specialist, under the clinical direction of a Consultant Cardiologist. She is supported by two part-time pharmacists, a senior pharmacist with a responsibility for education and service development, a clinic care co-ordinator and phlebotomy services.

Additional staff provide a contracted outreach service to Barnet PCT. This service is led by a senior pharmacist, who also leads on clinical governance for this service and for the clinics operating within Haringey PCT, and he is supported by a junior pharmacist and an administrator.

Another pharmacist has responsibility for the clinical governance arrangements for clinics operating in Camden and Islington PCTs and leads on education and training for practitioners working in the service.

Finally, a senior pharmacist (the author) has management responsibility for the pharmacists working in the service and undertakes research and development.

The staffing for the service is summarised in Table 19.

Staff	Hours per week
Whittington service	
Consultant Cardiologist	7
Anticoagulant Nurse Specialist	35
Cardiology Pharmacist	11
Anticoagulation Support Pharmacist	18
Senior pharmacist	7
Clinic Care Co-ordinator	26
Phlebotomist / Laboratory MLSO	20
Barnet PCT	
Project lead (senior pharmacist)	28
Anticoagulant practitioner (junior pharmacist)	35
Clinic administrator	35
Camden PCT	
Clinical governance and education pharmacist	35
Total	292

Table 19: Person-hours at the Whittington Anticoagulant & Stroke Prevention Service (October 2010)

With the exception of the extra personnel required to support the Barnet service, staffing for the service has remained static during the total data collection period. As new patients are constantly received into the Whittington service and others discontinue warfarin, patient numbers are never static. As of December 2010, there were 1,250 patients under the care of this service. A total of 13,494 visits to the Whittington clinic occurred in 2010, and clinic numbers continue to grow, reflecting national trends.³¹ With the exception of an unexplained downward blip in 2007, the increasing workload at the Whittington anticoagulant clinic is has increased between 2006 and 2010 (illustrated in Figure 9).

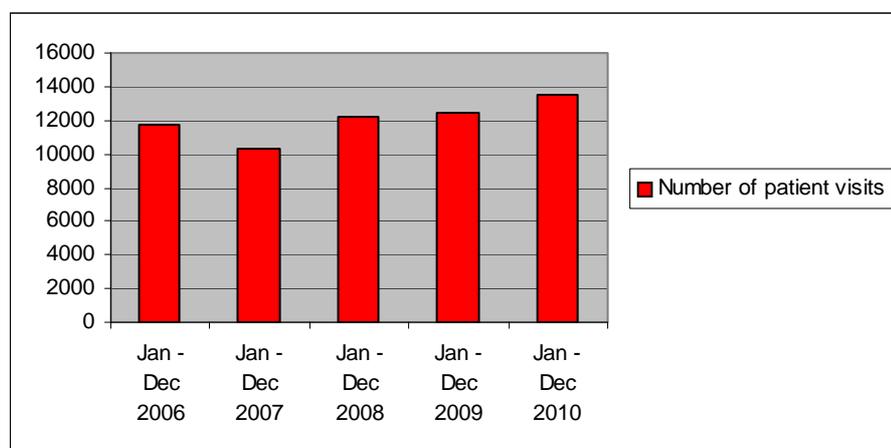


Figure 9: Number of patient visits to the Whittington anticoagulant clinic: 2006-10

Up to 300 patients attend the clinic each week, and there is an average of 7 new patients each week. Approximately 25% of clinic patients will wait to see one of the clinic staff. The remainder will travel home after phlebotomy and will be telephoned later the same day by the clinic staff with their INR and warfarin dose. Clinics are held on Monday – Thursday, with Friday reserved for emergencies only.

With the clinic operating to nearly full capacity and anticipated further increases in patient numbers, increasing pressure was being placed on both service premises and costs. The Whittington therefore actively encouraged the author to explore alternative models of service delivery for OAT monitoring. These will now be discussed.

4.6.3.1 Development of alternative models of service delivery

As discussed in Chapter 2, with the development of reliable & portable near patient testing (NPT) devices (coagulometers), it is no longer necessary to bring patients to the hospital for anticoagulation monitoring. Therefore, with appropriate support, it is now possible for the monitoring to take place in primary care and the Trust has been innovative in its developing its service to bring anticoagulation closer to the patient.^{13;151;152} This distributed service is summarised in Figure 10.

A successful nurse / pharmacist-led outreach service to two local GP surgeries has been running from the Whittington for the past 15 years. Approximately 80 patients attend these clinics. The anticoagulant nurse specialist or pharmacist visits these clinics every two weeks. Patients have timed appointments when their INR is measured by a NPT device from a capillary blood sample. The healthcare professional can then advise on the subsequent dose of warfarin from this test result. Approximately 15-20 patients are seen at each clinic (three-hour session). The travelling and waiting times for patients are negligible. Patient views of this service have not been formally assessed.

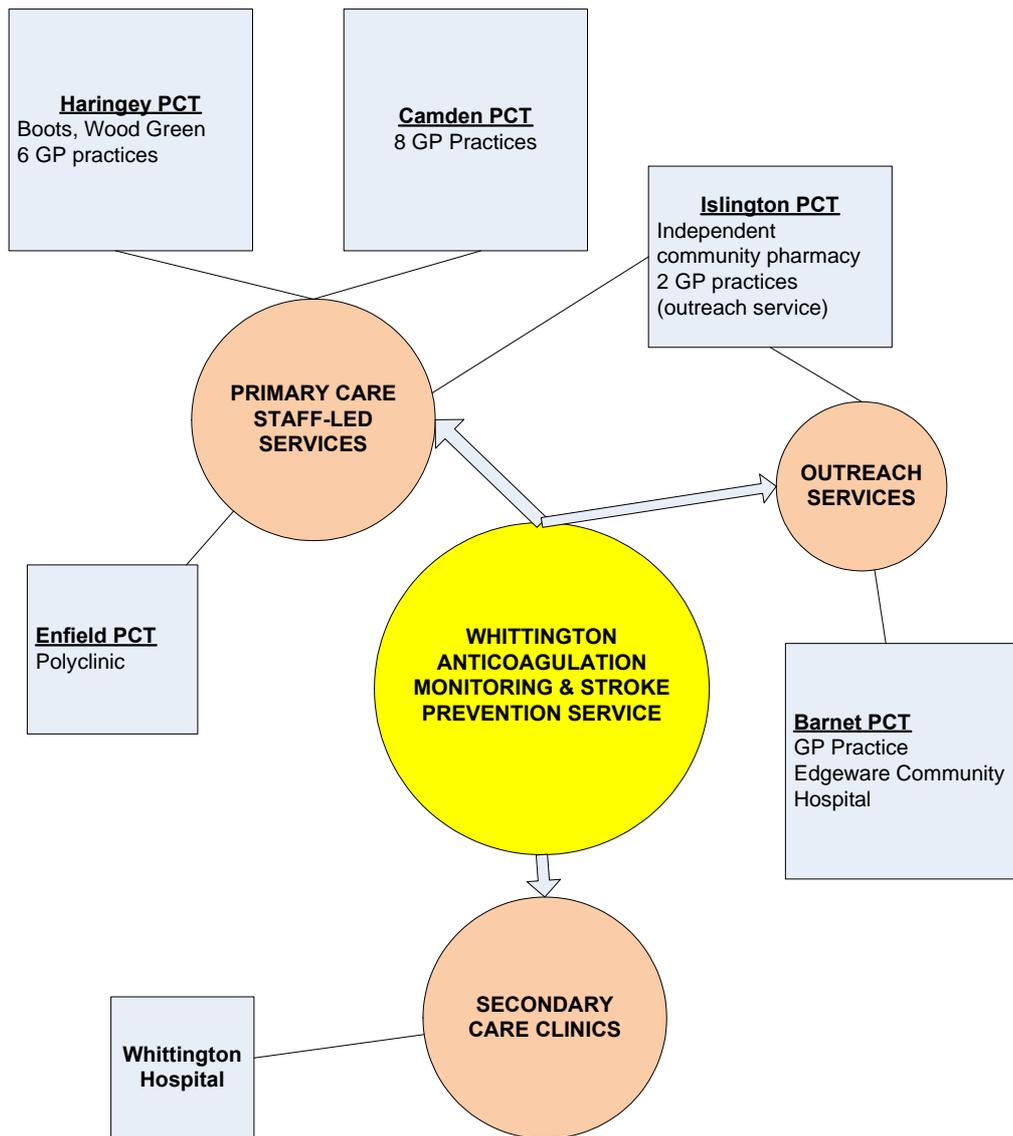


Figure 10: Distributed clinics of the Whittington Anticoagulation Monitoring Stroke Prevention and Service

A weekly community pharmacy service started in Islington in 2002, and Haringey in 2005. Patient views of the Islington service were formally assessed in 2003.¹⁵¹ Patient satisfaction was high with those interviewed found the service less disruptive compared to the hospital clinic.

As of March 2006, anticoagulation monitoring is one of the potential national enhanced services (NES) under the new GP contract.⁵³ These are services that were negotiated into the General Medical Services (GMS) contract as a key tool to help PCTs reduce demand on secondary care, and are commissioned to meet local need to national specifications and benchmark pricing. Under the terms of the Department of Health’s national specification for this service, providers would be responsible for sampling, testing and dosing patients according to locally agreed protocols approved by the Primary Care Trust (PCT).

As discussed in Chapter 2, when PbR was first introduced, a hospital commissioned anticoagulation monitoring service was considered expensive, resulting in local PCTs commissioning primary care anticoagulation monitoring services. The Whittington Hospital has worked closely with PCTs to facilitate the migration of anticoagulation monitoring service into the community.

Primary care anticoagulation monitoring services that have been commissioned locally are summarised in Table 20.

Year of starting	PCT	Service model	Number of sites (2010)
2002	Islington	Community Pharmacy (independent)	1
2005	Haringey	Community Pharmacy (Boots) GP practices	7
2007	Enfield	Community Pharmacy (Independent)	1
2008	Barnet	Outreach service from Whittington Hospital	2
2009	Camden	GP Practices	8

Table 20: Commissioned Primary Care Anticoagulation Monitoring Services in North London

This distributed service is supported by a robust clinical governance framework, which is underpinned by an electronic information management and advisory system and a structured education and accreditation programme. These components will now be considered.

4.6.3.2 Clinical governance framework of the Whittington Hospital Anticoagulation Monitoring and Stroke Prevention Service

The service has established a strong Clinical Governance Board for the North Central London Community based service. Membership of this Board includes patients; hospital consultants (haematology and cardiovascular); anticoagulant practitioners from each PCT; senior pharmacists with educational remit; senior pharmacists with governance remit; a commissioner from each PCT; a clinical GP lead from each PCT; an academic health informatist; an academic behavioural scientist and statistician; an academic legal advisor; an IT representative from Whittington Hospital.

The Clinical Governance Board reports both to the Clinical Governance Boards in the Hospitals as well as the Medicines Management Boards within the PCTs.

The clinical governance support offered to all clinic sites includes the following:

- i. Advice on complying with NPSA guidance in a community setting together with audit.
- ii. Access to INR result information by site, by INR range across the whole of North Central London Community sites. The Board receives anonymised INR data across all delivery sites in NC London – this forms a rich perspective of the anticoagulant and stroke prevention service by site, by dose range and by total service. It helps the declared intent that the service standards should aspire to be the same high quality for the whole of North Central London.
- iii. Access to collated information relating to NEQAS results and other quality measures
- iv. Access to quality measure of the educational processes
- v. Involvement in novel techniques to explore quality in service delivery and benefit from the learning that accrues; these techniques include “Root Cause Analysis”, “Cognitive Work Analysis”.
- vi. Access to our Clinical Standard Operating Procedures (CSOP) and Site Specific Operating procedures (SSOP).
- vii. Optional central clinical monitoring service, for audit and governance, by our anticoagulation experts
- viii. Optional clinical support telephone/email service.

The information management system and education and accreditation programme play key roles in supporting the service’s clinical governance framework. These will now be discussed.

4.6.3.3 The information management system

The service is supported by an electronic management and advisory system for anticoagulation and stroke prevention, which is a module of the underlying Electronic Health Record (EHR). It is a secure, web-enabled system available to any authorised clinician wherever they are situated, whether this is in the hospital environment or in primary care.

It has been developed by CHIME (UCL Centre of Health Informatics and Multiprofessional Education) and draws on experience of over a decade of European work. It plays a key role in the delivery of the clinical governance agenda, and also has modules for the management of patients with heart failure and coronary artery disease. The system has the following key features:

- i. Comprehensive electronic health record server
- ii. Consolidates all disease information into a whole-person record
- iii. Demographics service for patients and staff users
- iv. User authentication and role-based access policies
- v. Rigorous medico-legal and information governance of clinical data
- vi. Auditing of data entry, changes and of all accesses
- vii. Viewable audit log, to support security policy management
- viii. Standards based architecture (EN 13606), optimised for interoperability
- ix. Easy integration of other systems and data feeds
- x. Easy generation of messages in other standard formats

The anticoagulant module has the following key features:

- i. Trial-validated anticoagulation dosing and monitoring algorithms^{153;154;154}
- ii. Anticoagulant treatment plan management
- iii. Advisory system offers warfarin dosing and recommended monitoring interval
- iv. Ability to record adverse events
- v. Access to INR result information is offered in a confidential and customisable form. It can be accessed on a daily, weekly or other chosen interval at different levels; at a practitioner level; at a site level; at a PCT level; at a North Central London level; at a total service level
- vi. The INR data can be explored by therapeutic range level; by age; by date range
- vii. The INR data has the ability to be contrasted with INR results over the past 20 years.

This electronic management and advisory system was used by clinic staff to support the PST pilot.

4.6.3.4 Education and accreditation programme

The author has played a leading role in developing and delivering an education and accreditation programme for practitioners managing warfarin treatment. The education and accreditation programme has been created and designed in a flexible manner to enable safe practice in dealing with fundamental and more complex problems of oral anticoagulation and stroke prevention management in the outpatient or community settings. It aims to impart an understanding of the theory underpinning anticoagulation management together with training in the practical competencies that are required.

The course consists of one full day devoted to the required knowledge base and training in the use of the coagulometer and the electronic management and advisory system. This is followed by two half days of small group attendance at an anticoagulant and stroke prevention clinic, in which the knowledge and skills acquired can be practised in a supervised environment. All prospective anticoagulant practitioners will sit an OSCE (Objective Structured Clinical Examination) which comprises six “stations” which test the knowledge and competencies required to safely anticoagulate patients.

All practitioners are re-accredited every two years. The knowledge components include:

- i. An understanding of the pharmacology of vitamin K antagonists and the relevant medications
- ii. Blood coagulation, INR, Pharmacokinetics, Indications for anticoagulation
- iii. Side effects
- iv. Warfarin drug interactions
- v. Clinical governance

The skill components include:

- i. Using the coagulometer and the techniques of finger prick sampling of blood
- ii. Electronic management and advisory system demonstration
- iii. Patient counseling
- iv. Warfarin monitoring and dose adjustment together with case scenarios

Example pages from the educational workbook used in this programme can be found in Appendix 1.

4.6.3.5 The future direction of the Whittington Hospital Anticoagulation Monitoring and Stroke Prevention Service

The strategy of the service is to move, at a safe rate, towards a distributed service where the more complex patients have their anticoagulant control managed in the hospital setting (10-15%). The remainder will be managed in the following settings:

- i. The GP setting delivered by a practice nurse or the GP
- ii. An outreach service from the hospital to the GP practice
- iii. The Community Pharmacy
- iv. The patient self-testing
- v. The patient self-managing

A pilot self-testing service forms part of this strategy.

The service is conceptualised in Figure 11.

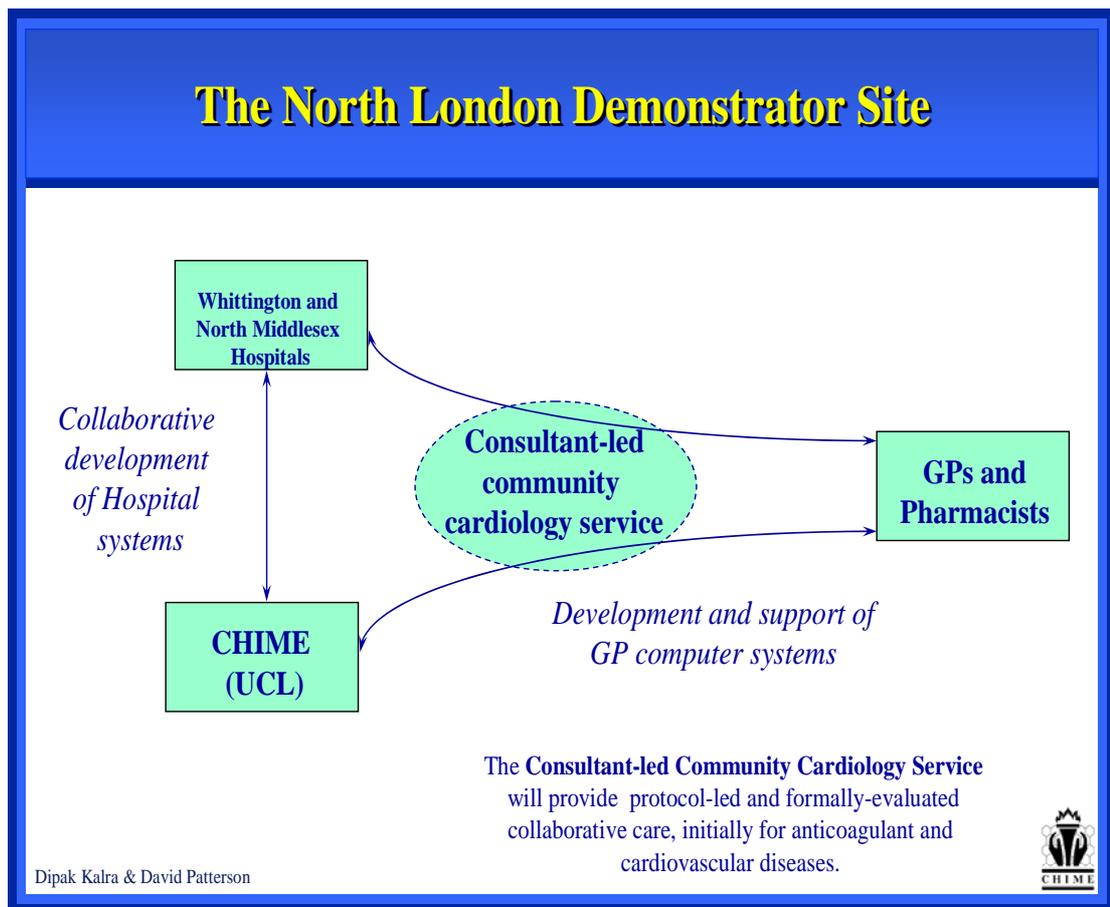


Figure 11: Conceptual model for The Whittington Hospital Anticoagulation Monitoring and Stroke Prevention Service

The Whittington cardiovascular service, of which the Whittington Hospital Anticoagulation Monitoring and Stroke Prevention Service forms a part, has been awarded the Government’s highly prestigious Customer Service Excellence standard, in recognition of the high level of customer care it provides. It is the only clinical cardiovascular department in the UK to have achieved this standard. Moreover, the anticoagulation monitoring and stroke prevention service has been singled out for an additional accolade; a recommendation has gone to the Cabinet Office to recognise the service as an example of transformational practice.

4.7 Endnote

This chapter has described the methodological approach, the research design, the methods used in this investigation, the data analysis process and the setting in which the research was conducted. The following three chapters will report on the results of this empirical work.

CHAPTER 5: PATIENTS' PERSPECTIVES ON SELF-MONITORING OF ORAL ANTICOAGULATION

Although the literature indicates some of the potential barriers and challenges to the adoption of patient self-monitoring, the views of patients have not been systematically studied. The work described in this chapter aims to fill that gap in knowledge.

The purpose of the work described in this chapter was to explore the perspectives of patients on warfarin self-testing and self-management. From establishing the patient-centred drivers, benefits, barriers and challenges of OAT patient self-monitoring, it was hoped to derive a set of suggested, or 'candidate', requirements of a service designed to support OAT patient self-monitoring.

Patients' perspectives on self-monitoring of OAT were determined through three studies. These studies were:

- i. An exploration of the experiences of self-monitoring patients
- ii. In-depth interviews with local patients who were not self-monitoring
- iii. A survey of a larger population of local patients who were not self-monitoring

These three studies were undertaken in a deliberately sequential fashion, with the results of one study informing the next (Figure 12).

Firstly, a small group of patients who were already self-monitoring their OAT were interviewed to provide an insight into the potential drivers, benefits and challenges to self-monitoring. Their views informed the next study - interviews conducted with a cohort of anticoagulated patients who were not self-monitoring to elicit their perspectives on OAT patient self-monitoring. However, the primary aim of these interviews was to develop an instrument to explore the perspectives of a larger group of patients on OAT self-monitoring, the final patient-centered study.

The approach to analysis of these studies, including triangulation of results, has been previously described (4.5). Once the data from all three studies had been analysed, these results were triangulated and a summary of these results is provided at the end of the chapter.

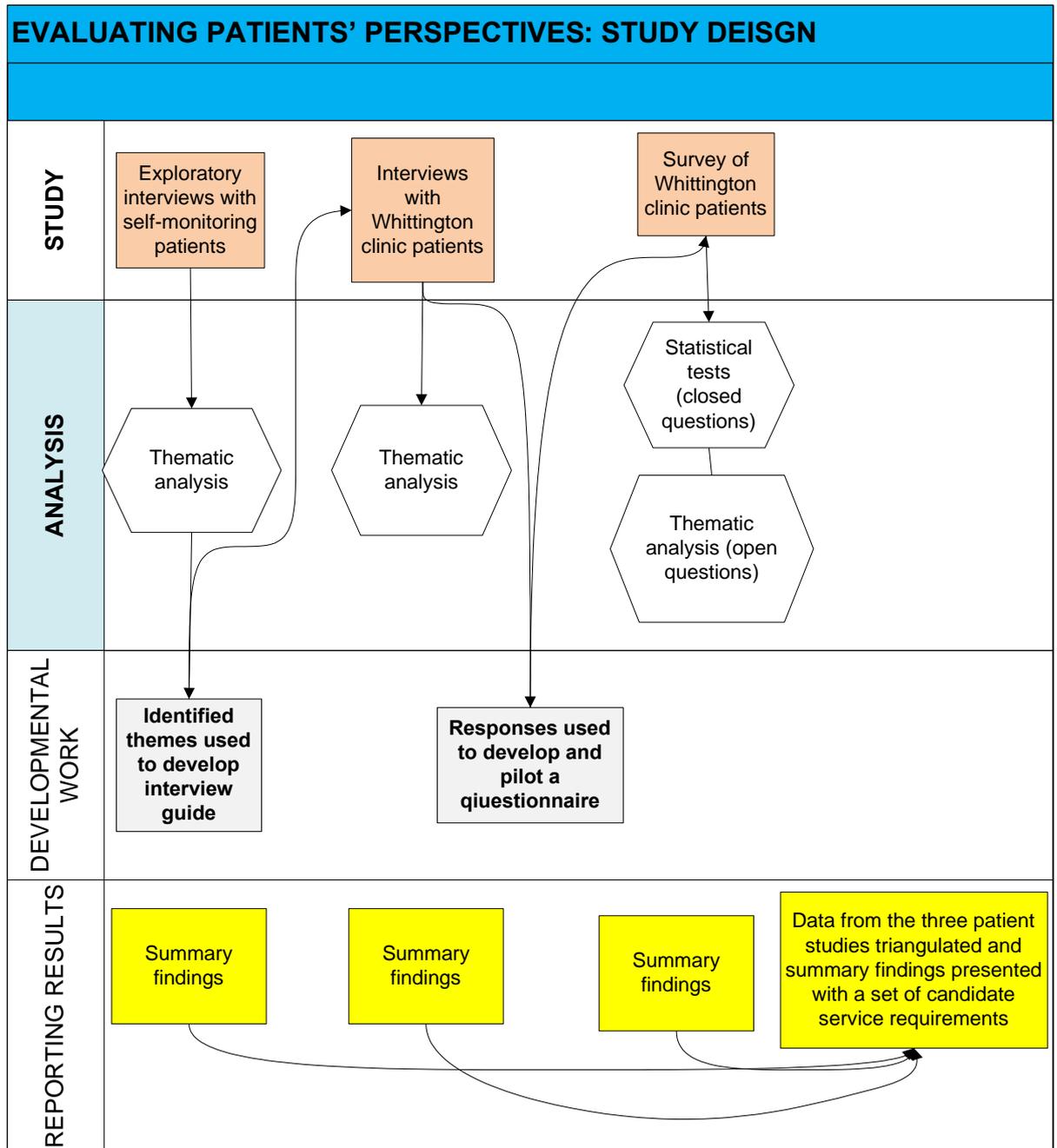


Figure 12: Study design for evaluating patients' perspectives on OAT self-monitoring

5.1 Patient study 1: An exploration of the experiences of self-monitoring patients

As an exploratory first step, it was felt that it would be useful to engage with those who were already self-monitoring to understand their motivations for undertaking anticoagulant self-monitoring, what type of support they had required and any difficulties experienced along the way. Although there are data to support the safety of OAT patient self-monitoring, no published work exploring patients' experiences of this could be found.

5.1.1 Aims and Objectives

The aim of this part of the research was to explore the perspectives of patients on warfarin self-testing and self-management (OAT patient self-monitoring). Within this aim, the objective was to identify the key drivers, benefits, and challenges of OAT patient self-monitoring. .

5.1.2 Recruitment of sample

Five patients were invited to take part in this study in May 2007.

As this work was exploratory, with a view to exploring the main issues around patient self-monitoring, small numbers were chosen. A mixture of purposive and convenience sampling was used. Purposive sampling in that the participants were self-monitoring patients who were thought to be able to articulate their experiences. Convenience sampling as these participants were near to hand, were known to the author or colleagues and were easy to recruit. One of the patients was known to the author, two were known to staff in the anticoagulant clinic at the Whittington and the remaining two were known to a colleague (JL) at a neighbouring Trust. JL sought obtained permission from his patients before they were approached by the author. Prior to starting the study, the author consulted with the Chair of the Local Research and Ethics Committee (LREC), who felt that formal ethical approval was not required for this set of informal interviews.

The methodological and data analysis approach to this study is summarised in Figure 13.

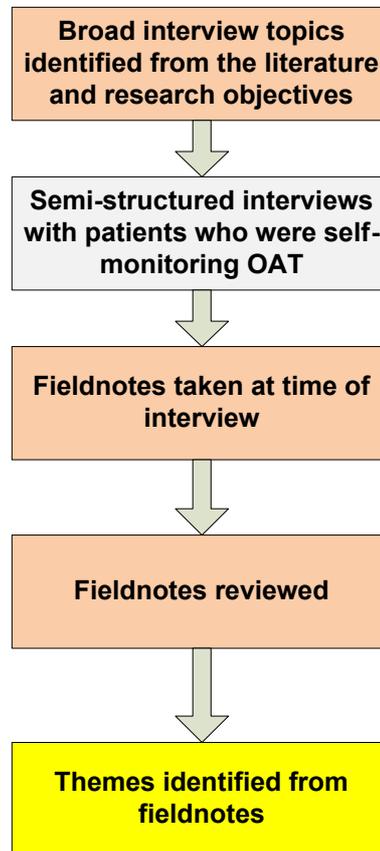


Figure 13: Patient Study 1: Methodological and data analysis approach

5.1.3 Method

Semi-structured interviews were used, with questions covering the following broad topics identified from the published literature and the research objectives:

- i. Introductory questions (method of management, length of time self-monitoring, duration of warfarin treatment and indication)
- ii. Starting self-monitoring (including drivers and potential barriers)
- iii. Information needs for OAT patient self-monitoring
- iv. Support for OAT patient self-monitoring
- v. The patient's self-monitoring journey (including challenges faced)

These exploratory topics only were served as ‘starting points’ only. Although some questions were pre-prepared, these were intended as a series of themes and prompts rather than a rigid interview script, to allow the subject to talk freely about his or her experience. Interviews were not audiotaped to allow participants to express their views more freely. Field-notes were taken at the time of interview.

Interview question prompts can be found Appendix 2.

5.1.4 Analysis

After the interview, the field-notes were read by the researcher and the data coded into themes. As this work was exploratory, it was felt appropriate just to describe identify thematic groupings only at a high level at this stage.

5.1.5 Results

5.1.5.1 Sample

Three people agreed to be interviewed; two men (M1 & M2) and one woman (F1). Their background information is shown in Table 21.

	M1	F1	M2
Age	62	58	36
Duration of treatment with warfarin	7 years	11 years	2 years
Indication for warfarin	Heart valve replacement	Dilated cardiomyopathy	Anti-phospholipid syndrome
Length of time self-monitoring	4 years	10 years	18 months
Self-managing or self-testing?	Self-managing	Self-managing	Self-testing

Table 21: Patient study 1: Demographic details of patients interviewed

5.1.5.2 Data collection

Two participants (M1 and F1) were interviewed by the author for between 30 and 45 minutes. Because of work patterns, it was difficult to schedule an interview with the third participant (M2). At the participant’s suggestion, questions were submitted by email.

5.1.5.3 Themes

Six main themes emerged from the interviews:

- i. Convenience
- ii. Independence
- iii. Warfarin dose adjustment
- iv. INR testing
- v. Coagulometer & consumables
- vi. Support for OAT patient self-monitoring

These will now be discussed. Selective quotations are used to illustrate pertinent comments.

Theme 1: Convenience

All participants cited convenience as a major motivating factor for starting OAT self-monitoring. This was both from the point of view of the freedom to schedule INR tests when convenient, and also with respect to avoiding busy, overcrowded hospital clinics.

"When travelling for either business or pleasure... to avoid the need to negotiate going to hospital should any of my symptoms change. It's hard to fit hospital blood tests with a busy job" (M2)

Theme 2: Independence

In addition to being more convenient, anticoagulation patient self-monitoring may bring more independence and empowerment.

"I want to be independent I want to have more control"(F1)

One interviewee (M2) viewed self-monitoring as a way of establishing 'normality' in his life; his main motivating factor for starting self-testing was the desire "*to live as normal a life as possible*".

Theme 3: Warfarin dose adjustment

The two participants who were self-managing their oral anticoagulation had different views on how to adjust their dose of warfarin to achieve INR control. Whilst F1 had her *“own way of doing it”*, M1 felt that having a dosing algorithm was essential:

“Having the proforma is critical gives me confidence” (M1)

In the early days of self-management, out of range INRs caused M1 some anxieties. However, this improved as he became more experienced at managing his treatment and he now felt that his INR was good.

“I am now confident that an INR of 2.9 is not a disaster” (M1)

However, M2 felt that he did not yet have the confidence to adjust his dose of warfarin, and phoned the anticoagulant clinic if his INR was too high or too low.

Theme 4: INR testing

Initially, one participant (M1) had difficulties in obtaining and testing an adequate blood sample. However, he became more proficient at using the coagulometer as time progressed. He felt that greater clarity on how to test his INR would have been helpful; for example, blood sampling techniques and alternative lancets available.

Although another participant (F1) did not indicate any difficulties with INR testing, she voiced a concern that it may not be suitable for all:

“Some people may not be able to do it the elderly for example” (F1)

Whilst the third participant (M2) found INR testing easy, with the coagulometer *“simple to use from day 1”*, he conceded that there may be issues with the dexterity required.

Theme 5: Coagulometer and consumables

The participants had slightly different approaches to assuring the accuracy of their machines. M1 and F1 periodically compared their INR results with the results obtained from an identical, externally quality assured machine. M2 had a venous blood sample tested at the Whittington alongside a simultaneous capillary blood test on his CoaguChek™ machine.

The CoaguChek™ machine is not 100% accurate when testing the INR of those, like M2, with anti-phospholipid syndrome. This proved to be both an obstacle at the start of self-testing, but also a factor that ensures his continued contact with the hospital anticoagulant clinic. M2 has found that the INR results are consistently 20% higher than those generated from reading a venous blood sample at the hospital. Although with hindsight he felt that this information would have been useful at the outset, he has devised his own system to deal with this:

"I have drawn up a table in Microsoft Excel to enable me to calculate my 'true' INR from the machine reading. Really this is the only factor in continuing with the warfarin clinic - to make doubly sure my INR readings are accurate" (M2)

M2 & F1 had concerns over the cost of the coagulometer. M2 claimed that the coagulometer is "very expensive" and that this initially deterred him from self-testing. The need to purchase lancets also adds to the cost. F1 felt that the cost may deter many people from self-monitoring anticoagulation. She considered the cost very carefully before proceeding.

Theme 6: Support for OAT patient self-monitoring

Support is an essential ingredient of the success of patient self-management.¹⁰⁴

Healthcare professionals at their respective hospitals were very supportive of F1 and M1 self-managing their oral anticoagulation. This support was especially valuable when they were starting self-management.

However, support was not just confined to healthcare professionals. Both spouses provided help along the way; from agreeing to fund the machine and setting it up (F1), to getting a blood sample (M1).

F1 felt that it could be valuable for those starting self-testing to speak to those already doing it:

"Some people might want support or to be able to talk to someone already doing it" (F1)

The manufacturer of the coagulometer (Roche) provided support to all participants, through their dedicated helpline and CoaguChek™ manual.

5.1.6 Limitations

This study in a small group of self-monitoring patients identified some drivers – convenience in INR testing and the need for independence – and also some challenges to OAT patient self-monitoring, which centred on INR testing and warfarin dose adjustment. It also highlighted the need for the patient to purchase the coagulometer as a potential barrier to uptake, and that support from healthcare professionals and family may be valuable when starting self-monitoring.

As this was a small, exploratory study, it was not possible to draw any firm conclusions from its findings. However, the results of this study informed the next two studies, which involved interviewing and surveying Whittington patients who were not self-monitoring. These were larger studies and form the bulk of the patient-centred part of this thesis. The remainder of this chapter discusses these studies.

5.2 Patient Study 2: Interviews with local anticoagulant clinic patients

The initial interviews with patients who were already self-monitoring provided some insight into some of the factors that might influence the uptake of OAT patient self-monitoring. However, this was a very small study with a cohort of patients who would not be representative of the general anticoagulant clinic population.

This section describes how in-depth interviews with a larger, more representative group of patients attending the anticoagulant clinic were conducted.

5.2.1 Aims and Objectives

The main aim of this study was to develop a questionnaire to elicit the views of a larger group of patients.

A secondary aim was to yield narrative data for qualitative analysis in order to explore the perspectives of patients on long-term warfarin on self-testing and self-management, including drivers, benefits, barriers and challenges.

5.2.2 Recruitment of sample

Invitation letters, accompanied by a study information sheet, were sent out to 23 patients attending the Whittington Anticoagulation Monitoring and Stroke Prevention Service in July and August 2007. These can be found in Appendix 3.

The sampling frame was the patient list of the Whittington Hospital Anticoagulation Monitoring and Stroke Prevention Service. These patients were attending either the Whittington Hospital clinic or one of its primary care outreach clinics for anticoagulation monitoring. At the time of sampling (June 2007), the size of this list was 912 patients.

A mixture of purposive and convenience sampling was used. Purposive sampling in that the sample was selected to represent a spread of ages, indications, duration of treatment and gender. Equally importantly, those selected were thought likely to be able to articulate their experience of being on warfarin. Convenience sampling as these participants were near to hand, were known to the author, were easy to recruit and were likely to respond. As the main aim of this study was to test, refine and extend the ideas and topics identified from the initial interviews, ultimately to develop a patient questionnaire, statistical representativeness was not sought.

There are no set rules governing sample sizes for interviews. Instead, they are determined by other factors such as the likely depth and duration of the interview and the number feasible for a single researcher to undertake.¹⁴³ Large qualitative studies rarely interview more than 50 or 60 people. Therefore, the sample size was largely determined by how many interviews a single researcher would be able to conduct and analyse; it was decided that nine interviews would be feasible.

The methodological and data analysis approach to this study is described in Figure 14.

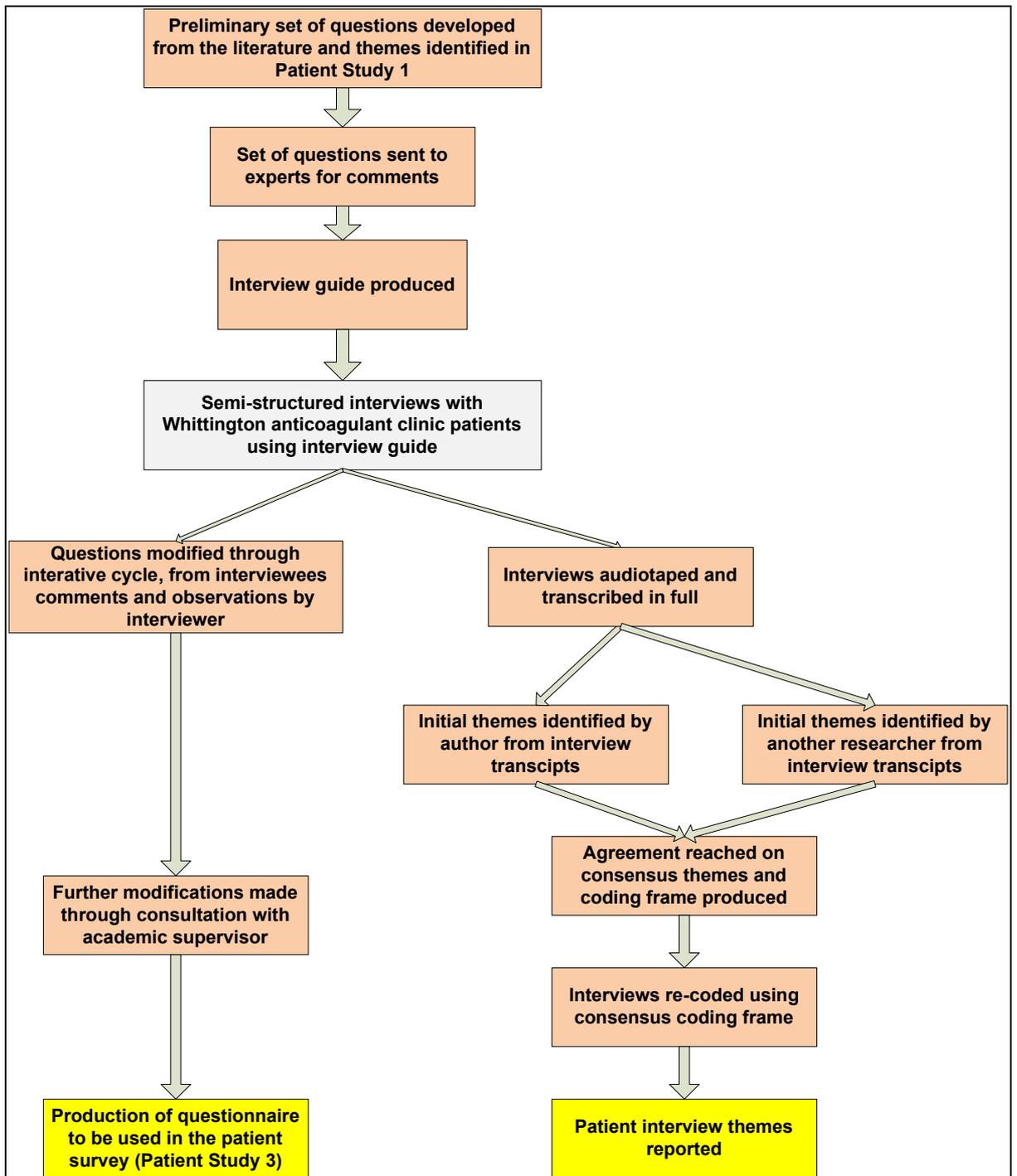


Figure 14: Patient Study 2: Methodological and data analysis approach

5.2.3 Method

The perspectives of this group of patients were collected through face-to-face interviews. This section describes how this was carried out, and how the data collection tool for this study was developed.

Local Research and Ethics approval was granted for this study. Relevant correspondence is in Appendix 4.

5.2.3.1 Development of the data collection tools – the interview guide and survey instrument

This developmental work took place over a period of six months, from June to December 2007, and is summarised in Table 22.

Activity	Outcome	Resulting Data Collection Tool
Examined existing questionnaires exploring attitudes and perspectives of anticoagulated patients described in published literature and from the emergent themes from the patient interviews in Patient Study 1.	<ul style="list-style-type: none"> ➤ Salient issues identified ➤ Questions written 	Preliminary set of questions
Preliminary set of questions sent to two experts for comments	<ul style="list-style-type: none"> ➤ Minor modifications made 	Interview guide
First interview guide used for first 4 interviewees	<ul style="list-style-type: none"> ➤ 40 amendments made to guide 	Prototype questionnaire
Prototype questionnaire used for final 6 interviewees	<ul style="list-style-type: none"> ➤ 32 amendments made to guide 	Amended prototype questionnaire
Discussions with supervisor	<ul style="list-style-type: none"> ➤ 31 amendments made 	Final questionnaire

Table 22: Overview of stages of developing the patient interview guide and questionnaire

Development of the interview guide

A preliminary set of questions was developed from two sources.

Firstly, emergent themes from the interviews with self-monitoring patients were used to construct the responses to some of the questions. The construction of these questions and response options is summarised in Table 23.

Secondly, patient questionnaires described in the published literature were reviewed. Studies exploring the perspectives of patients who were self-monitoring their OAT^{43;44;81;87} have previously been described in Chapter 3. Additionally, surveys exploring the attitudes and perspectives of anticoagulated patients (not self-monitoring) were reviewed.¹⁵⁵⁻¹⁵⁸

Salient issues were identified from these studies, particularly relating to perceived benefits and concerns about warfarin patient self-monitoring. In addition, questions to determine subjects' warfarin information needs were included and, in order to explore the feasibility of making this information available electronically, their experiences with computers.

This preliminary set of items was sent to two experts – an academic with an expertise in qualitative research and a lead pharmacist in anticoagulation - for comments. Some minor modifications were made. This resultant set of questions was used as the first interview guide, and can be found in Appendix 5.

Interview question	Mapping to emergent theme
<p>Now think about what you would like to change about your warfarin treatment & monitoring. Please tick a box to show which of these options are most attractive. You may tick more than one box.</p> <ul style="list-style-type: none"> ➤ Less frequent clinic visits ➤ Testing my INR (blood level) at home and phoning the clinic for advice on my dose ➤ Testing my INR (blood level) at home and adjusting the dose of Warfarin myself 	<p>Convenience Independence Independence</p>
<p>Now think about testing your own INR (“self-testing”). Please tick a box to show how much you agree with each of the following statements.</p> <ul style="list-style-type: none"> ➤ I would like to have more control over my warfarin treatment ➤ I would be able to prick my finger to get a blood sample ➤ I would be able to test my blood on the machine ➤ I would be able to buy a machine ➤ I would be happy to buy a machine 	<p>Independence INR testing INR testing Coagulometer and consumables Coagulometer and consumables</p>
<p>Now think about testing your own INR <u>and</u> adjusting the Warfarin dose yourself (“self-managing”). Please tick a box to show how much you agree with each of the following statements.</p> <ul style="list-style-type: none"> ➤ I would like to have more control over my warfarin treatment ➤ I would be able to adjust my dose of Warfarin ➤ I would be able to prick my finger to get a blood sample ➤ I would be able to test my blood on the machine ➤ I would be able to buy a machine ➤ I would be happy to buy a machine 	<p>Independence Adjusting warfarin dose INR testing INR testing Coagulometer and consumables Coagulometer and consumables</p>
<p>If we were to set up these “self-testing” and “self-management” programmes, there are a number of ways we could support you. We have listed some of these below. Please could you indicate how important these would be if you were self-testing or self-managing your warfarin treatment.</p> <ul style="list-style-type: none"> ➤ Provide the machine to measure your blood INR ➤ Give you more information / education ➤ Make it easy for you to contact the clinic if you have any concerns ➤ Check up on you regularly 	<p>Coagulometer and consumables Support Support Support</p>
<p>There may be other ways that the clinic could support patients who decide to self-test or self-manage their Warfarin treatment. If you can think of any, please write your suggestions in the space below. (Open question)</p>	<p>Support</p>

Table 23: Construction of patient interview questions and response options from emergent themes from Patient Study 1

Development and piloting the questionnaire

This first interview guide was used to conduct the first four patient interviews.

The rationale behind careful design and piloting of survey instruments has been previously described in Chapter 4. The following checks were conducted during the course of the patient interviews:

- i. That questions were unambiguous
- ii. That none of the questions caused offence or discomfort
- iii. For the closed questions that all possible responses were included
- iv. That each question measured what it was intended to measure
- v. That all relevant issues had been included
- vi. How the patient feels about the questions

After these four interviews, 40 amendments were made. Half of these amendments were suggested by the interviewees; the remaining 20 were initiated by the author based on the experience of conducting the interviews and the kinds of response elicited. The majority of changes were rewordings of questions for clarity, or formatting amendments.

The resulting prototype questionnaire was then piloted on the remaining six patients.

Further amendments were made after the remaining six interviews and through discussion with the academic supervisor. The final questionnaire was a 66-point instrument, to be used for the patient survey (section 5.3), which was divided into six sections:

- i. Warfarin treatment and current health
- ii. Attending the warfarin clinic
- iii. Self-monitoring warfarin
- iv. Education and support for those self-monitoring warfarin
- v. Experiences with using computers
- vi. Demographic data

5.2.3.2 Interview methodology

Each participant was interviewed by the author face-to-face. Signed informed consent was obtained before each interview was conducted. Participants were asked permission for the interview to be audiotaped. Additional relevant field notes were also taken with observations and reflections added after the interview.

As the primary aim of this part of the study was to develop and pilot the survey instrument to be sent out to a larger patient population, the interview was largely a “talk-through” of the interview guide. However, as a more qualitative analysis was also desired in order to obtain additional results (patient perspectives), through the course of the interview each participant was given opportunities to expand on comments and to raise issues that had not been addressed.

Additional information on warfarin PST and PSM was provided, using patient information leaflets, to allow the interviewee to reach a more informed view of OAT patient self-monitoring. These leaflets can be found in Appendix 6.

5.2.4 Analysis

The main purpose of the pilot study was to gain an insight into the experiences of patients who were on long-term warfarin, with the goal of using these data to develop and pilot a questionnaire to be used in the second phase of the study. The use of the interviews to develop and pilot the questionnaire has been described in 5.2.3.1. A secondary purpose was to yield narrative data for qualitative analysis.

As soon as possible after the interview, the author transcribed the audiotapes verbatim. Once the interviews were transcribed, the audiotapes were destroyed. These transcripts were then subjected to a thematic analysis. All of the interview transcripts were read and then re-read by the author, who then identified broad themes and also sub-themes within these broad themes. A master list of major themes and sub-themes – the coding frame - was compiled, and phrases in the interview transcripts were marked with different coloured pens to identify the different themes. Notes were also made in the margin to denote these themes and also any sub-themes.

Using the same methodology, another researcher conducted (JM) independently coded the interview data. The author and JM then compared their coding frames and, after discussion, a consensus was reached on a common coding frame. The interview transcripts were then re-coded using this consensus coding frame.

Data were tagged with participants' sex and identifying number (e.g. M1 refers to the first male participant to be interviewed).

5.2.5 **Results**

5.2.5.1 **Sample**

Ten patients agreed to be interviewed. Their demographic details are shown in Table 24. The majority of these participants were on lifetime treatment with warfarin, and had already been on it for more than 10 years.

	No. of patients
Age at time of interview (years)	
40 – 49	1
50 – 59	2
60 – 69	6
70 - 79	1
Sex	
Women	5
Men	5
Indication for warfarin	
Venous thromboembolism	2
Mitral stenosis	2
Heart valve replacement	3
Atrial fibrillation	2
Post-partum dilated cardiomyopathy with apical thrombosis	1
Duration of treatment at time of interview	
> 10 years	7
1 – 5 years	2
< 1 year	1
Planned total treatment length	
Lifetime	9
Six months	1

Table 24: Patient study 2: Demographic details of patients interviewed

One participant (M1) was also diabetic and tested his blood glucose at home. Three participants had tested their INR at home in the past. One (M3) of these had participated in a self-testing clinical trial conducted at UCLH; two (F2 & F5) had purchased coagulometers, although they rarely used them.

5.2.5.2 Data collection

Each participant was interviewed face-to-face with interviews taking between 40 and 90 minutes. Nine people were interviewed at the Whittington; one person was interviewed in her own home. One participant was accompanied by her husband, whose views were also included in the analysis. All participants granted permission for the interview to be audiotaped.

5.2.5.3 Themes

Seven main themes emerged from analysis of these interviews. These are summarised in Figure 15 and are discussed below. As before, selective quotations are used to illustrate pertinent comments.

However, three of these themes – impact of warfarin on everyday life, experiences of INR monitoring and the expert patient – are not included in the discussion because they were felt not to have a direct bearing on the shift to self-monitoring. Although an in-depth analysis of these themes would not have made a significant contribution to the research, the rich narrative generated will form the focus of a separate academic publication.

Instead, more value was attached to examining the relationship of variables within these themes with willingness to self-monitor in a quantitative manner. To this end, for the patient survey, described later in this chapter, statistical analysis will be used to correlate these factors with a willingness to self-monitor – for example, the relationship between willingness to self-monitor and how disruptive clinic visits were to the individual.

