An investigation into international community pharmacy anticoagulation management services

Brian Kehoe

A dissertation submitted to the University of Dublin, in partial fulfilment of the requirements for the Degree of Masters in Science in Health Informatics

2013

Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university. I further declare that this research has been carried out in full compliance with the ethical research requirements of the School of Computer Science and Statistics.

Signed: _____

Brian Kehoe

2nd September 2013

Permission to lend and/or copy

I agree that the School of Computer Science and Statistics, Trinity College may lend or copy this dissertation upon request.

Signed: _____

Brian Kehoe

2nd September 2013

Acknowledgements

I would like to thank everyone that helped me during this research assignment, particularly:

I would like thank my supervisor Gaye Stephens for her support, advice and feedback during the dissertation process. I would also like to thank Dr Lucy Hederman and Mary Sharp who provided me with valuable suggestions regarding my research proposal.

I would like to thank my classmates who provided me with knowledge, support and much needed distraction during the past two years.

I would like to thank my employers for the flexibility they have afforded me during the past year.

I would like to thank my parents and friends who provided me with encouragement and advice.

And my fiancée Eimear, who was always there to listen, support, understand and help.

Abstract

Warfarin is used for the treatment and prophylaxis of venous thromboembolism which forms a vital part of the stroke prevention strategy for people with atrial fibrillation. Regular blood tests are carried out to determine the patients INR to ensure that it is within the target range. In Ireland, INR monitoring services are carried out in hospital-based clinics and in GP surgeries. In order to keep patients within their target INR range, it is often necessary to adjust their warfarin dose. The process of INR monitoring and warfarin dosage adjustment is collectively known as anticoagulation management.

The use of warfarin in Ireland is increasing due to the ageing population and that fact that a larger proportion of elderly people will require anticoagulation therapy. There must be sufficient anticoagulation management services available in order to provide safe and effective treatment in the face of this increasing demand. The demand for hospital-based services is already placing a burden on the operation of outpatient departments. It is therefore clear that an alternate model of care delivery is required to provide a high quality, safe, cost effective and convenient service to patients.

There is a trend towards utilising community pharmacies in the delivery of an enhanced range of community-based services. The provision of community pharmacy anticoagulation management services is a prime example of this. There is a growing body of evidence that demonstrates that anticoagulation management services can be delivered safely and effectively in the community pharmacy setting.

The aim of this research was to study a number of community pharmacy anticoagulation management services to determine how these services were organised and how they operated. This information was gained through a detailed literature review process and by conducting semi-structured interviews with key personnel from the identified services. The emphasis of this research was on the health information systems and services utilised in the delivery of community pharmacy anticoagulation management services.

The research identified the main components required for the establishment of a community pharmacy anticoagulation service in Ireland. The readiness of the Irish health information infrastructure to support these components demonstrated that significant work and investment would be required to enable a state-of-the-art community pharmacy anticoagulation management service to be delivered in Ireland.

Table of Contents

1 Introduction 1

1.1 Study background 1

1.2 The research question(s) 2

1.3 Research objectives 3

1.4 Motivation for selecting this topic 3

1.5 Overview of the Dissertation 5

2 Literature Review 6

2.1 Introduction 6

2.2 Anticoagulation 6

2.2.1 Warfarin 6

2.2.2 Warfarin - Mode of action 7

2.2.3 Warfarin monitoring 8

2.2.4 New oral anticoagulants (NOAC) 9

2.2.5 Atrial Fibrillation 10

2.2.6 Stroke Prevention 11

2.3 Anticoagulation Management 13

2.3.1 Anticoagulation management service 13

2.3.2 Venous Blood Sampling in Hospital Clinic 13

2.3.3 Venous Blood Sampling in Primary Care 16

2.3.4 Point of Care Testing by Healthcare Professional 16

2.3.5 Patient Self-Testing/Management 18

2.4 Health Information Systems and Services 18

2.4.1 Clinical Decision Support System 18

2.4.2 Unique Health Identifier 22

2.4.3 Health Messaging 23

2.5 Community Pharmacy Services 26

3 Methodology 27

3.1 Introduction 27
3.2 Research Method 27
3.3 Research Design 27
3.4 Role of Literature Review....28
3.5 Case Study Design....29
3.6 Inclusion Criteria....29
3.7 Semi-structured Questionnaire Design....29
3.8 Data Collection 30
3.9 Ethical Considerations 30
4 Research 32
4.1 Introduction 32
4.2 Research Process....32
4.3 Case Study 1: Cloyne Pharmacy Anticoagulation Clinic, Ireland 33
4.3.1 Service Background....33
4.3.2 Health Information Systems....33
4.3.3 Service Evaluation....36
4.4 Case Study 2: North Central London Community Based Anticoagulant and Stroke Prevention Services, UK 37
4.4.1 Service Background....37
4.4.2 Health Information Systems....37
4.4.3 Service Evaluation....46
4.5 Case Study 3: Community Pharmacy Anticoagulation Management Service, New Zealand....47
4.5.1 Service Background....47
4.5.2 Health Information Systems....48
4.5.3 Service Evaluation....56
5 Analysis and Evaluation....57
5.1 Introduction 57