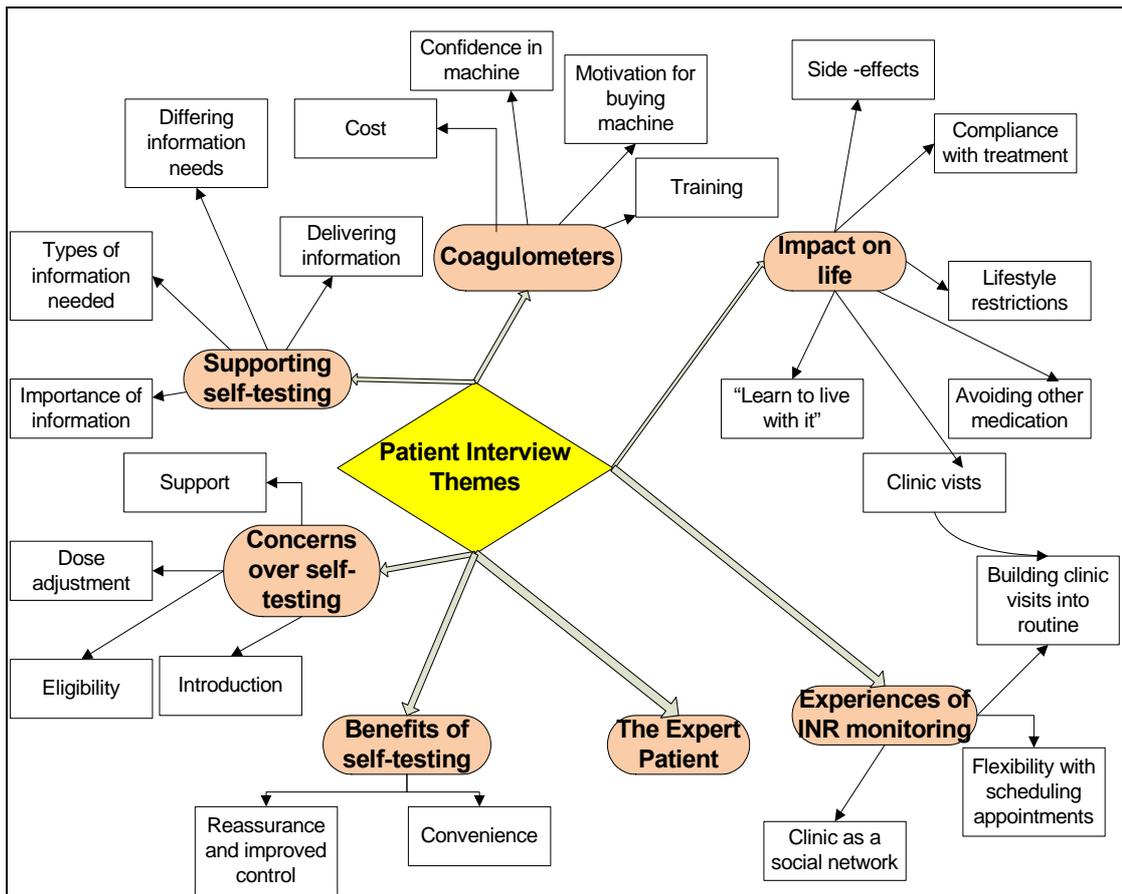


Figure 15: Patient study 2: Themes from interviews

Theme 1: Perceived benefits of patient self-testing

Potential benefits of anticoagulation self-monitoring cited in the literature include increased patient empowerment, improved patient - healthcare professional relationship, greater patient convenience and avoidance of damage to the veins through capillary sampling.

Participants' views of self-monitoring were largely positive. Most of the comments on the potential benefits of patient self-monitoring centred on increased convenience for them, particularly in terms of allowing freedom to travel. Some respondents felt that the ability to test their INR more frequently would be reassuring and might also result in fewer erratic INR results. These sub-themes of convenience and reassurance will now be considered.

Sub-theme 1: Convenience of patient self-monitoring

Most of the participants' comments on the potential benefits of patient self-monitoring centred on increased convenience for them, particularly in terms of travel.

“If you're on holiday it's ... it could be useful then ... or of you're away in out of the way places ...in the wilds of Scotland where you don't have local access to the major facilities”(M3)

But another dimension to greater convenience with self-monitoring was the ability to test INR when and where desired. In the words of participant M4:

“...in the comfort of your own home” (M4)

Sub-theme 2: Reassurance provided by patient self-monitoring

As discussed earlier, patient self-monitoring of oral anticoagulation is at least as safe as usual management. Increased frequency of testing may improve INR control in its own right and has been cited as a possible confounding factor in these trials.⁷⁸

Two participants felt that the ability to test their INR more frequently would be reassuring and may also result in fewer erratic INR results.

“Occasionally, you know, when you don’t have your appointments perhaps for maybe 3 or 4 weeks, you know, you ...I mean I personally tend to wonder if it’s actually at the right level or And again, I think that’s where this self-monitoring comes in. Because if you do get a little bit worried say within in a week or ... you could actually do it yourself and you would know, put your mind at rest.” (M3)

“Yeah. I ... I mean, I think that’s good that you can test your blood if you have any concerns about it, you know, rather than think, you know, I’ll go to the clinic in 3 weeks time I’ll test it then. Because my warfarin ... my INR’s been quite erratic. If I have a feeling I should be testing it that’s when I want to test it. I don’t want to wait 2 weeks because, you know. I could end up with a situation I was on holiday where I came back and it was 6.7. My other half laughed. He said ‘Oh well at least there’s no chance of you getting a blood clot on the plane’ (laughs)”(F5)

Theme 2: Concerns about patient self-testing

As well as the perceived benefits, it was equally important to tease out any concerns that participants may have about self-monitoring their INR. Potential disadvantages of patient self-monitoring cited in the published literature include increased anxiety and obsession with health, reduced access to healthcare professional, the cost of the coagulometer and the training & support that will be required. Our sample’s comments partially reflected these potential disadvantages - in that they had concerns about the support that would be provided for those self-testing and there was much discussion about purchasing the coagulometer - but they had additional concerns, including eligibility of patients to self-test, introduction of self-monitoring and adjustment of the warfarin dose. These will now be discussed, with the exception of the coagulometer which is discussed separately in this chapter.

Sub-theme 1: Support for patient self-monitoring

Support for patients who self-monitor was felt to be essential and two-dimensional. Firstly, a need for advice and support on an *ad-hoc* basis was identified. The ability to access this advice in a timely manner was also important. An alternative to a telephone helpline would be delivering support to those self-monitoring via email or a website. However, this was felt to have its limitations:

“I’d rather speak directly to somebody ... Without really speaking to you, you can’t ... well you can put words in speech what you can’t put on an email, put it that way ... You can say a lot in a matter of just one little sentence and get the right advice back.” (M5)

One participant felt that this support should be at least equal to the current satisfactory clinic support:

“And I guess that the other .. the other point is that you do feel confident too in the clinic because you realise that you can ring and can say “I’m doing this” or “Can I change the day?” as you ... as I’ve had to do on odd occasions over the past year. So having that back-up is quite helpful that if, you know, one ... if there is uncertainty then being able to contact or phone somebody is quite helpful. And the staff have been very helpful and reassuring about making plans where it might be a bit complex like, you know, for work or going away on an overseas trip and getting some advice about timescales for adjusting taking medication. So one or two times when it’s really been very, kind of reassuring to sit down and just talk through exactly what the plan is. This doesn’t happen too regularly but it is .. it is helpful in that circumstance.” (M2)

The ability to access this advice in a timely manner was also important.

“But then you can’t always get through to the clinic. Sometimes you can. I’m not saying always. But sometimes it is ... it’s like ‘Oh leave a message’ Like all these places. You ring, ring and leave a message and they don’t always come back. So really, you’d need to be I suppose if you were doing something like that you’d need then to be assured that you’d be guaranteed to get through to somebody.” (F3)

But helpline-type advice is only one aspect of support. Some participants were reluctant to completely lose contact with the existing specialist service and felt that regular follow-up sessions with their anticoagulant practitioners would be necessary to check on progress.

“It’s no good sort of just giving somebody a machine and saying ‘Well there you go. You know how to prick your finger and it’s up to you now’ sort of thing You know. There has to be some sort of monitoring or follow-up ... I would have thought something on the idea, as I say, of after an operation when you had perhaps a six-monthly check-up and then perhaps a yearly one. And even if you did that for the first sort of 2 years after, or 3 years after someone’s had the machine perhaps you could incorporate it in ... I mean, I don’t know how many have sort of yearly check-ups with warfarin. I mean, I actually come up every year to have like the heart checked and that and whether they could incorporate just a check.” (M4)

Views on the frequency of such clinic follow-up visits for self-testing patients varied, but one participant felt that the time interval between these visits should be not be prescriptive but instead meet the needs of individual patients.

I think it’s [clinic support] very important because if you have any concerns it’s like you say, it’s your health. It’s your health so it’s very important. (M5)

Sub-theme 2: Eligibility for patient self-monitoring

Some participants had doubts as to the ability of some patients to cope with self-monitoring, particularly the elderly and those with complex medical problems.

“I mean not being funny, perhaps not for sort of somebody like me who is again able, you know, to do these sort of things. But when you’re looking at people who are a bit older and as I say - I’ll reiterate it again - they don’t even know if they’ve taken their warfarin or, you know, forget that they’ve posted a letter and, you know, that would be to my mind a very hard thing to try to get across to somebody like that. Do you put a sort of an age limit on it or ...?. How do you define who is actually fully capable of doing ... you know, it is very difficult, I’ll admit. Very difficult. Because you’ve got people who are, you know I mean, they’re perhaps sort of in their 80’s but they, you know, they got minds of a 50 yr-old. I mean, so how do you, again, put a dividing line on it? I don’t think you could.” (M4)

Sub-theme 3: Introduction of patient self-monitoring

Views on the best way to introduce self-monitoring varied, with some participants favoured a ‘softly softly’ approach, with a slow introduction to self-monitoring to instil confidence.

“What I was thinking about was that this system [self-monitoring] should be introduced slowly – not given to them at the first instance when they come to the warfarin clinic... Perhaps within 3 or 6 months ... You should have them ... Perhaps you could get the lab people when they .. to take a set of readings here and then ask to use the machine to show its accuracy.” (M1)

Each person has a unique approach to self-management, and this approach may change over time. Patients’ perspectives shift over the course of their illness, due to changes in disease severity but also due to psychological factors.¹⁵⁹ This was reflected in the following comment:

“I guess one preliminary point I’d like is that I think your capacity to decide on (dosing) changes as you become more familiar with the process as it were, and really with what the warfarin is doing. And so in this sort of context you need to find out a bit more about the heart and the consultant (...) and that gives you greater confidence in a way in understanding what the Warfarin is doing and why the anticlotting agent is kicking in. So I think my confidence has grown as I’ve understood the problem a little more and in a little more detail. Having ... once you achieve that level, I ... I would certainly be happy to contemplate doing it at home and adjusting the dose myself.” (M2)

Sub-theme 4: Dose adjustment for self-management

There was some anxiety at the prospect of adjusting the dose of warfarin in the event of self-management:

“It’s ...I mean from my point of view, I mean I don’t know how many other people experience it but, you know, sometimes ... I mean I can go for a few months and it’s ... it’s quite level and it’s good. And then all of a sudden, for some reason, it will all, you know, just decide to play it’s own game and ... and, you know, if you get a situation like that then obviously people who find themselves in that situation have got to be able or to sort of regulate their own doses and manage, you know, because ... As I said to you just earlier on, ... I mean I’ve been on it for 14 years and even now I don’t know how to ... if my INR is high or ... I don’t actually know how to regulate my dose. It’s only because I come to the clinic. They then tell me it’s high, they then regulate it. So from that point you are, or I am at the moment, solely in their hands.” (M4)

Theme 3: Information requirements to support patients who are self-testing

The patient's knowledge and understanding of OAT is perceived to play an important part in the success of this treatment, and part of these interviews focused on the information needs of those self-testing oral anticoagulation.

Sub-theme 1: The importance of information

There were polarised views on the importance of providing information.

One interviewee was particularly vocal in his view that education was pivotal to any warfarin patient self-monitoring programme.

“I think if it's ... if it's going to be done, I think it's got to be a sort of a full educational programme more than just getting people to just take their own blood. Basically, what I'm saying at the end of it is I feel by doing this it's the educating of people that I think is the most important point.” (M4)

However, another interviewee felt that education would be of benefit only when new information had become available:

“You know, but if it's still in the same light that it was years ago, you know, I don't see ... I don't see the point of me learning it when you already know it.” (M5)

Some participants felt that they would need information on warfarin irrespective of whether they were self-monitoring their treatment.

“How to deal with bleeding? Well I'd need to know that anyway ... a lot of this would apply even if you weren't testing yourself? It still applies whether you're coming up here and having it done.” (F1)

Sub-theme 2: Types of information needed

There were contrasting views on the importance of different types of information. Information on diet and drug interactions in particular was thought to be important.

“It comes back to things like foods, what you’re allowed to eat and what you’re not. And another important point I would think from ... from that point of view is, again, it all comes down to educating people into it, is what other medication must you can actually take, you know, with warfarin.” (M4)

Other participants focused on the more ‘hands-on’ skills that they felt they would need to self-manage their oral anticoagulation testing and dosages, including an awareness of when to seek further help, an ability to recognise when the INR was too high and how to adjust their dose of warfarin.

“If you had access to the algorithm, I’m reasonably confident that you could actually kind of chart that [dose adjustments] yourself. That could be ... potentially the table that you would have in front of you and then potentially doing that on a weekly basis. One could do it more regularly but I think there is then kind of fluctuations and you would be forever changing your dose. So I think good advice about the degree of regularity of the checks and the nature of the sensitivity to the drug and the way in which you can manage that on a weekly basis I think would enable one to do it quite easily.” (M2)

“How warfarin works is a common skill, although I don’t really think I’d wanna know how that ... well, I don’t know ... maybe I would ... I mean I do .. but would I want to know?... Side effects ... that’s the same isn’t it? I don’t really need to know all this do I ... well I do actually because I would wanna know why ... if my INR was particularly high.” (F1)

Sub-theme 3: Differing information needs

People have varying information needs, both in the type and level of information and in the way in which it is delivered. This was observed by one participant:

“People are different in different ways aren’t they. Some people like a lot of instructions and things to read and others don’t ... they’d rather been shown and ... and a demonstration.” (F1)

Another participant felt that detailed information on anticoagulation would be beyond the capacity of some patients:

“[Detailed information is] too much for a normal patient to deal with. It depends on your medication and how educated they are.” (M1)

It is unclear if a lower intensity of training is needed for those self-testing compared to those who are self-managing. Some felt that those who were self-managing may need more intense education than those who were only self-testing:

“For self-testing all you need is to how to prick the finger or how to use the machine. For self-dosing you will need everything.” (M1)

Instilling confidence by offering a staged education programme was favoured by one participant:

“...a sort of progressive education into it, instead of just saying, ‘well, you know, there’s your machine, that’s how you use it, get on with it’ basically. ‘We’ll see you, sort of, you know, if you think we need to’ ...I think the basis of this I think is more education for people. It’s not so much the machines and getting people to do it and that. I think people would be quite, you know, willing to do it. Or a lot of people, I would think, would be quite willing to do it. But I think a lot of it would be that the ... they would be a bit apprehensive of, you know, as I said to you earlier, on how they would if their dose wasn’t right, how they would manage it and That would be, to my mind, where the apprehension would come in.” (M4)

Sub-theme 4: Delivery of information

Computer-based learning offers many potential advantages to patients wishing to self-monitor their oral anticoagulation. It allows the patient access to educational material in private when, and where, convenient. It has the potential to individualise material according to the patient’s needs, to reinforce learning and provide feedback on educational goals, and the ability to simulate life experiences.

When participants were asked for their opinions on delivery of warfarin information by information technology views were mixed. For example:

“I’d personally find it a very accessible way of obtaining information and interacting with the clinic.” (F1)

Versus ...

“I just ... I just paper form me, yeah. You’ve always got it there with you to mind, hadn’t you?” (M5)

Although one participant did not consider himself to be computer-literate, he would be happy to ask his partner to access warfarin information on the Internet:

“I’d get somebody to print it off for me... I could stick it in my health file then.” (M3)

A large number of patients attending the Whittington Anticoagulation Monitoring & Stroke Prevention Service are elderly, a group that is consistently under-represented in terms of Internet usage. This was highlighted as a potential barrier to delivery of electronic information by one participant:

“I may be being ageist but I don’t know if all of the older people may be ...I mean just thinking about my parents I mean they’re not on-line...thankfully.(laughs) Goodness knows what would happen if they were but yeah, I mean from my point of view that would be fantastic ... an email resource ... I mean I tend not to think of that because I’m kind of old-fashioned really (laughs) But having said that you might well say OK the people who are familiar with the Internet and there are a lot of older people as well who are fantastic with it. I think that’s actually very easy because if I was ... when I’m back at work picking up the phone and trying to get through to a clinic might be quite difficult whereas banging off an email or something or logging into a sort of chat thing would be much, much easier.” (F1)

Theme 4: The technology itself – Coagulometers

The technology itself – the coagulometer – stimulated much discussion through the course of these interviews. This can be considered as four sub-themes; cost, motivation for buying the machine, confidence in the machine and training.

Sub-theme 1: Cost

In order for a patient to self-test or self-manage their warfarin, they first need to purchase a coagulometer (current price of £400) on which to measure their blood INR. This is a very different economic model than that adopted for other forms of self-monitoring such as blood glucose (SMBG). The blood glucose testing machines are given out free to patients, often through diabetes clinics, and the diagnostics manufacturers make their money through the sale of consumables. This difference was not lost on some of the interviewees:

“Obviously £400 isn’t available to a lot of people to spend on something like that and diabetics get them free don’t they?”(F5)

“If they charged for the strips they would probably make more money anyway. So over a period of time, I mean, how many strips are you going to use compared to the machine? I mean, you know, you’re gonna use the machine once when you need it, obviously, and your strips. But you’ve only got one machine, but you’ll be using maybe hundreds of strips throughout your lifetime. It doesn’t really make a lot of sense actually.” (M4)

Many participants commented on the cost of this machine, with some taking the view that this represented a barrier to the uptake of INR self-testing.

“I think that’s going to be the biggest stumbling bloc. Now that is [the ability to buy a machine], again, a number one fly in the ointment for a lot of people, I would think. I mean I just looked at this sheet - £399 is a lot of money.” (M4)

It was felt that the cost of the machine would represent a barrier in certain sectors of the population, particularly the elderly:

“You know, when you’re talking about pensioners and things like that. You know £399 is probably a year’s electric bill or a year’s gas bill. Yes, that is a lot of for people to find.” (M4)

There were several suggestions as to how to alleviate this financial burden. These included part payment by the hospital:

“Well yeah. Even if they sort of said ‘ Well you can have it for this price ’ whatever. You know, if you put something towards it.” (F4)

The husband of one interviewee felt that a hire purchase scheme may help some people in spreading the financial burden:

*“You’d have to do it over alternate months of paying for it, I think. Really.”
(HF4)*

Roche Diagnostics, the manufacturer of the global market leader (CoaguChek™) operates a similar scheme where the user pays the company in instalments.

One gentleman who had participated in a self-testing trial in the past suggested having a bank of loan machines available:

“The ones that I’ve had in the past have always been on loan – I sign for them – and I then I just give it back and they sign it off and I watch and make sure that they do sign it off and then I won’t get charged for it should they say that I lose it.” (M3)

One solution proposed was to make a machine publicly available, for example in a community pharmacy. However, when one of the participants was questioned about this he argued that this proposal negated one of the big advantages of patient self-testing:

*“But that to me ... that in effect would be the same as going to a pharmacy to have your warfarin taken, wouldn’t it? There wouldn’t be a lot of difference. I mean, the idea or ... the actual sort of proposal is ... is to actually do it at home, in the comfort of your own home, when you want to do it sort of thing.”
(M4)*

There were concerns that if the person was unable to use the machine, either through lack of dexterity or through medical limitations, that purchasing it would be a waste of money. These fears are not ungrounded. A meta-analysis, led by Carl Heneghan at Oxford, has analysed the reasons behind dropouts in trials of OAT self-monitoring.¹⁰⁴ Difficulty measuring INR and lack of manual dexterity were cited by authors as reasons for patients dropping out of the study.

There were also concerns about the robustness of the machine:

“And also is there a guarantee with the machine that if – ‘cos you’ve got a have some sort of guarantee on it – that if it goes in a certain time then somebody hasn’t got to go and pay another £400 for a machine... You know, well £400, what backing am I going to get with it.” (HF4)

On a more philosophical level, there were some patients who adhered to the principle that the National Health Service (NHS) should pay for the machine since self-testing would ultimately be cost-effective for the NHS:

“Cos I think some of the answers you’re going to be given to your questions is ‘Well it’s the NHS. Why should I have to pay for it?’” (F4)

Sub-theme 2: Motivation for buying a coagulometer

Despite the significant financial outlay required, if there are perceived benefits people may be persuaded to purchase a coagulometer. However, in the absence of a specific reason, people may not be prepared to accept this financial commitment:

“If they’re going down the option to come to the clinic or buy a machine – it’s nearly £400 – so would you choose the clinic or the machine? If you’re not going abroad for any length of time ... I would ... I would ... I would not have bought that machine had I not a mother who was living abroad and I had to go and visit her. Because I wouldn’t be going abroad for longer than 2 weeks. So if I go abroad to long distance like that I go for 4 or 5 weeks. So you do need machine because it’s inconvenient to get your blood tested.” (F2)

One participant felt that if anticoagulation was only short-term, it was not worth purchasing a coagulometer:

“Well ... yeah ... let’s say agree because I don’t see why I’d want to particularly. If I was on it for life probably yes but let’s hope I’m not.” (F1)

This comment is consistent with both UK and international consensus guidelines, which recommend patient self-testing is only appropriate for those on long-term treatment.³⁶

Sub-theme 3: Confidence & trust in the machine

Quality assurance of near-patient testing machines is essential to ensure that results are reliable.⁵² Reassurance about the accuracy of the coagulometer was important to some participants.

Past experiences may affect the level of trust patients place in coagulometers. For example, one participant felt that a machine to measure blood INR would be prone to the same inaccuracies as a glucometer:

“And I know that every machine has a tolerance ... Because I have this problem ... I used to have the problem in Trinidad and there was ... with the machines and when I went to the distributors and they didn’t want to admit that there was a tolerance when all the literature shows that there is a tolerance, plus or minus.” (M1)

Two participants had had their blood tested on a portable coagulometer in the past, either through an outreach clinic in their GP’s surgery (M5) or in the course of a self-testing trial (M3). Both of their experiences highlighted a potential limitation of portable coagulometers, namely their loss of sensitivity at high INR values.

“So I done the training course and I proved that I could prick me finger, put the blood on the unit, it measured it and it always came up “Seek immediate medical advice” (laughs) And they couldn’t believe that their machine wouldn’t give a true reading. They took it ... pricked me finger as they took the blood out of the arm and they all went off to do their thing – get the results and so on. And I sat outside and wait and the lab result is what we would expect and their result was “help”!” (laughs) (M3)

But for some patients their views on using a coagulometer could be distilled down to basic trust and a perception that only something ordained or provided by the hospital is ‘good’:

“Well, I think that ... well I wouldn’t ... you see if I wasn’t just looking at it I wouldn’t trust it. I’d think ‘oh that’s a gadget’. I wouldn’t trust anything that wasn’t given to me by the hospital I have to say. But then that’s me.” (F1)

Sub-theme 4: Training in using the coagulometer

Many participants stated that instruction on using the coagulometer was a prerequisite for its use. However, one gentleman was almost blasé about capillary blood testing:

“I mean, really, to be honest, once you’ve been shown the machine - and actually sort of taking your blood is not hard is it as such?... If it’s ... if it’s a prick in the finger. Alright it might be if you were trying to go through into sort of arms and veins and things like that, that’s a different story. But if it is a proper machine that just does a finger prick, there can’t be anything really drastically hard about that. So I should think a lot a people will say ‘Yes. That’s fine. That’s no problem’.” (M4)

Those participants who had previously self-tested (F2, F5 and M3) were able to add valuable insights based on their experiences. Although F2 had purchased a machine, she did not feel confident enough to use it.

“I gave up with it. Because I thought I’m not going abroad so I don’t have to bother about it. So I have it but I must try and find it. But I have it and I have all the literature but it didn’t make a blindest difference to me because when I did test it didn’t come out right and I thought ‘I can’t be bothered with this’ and I put it down. So if you’re not having it up and the patient is not fully (confident) with it it’s a waste of time... The thing is, honestly, if I hadn’t used it I would have shipped it back to them.” (F2)

The manufacturer of the market-leading machine provides educational material on how to use the monitor in the form of written information and a video DVD. There were conflicting views on how useful this information was. Two participants felt that this was not sufficient in itself:

“I would have to be shown how to use my machine. Because, actually, physically reading the papers with didn’t make one bit of difference at all. (F2)

And the information sheet that you got with the piece of equipment was about an A (dot) size piece of paper with very small print – it was like rice paper – with all the information. I sat and read the whole lot ... (laughs) ... it took a while actually and-and it was quite small font, and ... ?”(M3)

However, the third participant felt that the video was beneficial:

*“You get a video with it which is pretty informative. I mean that’s quite good. Well you can watch it over and over again. If there’s a point you’re not happy about at least you’ve got that video. Whereas if you go to the clinic, like any visit to the doctor, you come out and you’ve forgotten what he’s said to you.”
(F5)*

5.2.6 Limitations

This study, interviewing a larger group of patients who were not self-monitoring, identified some potential benefits of patient self-monitoring, namely increased convenience and reassurance, and better INR control. Challenges centred on patient selection, educational support. As with the group of self-monitoring patients, the need for the patient to purchase a coagulometer was identified as a barrier to establishing a patient self-monitoring service.

The mixture of purposive and convenience sampling used in this study is a non-random method of selection and, as such, lacks external validity. However, the aim of this part of the study was to test ideas and topics to used in a larger study, rather than apply the findings to a wider population.

The next study – a survey of local anticoagulant clinic patients – aimed to explore the views of a wider population.

5.3 Patient Study 3: A survey of local anticoagulant clinic patients

The in depth discussions that took place during the interviews reported in the previous section allowed the important themes relevant to patient acceptance of self-monitoring to emerge in an open, uncontrolled unconstrained way, and for these issues to be explored in some detail. However, as non-randomised sampling method used, it could not be inferred that the views of this group were representative of anticoagulated patients at the Whittington in general. It was therefore important firstly to validate the themes with a wider sample of patients. Secondly, it was also desirable to obtain information on the proportion of patients who would be willing to self-monitor, and which patient characteristics were associated with a willingness, or not, to self-monitor. In contrast to the purely qualitative method of the previous section, it was therefore decided that a semi-structured questionnaire survey, which would yield data for quantitative analysis, would be the most appropriate method to use here.

This next section describes a survey of local anticoagulant clinic patients.

5.3.1 Aims and Objectives

The main aim of this study was to explore the perspectives of patients on long-term warfarin on patient self-testing and self-management, including drivers, benefits, barriers and challenges.

Within this aim there were two objectives:

- i. To establish the proportion of the clinic population who would be willing to self-monitor their OAT
- ii. To identify the patient characteristics associated with a willingness to self-monitor OAT

5.3.2 Recruitment of sample

Questionnaires were posted to 672 patients in August 2007.

5.3.2.1 Inclusion and exclusion criteria

The aim of this survey was to obtain the views of a cross section of the population who currently used the existing service. The sampling frame was the patient list of the Whittington Anticoagulant Monitoring and Stroke Prevention Service. The population of interest was adult patients attending one of the clinics of the Whittington Hospital Anticoagulation and Stroke Prevention Service, who met the following criteria:

- i. A long-term indication for warfarin
- ii. A good grasp of the English language

Both UK and international consensus guidelines agree that only patients who are on long-term treatment with oral anticoagulation should be considered for self-monitoring. The reasons behind this are largely pragmatic; by the time a person on short-term treatment is trained and proficient in self-monitoring, warfarin may have been discontinued.

Although it is acknowledged that excluding those who do not speak English is potentially discriminatory, including this group of patients would have created practical difficulties. If the questionnaire was completed by those who have very little command of English, this could have led to false information and error.

Although a relative or carer could assist with this task there is no way of guaranteeing the reliability of the person they seek help from. Within the current funding constraints, it was not possible to translate the questionnaire and supporting material into other languages. Also, the dominant coagulometer used in the UK is driven by an on-screen menu in English.

Patients' command of the English language was assessed by clinic staff before randomisation. A patient list was presented to them and they were asked to identify patients for whom completing the questionnaire might present problems. These patients were excluded from the sampling frame.

Exclusion criteria were as follows:

- i. Those who were on an alternative oral anticoagulation agent
- ii. Those who were out of the country long-term
- iii. Those who had been interviewed during the pilot study

The overwhelming majority of Whittington patients take warfarin, and an alternative anticoagulant agent is only prescribed if a person develops intolerance to warfarin. As all of the clinic dosing algorithms relate to warfarin, it was felt that if a patient was taking an another oral anticoagulant the clinic staff would not be able to offer sufficient support if they wished to self-monitor.

5.3.2.2 Sample size

The final questionnaire was a mostly structured instrument, pre-coded for ease of analysis, and included several questions with a binary or categorical response format. Advice from a statistician was sought, and a precision (width of confidence interval) of +/- 6% was deemed sufficient. The required sample size varies by the proportion answering "yes" to a question. The primary objective of the survey was to find out how many of our clinic population would be willing to self-test. This proportion - a "worst case scenario" for statistical purposes – was assumed to be 30%. Pooling of data from UK trials suggest that only 24% of eligible patients would agree to conduct self-monitoring.²⁸ On this basis, the sample size required to achieve the aforementioned precision for a true proportion of 30% was calculated. The required sample size was 224. Assuming a 30% response rate, this required 672 questionnaires to be sent out.

5.3.2.3 Sampling method

Systematic random sampling was applied until a total of 672 patients had been sampled. This was done using Excel™. All eligible patients were put into an Excel™ spreadsheet and, using the random worksheet function, each entry was assigned a random number. These entries were then re-ordered according to this random number and the first 672 entries selected.

The methodological and data analysis approach to this study is summarised below.

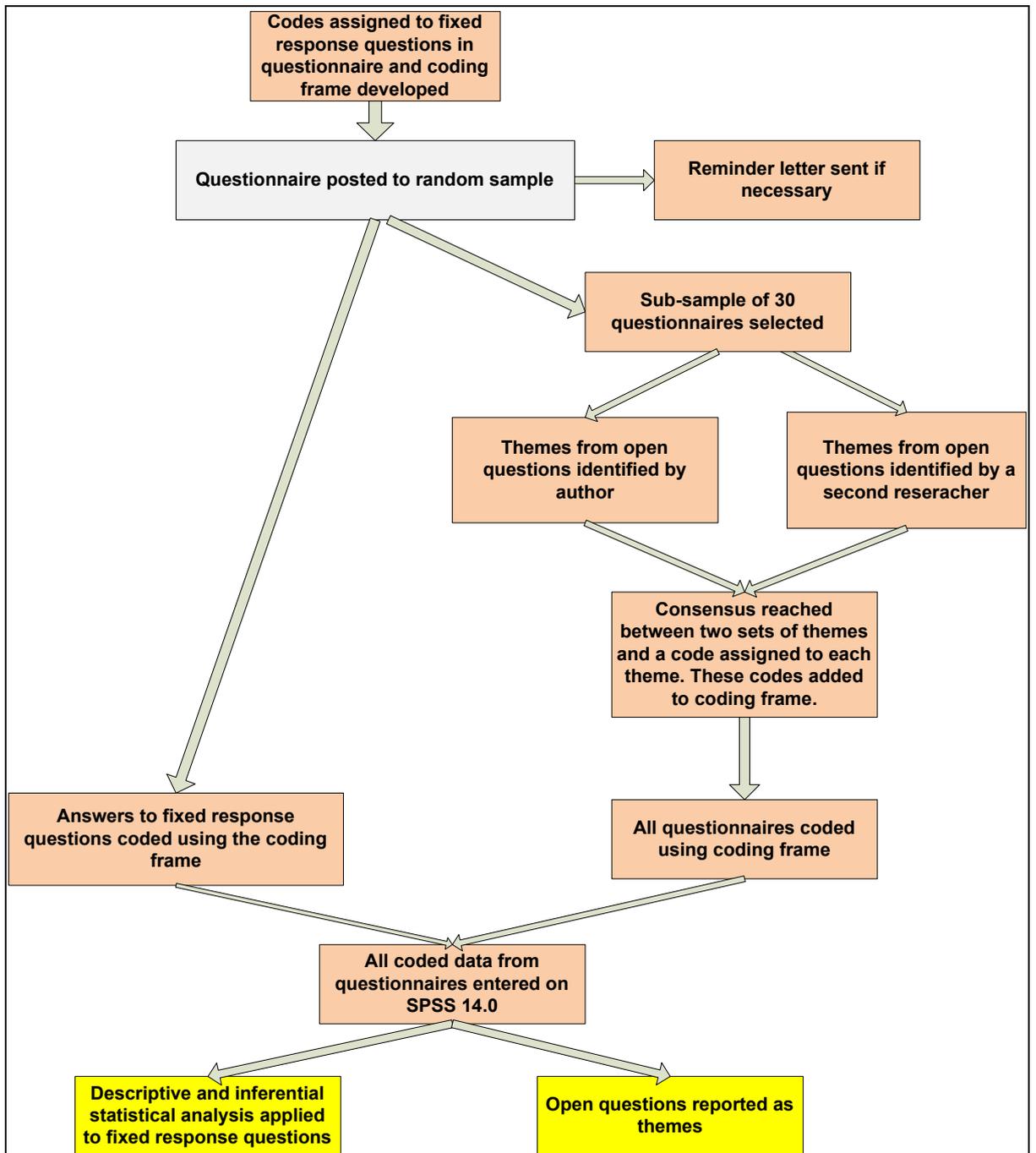


Figure 16: Patient Study 3: Methodological and data analysis approach

5.3.3 Method

The final questionnaire, covering letter, study information sheet and a postage-paid envelope for return were posted to 672 subjects. Assuming that the majority of participants would not be familiar with warfarin patient self-monitoring, an information sheet about self-monitoring was also provided to allow them to reach a more informed view of this method of monitoring. Following feedback from the previous study (Patient Study 2), the existing information sheets A and B were merged into one. A reminder letter was sent a month later to those who had not returned a questionnaire.

Respondents were given the opportunity to remain anonymous. However, they were asked if they would be willing to include their name with a view to participation in later stages of the study. Respondents were assured of the confidentiality of their responses.

The study invitation letter, study information sheet and reminder letter can be found in Appendix 7.

The questionnaire and information sheet on warfarin patient self-monitoring sent to patients can be found in Appendix 8.

Local Research and Ethics approval was granted for this study (as part of the same application for Patient Study 2). The relevant correspondence can be found in Appendix 4.

5.3.4 Analysis

Data from the returned questionnaires were coded and entered into SPSS 14.0, which was then used to generate statistical analyses. The coding process and subsequent statistical analyses will now be described.

5.3.4.1 Coding

Coding was used to conceptualise the responses to the survey and to classify these data into meaningful categories. Most of the questionnaire was made up of fixed responses, which were one of three types:

- i. Dichotomised (e.g. yes / no response choices)
- ii. Multiple choice (offering three or more choices. For some of these questions, there was no restriction on the number of responses which could be selected)
- iii. Scaled (one response code per response frame allowed. Likert scales were used to measure level of agreement)

A number – the ‘code’ - was assigned to each category, and from this a coding frame was developed. The coding frame comprised the responses to each question along with their unique numerical code.

The same numerical codes were assigned to the following response categories throughout the questionnaire:

Yes	1
No	0
Do not know	7
Does not apply	8
Missing response	9

For other response categories, a unique single or double-digit code was assigned to each response within each question. For ordinal data, higher numbers were used to indicate higher rank or more magnitude. For nominal data, sequential numbers were used.

But there was the possibility that such closed questions will miss some unanticipated patient concerns or perspectives. Therefore, some open-ended free-text questions were included. Here inductive coding was used, using a sample of data to develop a scheme, and then applying this to the whole. To develop codes for the open questions a sub-sample of 30 questionnaires was selected and the author transcribed responses to these questions together with a patient identifier number. From these responses, the main themes were identified by the author, who then coded the data into categories assigning a unique code to each category.

During the coding process a few problems were encountered. The first difficulty was where participants had supplied an ambiguous response, with their answer straddling two response categories. A record of these responses was made and answers evenly attributed to each category. The second problem was where one response to a question was requested, but the respondent answered with more than one response. In these instances, the responses were combined into pair and coded as a separate entity.

A second researcher (JM) then independently identified the main themes of the responses to open questions. Concordance between two sets of themes was achieved and these themes were then coded. Both researchers agreed on the approach for handling the response problems referred to above.

This coding frame was then tested on another batch of 30 questionnaires and some minor adjustments made. From the coding frame, a codebook was prepared. This was a master copy of the questionnaire, with the full range of valid codes and a unique variable label assigned to each question for the purposes of computer entry. Additionally, a coding transfer sheet was developed to facilitate transfer the responses from each questionnaire prior to computer data entry. Finally, all coded responses were entered on SPSS™.

5.3.4.2 Statistical analyses

All statistical analyses were performed using SPSS 14.0™. Advice from a statistician was sought.

Descriptive statistics were used to provide summaries about the sample. Frequency was expressed as a percentage with confidence intervals applied to indicate the spread of results where appropriate. The median value, with its associated interquartile range, was used to measure the central tendency where necessary.

Inferential statistics were used to examine the relationship of one variable with another. The test used depended on the type of data analysed. The tests used are summarised in Table 25.

Variable 1		Variable 2		
		<i>Binary</i>	<i>Nominal</i>	<i>Ordinal</i>
Variable 1	<i>Binary</i>	Chi-square / Fisher's Exact Test	Chi-square / Fisher's Exact Test	Mann-Whitney
	<i>Nominal</i>	Chi-square / Fisher's Exact Test	Chi-square / Fisher's Exact Test	Kruskal-Wallis
	<i>Ordinal</i>	Mann-Whitney	Kruskal-Wallis	Kendalls Tb

Table 25: Patient study 3: Statistical approach used to correlate patient survey data

Where a there was a choice of using Chi-Square or Fisher's Exact Test, the latter was used as it is considered to be more accurate and better suited for smaller data sets.

5.3.4.3 Assessing non-response bias

With mail surveys low response rates are the rule rather than the exception, and this can introduce a risk of bias. Those who do not respond may be very different from those who did respond. If substantial response bias is present, generalisability of the survey findings could be limited.

The following characteristics were available for both respondents and non-respondents:

- i. Age
- ii. Gender
- iii. Indication for warfarin
- iv. Clinic location

To assess bias for this survey these characteristics were compared for respondents and non-respondents. To determine if bias was statistically significant with respect to gender, indication and clinic location (nominal variables), Chi-square tests were conducted. When age was plotted on a histogram, it did not have a normal distribution. Using a t-test, a parametric test, would not have been appropriate and a Mann-Whitney test (non-parametric test) was performed instead.

5.3.5 Results

5.3.5.1 Sample

Of the 672 questionnaires that were sent 297 were returned, representing a response rate of 44 %. 158 of these questionnaires (53% of returns) were received after the reminder letter was sent out. The demographics of the survey respondents are summarised in Table 26.

	Number (n=297)
Gender	
Male	173
Female	121
Missing response	3
Age	
Older than 65 years	196
56 - 65 years	49
41 - 55 years	39
18 - 40 years	11
Missing response	2
Indication for anticoagulation	
Atrial fibrillation	145
Artificial heart valve	55
Venous thromboembolism	51
Mixed indication	21
Other	12
CVA or TIA	9
Missing response	4
Duration of anticoagulant treatment	
More than 5 years	134
1 year - 5 years	131
7 months - 11 months	18
1 - 6 months	6
Missing response	8
Ethnicity	
White British	185
White Irish	41
White Other	34
Black / Black British	18
Asian / Asian British	10
Mixed race	4
Other	1
Missing response	4
Education	
No formal qualifications	114
GCSE level	32
A level	17
Diploma / NVQ	20
Degree level	82
Unwilling to say	32

Table 26: Patent study 3- Demographics of survey respondents

Respondents were predominantly elderly, with 41% female and 58% male (3 respondents did not state which sex they were). The age range of respondents is shown below.

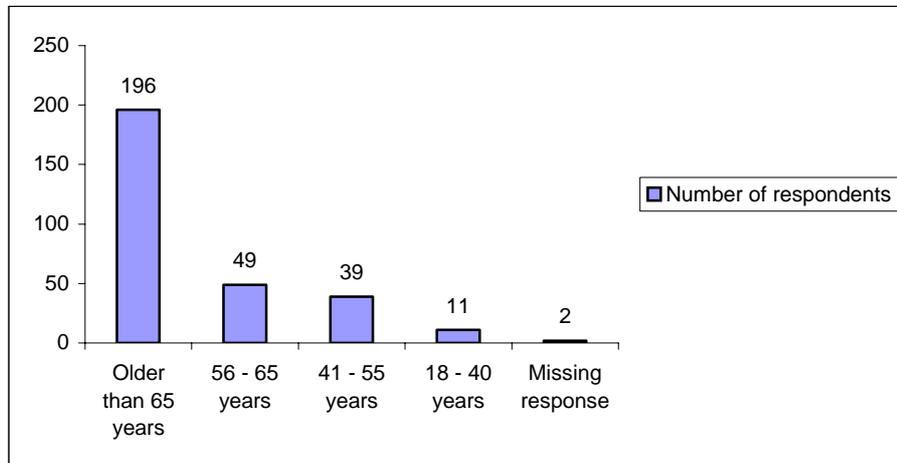


Figure 17: Patient study 3: Age of survey respondents

The majority of respondents (62%) were White British, with a further 25% from other white ethnic groups. English was the first language for 83% of those who responded to this question. There were nineteen different first languages cited. There was a wide variation in the educational level of respondents.

Nearly half of all respondents were taking warfarin for stroke prevention. Nearly all of the respondents (99%) had been on warfarin for at least one year, with over a half (134 patients) taking the drug for more than 5 years.

Approximately two-thirds of respondents (67%) were monitored by the anticoagulant clinic at the Whittington, with the remainder attending a primary care clinic. Most of the patients attending the Whittington clinic (94%) were on the 'mailing list.'

5.3.5.2 Assessing non-response bias

No significant non-response bias was detected with respect to age ($p=0.92$), gender ($p=0.09$) and clinic location ($p=0.49$). However, there was a significant difference between responders and non-responders with respect to the indication for OAT ($p=0.04$). These results are summarised in Table 27.

Indication for OAT	Responded to survey				Total
	No		Yes		
	n	%	n	%	
Other	39	80%	10	20%	49
CVA	11	64%	6	36%	17
Valve replacement	60	54%	52	56%	112
VTE	74	64%	42	36%	116
Atrial fibrillation / atrial flutter	223	63%	131	37%	354
Total	407	66%	241	34%	648

Table 27: Patient study 3: A comparison of responders and non-responders to the survey with respect to indication for oral anticoagulation

The indication of OAT was verified from the patient's electronic anticoagulant health record. Twenty-four respondents chose to remain anonymous and, therefore, their indication for OAT could not be determined. Consequently, they had to be excluded from this particular analysis.

5.3.5.3 Results

The questionnaire was split into five sections, with a final (sixth) section requesting demographic information to place responses in context:

- i. Warfarin treatment and current health
- ii. Attending the warfarin clinic
- iii. Self-monitoring warfarin
- iv. Education and support for those self-monitoring warfarin
- v. Experiences with using computers

Similar to some of the emergent themes from the patient interviews, discussed earlier in 5.2.5.3, the results from some sections of this questionnaire - warfarin treatment and current health, attending the warfarin clinic and experiences with using computers- did not make a significant contribution to the research as they do not have a direct bearing on self-monitoring. Consequently, these results are not presented here but will form the focus of a separate clinical academic publication. Instead, more value was attached to examining the relationship of these variables with willingness to self-monitor in a quantitative manner. Therefore, statistical analysis will be used to correlate these factors – for example, the relationship between willingness to self-monitor and current health.

The remaining two topics (sections) will now be discussed. Where appropriate, selective quotations are used to illustrate pertinent comments.

Self-monitoring warfarin

This section of the questionnaire explored attitudes towards warfarin self-monitoring. It aimed to establish what proportion of the study sample would be willing to self-test or self-manage their oral anticoagulation therapy. It also aimed to establish which aspects of self-monitoring were potential barriers to uptake of self-monitoring and, conversely, any factors associated with a willingness to self-monitor.

53% of respondents (150) said that they would be interested in self-testing their warfarin treatment if the Whittington clinic set up a programme to support them. [95% CI: 0.47 - 0.58] When asked the same question of self-management, this proportion did not differ.

Subjects were presented with a series of statements relating to factors that might influence their decision to self-test or self-manage their warfarin, and asked to indicate their strength of agreement on a scale from 2 – 6, with 6 being the most positive score and 2 the most negative score (negatively worded questions were reverse coded).

The median values for these responses are listed in Table 28, with the associated interquartile range to indicate the dispersion of results.

	Strength of agreement with statement	
	Median value	Interquartile range
Able to prick finger	5	4 – 6
Able to test blood	5	4 – 6
Able to adjust dose of warfarin	5	4 - 5
Miss other patients attending clinic	5	5 – 6
Like more control over warfarin	4	3 – 5
Miss staff at warfarin clinic	4	3 – 5
Able to buy machine	3	2 – 4
Happy to buy machine	3	2 – 4

Table 28: Patient study 3: Factors that might effect the decision of patients to self-monitor warfarin

Patient factors associated with a willingness to self-test

The patient sample willing to self-test was the same as those who were willing to self-manage. Therefore, for this analysis, all associations are made with those who were willing to self-test; two separate analyses – for patient self-testing and self-management – were not performed.

A variety of patient factors were found to have a significant positive correlation with a willingness to self-test are shown in Table 29.

Factor	Level of significance
Younger age (those < 65 years)	p < 0.001
Educated to a higher level (those educated to GCSE level and above)	p < 0.001
Clinic visits causing disruption to life	p= 0.002, p = 0.015
Good health (those with perceived “good” or “excellent” current health status)	p = 0.016
Fewer concomitant medicines	p = 0.037
Prior awareness of self-testing	p < 0.001
Ability to sample & test blood,	p < 0.001, p < 0.001
Ability & willingness to purchase coagulometer	p < 0.001, p < 0.001

Table 29: Patient study 3: Patient factors associated with willingness to self-test

Younger respondents ($z = -4.33, p < 0.001$) or those educated to a higher level ($z = -4.60, p < 0.001$) were significantly more likely to be interested in warfarin self-testing. The respondent's gender (Fisher's Exact Test, $p = 0.23$), whether English was their first language (Fisher's Exact Test, $p = 0.53$) or their ethnicity did not significantly affect whether they were interested in self-testing (X^2 -test, $X^2(5) = 8.31, p = 0.14$).

Where respondents had their warfarin treatment monitored (i.e. hospital or in primary care) did not significantly affect their willingness to self-test (X^2 -test, $X^2(2) = 2.89, p = 0.24$). Also, the frequency of warfarin monitoring ($Z = -.55, p = 0.58$) and the time commitment needed for these visits (both in terms of travel time ($Z = -1.83, p = 0.068$) and time spent in the clinic ($Z = -0.17, p = 0.86$) did not significantly affect respondents' willingness to self-test.

However, how easily the clinic visits fitted into respondents' lives significantly affected whether they were interested in self-testing, as assessed by the response to two attitudinal statements; *"I find it easy to plan my life around my Warfarin clinic visits"* ($Z = -3.01, p = 0.002$), and *"I find my Warfarin clinic visits disrupt my life"* ($Z = -2.44, p = 0.015$). Levels of satisfaction with the current service did not have a significant effect on the potential willingness to self-test in this study population. ($Z = -0.33, p = 0.74$)

Whether respondents required assistance with warfarin management at home did not significantly affect whether they would be willing to consider self-testing (Fisher's Exact Test, $p = 0.069$). Although there was a trend towards a willingness to self-test if the respondent considered that warfarin had had an impact on their life (Fisher's Exact Test, $p = 0.052$) or if they had experienced bleeding during treatment (Fisher's Exact Test, $p = 0.056$) this was not statistically significant.

If the respondent considered himself to be in good health, they were significantly more likely to be willing to self-test their warfarin treatment ($Z = -2.41, p = -0.016$). Similarly, the less concomitant medication the patient was taking, the more likely they were to be willing to self-test ($Z = -2.08, p = 0.037$).

Ninety-six respondents (33%) had heard of patients self-testing or self-managing their warfarin treatment before receiving the questionnaire. If respondents were aware of self-testing before the survey, they were more likely to be willing to do it (Fisher's Exact Test, $p = <0.001$).

A perceived ability to both obtain and test a blood sample was highly significantly associated with the likelihood of the patient self-testing. If a respondent felt that they would be unable to obtain a capillary blood sample, they were not likely to be interested in self-testing ($Z = -8.82, p < 0.001$). Similarly, if they thought that they would not be able to use the coagulometer they were also not likely to be interested in self-testing ($Z = -10.18, p < 0.001$). An ability to purchase the coagulometer was significantly associated with a willingness to self-test ($Z = -5.40, p < 0.001$) as was a willingness to buy the machine ($Z = -6.54, p < 0.001$).

Finally, there were two statements included in the questionnaire relating specifically to self-management of oral anticoagulation; whether patients would miss the clinic staff and if they felt they would be able to adjust their dose of warfarin. Those who felt that they would not miss the clinic staff were significantly more likely to want to self-manage their Warfarin ($Z = -5.28, p < 0.001$).

The association between the confidence of the respondent to adjust their dose and a willingness to undertake self-management was even more striking. Of the 61 respondents who 'disagreed' or 'strongly disagreed' that they would be able to adjust their dose of warfarin, only two felt they would like to self-manage.

Education and support for those self-monitoring Warfarin

Support for OAT self-monitoring

Respondents were asked to indicate how important the following elements of support for self-monitoring OAT were on a scale from 2 – 5, with 5 being the most positive score (very important) and 2 the most negative score (not important).

- i. Being provided with warfarin education
- ii. Making it easy for them to contact the warfarin clinic
- iii. Clinic providing coagulometer
- iv. Receiving regular clinic check-ups

The median score for all four elements was identical at 5 (very important). These results are presented graphically in Figure 18.

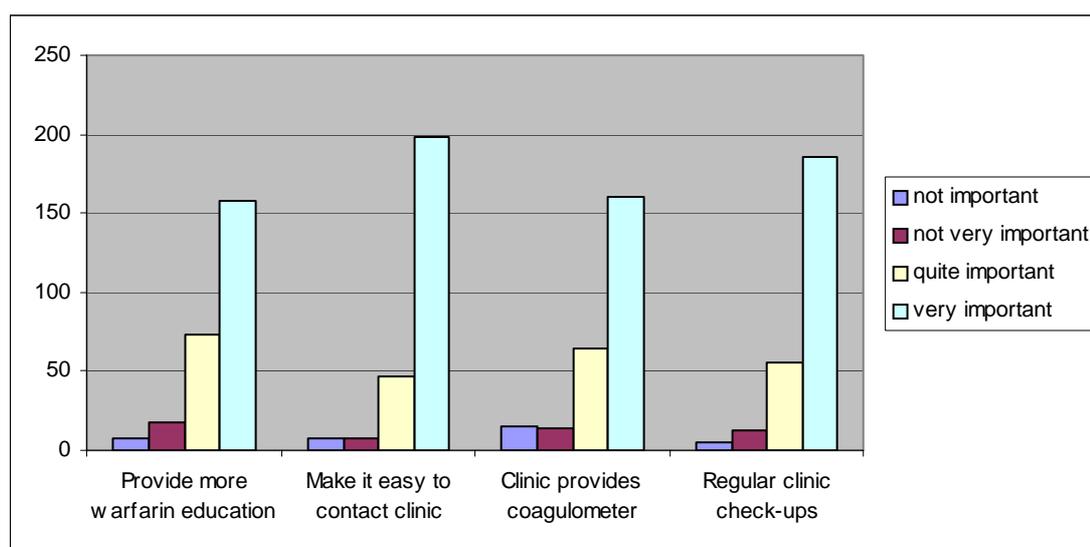


Figure 18: Patient study 3: Patients' views of the importance of elements of self-monitoring support

Respondents were then asked to suggest other ways that the clinic could support them if they were to self-monitor their oral anticoagulation. This generated suggestions from 56 respondents which are summarised in Table 30.

Support element	Number of respondents	Further information
Support from clinic staff	16	<ul style="list-style-type: none"> ➤ Domiciliary visits ➤ Telephone support ➤ Email support ➤ A dedicated website ➤ Sending INR by computer to clinic for remote monitoring
Lack of confidence in ability to self-monitor	12	
Clinic to provide coagulometer	9	
Other	7	<ul style="list-style-type: none"> ➤ Peer support ➤ Request to view evidence to support self-monitoring
Prefer to continue attending clinic	6	
Concerns about QC of coagulometer	6	

Table 30: Patient study 3: Survey respondents’ suggestions for self-monitoring support

However, not all of these comments related to ways that support could be offered, but instead respondents used the question as an opportunity to voice concerns about self-testing. An overarching concern was the ability to access the clinic for advice when required, echoing comments from the pilot interviews group.

Six patients stated a strong preference for continuing to have their INR monitored at an anticoagulant clinic.

“No own test. Leave it to the expert.” (Respondent 264)

Closely linked to this were respondents’ concerns about their ability to self-test:

“I prefer to have my blood test done by a professional person. I think I would find the strip difficult to use, although I have no problem testing my blood sugar with the monitor.” (Respondent 21)

Educational requirements for patient self-monitoring

Respondents were also presented with a list of potential educational requirements for OAT patient self-monitoring, and were asked to indicate which option would be useful. The results are represented in Figure 19 below.

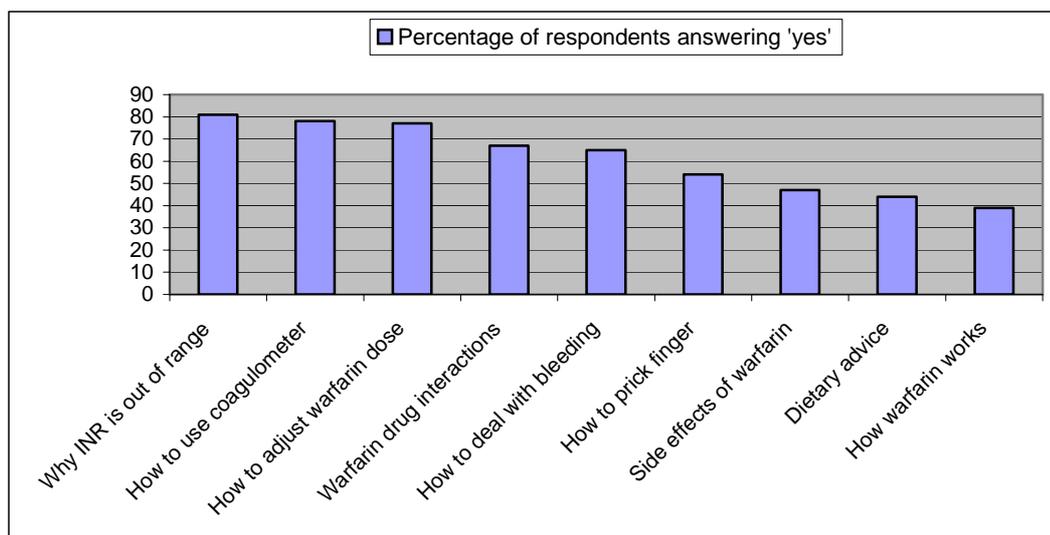


Figure 19: Patient study 3: Survey respondents’ requirements for individual educational elements to prepare them for anticoagulation self-monitoring

The more ‘practical’ skills were the most popular options – how to use the coagulometer, deciding why the INR is out of range and warfarin dose adjustment skills – although being taught finger-prick technique was less popular. This could be because some patients were also diabetic and were therefore familiar with this technique, or that simply respondents felt that it was straightforward and they did not require formal teaching.

Subjects were then asked to suggest other types of information or skills that might help them take a greater role in managing their warfarin treatment. A total of 25 respondents provided comments. As before, many of these respondents (n=13) expressed a preference to remain with the clinic or a lack of confidence to undertake self-monitoring.

“At 91, I do not want to be expected to do tests on myself. It is enough to manage myself from day to day without any extra responsibilities. I feel happier with trained hospital staff doing the testing.” (Respondent 159)

Seven patients requested a 'higher' level of warfarin information, supported by written information. Again, assistance with quality assurance of the coagulometer was important to some patients.

5.3.6 Limitations

Steps were taken during this study to increase its validity. Face, content and construct validity were increased by extensive piloting of the questionnaire, initially through expert review and then by using the instrument to conduct face-to-face interviews with ten patients. This piloting ensured that the questions were unambiguous and were likely to yield accurate information, that all possible responses were included, that questions would measure what they were intended to measure and that the questionnaire would include all relevant issues.

The main weakness of pre-coded responses may not accommodate all possible answers. This may force respondents to select pre-coded responses that do not fully represent their views, threatening validity. To try to mitigate this, although the questionnaire was largely structured, it also contained some optional questions requiring a free text response, accommodating more patients' views.

Biases can affect both the validity and reliability of an instrument. Although postal self-completion surveys eliminate interviewer bias, response bias can be accentuated. Therefore, reminders and second questionnaires were used to increase the response rate and non-response bias was measured. Response style ('yes-saying') bias was guarded against by including both positively and negatively-worded questions. Sampling bias was guarded against by using a randomised sampling.

Reliability in questionnaire studies relates to their reproducibility; that is ability of the instrument to produce the same results if it were tested it many times over. However, this is difficult to demonstrate in practice. If time had permitted, test-retest, a statistical method used to determine an instrument's reliability, could have been performed.¹³⁹ This would have entailed testing the questionnaire on a small number of the study sample twice, several weeks apart, and performing statistical tests to measure correlation. Although opinion is divided on which statistical tests are the best measure of correlation, Cohen's kappa coefficient (nominal data), weighted kappa (ordinal data) or Pearson's coefficient (interval data) are generally used.

This chapter has described three studies exploring patients' perspectives of OAT patient self-monitoring. The final section of this chapter consolidates and summarises these results and places them in the context of published work.

5.4 Summary of patients' perspectives on OAT self-monitoring

The findings from these three studies are summarised in Table 31. No weighting was applied to the results from the three individual studies; the first two studies recruited far smaller patient numbers. However, a different set of results was generated from each study. Therefore, to ensure a comprehensive set of findings, the results from all three studies are presented.

There are four distinct sections to this table – drivers, benefits, barriers and challenges to OAT patient self-monitoring - derived from the perspectives of anticoagulated patients. Sub-themes within these broad themes are described, with a summary of supporting evidence from each of the studies where available. Finally, these sub-themes are mapped to a suggested, or 'candidate', service requirement from a patient perspective and where it fits within the Donabedian framework.

These results will be triangulated with the findings from the next chapter, which will explore the perspectives of healthcare personnel.

Table 31: Summary of patients' perceptions of OAT self-monitoring (drivers)

Drivers	Patient perspectives			Derived candidate service requirement	Donabedian framework element
	Exploratory interviews with self-monitoring patients	Interviews with local anticoagulant clinic patients	Survey of with local anticoagulant clinic patients		
Convenience	Convenience cited as a major motivating factor for starting OAT self-monitoring	Convenience identified as a potential benefit	Patients were significantly more willing to self-monitor if clinic visits were disrupting their life	Self-monitoring service is acceptable to patients	Outcome
Independence	The need for more independence was a driver for starting OAT self-monitoring			Self-monitoring service is acceptable to patients	Outcome
Availability of support for patients	The support of healthcare professionals and family were important when starting to self-monitor.	Ability to access advice and for the clinic to provide regular reviews was important	Support from the clinic was considered very important if self-monitoring OAT. The availability of timely advice was a concern.	Provide ongoing support for patients (regular review and ad-hoc support)	Process
Awareness of OAT self-monitoring			Patients who were aware of self-testing before the survey were significantly more willing to self-monitor	Promote the self-monitoring service to patients	Structure

Table 31 (cont): Summary of patients' perceptions of OAT self-monitoring (benefits)

Benefits	Patient perspectives			Derived candidate service requirement	Donabedian framework element
	Exploratory interviews with self-monitoring patients	Interviews with local anticoagulant clinic patients	Survey of with local anticoagulant clinic patients		
Convenience	Convenience cited as a major motivating factor for starting OAT self-monitoring	Convenience identified as a potential benefit	Patients were significantly more willing to self-monitor if clinic visits were disrupting their life	Self-monitoring service is acceptable to patients	Outcome
Reassurance		The ability of test INR at home might be reassuring		Self-monitoring service is acceptable to patients	Outcome
Improved INR control		Self-monitoring may improve INR control		Self-monitoring service will be /is safe	Outcome

Table 31 (cont): Summary of patients' perceptions of OAT self-monitoring (barriers)

Barriers	Patient perspectives			Derived candidate service requirement	Donabedian framework element
	Exploratory interviews with self-monitoring patients	Interviews with local anticoagulant clinic patients	Survey of with local anticoagulant clinic patients		
Provision of the coagulometer	The need to purchase the coagulometer almost deterred two the patients interviewed from self-monitoring	Many participants felt that the cost of the machine was a barrier to the uptake of INR self-testing	Patients were significantly more willing to self-monitor if they were willing and able to buy a coagulometer	Facilitate provision of the coagulometer	Structure
Lack of confidence in testing INR	One participant had initial difficulties in testing INR	Many participants stated that instruction on using the coagulometer was a prerequisite for its use	Patients were significantly more willing to self-monitor if they were confident in their ability to test their INR	Provide patient training in self-testing and using the coagulometer	Process
Patient eligibility	One participant felt that not all patients would be able to self-monitor	Participants had doubts as to the ability of some patients to cope with self-monitoring		Construct patient eligibility and assessment criteria	Structure
Confidence in the accuracy of the coagulometer		Reassurance about the accuracy of the coagulometer was important to some participants	Concerns about QA of the coagulometer expressed	Establish process for quality assurance (QA) of coagulometer	Structure
Patient preference for alternative models of care			53% of sample willing to self-test. Six respondents expressed a wish to continue with current service model	Gauge patient demand Conduct options appraisal	Structure Structure

Table 31 (cont): Summary of patients' perceptions of OAT self-monitoring (challenges)

Challenges	Patient perspectives			Derived candidate service requirement	Donabedian framework element
	Exploratory interviews with self-monitoring patients	Interviews with local anticoagulant clinic patients	Survey of with local anticoagulant clinic patients		
Adjusting dose of warfarin	Self-managing patients had different ways of adjusting warfarin doses	Anxiety expressed at the prospect of adjusting the dose of his warfarin in PSM		Provide education and support for dose adjustment by patients (PSM)	Process
Educating self-monitoring patients			Being provided with warfarin information was very important to survey respondents (median score)	Develop and deliver an educational programme for patients	Structure Process
Support for self-testing patients	Support was valuable to self-monitoring patients	Support required in terms of regular review and ad-hoc advice	Regular clinic check-ups were very important to survey respondents (median score). Other means of support also identified.	Provide on-going support to self-monitoring patients	Process

5.4.1 Summary list of candidate service requirements from studies with patients taking oral anticoagulation

STRUCTURE

- Gauge patient demand for OAT self-monitoring
- Promote the self-monitoring service to patients
- Facilitate the provision of coagulometers (e.g. by funding coagulometer)
- Construct patient eligibility and assessment criteria
- Develop an educational programme for patients
- Establish a process for quality assurance (QA) of coagulometers

PROCESS

- Provide patient training in self-testing and using the coagulometer
- Deliver an educational programme to patients
- Provide education and support for dose adjustment by patients (PSM)
- Provide ongoing support to self-monitoring patients (regular review and ad-hoc support)

OUTCOME

- Self-monitoring service is safe
- Self-monitoring service is acceptable to patients

5.5 Discussion

This series of studies has explored how patients view self-monitoring of oral anticoagulation. Over half of our clinic population surveyed (53%) stated that they would be interested in self-testing or self-managing their warfarin treatment if the Whittington clinic set up a programme to support them. This is greater than would be expected from published data; pooling of data from UK trials suggest that only 24% of eligible patients would agree to conduct self-monitoring.²⁸

However, this observed difference may reflect the difference between trial conditions and real life, and the results of this survey are more consistent with two recently published studies assessing the potential uptake of OAT patient self-monitoring. In an American study led by Jacquelyn Quin, 211 anticoagulated patients from two clinics, the anticoagulation clinic service (ASC) and vascular service clinic (VSC), participated in a 15 minute telephone survey to assess their interest in self-testing.¹⁶⁰ 61% of those in the ASC group and 49% in the VSC group indicated that they would be interested in self-testing (non-significant difference). Closer to home, 44% of eligible patients audited at UCH agreed to self-monitor.⁸⁶

Whilst it is useful to know the level of potential uptake of OAT patient self-monitoring, one of the aims of this body of work was to gain a better understanding of how patients view self-monitoring of oral anticoagulation therapy. The focus in the literature has been on the societal, economic and technological drivers for OAT patient self-monitoring, but with little attention paid to the factors that what motivate patients to self-monitor, or the barriers and challenges that they may face.

The patient drivers, barriers and challenges to OAT self-monitoring identified in this body of work will now be summarised, together with the service requirements for an OAT self-monitoring service derived from the views of these patients.

5.5.1 Drivers for OAT patient self-monitoring

As the initial study of self-monitoring patients is limited by its size, it is impossible to draw any firm conclusions. However, these interviews may provide a little insight into some of the characteristics of these “early-adopters.” Relatively easy access to an informed healthcare professional played a big role in starting these patients on their self-management journey, and a “local champion” can be instrumental in offering patients a self-monitoring model of care.

Across the three studies, these drivers for self-monitoring translate into patient acceptability as an outcome measure for the service. Acceptability was characterised as providing the reassurance brought about by the ability to test the INR at home, the independence resulting from self-monitoring but, predominantly, in terms of providing a more convenient service.

The overwhelming motivation for all of these participants to start self-managing was convenience, providing them the flexibility to perform INR tests when and where convenient, especially for those with demanding jobs or who travelled frequently. This view was echoed by those not self-monitoring their OAT. From the point of view of the service provider, the need to cope with increasing volumes of patients coming through anticoagulation monitoring services has been cited as a driver for development of a patient self-monitoring model. But for the patient, busy clinics and associated long waiting times in clinic are potentially inconvenient, and those survey respondents who found clinic visits disruptive were significantly more likely to be willing to self-monitor.

Contrary to the author's expectations, the clinical setting where respondents had their warfarin treatment monitored did not significantly affect their willingness to self-test. The Whittington Stroke Prevention and Anticoagulation Monitoring Service is committed to moving the service nearer to the patient, and a third of this population sample had their oral anticoagulation monitored in primary care. It was possible that this patient cohort would be more willing to undertake self-testing, having already broken the 'umbilical cord' with the hospital clinic. This was not the case. However, because the patient is attending a service more convenient to them this may "balance out" a potentially increased willingness to assume more responsibility for their care.

5.5.2 Barriers to OAT patient self-monitoring

To establish the requirements for migration to a self-monitoring service, it is essential also to establish, and address, potential barriers. The main barriers identified were patient acceptance of self-monitoring, confidence in testing the INR, the need for the patient to purchase the coagulometer, and a preference for the current monitoring service. From these barriers, the following service requirements were derived:

STRUCTURE – Gauge patient demand; Facilitate provision of the coagulometer

PROCESS – Provide training in self-testing and in using the coagulometer

Making self-monitoring acceptable to patients is likely to be a considerable barrier to its uptake. From this survey, younger (less than 65 years), better-educated patients were more likely to be willing to self-monitor their oral anticoagulation. Relative youth as a predictor of uptake of PSM has also been reported in other studies.^{86;160} Carl Heneghan's meta-analysis suggested that patients who are new to warfarin treatment might be more willing to self-test.¹⁰⁴ Also, audit work conducted at UCH suggested that increased uptake was likely if patients were offered PSM from the start of treatment.⁸⁶ The results of this survey were not consistent with these earlier findings; the length of warfarin treatment did not significantly affect whether the respondents were interested in self-testing. In common with the UCH study, there was no gender-related difference in potential uptake.

Patients' confidence in their own skills and abilities to cope with self-testing was a recurrent theme throughout these studies. Confidence is a complex construct and is difficult to measure. People's beliefs that they can motivate themselves and regulate their own behaviour may play a vital role in their confidence to initiate and maintain self-management. Various psychological features affect health behaviour, but two are of particular interest in analysing the behaviour of those participating in self-care; locus of control and self-efficacy.

Locus of control is a psychological concept referring to an individual's expectations of who or what is responsible for what happens. There are three modifiable beliefs that a person may hold:¹⁶¹

- i. They have control over the illness & outcome ('Internal')
- ii. Healthcare professionals are responsible for managing their illness ('External') – this may be linked to the public image of healthcare services
- iii. The outcome of their illness is a matter of pure chance ('External') - may be determined by religious or socio-cultural views

If a person has an internal locus of control then they interpret events as being dependent on their own behaviour, as opposed to being contingent on luck, fate or the influence of others (external locus of control). Applying this theory to the health setting, those who have a strong internal locus of control may be more likely to take a more active role in managing their health, as they may feel that they have control over their own health and are more likely to pursue health-promoting behaviours. Results from diabetes locus of control research are conflicting; no published studies were found relating locus of control with oral anticoagulation management.

Self-efficacy is important for self-management behaviour, in both initiating and maintaining this behaviour. The theory of self-efficacy proposes that people avoid activities that they perceive as more than they can manage.⁹⁴ Two studies have reported improvements in self-efficacy in those who were self-managing their oral anticoagulation.⁴³

Whilst locus of control and self-efficacy provide a basis for analysing the behaviour of those engaging in self-care, Ajzen's theory of planned behaviour affords a more comprehensive view of self-care behaviour by identifying other possible important predictors of self-care behaviour. This widely-used social cognition model, asserts that health-related behaviour can be predicted by intention which is influenced by three factors: attitude, subjective norm and perceived behavioural control.¹⁶²

Attitude relates to the person's beliefs about the outcome of the health-related behaviour; that is, whether this will be good or bad, harmful or beneficial, pleasant or unpleasant. Subjective norm refers to the person's beliefs about the expectations of the key people in their life. Perceived behavioural control relates to the person's perceived control over the ability to perform the behaviour. The concept of behavioural control includes the concept of self-efficacy.

According to this theory, the stronger the behavioural intention to engage in a self-care behaviour, the more effort the individual is likely to put into performing self-care. A study of predictors of self-care behaviour in those with type 2 diabetes suggest that relationship exists between attitudes, perceived behavioural control, subjective norm and intent to perform self-care behaviour.¹⁶³ Of these, perceived behavioural control was the most predictive of behavioural intentions and actual performance of self-care behaviour.

In this study, those who felt that they would be able to test their own INR and adjust their dose of warfarin were significantly more likely to be willing to self-monitor. This is consistent with published data. Pooling of data from UK trials suggest that one of the main reasons for refusing to participate in self-monitoring trials was a fear of blood sampling.²⁸ Carl Heneghan also identified difficulty measuring INR, visual impairment and lack of manual dexterity as reasons cited by authors for patients dropping out of the study.¹⁰⁴ Two out of three of the self-monitoring patients interviewed admitted to initial difficulties in testing their INR, and it will be interesting to see if these experiences are replicated on a slightly larger scale through the patient self-testing pilot. These data suggest the inclusion of patient training on self-testing and using the coagulometer as a process element in the requirements framework is essential.

A 'leave it to the expert' dimension emerged through the study, with a small number of patients expressing a strong preference to continue to have their INR monitored at an anticoagulant clinic. Jacqueline Quin's study echoes these findings. Most of those who were not interested in self-testing did not want to assume responsibility for self-testing, or felt that anticoagulation monitoring was best undertaken by a healthcare professional. This finding challenges the assumption of policy-makers that patients will embrace self-management. On this basis, it would appear prudent to gauge patient demand before establishing an OAT patient self-monitoring service. The likely reality is that some patients may not be prepared to take the plunge, and ways of encouraging patients to self-test will need to be considered. One option, to be explored in the patient self-testing pilot, may be to offer patients an opportunity to try it for six months, with no obligation to continue self-testing after this trial period.

The requirement to purchase a coagulometer represents a significant barrier to patient self-monitoring oral anticoagulation in our clinic population, and finding a way to facilitate provision of these machines may be a necessary intervention to increase uptake of the service. Although 53% of survey respondents indicated that they would be willing to self-monitor their oral anticoagulation, when those who would be willing to self-monitor AND purchase a coagulometer were considered this proportion dropped to 15%. At £399, the price of a coagulometer is not insignificant, and currently is not funded by the NHS. There may be ways to ease this financial burden – for example, one of the coagulometer manufacturers has offered a scheme whereby the patient pays for the machine over several months. However, two problems of a more philosophical and ethical nature remain. Firstly, the necessity for the patient to fund the machine goes against the principle of the NHS being free at the point of care. Secondly, the cost of the machine may exclude the less affluent members of the clinic population, leading to an inequitable service.

Ironically, when introducing a patient self-monitoring service, the anticoagulation clinic could be a victim of its own success. Satisfaction with the current service has been cited as a reason for patients not participating in self-monitoring clinical trials²⁸ and has been found to be a reason for not wanting to self-test.¹⁶⁰ However, in this patient survey, levels of satisfaction with the current service did not have a significant effect on the potential willingness to self-test.

5.5.3 Challenges to OAT patient self-monitoring

Two key service requirements, centred on education and support, were derived from the challenges arose facing the establishment of an OAT patient self-monitoring service:

STRUCTURE – Develop an anticoagulation educational programme for patients

PROCESS – Deliver an anticoagulation educational programme for patients;

Provide education and support for dose adjustment by patients (PSM only)

The need for adequate educational preparation was echoed by many study participants, although views were mixed as to the content of any educational package. Whilst guidance on how to test the INR was thought to be very important, there was less agreement on whether patients needed theoretical knowledge of INR.

In addition to preparatory education, a need for support was voiced. This support could come from more than one source – healthcare professional, family and peers – and take the form of ongoing support and regular review.

Self-monitoring OAT was felt not to be suitable for all, with a need to identify those who would be eligible for this model of care.

Finally, some patients had concerns about the way in which self-monitoring would be introduced. They felt reluctant to completely sever their ties with the service they currently use. Whilst they welcomed the independence and flexibility that self-monitoring could bring, they wanted assurance that they would still retain contact with the service.

There was also the question of how quickly a patient self-testing service should be introduced, with some favouring a phased introduction. The accepted wisdom is that service redesign should be manageable and testing incremental changes is a safe way to learn about redesign and foster a more receptive culture.¹⁶⁴ This is the approach that has historically been adopted by the Whittington Anticoagulation Monitoring and Stroke Prevention Service, with incremental improvements in service reflecting increasing levels of empowerment, from the hospital consultant through to the anticoagulation nurse specialist to the community pharmacist or practice nurse.

Giving the patient the opportunity to assume greater responsibility for their oral anticoagulation is the next step on this journey. Nevertheless, this has to be implemented in a controlled manner, and it may be prudent to introduce a patient self-testing service initially with a view to “progressing” to self-management subject to the patient and clinician agreeing they are ready. Although a detailed discussion on service reorganisation is outside of the scope of this thesis, support for patient self-monitoring will need to be integrated into the current service, with resultant potential changes in workflow and staff roles. A preliminary exploration of the requirements for a patient self-testing service will be made through the pilot PST study.

In conclusion, this research described in this chapter has explored the perspectives of patients to identify the drivers, benefits, barriers and challenges to OAT patient self-monitoring, and a set of candidate service requirements has been derived. The other main stakeholders are the clinicians supporting self-monitoring patients, and those commissioning this model of care. The next chapter describes how the views of these healthcare professionals and managers were evaluated.

CHAPTER 6: EXPLORING THE VIEWS OF HEALTHCARE STAFF ON PATIENT SELF- MONITORING OF ORAL ANTICOAGULATION: A FOCUS GROUP STUDY

In the last chapter, the views of patients about self-monitoring of oral anticoagulation were explored. The convenience of self-testing, liberating the patient from regular anticoagulant clinic visits, was the main motivating factor for self-monitoring. The main barrier to patient uptake was the requirement to buy the coagulometer. Challenges included adequate educational preparation, and introduction and integration of PST / PSM into the anticoagulation monitoring service. However, ultimately, some patients may not have the confidence or willingness to self-monitor their OAT.

As this research was seeking to establish the requirements for a service to support patient self-testing and patient self-management, it was important to understand the views of those who would be supporting, commissioning and managing such a service.

Thomas Kuhn defined a paradigm as a worldview that is essentially an interrelated collection of beliefs shared by scientists (or healthcare professionals).¹⁶⁵ Traditionally, healthcare professionals have been wedded to a paradigm derived from the treatment of acute illness, which has been the focus of their professional education.¹⁶⁶ The healthcare professional's view of the management of oral anticoagulation may differ from those taking warfarin. Whilst this may not necessarily present problems, difficulties may arise when the goals and expectations of each group do not match.

In recent years, the NHS has moved towards a system that is highly dependent on the effective commissioning of services by primary care trusts (PCTs). At the time of conducting this study (September 2009), PCTs were responsible for commissioning services from secondary care. In effect PCTs were responsible for ensuring that patients received the support they need; this would include self-care support.

From a financial perspective, the support of commissioners and hospital managers is essential. The PCT will need to be assured that OAT self-monitoring represents the best use of finite resources to meet the needs of their local population. From the point of view of hospital managers, the establishment of an OAT self-monitoring service should be a cost-effective way to increase service capacity without incurring loss of revenue to the organisation.

As discussed earlier (3.8), the views of all of these stakeholders – healthcare professionals, commissioners and hospital managers - have not been systematically studied. Therefore, the aim of this part of the research was to explore clinicians' and managers' views on patients self-monitoring their oral anticoagulation. From establishing the drivers, benefits, barriers and challenges of OAT patient self-monitoring from the perspectives of healthcare personnel, it was hoped to derive a set of suggested, or 'candidate' requirements of a service designed to support OAT patient self-monitoring.

This was done through two focus group meetings. The rationale underlying the choice of this methodology has been previously described in Chapter 3 (4.4.2).

The design of this focus group study is summarised in Figure 20.

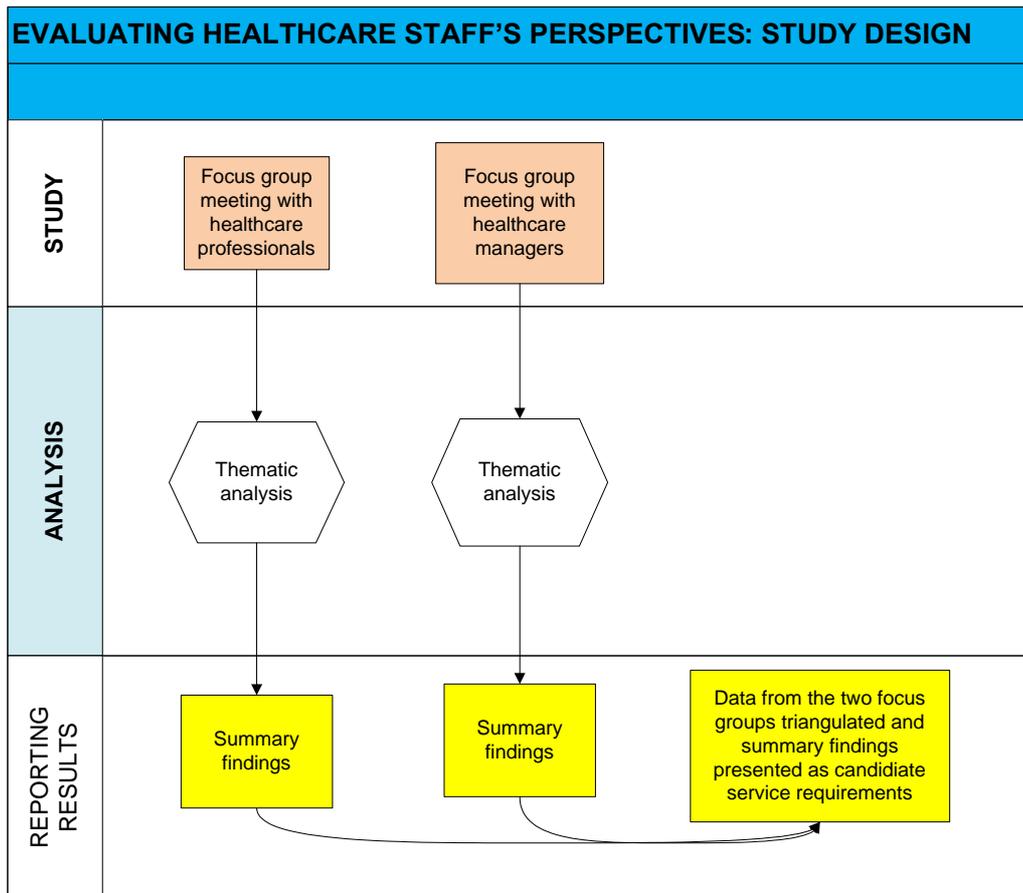


Figure 20: Evaluating the perspectives of healthcare staff on OAT patient self-monitoring: Study design

This chapter describes how these focus group meetings were conducted and their findings.

6.1 Aim and Objectives

The aim of this part of the research was to explore the perspectives of clinicians and healthcare managers on warfarin patient self-testing and self-management.

Within this aim, there were two objectives:

- i. To identify the key drivers, benefits, barriers and challenges of OAT patient self-monitoring from the perspectives of clinicians and healthcare managers
- ii. To derive a set of candidate requirements for a service to support OAT patient self-monitoring from the perspectives of clinicians and healthcare managers

6.2 Recruitment of sample

Twelve individuals who were delivering, or who had managerial responsibility for, anticoagulation monitoring, or who were responsible for commissioning these services were identified by the author or colleagues working in the Whittington Anticoagulation Monitoring and Stroke Prevention Service. These were individuals that were known to the author and colleagues; they had either collaborated with them to develop anticoagulation monitoring services, and / or were thought to have valuable insights into OAT patient self-monitoring. A mixture of purposive and convenience sampling was used. Purposive sampling in that the sample was selected to represent the views of different stakeholders from both sides of the healthcare interface (secondary and primary care). Convenience sampling in that these participants were near to hand, easy to recruit and were likely to respond.

The aim was to hold two focus groups of six individuals; focus groups typically have between six and twelve participants.¹³⁹ As many researchers advocate homogeneity within each group,¹⁴³ two separate meetings were held - one group with healthcare professionals and the other with managers - as opposed to one meeting with all participants:

Group One with healthcare professionals, comprising hospital doctors, general practitioners (GPs), hospital nurse specialists, practice nurses, community pharmacists and hospital pharmacists.

Group Two comprising healthcare managers, including representatives from primary care, clinical governance and general hospital management.

Written invitations were sent out by email to twelve healthcare staff in August 2009, along with an information sheet for the study. The invitation letter and study information sheet can be found in Appendix 9. The author asked potential participants whether they are willing to be involved; once a positive response was received, the author contacted the participants with the dates of the focus groups and sent the consent form for them to read.

Local Research and Ethics approval was granted for this study. Relevant correspondence is in Appendix 10.

6.3 Method

The methodological and data analysis approach to this study is summarised below.

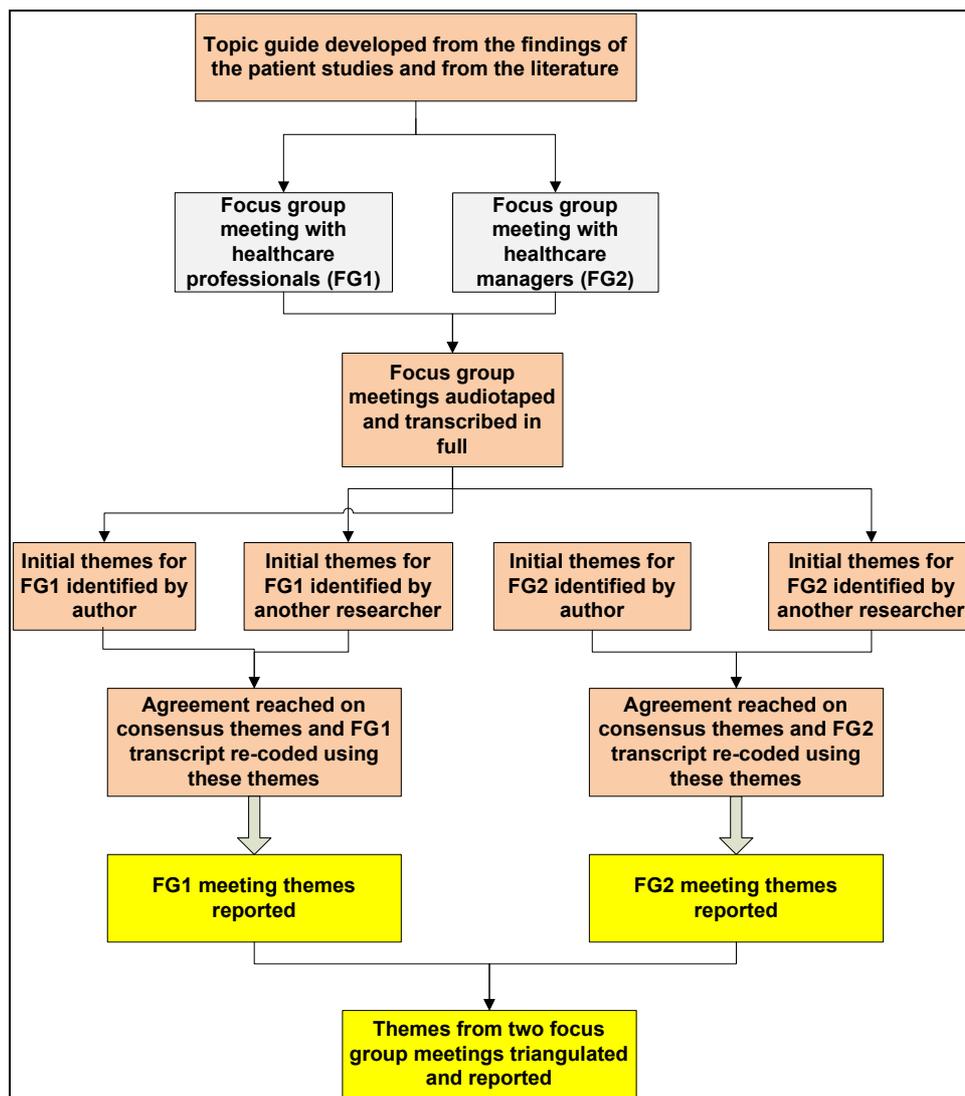


Figure 21: Focus group study with healthcare staff: Methodological and data analysis approach

6.3.1 Development of focus group topic guide

A topic guide was developed with the aim of generating discussion about topics of interest. The overall aim was to identify the drivers, benefits, barriers and challenges to setting up and delivering an OAT patient self-monitoring service. The topic guide

was developed from two main sources: emergent themes from the patient-centred studies and the published literature.

The first source was the list of emergent themes from the patient-centred studies reported in the last chapter. These were used in one of two ways; either in the construction of the question itself, or to generate response prompts. The construction of these questions and response prompts is summarised in Table 32.

Further topics were identified from the published literature. As described in section 3.8, one published study was located exploring the barriers to OAT patient self-monitoring from the point of view of American anticoagulant practitioners.⁹⁵ As the main barriers identified were financial ones, additional prompts relating to service funding were included.

Further insight was gained from published studies of healthcare professionals' perspectives of patient self-management of long-term conditions.¹⁶⁷ A reluctance to embrace sharing care with patients emerged from this work. Therefore two questions exploring sharing responsibility with patients were included.

Finally as there is currently a lack of clarity around accountability for self-management, a question to explore managing any extra risk incurred with OAT patient self-monitoring was included.

The topic guide can be found in Appendix 11.

Study objective	Emergent themes from triangulated results from patient studies	Use in focus group topic guide	
		Interview question	Response prompts (where provided)
Drivers for OAT patient self-monitoring	Availability of support	Participants asked for their views on how to support self-monitoring patients	Check up on patients regularly Make it easy for patients to contact the clinic if they have concerns
Barriers to OAT patient self-monitoring	Patient acceptability	Participants asked if they thought their patient population was ready to self-monitor.	The proportion of patients who would be interested in PST or PSM
	The need for the patient to purchase the coagulometer	Participants asked for their views on the barriers to implementing a self-monitoring service	Patient engagement Cost of the coagulometer
		Participants asked if they thought their patient population was ready to self-monitor	The proportion of patients who would be able to buy a coagulometer
		Participants asked for their views on how to support self-monitoring patients	Provide patients with the coagulometer
		Lack of confidence in testing INR	Participants asked if they thought their patient population was ready to self-monitor
	Patient eligibility	Participants asked how patients who wished to self-monitor should demonstrated competency	
		Participants asked which types of patients would benefit from self-monitoring	Exclusion criteria? Criteria for PST different from PSM
Challenges of OAT patient self-monitoring	Educating self-monitoring patients	Participants asked for their views on how to support self-monitoring patients	Provide more information or education about warfarin
		Participants asked for specific educational requirements to prepare a patient for self-monitoring	
	Adjusting dose of warfarin	Participants asked if they thought their patient population was ready to self-monitor	The proportion of patients who would be able to adjust their dose of warfarin

Table 32: Focus group study with healthcare staff: Construction of topic guide from emergent themes from patient-centred studies

6.3.2 Conducting the focus group meetings

Two focus meetings, with six people per group, were held in a private room in the pharmacy department at the Whittington Hospital in September 2009. Meetings were audiotaped with the subjects' permission. Each group had two facilitators; the author leading the discussion using the topic guide, and one other making contemporaneous field notes. Before the discussion commenced, participants were asked for written consent and given a brief information sheet about self-monitoring of oral anticoagulation to read. This information sheet can be found in Appendix 12.

6.4 Analysis

Discussions from the two focus group meetings were transcribed verbatim by the author. Transcriptions were anonymised, both in the transcription of the tape recordings and in written field recordings. Data were read to identify an initial list of themes and subthemes. The transcripts were then re-read and the audiotapes listened to a second time to refine these themes. As small numbers of subjects were involved, themes were inputted manually in a spreadsheet.

Using the same methodology, another researcher with expertise in qualitative analysis (JM) independently read the transcriptions to identify themes and subthemes. The author and JM then compared their analyses and, after discussion, a consensus was reached on a common set of themes. The focus group transcripts were then re-coded using this set of consensus themes.

The focus groups observers' notes were also reviewed to take into account their observations, especially non-verbal cues and their perceptions of the reactions and interactions of the participants.

Finally, the results from the two focus groups were triangulated. The approach to triangulation of results has been previously described in Chapter 4 (4.5.4).

6.5 Results: Focus Group One – Healthcare Professionals

6.5.1 Sample

All six healthcare professionals invited agreed to participate in this focus group. The composition of the focus group is summarised in Table 33. The participant code comprises the participants' sex and identifying number (e.g. M1 refers to the first male participant in the study).

Participant code	Job title	Role	Location
M1	Consultant Cardiologist	Clinical Lead for Anticoagulation Monitoring Services	Acute Trust
M2	Consultant Haematologist	Clinical Lead for Anticoagulation Monitoring Services. Involved in a patient advocacy group for OAT self-monitoring on national level.	Acute Trust
F1	General Practitioner	General Practitioner	Primary Care
M3	Specialist Anticoagulation Pharmacist	Formally managed a large anticoagulation monitoring service.	Acute Trust
M4	Community Pharmacist	Commissioned to provide Anticoagulation Monitoring Service	Primary Care
F2	Clinical Nurse Specialist, Diabetes	Supports self-monitoring diabetic patients in primary and secondary care	Acute Trust

Table 33: Focus group study with healthcare staff: Healthcare professionals participating in Focus Group One

6.5.2 Data collection

The focus group meeting took place over 50 minutes. All subjects gave written consent.

All topics on the focus group guide were covered in the order on the guide. All of the group were very engaged and vocal. This generated an enthusiastic discussion, limiting the scope or need for the moderator to interject.

6.5.3 Themes

The main themes and sub-themes arising from the meeting are summarised in Table 34.

Main theme		Sub-themes
Theme 1	Drivers for OAT patient self-monitoring	Raised awareness of OAT patient self-monitoring
		Healthcare provider drivers
Theme 2	Barriers to OAT patient self-monitoring	Financial barriers
		Patient readiness
		Impact on primary care
Theme 3	Risk management	Areas of risk
		Accountability
		Patient – clinician relationship
Theme 4	Learning lessons from others	Patient self-management of other long-term conditions
		Patient self-monitoring of OAT in other countries
Theme 5	Service redesign	Options appraisal for delivering self-monitoring
		Alternative models of INR monitoring
		PST or PSM?
		Coagulometer provision
Theme 6	Requirements for an OAT patient self-monitoring service	Patient selection criteria
		Education
		Ongoing support
		Establish agreed channels of communication
		Manage risk
		Define arrangements for quality assurance of coagulometers
		Ethical considerations

Table 34: Focus group study with healthcare staff: Main themes and sub-themes arising from meeting of Focus Group One (Healthcare Professionals)

6.5.3.1 Theme 1: Drivers for OAT patient self-monitoring

Identification of the drivers for OAT patient self-monitoring is important as these not only provide justification for establishing a self-monitoring service, but also give an insight into the anticipated benefits of patient self-monitoring. The group anticipated that a growing awareness of, and interest in, self-monitoring amongst anticoagulated patients would act as a driver for uptake of OAT self-monitoring. This growing awareness is likely to come through three main routes:

- i. Marketing of technology
- ii. Seeing other patients with personal coagulometers
- iii. Patient advocacy groups

Roche has marketed their CoaguChek™ machine directly to patients using a variety of media, including daily newspapers (Daily Telegraph, Daily Mail), Saga magazine, Easy Jet in-flight magazine and posters on the London Underground. Patients subsequently purchasing machines and then expecting clinics to support them in self-monitoring has created problems:

*“So they’d paid £199, and picked up a device and now wanted to know what to do with it, which wasn’t of course part of the Roche promotional campaign”
(M3)*

Discounts offered by Roche on coagulometers may persuade patients to purchase machines. However, the group considered that the two biggest drivers for patients making that commitment was the potential timesaving benefit, and avoidance of time away from work.

From the point of view of secondary care, patient self-monitoring represented a means to ease congested clinics. Primary care participants felt that offering a financial incentive to GPs to support self-monitoring patients would increase its uptake. Nevertheless, there was a joint commitment across the interface to both shared decision-making between healthcare professionals and patients, and to increasing patient empowerment.

6.5.3.2 Theme 2: Barriers to OAT patient self-monitoring

The group identified two main financial barriers to OAT patient self-monitoring. Firstly, the issue of payment for those supporting OAT patient self-monitoring was raised, more particularly in terms of training patients. Although the National Enhanced Service (NES) element of the General Medical Services (GMS) contract¹⁶⁸ offers a mechanism for commissioning self-monitoring services in primary care, the reimbursement for anticoagulant services does not take into account the costs of training. Consequently, it was felt that clarity around reimbursement for those training self-monitoring patients was needed.

Secondly, echoing the results from the patient study, there was the cost to the patient of the coagulometer. Not only did the patient have to pay for the machine but also, by doing so, is in effect paying for a proportion of their healthcare, contrary to the fundamental ethos of the NHS as care delivered free at the point of delivery.

*“I wonder whether because the NHS is seen as being free at the point of delivery that has made patients in this country a little bit more ... well, less willing to take on aspects of their own management, whereas in Germany or France where it’s a split system there might be a different approach to that”
(M3)*

It was suggested that supplying coagulometers on private prescription – in effect, exempting them from VAT – would partially ease this financial burden.

This topic generated further discussion about the economic model used by the manufacturers of the coagulometers. In stark comparison to coagulometers, the blood glucose testing machines are often given out free to patients, and the manufacturers make their money through the sale of consumables.

However, aside from the cost of the coagulometer, there was a fear that some patients were not ready to embrace self-monitoring, either through a lack of confidence or a lack of ability. This supported the views of some of the participants in the patient study.

The potential impact of OAT patient self-monitoring on primary care invoked strong feelings. Although it was felt that self-monitoring was too large a leap from a secondary care monitoring service, supporting a patient self-monitoring service from primary care left staff vulnerable to excessive workload and potential litigation. Self-monitoring patients may have high expectations of their GP supporting them, but there was not confidence in the GP having the knowledge to do so.

*“It’s embarrassing when you don’t know anything compared to your patient.”
(F1)*

Therefore, GPs may need to build expertise to support this group of patients.

6.5.3.3 Theme 3: Risk management

As discussed earlier in this thesis (3.6), under trial conditions OAT patient self-monitoring is at least as safe as routine management. However, because of warfarin’s narrow therapeutic range, its complex pharmacokinetics and its adverse effects profile, monitoring of OAT by any method can be challenging.¹⁶⁹ It is essential that the introduction of an OAT patient self-monitoring service should not introduce new risks.

The risks identified by the group included potential additional risks to the patient incurred through self-monitoring, but also risks to the professional, particularly around issues of accountability. Managing the potential risks to the professional invoked intense debate within the group. However, all of the participants concurred on the uncertainty around the medicolegal position and the potentially destructive effect of litigation on all concerned. A number of areas of risk were identified and are listed in Table 35.

PST	Compliance with testing
	Patients faking INR results
	Over-testing
	Offers patients the ability to play around with dose
PSM	Dose adjustment
Increased patient anxiety levels	Through closer attention to monitoring and medical condition

Table 35: Focus Group One: OAT patient self-monitoring - areas of risk

Most participants felt that the area of greatest risk was a patient adjusting their dose of warfarin when fully self-managing.

“There’s a big step between self-testing and self-management. A really big step. And that’s where everything could go wrong.” (F2)

Adverse events could arise from the patient misinterpreting their INR or over-reacting to one reading. Unlike self-monitoring of blood glucose (SMBG), the INR does not represent an instant phenomenon, and the group felt that patients needed to understand this concept before self-managing their OAT.

However, one participant challenged the group view that PSM is inherently more hazardous, and contended that in PST, where there is a gap between a patient testing their INR and receiving advice from their anticoagulation practitioner, there is a significant organisational risk.

Issues of accountability invoked strong feeling in the group. The medicolegal position is unclear, with legislation lagging behind practice. Litigious action was a big concern:

“And, of course, you’ve got the criminal court and the civil court and so, yes, you may not be prosecuted but you may well be sued or as an individual outside the Trust” (M3)

A mismatch between the professional framework suggested by the General Medical Council (GMC) and encouraging the patient to take more responsibility for their care was identified.

“But there are two courts aren’t there? There’s the legal courts – and the [question of whether] you’ve been negligent and whether you’re going to be paid out – and then there’s the GMC, I think has a very big influence.” (F1)

Where responsibility sits provoked debate amongst the group, with some feeling that it rested with the clinician and others contending that the patient should bear responsibility. The accountability of pharmacists operating in an extended role was felt to be even more unclear.

“I think I would see it as still accountability resting with the [] physician and I would, as a pharmacist, fit in somewhere in between. So I very much see accountability lying with us other than the patient and the self-testing scenario” (M3)

Patient self-monitoring of oral anticoagulation forms part of the continuum of shared decision-making, and an underlying conflict between the current medico-legal framework and the concept of shared decision-making was identified:

“There’s an analogy between shared decision making and this sort of self-management. And the problem is that the medico-legal framework that I perceive myself as working in as a doctor, and certainly my GP colleagues perceive themselves working in, is a paternalistic one where we have responsibility for the patient well being.” (F1)

Patient self-monitoring was also felt to be vulnerable to less tangible risks through changes to the patient – clinician relationship, largely through the loss of benefits of a face-to-face interaction. For instance, there was less opportunity for behaviour modification:

“What self-testing doesn’t do, it doesn’t give them a slap on the wrist, that’s the trouble.” (M4)

The nature of the role of both the patient and the healthcare professional within a self-monitoring model was also questioned, and there was a fear that a self-monitoring patient will be less compliant and take more risks.

6.5.3.4 Theme 4: Learning lessons from others

The group felt care was needed in extrapolating experiences with self-care of other long-term conditions (LTCs) to self-monitoring of OAT.

Self-care of diabetes, hypertension, and asthma may provide valuable insight into setting up an OAT patient self-monitoring service.

“Why not use the same model that we use for all other illnesses?” (F1)

However, the group felt that important differences between OAT patient self-monitoring and self-care of some LTCs needed to be considered. A few of these points have been touched upon earlier. Although self-care of asthma and diabetes also involve dose titration, the test result on which a dose is based reflects an immediate phenomenon unlike an INR which may reflect an event that happened two or more days earlier. Similarly, a blood glucose measurement or a peak flow provides immediate feedback to a diabetic or asthmatic patient if something is going wrong.

A diabetic patient may monitor their blood glucose many times a day, whereas an anticoagulated patient should test their INR at a maximum frequency of once a week. In addition, the cost to the patient of the technology to monitor their INR is comparatively more expensive.

Whilst it is important to acknowledge these differences, the group felt that lessons could still be learnt. For example, adopting the “train-the-trainer” approach used to educate those about to self-monitor their blood glucose, may prepare those wishing to self-monitor their OAT. Indeed, this approach has been adopted in one area of the UK as described earlier.

In Chapter Two, an international perspective on OAT patient self-monitoring was given. The group felt that a greater understanding of the success factors for adoption of OAT patient self-monitoring may come from examining the differences between the UK and Germany, where this model of monitoring is more widespread.

“The health system, you know, in Germany is different and the uptake there is 75% so there must be something financial must be one but all these issues we have mentioned ... it must be the health system, the system as a whole” (M2)

The group identified financial and cultural factors that may contribute to the successful uptake of OAT patient self-monitoring in Germany:

- i. Healthcare not free at point of delivery (split system)
- ii. A long history of SMBG
- iii. SMBG is a health insurance requirement
- iv. Patient self-monitoring is a cultural norm

“I wonder whether because the NHS is seen as being free at the point of delivery that has made patients in this country a little bit more ... well, less willing to take on aspects of their own management, whereas in Germany of France where it’s a split system there might be a different approach to that.” (M3)

6.5.3.5 Theme 5: Service redesign

In order for the service to change to one that involves an element of OAT patient self-monitoring, consideration needs to be given as to how the service will change and the options for service redesign. Before introducing a new service it is necessary to compare the options for its delivery. This group felt strongly that there needed to be a ‘halfway house’ between management by the secondary care clinic and patient self-monitoring, and that there was merit in adopting a similar model to long-term conditions by training primary care professionals - GPs, practice nurses and pharmacists - to manage self-monitoring patients.

“But then why not use the same model that we use for all other illnesses? Which is blood pressure being the classic example, you know, for the straightforward train primary care including pharmacists and practice nurses and GPs to manage.” (F1)

Again, there was concern that GPs would not be able to build sufficient expertise to support this group of patients, and if they were to do so patients should be requested to phone them at specified times when the GP would be able to access specialist advice.