5.2 Case Study Analysis.....57
5.2.1 CDSS.....57
5.2.2 UHI.....59
5.2.3 Health Messaging.....60
5.3 Warfarin services in Ireland.....62
5.4 Health Information Systems and Services in Ireland.....64
5.4.1 CDSS.....64
5.4.2 Unique Health Identifier.....65
5.4.3 Health Messaging.....67
5.5 Potential for Community Pharmacy Anticoagulation Management Service in Ireland 69
5.6 Evaluation.....72
6 Conclusions and Future Work.....73
6.1 Introduction.....73
6.2 Research Findings.....73
6.3 Gap Analysis.....73
6.4 Limitations of the Study.....74
6.5 Recommendations for Future Work.....75
6.6 Reflections on the Study.....75
7 References.....76
Appendix 1 – Interview Themes for Semi-structured Interviews.....94
Appendix 2 – Cloyne Pharmacy Anticoagulation Clinic, Ireland.....96
Appendix 3 – North Central London Community Based Anticoagulant and Stroke Prevention Services, UK.....105
Appendix 4 – Community Pharmacy Anticoagulation Management Service, New Zealand.113

List of Figures and Illustrations

Figure 2-1 Impact of standards on interfaces.....25
Figure 2-2 HL7 v2.x message structure 26
Figure 4-1 Clinic Visit Details screen in Access CDSS (Left) and Initial web-based CDSS (Right) .39
Figure 4-2 HeartBeat Anticoagulation Plan Screen.....41
Figure 4-3 Overview of NHS Care Record Spine 43
Figure 4-4 Conceptual overview diagram of the N3 network 45
Figure 4-5 Summary of Testing Process 49
Figure 4-6 INR Online Dose Calendar.....50
Figure 4-7 Connected Health 3 Tier Model 53
Figure 4-8 Integrated Healthcare Model.....55
Figure 5-1 Example of how IHI service could be structured.....66
Figure 5-2 Service Model Diagram.....69

Abbreviations

AC	Anticoagulation
AF	Atrial Fibrillation
AJAX	Asynchronous JavaScript and XML
AMS	Anticoagulation Management Service
ANSI	American National Standards Institute
API	Application Programming Interface
BCSH	British Committee for Standards in Haematology
CDA	Clinical Document Architecture
CDSS	Clinical Decision Support System
CEN	European Committee for Standardization
CGB	Clinical Governance Board
CHIME	Centre for Health Informatics and Multiprofessional Education
COPD	Chronic Obstructive Pulmonary Disease
CORU	Clinical Operational Research Unit
CUH	Cork University Hospital
CVA	Cerebrovascular Accident
DHB	District Health Boards
DPS	Drugs Payment Scheme
DVT	Deep Vein Thrombosis
ED	Emergency Department
EHR	Electronic Healthcare Record
EPR	Electronic Patient Record
GEHR	Good European Health Record
GMS	General Medicines Scheme
GP	General Practitioner
GPIT	General Practice Information Technology
HCP	Health Care Professional
HF	Heart Failure
HIMSS	Healthcare Information and Management Systems Society
HIQA	Health Information and Quality Authority
HISO	Health Information Standards Organisation
HIT	Health IT
HL7	Health Level Seven International

HSE	Health Service Executive
HWNZ	Health Workforce New Zealand
ICGP	Irish College of General Practitioners
ICT	Information and Communications Technology
IHI	Individual Health Identifier
INR	International Normalised Ratio
ISI	International Sensitivity Index
ISO	International Organization for Standardization
MRN	Medical Record Number
N3	National Network for the NHS
NCAT	National Centre for Anticoagulation Training
NCHD	Non Consultant Hospital Doctor
NCI	National Client Index
NCLASPS	North Central London Community Based Anticoagulant and Stroke Prevention Services
NCP	National Clinical Programme
NEQAS	National External Quality Assessment Scheme
NHI	National Health Index
NHS	National Health Service
NIMIS	National Integrated Medical Imaging System
NOAH	NHI Online Access for Health
NPSA	National Patient Safety Association
NZHIS	New Zealand Health Information Service
OAT	Oral Anticoagulant Therapy
ODP-RM	Open Distributed Processing Reference Model
OSCE	Objective Structured Clinical Examination
PACS	Picture Archive and Communication System
PCRS	Primary Care Reimbursement Service
PDS	Personal Demographics Service
PMS	Practice Management System
POC	Point-of-Care
POCT	Point of care Testing
PORT	Prevention of Stroke Patient Outcomes Research
PSI	Pharmaceutical Society of Ireland