There was strong support for community pharmacists supporting this service delivery, including the option of siting publicly available coagulometers in pharmacies.

“There’s some very interesting literature in terms of patient behaviour and a patient tends to be monogamous with their pharmacist but they’re not monogamous with their GP” (M1)

A domiciliary service, where the patient has their blood tested at home by a healthcare professional, is an alternative to the patient attending an anticoagulation clinic or testing their INR at home. However, there was disagreement within the group as to who was best placed to provide this service, a practice nurse or district nurse.

Within a self-monitoring service, there is the option for the patient to self-test or self-manage. As discussed earlier, the majority of the group felt that self-management carried the greater risk and, for this reason PST was the preferred model. Dose adjustment was felt to be challenging for healthcare professionals and patients alike.

“We don’t understand how to do it, we don’t understand the algorithms and we think it’s specialised and dangerous ... Now if GPs are feeling like that I suspect patients may have a bit of difficulty unless the algorithms are very straightforward and that’s the bit that worries me.” (F1)

However, it was questioned whether one can separate self-testing and self-dosing once the patient has a machine, with an acknowledgement that there is likely to be some ‘unofficial’ self-management.

The requirement for the patient to purchase a coagulometer had been identified as a potential barrier, and the group felt that the availability of a loan machine might allow patients to ‘try before they buy’.

6.5.3.6 Theme 6: Service requirements

Finally, the group considered the requirements for an anticoagulation monitoring service to support patient self-monitoring.

It was felt essential to define patient inclusion and exclusion criteria. Patient selection criteria published in consensus guidelines are broad^{36;52}, but this group agreed upon a relatively narrow set of criteria. These are summarised in Table 36.

Inclusion criteria	Exclusion criteria
Long-term indication for OAT	Psychotic illness
Ability to buy coagulometer	Mental impairment
Sufficient dexterity	
Able to demonstrate ‘understanding’	

Table 36: Focus Group One: Inclusion and exclusion criteria for OAT patient self-monitoring

It was not clear how a patient’s understanding of OAT would be demonstrated. There was also some support to establish the service with ‘super-selected’ patients, who may be a cohort of healthcare professionals on warfarin.

In addition to identifying inclusion and exclusion criteria, the group felt that it was important to define the action to be taken when someone who is deemed unsuitable to self-monitor turns up at the clinic with a machine.

“You can’t stop them from buying their own machine. However, you can stop ... you can refuse to help them. And it’s a tricky one. Withdrawal of co-operation. But then there is a duty of care” (M1)

Education was required for both patients and healthcare professionals. Although the content of these programmes was not defined, a longitudinal approach to patient education was desirable:

“It [patient education] has to be done over time – an hour of education, you’ll only remember the first 10 minutes if you’re lucky” (M1)

In addition to initial education, ongoing support for both patients and the GPs supporting them was needed. Although the GP representative of the group did not feel that she had to be an expert in OAT management, she needed to know who to call for advice and for them to be available at specified times.

“You’d have to look at how you run [the self-testing] service. So you might only run it on certain days when you know you could get through to somebody who would, you know be available right then. But then your patient would only be able to come on those certain days. But then it would save them coming up here.” (F2)

GPs' requirement for timely access to expert advice, and a robust system to ensure that a self-testing patient received prompt advice in response to a self-reported INR were also felt to be essential.

In terms of managing the additional risks associated with OAT patient self-monitoring, the group identified the following requirements:

- i. Patient signs a written agreement
- ii. Clear dosing algorithms – for PSM but also to aid non-specialist clinicians to advise patients who are self-testing
- iii. Clarity on what constitutes negligence under self-care
- iv. Professional bodies (GMC) to carry out a review of self-care

Lastly, there was the dilemma of how to deal with potential inequities of a service that is partially predicated on a patient's ability to pay for some of their care.

6.6 Results: Focus Group Two

6.6.1 Sample

All six healthcare professionals managers invited agreed to participate in this focus group. The composition of the focus group is summarised in Table 37. As before, the participant code comprises the participant's sex and identifying number (e.g. M1 F3 refers to the first third female participant in the study).

Participant code	Job title	Role	Location
F3	Deputy Director of Nursing	Clinical Governance & educational lead in Trust. Ex warfarin patient	Acute Trust
F4	Assistant Director of Finance	Assistant Director of Finance	Acute Trust
M5	Commissioner, Primary Care Trust	Commissions primary care anticoagulation monitoring services	Primary Care
F5	Deputy head of Medicines Management, Primary Care Trust	Commissions primary care anticoagulation monitoring services	Primary Care
F6	Director of Integrated Care	Remit for patient care across the interface	Acute Trust
F7	Specialist Anticoagulation Pharmacist	Manages patients attending anticoagulation monitoring service	Acute Trust

Table 37: Focus group study with healthcare staff: Healthcare Managers participating in Focus Group Two

6.6.2 Data collection

The focus group meeting took place over 50 minutes. All subjects gave written consent.

All topics on the focus group guide were covered in the order on the guide. There was a heated but amicable discussion, largely driven by two participants (M5 and F5). Two participants (F3 and F4) were more reticent and needed to be actively drawn in to the discussion by the moderator. In comparison to the first focus group, there was lots of overlapping conversation and interruptions, and many questions about a potential warfarin patient self-monitoring service to the moderator.

6.6.3 Themes

The main themes and sub-themes arising from the meeting are summarised in Table 38.

Main theme		Sub-themes
Theme 1	Drivers for OAT patient self-monitoring	Patient drivers
		Healthcare provider drivers
		Department of Health policy drivers
Theme 2	Barriers to OAT patient self-monitoring	Financial barriers
		Patient readiness
		Clinical risk
		Loss of "value-added" service through reduced contact between professional & patient
		Alternative models of INR monitoring
		The technology facilitating OAT self-monitoring
		Ethical concerns
Theme 3	Demonstrating feasibility	Areas of risk
		Accountability
		Patient – clinician relationship
Theme 4	Learning lessons from others	Patient self-management of other long-term conditions
Theme 5	Service redesign	Options appraisal for delivering self-monitoring
		Skill mix to deliver a self-monitoring service
Theme 6	Requirements for an OAT patient self-monitoring service	Patient selection criteria
		Education
		Ongoing support
		Establish agreed channels of communication
		Manage risk
		Define arrangements for quality assurance of coagulometers
Ethical considerations		

Table 38: Focus group study with healthcare staff: Main themes and sub-themes arising from meeting of Focus Group Two (Healthcare Managers)

6.6.3.1 Theme 1: Drivers for OAT patient self-monitoring

Supporting the results of the patient study, the group felt that the avoidance of clinic visits with the advantages that brings – easier childcare arrangements and avoiding time out of work were cited as examples – and the convenience of testing INR when travelling were important in persuading patients to self-monitor.

In addition to increasing capacity, OAT patient self-monitoring was felt to be the “direction of travel”, not only reflecting Department of Health (DH) policy, but also fitting with changes in the healthcare landscape:

“The other bit for me [is] the development of poly-systems, but you know ... the changes in system around North Central London and needing to reconfigure acute Trusts and all that sort of stuff and pushing however many centres of outpatients into the community might actually really happen over the next 3 – 5 years.” (F6)

“I think in the future, you know, the way the system is changing, GP practices are going to have to shift their... the way they work, in terms of their workforce, and they are going to need to explore things which are much more about self-monitoring as well.” (F6)

Although there was consensus that OAT patient self-monitoring fitted with DH policy, it was felt that there was no robust evidence that it would work in practice, or that it was the model of care that patients want, and there was some criticism that policy did not always consider the affordability of service changes.

6.6.3.2 Theme 2: Barriers to OAT patient self-monitoring

The barriers to OAT patient self-monitoring, especially concerning the potential cost-burden and clinical risk, generated lively and extensive discussion.

There was strong agreement that financial issues needed to be resolved before establishing an OAT patient self-monitoring service. The main concern of the commissioners was the affordability of a self-monitoring service to the PCT.

“Because, you know, let’s be serious about this ... it is cost at the end of the day, it’s not a PCT who’s struggling. It’s all very good the Government saying this is the policy and everything else, we’ve always got to do affordability models and if, at the end of the day, we can’t afford it, we can’t afford it. I mean, this is pushed through ‘til there’s nothing left to give.” (M5)

It was unclear who would pay for the machines and testing strips, and not all PCTs would be happy to fund this service especially if patient numbers increased. A clear business case at the outset was felt to be essential, with a guaranteed financial payback:

“If it’s not paying back you’re going to struggle getting it off the ground ... seriously.”(M5)

Financial disincentives from a secondary care viewpoint were also identified. INR monitoring outpatient visits generate valuable income for the acute Trust, and there may be a reluctance to relinquish this income stream.

“You don’t want to lose money at the hospital. We don’t want to lose money at the PCT.” (M5)

Or in the words of the Trust’s Assistant Director of Finance:

“Don’t do it!” (F4)

A recurring theme in both the patient and healthcare staff studies was the ability and willingness of patients to buy the coagulometer. Again, this group doubted that many patients were able to buy a coagulometer and would be prepared to assume the extra responsibility of OAT self-monitoring.

Fear of litigation was identified as another obstacle to the uptake of OAT patient self-monitoring, with clarity lacking. Mismanagement of self-monitoring may also result in financial risk:

“Can I just ask if anybody has spoken to the NHS Litigation Authority? Because if a patient screws up on their testing and dies, would we get sued? The Litigation Authority would do the court case but would our [hospital insurance] premiums go up because we were doing this.” (F4)

Support from the acute Trusts for GPs supporting this service was considered essential:

“You know, the PCT ... certainly the clinical people will not take on a clinical risk if they don’t feel they’re supported ... I think there has to be some real clinical engagement and honesty about who’s responsible and, yes, we’re going to carry on supporting you, we’re not just leave you out there in the wilderness.” (M5)

The group felt that primary and secondary care needed to share clinical risk, and the governance arrangements for a patient self-monitoring service needed to be defined, especially to cover patients moving between primary and secondary care:

“It can become very complicated, especially when you talk about clinical ownership. At what point is it your patient? When I ring you up and say ‘Mr Jones is coming now’ and you say ‘Right. I’ll expect him’ Have you now taken clinical responsibility? That’s the question that’s asked all the time. What’s the stage ... if that patient ... if something happens to that patient between leaving the GP practice and coming to you, who ... who’s taking clinical responsibility?” (M5)

These governance arrangements should also include the respective responsibilities of the patient and healthcare professional.

“There definitely has to be something and the patient has to sign up to that contract to say this is your responsibility... I think there has to be something where the patient takes clinical ownership or responsibility for their actions and what they’re doing.” (M5)

“I think there has to be some ownership by the patient of responsibility. That’s the thing. I think we’re all happy saying it somebody else’s but I think if a patient takes this, by implication, they’re taking on some of the responsibility” (M5)

In addition to clarifying lines of accountability and persuading the patient to take some ownership, shared care with patients on oral anticoagulation presents other challenges. There is the risk that patients will not comply with testing, or wilfully misreport INRs, and that they will not view their condition seriously:

“Is there is a danger that if it moves to self-testing, patients are offered self-testing they start to think ‘Ooh. Well it can’t be that bad if I can just do this at home’?” (F4)

OAT monitoring is not merely dose adjustment, and the group felt that the patients would lose other elements of care, such as health screening and opportunities for behaviour modification, through reduced contact with a healthcare professional. There was also a danger that patients may perceive self-monitoring as a reduced level of care:

“People like ... I mean, that’s why people come to hospital because they like to be seen by a person and go to a building and feel they’re being treated. I just wonder if they do it home, they feel the same level of ... of care” (F3)

Patients may feel that alternative primary care INR monitoring models are more attractive than self-monitoring:

“But more important, would the patient if we provided something more local would they be more than happy with that and not bother about self-testing? Or are they saying because at the moment there’s nothing, it’s either hospital or nothing they’ll take self-testing?” (F5)

Therefore it might be premature to embrace self-monitoring as a solution to an overstretched hospital INR monitoring service until all options are mapped out.

At the time of the focus group meeting, there were two, identically priced, coagulometers marketed for patient use. This lack of competition in the coagulometer market, leading to the relatively high cost of the machines, was felt in itself to be a barrier to uptake of self-monitoring. However, if patient self-monitoring was to become more widespread, an increase in demand for these machines may persuade other diagnostic manufacturers to enter the market:

“It’ll be like generics really. Once people start using a lot of them, someone else will come on the market and prices will eventually fall.” (F5)

Although the group had an expectation that the price of coagulometers would eventually fall, there would still be a potential need to replace machines that are broken, adding to the financial burden.

On ethical grounds, some in the group were uncomfortable about an OAT self-monitoring service that excludes those who cannot afford a coagulometer:

“Is that not ethical?” (F3)

Overall, the group felt that it was far from certain that an OAT self-monitoring service could be established and managed successfully. Whilst a small pilot of 50 patients may be feasible, it was unclear if this could then be scaled up to 1000 patients.

6.6.3.3 Theme 3: Demonstrating feasibility

The group believed that there were two ways of demonstrating the feasibility of a large-scale INR patient self-monitoring service; by building a business case and establishing a pilot service.

The PCT representatives wanted a business model that would demonstrate that INR patient self-monitoring is cost-effective, with a return on investment required within the first financial year. The aspiration was that the cost of the patient self-monitoring service would be partially offset by a reduction in inpatient episodes. The financial risk for both primary and secondary care was felt to be significant, creating tensions within the group.

A meaningful pilot was felt to be key to demonstrating feasibility of an INR patient self-monitoring service. Essential elements identified by the group are listed below:

- Use a cross section of people (e.g. different age groups, different genders)
- Enrol 10- 20% of patient population
- Evaluate financial impact, inpatient / outpatient activity, patient acceptability and impact on Trust productivity
- Confine to one PCT, ideally around an emerging polysystem local to hospital

6.6.3.4 Theme 4: Learning lessons from others

The group felt that important differences between OAT patient self-monitoring and SMBG in diabetes needed to be considered. There was a view that the required high frequency of blood glucose tests has driven self-testing in diabetes:

“In fairness, diabetes is not something you can say come back in 6 weeks and we’ll test you again it’s got to be a daily thing. So I think the condition has driven self-testing. Whereas this, you can leave it 4 or 5 weeks, test in between, so it’s not an everyday sort of occurrence, it’s not ... for a lot of patients it’s not that inconvenient to come every 6 to 8 weeks.” (M5)

In contrast to the high cost to the patient of the technology to monitor their INR, diabetic patients are either given glucometer from the diabetes outpatient clinic or purchase them cheaply.

In the early days of patient self-care of asthma, there were also concerns about its safety:

“As a practice nurse ... I was just thinking when we are getting into self-management of asthma, there was the same sort of worry and concerns.” (F6)

6.6.3.5 Theme 5: Service redesign

There was some discussion about redesign of the anticoagulation monitoring service to include patient self-monitoring, largely centred on service delivery options and where a self-monitoring service should be run from. Although there was some support for a publicly sited coagulometer, not all of the group agreed that this was a good option:

“But that’s similar to what we have now though? Isn’t it similar?” (F5)

There was more support for setting up a patient network, where patients own and share a machine:

“I like that idea though. I think if you did that as a self-help group almost where people met and did their own thing maybe that would be more palatable.” (M5)

There opposing views as to where a patient self-monitoring service should be established. Although a few members of the group felt that self-monitoring patients should be supported from the acute Trust, others contended that this could be done in primary care:

“Once they’re stable, I think they can then move to the next level down where a GP or a pharmacist or somebody else could do it. It doesn’t need to be the hospital.” (M5)

However, this generated accusations that primary care would be “cherry-picking” the more stable patients, with the following note of caution:

“You can’t ever cherry pick just good, stable patients because everybody will destabilise at some point.” (F7)

However, there was a counter-view that those with poor INR control would be more motivated and would benefit from self-monitoring:

“Some of the poorer controlled patients actually want to self-test because they want to stop coming to hospital each week.” (F7)

6.6.3.6 Theme 6: Requirements for an OAT self-monitoring service

In contrast to the first focus group, there was no detailed discussion on patient selection criteria for self-monitoring. Instead, the group felt that individual risk assessments to decide if patients would be suitable to self-monitoring would be of benefit.

Education, as well as ongoing support, was needed to prepare patients for self-monitoring. Regular patient reviews would also satisfy the requirement for regular quality assurance of the coagulometers:

“We need to give people a lot of education and I think we need to be seeing them or we need to, you know, validate their machines probably twice a year.” (F7)

But ongoing support was not just confined to patients. If patient self-monitoring is to be supported in primary care, staff will need support also:

“Even though ... even though we’d be happy to take it on, I think, clinically in the PCT, it’d still be nice to know that the higher level of clinical ability in the hospital is still there supporting us and hasn’t just walked away and said ‘It’s yours’ and forget about it.” (M5)

Establishing agreed channels of communication was felt to be essential, both between patient and healthcare professional and between primary and secondary care. Lines of communication must be structured to accommodate patients moving between providers and sectors.

Managing risk was a thread that ran throughout the meeting. As well as recognising the areas of risk, the group felt that there must be ways of assessing and mitigating against these risks from the outset. Their suggestions are listed below:

- i. Establish a formal shared care agreement
- ii. Define where clinical responsibility lies
- iii. Agree protocols between PCT and hospital re: patient transfer
- iv. Elaborate ethical / legal framework

As discussed earlier, there was much debate over the financial aspects of moving to OAT patient self-monitoring, and there was a need to ensure that a self-monitoring service would be financially viable (6.6.3.3).

There was a fear that patients would not want to self-monitor, and that the service needed to canvass their views to gauge demand before going further:

“I know it’s the direction of travel but I’m still not convinced that we’ve actually asked the end user what they really want.” (M5)

It was felt that other options for OAT monitoring should be explored and evaluated in the context of a full options appraisal, also discussed in Focus Group One.

The need for policies to manage risk associated with shared care and patient transfer has already been identified. Additionally, the group felt strongly that there should be an overarching corporate strategy drawn up before demand for patient self-monitoring grows, setting out how to manage a fully operational service. This was necessary to both foster partnerships between primary and secondary care, and also to review and revise the financial model to enable shared care.

6.7 Summary of healthcare staff's perspectives on OAT patient self-monitoring

The findings from these three studies are summarised in Table 39.

The approach taken is consistent with that adopted for the patient-centred studies. There are four distinct sections to this table – drivers, benefits, barriers and challenges to OAT patient self-monitoring - derived from the perspectives of these healthcare professionals. Sub-themes within these broad themes are described, with a summary of supporting evidence from each of the studies where available. Finally, suggested, or 'candidate', service requirements are derived from these sub-themes, and these are then mapped to Donabedian's framework.

Table 39: Summary of healthcare staff’s perceptions of OAT self-monitoring (drivers)

Drivers	Perspectives of healthcare staff		Derived service requirement	Donabedian framework element
	Focus group 1 (Professionals)	Focus group 2 (Managers)		
Patient convenience	Potentially timesaving benefit and avoids time away from work	Potentially timesaving benefit, avoids time away from work and convenient when travelling		
Increasing service capacity	Ease congested clinics	Ease congested clinics		
DH policy		Development reflects DH policy and changes in healthcare landscape		
Awareness of OAT self-monitoring	A growing awareness of self-monitoring amongst anticoagulated patients will act as a driver for uptake		Promote the self-monitoring service to patients	Structure

Table 39 (cont): Summary of healthcare staff’s perceptions of OAT self-monitoring (benefits)

Benefits	Perspectives of healthcare staff		Derived service requirement	Donabedian framework element
	Focus group 1 (Professionals)	Focus group 2 (Managers)		
Patient convenience	Potentially timesaving benefit and avoids time away from work	Potentially timesaving benefit, avoids time away from work and convenient when travelling	Self-monitoring service is acceptable to patients	Outcome
Increasing service capacity	Ease congested clinics	Ease congested clinics		

Table 39(cont): Summary of healthcare staff’s perceptions of OAT self-monitoring (barriers)

Barriers	Perspectives of healthcare staff		Derived service requirement	Donabedian framework element
	Focus group 1 (Professionals)	Focus group 2 (Managers)		
Provision of the coagulometer	Cost of coagulometer may deter patients from self-monitoring Make a loan machine available	Cost of coagulometer may deter patients from self-monitoring Lack of competition in market pushes up prices of coagulometers	Facilitate provision of the coagulometer	Structure
Financial barriers	Reimbursement will be required for supporting self-monitoring Offering financial incentives to GPs could increase uptake	Affordability to PCTs Loss of income stream to acute Trust	Ensure engagement from those delivering and commissioning OAT monitoring Establish financial feasibility Self-monitoring service is cost-effective	Structure Structure Outcome
Lack of patient confidence in testing INR	Patients may lack confidence to self-monitor	Patients may lack confidence to self-monitor	Provide patient training in self-testing and using the coagulometer	Process
Confidence in the accuracy of the coagulometer	Define QA arrangements for coagulometer	Define QA arrangements for coagulometer	Establish process for quality assurance (QA) of coagulometer	Structure
Patient preference for alternative models of care	Canvass patients’ views	Patients may feel that other ways of monitoring INR more attractive	Gauge patient demand	Structure

Table 39 (cont): Summary of healthcare staff’s perceptions of OAT self-monitoring (barriers)

Barriers	Perspectives of healthcare staff		Derived service requirement	Donabedian framework element
	Focus group 1 (Professionals)	Focus group 2 (Managers)		
Patient eligibility	<p>Patients may lack ability to self-monitor</p> <p>Consensus reached on eligibility criteria</p> <p><u>Inclusion criteria</u> - Long-term indication for OAT; ability to buy coagulometer; sufficient dexterity; able to demonstrate ‘understanding’</p> <p><u>Exclusion criteria</u> - Psychotic illness; mental impairment</p> <p>Establish the service with ‘super-selected’ patients</p> <p>Define action to be taken when someone who is deemed unsuitable to self-monitor purchases a machine</p>	<p>Patients may lack ability to self-monitor</p> <p>No consensus reached on eligibility criteria</p> <p>Debate over whether those with poor INR control should be excluded</p> <p>Risk assess patients</p>	Construct eligibility criteria	Structure

Table 39 (cont): Summary of healthcare staff's perceptions of OAT self-monitoring (barriers)

Barriers	Perspectives of healthcare staff		Derived service requirement	Donabedian framework element
	Focus group 1 (Professionals)	Focus group 2 (Managers)		
Lack of clarity on accountability	<p>Medicolegal framework not keeping pace with shared decision-making</p> <p>Elaborate Ethical / legal framework including clarity on what constitutes negligence under self-care</p> <p>Professional bodies (GMC) to carry out a review of self-care</p> <p>Fear of litigation</p> <p>Primary care staff vulnerable to litigation</p>	<p>Define where clinical responsibility lies</p> <p>Elaborate Ethical / legal framework including clarity on what constitutes negligence under self-care</p> <p>Professional bodies (GMC) to carry out a review of self-care</p>	Clarify issues of accountability and clinical responsibility	Structure
Ethical		A service predicated on patient's ability to pay (for coagulometer) is inequitable	<p>Facilitate provision of the coagulometer</p> <p>Address potential inequities in the service</p>	<p>Structure</p> <p>Structure</p>

Table 39 (cont): Summary of healthcare staff's perceptions of OAT self-monitoring (challenges)

Challenges	Perspectives of healthcare staff		Derived service requirement	Donabedian framework element
	Focus group 1 (Professionals)	Focus group 2 (Managers)		
Adjusting dose of warfarin (PSM)	Dose adjustment in PSM is an area of potential risk Make available dosing algorithms		Provide education and support for dose adjustment by patients (PSM)	Process
Educating self-monitoring patients	Education required for patients	Education required for patients	Develop and deliver an educational programme for patients	Structure Process
Educating healthcare professionals	Education required for healthcare professionals GPs' knowledge may not meet patients' expectations		Develop and deliver an educational programme for primary care staff supporting self-monitoring patients	Structure Process
Availability of support for patients	Required for patients	Required for patients	Provide ongoing support for patients (regular review and ad-hoc support)	Process
Supporting primary care staff	Ongoing support required for primary care staff supporting self-monitoring patients	Ongoing support required for primary care staff supporting self-monitoring patients	Provide ongoing support for primary care staff supporting self-monitoring patients	Process

Table 39 (cont): Summary of healthcare staff’s perceptions of OAT self-monitoring (challenges)

Challenges	Perspectives of healthcare staff		Derived service requirement	Donabedian framework element
	Focus group 1 (Professionals)	Focus group 2 (Managers)		
Redesigning the service	<p>Operate from primary care</p> <p>Use community pharmacists and site public coagulometers in community pharmacies</p> <p>Domiciliary service offers an alternative to self-monitoring</p> <p>PST preferred model</p>	<p>No consensus on whether a self-monitoring service should be operated from primary or secondary. Support for PST team</p> <p>Mixed views on siting public coagulometers in community pharmacies</p> <p>Set up patient networks</p>	Conduct options appraisal	Structure

Table 39 (cont): Summary of healthcare staff’s perceptions of OAT self-monitoring (challenges)

Challenges	Perspectives of healthcare staff		Derived service requirement	Donabedian framework element
	Focus group 1 (Professionals)	Focus group 2 (Managers)		
Managing financial risk		<p>Need to build business case to demonstrate that self-monitoring is cost-effective</p> <p>Meaningful pilot to demonstrate feasibility</p>	Establish financial feasibility	Structure
Managing clinical risk	<p>Risk of patient non-compliance with self-testing</p> <p>Robust system to ensure that a self-testing patient receives prompt advice in response to INR essential</p> <p>Patient to sign a written agreement</p> <p>Define governance arrangements for primary and secondary care to share care, and for responsibilities of patients and staff</p> <p>Loss of intangible benefits of face-to-face interaction – e.g. behaviour modification</p>	<p>Risk of patient non-compliance with self-testing</p> <p>Robust system to ensure that a self-testing patient receives prompt advice in response to INR essential</p> <p>Agree protocols between PCT and hospital with respect to patient transfer</p> <p>Agreed channels of communication between primary and secondary care</p> <p>Loss of intangible benefits of face-to-face interaction – e.g. behaviour modification</p>	<p>Establish a formal shared-care agreement between patient and clinician</p> <p>Establish a formal shared-care agreement between primary care and secondary care</p> <p>Self-monitoring service is safe</p>	<p>Structure</p> <p>Structure</p> <p>Outcome</p>

6.7.1 Summary list of candidate service requirements from focus group meetings with healthcare staff

STRUCTURE

- Gauge patient demand for OAT self-monitoring
- Conduct an options appraisal (i.e. explore other methods of OAT monitoring / define delivery of OAT self-monitoring service)
- Establish financial feasibility of service
- Ensure engagement of those delivering and commissioning OAT monitoring
- Promote the self-monitoring service to patients
- Facilitate the provision of coagulometers (e.g. by funding coagulometer)
- Construct patient eligibility and assessment criteria
- Develop an educational programme for patients
- Develop an educational programme for primary care staff supporting self-monitoring patients
- Establish a formal shared-care agreement between patient and clinician
- Establish a formal shared-care agreement between primary care and secondary care
- Establish a process for quality assurance (QA) of coagulometers
- Establish an OAT self-monitoring policy
- Clarify issues of accountability and clinical responsibility
- Address the potential inequities of the service

PROCESS

- Provide patient training in self-testing and using the coagulometer
- Deliver an educational programme to patients
- Develop an educational programme to primary care staff supporting self-monitoring patients
- Provide education and support for dose adjustment by patients (PSM)
- Provide ongoing support to self-monitoring patients (regular review and ad-hoc support)
- Provide ongoing support to primary care staff supporting self-monitoring patients

OUTCOME

- Self-monitoring service is safe
- Self-monitoring service is acceptable to patients
- Self-monitoring service is cost-effective

6.8 Discussion

This study has explored how those delivering, managing and commissioning oral anticoagulation monitoring services view patient self-monitoring. Service requirements for an OAT patient self-monitoring service have been derived from their perceptions, and these requirements have been mapped to Donabedian's framework.

In terms of outcomes, the self-monitoring service should be acceptable to patients, safe and cost-effective. However, the majority of the derived service requirements were structural elements – i.e. the context for the service, including the organisational framework and the resources required to deliver the service. In particular, broad agreement between the two groups lent strong support for the following candidate service requirements:

- Gauge patient demand
- Address potential inequities in the service
- Facilitate provision of the coagulometer
- Construct patient eligibility and assessment criteria
- Establish a formal shared-care agreement between patient and clinician
- Establish a formal shared-care agreement between primary and secondary care
- Clarify issues of accountability and clinical responsibility
- Establish financial feasibility

These requirements will now be briefly discussed.

OAT patient self-monitoring was thought to have benefits for both the healthcare provider and the patient. At a time when anticoagulation monitoring clinics are overstretched, self-monitoring was an attractive alternative service delivery option to increase capacity. Echoing the results of the patient-centred studies, patients may find self-monitoring more convenient. However, other methods of INR monitoring may be more attractive to patients – for example, going to a GP clinic – or they may simply prefer to continue attending a secondary care clinic. Therefore, it was thought necessary to gauge the patient demand for a self-monitoring service before implementation.

The requirement for the patient to purchase their coagulometer was a significant issue for both groups. Uptake of self-monitoring by patients is threatened by their ability to purchase a coagulometer. As described earlier in this thesis, although 53% of patient survey respondents indicated that they would be willing to self-monitor their oral anticoagulation, when those who would be willing to self-monitor AND purchase a coagulometer were considered this proportion dropped to 15%.

This raises an ethical dilemma: should a service that is predicated on the patient's ability and willingness to pay be introduced? More philosophically, in paying for the machine, in effect, the patient is paying for a proportion of their healthcare, contrary to the fundamental ethos of the NHS as care delivered free at the point of delivery. Siting public coagulometers in community pharmacies was suggested as a way to make them available to patients who wish to self-monitor. However, this produced a mixed response, and some participants felt that this option negated the benefit of the patient being able to test the INR in their own home.

Both groups felt it was essential to define those who would be able to self-monitor, either by agreeing selection criteria, or by carrying out individual risk assessments on patients. With the current model of anticoagulation monitoring, education is provided to the patient, and then an assessment is made of their understanding of anticoagulation and their ability to comply with both treatment and INR testing. In essence they are 'risk-assessed'. Introducing patient self-monitoring entails greater partnership working with patients, and a confidence that they will take warfarin and test their INR in the manner agreed. Therefore, there is a continuing need to ensure that the patient understands their treatment, and will comply with treatment and testing. At the Whittington, a structured tool is being developed to assess how patients on warfarin will comply with treatment and testing. This tool could be adapted for use to risk-assess those wishing to self-monitor.

Managing any potential new risks generated lively discussion in both groups. With the introduction of OAT patient self-monitoring, care would be shared in two ways: between primary and secondary care providers (as with the current models of service delivery), but also an increased sharing of care between patient and healthcare professional.

There was a need to define the governance arrangements for this shared care. This included establishing a formal shared-care protocol between primary and secondary care, which would include protocols for patient transfer between GP and hospital in the event of the patient becoming clinically unstable. The respective roles and responsibilities of patient and healthcare professional will also need to be clearly defined, and a form signed by both parties may form part of this agreement

There was great unease in both groups about the lack of clarity around accountability and what constitutes negligence under self-care. It is clear that legislation lags behind practice and policy. Although out of the scope of local implementation, both groups felt that the following were necessary steps:

- i. Elaboration of the legal framework to clarify what constitutes negligence under self-care
- ii. A review of self-care conducted by the professional bodies (e.g. the GMC)

There was no consensus across the two groups where the patient self-monitoring service should be delivered - in primary or secondary care.

This study highlighted tensions between primary and secondary care over sharing financial risk. The economic implications of introducing in primary care are complex. There is a financial risk to secondary care in terms of loss of income from anticoagulant outpatient clinic visits. As discussed earlier in this thesis (3.14), the cost-effectiveness of OAT patient self-monitoring is unproven at best. Therefore, implementation of this service may also incur financial risks for the commissioners. The view from the second focus group of commissioners and managers is that, similar to sharing clinical risk, any financial risk should also be shared.

In Chapter Two, the situation in Germany and USA, where there has been greater uptake of OAT patient self-monitoring, was discussed along, with factors in these countries that may have facilitated this model of care. The focus group of healthcare professionals agreed that there were important cultural and healthcare funding differences between Germany and the UK that limit the transferability of the German model to the UK. Self-management is a cultural norm in Germany, and healthcare is not free at the point of delivery. Germany also has a long history of self-monitoring of blood glucose (SMBG), and patient engagement in SMBG is an insurance requirement.

In the next chapter, the candidate service requirements from this chapter and the patient-centred studies will be triangulated to present a combined set of candidate requirements for an OAT patient self-monitoring service. This combined set of candidate service requirements will then be incorporated into the design of a PST pilot service, which will then be implemented and evaluated at the Whittington Hospital.

6.9 Limitations

The main limitation of this study was its size and scope – just twelve participants recruited from one locality. However, they provided a valuable and unique insight into the perspectives of those delivering, managing and commissioning anticoagulation monitoring services on OAT patient self-monitoring.

These focus groups, especially the second one, were potentially limited by the views of the more vocal participants dominating those of the rest of the group. The moderator attempted to counteract this by actively drawing the quieter members of the group into the discussion.

Also, as with any focus group, it cannot be assumed that individuals in a focus group are expressing their definitive individual view. They are speaking in a specific context and the nature of the group discussion may discourage some people from trusting others with sensitive information. Ideally, if time and resources had permitted, these focus groups would have been followed up by one-to-one interviews.

CHAPTER 7: A VALIDATION OF A SET OF CANDIDATE REQUIREMENTS FOR AN ORAL ANTICOAGULATION PATIENT SELF-MONITORING SERVICE

The last two chapters have described the empirical work undertaken to establish a multi-stakeholder perspective of patient self-monitoring of oral anticoagulation. From the perspectives of these stakeholders - anticoagulated patients, professionals and managers - candidate requirements for a service model to support the successful adoption of OAT patient self-monitoring have been derived.

The perspectives of these stakeholders and the derived candidate service requirements have been previously summarised, for each group, in Table 31 and Table 39 respectively.

In Table 40, these results are triangulated to present a combined set of candidate requirements for an OAT patient self-monitoring service within the framework of Donabedian's triad of structure, process and outcome. This framework has been previously described (1.3.2). In summary, structure is the set of elements that will enable care to be given to those self-monitoring their oral anticoagulation. Process relates to the activities required to provide care to this group of patients. The structure needs to be in place for the process to occur. For example:

- The financial feasibility of the service needs to be established to allow it to be delivered
- An educational programme for patients needs to be developed before education can be delivered

Finally, outcomes refer to both individual patient clinical outcomes and to service outcomes, including those related to finance.

This chapter describes how these candidate service requirements were validated through a pilot oral anticoagulation patient self-testing service – the pilot PST service - at the Whittington Hospital.

Table 40: Candidate requirements for an OAT patient self-monitoring service

Candidate service requirement	Derivation of service requirement	
	Studies with patients (Table 31)	Studies with healthcare personnel (Table 39)
STRUCTURE		
Gauge patient demand	√	√
Conduct service options appraisal		√
Establish financial feasibility of service	√	√
Ensure engagement from those delivering and commissioning OAT management		√
Promote the self-monitoring service to patients	√	√
Facilitate provision of coagulometer	√	√
Construct patient eligibility and assessment criteria	√	√
Develop an educational programme for patients	√	√
Develop an educational programme for primary care staff supporting patients		√
Establish a formal shared-care agreement between patient and clinician		√
Establish a formal shared-care agreement between primary care and secondary care		√
Establish process for quality assurance (QA) of coagulometer	√	√
Establish an OAT self-monitoring policy		√
Clarify issues of accountability and clinical responsibility		√
Address potential inequities in the service		√

Table 40 (cont): Candidate requirements for an OAT patient self-monitoring service

Candidate service requirement	Derivation of service requirement	
	Studies with patients (Table 31)	Studies with healthcare personnel (Table 39)
PROCESS		
Provide patient training in self-testing and using the coagulometer	√	√
Deliver anticoagulant education for self-monitoring patients	√	
Provide education and support for dose adjustment by patients (PSM)	√	√
Deliver anticoagulant education for primary care staff supporting patients		√
Provide ongoing support to patients	√	√
Provide ongoing support to primary care staff supporting self-monitoring patients		√
OUTCOME		
Self-monitoring service is safe	√	√
Self-monitoring service is acceptable to patients	√	√
Self-monitoring service is cost-effective		√

The design of the pilot PST study is summarised in Figure 22.

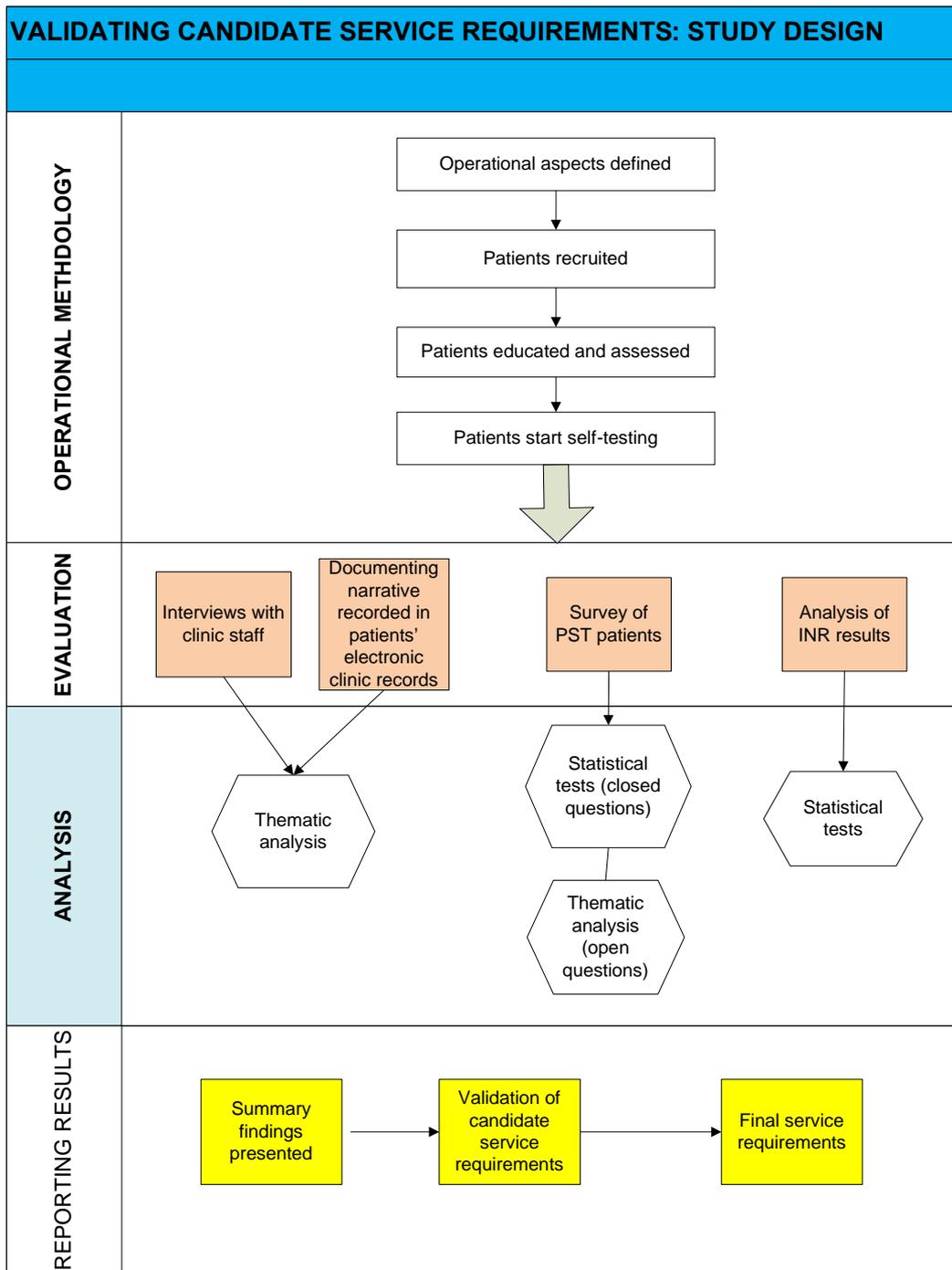


Figure 22: Validating candidate service requirements for an OAT patient self-monitoring service – study design

There were two main stages to this study: the operational stage and the evaluation of the pilot. These will be described in the remainder of this chapter.

7.1 Aims and objectives

The aim of the PST pilot was to validate a set of candidate requirements for a service to support patient self-monitoring of oral anticoagulation.

Within this there were the following objectives:

- i. To determine whether a cohort of Whittington clinic patients could achieve therapeutic INR values through self-testing
- ii. To determine patients' motivations for, and expectations of, self-testing
- iii. To determine patients' experiences of self-testing
- iv. To determine clinic staff's experiences of supporting self-testing

7.2 Operational methodology

The establishment and operation of the PST service is summarised in Figure 23.

The Chair of the Local Research and Ethics Committee was consulted prior to starting this pilot. As the pilot was considered to be a service development, as opposed to pure research, ethical approval was not required.

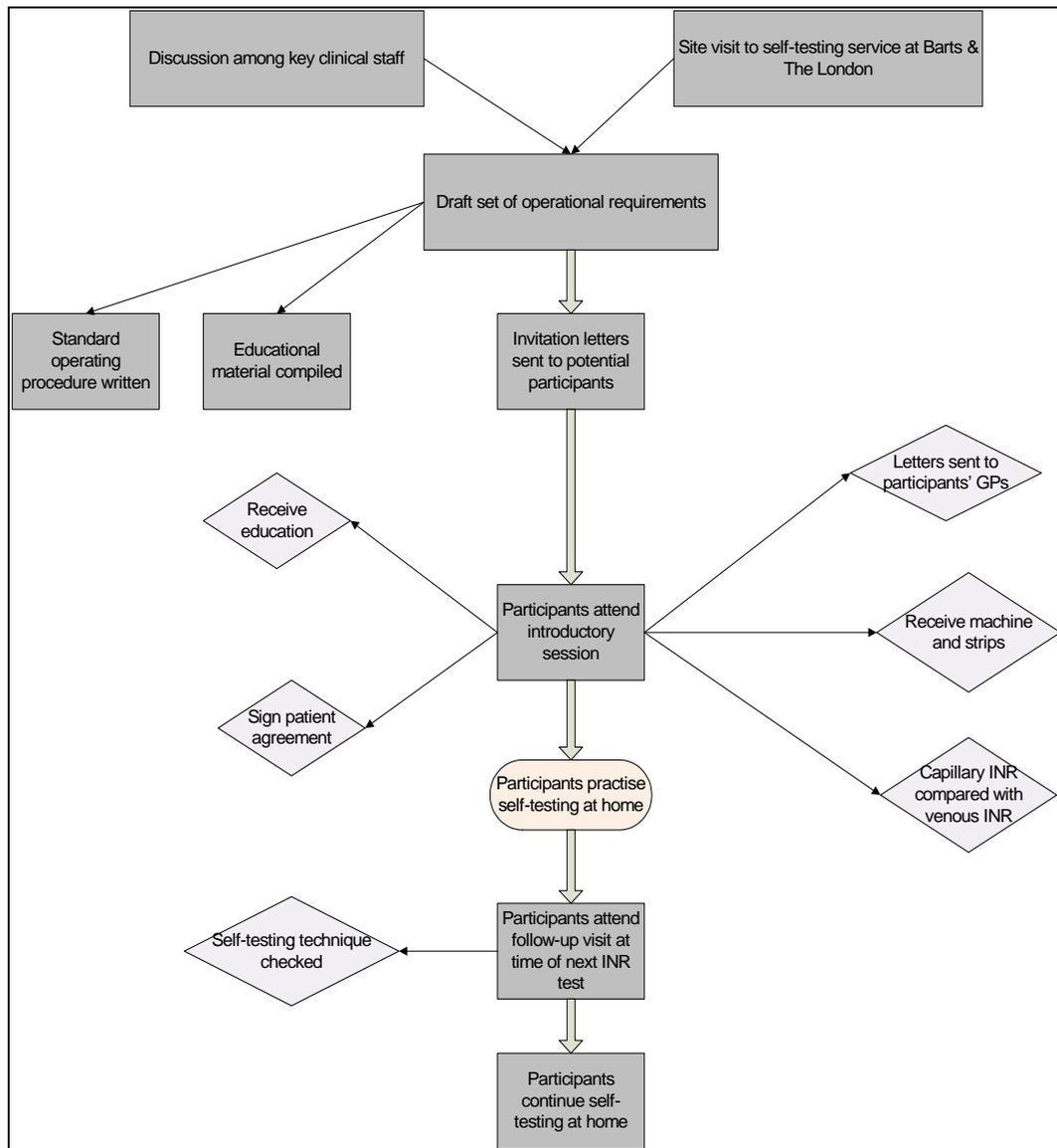


Figure 23: Establishing and operating the PST pilot service

The five main stages of this study were as follows:

- i. Establishing operational requirements
- ii. Operating the pilot
- iii. Determining patients' motivations, expectations and experiences
- iv. Determining the safety of the service
- v. Determining clinic staff's experiences

The stages to this study will now be discussed.

7.2.1 Establishing the operational requirements for the PST pilot

This pilot PST service was set up by two senior anticoagulation pharmacists (SD and FA) under the guidance of the author. A series of discussions to map out how the service should be delivered took place between these three individuals, with input from the clinical lead for the Whittington Oral Anticoagulation Monitoring & Stroke Prevention Service in the autumn of 2009.

Two sources were used to inform the key operational requirements for the PST pilot:

- i. Experiences of those working with self-testing patients at Barts and The London Hospital
- ii. Candidate service requirements derived from the empirical work with patients, healthcare professionals and managers

Using the published literature and information from colleagues both within the NHS and the pharmaceutical industry, the author identified that Barts and The London Hospital had a well-established OAT patient self-testing service. The author contacted this service and was granted an interview and permission to conduct a site visit. Therefore, in September 2009, the author and FA paid a visit to their anticoagulation nurse specialist to see if lessons could be learnt from their experience.

As the aim of this study was to validate a set of candidate requirements for an OAT patient self-monitoring service derived from the earlier empirical work described in this thesis, it was important to incorporate these requirements into the design of the PST pilot service.

The sources of the key operational decisions for the PST pilot are summarised in Table 41.

Key operational decision	Derivation of decision	
	Candidate service requirement	Barts & London
Patient self-testing service option selected	Conduct service options appraisal	Yes
Engage key stakeholders	Ensure engagement from those delivering and commissioning OAT management	Yes
1. Ensure that GP is happy to prescribe the INR testing strips	Ensure engagement from those delivering and commissioning OAT management	
2. Seek position of PCTs around provision of testing strips	Ensure engagement from those delivering and commissioning OAT management Establish financial feasibility of service	
3. Inform key hospital clinicians and managers informed about PST pilot	Ensure engagement from those delivering and commissioning OAT management	
Make a loan machine available	Facilitate provision of coagulometer	
Relatively inclusive patient selection criteria used	Construct patient eligibility and assessment criteria	
Pre-screen patients with respect to NPT		Yes
Develop and deliver a patient education programme	Develop an education programme for patients Deliver an education programme for patients	
Establish a process for QA of coagulometer	Establish a process for QA of coagulometer	Yes
Establish a formal agreement between patient and anticoagulant service (patient agreement form)	Establish a formal shared-care agreement between patient and clinician	Yes
Develop a standard operating procedure	Establish an OAT self-monitoring policy	Yes
Support self-testing patients throughout pilot	Provide ongoing support to patients	

Table 41: Derivation of key operational decisions taken when establishing the PST pilot

However, for operational, logistical or ethical reasons it was not possible to include all of the (triangulated) candidate requirements listed at the beginning of this chapter. This PST pilot was established for service as well as research reasons. Prior to its implementation, a number of patients had expressed an interest in self-testing, and some had gone a step further and purchased a coagulometer. At that time, the service was not configured to support these patients, and there were concerns about them self-testing without this support. Establishing a means to support these patients became a priority for the Whittington Anticoagulation Monitoring and Stroke Prevention Service.

Consequently, time did not permit a thorough service options appraisal and, to expedite implementation, the service was delivered within existing resources and directly from secondary care. As a result of this decision, most of the requirements relating to an OAT patient self-monitoring service if it were being delivered from primary care – for example, education and supporting primary care staff – could not be validated. Selection of a PST model, as opposed to PSM or a mixed model, meant that it was not appropriate to provide advice on warfarin dosing to patients.

The financial feasibility of the service was also not assessed prior to service.

Participants at the second focus group meeting felt that to assess the feasibility of a scaled up service, it was essential to enrol at least 10% of the clinic population into a pilot (6.6.3.3). As this pilot enrolled fourteen patients, it was felt that assessing financial feasibility would not produce meaningful and useable data for such an evaluation.

As the likely demand for a patient self-testing service had been assessed in the earlier survey of Whittington clinic patients, demand for a PST service was not assessed again. Time constraints also precluded a detailed consideration of the potential inequities of the service.

Aside from the research agenda, this was a pilot service to establish if it was possible to support those who wished to self-test their OAT from the Whittington anticoagulant clinic. Therefore, as the future of the service was not guaranteed, it was felt unethical to promote it widely to patients.

Table 42 summarises which of the candidate service requirements were included in the pilot, and the reasons for excluding the rest of the requirements.

Candidate requirement included in pilot	Candidate requirement excluded from pilot	Reason for exclusion
STRUCTURE		
Conduct service options appraisal (limited)	Establish financial feasibility of service	Relevance and value unclear
Ensure engagement from those delivering and commissioning OAT management	Gauge patient demand	Likely patient uptake estimated in earlier empirical work
Facilitate provision of coagulometer	Promote the self-monitoring service to patients	Unethical
Construct patient eligibility criteria	Develop an educational programme for primary care staff supporting patients	Pilot service not delivered from primary care
Develop an educational programme for patients	Establish a formal shared-care agreement between primary care and secondary care	
Establish a formal shared-care agreement between patient and clinician	Address potential inequities in the service	Beyond constraints of time
Establish process for quality assurance (QA) of coagulometer		
Draft an OAT self-monitoring policy		
Clarify issues of accountability and clinical responsibility (partially)		
PROCESS		
Provide patient training in self-testing and using the coagulometer	Provide education and support for dose adjustment by patients (PSM)	Not a PSM service
Deliver anticoagulant education for self-monitoring patients	Deliver anticoagulant education for primary care staff supporting patients	Pilot service not delivered from primary care
Provide ongoing support to patients	Provide ongoing support to primary care staff supporting self-monitoring patients	
OUTCOME		
Self-monitoring service is safe	Self-monitoring service is cost-effective	Relevance and value unclear
Self-monitoring service is acceptable to patients		

Table 42: Inclusion and exclusion of candidate service requirements in the PST pilot

The next section describes how each of the key operational decisions was made.

7.2.1.1 Patient self-testing service option selected

In setting up an OAT patient self-monitoring service, the different variables of the self-monitoring process need to be defined and decisions taken on how this service will be delivered. As discussed in earlier chapters, patient self-monitoring of oral anticoagulation can comprise patient self-testing or patient self-management.

Therefore, there were three main options for the pilot service:

- i. Patient self-testing only
- ii. Patient self-testing and patient self-management (mixed model)
- iii. Patient self-management only

It was decided to start with a self-testing service with the option of extending this into a self-management service at a later stage. Barts and The London Hospital operates only a self-testing service.

The reasons for this were three-fold. Firstly, as the clinic still bore responsibility for adjusting the patient's dose of warfarin a self-testing model was felt to carry the lowest risk, a view endorsed by the healthcare professionals and managers interviewed earlier in this research. Secondly, a gradual "progression" from self-testing to self-management was in keeping with the ethos of the service, which favours a cautious implementation of service developments. Finally, although the patient educational requirements for OAT patient self-testing and self-management are not entirely clear, preparing patients for self-testing was felt to require less educational investment.

7.2.1.2 Engage key stakeholders

The results of the empirical work highlighted the need to ensure the support of key stakeholders at an early stage. To comply with this requirement, GPs, commissioners and key hospital staff were engaged at an early stage.

Confirmation from the patient's GP that they were happy to prescribe the INR testing strips was needed before the patient was allowed to start self-testing. Whilst the clinic provided strips for the duration of the pilot period, participants' GPs were asked if they would be prepared to supply these strips after the pilot. This was included in a standard letter sent to the GP at the start of the pilot.

Although supply of testing strips was not raised as an issue during the earlier focus group meetings with healthcare personnel, or through interviews with self-monitoring patients, this is not reflective of the experiences of some patients in the UK.¹⁷⁰

The position of commissioners on provision of testing strips was also sought by email. As this was a pilot service, at this stage there was no broader discussion about funding a scaled-up service.

Key hospital staff – consultant haematologists and haematology laboratory manager - were also informed of the pilot via email.

7.2.1.3 Make a loan coagulometer available

The requirement for the patient to purchase the coagulometer was identified as a barrier to uptake of OAT patient self-monitoring in both the patient and healthcare personnel studies. Financial constraints meant that the anticoagulation service was not able to provide a machine to those who were eligible for self-testing.

As a compromise, to allow patients to 'try before they buy', funding was made available to provide a loan coagulometer for the duration of the pilot if required. However, it was made clear to participants that coagulometers were given to them by the clinic for the duration of the pilot only. If they wished to continue testing at home after this six-month period, they would be expected to purchase their own machine.

7.2.1.4 Relatively inclusive patient selection criteria

The challenge of identifying those patients who are suitable for self-testing has been previously discussed in section 3.11. Empirical work, presented in Chapter 5, found that some Whittington warfarin patients had concerns that not all patients would be able to self-test, particularly those who are elderly or have complex medical problems. Although there was some debate as to whether those with poor INR control should be included, healthcare professionals and managers felt that inclusion criteria should be as broad as possible, perhaps starting with those patients who are “self-selecting” and hence highly motivated. This inclusive approach was adopted in this pilot and is described further in 7.2.2.

Barts and the London suggested an additional screening criterion after initial enrollment into the pilot – ensuring that the coagulometer is able to deliver an accurate INR reading for the patient. In a minority of patients, the coagulometer is unable to deliver an accurate INR. For example, the presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (LA), and a high haematocrit value can potentially lead to elevated INR values. Therefore, to ensure that the coagulometer will deliver an accurate reading, before self-testing starts two contemporaneous patient blood samples – a capillary sample measured on the coagulometer and a venous sample measured in the hospital haematology laboratory – should be within 0.4 INR units of each other.

7.2.1.5 Develop an educational programme

All stakeholder groups identified the need for adequate educational preparation for OAT patient self-monitoring.

The education of those wishing to undertake self-monitoring has been previously discussed in section 3.12.1. In summary, there is no standardised educational package for OAT self-testing patients in the UK. There is insufficient detail in the published literature to define the length and content of the educational session. More data are available for educational support for OAT self-managing patients. However, it is unclear if a lower intensity of training would be required for self-testing (duration of training described for self-management varied from 3 hours to 16 hours).

The main challenge of developing an educational programme to support those wishing to self-test is the diversity of information needs in this group of people, as evidenced by the results of the patient interviews and survey conducted earlier in this research. However, although there was variation in both the type and depth of information needed, the more 'practical' skills – for example, use of the coagulometer - were the ones for which many patients felt they would need support if they were to self-test.

Therefore, although some more didactic underpinning material was included, the educational session was designed to be very much 'hands on'. The structure and content of the session was developed by the senior anticoagulation pharmacists (SD and FA) under the guidance of the author. In the first instance, they obtained the names of anticoagulation monitoring services that were supporting self-testing from the author and from the medical representative of Roche (the manufacturer of the coagulometer). They then contacted a number of centres, including Barts and The London, Nottingham University NHS Trust, South Manchester University NHS Trust and Birmingham, known to be operating a PST service. The content of their education sessions was reviewed, with a view to an aspiration that the session was as practical as possible, and a culmination used a template for the PST programme at The Whittington.

The aims and objectives of the session, in terms of what the participants were expected to be able to describe at the end of the educational session, are listed below:

- The theory of blood coagulation and how warfarin works
- Indications for oral anticoagulation and target INRs
- Why regular monitoring is needed
- The influence of diet and lifestyle and of other medicines on INR readings
- The concept of self-testing of INR
- How to test the INR
- Quality control of INR tests
- The necessary health and safety measures associated with carrying out an INR test

Participants were also required to perform at least one satisfactory INR test using the coagulometer.

7.2.1.6 Establish a formal agreement between patient and anticoagulant service

Liability for patient self-testing was a concern expressed by clinicians and managers in the focus groups. Although it is far from clear where accountability rests, the respective responsibilities of both the patient and the clinic should be understood and documented at the start of self-testing. Therefore, a written agreement between the patient and the anticoagulant clinic, similar to one used at Barts and The London, was drawn up and signed by both patient and a member of the clinic staff. This agreement can be found in Appendix 13.

Although this is not a contract in strict legal terms, it does set out respective responsibilities. One copy was kept by the patient; a copy retained by the clinic; and a third copy sent to the patient's GP.

7.2.1.7 Establish a process for QA of coagulometer

The CoaguChek™ XS machine was selected for this pilot. The Whittington Anticoagulation Monitoring and Stroke Prevention Service has a long history of working with CoaguChek™ machines, and staff felt confident that they would be able to support patients in their use. And, in accordance with consensus guidelines, this device has had a positive evaluation from the Centre for Evidence Based Purchasing (formerly the MHRA and MDA).¹⁷¹

As discussed in earlier chapters, to ensure accuracy of INR readings, the coagulometer needs to be regularly quality assured. This is mandated in consensus guidelines,^{36;52} and was required by both patients and healthcare personnel in this body of research. Two options that complied with this requirement were identified:

- i. Two contemporaneous capillary samples; one measured on the patient's machine the other on the clinic's coagulometer which has been subject to external quality assurance.
- ii. One capillary sample measured on the patient's machine; one contemporaneous venous sample measured in the hospital haematology laboratory.

There is no consensus as to the best method of QA. The second method was selected to provide patients with the reassurance that the CoaguChek™ was “as good” as the hospital INR tests they were accustomed to.

7.2.1.8 Develop a standard operating procedure

An operational plan for managing a PST service was identified as a requirement by the healthcare personnel attending the focus group meetings. This need was met by a standard operating procedure, developed by the senior anticoagulation pharmacists (SD and FA) under the guidance of the author, drawing on the experiences of the PST service at Barts and The London.

A standard operating procedure (SOP) has been defined as “a written set of instructions that someone should follow to complete a job safely, with no adverse effect on personal health or the environment, and in a way that maximizes operational and production efficiency.”¹⁷² An SOP was felt to be essential to describe the steps and activities of the service, to ensure that it operated in a consistent manner, so promoting a quality service. The contents of the SOP are summarised in Table 43.

	➤ Aim of SOP
	➤ Criteria for accepting patients to self-test
	➤ Patient training
	➤ GP notification
	➤ Procedure for patient self-testing
	➤ Quality control
	➤ Maintenance of CoaguChek™ machine
	➤ Disposal of waste
	➤ Six-month clinic review
Appendix 1	Initial assessment sheet for home monitoring of INR
Appendix 2	Questions to be asked by clinic staff when self-testing patient communicates INR
Appendix 3	Procedure for communicating INR results

Table 43: Contents of the Whittington OAT patient self-testing standard operating procedure

7.2.1.9 Support patients throughout the pilot

In addition to providing dosing advice in response to patient-measured INRs, the empirical work identified two type of support that might be needed by self-testing patients: regular review and ad-hoc advice. Although the time span of the pilot would not permit a regular review, clinic staff would need to respond to patients’ INRs and to ad-hoc requests for advice.

All stakeholder groups felt that a reliable means of communication was essential to foster support provision, especially with communication of INR results. As clinic staff felt that more than one method would provide more flexibility for the patient, both a dedicated telephone line and an email address were set up.

The rationale behind the key operational decisions has been described. The next section outlines how the PST pilot was operated.

7.2.2 Recruitment of sample to PST pilot

Eligible patients were Whittington clinic patients who had previously expressed a desire to self-test to clinic staff or to the author. Clinic staff and the author assessed these patients for suitability for self-testing using the criteria presented in Figure 24.

On lifelong oral anticoagulation
Good command of English (or a carer or family member available who can translate)
Good manual dexterity (or a carer or family member available who can assist with testing).

Figure 24: Patient inclusion criteria for the warfarin PST pilot

No other assumptions were made about the patient's ability to self-test; the most important selection criterion was an expressed desire to self-test. Previous poor compliance, either in terms of medication or clinic visits, and poor INR control were not regarded as exclusion criteria. The Whittington Anticoagulation Monitoring and Stroke Prevention Service does not manage children so, by default, all patients were > 18 years old.

Invitation letters were sent to 21 patients in March 2010, along with an information sheet about patient self-testing. The letter included a form, which the patient was asked to complete and return, indicating their intent to participate in the pilot. This letter and information sheet can be found in Appendix 14.

7.2.3 Delivery of educational programme for patients participating in the PST pilot

After receiving their written agreement to participate in the pilot, self-testing patients were invited to attend an educational session.

The education session was held in the Pharmacy Department at The Whittington Hospital and was delivered by one or both of the senior anticoagulation pharmacists. There were approximately six patients in each group; the session lasted for three hours. The content of the educational material is summarised in Table 44.

➤ Self-testing of oral anticoagulation, including advantages and responsibilities of patient and healthcare professional
➤ Point of care INR testing vs. laboratory INR testing
➤ Blood coagulation and warfarin
➤ Indications for warfarin
➤ Effects of medication, diet and lifestyle on INR
➤ Practical session on self-testing technique

Table 44: PST pilot: Summary of content of the patient educational session

Before arriving at the session, each patient had an INR measured in the laboratory from a venous sample of blood. This was then compared with a reading taken from a capillary sample measured on the CoaguChek™ XS machine. If the INR readings were within 0.4 units agreement, the patient was allowed to continue with the pilot. In the event of readings with a divergence of greater than 0.4 INR units, a repeat comparison and discussion with the Consultant Haematologist were required.

At the end of the session, patients signed the agreement between them and the clinic (as discussed earlier), and took their machine and a starter pack of test strips home. A record was kept of the lot number of patients' CoaguChek™ XS machines (in case of a recall), batch numbers of test strips and comparative INR readings.

On completion of training the senior anticoagulation pharmacists notified the patient's GP that the patient had demonstrated that they could self-test their INR using a CoaguChek™ XS machine. A copy of the patient agreement was also faxed to the GP.

7.2.4 Implementation of patient self-testing pilot

Pilot patients were advised to practise testing their INR before attending the clinic for their next INR check as normal. At this follow-up visit, the patient's self-testing technique was assessed by the senior anticoagulation pharmacist (FA or SD). Once they were confident that the patient's technique was satisfactory, the patient was instructed to perform their next scheduled INR test at home on the CoaguChek™ XS, and to inform the clinic of the result via the dedicated phone line, or via email, before 1pm on the day of testing. Clinic staff would then advise on the subsequent dose and testing interval. Patients were issued with a box of testing strips.

These patients then tested their INR at home for the six-month pilot period. Patients telephoned or emailed their results to the clinic and staff then recorded these results in the patients record in the clinic's electronic advisory system. They then advised the patient on the dose of warfarin, and on when to check their INR again. The length of time between tests was dependent on the INR result; i.e. if a result was not in the patient's target INR range they would be required to perform an INR test sooner than if the INR was in range. Patients were also encouraged to report any signs of bleeding or thrombosis when they contacted the clinic.

The next section describes with how the pilot was evaluated.

7.3 Evaluation methods

There were four strands to the evaluation of this PST pilot:

- i. Auditing INR control of self-testing patients
- ii. Determining patients' motivations for, and expectations of, anticoagulation self-testing
- iii. Determining patients' experiences of anticoagulation self-testing
- iv. Determining clinic staff's experiences of patient self-testing

These will now be described.

7.3.1 Auditing INR control of self-testing patients

In order to validate the candidate requirements, safety of the PST service had to be demonstrated. Options for assessing the safety of anticoagulation control have been discussed previously (3.6.1). In this pilot, safety was assessed by patients' INR control during the pilot compared with the pre-pilot period.

Using their electronic anticoagulant record, INR readings during the pilot period and for the six months prior to the pilot were collected for each patient.

Additionally, the patient's electronic anticoagulant record was searched for entries relating to bleeding or thrombotic episodes. As it is thought that more frequent testing may contribute to improvement in INR control,⁷⁵ the median time between INR tests was also calculated for pre and post pilot periods.

Patients who were not taking warfarin prior to self-testing were omitted from these analyses.

7.3.2 Determining patients' motivations for, and expectations of, anticoagulation self-testing

One objective of this study was to determine patients' motivations for, and expectations of, self-testing. Exploring these patients' views was important for two reasons. Firstly, it was hoped that their perspectives would help to validate some of the candidate requirements. But also, one of the overarching aims of this research was to explore the perspectives of patients on self-monitoring of oral anticoagulation.

7.3.2.1 Developing the pre-pilot patient questionnaire to measure patients' motivation for, and expectations of, self-testing

Although two published PST studies included an assessment of patient acceptability of self-testing,^{76,118} an extensive literature search did not find any research exploring the expectations and perspectives of self-testing patients. Therefore, a preliminary set of questions was developed by the author, building on the empirical work described in this thesis with a focus on patients' motivation for PST, anticipated benefits, concerns and anticipated support for self-testing.

As the wording of a questionnaire is fundamental to both the validity and reliability of a study, this set of questions was sent to two experts – a qualitative researcher and an anticoagulation practitioner - for comments. Minor modifications in wording were made as a result of their feedback.

The final questionnaire was a 12-point instrument, and can be found in Appendix 15.

7.3.2.2 Administering the questionnaire

Patients participating in the self-testing pilot were asked to complete the questionnaire at their initial educational session. A covering letter was also provided and can also be found in Appendix 15.

7.3.3 Determining patients' experiences of anticoagulation self-testing

Another objective of this study was to determine patients' experiences of self-testing, in particular if their experience of self-testing matched their expectations. As with the pre-pilot questionnaire, these were studied to help validate the candidate service requirements and to fulfil one of the overarching aims of the research.

7.3.3.1 Developing the post-pilot patient questionnaire

A set of questions for the post-pilot questionnaire was developed by the author. As the objective was to determine the patients' experiences of self-testing, many of the questions were similar to those included in the pre-pilot questionnaire with appropriate changes of wording. For example, "What benefits do you think you will get from self-testing" became "What benefits (if any) do you think you have got from self-testing".

Another measure of the success of the PST pilot was its acceptability by patients. Therefore questions were included to determine patient acceptability and any derived benefits. Additional questions to validate specific candidate requirements – for example, education and support and willingness and ability to purchase a coagulometer - were also included.

7.3.3.2 Administering the post-pilot questionnaire

A questionnaire, along with a covering letter and postage paid envelope, was posted to each patient completing the pilot at the end of the pilot period. The questionnaire and covering letter can be found in Appendix 16.

7.3.4 Determining clinic staff's experiences of patient self-testing

In addition to having a safe service that is acceptable to patients, a successful PST service must be acceptable to clinic staff, and integrate delivery into the existing clinic structure. Although published evidence is available to demonstrate the safety of patient self-testing, no studies were found that explored clinic staff's experiences of establishing and supporting a self-testing service.

The author had regular – at least two-weekly – oral progress updates with staff supporting the service, and recorded key issues and problems discussed on a spreadsheet. Additionally, the author reviewed the electronic anticoagulant record of each patient on a weekly basis and recorded any relevant narrative in the same spreadsheet.

One of the senior anticoagulation pharmacists (SD) had earlier participated in one of the focus groups. At the end of the pilot period she was asked to verify the emergent themes from the focus group meeting she attended in the light of her experiences of the pilot. Field notes were made by the author during the interview. However, the interview was not audiotaped, to allow SD to speak more freely about her experiences.

The question guide used for this interview can be found in Appendix 17.

7.4 Analysis of results

This section describes how data from the PST pilot were analysed. All statistical analyses were performed using SPSS 17.0.

7.4.1 Auditing INR control of self-testing patients

The safety of the pilot service was evaluated by retrospective audit of the participants' INR results.

Percentage time in therapeutic range (TIR) was used to assess INR control in this study. The rationale for using this method has been previously discussed (4.5.3).

For each patient, percentage TTR for the pilot period, and for the six months prior to the pilot, was calculated using the method of linear interpolation described by Rosendaal et al.¹⁴⁶ Median percentage TRR values for these two testing periods were then calculated and compared using a Wilcoxon test. The interquartile range (IQR) for both median values was calculated to measure the extent of the spread of values. Median times between tests for the pilot period and the pre-pilot period were also compared using a Wilcoxon test.

Where given, statistical significance was defined as $p < 0.05$.

7.4.2 Determining patients' expectations of anticoagulation self-testing

Patients' responses to these questions were summarised into categories, with illustrative quotations used where appropriate. For the few questions that had a fixed response, the median value, with the interquartile range, was used to measure the central tendency where necessary. These coded data were entered on SPSS, which was used to generate the statistics.

Data were tagged with participants' sex and identifying number (e.g. M1 refers to the first sequential male respondent).

7.4.3 Determining patients' experiences of anticoagulation self-testing

As before, this questionnaire comprised mostly open-ended free-text questions and the responses were also categorised as before. For the few questions that had a fixed response, the median value, with its associated interquartile range, was used to measure the central tendency where necessary.

Coded data from the returned questionnaires were entered into SPSS 17.0.

7.4.4 Determining clinic staff's experiences of patient self-testing

Data collected from the verbal updates with clinic staff and from the patients' electronic anticoagulation records were organised by topics and themes. As small numbers of subjects are involved, this was done manually using a simple spreadsheet.

Similarly, data from the interview with SD were organised by themes.

7.5 Results

7.5.1 Sample

Twenty-one patients were invited to participate in the PST pilot; fourteen patients accepted, five declined and no response was received from two patients. Where stated, the reasons for declining to participate were satisfaction with current service; new diagnosis of breast cancer; lack of confidence. The demographics of patients accepted into the self-testing pilot are summarised in Table 45.

Number or mean value	
Male (n)	12
Female (n)	2
Median age (years) (IQR)	60.5 (51 – 67.8)
Indication for anticoagulation	
Atrial fibrillation	4
Replacement heart valve	4
Venous thromboemboli	1
Other	5
Target INR	
2.5	10
3.5	4

Table 45: PST pilot: Patient demographics (n=14)

Eleven patients used the loan coagulometers provided by the hospital; three patients purchased their own machines.

One patient dropped out after the initial training session as, despite repeated attempts, he was unable to get a satisfactory capillary blood sample. He declined offers of further training. Therefore, in total, thirteen patients completed the pilot.

Two patients were aided by carers, and these carers participated in the initial training.

7.5.2 Patient recruitment

There was a staged recruitment of these fourteen patients into the PST pilot. The first six patients attended an education session in March 2010; a second cohort of four patients attended a session in April 2010. The remaining four patients were trained either in pairs or on a one-to-one basis in June and July 2010. With the exception of one patient who was managed by the thalassaemia clinic, all participants attended a follow-up appointment at the anticoagulant clinic within a month of their education session.

7.5.3 INR audit data

INR data for the six-month pilot period and for the six-months immediately prior to the pilot were collected for eleven patients completing the pilot. As two patients started self-testing soon after starting warfarin, pre-audit INR data were not available. Hence, they were excluded from this analysis.

The median percentage time in therapeutic range (%TIR) was significantly higher in the pilot period than the pre-pilot period (75.8% vs 63.4%, $p = 0.03$) (Table 46)

	% Time in therapeutic range (TIR)	
	Pilot period	Pre-pilot period
Median	75.8	63.4
IQR	72.5 – 85.0	49.8 – 80.7
Minimum	59.5	32.3
Maximum	100.0	94.2

Table 46: PST pilot: Percentage time in therapeutic range - Self-testing pilot period vs pre-pilot period (n=11)

There was no significant increase in frequency of testing between the two groups. The median number of days between INR tests in the self-testing pilot period was 22.5; the median time interval was 28.0 days in the pre-pilot period ($p = 0.05$).

One patient had an INR < 1.5 (1.3) and another had one INR > 5 (5.5) in the self-testing pilot period. The low INR was a consequence of the patient stopping warfarin on his doctor's instruction; he subsequently restarted it. There was no clear reason recorded for the high INR.

There were no INRs < 1.5 and one INR > 5 (5.5) in the pre-pilot period. It was likely this high INR was the result of a course of antibiotics and antifungals.

There were two pilot patients that were not included in this analysis as they had no INR results in the six months prior to the pilot. They achieved a median TRR during the pilot period of 76.4% and 86.5%.

7.5.4 Adverse events

No bleeding or thromboembolic events were reported during the pilot.

7.5.5 Patients' expectations of self-testing

Questionnaires were given to all pilot patients (n=14) at their introductory training session. All patients completed the questionnaire.

7.5.5.1 Themes from the pre-pilot questionnaire: patients' expectations of self-testing

Source of information about self-testing

As the majority of the pilot patients had approached the clinic about self-testing – in effect, self-referring – it was of interest to know where they had heard of warfarin PST. One of the candidate service requirements was to promote the self-monitoring service to patients, and therefore information about suitable forums for this might be useful.

Half of these patients had heard about self-testing through the Whittington Hospital. The results are summarised in Table 47.

Source of information about warfarin PST	Number of patients
Whittington anticoagulant clinic	4
Whittington Hospital (unspecified location)	3
GP surgery	2
Hospital consultant	2
Newspaper	1
Charitable foundation	1
(London) Heart Hospital	1

Table 47: PST pilot: Source of pilot patients' initial information about warfarin PST

Motivations for self-testing

Similarly, to tailor any future promotional activity, a knowledge of patients' motivations for self-testing might prove useful. Patients were asked to rank the difficulty they had in deciding to participate in the pilot on a 5-point Likert scale from 1 = "no difficulty" to 5 = "a lot of internal debate". Almost all of the patients (n=13) had no difficulty in reaching this decision; median score was 1 (IQR = 1 to 1). As these patients were essentially self-referring, this was an unsurprising result.

Although there were a number of different reasons for the pilot patients expressing a desire to self-test (summarised in Table 48), the dominant factor was the convenience afforded by self-testing whilst travelling, either for work or leisure.

Motivating factor	Number of patients
Travel	6
Avoidance of hospital visits	4
Wish to self-care	2
Convenience	2
Reassurance	1
Time saving	1
Recommendations from medical colleagues	1
Increase stability of INR	1
Difficulty with venepuncture	1

Table 48: PST pilot: Motivating reasons for warfarin self-testing amongst participants

Amongst this group, avoidance of hospital visits was also a frequently cited reason, especially in terms of travelling to the hospital and finding parking once there.

One of the pilot patients had thalassaemia and, by necessity, had to attend the hospital regularly. Therefore, there was a debate amongst clinic staff when recruiting for the pilot as to any potential benefits he may achieve. However, he expressed desire to have a greater role in self-care (one of two patients stating this motivation), which is an equally strong potential benefit of self-testing.

The availability of a loan coagulometer was a deciding factor for participation in the pilot for seven of the eleven patients who were given a machine for the duration of the pilot. The education and support provided by the service were also strong factors.

Benefits of self-testing

The pilot patients' anticipated benefits largely mirrored their motivations for trying self-testing and are summarised in Table 49.

Anticipated benefits of self-testing	Number of patients
Convenience (including avoiding travelling to hospital)	5
Time saving	3
Better INR control	3
Reassurance	2
Independence / more autonomy	2
None	1
Step towards PSM	1
Unsure	1

Table 49: PST pilot: Participants' anticipated benefits of self-testing

Concerns about self-testing

The majority of the pilot patients (n=10) had no concerns about self-testing. For the remainder of patients concerns focused on their ability to perform an INR test and the accuracy of the coagulometer:

“Previous machine correlated poorly with venous blood so I have a lingering doubt about not having a venous test regularly” (M4)

Reassurance about the accuracy of coagulometers, which could be provided through education, support and quality assurance, was also important to some of the patients interviewed earlier in this research. Their concerns were partly predicted on past experiences, either with coagulometers or glucometers.

However, it is important at this point to note another important difference in monitoring blood glucose and INR. Although it is essential that the accuracy of both of these types of machines is assured, it can be argued that this is more critical in the case of coagulometers. In contrast to blood glucose control, there are often no signs that the INR is not therapeutic, and the only means of assessment is the coagulometer.

Support for self-testing

Patients were asked for their requirements both in terms of education prior to starting PST, and also ongoing support whilst self-testing.

Very little was required from this group of patients in terms of clinical information about warfarin. Where stated, educational requirements centred on the more technical aspects of patient self-testing and use of the coagulometer. One patient stated that he needed no educational support and three felt that minimal input was needed. The results are summarised in Table 50.

Educational element required before self-testing	Number of patients
Coagulometer use and INR testing	6
Overview / background to PST	2
"Top-up" education	2
Problem solving	1

Table 50: PST pilot: Educational requirements of participants prior to self-testing

This pilot group had modest expectations of support from the anticoagulant clinic whilst self-testing. Over half of the group (n=8) expected the clinic to recommend the dose of warfarin in response to the self-measured INR. Other requests centred on technical support for the coagulometer.

Sustainability of pilot

Patients were asked about two issues that may have an impact on them continuing self-testing once the pilot had finished.

Earlier stages of this research, identified patients' reluctance or inability to purchase a coagulometer as a potential barrier to its uptake. Using a 5-point Likert scale, from 1 – “very unlikely” to 5 = “very likely”, patients were asked how likely they were to buy a coagulometer once the pilot had ended. As four patients had already purchased a coagulometer, this question was not applicable to them. For the remaining ten patients who responded to this question, the median response was 4 = “likely” (IQR = 2.5 to 5).

The reluctance of GPs to prescribe INR test strips has also been earlier identified as a potential barrier to warfarin PST (2.5.3). Whilst eight of these patients' GPs were happy to prescribe strips, the remaining six patients were unsure of how their GP would react, largely because they had not discussed the issue with the GP.

Two of the four patients who had purchased a machine had not discussed test strip prescriptions with their GP. One of this group of patients stated that her GP had overcome an initial reluctance to prescribe:

*“My GP now prescribes my test strips. Two years ago he was not happy with self-testing. So I'm not sure if he is happy about it or not, but as he now prescribes the strips maybe he is growing more comfortable with self-testing”
(F2)*

7.5.6 Patients' experiences of self-testing

Questionnaires were posted to all patients completing the pilot (n=13); eight patients returned their questionnaires.

7.5.6.1 The post-pilot questionnaire: patients' experiences of self-testing

The post-pilot questionnaire was divided into four sections; experiences during the pilot (which included benefits and difficulties) support for self-testing, feasibility of continuing self-testing and final thoughts. These will now be discussed.

Experiences during the pilot

All respondents rated their experience as 'very positive'; median score was 1 (IQR = 1 to 1)

Patient-reported benefits of self-testing centred around two main themes; convenience and reassurance. The ability to test the INR whilst away from home and the avoidance of hospital visits, with the associated traveling, meant that the benefit that half of this group of patients derived from self-testing was convenience. Additionally, over half of this group embraced the greater control they achieved through testing their INR when they felt it was necessary, and the reassurance this brought:

"The security of knowing that if I feel unwell and suspect my INR may be very out of range, I can test it to find out as soon as possible whether my guess that it is out of range is correct" (F2)

"The ability to monitor the effect of my daily intake has on my blood gives me unmeasurable (sic) peace of mind. I can see this in my own home. Wao!" (M1)

There were no unanticipated benefits reported.

Where reported, patients had difficulties with either getting a large enough blood sample, or with applying this blood sample to the test strip. This affected over half of this patient group, and sometimes resulted in wasted test strips.

“At the start a problem with obtaining enough blood. This solved when I was shown how to adjust the 'size' of the lancet blade - No problem now.” (M5)

Some of these difficulties may be circumvented by education and training.

“I used to waste a few strips - but I waste fewer now since I was shown, on the pharmacists self testing training session at the beginning of this pilot, a better way to apply the blood to the strip. Before that I was doing it the way I was shown on the Roche self testing DVD that came with the machine.” (F2)

Supporting self-testing

The majority of respondents did not feel that any changes to the educational programme provided by the clinic were necessary.

“Any more (education) would have been counter productive. You have to try to learn from your mistakes.” (M3)

However, a few patients felt that extra practice with self-testing and a more robust assessment of patients' technique may be beneficial. No changes to other aspects of the educational programme were suggested.

Most patients felt that the support provided during the pilot was 'great' or 'excellent'

“The support is excellent. Full marks.” (F2)

No suggestions for improvement were received.

Continuing self-testing

All eight patients who returned the post-pilot questionnaire wished to continue self-testing after the pilot. The overwhelming reason for wanting to do this was convenience.

“Being able to self-test gives you freedom in looking after your INR results without going to hospital to do this and for holidays.” (F2)

However, some patients may find it difficult to buy a machine.

All patients who answered the question – there was one missing response – stated that they would be ‘very willing’ to purchase a coagulometer at the end of the pilot; median score was 1 (IQR 1 to 1). However, when questioned about ability to buy a coagulometer the median score dropped to 2 with a greater variation in score (IQR 1 to 3.5).

For three patients, the ability to purchase a coagulometer was contingent on acquiring the means to do so:

“I will pay through my benefit” (M1)

“(I) will have to borrow the money” (M3)

“Should my machine break it would be difficult to afford another. But I seem to remember Roche told me that you can pay in instalments and that would be possible.” (F2)

Endnote

Seven patients would recommend warfarin PST to a friend; one respondent did not answer this question. Again, convenience was the overwhelming reason for advocating self-testing.

“The freedom and control of looking after your health at a time and place convenient to you. Thanks for the chance to try this out.” (M3)

However, control was also cited as a reason for recommendation by three respondents.

“A feeling of being in control. Ability to respond quickly to changes in INR.” (M4)

7.5.7 Anticoagulant clinic staff's experiences of patient self-testing

7.5.7.1 Themes from formal oral progress updates with staff and their entries in the pilot patients' anticoagulation records

Data from the progress updates with clinic staff (SD and FA) running the PST pilot, and analysis of the content they had entered into the pilot patients' electronic anticoagulation record were categorized into six broad themes (Table 51)

INR testing
Communication of INR results
Patient selection
Self-management
Feasibility of PST
Marketing of coagulometers

Table 51: PST pilot: Themes emerging from discussion with staff

These will now be discussed.

Theme 1: INR testing

INR testing can be broken down in three sub-themes: patient capability, concordance between venous and capillary samples and patient confidence in readings. These will now be considered.

Some patients had initial difficulties in obtaining an adequate sample of capillary blood on which to perform an INR test. Although two of these patients also measured their blood glucose at home, they still found measuring their INR a challenge. Specific problems included using the correct depth setting on the lancet, positioning the finger over the testing strip and incorrect technique, including stabbing or squeezing the finger. Some of these problems were compounded by nervousness and one patient had commented that if the prescribed gap between INR tests was long, he forgot how to test his INR.

As discussed earlier (7.2.1.4), concordance between capillary and venous samples is a pre-requisite for patient self-testing. This created difficulties during the pilot in two ways. Firstly, two patients were reluctant to return to the clinic for a second comparative test. Secondly, there were initial difficulties in getting matching INRs from another patient; further management advice was sought from the consultant hematologist and the patient was allowed to continue with the pilot once concordant samples were obtained.

There was a perception amongst clinic staff that many patients did not trust the INR result generated by the coagulometer, which has been borne out by the comments of some of the pilot patients. However, this distrust was not confined to self-testing but extended to use of the coagulometer for INR monitoring in primary care (i.e. when used by primary care staff for community based clinics).

Theme 2: Communication of INR results

Regular INR tests are essential to the safe management of oral anticoagulation, to ensure that the patient is not at risk of bleeding or thrombosis.¹⁴ One of the responsibilities of the self-testing patient was to perform the INR test at the mutually agreed time interval, and inform the anticoagulant clinic of the result by 1pm on the day of testing.

Reliable communication of INR results by patients to the clinic staff caused considerable problems during the pilot. These problems were related to patient compliance and staff engagement.

Two patients emailed their results to the clinic; the remainder used the telephone. However, the dedicated telephone was not always used, which risked results not being picked up in a timely manner. Equally, the dedicated email account was not used by patients, risking communication of results to a person who was on annual leave.

Clinic staff had to put considerable effort into following up patients who had not communicated their INR results at the prescribed time. At one stage in the pilot, over half of those enrolled were not communicating their results at the correct time. At one point, a patient who spends much of his time in Nigeria was six weeks overdue with his INR test result and uncontactable, raising serious safety concerns. Another patient headed off to Thailand with his coagulometer and the clinic did not hear from him for over three months.

Non-compliance with testing may be addressed by education. There was an initial perception amongst some patients that if their INR was within range they did not need to contact the clinic. One patient started a course of antibiotics during the pilot and deferred his INR test until he felt better.

Engagement from clinic staff is equally important and initially one of the clinic staff was resistant to this service development and not passing on patients' messages. However, as the pilot progressed she became more engaged, and the feeling of those running the pilot was that there was a lack of understanding which might have been prevented by involving her in the development of the pilot service at an early stage.

Theme 3: Patient selection

Issues surrounding patient selection came up through discussions with clinic staff. Acceptance (or refusal) of patients for self-testing created some ethical dilemmas. There was a potential referral for a stroke patient, who was a candidate for oral anticoagulation but for whom self-testing, with the assistance of her daughter, was the only option for monitoring. Denying her the opportunity to self-test would have been denying her an effective treatment. However, the patient's prognosis was poor and anticoagulating her may not have improved her quality of life, and may have denied another patient the chance to self-test.

There were concerns over the equity of the service. Three of the pilot patients were retired doctors, and there was a fear that self-testing was the preserve of the knowledgeable few.

Clinic staff were keen to accept one patient into the pilot as he was “difficult”, and his self-testing would potentially reduce contact with him!

One patient accepted on to the pilot was new to oral anticoagulation and self-testing from the start of treatment did not pose any problems.

Theme 4: Self-management

There was not only a desire expressed by some patients at the start of the pilot to adjust their own dose of warfarin, but also three patients admitted to self-managing during the pilot. The quote below is taken from the electronic record of one of the pilot patients:

“Just returned from trip to Africa. No change to meds but diet and lifestyle have been different while away. Going to Bangkok tomorrow for 3 weeks. INR from self-testing yesterday. Has taken an extra day of 3mg instead of 4mg as INR high”

By the end of the pilot, another patient was reaching a consensual decision with clinic staff on dose. He had steadily grown in confidence during the pilot, from being initially non-compliant with self-testing to phoning in INR results on time and offering dosing suggestions for discussion; clinic staff described this as a “complete turn-around”.

Theme 5: Feasibility of PST

Concerns were expressed over the feasibility of patient self-testing of OAT, especially in the early days of the pilot. It was felt that operating the pilot was labour-intensive, particularly in terms of educating patients and performing comparative blood samples, and there were doubts that this investment would reap few rewards.

A few logistical issues were raised during the pilot.

The operation of the pilot was underpinned by a standard operating procedure. But it was felt that this needed to be expanded to better support the clinic nurse specialist and administrator, especially to guide them when patients phone in INR results.

It was felt essential that local PCTs were consulted at the start of the pilot. Although Camden and Haringey were happy for their GPs to prescribe testing strips, the position of Islington and Barnet PCTs remained unclear.

Theme 6: Marketing of coagulometers

Towards the end of the pilot period, Roche invested in a more intensive marketing campaign for its CoaguChek™ XS machine for self-testing. This strategy included a temporary price reduction for the CoaguChek™ XS (to £299), implementation of support to anticoagulant clinics from a dedicated nurse, awareness evenings and advertising directly to patients in daily newspapers and on the London Underground. However, much of the campaign's resources were directed towards primary care, including visits to GP practices and advertisements placed in GP's magazines.

This resulted in a small surge of interest from patients. In August 2010, seven patients approached the clinic; six of these were male. Although it was decided not to include these patients in the PST pilot, two of them went ahead and purchased machines and the clinic staff felt compelled to train and support them.

7.5.7.2 Themes from post-pilot interview with clinic staff

One of the anticoagulation pharmacists running the pilot (SD) was interviewed after the pilot was completed. The interview took 40 minutes and took place in a private room in the Pharmacy department at the Whittington Hospital.

The interview with SD centered around four themes that emerged from the focus group that she attended – concerns; risk; feasibility and service redesign. A fifth theme – benefits – emerged from this interview. These will now be described.

Theme 1: Concerns about self-testing

Concerns about self-testing related to timely communication of results between the patient and anticoagulation clinic and patient selection criteria.

During the pilot, four patients needed to be contacted every time for their INR results. However, the remaining patients were more “*organised, conscientious or scientific*”, reflecting the group as a microcosm for the “*spread of humanity*”. The reasons for patients not communicating their INR results were multifaceted. However, SD did offer this insight:

“A few times we’ve had to chase results but people are testing ... they’re just choosing not to communicate their results. But I think that’s their little bit of rebellion. I can be a patient but I don’t have to be in a hospital”

Although reported INR results during the pilot appeared better than those achieved pre-pilot, SD felt that this was not so much better results *per se*, but instead the reporting of better results. There was some evidence that patients were either measuring their INR only when they felt the results would be good, or testing more often than asked to but not reporting the additional results.

There has been debate in the literature, and within the focus group discussion, over whether those with a history of poor INR control should be considered for PST. SD felt strongly that those with poor INR control should be offered the chance to self-test:

“Some patients feel frustrated with anticoag and feel frustrated that they have to come into hospital when they feel quite healthy They don’t like someone else managing it and rebel against it”

These patients were likely to be, but not exclusively, young or middle-aged men and SD had already identified a small number who “*might pick up if they are given the responsibility to do it themselves*”.

However, SD felt that the overriding priority is that a PST service should be inclusive, and that potential inequity presented more difficulty:

“(the) worst problem with this service is that it’s impossible to make it equitable”

As the service has limited resources and a large number of patients, funding coagulometers is impossible. Therefore, PST becomes the preserve of those who are able to buy a machine. In SD’s words:

“(It is) difficult to be inclusive when there is a financial cost associated with it”

But it is not only the financially disadvantaged who are excluded; language barriers may also exclude ethnic minorities.

For the duration of the pilot, patients were given a loan machine to “try before they buy”, on the condition that this is returned to the hospital at the end of the pilot period. However, SD felt that this was not a workable proposal in the future. In addition to potential difficulties in persuading patients to relinquish the loan machines, SD felt that it was wrong to raise people’s expectations by giving them a machine if they were not ultimately in a position to purchase one of their own. By doing this, there is a risk, at best, of disaffection, but also of the patient dropping out of the anticoagulation monitoring service.

Theme 2: Risk management

Risk management centred around shared responsibility; between patient and anticoagulation practitioner and between anticoagulation practitioners in primary and secondary care.

Before patients were enrolled on the pilot, they signed a patient agreement form which outlined the respective responsibilities of the self-testing patient and clinic. SD felt that a signed agreement of this nature was essential to protect the clinic from liability, and to clarify the relationship between the patient and clinic. The PST service represents...

“... a remodelling of the relationship that has to be formalised”

A focus group concern that patients who are self-testing are less likely to take their medical condition seriously was not borne out in this pilot. Although patients were less dependent on the clinic - and some quite blasé about contacting the clinic - they did not devalue either their condition or medication.

To mitigate potential risks, the focus group felt that an evaluation of patient competence was undertaken, at least on an annual basis. The pilot patients were assessed on use of the coagulometer at their initial training session and again at their follow-up clinic session. SD agreed that this was necessary, as was six-monthly QC of the patient's coagulometer. Whilst she stopped short of endorsing top-up educational sessions, she also felt there was merit in re-enforcement of educational messages through a newsletter. However, she felt that a formal re-evaluation should be reserved for those patients about whom the clinic staff had concerns.

The focus group also identified a need to have an agreed protocol between the hospital clinic and primary care in the event of patient transfer. Anticoagulated patients are often well for a long time, but can become suddenly unwell, or need to have a procedure, and will then require more intensive monitoring. But whilst it was acknowledged that a formalised agreement was necessary, there could be difficulties in accommodating all patients' needs.

“(all patients) are individuals with different care needs so one model doesn't really fit all”

SD concurred with the view of the focus group that there was a risk that the self-testing patient could lose “value-added” service through reduced contact with their healthcare professional. She confessed that is “*quite easy to be casual*” when a patient phones in their INR results and that they were not always subject to the same scrutiny as in a face-to-face contact. However, the same argument can be applied to those patients who are on the clinic's mailing list.

Theme 3: Feasibility of patient self-testing service

SD felt that, in the current climate, a larger scale PST service was not feasible. There are too many patients, and consideration needed to be given to the time required to train patients and also to the acquisition cost of the coagulometers. The attention that needed to be devoted to preparing and supporting an individual to self-test was arguably disproportionate to that given to the anticoagulated population at large; the needs of the one outweighing the needs of the many.

Before considering scaling-up the pilot, two things needed to happen; extra resources in terms of personnel, and an assurance from the PCTs that test strips would be funded.

Theme 4: Service redesign

If a larger scale patient self-testing service were enabled, some thought would need to be given to the best way of operating this service. SD felt that there were three options:

- i. Include a PST strand in the service's existing clinical governance framework to allow PST to be initiated and supported in both primary and secondary care.
- ii. Manage all PST patients at one centralised service.
- iii. Management by the patient's GP

On balance it was felt that the third option was the better one as the patient was likely to be attending the GP's surgery regularly, and also the INR results would go directly to the GP (as the prescriber). However, SD identified a potential training need of primary care practitioners:

“Community practitioners are not as well informed as hospital practitioners”

Regardless of where, and by whom, the self-testing patient is supported, quality of the service in terms of both INR control and QC of coagulometers must be ensured.

At the healthcare professional focus group meeting, it was proposed that patients could set up networks where they could avail of a shared coagulometer. However, SD felt that this approach had a number of drawbacks. There were potential health and safety risks in the use of blood testing equipment, and safeguards would need to be put in place to ensure the machines were quality controlled and that the strips and solutions were stored correctly.

Changes to the skill mix within the anticoagulation monitoring service may be needed to support PST. Although SD felt that skill mix does not matter, the linchpin was the clinic administrator, who has an important role highlighting when people are not reporting tests. She felt that higher grades of staff are not needed to run a PST service provided there are good guidelines.

Theme 5: Benefits of PST

SD felt that there was a need to offer patient self-testing as an option for the Whittington clinic patients. The current method of monitoring does not meet the needs of a proportion of the population, and within an increasing clinic population it is necessary to accommodate the different needs. There should be an emphasis on improving services and meeting individual patient needs:

“Because it’s a long term relationship you have to facilitate it”

In her view, the main problem with traditional anticoagulation clinics is that they can be time consuming and difficult to access:

“A young working man with a family to support shouldn’t have to spend three hours of his week, two weeks a month in an ac clinic”

In addition to providing a more patient-centred and convenient service, PST may improve safety through increased frequency of testing, although this brings increased financial pressure. But benefits may not only be conferred on the patient, but also on society:

“Financial benefit to society might offset any increased costs to ac services”

7.6 Validation of candidate service requirements

This PST pilot was a success in terms of being safe and acceptable to patients. From an operational point of view, anticoagulant clinic staff were able to support these patients and felt that it had clear benefits for some patients. However, they had concerns about the equity of the service and its scalability from a pilot, and they experienced problems with timely communication of INR results from patients.

The aim of this PST pilot was to validate the candidate requirements for an OAT patient self-monitoring service, derived from the empirical work described earlier in this thesis. For operational reasons, not all of these candidate requirements could be validated, and this has been discussed earlier. But, where possible, the candidate service requirements identified from these studies were incorporated into the design of this pilot.

Table 52 summarises the outcome of validating these candidate service requirements. Some elements could not be fully validated in a PST pilot. It was essential that this research was ethical, adhering to the core principle of ‘doing no harm’ to study participants.²⁷ For example, it would have been unethical to offer some patients education and none to others. Thus, as it is not known if the pilot would have been successful in the absence of educational support, this candidate requirement could only be partially validated.

The same ethical consideration applies to providing self-testing training and ongoing support to patients. However, these requirements could be validated using measures other than the success of the pilot. Pilot patients emphasised the importance of being trained on how to self-test and to use the coagulometer, and felt that initial difficulties with self-testing could have been avoided if greater attention had been paid to this in the initial educational session. The provision of support was an important factor in persuading patients to participate in the pilot, and positive feedback was received for the support given.

Service options were appraised in the early stages of the development of the pilot. Building on the findings of the focus group meetings, a PST model was selected and was found to be safe. However, in the absence of a direct comparison with a PSM service, it is not possible to conclude that this is the preferred model of care for this group of patients. The next stage of development of this service – ‘progressing’ some of these patients to PSM – might help answer this question.

Although, for operational reasons, the pilot service was delivered from secondary care, clinic staff felt that primary care might be the best place from which to support PST. This assertion broadly supports the discussions in the focus group meeting. Therefore, further development of the service may be to engage general practitioners, currently delivering the primary care anticoagulation monitoring clinics, in supporting self-testing patients.

Engagement of all Whittington anticoagulant clinic staff was found to be essential. The anticoagulant nurse specialist and clinic administrator were not involved early in the process, an oversight that resulted in their initial resistance to the pilot. Two strategies might have avoided this. Firstly, earlier engagement with these individuals, involving them at the developmental stage of the pilot. Secondly, whilst the standard operating procedure (SOP) used in the pilot was felt to be beneficial and an essential requirement, in future it should incorporate the roles of all clinic staff.

The empirical work suggested that two formalised shared care agreements were needed: one between primary and secondary care, and another between patient and clinician. As this pilot service was run from secondary care, the first shared care agreement could not be tested. However, through the insight gained by supporting self-testing patients, clinic staff felt that some form of agreement between primary and secondary care was needed, although there were doubts that this could accommodate the needs of all patients. Therefore, if a shared care agreement between primary and secondary care is to be tested in future, consideration may need to be given to making it as broad as possible to embrace different patient needs.

The shared-care agreement between patient and clinician was the patient agreement form signed by both parties at the start of self-testing. Although this set out the respective responsibilities, it was felt that some patients did not fully comply, particularly around timely communication of INR results. Nonetheless, clinic staff felt that this form was an essential requirement of the service, to both define the relationship between patient and clinician and to protect the clinic from liability.

There are ways to persuade the patient to report their INRs in a timely fashion. Firstly, the importance of complying with this requirement should be given more emphasis at the educational session and the risks of non-compliance outlined. Research commissioned by the National Patient Safety Agency found that some patients do not understand the meaning of INR readings.¹⁶⁹ Secondly, stronger wording could be employed in the patient agreement form. Although flexibility in communication methods with the clinic was already built into the service, with the option of providing results by telephone or email, the facility to provide INRs by text could be explored.

However, it needs to be accepted that, regardless of additional measures put in place, there may always be some patients who are less compliant with testing. Relatively inclusive eligibility criteria were used in the pilot, and this is discussed further in Chapter 9. However, to mitigate the risk of non-compliance with INR testing, those with a history of continually not attending the anticoagulant clinic on the agreed appointment date may need to be excluded from self-testing in the future. There is no evidence that those who are non-compliant with clinic visits for INR monitoring will fail to communicate their self-measured INR values in a timely fashion, and there is a possibility that the empowerment that may come from self-monitoring will encourage them to self-test at the prescribed intervals. Nonetheless, this is a gamble, and one that has to be traded against managing the risk of non-compliance with INR testing.

Although, the pilot did not set out to test the candidate requirement to promote the service to patients, Roche embarked on an intensive marketing strategy for the CoaguChek™ machine during the lifetime of the pilot. This resulted in a surge of interest in self-testing from patients, so much so that it became problematic for clinic staff to deal with requests for support. This not only emphasised the impact of increased awareness of self-testing, but also the need to have a process to deal with the patient interest that this generates.

Validating the findings from empirical work with patients and healthcare personnel, the requirement for the patient to purchase a coagulometer was again found to be a significant barrier to the uptake of OAT patient self-monitoring. Although the availability of a loan machine was a strong motivating factor for patient participation in this pilot, its sustainability needs to be ensured. Since the end of the pilot there have been difficulties in persuading patients to relinquish their machines. There is also the potential of raising people's expectations by giving them a machine if they were not ultimately in a position to purchase one of their own.

There are ways to circumvent these problems. Firstly, as has happened at Barts and The London, patients could be asked for a deposit when they are issued with the machine, refundable on its return. Secondly, patients may be asked to sign a statement on the patient agreement form that they are willing and able to purchase a coagulometer at the end of the loan period.

This section has discussed the validation of the candidate service requirements that could be included in this PST pilot. Further validation of these requirements, and validation of the requirements that needed to be excluded from this pilot service model, is a fertile ground for future research. Some of these options have already been outlined in this section; for example, engaging GPs to provide a patient self-testing service. Other options will be described at the end of the Chapter 9.