PSNZ	Pharmaceutical Society of New Zealand
PT	Prothrombin Time
SCSS	School of Computer Science and Statistics
SDO	Standards Development Organisations
SOP	Standard Operating Procedures
SynEX	Synergy on the Extranet
SynOD	Synapses Object Dictionary
SynOM	Synapses Object Model
TMS	Transaction and Messaging Service
TTR	Therapeutic Time in Range
UC	Usual Care
UCC	University College Cork
UCL	University College London
UHI	Unique Health Identifier
UPI	Unique Patient Identifier
VKA	Vitamin K Antagonist
VOIP	Voice Over IP
VPN	Virtual Private Network
WHO	World Health Organisation

1 Introduction

1.1 Study background

The delivery of health screening services such as blood pressure and cholesterol measurements is an established part of many community pharmacies both in Ireland and internationally. These point-of-care (POC) tests are relatively simple to carry out and give the general public information on certain aspects their health status. Technological advances mean that tests which previously required a sample to be taken from the patient and sent to a laboratory for analysis can now be carried out as a point-of-care service. From an international perspective, one of the innovations in this area is the delivery of point-of-care testing for patients on warfarin therapy through community pharmacies (Amruso 2013).

Warfarin is the most commonly prescribed oral anticoagulant therapy (OAT) worldwide (Stafford *et al* 2011). It is used for the treatment and prophylaxis of venous thromboembolisms and for the prevention of stroke in patients who have been diagnosed with atrial fibrillation (AF) and in patients who have mechanical heart valves (Keeling *et al* 2011). Warfarin alters the physiological process of blood coagulation thus reducing the chance of clot formation. The time taken for a patient's blood to clot is measured by international normalised ratio (INR) and the usual target range for patients on warfarin therapy is between 2.0 and 4.0 (Ryan *et al* 2008).

Patients who are on warfarin therapy require a high level of monitoring from healthcare professionals. This is due to the fact that warfarin has a narrow therapeutic index, has many drug and food interactions and its clinical effects can be altered by co-morbidities. It is estimated that approximately 57,000 people are currently receiving warfarin therapy in Ireland (Ryan *et al* 2008; Marsden and Smyth 2012). In the usual care (UC) model the patients on warfarin therapy are required to attend hospital clinics on a regular basis for venous blood tests and dosage adjustment. The frequency of these visits can vary from every week to every 4-6 weeks depending on their current level of control. The advent of near patient testing has enabled anticoagulation management to move away from models utilising venous blood sampling which requires laboratory testing and enables anticoagulation management to take place in non-traditional settings such as community pharmacies.

A recent meta-analysis looking at the quality of warfarin control in the US found that specialised warfarin clinics achieved therapeutic INR in only 63% of their patients and the

remainder, some 37%, were either under or over anticoagulated (Zabinski and Valley 2009). Many observational studies have shown that OAT is frequently underused in AF patients in daily practice, with reported percentages of OAT prescription between 30 and 60% (Nieuwlaat *et al* 2006). In New Zealand, the outcomes of a pilot program of a Community Pharmacy Anticoagulation Management Service (CPAMS) demonstrate a model of care that pharmacists can deliver to improve health outcomes for patients. The Pharmaceutical Society of Australia strongly believes it would be timely to have an expanded trial in Australia of a pharmacist-led service in the community pharmacy setting. This would operate in collaboration with general practitioners to provide patients with warfarin management services (Pharmaceutical Society of Australia 2011).

In a systematic review which examined organisational strategies to improve patient care, it was found that professional performance could be improved by altering a number of features within the healthcare system. A major outcome was that the use of computer systems could facilitate revised roles for allied healthcare professionals by providing access to extended knowledge bases. It was also found that integrated care services which included multidisciplinary teams and computer systems improved patient outcomes and improved cost effectiveness of service delivery (Wensing *et al* 2006).