Table 52: Validation of OAT patient self-monitoring candidate service requirements derived from earlier empirical work

Candidate service requirement	Validated by pilot?	Supporting evidence from pilot
STRUCTURE		
Establish financial feasibility of service	No	
Gauge patient demand	No	Validation through pilot not required as demand had been assessed through patient survey.
Conduct service options appraisal	Yes	<p>Service options appraisal conducted at developmental stage.</p> <p>PST model selected safe and well accepted by patients. However, in the absence of a direct comparison, cannot assert that PST is better than PSM</p> <p>For operational reasons, the pilot service was delivered from secondary care. However, clinic staff felt that primary care might be the best place from which to support PST.</p>
Ensure engagement from those delivering and commissioning OAT management	Yes	<p>Lack of involvement of all clinic staff in the development of the PST pilot was felt to be a reason for their initial resistance to the pilot</p> <p>The SOP should be extended to include the clinic administrator and nurse specialist</p> <p>Agreement from clinic staff that PCTs need to be consulted at start of process to ensure provision of testing strips.</p>
Promote the self-monitoring service to patients	Yes	There was a surge of interest in self-testing from patients following a more intensive marketing strategy by Roche
Facilitate provision of coagulometer	Yes	<p>The availability of a loan machine was a deciding factor for participating in the pilot for over half of this group of patients. However, clinic staff felt that this was not a workable solution in the future.</p> <p>Although patients were 'very willing' to buy a coagulometer at the end of the pilot period, three out of the eight respondents indicated that they would have difficulty in doing so.</p>
Construct patient eligibility and assessment criteria	Yes	<p>The PST service was safe. Relatively inclusive selection criteria constructed based on the results from the empirical work.</p> <p>For those with historic poor INR control, time in therapeutic range significantly improved during the pilot.</p>

Table 52 (cont): Validation of OAT patient self-monitoring candidate service requirements derived from earlier empirical work

Candidate service requirement	Validated by pilot?	Supporting evidence from pilot
Develop an educational programme for patients	Partially	<p>Pilot patients achieved good therapeutic control after an educational session. Although it is not known how these patients would have fared in the absence of educational preparation, the education offered was an important factor for some deciding to participate in the pilot.</p> <p>The content of the programme delivered felt to be optimal by most patients.</p> <p>Clinic staff felt that education may address potential non-compliance with testing</p>
Develop an educational programme for primary care staff supporting patients	No	
Establish a formal shared-care agreement between primary care and secondary care	Partially	<p>Although clinic staff felt that an agreement was needed there were misgivings that this could accommodate the many needs of all patients.</p>
Establish a formal shared-care agreement between patient and clinician	Yes	<p>PST pilot was safe. However, despite a variety of methods available, there was a lack of timely communication of INR results from some patients.</p> <p>Patient agreement form felt to be an essential requirement by clinic staff.</p> <p>All patients signed this form. However, many patients did not comply with all the listed responsibilities, particularly around communication of INR results.</p>
Establish process for quality assurance (QA) of coagulometer	Yes	<p>Some patients (n=4) had concerns about the accuracy of the coagulometer at the start of the pilot</p> <p>Perception amongst clinic staff that many patients did not trust the INR result generated by the coagulometer.</p> <p>Clinic staff felt that six-monthly QC of the coagulometer is an essential quality requirement of the PST service.</p>
Establish an OAT self-monitoring policy	Yes	<p>Develop a standard operating procedure</p> <p>PST was safe. However, the SOP may need to be broadened to include other clinic staff supporting the service</p> <p>The SOP was felt to be essential to support clinic staff supporting the PST service</p>
Clarify issues of accountability and clinical responsibility	Yes	<p>A signed agreement between patient and clinic (patient agreement form) felt to be essential to protect the clinic, and individuals, from liability</p>

Table 52 (cont): Validation of OAT patient self-monitoring candidate service requirements derived from earlier empirical work

Candidate service requirement	Validated by pilot?	Supporting evidence from pilot
Address potential inequities in the service	Yes	Clinic staff interviewed had concerns about the equity of the service. Three of the pilot patients were retired doctors, and there was a fear that self-testing was the preserve of the knowledgeable few.
PROCESS		
Provide patient training in self-testing and using the coagulometer	Yes	Educational requirements of many of this group of patients (n=6) focused on self-testing and the use of the coagulometer Initial difficulties with self-testing with some patients Although most patients felt that the content of the educational programme to be optimal, a few patients felt that more attention should have been paid to self-testing technique.
Deliver anticoagulant education for self-monitoring patients	Partially	Pilot patients achieved good therapeutic control after an educational session. Although it is not known how these patients would have fared in the absence of educational preparation, the education offered was an important factor for some deciding to participate in the pilot. Clinic staff felt that education might address potential non-compliance with testing.
Provide education and support for dose adjustment by patients (PSM)	No	
Deliver anticoagulant education for primary care staff supporting patients	No	
Provide ongoing support to patients	Yes	Support offered was an important factor for some deciding to participate in the pilot. However, expectations of support were modest. As a minimum requirement, the majority of patients (n=8) needed support in terms of dosing recommendations. Other requests centred on technical support for coagulometer. Positive feedback from patients for support provided during pilot with no suggestions for improvement.
Provide ongoing support to primary care staff supporting self-monitoring patients	No	

Table 52 (cont): Validation of OAT patient self-monitoring candidate service requirements derived from earlier empirical work

Candidate service requirement	Validated by pilot?	Supporting evidence from pilot
OUTCOME		
Self-monitoring service is cost-effective	No	
Self-monitoring service is safe	Yes	<p>Quality of the service needs to be ensured in terms of INR control</p> <p>No bleeding or thromboembolic events were reported during the pilot period. However, as the time period was short and the numbers of patient few, the likelihood of these events occurring was low.</p> <p>PST resulted in a statistically significant improvement in INR control. However, clinic staff felt that improved INR results may have been a result of selective reporting by patients than better results <i>per se</i>.</p>
Self-monitoring service is acceptable to patients	Yes	<p>All patients wished to continue with self-testing at the end of the pilot period</p> <p>Half of the group of patients responding to the post-pilot questionnaire reported that self-testing was convenient. Over half of this group felt reassured through the improved INR control that PST brought</p>

7.7 Conclusion

This pilot has demonstrated that it is feasible to support a small group OAT self-testing patients from the Whittington Hospital Anticoagulation and Stroke Monitoring Service. Candidate service requirements derived from the earlier empirical work with patients and healthcare staff were incorporated into the design of this pilot, and many of these requirements could be validated.

Patient experiences were positive, and they welcomed the convenience, reassurance and greater personal control that self-testing afforded. A minority of patients admitted to limited self-dosing during the pilot, and the next stage of this service development will be to offer self-management to some patients.

Although clinic staff operating the service felt that the anticoagulation monitoring service should support those who wished to self-test, they had concerns. Some patients were not conscientious about communicating their results to the clinic, which entailed considerable effort in follow-up. The necessity to purchase the coagulometer may place self-testing out of reach for many patient, resulting in an inequitable service.

Although a small group of patients enthusiastically embraced this model of care, scaling-up the service from a pilot to a larger group of patients may not be feasible without extra resources and assurances from PCTs that test strips will be funded.

7.8 Limitations

Steps were taken during this study to increase its reliability and validity. The first patient questionnaire was sent to two experts to ensure that questions were unambiguous and were likely to yield accurate information. Ideally, both questionnaires should have been piloted on a small number of patients before its use. However, the total patient numbers were small (n=14), and piloting the questionnaire would have reduced this number further.

As the first questionnaire was completed at the educational session, there was a 100% response rate. However, the second questionnaire was posted out to PST patients, risking accentuating response bias. With hindsight, a reminder and second questionnaires should have been used to increase the response rate.

Reliability in questionnaire studies relates to their reproducibility; that is ability of the instrument to produce the same results if it were tested it many times over. However, this is difficult to demonstrate in practice. If time had permitted, test-retest, a statistical method used to determine an instrument's reliability, could have been performed.¹³⁹ This would have entailed testing the questionnaire on a small number of the study sample twice, several weeks apart, and performing statistical tests to measure correlation. Although opinion is divided on which statistical tests are the best measure of correlation, Cohen's kappa coefficient (nominal data), weighted kappa (ordinal data) or Pearson's coefficient (interval data) are generally used.

However, the main limitations to this study were its size and scope.

This was a small pilot study, set up primarily to meet the needs of a small group of patients in North London and to validate some candidate service requirements of an OAT patient self-monitoring service identified in earlier chapters. Therefore, its generalisability to a wider population is limited.

To gain a more comprehensive view of the operational requirements of a PST service, it would have been desirable to conduct site visits and interviews with other centres, both nationally and internationally, offering this service. However, lack of resources did not permit this and, instead, an established UK service, recommended by the coagulometer manufacturer, was chosen as an exemplar site.

There are plans for further validation of the candidate service requirements. Some of these have been described earlier in this chapter. Other proposed plans will be discussed in Chapter 9.

CHAPTER 8: THE REQUIREMENTS FOR AN ORAL ANTICOAGULATION PATIENT SELF-MONITORING SERVICE

Through identification of the drivers, benefits, barriers and challenges, this investigation set out to derive a service model that would foster the successful adoption of patient self-monitoring of oral anticoagulation. A set of candidate service requirements was derived from evaluating the perspectives of key stakeholders. The majority of these requirements were then tested in the context of developing and implementing a pilot PST service.

The investigation was divided into three main studies:

- i. Patient perspectives of self-monitoring of OAT
- ii. Healthcare provider perspectives of patient self-monitoring of OAT
- iii. Validation of a set of candidate requirements for an OAT patient self-monitoring service through a pilot patient self-testing service

In this chapter the results of these three studies, and key findings from the literature where pertinent, are triangulated to produce a blueprint of the service requirements to enable the establishment of a successful OAT patient self-monitoring service.

These service requirements are presented within Donabedian's framework in two sections:

- i. Validated service requirements
- ii. Unvalidated service requirements

Each requirement of the service model is accompanied by a short description if required. Following this, in boxed text, is a summary of the evidence for its derivation, including published literature where this is pertinent, followed by the source of this evidence.

Evidence sources are coded as summarised in Table 53.

Lit = Literature
EP = Expert Patient interview
PI = Patient interview
PS = Patient survey
G1 = Focus Group 1 (healthcare professionals)
G2 = Focus Group 2 (healthcare managers)
Pilot = PST Pilot

Table 53: Evidence sources for service requirements

8.1 Validated requirements for an OAT patient self-monitoring service

Service requirements were validated in one of two ways, and are summarised in Table 54.

Firstly, as discussed in the last chapter, candidate requirements could be validated through testing in the PST pilot service.

However, the PST pilot is not the only method of validation. For operational, logistical or ethical reasons it was not possible to test all of the candidate service requirements through the PST pilot. Therefore, candidate requirements that could not be included in the PST pilot were considered to be validated if consensus was reached across the stakeholder groups, or if one stakeholder group asserted the requirement very strongly i.e. it was almost a unanimous opinion amongst those stakeholders.

STRUCTURE	METHOD OF VALIDATION
➤ Gauge patient demand for OAT self-monitoring	Pilot
➤ Conduct an options appraisal (i.e. explore other methods of OAT monitoring / define delivery of OAT self-monitoring service)	Pilot
➤ Establish financial feasibility of service	Strength of assertion
➤ Ensure engagement of those delivering and commissioning OAT monitoring	Pilot
➤ Promote the self-monitoring service to patients	Pilot
➤ Facilitate the provision of coagulometers (e.g. by funding coagulometer)	Pilot
➤ Construct patient eligibility and assessment criteria	Pilot
➤ Develop an educational programme for patients	Consensus view
➤ Establish a formal shared-care agreement between patient and clinician	Pilot
➤ Establish a formal shared-care agreement between primary care and secondary care	Strength of assertion
➤ Establish a process for quality assurance (QA) of coagulometers	Pilot
➤ Establish an OAT self-monitoring policy	Pilot
➤ Clarify issues of accountability and clinical responsibility	Pilot
➤ Address the potential inequities of the service	Pilot
PROCESS	
➤ Provide patient training in self-testing and using the coagulometer	Pilot
➤ Deliver an educational programme to patients	Consensus view
➤ Provide education and support for dose adjustment by patients (PSM)	Consensus view
➤ Provide ongoing support to self-monitoring patients	Pilot
OUTCOME	
➤ Self-monitoring service is safe	Pilot
➤ Self-monitoring service is acceptable to patients	Pilot
➤ Self-monitoring service is cost-effective	Strength of assertion

Table 54: Validation of service requirements for an OAT patient self-monitoring service

These requirements will now be described further.

STRUCTURE

Gauge patient demand

Although in recent years there has been a gradual move away from the traditional, paternalistic model of healthcare, some patients may be reluctant to assume more responsibility for their health.

A 2010 meta-analysis of 14 OAT patient self-monitoring (both PST and PSM) trials found that, on average, 68% of eligible people would not or could not take part.	Lit ⁹¹
Some patients prefer to leave OAT monitoring to healthcare professionals	Lit ¹⁶⁰ , PS
Although 53% of local patients surveyed indicated that they would be willing to self-test or self-manage their OAT, a small number of patients expressed a strong preference not to self-monitor. Younger, better-educated patients were more likely to be prepared to monitor their own OAT.	PS
Some patients are not ready to embrace self-monitoring	G1, G2
Patients' views should be sought to gauge demand before establishing a self-monitoring service.	G1
Patients may feel that other ways of monitoring INR more attractive	G2

Recommended requirement:

To elicit the views of the potential end users to confirm demand before developing an OAT patient self-monitoring service.

Conduct an options appraisal

In setting up an OAT patient self-monitoring service, an options appraisal can be thought of in two broad contexts. Firstly, the different variables of the self-monitoring process need to be defined and decisions taken on how this service will be delivered. Secondly, it is also necessary to establish whether other methods of OAT monitoring would be as attractive, or more attractive, to patients (e.g. attending an OAT monitoring clinic at a GP surgery).

A preference for another method of monitoring is one of the reasons for attrition in OAT patient self-monitoring trials.	Lit ¹⁰⁴
Although 53% of sample indicated that they would be willing to self-test, a small number of patients expressed a strong preference to continue with current service model	PS
Alternative ways of delivering OAT monitoring need to be explored in the context of a full options appraisal. Other services in primary care may be more attractive to patients.	G1, G2
Service options appraisal conducted at developmental stage of a successful pilot.	Pilot

Recommended requirement:

To conduct an options appraisal before establishing an OAT patient self-monitoring service, which should include a consideration of alternative ways of service delivery.

Establish financial feasibility of service

NHS resources are finite and the feasibility of any new service needs to be established before implementation. The financial impact is likely to be felt across the healthcare interface. Primary care is commissioning, and hence paying for, care. However, the movement of patients away from the traditional outpatient setting could represent a substantial loss of revenue for an acute hospital Trust.

A cost-effectiveness analysis UK-specific data has estimated that wide adoption of OAT patient self-monitoring would cost the UK an extra £8 – 14.3 million per year.	Lit ²⁸
Clarity needed over who will pay for the machines and strips	G2
Clarity around reimbursement for those training and supporting self-monitoring patients needed.	G1
Build a business case and run a meaningful pilot service to establish feasibility	G2

Recommended requirement:

Financial feasibility needs to be demonstrated from the point of view of both primary and secondary care

Ensure engagement of those delivering and commissioning OAT monitoring

Engagement is not confined to patients. Buy-in from healthcare professionals, clinic support staff and commissioners is also essential.

Clinicians' poor attitude is cited as a barrier to uptake of self-management of long-term conditions. ^{108;109}	Lit ¹⁰⁵⁻¹⁰⁹
Support from healthcare professionals is likely to be a key factor in increasing uptake of patient self-management.	Lit ⁹⁷
Reimbursement will be required for supporting self-monitoring	G1
Consult PCTs before setting up service	Pilot
Ensure all staff supporting self-testing patients are informed and engaged. Lack of involvement of all clinic staff in the development of the PST pilot was felt to be instrumental in initial resistance to the pilot.	Pilot

Recommended requirement:

To engage healthcare providers, managers and commissioners at an early stage of the development of a patient self-monitoring service.

Promote the self-monitoring service to patients

Increasing the awareness of self-monitoring amongst patients may act as a driver for its uptake.

Patients who were aware of self-testing before the survey were significantly more willing to self-monitor	PS
A growing awareness of self-monitoring amongst anticoagulated patients will act as a driver for uptake	G1
During the course of the pilot, there was a surge of interest in self-testing from patients following a more intensive marketing strategy by Roche	Pilot

Recommended requirement:

To promote the self-monitoring service directly to patients.

Facilitate provision of coagulometers

It is necessary for the patient to have a personal coagulometer for them to test their INR at home. The cost of the coagulometer - £399 (ex. VAT) at the time of writing this thesis – is currently borne by the patient.

The cost of the coagulometer initially deterred patients from self-monitoring	EP
Although 53% of local patients said that they would be willing to self-test or self-manage their OAT, only 15% of the sample surveyed indicated they would be willing to self-monitor AND purchase a coagulometer.	PS
Patients considered that it was “very important” (median score) that the clinic provided their coagulometer.	PS
The cost of the coagulometer is a barrier to self-monitoring, especially in certain sectors of the population	PI, G1, G2
A service predicated on patient’s ability to pay (for coagulometer) is inequitable	G2
The availability of a loan machine was a deciding factor for participating in the pilot for over half of this group of patients.	Pilot
Although patients were ‘very willing’ to buy a coagulometer at the end of the pilot period, three out of the eight respondents indicated that they would have difficulty in doing so.	Pilot

Recommended requirement:

To facilitate the no-cost or low-cost provision of coagulometers to encourage wide adoption of patient self-monitoring.

Construct patient eligibility and assessment criteria

There are no clearly defined selection criteria for OAT patient self-monitoring with most of the published trials using highly selected groups of patients.

Lack of evidence as to which patients are suitable for OAT patient self-monitoring. Consensual recommendations for inclusion and exclusion criteria made in national and international guidelines are broad.	Lit ^{36;52}
Concerns over the ability of some patients to monitor their OAT and a need to agree on selection criteria.	PI, G1, G2
Require a formal method to assess patients' competence to self-monitor; this may include a risk-assessment of each patient. This should include demonstration of competence to perform an INR test. ^{52;173} In the case of PSM, patients need to demonstrate that they can correctly interpret an INR test. ⁵² Competency should be reassessed at regular intervals. ³⁶	Lit, G2, Pilot
Selecting relatively inclusive selection criteria constructed on the basis of the results from the empirical work, the PST pilot service was safe. This included patients with historically poor INR control.	Pilot

Recommended requirement:

To reach local consensus on patient inclusion and exclusion criteria for OAT self-monitoring, and on a method to assess competence.

Develop an educational programme for patients

Although there is a national programme in Germany, there is no standardised educational programme in the UK to prepare patients for OAT self-monitoring.

Education is a requirement to prepare patients for self-monitoring.	Lit, ³⁶ PI, PS, G1, G2
Although there is no evidence to guide the intensity of this training, and standardisation of training is thought to be a “pressing requirement”.	Lit ¹⁷⁴
Patients thought that providing education for those undertaking OAT self-monitoring was “very important” (median score).	PS
The education offered was an important factor for some patients in deciding to participate in the PST pilot	Pilot
Pilot patients achieved good therapeutic control after an educational session. However, it is not known how these patients would have fared in the absence of educational preparation.	Pilot
Clinic staff felt that education might address potential non-compliance with testing.	Pilot

Recommended requirement:

To develop an educational programme to prepare patients to self-monitor their OAT.

Establish a formal shared-care agreement between patient and clinician

Sharing care entails redefining the relationship between patient and clinician, with a clarification of respective responsibilities. As with shared care agreements, traditionally used to allow the seamless transfer of patient treatment from the secondary care to general practice, a shared-care agreement between patient and clinician will foster sharing responsibility for anticoagulation monitoring.

In line with the Midlands Therapeutic Advisory Committee's Policy on Effective Shared Care Agreement¹⁷⁵, this should be consensual, and include clear definitions of respective responsibilities and communication networks. Accurate, timely information flow is essential to any anticoagulation monitoring service and self-testing patients will need a means to communicate their results to their healthcare provider, and the provider will be required to respond back to them in a timely fashion.

Both patients and practitioners should maintain documentation of communication with each other.	Lit ¹⁷³
Patients need a reliable, mutually agreeable method (or methods) to communicate their INR results to their anticoagulation practitioner.	Lit ¹⁷³ , G2, Pilot
Healthcare professionals need to be responsive to patient-reported INRs	Lit ¹⁷³ , G1, G2
There is a risk of patient non-compliance with self-testing	G1,G2
Establish a formal shared care agreement between healthcare provider and patient.	Lit ^{52;173;173} , G1
A formal shared care agreement between patient and clinic (patient agreement form) felt to be essential to protect the clinic, and individuals, from liability	Pilot

Recommended requirement:

To establish a shared-care agreement between patient and clinician to define respective responsibilities and to clarify lines of communication.

Establish a formal shared-care agreement between primary care and secondary care

A shared-care agreement will be needed to allow the seamless transfer of care from primary care to secondary care in the event of the patient's INR control becoming unstable, and back to primary care once they have stabilised. This should include respective responsibilities and communication networks.

Agree protocols for patient transfer between primary and secondary care	G2, Pilot
Need robust lines of communication between primary and secondary care to facilitate patient movement across the interface	G2
Define governance arrangements for primary and secondary care to share care	G1

Recommended requirement:

Establish a formal shared-care agreement between primary care and secondary care including procedures for escalating concerns urgently.

Establish a process for quality assurance (QA) of coagulometers

Providing assurance of the accuracy of the coagulometer is important for two reasons. Firstly, this is needed to foster patient confidence in the machine. Secondly, it is essential that the accuracy of the coagulometer is assured to operate a safe self-monitoring service. Although most devices automatically run an internal quality control (IQC) each time the machine is used, they also need to be externally quality controlled (EQC) at regular pre-defined intervals.

Discuss the potential use of coagulometers with the local point-of-care committee (or haematologist). Local procurement policy should be adhered to.	Lit ¹⁷⁴
Reassurance about the accuracy of the coagulometer was important to some patients	PI, Pilot
Concerns about QA of the coagulometer expressed	PS
Establish robust procedures for QA of machines. Detailed guidance is provided in the UK consensus guideline.	Lit ¹⁷⁴ , G1, G2, Pilot
Perception amongst clinic staff that many patients did not trust the INR result generated by the coagulometer	Pilot

Recommended requirement:

Establish a process for quality assurance of coagulometers.

Establish an OAT patient self-monitoring policy

A policy is needed to ensure the safe operation of the service on a day-to-day basis. If this policy is sufficiently broad, it may also foster partnership between primary and secondary care.

Corporate strategy needs to be drawn up before demand for patient self-monitoring grows, setting out how to manage a fully operational service.	G2
A standard operating procedure supported the PST pilot. This was felt by clinic staff to be an essential requirement.	Pilot

Recommended requirement:

To establish a policy to manage an OAT patient self-monitoring service. This should encompass as many stakeholders as feasible.

Clarify issues of accountability and clinical responsibility

Moving from a paternalistic model of care to one that shares care with patients may introduce new risks. Where accountability sits is unclear.

Define where clinical responsibility lies before launching service	G2
Clarification on what constitutes negligence in self-care	G1, G2
Elaboration of the existing legal framework to consider self-care	G1, G2
Review of the legal aspects of self-care by the professional bodies (e.g. GMC)	G1
A signed agreement between patient and clinic (patient agreement form) felt to be essential to protect the clinic, and individuals, from liability	Pilot

Recommended requirement:

To clarify issues of accountability and clinical responsibility. Whilst clinical responsibilities of those delivering the service may be defined prior to service launch, much of this clarification is outside the direct control of the anticoagulant service provider. (It may be necessary to lobby professional bodies and defence bodies to develop national guidance on this vital issue)

Address the potential inequities of the service

As discussed earlier, currently participation in self-monitoring is predicated on the patient’s ability to purchase a coagulometer. However, language barriers may also prevent some ethnic groups from participating. Firstly, coagulometers deliver their messages to users in English only. Secondly, extra resources will be needed to deliver educational material and support to those for whom English is not their first languages.

Establish a way to deal with a potentially inequitable service. This may involve facilitating provision of the coagulometer as discussed earlier or the availability of resources in languages other than English.	G2, Pilot
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Recommended requirement:

To address the potential inequities resulting from the introduction of an OAT patient self-monitoring service, for example by providing multi-lingual educational resources.

PROCESS

Provide patient training in self-testing and using the coagulometer

Acquiring a good capillary blood sample and using the coagulometer to generate an INR are core tasks for patients assuming responsibility for self-monitoring INR. Patients' confidence in their ability to perform these tasks appears pivotal to the success of OAT self-testing.

One participant had initial difficulties in testing INR	EP
Many participants stated that instruction on using the coagulometer was a prerequisite for its use	PI
Patients were significantly more willing to self-monitor if they were confident in their ability to test their INR	PS
Patients may lack confidence to test INR	G1, G2
There is a need, both perceived and actual, for training in how to use the coagulometer.	PI, PS, Pilot
There were initial difficulties with self-testing with some PST pilot patients	Pilot
Some of the PST pilot patients felt that more attention should have been paid to self-testing technique during the educational session.	Pilot

Recommended requirement:

To train all patients undertaking OAT self-monitoring on self-testing and on the use of the coagulometer.

Deliver an educational programme to self-monitoring patients

As discussed earlier, there is no standardisation of the content of an educational programme in the UK to prepare patients for OAT self-monitoring.

Education is a requirement to prepare patients for self-monitoring.	Lit, ³⁶ PI, PS, G1, G2
Although there is no evidence to guide the intensity of this training, and standardisation of training is thought to be a “pressing requirement”.	Lit ¹⁷⁴
Patients thought that providing education for those undertaking OAT self-monitoring was “very important” (median score).	PS
The education offered was an important factor for some patients in deciding to participate in the PST pilot	Pilot
Pilot patients achieved good therapeutic control after an educational session. However, it is not known how these patients would have fared in the absence of educational preparation.	Pilot
Clinic staff felt that education might address potential non-compliance with testing.	Pilot

Recommended requirement:

To provide the resources and facilities to deliver an educational programme to prepare patients to self-monitor their OAT.

Provide education and support for dose adjustment by patients (PSM)

If a patient is self-managing their OAT, they are both testing their INR and adjusting the dose of warfarin. They may need assistance to help them decide an appropriate dose.

Self-managing patients had different ways of adjusting warfarin doses	EP
Anxiety expressed at the prospect of adjusting the dose of warfarin in PSM	PI
There was a perceived need for training in dose adjustment skills.	PI, PS
Make clear dosing algorithms available for patients who are self-managing, and to aid primary care practitioners supporting self-testing patients.	G1, Lit ⁵²
Dose adjustment in PSM is an area of potential risk	G1

Recommended requirement:

To provide education and support in dose adjustment for patients who are self-managing their OAT.

Provide ongoing support for self-monitoring patients

Patients require ongoing support throughout their OAT self-monitoring journey.

Three types of support were identified through the course of this research

- i. Provision of dosing advice in response to patient-reported INRs
- ii. Regular review
- iii. Provision of ad-hoc advice

Regular (at least yearly) reviews are required.	Lit ^{52;173} , G2
Healthcare professionals need to be responsive to patient-reported INRs	Lit ¹⁷³ , G1, G2
The support of healthcare professionals was important when starting to self-monitor.	EP
Ability to access advice and for the clinic to provide regular reviews was important	PI
Patients thought it was “very important” (median score) that they received regular clinic check-ups	PS
Patients considered making it easy for them to contact the clinic when self-monitoring to be “very important” (median score).	PS
Ongoing support is required for self-monitoring patients	G1, G2,
Support offered was an important factor for some deciding to participate in the pilot. Positive feedback from patients for support provided during pilot with no suggestions for improvement.	Pilot

Recommended requirement:

To establish a clinical support and a communications infrastructure to support self-monitoring patients. This needs to include clearly specified communications channels for urgent patient concerns.

OUTCOME

Self-monitoring service is safe

For patient self-monitoring of OAT to be considered feasible it must be at least as safe as usual care. Safety can be measured in terms of hard clinical endpoints - i.e. incidence of bleeding and thromboembolism – and INR control.

Patient self-monitoring may improve INR control	PI
Potential additional risks incurred by patient self-monitoring need to be managed	G1,G2
Quality of the service needs to be ensured through audit of INR results	Pilot
No bleeding or thromboembolic events were reported during the pilot period. However, as the time period was short and the numbers of patient few, the likelihood of these events occurring was low.	Pilot
INR control during pilot period was at least as good as that achieved in the six months prior to the pilot	Pilot

Recommended requirement:

To conduct regular audits of a patient self-monitoring service to ensure its safety, examining both INR control and the incidence of treatment complications.

Self-monitoring service is acceptable to patients

Safety of the service is not the only outcome measure. For the service to be successful, it needs to be acceptable to patients.

Convenience cited as a perceived and actual patient benefit of OAT self-monitoring	EP, PI, PS
The reassurance of being able to test the INR at home when desired was a potential benefit	PI
All patients wished to continue with self-testing at the end of the pilot period	Pilot

Recommended requirement:

To conduct regular patient reviews to ensure that PST / PSM remains the preferred method of monitoring.

Self-monitoring service is cost effective

The quality of a clinical service is not only measured on its safety and acceptability by patients; it also has to make good use of precious NHS resources. Published analyses have suggested that patient self-monitoring is unlikely to be cost-effective in the UK¹²⁸

Need to build business case to demonstrate that patient self-monitoring is cost-effective	G2
Affordability to PCTs and the potential loss of income for the acute Trust need to be considered	G2

Recommended requirement:

To develop a business case for a patient self-monitoring service and conduct periodic financial audits to ensure that the patient self-monitoring service is cost-effective to all stakeholders.

8.2 Unvalidated requirements for an OAT patient self-monitoring service

As discussed earlier, it was not possible to validate all of the candidate requirements in this investigation. This section lists these unvalidated requirements, which are summarised in Table 55.

STRUCTURE
➤ Develop an educational programme for healthcare professionals supporting self-monitoring patients
PROCESS
➤ Deliver an educational programme primary care staff supporting self-monitoring patients
➤ Provide ongoing support to primary care staff supporting self-monitoring patients

Table 55: Unvalidated candidate service requirements for an OAT patient self-monitoring service

STRUCTURE

Develop an educational programme for healthcare professionals supporting self-monitoring patients

Educational preparation may not only be confined to patients. If a patient self-testing service is to be delivered in primary care, practitioners may not have the requisite warfarin management skills and confidence to support patients. In addition, some healthcare professionals may be personally committed to a paternalistic paradigm, and may therefore need to develop new skills if they are to work in partnership in patients.

To achieve successful patient education, those training patients should themselves be trained.	Lit ³⁶
Healthcare professionals will also need education to prepare them to support self-monitoring patients.	G1
GPs' knowledge may not meet patients' expectations	G1

Recommended requirement:

To develop an educational programme to prepare healthcare professionals to support self-monitoring patients.

PROCESS

Deliver an educational programme to primary care staff supporting self-monitoring patients

As discussed above, primary care practitioners may need educational support.

To achieve successful patient education, those training patients should themselves be trained.	Lit ³⁶
Healthcare professionals will also need education to prepare them to support self-monitoring patients.	G1
GPs' knowledge may not meet patients' expectations	G1

Recommended requirement:

To deliver an educational programme to prepare healthcare professionals to support self-monitoring patients. Additional peer support activities may be required to help convince/reassure those who are reluctant to endorse self-monitoring.

Provide ongoing support to primary care staff supporting self-monitoring patients

As with patients, if a self-monitoring service is to be delivered in primary care, healthcare staff may require expert support.

Support from hospital clinic required for GPs and practice nurses if patient self-monitoring is to be delivered in primary care	G1, G2
Support should be from clearly identified individuals available at pre-specified times	G1

Recommended requirement:

To establish expertise to support those delivering care to self-monitoring patients.

8.3 Conclusion

This chapter has summarised the requirements for a service to successfully support patient self-monitoring of OAT, presented within Donabedian's framework of structure, process and outcome. It has considered both the requirements that could be validated through the course of this empirical work, and those that could not be validated.

In the next chapter, the key findings from this investigation will be discussed, the limitations of this research considered and options for future work, including options for further validation of these requirements, suggested.

CHAPTER 9: DISCUSSION

9.1 Introduction

Patient self-management is increasingly recognised as a way of responding to the considerable challenge of providing care for those with a long-term condition, and, as such, is enshrined in Governmental policy. However, it has not yet achieved widespread penetration across the NHS, and the reasons for this are unclear.

This research has focused on one area of patient self-management – self-monitoring of oral anticoagulation therapy – and has investigated the requirements for the wide-scale uptake of an OAT patient self-monitoring service that would be well accepted by patients and healthcare providers. Relevant literature pertaining to patient self-monitoring of OAT, and self-management of long-term conditions in general, was reviewed. A combination of qualitative and quantitative methodological approaches was adopted to engage with the key stakeholder groups who would most directly be involved in commissioning, delivering and receiving such a service (patients, healthcare professionals, and healthcare managers). Through these groups, this research has identified the drivers for, principal benefits and challenges of, and the barriers to, establishing a patient self-monitoring service from a multi-stakeholder perspective. From these perspectives, candidate requirements for an OAT patient self-monitoring service were derived, which were then tested through a patient self-testing pilot. An overarching goal of any clinical service should be the provision of high quality care. Donabedian's structure-process-outcome triad, more traditionally used to document a clinical service from a quality perspective, was used as a framework to categorise these requirements.

The last chapter presented the requirements for establishing and delivering an OAT patient self-monitoring service, placing them within Donabedian's framework, and mapped these to the evidence that supports each recommendation. In this penultimate chapter, the key findings from the empirical work will be summarised, and the key challenges in establishing an OAT patient self-monitoring service described. Then, the requirements for an oral anticoagulation patient self-monitoring service, discussed in the preceding chapter, will be summarised, the appropriateness of using Donabedian's framework considered and thought given to

the generalisability of these requirements to self-management of long-term conditions. Finally, the limitations to this research and opportunities for future work will be discussed.

9.2 Summary of findings

The empirical work in this thesis evaluated the views of three stakeholder groups:

- i. Patients – eliciting the views of expert patients and the broader clinic population using interviews and a survey
- ii. Healthcare professionals - using focus group methodology and interviews
- iii. Healthcare managers – using focus group methodology

For each of these three stakeholder groups, the key drivers and barriers to OAT patient self-monitoring, and the factors that would incentivise these groups to embrace self-monitoring will be discussed.

9.2.1 Key findings from empirical work with patients

Overwhelmingly, increased convenience was an important driver for, and a perceived potential benefit of, patient self-monitoring of oral anticoagulation. Although the first set of interviews with those who were already self-monitoring involved small numbers, all of these patients stated that convenience was a driver for wishing to embrace OAT self-monitoring. For some this gave them the freedom to travel or spend lengthy periods overseas. For others it simply liberated them from attending the anticoagulant clinic.

These views were supported by interviews with the group of patients who were not self-monitoring, who felt that self-monitoring would be more convenient for them. Other drivers identified were the potential to improve INR control – an advantage borne out in the PST pilot – and a desire for greater personal control over their health.

Although over half of the patients surveyed indicated that they would be interested in self-monitoring their OAT, a lack of confidence in their ability to self-test and to take more responsibility for their treatment was expressed by around 6% of patients, with a third of these patients explicitly stating that they would prefer to “leave it (OAT monitoring) to the expert”. In the initial stages of the pilot, over half of those recruited found it difficult to self-test but both confidence and ability grew as the pilot progressed.

However, the most significant barrier to patients undertaking OAT self-monitoring was the requirement for them to fund the coagulometer. Only 17% of survey respondents felt that they would be able to buy the coagulometer; the proportion of those who were content to fund the machine was lower still (15%). The Whittington Hospital population includes pockets of considerable social deprivation, and objections to patient self-monitoring were mostly on the grounds of affordability. If a clinic population in another area was surveyed, this objection may not have been so strong. However, the patient interviews also uncovered a few objections on a more philosophical level – i.e. if a patient is part-funding their care NHS treatment is no longer free at the point of care.

Therefore, subsidising or providing a coagulometer may persuade patients to embrace OAT self-monitoring. This is discussed further in 9.3.4

9.2.2 Key findings from empirical work with healthcare professionals

Those delivering anticoagulation monitoring services viewed a self-care model as a means to increase clinic capacity. Continued growth in the use of oral anticoagulation has lead service providers to consider options for relieving pressure on already overcrowded secondary care clinics. Locally, this has resulted in the formation of a distributed service with commissioned clinics in GP surgeries and community pharmacies in addition to the traditional hospital clinic. A patient self-monitoring service presents an attractive option for increasing capacity yet further.

However, healthcare professionals were not comfortable about the increased clinical risk arising from patients not complying with testing or mismanaging dose adjustment. Uncertainty around the medicolegal position compounded their anxieties. Primary-care health professionals also had concerns that they would not have the skills to support a self-monitoring patient if the service was delivered from there rather than secondary care.

The necessary incentives centred on preparing and supporting primary-care practitioners to deliver OAT patient self-monitoring services. This was both in terms of initial education to prepare them for their new role, and ongoing access to defined expert support thereafter.

9.2.3 Key findings from empirical work with healthcare managers

Like their healthcare practitioner colleagues, managers viewed OAT patient self-monitoring as a way to increase clinic capacity. But there was more discussion about how developing a patient self-monitoring service was a necessary step in aligning the service to changes in the healthcare landscape.

Again, there was anxiety over the clinical risk that may result from a patient self-monitoring service, with concerns of potential litigation and the lack of clarity of the medicolegal position. But their anxieties did not stop with clinical risk. It was also felt that there was considerable financial risk, both in primary care through commissioning a patient self-monitoring service and also in the acute Trust through loss of income.

To mitigate both of these types of risk, and to ensure commissioning of a patient self-monitoring service, two actions were desired. Firstly, a robust business case was needed to support financial feasibility. But, perhaps, the more challenging task was to define where clinical responsibilities and accountabilities lie.

9.3 The key challenges in establishing an OAT patient self-monitoring service

This research has established strong drivers for establishing an OAT patient self-monitoring service. It fits with the direction of travel in the NHS and seems to offer a solution to the capacity issue. It affords patients greater convenience and empowerment and may improve INR control. However, the rate of adoption in the UK is low and this research has sought to identify what is needed to make patient self-monitoring acceptable to patients, clinicians and managers.

Some of the barriers to OAT patient self-monitoring – financial, clinical and legal – have been summarised in the last section, as have the measures that should be considered to encourage adoption of a self-monitoring model of care. However, some specific challenges identified through this empirical work – risk management, education and support, patient selection and service funding - warrant further consideration. These will now be discussed.

9.3.1 Managing the risks of sharing care with patients

Anticoagulation therapy is inherently high risk with errors involving anticoagulants in the top ten causes of claims against NHS Trusts.¹⁶⁹ Although sharing the responsibility for anticoagulation monitoring with patients may bring benefits, it is also essential to ensure that clinical care remains safe.

Therefore, from the outset, it is important to identify where new risks may be introduced and to set up systems to avoid these risks. Through the course of this research, such areas of new potential risk were identified and these are summarised in Table 56.

Patient selection, education and assessment
Patient incorrectly deemed suitable for self-management
Incorrect patient selection criteria used
Inadequate education
Patient incorrectly assessed as competent to self-manage
Measuring INR
Coagulometer inaccurate (failure of QC)
Reads coagulometer incorrectly
Capillary sampling incorrect
Patients not testing INR at prescribed intervals
Reporting INRS
Patients misreporting INRS (PST only)
Unclear communication of INRs or doses
Dose adjustment
Patients 'unofficially' adjusting doses of warfarin (PST)
Misreads algorithm (PSM)
Fails to use algorithm (PSM)
Does not contact clinic out of range of algorithm (PSM)
Review
No regular review / inadequate review

Table 56: Potential risks arising from patient self-monitoring or oral anticoagulation

The importance of appropriate patient selection, patient education and quality assurance of coagulometers to mitigate some of these risks have been previously discussed. However, even if these measures were put into place to minimise those risks, OAT self-monitoring could still result in harm to the patient. As discussed earlier in the thesis (3.15), legislation has not kept pace with practice, and it is unclear where accountability lies within this new shared-care model.

Although a patient agreement form setting out respective responsibilities was used in the PST pilot, this was not a contract as such and it is not known if this would bear any legal weight to defend a clinician if mistakes were made that could be attributed to the patient. The SMART trial, conducted in Birmingham, was the pivotal UK-based evaluation of patient self-management of oral anticoagulation.⁴⁹ Of note, only 65 of the 193 patients completing the trial continued self-managing outside of trial conditions. The reason given was a lack of GP support, largely because of their fear of litigation.¹⁷⁶

Similarities (and differences) to self-monitoring of blood glucose (SMBG) in diabetes have been described throughout this thesis. Both have been made possible through a combination of combination of medical & social forces. Electronic miniaturisation has made home testing suitable for use by lay people, and treatment management involves adjusting the dose of a drug in response to testing a drop of capillary blood.

No test cases involving SMBG were found. However, a review of potential liability of the clinician in diabetes self-care considered that five legal theories are likely to be raised if a patient is injured by self-care treatment.¹⁷⁷ These are summarised in Table 57, along with ways to mitigate these risks.

Legal theory	Mitigation
Failure to provide adequate education	Well designed educational programme
Failure to determine patient's suitability for self-care, or to review competence at regular intervals	Robust selection criteria Regular reviews Offer retraining at regular intervals
Unrealistic promises from clinician of benefits of self-care (breach of contract)	Provide clear, evidence-based information at start of self-monitoring
Injury caused to patient by carer participating in programme (imputed negligence)	If carer to be involved in self-care, they must be educated and assessed as competent
Failure to inform patient of risks (lack of informed consent)	Informed consent to be formally sought and granted

Table 57: Legal theories likely to be raised if a patient is injured by self-care treatment and ways of mitigating against them

In the words of the author of this review:

“The most likely approach to litigation would be to predicate a malpractice action on the failure of clinician to comply with proper standard of care in providing self-care education”

9.3.2 Education, support and communication

This research identified the need for patient education, and also for ongoing patient support.

As discussed earlier, there is no standardised educational programme in the UK for those wishing to self-monitor their oral anticoagulation. Certainly, training on how to get a good capillary blood sample and then generating an INR is essential: many patients in the PST pilot had initial difficulty in using the coagulometer. Diabetes literature suggests that that self-monitoring may be of no therapeutic benefit if patients receive insufficient education or lack the confidence or support to respond to their results.¹⁷⁸

The Whittington Anticoagulation Monitoring and Stroke Prevention Service has an established training and accreditation programme, which has been described in Chapter Two. There may be scope to develop this to suit the needs of the self-monitoring patient.

Although there is a significant initial time commitment to delivering this education and training, providing ongoing support presents more challenges. An infrastructure to support self-monitoring patients needs to be established. Although it remains unclear where this should be delivered, there was more support from the healthcare professionals and managers that this should come from primary care. However, questions remain as to who should support these patients and whether this support can be integrated into current community anticoagulation monitoring services (where they exist).

Computers may also offer opportunities to educate and support those self-monitoring their OAT. There is evidence that educated and well-motivated patients can make good use of web portals to their electronic health record (EHR), to view test results and to access linked educational materials.⁹⁷ There is a limited evidence base evaluating the use of the use of computers in supporting OAT self-monitoring,¹⁷⁹⁻¹⁸¹ and in self-management of long-term conditions.¹⁸²

Although a randomised controlled study of patients with heart failure accessing their on-line healthcare record suggested modest benefits,¹⁸³ importantly, this study did demonstrate a trend towards improvement in patient satisfaction with doctor-patient communication. Good communication is vital in the safe management of chronic disease, and particularly in the management of oral anticoagulation. If this potential benefit were borne out in the anticoagulated patient population, this would be a significant advance.^{184;185}

However support is not confined to patients. Healthcare professionals interviewed during the course of this research felt that expert support would be essential for them to deliver a patient self-monitoring service. They also need to be equipped with the skills to allow them to work in partnership with patients. To this end, the Co-Creating Health programme may be of help. Since 2007, this programme has aimed to embed self-management support within UK health services.¹⁸⁶ It does this by developing the skills and attitudes of both people with long term conditions and clinicians, and ensuring systems and services are designed to support and facilitate patient self-management.

9.3.3 Patient selection

There is no accurate, standardised way to predict who will be competent at self-monitoring, nor is there a level of benefit from self-monitoring at which it is recommended, or level of harm at which it is not recommended.

The inclusion and exclusion criteria used in published trials have been summarised previously in Table 16. Additionally, the largest PST study – The Home INR Study (THINRS) – included a multivariate logistic model to identify which patient characteristics are predictors of competency status.⁹³ Three characteristics were significantly associated with a failure to perform PST: age, prior stroke and poor manual dexterity.

All of the stakeholder groups expressed concern that not all patients would be able to monitor their OAT, and that selection criteria are needed. However, the challenge is selecting the correct criteria. This is illustrated by the lack of consensus in this empirical work. The findings from each of the stakeholder groups are summarised in Table 58.

Stakeholder	Inclusion criteria	Exclusion criteria
Patient	None identified	Elderly Those with complex medical problems
Healthcare professional	Long-term indication for OAT	Psychotic illness
	Ability to buy coagulometer	Mental impairment
	Able to demonstrate 'understanding'	
	Sufficient dexterity	
Healthcare manager	Consensus not reached. Disagreement as to whether to exclude those with poor INR control	

Table 58: Summary of patient selection criteria for OAT self-monitoring identified by the empirical work

With the existing need for the patient to purchase a coagulometer, currently self-monitoring patients are essentially self-selecting. That is, those that can afford the coagulometer and are sufficiently motivated and informed put themselves forward for self-monitoring. This is not an inclusive service and, therefore, far from satisfactory.

The inclusion of only those who have a long-term indication for oral anticoagulation is pragmatic. It would not be a prudent investment to include those on short-term treatment, both in terms of the patient purchasing the coagulometer and also the resources required to educate the patient.

The inclusion of those with historical poor INR control generated much discussion and debate amongst the healthcare staff. In terms of risk avoidance, conventional wisdom suggests that this group of patients should be excluded. However, conversely, INR control may improve if the patient is empowered to take more control over their care. The results of the SMART trial suggest the latter is true.⁴⁹ Self-managed patients with poor control before the study showed an improvement of control (between 15 and 20%) not seen in the routine care group.

This was also borne out in the PST pilot, and, as a result, the case for including those with poor control was strongly supported by the healthcare professionals managing the pilot. However, those with a history of frequently not attending the anticoagulant clinic on the agreed appointment date may need to be excluded from self-testing in the future.

9.3.4 Funding the service

The financial challenges facing establishing an OAT patient self-monitoring service are significant.

To make the service available for all who would be able and willing to self-monitor, the provision of coagulometers must be facilitated. A number of options were identified through the course of this research and these are summarised in Table 59.

Option	Source
Supply coagulometers on private prescription to exempt them from VAT	G1
Making a publicly-sited coagulometer available for self-monitoring patients to use (e.g. in a community pharmacy) (Mixed views)	PI, G1, G2
Set up a patient network where patients own and share a machine	G2
Making loan machines available for patients to “try before they buy”	PI, G1
Clinic should provide or part-fund the coagulometer	PS, PI
Need to engage with the diagnostics industry to reduce cost of coagulometer and extend guarantee	G2, PI

Table 59: Options for facilitating the provision of coagulometers to patients

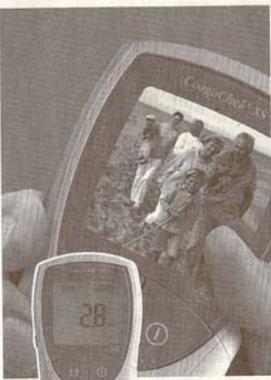
(Code: PI = patient interview; PS = patient survey; G1 = focus group 1; G2 = focus group 2)

A sensitivity analysis conducted by Roche, suggests that £199 is the lowest price at which their CoaguChek™ machine could be sold.¹⁸⁷ It is not possible to adopt the economic model used for glucometers. Although glucometers are cheaper to manufacture (at ~ £70) they sell for a lot less than this. However, as many more strips would be used in contract to INR testing strips, much more money can be clawed back on consumables.

Over the past year, Roche has offered a £100 discount as part of its marketing campaign for its CoaguChek™ machine (Figure 25), bringing the cost of the machine down to £299.

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 *Terms and conditions apply. See online for more details www.coaguChek.co.uk or call our careline.
 Careline operational hours are Monday to Friday from 9am to 8pm.

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Roche

References:
 1. Gadsbour APA, et al. J Thromb Haemost 2004;2:584-91.
 2. Garcia-Nunez JM, et al. Cochrane Database of Systematic Reviews, issue 4, 2010.
 Roche Diagnostics Ltd, Charles Avenue, Burgess Hill RH15 9RY United Kingdom
www.coaguChek.co.uk
 Company registration no: 571548

Figure 25: Advertisement for CoaguChek™ XS, Daily Telegraph, May 21st 2010

Another way of providing machine is through charitable donations through bodies such as The Children's Heart Foundation, Anticoagulation Europe and The British Heart Foundation. However, there are waiting lists for such support.¹⁷⁶

The cost of the machine is not the only financial consideration. Published analyses have suggested that patient self-monitoring is unlikely to be cost-effective in the UK^{28,128}, and the empirical work in this investigation suggests that commissioners will need persuading to fund a patient self-monitoring service and the strips.

As this thesis was being finalised (April 2012), two new oral anticoagulants - dabigatran and rivoroxaban - had gained marketing authorisation for stroke prevention in those with atrial fibrillation. More selective than existing vitamin K antagonists – dabigatran is a direct thrombin inhibitor and rivoroxaban inhibits Factor Xa – they are leading the vanguard of new anticoagulant agents, including apixiban.

Unlike existing OAT, these oral agents do not require routine monitoring of coagulation, and this may help ease the pressures on overstretched anticoagulation monitoring services. However, despite their initial promise, some are urging caution with these new agents.¹⁸⁸

They are not without clinical risk. As with warfarin, these agents are associated with haemorrhagic risk and reports of bleeding continue to emerge, especially in those with renal impairment. Unlike warfarin, there is currently no antidote. Another concern centres on those who are poorly compliant with treatment. Whilst the INR provides an objective measure that a person taking warfarin is optimally anticoagulated, there is no such quantifiable test with the new agents.

There is also a financial risk. Although the new agents will compete for the attention of those commissioning anticoagulation monitoring services, they will come at a cost with dabigatran priced at approximately £66 per month. The position of the commissioners is currently unclear.

Although evidence to support the use of the new agents is emerging, they are unlikely to be granted marketing authorisation for use in those with metal heart valve replacement in the near future.

Therefore, it is too soon to consign warfarin to the pharmaceutical rubbish bin, and anticoagulation monitoring services will need to continue to develop to meet capacity needs and the expectations of patients. Initial indications are that the new agents may be reserved for those intolerant of warfarin, or for those with labile INRs in the absence of compliance issues. Although their introduction may be limited, these new agents are likely to impact on the structure and delivery of anticoagulation monitoring services. Thus, for these services to remain relevant and viable, they will need to take into consideration the needs of patients taking the new agents as part of their continuing development.

9.4 Validated requirements for establishing and delivering an OAT patient self-monitoring service

In the last chapter, the service requirements for a patient self-monitoring model of care were described. The validated elements of this model – the blueprint for the service - are summarised in Figure 26.

STRUCTURE
➤ Gauge patient demand for OAT self-monitoring
➤ Conduct an options appraisal (i.e. explore other methods of OAT monitoring / define delivery of OAT self-monitoring service)
➤ Ensure financial feasibility of service
➤ Ensure engagement of those delivering and commissioning OAT monitoring
➤ Promote the self-monitoring service to patients
➤ Facilitate the provision of coagulometers (e.g. by funding coagulometer)
➤ Construct patient eligibility and assessment criteria
➤ Develop an educational programme for patients
➤ Establish a formal shared-care agreement between patient and clinician
➤ Establish a formal shared-care agreement between primary care and secondary care
➤ Establish a process for quality assurance (QA) of coagulometers
➤ Establish an OAT self-monitoring policy
➤ Clarify issues of accountability and clinical responsibility
➤ Address the potential inequities of the service
PROCESS
➤ Provide patient training in self-testing and using the coagulometer
➤ Deliver an educational programme to patients
➤ Provide education and support for dose adjustment by patients (PSM)
➤ Provide ongoing support to self-monitoring patients
OUTCOME
➤ Self-monitoring service is safe
➤ Self-monitoring service is acceptable to patients
➤ Self-monitoring service is cost-effective

Figure 26: Validated requirements for an oral anticoagulation self-monitoring service

Throughout this thesis, Donabedian's triad has been used as a framework to categorise these service requirements. As an OAT patient self-monitoring service would need to be of high quality, conceptual frameworks to describe quality were reviewed in Chapter 1 and Donabedian's triad of structure, process and outcome was proposed as the most suitable framework for this research. Was Donabedian's triad, therefore, a suitable framework into which to place the requirements for an OAT patient self-monitoring service?

To recap, the framework selected aimed to meet five objectives:

To support the design of the service

The design of this service was reflected in the structural elements of the service, which include the patients who are self-monitoring and the professionals who are supporting them. The structure also includes the service elements in place to support these individuals and to enable them to undertake the necessary healthcare processes: for example the establishment of formal shared-care agreements.

To specify the processes that will support implementation of the service

These are reflected in the process elements that enable the activities that must be undertaken to provide care to this group of patients; for example, providing ongoing clinical advisory support to self-monitoring patients.

To establish the measures used to assess the quality of the service

Finally, outcomes are the desired outcomes of the service. These can be considered at a system level – for example, that the service is cost-effective – or at an individual level: for example that the service is safe.

Although this framework meets these first three objectives, arguably the final two objectives arguably provide more compelling support for the use of Donabedian's framework, and for the engagement of the main stakeholders, in this research. These will now be considered.

To cultivate a shared view of the service across the stakeholder groups

The service requirements were derived from the perspectives of the main stakeholders, and placed within a formal framework. Most of the service requirements defined as structural and process elements in this framework are derived mainly from the barriers and challenges they identified in establishing and implementing an OAT patient self-monitoring service – that is, the design of the service and the way that it is conducted aim to both overcome the barriers of patient self-monitoring, and to meet its challenges. By contrast, outcomes are derived from the professionals and patients perceptions of the service’s benefits, including its drivers. These outcomes can also be viewed as a means of measuring the success of overcoming the financial and clinical risks perceived by professionals to be associated with the service.

To define and connect components of the service

Many of the OAT service requirements identified for OAT could be mapped to a discrete category within the triad. However, the framework did not prove a perfect fit for all service elements. For example, some elements within the structure of the service –establishing a process for QA of coagulometers and establishing a formal shared-care agreement between patient and clinician – overlap with the outcome of a safe OAT patient self-monitoring service. This is not necessarily a failing of the model as one would expect the structure and processes of the service model to engender the desired outcome. Indeed, in this service model, structure is related to process and outcome, and process is related to outcome. This is represented in Figure 27 below.

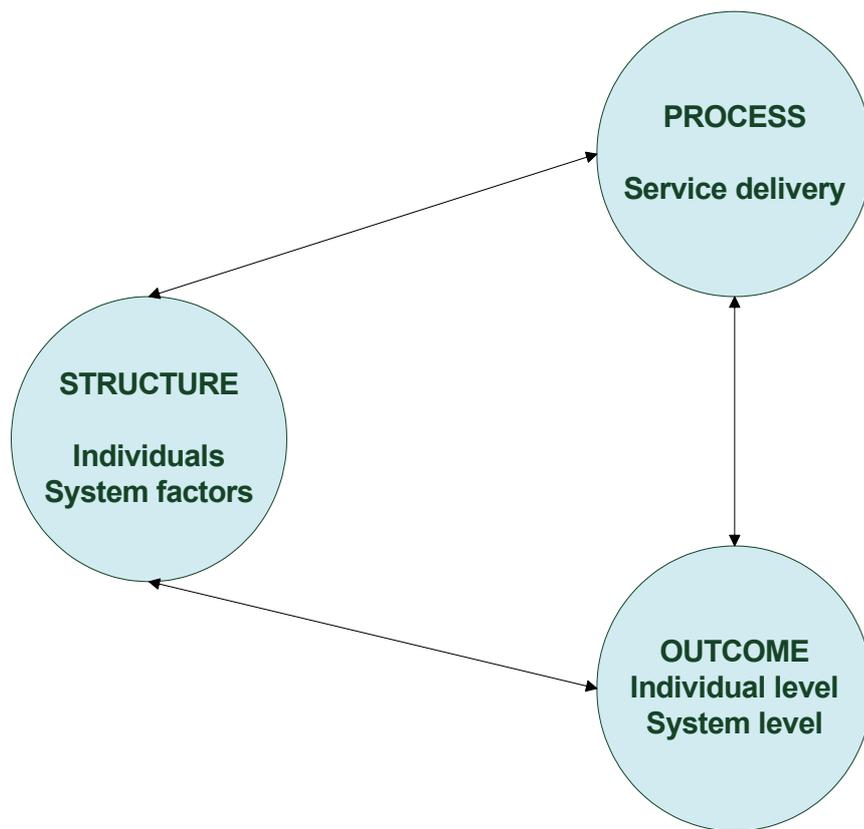


Figure 27: Relationship between structure, process and outcome elements of an anticoagulation patient self-monitoring service model (Adapted from Kunkel et al¹⁸⁹)

Structure is related to process characteristics; for example, an educational programme for patients needs to be developed before it can be delivered. Structure is also related to outcome characteristics; for example, establishment of formal shared-care agreements to foster safer anticoagulation management. But if, for example, ongoing support is not given to patients, the resulting service may not be a safe one. Thus, process is also related to outcome. This suggests that although structural elements are important in providing a high quality service, activities undertaken to deliver service also contribute to service quality.

In addition to the conceptual overlap described, the line between structure and process can be blurred. It could be argued that some of the structural elements are also, in themselves, processes. For example: although an assessment of patient demand needs to be put in place before the service itself is implemented, the act of gauging that demand could be viewed as a process element.

In conclusion, this research suggests that Donabedian's triad is an appropriate framework to categorise the requirements of an OAT patient self-monitoring service, although not a perfect fit for every requirement. It is also apparent that the structure, process and outcome service elements are often closely inter-related.

9.4.1 Requirements for establishing and delivering a service to support self-management of long-term conditions

At the start of this investigation oral anticoagulation was considered as an example of a long-term condition. Treatment is often lifelong, and clinical expertise is needed to adjust its dose.

There was initially an expectation that many of the recommendations made in this thesis may be applicable to other self-care of long-term conditions. Diabetes, asthma, hypertension and arthritis have been most extensively evaluated in the context of patient self-management, and the key elements of these interventions are compared with patient self-monitoring of OAT in Table 60.

There are some generic key elements. Self-management of all of these long-term conditions necessitates the patient assuming greater responsibility for their healthcare, with decisions shared between patient and clinician. This new way of working requires both patients and healthcare staff to acquire new skills to enable shared decision-making. The risks of patient self-management will need to be assessed and mitigated, and the service will need to be funded and integrated into healthcare system. Most of the interventions involve titrating the dose of a drug to a pre-specified endpoint, and still more have clear therapy goals.

Condition	Aim	Key elements
OAT	To maintain the INR within the prescribed therapeutic range to prevent bleeding and thromboembolic episodes	Adjusting dose of drug in response to blood test
		Clear therapy goal (INR)
		Responding to signs of under-anticoagulation
		Assuming greater responsibility for healthcare
		Responding to signs of over-anticoagulation
Diabetes	To maintain day-to-day control of blood glucose, detect hypoglycaemia and assess control during any illness.	Adjusting dose of drug in response to blood test
		Clear therapy goal (BG / HbA1C)
		Management of eating behaviours
		Management of depression
		Integration of complex regimen into lifestyle
Asthma	To prevent acute exacerbations through avoidance of triggers, monitor symptoms and consequent adjustment of treatment and improve treatment adherence	Self-care of trigger factors
		Monitor disease activity
		Adjust treatment to peak flow results
		Relaxation techniques
		Adjusting treatment to written action plan
		Adjusting treatment to symptoms
Hypertension	To maintain blood pressure within acceptable limits	Clear therapy goal (BP)
		Relaxation response
		Anxiety management
Arthritis	To reduce pain and improve physical and psychological functioning	Improve coping

Table 60: Key elements of self-management interventions in OAT, diabetes, asthma, hypertension and arthritis.

Equally there are tasks that are specific to self-management of each long-term condition. Additionally, patient self-monitoring of OAT requires the patient to purchase a relatively expensive machine. Therefore this derived service model for an OAT patient self-monitoring service is unlikely to be generalisable to self-management of other long-term conditions. Each disease state requires different interventions, and the requirements for need to be mapped out on a case-by-case basis.

9.5 Limitations of this research

Individual study limitations have been described in the relevant chapters. There were also some general limitations to this research.

The first part of this study – the interviews with self-monitoring patients - was limited by its size; just three patients who were self-managing their oral anticoagulation were interviewed. These were very motivated, self-monitoring patients and, as such, were not representative of the general patient population. Recognising this, these interviews were used only to provide an early insight into the characteristics of these “early-adopters.” Methodologically, the purpose of these interviews was to get a feel for the main issues associated with OAT patient self-monitoring to inform the subsequent stage of the study. A larger group of patients were then interviewed using a more comprehensive interview guide, which in turn was used to develop a questionnaire. This questionnaire was then distributed to a much larger group of patients.

The next stage of the investigation elicited the views of healthcare professionals and managers gathered into focus groups. Resource constraints limited this to a small and geographically local (north London) group. Because of the significant emerging issue of funding of coagulometers, a representative from the diagnostics industry may have added a valuable perspective. However, during the course of the research the author had informal discussions with these representatives, and also attended meetings and seminars organised by Roche to keep abreast of current and future developments.

The main limitations of this research are its size and scope. It is not certain how generalisable the results of this research are to other clinical settings or patient populations. The setting for this research is a single anticoagulation monitoring service at a British District General Hospital (DGH), and it would have also been desirable to have spoken with those involved with anticoagulation care outside of the immediate locality. Although the author visited the anticoagulant clinic at Barts & The London, a broader perspective would have been gained by visiting more centres, including those overseas, especially in Germany where patient self-monitoring is prevalent. Nonetheless, it is believed that the methods used to investigate requirements in this setting would be applicable to other Trusts.

The PST pilot involved small numbers – just fourteen patients. However, the number of patients self-testing continues to grow and some are going on to self-manage and may form the basis of future work.

9.6 Future work

This research has identified several opportunities for future work.

For operational, logistical or ethical reasons it was not possible to include all of the candidate requirements in the PST pilot. A larger pilot to validate all of the results is desirable, and this may expose other requirements not previously identified.

The feasibility of conducting further work is largely dependent on resources – time and money. Within Europe, there is a growing interest in enriched patient engagement with long-term conditions. Money is following this interest, and an opportunity that could be explored is to seek an EU project grant to continue research. I would recommend four specific areas for such research.

Firstly, as risk aversion by healthcare professionals and managers was a major barrier to establishing an OAT patient self-monitoring service, establishing the areas of risk should be a priority. In Chapter 6, the need to risk-assess patients wishing to undertake self-monitoring was discussed. However, the person approach is only one way to view human error. James Reason has established that most incidents are a result of systemic failures.¹⁹⁰ He holds that most systems will have a number of defensive layers, but these layers are like Swiss cheese, with each layer having a number of holes that are continually shifting location.

The presence of these holes in any one "slice" does not normally cause a bad outcome. However, if the holes in each defensive layer are aligned, this sets up an opportunity for error. Reason suggests that the holes in the defences arise as a result of active failures and latent conditions. Active failures are the unsafe acts committed by people who are in direct contact with the patient or system, in the form of slips, lapses, fumbles, mistakes and procedural violations. Latent conditions are "resident pathogens" within the system, arising from decisions by those who have designed the system.

The Whittington Anticoagulation Monitoring and Stroke Prevention Service has an existing programme of Root Cause Analysis (RCA) to identify both active failures and latent conditions in response to reported errors and near-misses in the service. Root Cause Analysis is a systematic method of trying to find out more about incidents and near-misses, and involves a multidisciplinary group including clinicians and risk-management academic staff.

In contrast to active failures, latent conditions can be identified and remedied before an adverse event occurs. As with RCA, Failure Mode and Effect Analysis (FMEA) uses a multidisciplinary team, but it is a prospective methodology that proactively identifies failure modes that pose the greatest risk in a system of process. Therefore, it is proposed that the existing Root Cause Analysis programme is extended to use FMEA to identify the latent conditions of a patient self-monitoring service, using hypothetical scenarios.

Secondly, there is a pressing need for a more informed view of the legal implications of patient self-monitoring of OAT, and of self-care of long-term conditions in general. I would recommend consulting with key stakeholders – healthcare professionals, managers, legal professionals and representatives from the professional bodies – with feedback on hypothetical scenarios, to establish a consensus view.

Thirdly, further validation of the requirements for an OAT patient self-monitoring services could be achieved by involving patients, healthcare professionals and managers outside of London – the needs of a rural community may differ from an urban one – and outside of the UK. There are two main options for doing this. The methodology and instruments used in this research could be applied to these different populations. However, whilst providing further validation of the instruments used, this approach would be relatively time and resource intensive. More importantly, there are some candidate requirements that cannot be fully validated in the context of a PST pilot. For example, it would be unethical to provide support to some patients but not to others.

Therefore, an alternative method could be considered such as a Delphi survey. This is a method to obtain group consensus on key issues, through an iterative cycle, via email.¹⁴³ As there are no geographic boundaries, international perspectives can be gained.

Lastly, the web-based information management system supporting the Whittington Anticoagulation and Stroke Prevention Service has been previously described, and from 2012, it will be technically possible for Whittington patients to access their electronic healthcare record (EHR) embedded in this system, and also to use the decision support it offers for warfarin dose adjustment. Because practitioners can also access these records to review their patients' progress, patients could use the system to manage their anticoagulation independently but not in isolation. The potential benefits of this are compelling – to empower, engage, support and educate the patient – but are yet to be proven, and present an exciting future research opportunity.

CHAPTER 10: CONCLUSION

The UK has been slow to embrace patient self-monitoring of oral anticoagulation and, prior to this research, there was no work undertaken to establish the reasons behind this. Using a methodological approach, this research has explored the perspectives of the key stakeholders to gain a better understanding of what should be included in a service model that would foster the successful development and delivery of an OAT patient self-monitoring service.

This investigation has resulted in an in-depth understanding of the issues of establishing and delivering an OAT patient self-monitoring service. The main concerns of the three stakeholder groups are identified in Table 61, and are mapped to service requirements.

Stakeholder group	Key concern	Service requirement
Patient	The need to purchase the coagulometer	Facilitate provision of the coagulometer
Healthcare professional	Increased clinical risk and fear of litigation	Construct patient eligibility and assessment criteria Establish a formal shared-care agreement between patient and clinician Provide ongoing support to self-monitoring patients Establish a process for quality assurance (QA) of coagulometers Clarify issues of accountability and clinical responsibility
Healthcare manager	Financial risk	Establish financial feasibility of service

Table 61: The key concerns of stakeholder groups mapped to service requirements

The ability and willingness of patients to purchase a coagulometer cannot be underestimated. Patients may be more willing to purchase a coagulometer if they can realise the benefits associated with self-monitoring. To this end, a loan coagulometer could allow them to 'try before you buy'. However, the anticoagulation service may need to acquire funding for some machines to allow a larger sub-section of the clinic population the opportunity to self-monitor.

Steps need to be taken to ensure that the introduction of patient self-monitoring does not introduce new risks. Clinical staff will need to feel confident about change, and may need education, training and support to prepare them for a new role. There are likely to be implications in terms of their patterns of work, their workloads, and their relationships with self-monitoring patients and their responsibilities.

Finally, the service must not incur financial risk to either to the commissioners or to secondary care. For a service model whose cost-effectiveness is unproven at best, this is challenging in the current economic climate.

However, the principal aim of this research was to derive a set of requirements for a service to support OAT patient self-monitoring. These requirements are presented as a conceptual model below.

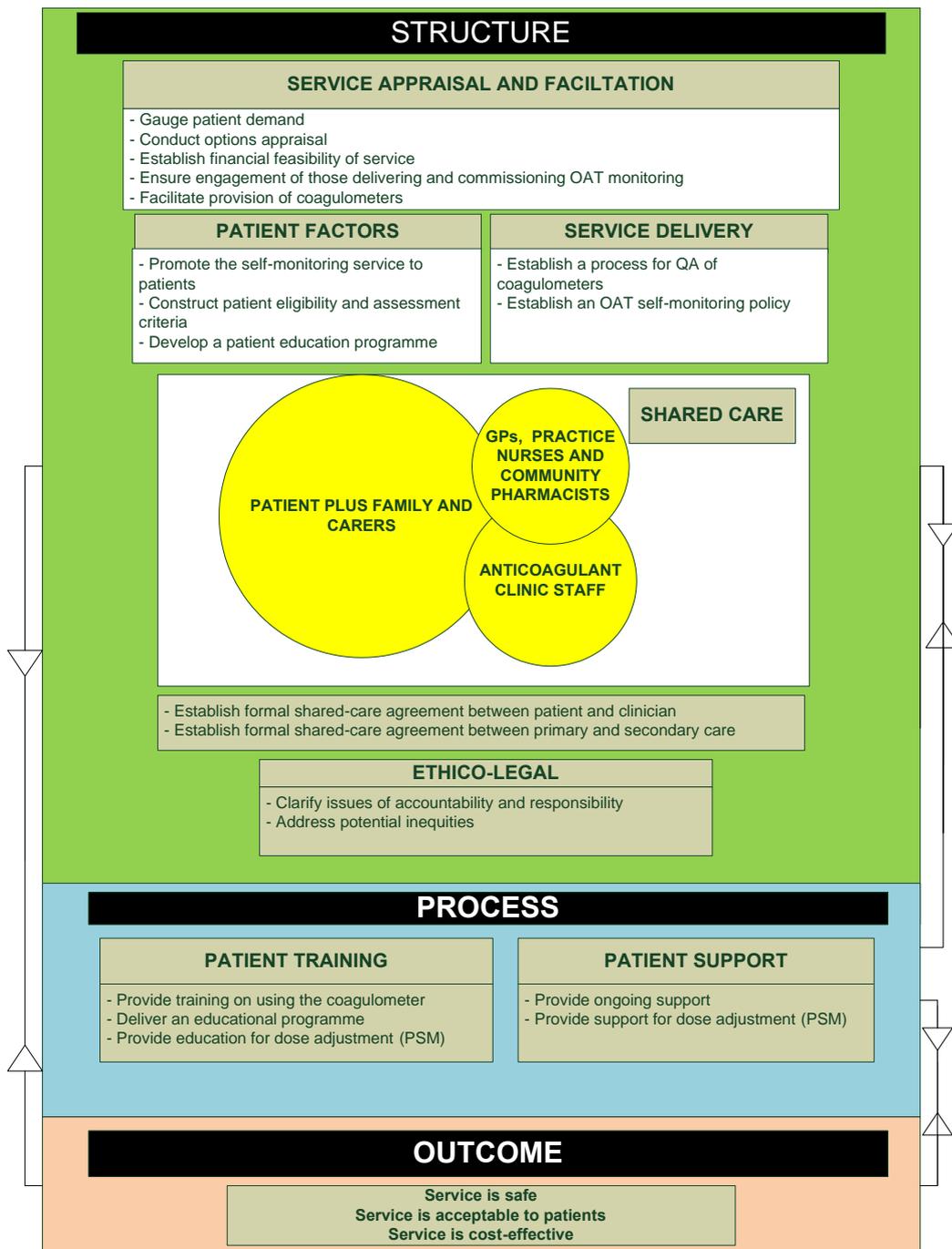


Figure 28: A conceptual model of the requirements for an oral anticoagulation self-monitoring service

Although this model is unlikely to be generalisable to self-management of other long-term conditions, the method of investigation used in this research could be applied to derive a set of specific service requirements for other conditions. This method of deriving service requirements from the perspectives of key stakeholders is pertinent when considered against the background of the future model of NHS services.

Policy makers are emphasising the need for integrated care.¹⁹¹ Greater integration of care inevitably involves multiple stakeholders, and future services will need to be developed to accommodate all of their needs. Integration can occur between health and social care (horizontal integration) or across primary, community and secondary care providers (vertical integration). In April 2011, the author's employing NHS Trust vertically integrated with the provider arm of two PCTs to form an integrated care organisation (ICO). This may offer exciting new opportunities for more holistic integration.

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APPENDIX 1: SAMPLE PAGES FROM THE WORKBOOK USED IN EDUCATIONAL PROGRAMME FOR ANTICOAGULATION PRACTITIONERS

CLINICAL USE OF WARFARIN

PHARMACOKINETICS AND METABOLISM

Knowledge of the pharmacokinetics of warfarin is essential to understanding the response to therapy.

Warfarin is a racemic mixture of stereoisomers, which are 99 percent bound to **albumin**. However, because of redistribution of the displaced drug throughout the body, administration of another drug that displaces warfarin from its binding site (e.g. NSAIDs), or uraemia, does *not* lead to an enhanced drug effect. However, there may be a *temporary* increase in anticoagulant response until a new steady-state is established.

Warfarin is almost completely **absorbed** from the GI tract and can be detected in the plasma one hour after oral administration. However, the relationship between plasma concentration of warfarin and its effect is complex. As warfarin's effect on vitamin K clotting factors is a function of both their synthesis rate and degradation rates, there is no simple correlation between plasma concentration and therapeutic effect.

The mean plasma **half-life** is approximately 40 hours, and the duration of effect is two to five days. When starting warfarin treatment, it would normally take about 5 half-lives (i.e. 8 days) to reach constant plasma concentration (steady state). Therefore, when initiating Warfarin therapy loading doses are used to bring the steady state forward. Because of warfarin's long half-life, it takes at least 48 hours to see the maximum effect of a change in dose.

The drug is eliminated almost entirely by **metabolism** in the liver to inactive metabolites that are excreted in the urine and stool. Therefore, liver dysfunction can potential the response to Warfarin both through impaired synthesis of clotting factors and decreased Warfarin metabolism.

A number of factors account for the marked **variability in warfarin dose requirement** between individuals; 10- or 20-fold differences are not uncommon! These include:

- Genetically determined differences in liver enzyme activity – leads to marked differences in clearance. Other drugs also affect the activity of these enzymes
- Variation in vitamin K availability
- Variation in clotting factor turnover
- Differences in the extent of plasma protein binding

Warfarin crosses the placenta, and is not given in the initial or latter stages of **pregnancy**. The drug is teratogenic (6 – 14 weeks is the critical period), and causes intracranial haemorrhage in the baby during delivery.

In summary:

Oral absorption	> 95%
Plasma protein binding	Strongly bound to plasma albumin
<i>Metabolism</i>	Extensive metabolism in liver by cytochrome P450 enzymes, of which CYP2C9 is most important
<i>Half-life</i>	Highly variable. Usually around 40 hours.

Initial onset of action	5 days
Time for dose change to take effect	2 days
Time for INR to return to normal after stopping treatment	>5 days

MONITORING WARFARIN

The effect of warfarin is measured by measuring the prothrombin time (PT) which is then expressed as an International Normalised Ratio (INR).

The prothrombin time is the time taken for citrated plasma to clot after the addition of calcium and tissue thromboplastin. The INR is then expressed as the ratio of the PT of the patient to the PT of a pool of plasma from healthy subjects on no medication.

However, thromboplastins are not standardised among manufacturers or between batches from the same manufacturer. This can lead to significant variability in PT results for warfarinised patients. To overcome this, all commercially available thromboplastins are compared to an international reference thromboplastin and assigned an International Sensitivity Index (ISI). This value is used to mathematically convert the PT to the INR as follows:

$$\text{INR} = (\text{PT patient} / \text{PT mean normal})^{\text{ISI}}$$

The aim of the INR system, approved by the WHO in 1983, is to provide a more uniform and safe oral anticoagulation therapy.

TARGET INR

Warfarin treatment is managed to keep the patient's INR at an optimum level – the target INR. The target INR is that which reduces the risk of thromboembolic events without producing an unacceptable risk of haemorrhage, and this value varies according to the condition being treated. This can be expressed as a range of values (e.g. 2.0 – 3.0) or, increasingly, as a single value (e.g. 2.5). The British Haematological Society guidelines advise on the target INR and duration of treatment.

APPENDIX 2: AN EXPLORATION OF THE EXPERIENCES OF SELF-MONITORING PATIENTS – INTERVIEW PROMPTS

Introductory questions

Do you self-test or self-manage?

How long have you been doing this for?

How long were you on warfarin before you started self-monitoring?

Starting out

Do you remember how you first heard about self-monitoring?

What was your initial reaction?

Did anything put you off doing it?

What was your main motivation to “give it a go”?

What other factors would have persuaded you to try it out?

Information needs at the beginning

Where did you seek out further information?

What information were you given?

Support

Who supported you in self-monitoring?

The journey

What has become easier as you have become more used to self-monitoring?

Has anything become more difficult?

Were there any points where you would have given up?

What factors tipped the balance?

Information needs through the journey

Is there any information that you were not given at the outset that, with hindsight, would have been useful?

And finally ...

Do you have any pearls of wisdom for those thinking of self-monitoring?

APPENDIX 3: INTERVIEWS WITH LOCAL ANTICOAGULANT CLINIC PATIENTS - STUDY INVITATION LETTER AND PATIENT INFORMATION SHEET

The Whittington Hospital 
NHS Trust

[Insert date]
[Insert patient name]
[Insert patient address]

Bridget Coleman
Anticoagulation Monitoring &
Stroke Prevention Service
C/o Pharmacy Department
Whittington Hospital
Magdala Avenue
London
N19 5NF

Re: Patients' views on developing the anticoagulant service

Dear [insert patient name]

I am writing to you, as a patient taking warfarin, to see if you would be interested in taking part in a small research study.

It is now possible for people to play a greater role in looking after their warfarin treatment by measuring their own blood INR at home on a small handheld machine. With education and support some patients may also be able to adjust the dose of warfarin by themselves. However, we are not sure if this is something that patients would want to do, and what type of education and support patients might need to take on this greater role.

As part of an MPhil / PhD degree in Health Informatics, I am trying to find out if patients taking warfarin would be willing to take a greater role in managing their treatment, and what support they might need to do this. I hope to send out a questionnaire to find out what patients feel about this, and about their experiences of taking warfarin and attending the anticoagulant clinic. However, before doing so I need to "test out" this questionnaire on a small number of patients to check that I am asking the right questions in the right way.

Therefore, I am inviting you to test out this questionnaire by going through the questions with me in the form of an interview. This can take place either at the Whittington, or in your own home, and will last for no more than 45 minutes. All information obtained will be treated confidentially.

Full details are on the enclosed information sheet and I ask that you read this carefully. If you would like to take part, please either phone me (020 7288 5726), email me (bridget.coleman@whittington.nhs.uk) or alternatively return the reply page in the stamped addressed envelope provided. I can then arrange the interview for a mutually convenient time and place. You will be asked to sign a consent form on the day of the interview. Please do not hesitate to contact me by phone or email if you need further information before making a decision.

Thank you for taking the time to read this letter, and I hope to get the opportunity to interview you.

Yours sincerely,

Bridget Coleman
Pharmacist, Anticoagulant Monitoring & Stroke Prevention Service

Re: Patients' views on developing the anticoagulant service

I would like to be interviewed to test out the patient questionnaire

Name: _____

Preferred way to contact: [please give telephone number, address or email address]

Patient Information Sheet

Patients' views on developing the anticoagulant service

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The aim of this study is to find out how we can help people to play a greater role in looking after their warfarin treatment. It is now technically possible to measure your own blood INR at home on a small handheld machine. With education and support some patients may also be able to adjust the dose of warfarin by themselves. Clinical studies have shown that this is a safe way of monitoring warfarin treatment.

However, there has been little research to show what type of education and support patients might need to take on this greater role. Also, we are not sure if this is something that patients would want to do.

This is a good opportunity to explore these issues with you, and also to find out what you feel about taking warfarin and attending the anticoagulation clinic. We are doing this by sending out a questionnaire to seek the views of a large group of patients. But before doing this we need to “test out” the questionnaire on a small group of patients to make sure that we are asking the right questions.

Why have I been chosen?

You have been invited to take part because you are taking warfarin and attend one of the Whittington anticoagulant clinics for blood monitoring. Once this questionnaire has been tested out with eight other patients, it will be sent out to another 400 patients.

Do I have to take part?

No. It is entirely up to you whether or not to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you wish to withdraw from the study you may do so at any time and without giving reason. If you decide not to take part in the study, this will not affect the standard of care that you receive.

What will happen to me if I take part?

If you agree to take part, you will be invited to attend an interview. This will take part at a convenient time and location – either in the anticoagulant clinic or in your own home if desired – and should take no longer than 45 minutes. The interview will be with Bridget Coleman, and you will be asked to share your views on taking warfarin, your experiences of attending the anticoagulant clinic, your views on playing a greater role in monitoring your treatment and what type of education and support you would need to do this.

With your permission, the discussion will be audio-taped, and this will then be transcribed onto a paper document at a later stage. Both the tapes and the paper documents will be kept in a locked cupboard. We will look at the responses to find out which topics are important to you, and will use these in the questionnaire that will be sent out to a larger group of patients. Things that you say during the interview may be quoted in reports, publications or presentations arising from this research. However, all quotations will be anonymous.

What do I have to do?

If you accept this invitation to be interviewed, we would like you to turn up for the interview at the agreed time. There will be no change to the management of your warfarin treatment.

What are the possible disadvantages and risks in taking part in this study?

There are no risks to you taking part in this study and we do not anticipate that the interview will cause any distress.

What are the possible benefits of taking part?

The information that we get from this study may help us to develop your anticoagulation service. You will have a direct input into this process.

What happens when the research study stops?

Management of your warfarin treatment and your clinic visits will remain unchanged.

What if there is a problem?

If you have any concerns about the study, or any complaint about the way that you have been dealt with during the study, you should speak to Bridget Coleman on tel: 020 7288 5726, or Dr David Patterson on tel:020 7288 5310 who will try to deal with your concerns. If you remain unhappy, you can complain formally through the NHS Complaints Procedure. Details are available from the Whittington Hospital Patient Advocacy & Liaison Service (PALS) on tel: 020 7288 5784

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of this research will be kept strictly confidential. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognized from it. We would like to let your GP know that you are taking part in this study, but will only do so if you agree to this.

What will happen to the results of the research study?

The results will be included in a dissertation to be written by Bridget Coleman for an MPhil / PhD in Health Informatics with the Centre for Health Informatics & Multiprofessional Education (CHIME) at University College London. It is hoped to present the results at relevant local, national and international meetings and to submit a written report for publication in medical or health informatics journals. The results will also be made available to all patients attending the anticoagulant clinic by posting them on the patient information board in the clinic area.

But ultimately, it is hoped that the results of the study will help us to develop our anticoagulation service.

Who is organizing and funding this study?

This study is being organised by Bridget Coleman (Pharmacy Department & Anticoagulant Clinic, Whittington Hospital), in collaboration with Jeannette Murphy (CHIME, University College London). This study is not being financially sponsored.

Who has reviewed the study?

The Moorfields & Whittington Research Ethics Committee Hospital has reviewed this study.

Contact for further information

If you would like any further information please contact Ian Man, Lead Pharmacist - Anticoagulant Service on tel: 020 7288 3516

Thank you for reading this sheet

APPENDIX 4: ETHICAL APPROVAL LETTER FOR PATIENT-CENTRED STUDIES

**Moorfields & Whittington Research Ethics Committee
South House, Block A
Royal Free Hospital
Pond Street
London
NW3 2QG**

**Telephone: 020 7794 0552
Facsimile: 020 7794 0714**

Miss Bridget Coleman
Medicines Management Pharmacist
Whittington Hospital
Magdala Avenue
London, N19 5NF

11 July 2007

Dear Miss Coleman

Full title of study: **The role of information in empowering patients to monitor their oral anticoagulation treatment**
REC reference number: **07/Q0504/48**

Thank you for your letter of 25 June 2007, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application		02 May 2007
Investigator CV		01 May 2007
Protocol	2.0	01 April 2007
Covering Letter		02 May 2007
Questionnaire	6.0	04 June 2007
Letter of invitation to participant	1.1 pilot	01 May 2007
Letter of invitation to participant	2.1 Main survey	01 May 2007
GP/Consultant Information Sheets	1.0	25 June 2007
Participant Information Sheet: Main survey	2.2	04 June 2007
Participant Information Sheet: Pilot	1.2	04 June 2007
Participant Consent Form	2.0	04 June 2007
Response to Request for Further Information		25 June 2007
Supervisor CV		30 April 2007

R&D approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for R&D approval from the relevant care organisation, if they have not yet done so. R&D approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly. Guidance on applying for R&D approval is available from <http://www.rdforum.nhs.uk/rdform.htm>.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Feedback on the application process

Now that you have completed the application process you are invited to give your view of the service you received from the National Research Ethics Service. If you wish to make your views known please use the feedback form available on the NRES website at:

<https://www.nresform.org.uk/AppForm/Modules/Feedback/EthicalReview.aspx>

We value your views and comments and will use them to inform the operational process and further improve our service.

07/Q0504/48

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Linda Ficker
Vice-Chair

Email: katherine.clark@royalfree.nhs.uk

Enclosures: *Standard approval*

Copy to: R&D Office, Whittington Hospital NHS Trust

**APPENDIX 5: INTERVIEWS WITH LOCAL
ANTICOAGULANT CLINIC PATIENTS -
PRELIMINARY INTERVIEW GUIDE**

**WHITTINGTON HOSPITAL
ANTICOAGULATION AND STROKE
PREVENTION SERVICE**

HELPING US TO DEVELOP YOUR ANTICOAGULANT SERVICE

PATIENT QUESTIONNAIRE

IMPORTANT: Your answers to these questions will remain confidential

Please answer the questions as completely as possible. There are no right or wrong answers. We are interested only in your personal views, so please tell us what you feel and not what you think we may want to hear.

**PLEASE RETURN YOUR COMPLETED
QUESTIONNAIRE IN THE POSTAGE-PAID
ENVELOPE PROVIDED**

Thank you very much for taking part in this survey

**Bridget Coleman
Anticoagulation & Stroke Prevention Service, Whittington Hospital
June 2007**

SECTION A: YOUR WARFARIN TREATMENT

The following questions relate to your Warfarin treatment and how you manage it. Please answer by ticking the relevant box.

1. Can you tell me how long have you been taking warfarin?

1- 6 months 7 months to 1 year 13 months to 5 years More than 5 years I don't know

2. Can you tell me why you are taking warfarin? You may need to tick more than one box.

Atrial Fibrillation (Irregular heartbeat)	<input type="checkbox"/>	Metal heart valve	<input type="checkbox"/>
Deep Vein Thrombosis (Clot in leg)	<input type="checkbox"/>	I don't know	<input type="checkbox"/>
Pulmonary embolism (clot in lung)	<input type="checkbox"/>	Other (please state)	<input type="checkbox"/>

3. Does someone help you manage your warfarin at home? YES NO

4. If someone helps you with your warfarin, can you tell me who this is?

Husband / wife / partner	<input type="checkbox"/>	Friend / neighbour	<input type="checkbox"/>
Son / daughter	<input type="checkbox"/>	Healthcare professional	<input type="checkbox"/>
Other family member	<input type="checkbox"/>	Other (please state who)	<input type="checkbox"/>

5. Do you feel that being on warfarin has had an impact on your life? YES NO

6. Would you like to make any further comments?

7. Has your warfarin ever caused any bleeding YES NO

8. Would you like to make any further comments?

9. Do you ever feel anxious about your warfarin? YES NO

10. Would you like to make any further comments?

11. What do you feel is the worst thing about taking warfarin? Please tick just one box.

Having to watch what I eat	<input type="checkbox"/>	Having to attend the clinic for frequent blood tests	<input type="checkbox"/>
Having to watch what other medicines I take	<input type="checkbox"/>	There is nothing bad about taking warfarin	<input type="checkbox"/>
Living with the risk of bleeding	<input type="checkbox"/>	Other (please state what this is)	<input type="checkbox"/>

12. How would you describe your current health?

Excellent	<input type="checkbox"/>	Good	<input type="checkbox"/>	Not very good	<input type="checkbox"/>	Terrible	<input type="checkbox"/>
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13. Can you tell me (roughly) how many different medicines (other than warfarin) you take each day?

More than 6	<input type="checkbox"/>	3 - 5	<input type="checkbox"/>	1 - 2	<input type="checkbox"/>	None	<input type="checkbox"/>
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SECTION B: ATTENDING THE WARFARIN CLINIC

The following questions relate to your warfarin clinic visits and how you feel about them. Please answer by ticking the relevant box.

14. Where do you usually have your warfarin treatment monitored?

At the Whittington	<input type="checkbox"/>	At a GP's surgery	<input type="checkbox"/>	At a community pharmacy	<input type="checkbox"/>	At home	<input type="checkbox"/>
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15. If you attend the warfarin clinic at the Whittington, are you on the mailing list (that is, you don't wait to see the staff in the clinic after you have your blood taken but have your results posted to you)

YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
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16. Can you estimate how many times you have been to the warfarin clinic in the last six months?

More than 6	<input type="checkbox"/>	3 - 5	<input type="checkbox"/>	1 - 2	<input type="checkbox"/>	None	<input type="checkbox"/>
-------------	--------------------------	-------	--------------------------	-------	--------------------------	------	--------------------------

17. How do you usually travel to the warfarin clinic?

By car	<input type="checkbox"/>	By hospital transport	<input type="checkbox"/>
I walk	<input type="checkbox"/>	By taxi	<input type="checkbox"/>
By bus	<input type="checkbox"/>	Other (please state)	<input type="checkbox"/>

18. Can you tell me how long this journey usually takes you?

Less than 15 minutes	<input type="checkbox"/>	15 – 29 minutes	<input type="checkbox"/>	30 – 60 minutes	<input type="checkbox"/>	More than 1 hour	<input type="checkbox"/>
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19. Can you estimate the time you usually spend in the warfarin clinic (from walking in the door to walking out)?

Less than 15 minutes	<input type="checkbox"/>	15 – 29 minutes	<input type="checkbox"/>	30 – 60 minutes	<input type="checkbox"/>	More than 1 hour	<input type="checkbox"/>
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20. Now think about your clinic visits? Please tick a box to show how much you agree with each of the following statements.

	5 Strongly agree	4 Agree	3 Uncertain	2 Disagree	1 Strongly disagree
I find it easy to plan my life around my Warfarin clinic visits	<input type="checkbox"/>				
I have complete trust in the Warfarin clinic staff	<input type="checkbox"/>				
I have complete trust in the computer used in the Warfarin clinic	<input type="checkbox"/>				
I find my Warfarin clinic visits disrupt my life	<input type="checkbox"/>				

21. Have you heard of patients “self-testing” or “self-managing” their warfarin?

YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
-----	--------------------------	----	--------------------------

22. Now think about what would you like to change about your warfarin treatment & monitoring. Please tick a box to show which of these options are most attractive. You may tick more than one box.

Less frequent clinic visits	<input type="checkbox"/>	An alternative to warfarin that does not need monitoring	<input type="checkbox"/>
Spending more time with clinic staff	<input type="checkbox"/>	Testing my INR (blood level) at home and phoning the clinic for advice on my dose	<input type="checkbox"/>
Spending less time with clinic staff	<input type="checkbox"/>	Testing my INR (blood level) at home and adjusting the dose of Warfarin myself	<input type="checkbox"/>

23. Please write any other suggestions in the space below
(narrative)

SECTION C: SELF-MONITORING WARFARIN

The following questions relate to patients taking a greater role in managing their warfarin treatment. Please answer by ticking the relevant box.

PLEASE READ THE ENCLOSED INFORMATION SHEET "A" ON WARFARIN SELF-TESTING.

24. Now think about testing your own INR ("self-testing"). Please tick a box to show how much you agree with each of the following statements.

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
I would be able to prick my finger to get a blood sample	<input type="checkbox"/>				
I would be able to test my blood on the machine	<input type="checkbox"/>				
I would be able to buy a machine	<input type="checkbox"/>				
I would be happy to buy a machine	<input type="checkbox"/>				
I would miss the other patients attending the anticoagulant clinic	<input type="checkbox"/>				
I would like to have more control over my warfarin treatment	<input type="checkbox"/>				

25. We might be able to set up a programme where we could support patients who would like to test their own blood INR at home. If this were to happen would you be interested?

YES NO

PLEASE READ THE ENLCOSED INFORMATION SHEET “B” ON WARFARIN SELF-MANAGEMENT

26. Now think about testing your own INR and adjusting the Warfarin dose yourself (“self-managing”). Please tick a box to show how much you agree with each of the following statements.

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
I would be able to prick my finger to get a blood sample	<input type="checkbox"/>				
I would be able to test my blood on the machine	<input type="checkbox"/>				
I would be able to buy a machine	<input type="checkbox"/>				
I would be happy to buy a machine	<input type="checkbox"/>				
I would miss the other patients attending the anticoagulant clinic	<input type="checkbox"/>				
I would miss the regular contact with the clinic staff	<input type="checkbox"/>				
I would be able to adjust my dose of Warfarin	<input type="checkbox"/>				
I would like to have more control over my warfarin treatment	<input type="checkbox"/>				

27. We might be able to set up a programme where we could support patients who would like to test their own blood INR and adjust their dose of warfarin at home. If this were to happen would you be interested?

YES

NO

28. If we were to set up these “self-testing” and “self-management” programmes, there are a number of ways we could support you. We have listed some of these below. Please could you indicate how important these would be if you were self-testing or self-managing your warfarin treatment.

Give you more information / education

Very important	Quite important	Not very important	Not important
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Make it easy for you to contact the clinic if you have any concerns

Very important	Quite important	Not very important	Not important
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Provide the machine to measure your blood INR

Very important	Quite important	Not very important	Not important
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Check up on you regularly?

Very important	Quite important	Not very important	Not important
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

29. There may be other ways that the clinic could support patients who decide to self-test or self-manage their Warfarin treatment. If you can think of any, please write your suggestions in the space below.

SECTION D: WARFARIN INFORMATION NEEDS

The following questions relate to the types of information or skills that you might need to take a greater role in managing your warfarin treatment. Please answer by ticking the relevant box.

30. Did someone talk to you about your warfarin when you first started treatment?

YES NO I CANNOT REMEMBER

31. Now imagine that you have decided to either test your own blood INR at home with the anticoagulant clinic still adjusting your dose of warfarin (“self-test”), or that you are going to test your own blood INR and adjust your dose of warfarin at home (“self-manage”). Listed below are some examples of information or skills that you might find useful. Please could you tick a box to show which of these you would need. You may tick more than one box.

	I would need to know this if I was “self-testing” – i.e. testing my own blood INR at home but the clinic staff still adjusting the dose of my warfarin	I would need to know this if I was “self-managing” – i.e. testing my own blood INR <u>and</u> adjusting my dose of warfarin at home
How to prick my finger to get a blood sample	<input type="checkbox"/>	<input type="checkbox"/>
How to use the blood INR testing machine	<input type="checkbox"/>	<input type="checkbox"/>
How Warfarin works	<input type="checkbox"/>	<input type="checkbox"/>
Side effects of Warfarin	<input type="checkbox"/>	<input type="checkbox"/>
How Warfarin interacts with other medicines	<input type="checkbox"/>	<input type="checkbox"/>
How to deal with bleeding	<input type="checkbox"/>	<input type="checkbox"/>
How to communicate with healthcare staff (e.g. doctors, nurses, pharmacists)	<input type="checkbox"/>	<input type="checkbox"/>
How to solve problems	<input type="checkbox"/>	<input type="checkbox"/>
How to tell if my INR (blood test) is too high	<input type="checkbox"/>	<input type="checkbox"/>
How to tell if my INR (blood test) is too low	<input type="checkbox"/>	<input type="checkbox"/>
How to manage my diet whilst on warfarin	<input type="checkbox"/>	<input type="checkbox"/>
Other (please specify in the space below)	<input type="checkbox"/>	<input type="checkbox"/>

SECTION E: EXPERIENCES WITH USING COMPUTERS

The following questions relate to your experiences with using computers Please answer by ticking the relevant box.

32. Do you have access to the Internet? YES NO

If the answer to this question is “no”, please skip ahead to question 36. If the answer is “yes” please carry on.

33. Where do you use the Internet most of the time?

At home	<input type="checkbox"/>	In an internet cafe	<input type="checkbox"/>
At work	<input type="checkbox"/>	Other (please state where in the space below)	<input type="checkbox"/>
In a public library	<input type="checkbox"/>		

34. If we made Warfarin information available on the Internet would you look at it??

YES NO MAYBE

35. Have you ever used an Internet chat room? YES NO

36. Do you use email? YES NO

37. If you do use email, could you tell me how happy would you be to communicate with the anticoagulant clinic by email?

Very happy Happy Not very happy Unhappy

38. Please add any other comments you would like to make about using the Internet and email for warfarin information and communication with the clinic

SECTION E: ABOUT YOU

Finally, to help us classify your answers and make our statistical comparisons, would you mind answering the following few questions?

39. Please could you indicate your age

18 – 40 yrs 41 – 55 yrs 56 – 65 yrs Older than 65 yrs

40. Please could you indicate your sex

MALE FEMALE

41. Which ethnic group would you say you belong to?

White (British) Asian (or Asian British)

White (Irish) Chinese

White (other) Mixed race

Black (or Black British) Other (please state which)

42. What is your first language?

43. How would you describe your educational background? (please indicate highest level)

No formal qualifications Diploma / NVQ level

Passed GCSE / O Levels / CSEs Degree level and above

Passed A levels Rather not say

44. We may want to ask for your help again in the near future. Please could you tick the relevant box to indicate if you would be happy to take part.

YES

NO

45.	Please add any further comments in the space below.

46.	Finally, please add your name in the space below. Unless you have indicated that you would be happy to take part in a follow-up study, we will destroy this sheet as soon as we have let your GP know that you have completed this questionnaire. Please be assured that your replies to these questions will remain confidential.

Thank you for your help in completing this questionnaire!

APPENDIX 6: INTERVIEWS WITH LOCAL ANTICOAGULANT CLINIC PATIENTS - PATIENT INFORMATION SHEETS A AND B

INFORMATION SHEET A

Warfarin self-testing

What is warfarin self-testing?

Warfarin self-testing is when you test your blood INR at home, but then contact the anticoagulant clinic to adjust your dose of warfarin.

How would I test my own INR?

You place a testing strip in a small, handheld machine. Then you prick your finger and place a small drop of blood onto the strip. The machine will then tell you what your INR is within a couple of minutes. Currently, there are two self-testing monitors for use by patients; the CoaguChek™ XS by Roche Diagnostics and the INRatio by Sysmex. Here are pictures of these machines:



CoaguChek™ XS



INratio

How often would I need to test my INR?

The clinic staff will advise you on when you should test your INR.

Is this a safe way of managing my warfarin?

Studies have shown that people who self-test their own warfarin therapy are at the correct INR at least as often as those who have their blood tested in an anticoagulant clinic.

What would happen if I had problems with measuring my blood INR?

In these circumstances you would contact the anticoagulant clinic for advice

Are the testing strips available on prescription?

Yes

Are these machines available on prescription?

No. You would need to buy them yourself.

How much do these machines cost?

Both of these machines cost £399.

How accurate are these machines?

Both of these machines have been passed by the regulatory authorities in the UK. We use the CoaguChek™ machine in our GP and community pharmacy clinics.

INFORMATION SHEET B

Warfarin self-management

What is warfarin self-management?

Warfarin self-management is when you test your blood INR at home, and then adjust your own warfarin dosage within limits set by the anticoagulant clinic.

How would I test my own INR?

You place a testing strip in a small, handheld machine. Then you prick your finger and place a small drop of blood onto the strip. The machine will then tell you what your INR is within a couple of minutes. Currently, there are two self-testing monitors for use by patients; the CoaguChek™ XS by Roche Diagnostics and the INRatio by Sysmex. Here are pictures of these machines:



CoaguChek™ XS



INratio

How often would I need to test my INR?

The clinic staff will advise as to how often you should test your INR

Is this a safe way of managing my warfarin?

Studies have shown that people who manage their own warfarin therapy are at the correct INR at least as often as those who have their warfarin managed by a doctor, nurse or pharmacist.

What would happen if my INR was very high or very low, or if I had any problems with adjusting my warfarin?

In these circumstances you would contact the anticoagulant clinic for advice

Would the clinic check up on how I was getting on?

Yes. The clinic would like to review your warfarin treatment at least once a year

Are the testing strips available on prescription?

Yes

Are these machines available on prescription?

No. You would need to buy them yourself.

How much do these machines cost?

Both of these machines cost £399.

How accurate are these machines?

Both of these machines have been passed by the regulatory authorities in the UK. We use the CoaguChek™ machine in our GP and community pharmacy clinics.

APPENDIX 7: A SURVEY OF LOCAL ANTICOAGULANT CLINIC PATIENTS – STUDY INFORMATION SHEET, STUDY INVITATION LETTER AND REMINDER LETTER

Patient Information Sheet

Patients' views on developing the anticoagulant service

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The aim of this study is to find out how we can help people to play a greater role in looking after their warfarin treatment. It is now technically possible to measure your own blood INR at home on a small handheld machine. With education and support some patients may also be able to adjust the dose of warfarin by themselves. Clinical studies have shown that this is a safe way of monitoring warfarin treatment.

However, there has been little research to show what type of education and support patients might need to take on this greater role. Also, we are not sure if this is something that patients would want to do.

This is a good opportunity to explore these issues with you, and also to find out what you feel about taking warfarin and attending the anticoagulation clinic. We are doing this by sending out a questionnaire to seek the views of a large group of patients.

Why have I been chosen?

You have been invited to take part because you are taking warfarin and attend one of the Whittington anticoagulant clinics for blood monitoring. This questionnaire has been sent out to over 600 patients.

Do I have to take part?

No. It is entirely up to you whether or not to take part. We have no way of knowing if you have decided not to take part in the study, and this decision will not affect the standard of care that you receive.

What do I have to do?

If you decide to take part, simply complete the enclosed questionnaire and return it to us in the enclosed reply-paid envelope.

What are the possible disadvantages and risks in taking part in this study?

There are no risks to you taking part in this study. The only disadvantage is the time it will take you to complete the questionnaire.

What are the possible benefits of taking part?

The information that we get from this study may help us to develop your anticoagulation service. You will have a direct input into this process.

What happens when the research study stops?

Management of your warfarin treatment and your clinic visits will remain unchanged.

What if there is a problem?

If you have any concerns about the study, or any complaint about the way that you have been dealt with during the study, you should speak to Bridget Coleman on tel: 020 7288 5726, or Professor David Patterson on tel: 020 7288 5310 who will try to deal with your concerns. If you remain unhappy, you can complain formally through the NHS Complaints Procedure. Details are available from the Whittington Hospital Patient Advocacy & Liaison Service (PALS) on tel: 020 7288 5784

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of this research will be kept strictly confidential. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognized from it. We would like to let your GP know that you are taking part in this study, but will only do so if you agree to this.

What will happen to the results of the research study?

The results will be included in a dissertation to be written by Bridget Coleman for an MPhil / PhD in Health Informatics with the Centre for Health Informatics & Multiprofessional Education (CHIME) at University College London. It is hoped to present the results at relevant local, national and international meetings and to submit a written report for publication in medical or health informatics journals. The results will also be made available to all patients attending the anticoagulant clinic by posting them on the patient information board in the clinic area.

But ultimately, it is hoped that the results of the study will help us to develop our anticoagulation service.

Who is organizing and funding this study?

This study is being organised by Bridget Coleman (Pharmacy Department & Anticoagulant Clinic, Whittington Hospital), in collaboration with Jeannette Murphy (CHIME, University College London). This study is not being financially sponsored.

Who has reviewed the study?

The Moorfields & Whittington Hospital Research Ethics Committee has reviewed this study.

Contact for further information

If you would like any further information please contact Ian Man, Lead Pharmacist - Anticoagulant Service on tel: 020 7288 3516

Thank you for reading this sheet



The Whittington Hospital **NHS**

NHS Trust

[Insert date]
[Insert patient name]
[Insert address]

Bridget Coleman
Anticoagulation Monitoring &
Stroke Prevention Service
C/o Pharmacy Department
Whittington Hospital
Magdala Avenue
London
N19 5NF

Re: Patients' views on developing the anticoagulant service

Dear [insert patient name]

I am writing to you, as a patient taking warfarin, to see if you would be interested in taking part in a small research study.

It is now possible for people to play a greater role in looking after their warfarin treatment by measuring their own blood INR at home on a small handheld machine. With education and support some patients may also be able to adjust the dose of warfarin by themselves. However, we are not sure if this is something that patients would want to do, and what type of education and support patients might need to take on this greater role.

As part of an MPhil / PhD degree in Health Informatics, I am trying to find out if patients taking warfarin would be willing to take a greater role in managing their treatment, and what support they might need to do this. Today, you have been chosen at random to receive a questionnaire to find out what you think about this, and to ask you about your experiences of taking warfarin and attending the anticoagulant clinic.

Your views are important. The Anticoagulation & Stroke Prevention Service is committed to ongoing service development. However, we need to be sure that these developments are what our patients want, and that we are able to support them in a relevant way. The results of the questionnaires will be used to tell us if the service should be developed to support patients who are willing to play a greater role in managing their oral anticoagulation, and how we can help them do this.

Your participation is entirely voluntary, and your answers to the questions are strictly confidential. The questionnaire should take no longer than 30 minutes to complete. Full details are on the enclosed information sheet and I ask that you read this carefully. If you have any questions about this survey please either phone me (020 7288 5726), email me (bridget.coleman@whittington.nhs.uk). If you decide to complete this questionnaire please return it to me in the stamped addressed envelope provided.

Thank you for taking the time to read this letter.

Yours sincerely,

Bridget Coleman
Pharmacist, Anticoagulant Monitoring & Stroke Prevention Service



♥ **Clinical & Academic Department of Cardiovascular Medicine**

January 2008

Patients' views on developing the anticoagulant service

A questionnaire about developing our anticoagulation monitoring service was recently posted to you. If you have already returned your questionnaire, thank you and please accept my apologies for bothering you.

It is entirely up to you whether or not to take part in this survey. However, your views are important and I would like to hear from you. But if you do not wish to take part, you do not need to give a reason and the care you receive from us will not be affected.

If you have any comments or questions about the questionnaire, or need help with completing it, please do not hesitate to contact me on 020 7288 5726 or via email (bridget.coleman@whittington.nhs.uk). The phone line is open 10.30 to 5.00, Tuesday to Friday. I will do my best to answer any questions you might have.

Thank you for your time

Bridget Coleman, BSc, MSc, MRPharmS
Senior Pharmacist, Anticoagulation Monitoring & Stroke Prevention Service,
Whittington Hospital

**APPENDIX 8: A SURVEY OF LOCAL
ANTICOAGULANT CLINIC PATIENTS – STUDY
QUESTIONNAIRE AND PATIENT INFORMATION
SHEET A**

WHITTINGTON HOSPITAL
ANTICOAGULATION MONITORING AND
STROKE PREVENTION SERVICE

HELPING US TO DEVELOP YOUR ANTICOAGULANT SERVICE

PATIENT QUESTIONNAIRE

IMPORTANT: Your answers to these questions will remain confidential

Please answer the questions as completely as possible. There are no right or wrong answers. We are interested only in your personal views, so please tell us what you feel and not what you think we may want to hear. It should take you about 15 – 20 minutes to complete this questionnaire.

**PLEASE RETURN YOUR COMPLETED
QUESTIONNAIRE IN THE POSTAGE-PAID
ENVELOPE PROVIDED**

Thank you very much for taking part in this survey

Bridget Coleman, BSc, MSc, MRPharmS
Senior Pharmacist, Anticoagulation & Stroke Prevention Service, Whittington
Hospital
January 2008

SECTION A: ABOUT YOUR WARFARIN TREATMENT

The following questions relate to your warfarin treatment and how you manage it. Please answer by ticking the relevant box.

1. Can you tell me how long have you been taking warfarin?

1- 6 months 7 months to 11 months 1 year to 5 years More than 5 years I can't remember

2. Can you tell me why you are taking warfarin? You may need to tick more than one box.

Atrial Fibrillation (Irregular heartbeat)	<input type="checkbox"/>	Artificial heart valve	<input type="checkbox"/>
Deep Vein Thrombosis (Clot in leg)	<input type="checkbox"/>	I don't know	<input type="checkbox"/>
Pulmonary embolism (Clot in lung)	<input type="checkbox"/>	Other (please give details)	<input type="checkbox"/>
		<div style="border: 1px solid black; height: 40px; width: 100%;"></div>	

3. Does someone help you manage your warfarin at home? YES NO

4. If someone helps you with your warfarin, can you tell me who this is?

Husband / wife / partner	<input type="checkbox"/>	Friend / neighbour	<input type="checkbox"/>
Son / daughter	<input type="checkbox"/>	Healthcare professional	<input type="checkbox"/>
Other family member	<input type="checkbox"/>	Other (please state who in the space below)	<input type="checkbox"/>
		<div style="border: 1px solid black; height: 40px; width: 100%;"></div>	

5. Do you feel that being on warfarin has had an impact on your life? YES NO

6. Please add any further comments below

7. **Have you had any bleeding or bruising since taking warfarin?**

YES

NO

8. **Please add any further comments below**

9. **Do you ever worry about being on warfarin?**

YES

NO

10. **Please add any further comments below**

11. What do you feel is the worst thing about taking warfarin? Please tick just one box.

Having to watch what I eat	<input type="checkbox"/>	Having to attend the clinic for frequent blood tests	<input type="checkbox"/>
Having to watch what other medicines I take	<input type="checkbox"/>	Living with the risk of bleeding	<input type="checkbox"/>
Having to watch how much alcohol I drink	<input type="checkbox"/>	Other (please give details below)	<input type="checkbox"/>

12. How would you describe your current health?

Excellent Good Not very good Poor

13. Can you tell me (roughly) how many different medicines (other than warfarin) you take each day?

6 or more 3 - 5 1 - 2 None

SECTION B: ABOUT ATTENDING THE WARFARIN CLINIC

The following questions relate to your warfarin clinic visits and how you feel about them. Please answer by ticking the relevant box.

14. Where do you usually have your warfarin treatment monitored?

At the Whittington At a GP's surgery At a community pharmacy At home

15. If you go to the warfarin clinic at the Whittington, are you on the mailing list? That is, you go home after your blood is taken and someone from the clinic posts your results to you or phones you.

YES NO

16. Can you tell me how many times (roughly) you have been to the warfarin clinic in the last six months?

6 or more	<input type="checkbox"/>	3 - 5	<input type="checkbox"/>	1 - 2	<input type="checkbox"/>	None	<input type="checkbox"/>
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17. How do you usually travel to the warfarin clinic?

By car	<input type="checkbox"/>	By hospital transport	<input type="checkbox"/>
I walk	<input type="checkbox"/>	By taxi	<input type="checkbox"/>
By bus	<input type="checkbox"/>	Other (please give details in space below)	<input type="checkbox"/>
<div style="border: 1px solid black; height: 40px; width: 100%;"></div>			

18. Can you tell me how long this journey usually takes you?

Less than 15 minutes	<input type="checkbox"/>	15 – 29 minutes	<input type="checkbox"/>	30 – 60 minutes	<input type="checkbox"/>	More than 1 hour	<input type="checkbox"/>
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19. Can you estimate the length of time you usually spend in the warfarin clinic? (from arriving at the hospital / pharmacy /GP surgery to leaving)

Less than 15 minutes	<input type="checkbox"/>	15 – 29 minutes	<input type="checkbox"/>	30 – 60 minutes	<input type="checkbox"/>	More than 1 hour	<input type="checkbox"/>
----------------------	--------------------------	-----------------	--------------------------	-----------------	--------------------------	------------------	--------------------------

20. Now think about your clinic visits. Please tick a box to show how much you agree with each of the following statements.

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
I find it easy to plan my life around my Warfarin clinic visits	<input type="checkbox"/>				
I have complete trust in the Warfarin clinic staff	<input type="checkbox"/>				
I have complete trust in the computer used in the Warfarin clinic	<input type="checkbox"/>				
I find my Warfarin clinic visits disrupt my life	<input type="checkbox"/>				

21. Have you heard of patients “self-testing” or “self-managing” their warfarin?

YES

NO

22. If you have heard of patient “self-testing” or “self-managing” their warfarin, can you tell me where you heard of this?

SECTION C: ABOUT TESTING YOUR BLOOD INR AT HOME

The following questions relate to patients taking a greater role in managing their warfarin treatment. Please answer by ticking the relevant box.

FIRST, PLEASE READ THE ENCLOSED INFORMATION SHEET “A” ON TESTING YOUR BLOOD INR AT HOME.

23. Now imagine you are going to test your own INR at home, but to adjust your dose of warfarin you will contact the anticoagulant clinic (“self-testing”). Please tick a box to show how much you agree with each of the following statements.

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
I would be able to prick my finger to get a blood sample	<input type="checkbox"/>				
I would be able to test my blood on the machine	<input type="checkbox"/>				
I would be able to buy the machine	<input type="checkbox"/>				
I would be happy to buy the machine	<input type="checkbox"/>				
I would miss the other patients attending the anticoagulant clinic	<input type="checkbox"/>				
I would like to have more control over my warfarin treatment	<input type="checkbox"/>				

24. We might be able to set up a programme where we could support patients who would like to test their own blood INR at home. If we could do this would you be interested in taking part?

YES NO

25. Now imagine that you are going to test your own INR and adjust your warfarin dose yourself (“self-managing”). Please tick a box to show how much you agree with the following statements.

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
I would miss the regular contact with the clinic staff	<input type="checkbox"/>				
With training, I would be able to adjust my dose of warfarin	<input type="checkbox"/>				

26. We might be able to set up a programme where we could support patients who would like to test their own blood INR and adjust their dose of warfarin at home. If we could do this would you be interested in taking part?

YES NO

27. There are a number of ways we could support you in testing your blood INR at home. We have listed some of these below. Please could you indicate how important you think these would be.

Give you more information / education about warfarin

Very important	Quite important	Not very important	Not important
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Make it easy for you to contact the clinic if you have any concerns

Very important	Quite important	Not very important	Not important
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The clinic to provide the machine to measure your blood INR

Very important	Quite important	Not very important	Not important
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The clinic to check up on you regularly (e.g. once every six months)

Very important	Quite important	Not very important	Not important
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

28. There may be other ways that the clinic could support patients who decide test their blood INR at home. If you can think of any, please write your suggestions in the space below.

SECTION D: ABOUT WARFARIN INFORMATION

The next question relates to the types of information or skills that you might need to take a greater role in managing your warfarin treatment.

29. Firstly, did someone give you information about warfarin (written information or verbal information) when you first started treatment?

YES

NO

I CANNOT
REMEMBER

30. Now, imagine that you are going to self-manage your Warfarin treatment (that is, test your own blood INR and adjust your dose of warfarin at home). I have listed some pieces of information or skills that may help you do this. Please could you tick the relevant box to show me which of these you would need. You may tick more than one box.

- | | |
|--|--------------------------|
| How to prick my finger to get a blood sample | <input type="checkbox"/> |
| How to use the blood INR testing machine | <input type="checkbox"/> |
| How Warfarin works | <input type="checkbox"/> |
| Side effects of Warfarin | <input type="checkbox"/> |
| How Warfarin interacts with other medicines | <input type="checkbox"/> |
| How to deal with bleeding | <input type="checkbox"/> |
| How to work out why my INR is too high or too low | <input type="checkbox"/> |
| How to adjust my dose of warfarin if my INR is too high or too low | <input type="checkbox"/> |
| How to manage my diet whilst on warfarin | <input type="checkbox"/> |
| Other (please give details in the space below) | <input type="checkbox"/> |

SECTION E: ABOUT YOUR EXPERIENCES WITH USING COMPUTERS

The following questions relate to your experiences with using computers Please answer by ticking the relevant box.

31 Do you have access to the Internet? YES NO

If the answer to this question is “no”, please skip ahead to question 35. If the answer is “yes” please carry on.

32 Where do you use the Internet most of the time?

At home In an internet cafe

At work Other (please state where in the space below)

In a public library

33. If the clinic put warfarin information on the Internet would you look at it?

YES NO MAYBE

34. Have you ever used an Internet chat room? YES NO

35. Do you use email? YES NO

36. If you do use email, could you tell me how happy would you be to communicate with the anticoagulant clinic by email?

Very happy Happy Not very happy Unhappy

37. Please add any other comments you would like to make about using the Internet and email for warfarin information and communication with the clinic

SECTION F: ABOUT YOU

Finally, to help us classify your answers and make our statistical comparisons, would you mind answering the following few questions?

38 Please could you indicate your age

18 – 40 yrs 41 – 55 yrs 56 – 65 yrs Older than 65 yrs

39. Please could you indicate your sex

MALE FEMALE

40. Which ethnic group would you say you belong to?

White (British) Asian (or Asian British)

White (Irish) Chinese

White (other) Mixed race

Black (or Black British) Other (please state which)

41. What is your first language?

42. How would you describe your educational background? (please indicate highest level)

No formal qualifications Diploma / NVQ level

GCSE / O Levels / CSEs Degree level and above

A levels Rather not say

43.	Please add any further comments in the space below.

44. We may want to ask for your help in this research in the future. Please could you tick the relevant box to indicate if you would be happy to take part.

YES

NO

45.	Finally, please could you add your name in the space below. Unless you have indicated that you would be happy to take part in a follow-up study, we will destroy this sheet as soon as we have let your GP know that you have completed this questionnaire. Please be assured that your replies to these questions will remain confidential.

Thank you for your help in completing this questionnaire!

Information Sheet A: Testing your blood INR at home

How would I test my own INR?

You place a testing strip in a small, handheld machine. Then you prick your finger and place a small drop of blood onto the strip. The machine will then tell you what your INR is within a couple of minutes. Currently, there are two self-testing monitors for use by patients; the CoaguChek™ XS by Roche Diagnostics and the INRatio by Sysmex. Here are pictures of these machines:



CoaguChek™ XS



INratio

What is warfarin self-testing?

Warfarin self-testing is when you test your blood INR at home, but then contact the anticoagulant clinic to adjust your dose of warfarin.

How often would I need to test my INR?

The clinic staff will advise you on when you should test your INR.

What would happen if I had problems with measuring my blood INR?

In these circumstances you would contact the anticoagulant clinic for advice

What is warfarin self-management?

Warfarin self-management is when you test your blood INR at home, and then adjust your own warfarin dosage within limits set by the anticoagulant clinic.

What would happen if my INR was very high or very low, or if I had any problems with adjusting my warfarin?

In these circumstances you would contact the anticoagulant clinic for advice

Would the clinic check up on how I was getting on?

Yes. The clinic would like to review your warfarin treatment at least once a year

Is testing my own INR a safe way of managing my warfarin?

Studies have shown that people who monitor their own warfarin therapy are at the correct INR at least as often as those who have their blood tested in an anticoagulant clinic.

Are the testing strips available on prescription?

Yes

Are these machines available on prescription?

No. You would need to buy them.

How much do these machines cost?

Both of these machines cost £399.

How accurate are these machines?

Both of these machines have been passed by the regulatory authorities in the UK. We use the CoaguChek™ machine in our GP and community pharmacy clinics.

APPENDIX 9: EXPLORING THE VIEWS OF HEALTHCARE PROFESSIONALS – STUDY INVITATION LETTER AND INFORMATION SHEET

The Whittington Hospital 
NHS Trust

[Date]

[Addressee]

**Bridget Coleman
Anticoagulation Monitoring &
Stroke Prevention Service
C/o Pharmacy Department
Whittington Hospital
London
N19 5NF**

Re: Views on patient self-monitoring of oral anticoagulation

Dear [name],

I am writing to you, as someone who may have an interest in patients taking oral anticoagulants, to invite you to take part in a small research study.

It is now possible for people to play a greater role in looking after their warfarin treatment by measuring their own blood INR at home on a small handheld machine. With education and support some patients may also be able to adjust the dose of warfarin by themselves.

As part of an MPhil / PhD degree in Health Informatics, I am trying to establish the barriers to setting up an oral anticoagulation patient self-monitoring service and to explore what support patients may require. The first stage of this research project, conducted last year, explored our patients' views on self-monitoring. The results indicate that there is a limited demand amongst patients for this method of management. However, for self-monitoring of oral anticoagulation to be successful the support of healthcare professionals is also essential. There is no published research exploring the views of this group of people.

Therefore I am trying to recruit healthcare professionals to attend a focus group, to share their views on patient self-monitoring of oral anticoagulation. These will take place at the Whittington Hospital, and will last for around 45 minutes. All information gathered will be treated confidentially.

Further details are on the enclosed study information sheet. If you would like to take part please either email me (bridget.coleman@whittington.nhs.uk), phone me (020 7288 5672) or return the reply sheet in the stamped addressed envelope provided. If you have any questions about this study please feel free to either phone or email me. If you decide to participate, I will contact you with the date, time and location for the focus group meetings

Thank you for taking the time to read this letter and I hope to see you at one of the groups.

Yours sincerely,

Bridget Coleman
Pharmacist, Anticoagulant Monitoring & Stroke Prevention Service

Reply sheet

I would like to volunteer to take part in the patient self-monitoring of oral anticoagulation focus group

Name: (Please print)

Best way to contact: (Please provide an email address, telephone number or postal address)

Study Information Sheet

Healthcare professionals' views on patient self-monitoring of oral anticoagulation

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The aim of this study is to find out what healthcare professionals think about patients playing a greater role in looking after their warfarin treatment. It is now technically possible for patients to measure their own blood INR at home on a small handheld machine (a coagulometer). With education and support some patients may also be able to adjust the dose of warfarin by themselves. Clinical studies have shown that this is a safe way of monitoring warfarin treatment.

The results of the first stage of this research project, conducted last year, explored patients' views of self-monitoring. The results indicate that there is a limited demand amongst patients for this method of monitoring.

However, for self-monitoring of oral anticoagulation to be successful the support of healthcare professionals is also essential. There is no published research exploring the views of this group of people. Therefore we would like to find out what you think about patient self-monitoring of oral anticoagulation.

Why have I been chosen?

You have been invited to take part because you look after patients who are taking warfarin, or have an interest in the management of these patients.

What will happen to me if I take part?

If you agree to take part, you will be invited to attend a focus group meeting (6 people in each group). This will be held in the Whittington Hospital Pharmacy Department, which has a private seminar room. There will be two focus groups held on separate days. These will be facilitated by Bridget Coleman (Principal Pharmacist – Medicines Management) and Ian Man (Lead Pharmacist, Anticoagulation). In these groups you will be encouraged to share your views

about patient self-monitoring of oral anticoagulation, particularly how we could support patients who are self-monitoring, and any barriers to establishing this service.

The focus group meeting will last for about 45 minutes. Bridget Coleman will facilitate this discussion using a topic guide. But it is important that you express whatever views you wish and for the discussion to follow your ideas. Ian Man will take written notes on the discussion. With your permission, the discussion will also be audiotaped.

At a later stage, Bridget Coleman will transcribe the audiotaped discussion onto a paper document. This will then be analysed to pick out themes in the discussion which were important to you.

Expenses & payments

As this research is not being funded we will not be able to offer you any payment for participating. However, we will provide light refreshments.

Do I have to take part?

No. It is entirely up to you whether or not to take part. Things that you say during the interview may be quoted in reports, publications or presentations arising from this research. However, all quotations will be anonymous.

What do I have to do?

If you decide to take part, simply notify Bridget Coleman by telephone, email or post. You will then be contacted with the dates of the focus groups and be sent a consent form to read.

What are the possible disadvantages and risks in taking part in this study?

There are no risks to you taking part in this study. The only disadvantage is the time it will take you to attend the focus group meeting and to answer any subsequent questions.

What are the possible benefits of taking part?

The information that we get from this study may help us to develop the anticoagulation monitoring service. You will have a direct input into this process. Also, you may learn a little bit more about anticoagulation patient self-monitoring, and you will hear the views of colleagues.

What happens when the research study stops?

If we come across any points that we do not understand when we are analysing the results, we may need to contact you for clarification. Also, once the analysis is complete, we may need to get your views on the results.

What if there is a problem?

If you have any concerns about the study, or any complaint about the way that you have been dealt with during the study, you should speak to Bridget Coleman on tel: 020 7288 5672, or Dr David Patterson on tel: 020 7288 5310 who will try to deal with your concerns. If you remain unhappy, you can complain formally through the NHS Complaints Procedure. Details are available from the Whittington Hospital Patient Advocacy & Liaison Service (PALS) on tel: 020 7288 5784

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of this research will be kept strictly confidential. Any information about your views that leaves the hospital will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?

The results will be included in a dissertation to be written by Bridget Coleman for an MPhil / PhD in Health Informatics with the Centre for Health Informatics & Multiprofessional Education (CHIME) at University College London. It is hoped to present the results at relevant local, national and international meetings and to submit a written report for publication in medical or health informatics journals.

But ultimately, it is hoped that the results of the study will help us to develop our anticoagulation service.

Who is organising and funding this study?

This study is being organised by Bridget Coleman (Pharmacy Department & Anticoagulant Clinic, Whittington Hospital), in collaboration with Jeannette Murphy (CHIME, University College London). This study is not being financially sponsored.

Who has reviewed the study?

The Moorfields & Whittington Research Ethics Committee Hospital has reviewed this study.

Contact for further information

If you would like any further information please contact Ian Man, Lead Pharmacist - Anticoagulation on tel: 020 7288 3516

Thank you for reading this sheet

APPENDIX 10: EXPLORING THE VIEWS OF HEALTHCARE PROFESSIONALS – ETHICAL APPROVAL LETTER

The Whittington Hospital 
NHS Trust

**Research Management and
Governance**
Undergraduate Centre
Whittington Hospital
Magdala Avenue
London
N19 5NF

19th May 2009

Ms Bridget Coleman
Principal Pharmacist (Medicines Management)
Whittington Hospital
Magdala Avenue
London
N19 5NF

Tel: 020 7288 3405

Fax: 020 7288 5822

Senga.Steel@whittington.nhs.uk

Dear Ms Coleman,

Title: Exploring clinicians' and managers' views on patient self-monitoring of oral anticoagulation: a focus group study

REC Ref No: 09/H0721/16

I am pleased to note that Moorfields & Whittington Research Ethics committee reviewed this study and concluded that there is no ethical objection to this research being conducted at this site.

The RM&G Department has also reviewed this study and is satisfied that it meets the necessary research governance standards. The RM&G Department is pleased to give the approval of the Whittington Hospital NHS Trust for this research to proceed according to the study protocol. This approval is only valid concurrently with the appropriate ethical consideration for this study and is therefore subject to the conditions set out by Moorfields & Whittington Research Ethics Committee and the conditions set out in this letter. Should you fail to adhere to these conditions, the Trust would consider your approval to undertake research to be invalid.

The study has been registered with the finance department who will contact you directly regarding any queries over the financial aspects of this study.

You will be aware that as Principal Investigator you have various responsibilities under the Department of Health's *Research Governance Framework for Health and Social Care*. Please be reminded of your responsibilities as outlined in Appendix A to this letter.

All researchers undertaking research within the Trust are reminded of their duties and responsibilities under the Health and Safety at Work Act 1974, contained in Appendix B and the Data Protection Act 1988 contained in Appendix C to this letter.



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Chairman: Mr Joe Liddane Chief Executive: Mr David Sloman

APPENDIX 11: EXPLORING THE VIEWS OF HEALTHCARE PROFESSIONALS – FOCUS GROUP TOPIC GUIDE

FOCUS GROUP GUIDE

THE PURPOSE OF THIS STUDY

Welcome to everyone and thank you for coming. Introductions.

The aim of this group discussion is for you to share your views on patient self-monitoring of oral anticoagulation. But I would like you to talk more amongst yourselves about this than to me.

We would like to audiotape the conversation if that's OK with you. Ian will take some notes in case we need to clarify any points on the tape later that we do not understand.

Just a few ground rules before we get started; minimise side conversations; one person at a time. Most importantly, it is important that you give us your honest views about this.

To start, I am giving you an information sheet about warfarin self-monitoring and I would like you to spend a few minutes to read this. Then we will get started, firstly going around the group to allow everyone to introduce themselves.

A. YOUR OWN EXPERIENCES OF WARFARIN SELF-TESTING

Firstly, I would like to know about your experience of patients self-testing their INR.

1. Have you ever been approached by patients who wish to self-test?
2. Have you supported patients in self-testing their INR?

B. THE PATIENT'S VIEW

3. For patient self-testing or self-management to be successful, patient buy-in is essential. Do you think our patient population are ready to do this?

Prompts

What proportion of our patient population would you guess be interested in self-testing? (50%)

What proportion of our patient population do you think feel they would be able to test their own INR? (57%)

What proportion of our patient population do you think would be able to buy a coagulometer? (16%)

What proportion of our patient population do you think would be able to adjust their dose of warfarin? (53%)

What proportion of our patient population would you guess be interested in self-managing their warfarin? (50%)

C. YOUR VIEWS ON SELECTING PATIENTS FOR SELF-TESTING

As yet, there are no clearly defined selection criteria for self-testing and self-management of oral anticoagulation. It would be useful to get your thoughts on which patients would be suitable or unsuitable for this method of management.

4. Which types of warfarin patients do you think would most benefit from self-testing?

Prompts

Exclusion criteria?

Different criteria for self-management

D. SUPPORTING THE SELF-TESTING PATIENT

There are a number of potential ways that we could support patients who are self-testing and I would like to get your thoughts on this.

5. How do you think we could support patients who would like to self-test their warfarin?

Prompts

Providing more information / education about Warfarin (78%)

Making it easy for patients to contact the clinic if they have any concerns (82%)

Providing the coagulometer (76%)

Checking up on patients regularly (81%)

There is no standardisation of education for anticoagulated patients, including those willing to undertake self-monitoring of OAT. Hence, it would be useful to obtain your views on what educational support should be given to those self-testing.

6. What should patients be able to demonstrate they know, or can do, before they self-test?

Prompts:

How to take a good finger-prick blood sample

How to use the coagulometer

How warfarin works

Side effects of warfarin

How warfarin interacts with other medicines

How to deal with bleeding

How to manage the diet whilst on warfarin

7. Do you think there would be any additional training requirements to prepare the person to self-manage?

Prompts

How to work out why the INR is too high or too low

How to adjust the dose of warfarin if the INR is too high or too low

E. SHARING RESPONSIBILITY WITH THE PATIENT

If we were to support self-testing, this would result in more collaborative working with patients. This, in turn, may lead to a redefining of respective roles and responsibilities, and I would find it useful to get your views on this.

8. Do you think the relationship between healthcare professional and patient will alter once the patient is self-testing? If yes, how?

9. If a patient was to self-test how do you see responsibilities shared between the healthcare professional and patient?

For any service development, it is important to have robust clinical governance arrangements. However, from a medico-legal viewpoint it is not clear where accountability rests when a person is self-testing.

10. What do you consider to be the main risks associated with a self-testing service?

11. How could we reduce these risks?

F. BARRIERS TO IMPLEMENTING SELF-TESTING

Published trials suggest that patients may be reluctant to self-test their INR, with reported low participation rates and high attrition rates. The reasons behind a reluctance to participate in these trials are unclear. Therefore, I thought it would be useful to get your thoughts on potential barriers to implementing a self-testing service.

12. What do you feel are the main barriers to developing a self-testing service?

Prompts:

Patient engagement

Cost of coagulometer

Cost of self-testing

Loss of revenue for the Trust

Liability concerns

Attitude of clinicians

PCT commissioning

13. How can we overcome these barriers?

G. SUMMING UP

14. Finally, would you be happy for warfarin self-testing or self-management to be introduced at the Whittington?

I would like to thank you all for going along today and for giving your valuable time and views. I hope that you have enjoyed taking part. If there are any points we need to clarify we may contact you again. We may also send a copy of our discussion to some of you, and will ask you to correct any of the points you feel we may have got wrong.

Thanks once again

APPENDIX 12: EXPLORING THE VIEWS OF HEALTHCARE PROFESSIONALS – FOCUS GROUP INFORMATION SHEET

Warfarin self-monitoring

How is the INR tested at home?

The patient places a testing strip in a small, handheld machine (the coagulometer). Then they prick their finger and place a small drop of blood onto the strip. The coagulometer will then tell them what their INR is within a couple of minutes. Currently, there are two coagulometers suitable for use by patients; the CoaguChek™ XS by Roche Diagnostics and the INRatio by Sysmex. Here are pictures of these machines:



CoaguChek™ XS



INRatio

What is warfarin self-testing?

Warfarin self-testing is when the patient tests their INR at home, but then contacts the anticoagulant clinic to adjust their dose of warfarin.

How often would the patient need to test their INR?

The clinic staff will advise the patient on when they should test their INR.

What would happen if the patient has problems with measuring their INR?

In these circumstances they would contact the anticoagulant clinic for advice

What is warfarin self-management?

Warfarin self-management is when the patient tests their INR at home, and then adjusts their own warfarin dosage within limits set by the anticoagulant clinic.

What would happen if the patient's INR was very high or very low, or if they had any problems with adjusting their warfarin dose?

In these circumstances the patient would contact the anticoagulant clinic for advice

Is self-monitoring a safe way of managing warfarin treatment?

Clinical studies have shown that people who monitor their own warfarin therapy are at the correct INR at least as often as those who have their blood tested in an anticoagulant clinic.

Are the testing strips available on prescription?

Yes

Are these machines available on prescription?

No. The patient would need to buy them.

How much do these machines cost?

Both of these machines cost £399.

How accurate are these machines?

Both of these machines have been passed by the regulatory authorities in the UK. We use the CoaguChek™ machine in our GP and community pharmacy clinics.

APPENDIX 13: PATIENT SELF-TESTING PILOT – SHARED-CARE AGREEMENT BETWEEN ANTICOAGULANT CLINIC AND PATIENT

Whittington Health 



The Government Standard

Anticoagulant Clinic
Magdala Avenue, London N19
5NF

Appointments / Advice and
Information: 0207 288 3228
Fax: 0207 288 5010

Clinical, Academic Department
of Cardiovascular Medicine 
& Pharmacy Department 

Anticoagulation Clinic & Patient Agreement

Agreement for the Use of a CoaguChek™[®] Machine for Self-Testing INR

This is an agreement for self testing between The Whittington Hospital
NHS Trust and:

Patient Details:

<Enter patient details here>

<Enter GP details here>

Patient Anticoagulation History:

Indication of Anticoagulation:	
Target INR range:	
Type of Anticoagulant/strength:	
Start date of Anticoagulation:	
Start date of self testing:	

If self testing; the patient is responsible for testing his/her INR. The patient is not responsible for dosing. The dosing remains the responsibility of the Anticoagulation Clinic.

Patient Self-Testing Agreement

Patient Training Record

Patient Name: _____

Trainer Name: _____

The training session is being carried out to ensure the correct use of the CoaguChek™ monitoring device. Please check off boxes to confirm the following information has been given, and sign to confirm this:

Criteria	✓
Meter Set Up	
Display check	
Date Format	
Date Setting	
Time Format	
Time Setting	
Set Test Measurement	
Beep Tone	
Therapeutic Range	
CoaguChek™ XS Test	
Storage conditions	
Handling test strip	
Calibration Code Chip	
Changing Code Chip	
Onboard Quality Control	
Sample dosing area	

Criteria	✓
Obtaining a Finger Prick Sample	
Hand washing	
Sites for taking a sample	
Time limits	
Sampling problems	
Recording Results	
Anticoagulation Record	
Memory	
Retrieving saved results	
Maintenance & Troubleshooting	
Cleaning meter	
Common error codes	
Technical support	
CoaguChek™ Patient	
Care Line:	
0808 100 7666	

Criteria	✓
Performing a Test	
Switch meter on	
Checking screen	
Insertion of test strip	
Confirm code lot number	
Strip warming	
Operation lancet	
Device components	
Removal of protective cap	
Priming device	
Depth setting	
Firing lancet	

I confirm that I have received the information on the above criteria from the above named trainer. I confirm that I should still read the user manual accompanying my CoaguChek™[®] XS device in conjunction with this training. If I require any further technical information I will ring the technical support helpline, or refer back to my Anticoagulation pharmacist/nurse specialist at the Whittington Hospital NHS Trust.

Date: _____

Patient Sign: _____

Trainer Sign: _____

Patient Self-Testing Agreement

Patient Responsibilities

1. I have a CoaguChek™[®] monitor. To ensure my own safety I agree to work in partnership with Whittington Hospitals NHS trust Anticoagulation Clinic.
2. I have been trained in the use of the CoaguChek™[®] XS meter.
3. I will perform INR tests at mutually agreed intervals and will inform the Anticoagulation Clinic of the results via the dedicated answer machine before 1 pm on the day of testing. I will leave my name; date of birth, hospital/NHS number, contact number and INR result on the answer machine.
4. I will repeat any test if my INR is less than 1.5 or greater than 5.
5. If my INR is less than 1.8 and I have a mechanical heart valve I will contact an anticoagulation pharmacist/nurse specialist via the dedicated telephone lines for advice.
6. If my INR is greater than 8 or un-recordable I will inform an anticoagulation pharmacist/nurse specialist immediately via the dedicated telephone lines.
7. I will act on the advice given by the anticoagulation pharmacist/nurse specialist with regard to dosages and test interval. I understand that the maximum permitted interval for testing is 12 weeks.
8. I understand that it is my responsibility to order supplies of test strips and finger prick lancets from the manufacturer or obtain them from clinic, as appropriate. Maintenance of the machine is also my responsibility.
9. I will dispose of used lancets, other sharps and contaminated waste carefully.
10. I will inform the anticoagulation pharmacist/nurse specialist if starting new medications (conventional and unconventional), before and after dental and surgical procedures, changes in medications/diet/alcohol/herbal remedies, missed doses, recent hospital admissions, if unwell/diarrhoea and vomiting.
11. If I do experience any unexplained or excessive bleeding or bruising I will contact the Anticoagulation Clinic for advice.

12. I will attend the Anticoagulation Clinic for follow up appointments every 6 months or sooner if the Anticoagulation Clinic requires. At all appointment I will bring my CoaguChek™[®] machine and test strips currently in use, for a comparative venous blood sample.
13. I will inform the Anticoagulation Clinic if I intend to travel abroad and self-test.
14. I will inform the Anticoagulation Clinic if I decide to stop self-testing or move house to a different area so that arrangements can be made for alternative management of my treatment.
15. I will return the CoaguChek™[®] XS machine back to the clinic once the programme is complete.

CoaguChek™ Agreement

Anticoagulation Clinic Responsibilities

1. The Anticoagulation Clinic agrees to support the above named patient with his / her self-testing provided that the conditions listed above are met.
2. The Anticoagulation pharmacist/nurse specialist will be available during normal office hours for help and advice.
3. After the patient has contacted the Anticoagulation Clinic with a result, advice on dosing will be given the same day. The patient will be only contacted by telephone if there is a dosage change within the next three days. This advice will also be confirmed with a single sheet therapy record. This will be posted first class to the patient the same day and should arrive within 3 working days.
4. The Anticoagulation Clinic will provide an external quality control by comparative testing of patient's capillary blood INR by the patients own CoaguChek™[®] meter and the Anticoagulation Clinic method (Venous testing). Patients will be sent an appointment for review every 6 months.
5. In the event that conditions are not met; the Anticoagulation Clinic will offer the patient a normal clinic service without any regard to self-testing.
6. The Anticoagulation Clinic will inform the patient's General Practitioner of his/her intentions to start self-testing, stop self-testing or of any failure to comply with this agreement.
7. The patient has received appropriate training and has been supplied with a CoaguChek™[®] patient pack.

Contact Telephone Numbers:-

**CoaguChek™[®] (Roche™) patient care line
0808 100 7666**

**For the Anticoagulation Clinic:-
020 7288 3228**

(Please leave messages on the answer machine before 1pm on weekdays only)
Anticoagulation Clinic Working Hours: Monday to Thursday 9am – 5:30pm

Anticoagulation Clinic & Patient Agreement

Signatures

The patient detailed has received the appropriate training and a copy of the agreement for self-testing their INR using a CoaguChek™[®] XS monitor. The patient agrees to abide by this agreement.

Signed on behalf of the Anticoagulation Clinic:

Print Name & Sign: _____

Date: _____

I have read and understand the self-testing agreement outlined above and agree to abide by the terms set out by the Anticoagulation Clinic. I understand that if I fail to comply with the above the Anticoagulation Clinic cannot support me with self-testing.

Patient Signature:

Print Name & Sign: _____

Date: _____

Patient Self-Testing Agreement

Record of Initial Training & month 6 Reviews

Review Date	Capillary INR (Patients own machine)	Venous INR	Comments/Issues Identified
Training 1			
Training 2			
6 month review			

APPENDIX 14: PATIENT SELF-TESTING PILOT – INVITATION LETTER AND INFORMATION SHEET



The Government Standard

**Clinical & Academic
Department**

The Whittington Hospital 

NHS Trust

Anticoagulant Clinic
Magdala Avenue, London N19 5NF

Appointments: 0207 288 3516
Advice and Information: 0207 288
5390

Fax: 0207 288 5010

e-mail: pst@whittington.nhs.uk

Dear Mr/Mrs/Miss.....

As part of an ongoing commitment to improving the quality of care we offer, the Whittington Hospital Anticoagulation Clinic is developing a new patient self-testing service. This is where those taking warfarin can test their International Normalised Ratio (INR) using a machine that they have at home instead of attending the hospital for blood tests. The INR is measured by inserting a test strip into the monitoring device, and then pricking a finger and putting a small drop of blood on the strip. Staff in clinic will advise on the dose of warfarin.

Several studies have shown that this type of anticoagulation monitoring is as safe and effective as attending hospitals for INR tests. It also gives more flexibility to patients who find it inconvenient to attend the hospital regularly for blood tests. Other hospitals that already provide this service include Barts and The London NHS Trust, University College London Hospitals NHS Trust and the North Middlesex Hospital NHS Trust.

To ensure that we are supporting patient self-testing in the best possible way, we are only opening this up small group of people in the first instance, and we would like to invite you to take part. As a first step, we will compare your INR using the patient-self-testing machine against our hospital INR testing machine to ensure that the results are similar. We will then provide full training on obtaining a finger-prick blood sample and on using the patient self testing machine. If you already own a self-testing machine, we may ask you to demonstrate that you can use it before you can self-test. We will provide information, and answer any questions that you may have about this service and how we will support you.

Following this training, you may start to test your INR at home with support from the anticoagulation clinic.

We would like to invite you to take part in this project which will last for approximately six months initially. But before you decide whether you would like to participate or not, please could you take a look at the enclosed information sheet. Once you have done this, please could you complete the attached form and return it to us with your decision as soon as possible so that training dates and times can be arranged for all participants. We look forward to hearing from you.

Best wishes,

The Anticoagulation Team
Professor David Patterson (Clinical Director)
Bridget Coleman, Sister Choi, Faiza Abdow, Sarah Davis,

**Registration form for Warfarin Self-Monitoring program starting in
early 2010**

Please complete this form and send it to the following address:

Anticoagulation Clinic - Clinic 3A Outpatients Block
Whittington Hospital
Magdala Avenue
London
N19 5NF

Full Name:

I have read and understood the information in the letter attached. I understand that self monitoring my own INR increases my responsibilities as a patient and that the anticoagulation clinic will continue to be involved in monitoring my warfarin. Please tick one of the following options.

I would like to participate in the program and am willing to undertake the training involved.

I do not wish to participate in this program.

Please add any additional comments if you would like

Please sign and date in the box below.

Signature:

Date:

INFORMATION SHEET

Who will provide the monitoring equipment?

If you do not have a self-testing machine at home already, the hospital will provide one for you with enough supporting equipment for six months. However, we cannot guarantee that you will be able to keep this machine after this six-month time period. Although the Whittington will not be able to supply test strips after the six month project is over, these strips can usually be obtained on prescription; but you will need to discuss this with your GP.

What if I already have a self-testing machine?

If you already have a self-testing machine, you need to obtain test strips and other materials from your normal source. This may be from your GP or purchasing them privately. You will use your own machine.

Who will advise me about what dosage to take and when I should next monitor my INR?

Experienced anticoagulation clinic staff who are pharmacists, nurses or doctors, will continue to give you advice about how much warfarin to take and when to measure your next INR. However it will be your responsibility to inform us of your results when you measure your INR. This can be over the phone or via email. All changes in dosage should be discussed with a member of anticoagulation staff.

How will I record my INRs?

You will be required to keep a record of each INR that you self test in your yellow book and your current dosage. You will also be expected to communicate your results to the anticoagulation clinic via email or telephone.

What will happen at the end of the six months?

It is likely that the anticoagulation clinic will be able to continue to support you self monitoring your INRs at the end of the six month period. However at the moment, we cannot guarantee that we will be able to do this.

Will I need to continue visiting the hospital clinic for anticoagulation monitoring?

You will still need to attend the hospital at the beginning and at the end of the six month period to compare your INR taken using your own machine against the hospital INR testing machine for quality control purposes. If during the six month period you do have a very high INR or an unreadable result, we suggest that you contact the anticoagulation clinic during working hours, or attend a hospital as soon as possible if this occurs outside of anticoagulation clinic hours.

Will I need to give any feedback?

As this is a new service for the hospital, we will be very keen to hear about your experiences and may ask you to fill out questionnaires or keep a diary so that we can make any necessary changes based on your views.

Will my GP be informed if I decide to take part in this service?

Your GP will be informed that you have been invited to participate in this service.

What happens if I decide that I do not want to continue to take part, or I have a problem using the self-testing machine?

You can choose not to participate at any time and your normal anticoagulation clinic will resume responsibility for testing and monitoring your INR. If you have any problem using the self-testing machine, the anticoagulation clinic will try and help you to resolve it or will ask you to take a blood sample at the hospital.

When will this start?

The exact date has not been confirmed yet, but it is expected to start in early 2010

Where do I get more information?

If you would like to have more information about self-monitoring of warfarin before you decide whether or not to take part, please visit www.anticoagulationeurope.org if you have internet access, or contact the anticoagulation clinic on 0207 2885390 and ask to speak to Faiza Abdow or Sarah Davis. Alternatively you can email us on pst@whittington.nhs.uk.

**APPENDIX 15: PATIENT SELF-TESTING PILOT –
PRE-PILOT PATIENT QUESTIONNAIRE AND
COVERING
LETTER**

The Whittington Hospital 
NHS Trust

**WHITTINGTON HOSPITAL
ANTICOAGULATION MONITORING AND
STROKE PREVENTION SERVICE**

HELPING US TO DEVELOP YOUR ANTICOAGULANT SERVICE

PATIENT SELF-TESTING

IMPORTANT: Your answers to these questions will remain confidential

Please answer the questions as completely as possible. There are no right or wrong answers. We are interested only in your personal views, so please tell us what you feel and not what you think we may want to hear.

Bridget Coleman, BSc, MSc, MRPharmS
Senior Pharmacist, Anticoagulation & Stroke Prevention Service, Whittington
Hospital
April 2010

THE BENEFITS OF SELF-TESTING

6. At this stage, what benefits do you think you will get from self-testing your INR?

CONCERNS ABOUT SELF-TESTING

7. At this stage, do you have any concerns or anxieties about self-testing?

8. On a scale of 1 to 5, how likely are you to purchase a coagulometer once this pilot has ended; 1 = very unlikely and 5 = very likely?

SUPPORTING SELF-TESTING

9. What education do you expect to receive before undertaking self-testing?

10. What support do you expect to receive from the clinic staff whilst you are self-testing?

Thank you for answering these questions!

April 2010

The patient self-testing service pilot

Thank you for taking part in this pilot scheme.

In order to find out how we can best support patient self-testing, I would like to ask you a few questions. As one of those participating in the pilot scheme, your views are important. But if you do not wish to answer these questions, you do not need to give a reason and the care you receive from us will not be affected.

Thank you for your time

Bridget Coleman, BSc, MSc, MRPharmS
Senior Pharmacist, Anticoagulation Monitoring & Stroke Prevention Service,
Whittington Hospital

**APPENDIX 16: PATIENT SELF-TESTING PILOT –
POST-PILOT PATIENT QUESTIONNAIRE AND
COVERING LETTER**

**WHITTINGTON HOSPITAL
ANTICOAGULATION MONITORING AND
STROKE PREVENTION SERVICE**

HELPING US TO DEVELOP YOUR ANTICOAGULANT SERVICE

PATIENT SELF-TESTING

IMPORTANT: Your answers to these questions will remain confidential

Please answer the questions as completely as possible. There are no right or wrong answers. We are interested only in your personal views, so please tell us what you feel and not what you think we may want to hear.

Bridget Coleman, BSc, MSc, MRPharmS
Senior Pharmacist, Anticoagulation & Stroke Prevention Service, Whittington
Hospital
February 2011

YOUR DETAILS

Your name

Date

SECTION B: ABOUT SELF-TESTING YOUR INR

1. YOUR EXPERIENCES DURING THE PILOT

1. On a scale of 1 to 5, how would you rate your experience of self-testing your INR; 1 = very positive and 5 = very negative?

2. What benefits (if any) do you think you have got from self-testing your INR?

3. Were there any benefits that you thought that you would get from self-testing but didn't happen?

4. What difficulties did you have (if any) with self-testing your INR?

2. SUPPORTING SELF-TESTING

5. Should we consider any changes to the education you received before you started self-testing?

6. Should we consider any changes to how the clinic staff support you whilst you are self-testing?

3. CONTINUING SELF-TESTING

7. Would you like to continue with self-testing after this pilot?

8. Are there any specific reasons why you wish to continue / discontinue self-testing?

9. On a scale of 1 to 5, how willing are you to purchase a coagulometer (cost = £399) now that this pilot has ended; 1 = very willing and 5 = very unwilling?

10. On a scale of 1 to 5, how able are you to purchase a coagulometer now that this pilot has ended; 1 = very able and 5 = completely unable?

4. FINAL THOUGHTS

11. Would you recommend self-testing to a friend if he / she was taking warfarin?

12. What reason would you give to your friend for doing self-testing / not doing self-testing

February 2011

The patient self-testing service pilot

Thank you for taking part in this pilot scheme.

It is important for us to learn from your experiences, and I would like to ask you a few questions. As one of those participating in the pilot scheme, your views are important. But if you do not wish to answer these questions, you do not need to give a reason and the care you receive from us will not be affected.

Thank you for your time

APPENDIX 17: PATIENT SELF-TESTING PILOT – ANTICOAGULANT CLINIC STAFF INTERVIEW GUIDE

Introduction

Thank you

Purpose = to gauge your level of agreement with the views expressed at the focus group meeting, based on your experiences with the PST pilot, and to try to address questions posed at this meeting

Section 1: Perceived problems, barriers & risks

1. Shared care with patients – much discussion about this. Questions raised ...

Are Pts honest, reliable? If self-test will they lie, misreport results?

Danger of PST patients not viewing condition seriously?

Must pt take some ownership? How enforce this? Get pt to sign disclaimer? Or use consent form

Compliance with testing – a view that the patient needs to agree to certain conditions before being admitted to programme

2. Shared responsibility between primary / secondary care

PCT reps felt that clarity on governance arrangements and relative responsibilities needed before they sign up to this

Must have agreed protocols between PCT and hospital re pt transfer

3. Loss of "value-added" service through reduced contact between professional & patients

OAT monitoring not just dose adjustment - lose other elements?

4. Logistical problems from service perspective

Is it possible to scale up from 50 pt to 1,00 or 1,500? Fear of repatriating patients back into service

Section 2: Service Redesign

5. Options appraisal

One step vs 2 step (from hospital to self testing or hospital to community and then to self testing)

Perhaps should not be thinking in first instance in whole sale migration to self-testing. Concentrate firstly on moving pts to primary care

Patient networks - share machines. Pt self-help groups – get together, help one another with testing; share machines – but would not suit all patients – perhaps best for retirees’

6. Personnel

Staffing levels / expertise / staff mix

Section 3: Service requirements

7. Patient selection

Initially, do not exclude anyone – rationale – need to see who can/cannot cope – so want as broad a group as possible.

Debate: whether pts with poor control should be excluded

8. Evaluation of patient competence

One view – must assess each pt – risk assessment

Yearly or twice yearly re-evaluation of pts (requirement); maybe retraining – part of contract (but increases cost)

9. Communication channels

eg phone helpline (?eventually done on line) – could this be automated ? use text messaging – answer questions, take readings, give advice on adjusting dose; tell patient to see doctor/nurse/pharmacist – complex record keeping system needed – chase up pts – need know when to call – what do if cannot track down pt

Must be able to accommodate pts moving back and forth between venues/providers/programmes. Eg most may start with hospital – once stable move to primary care and then to self-testing

10. Draft strategy / policy

Need to have policy (?local, national) before demand grows – need to know in principle whether affordable, scalable. Counter view – could prove a waste of time, resources.

12. Equity

How does one deal with potential inequity of service?