The purpose of this research is to analyse international community pharmacy anticoagulation management services and review the approach taken in the development of the various services. It will also be necessary to investigate the health information systems required to enable a safe, scalable system to be put in place in Ireland. This includes health information systems required for the delivery of the service and also health information systems required to enable an integrated care service to be provided in conjunction other healthcare professionals. This will be based on knowledge gained from Irish and international sources and domain experts that will determine a suitable template for the Irish healthcare system.

1.2 The research question(s)

The goals for this dissertation were to produce an article of research which would contribute to the body of knowledge in this area, to utilise the author's professional experience and to research an area which is of interest to the author.

After a period of reflection and preliminary research, the research topic which emerged was:

What lessons can be learned from the international experience to assist the development of suitable health information support services for a community pharmacy anticoagulation management service in Ireland?

This primary research question then led to a number of additional research questions:

- What is the current state of anticoagulation management services in Ireland?
- What is the current state-of-the-art in relation to anticoagulation management services delivered through community pharmacies internationally?
- What health information services are in use internationally in community pharmacy anticoagulation management services?
- How could Ireland's current health information infrastructure support the delivery of a community pharmacy anticoagulation management service?

1.3 Research objectives

The objectives of this research are to initially complete a thorough literature review covering the areas of anticoagulation and current anticoagulation management models, the development and expansion of community pharmacy services and the operation of community pharmacy anticoagulation management services on a national and international level. A number of suitable case studies will be identified from the initial literature review according to defined inclusion criteria and extensive background research will be carried out to gain an understanding of the organisation and operation of these services. Interviews will then be conducted with representatives of these services to develop a specific understanding of each service guided by the interview themes which were submitted as part of the ethics approval process. The knowledge and understanding gained from the literature review, detailed case studies and interviews will then be used to draw conclusions as to how a community pharmacy anticoagulation service could operate in Ireland and what health information support services would be needed to facilitate such a service.

1.4 Motivation for selecting this topic

Technological advancements have increased the complexity of tests which can be provided as a POC service. These include INR testing, which is a measurement used in the management of patients on warfarin therapy (Best Practice Journal 2009) and HbA1c testing, which is a

measurement used to assess the control of blood sugar levels in diabetic patients over a number of months (Papastergiou *et al* 2012).

A number of countries have anticoagulation management services which are delivered through community pharmacies and lessons learned from the experience of these services could influence the development of similar services in Ireland. There is a small scale example of an anticoagulation management service running in one pharmacy in Ireland at present (Walsh 2012). The development of this service could also provide valuable lessons from an Irish context. The recent development of the community pharmacy anticoagulation management service in New Zealand could also provide valuable lessons on how the service is structured, operated and monitored. Following on from an initial pilot of 16 pharmacies (Health Workforce New Zealand 2011), a nationwide service began to roll out during 2012. A report was commissioned to analyse the operation of the pilot service and it found that the community pharmacy anticoagulation management service showed positive performance in the areas of cost-effectiveness, safety and efficacy (Shaw, Harrison and Harrison 2011). These services provide convenient access to patients who already attend the pharmacy on a monthly basis to collect warfarin.

The electronic systems used to support the delivery of CPAMS in the various international locations deviate from the optimal standards from a HI point of view e.g.: use of fax and email to transmit results between pharmacies and GP's (Jackson *et al* 2005; Shaw, Harrison and Harrison 2011). By identifying these inadequacies, it provides opportunities to specify a model for the delivery of an Irish service which ensures privacy, safety and interoperability.

The Health Service Executive (HSE) outlined a number of deliverables in the National Clinical Care Programme for Stroke Prevention in 2012. One of the deliverables in terms of quality was to "Increase anticoagulation in known atrial fibrillation" (HSE 2012a). Patients taking warfarin require access to testing services to ensure they do not experience under-dosing or over-dosing events. It has been seen that warfarin may underutilised where access to INR monitoring services is not sufficient. (Jackson *et al* 2004)

Current HSE strategy is to treat patients at the lowest complexity of care within the Irish health system and requires that patients have access to services outside of secondary care where possible. This allows the secondary care resources to be utilised for complex cases where specialist care is required. However, the facilities need to be available for the routine care of patients in the primary care setting. GP's are facing an increased workload due to the focus on

moving patients from secondary to primary care. This workload is set to increase with government plans to provide free GP care to the entire population. This provides an opportunity for community pharmacies to facilitate the needs of patients on warfarin therapy. There has already been expansion of the services provided by community pharmacies with the introduction of programmes such as provision of emergency hormonal contraception and the delivery of the winter influenza vaccination service (HSE 2011, 2013a). These programmes demonstrate the confidence the health service authorities have for the community pharmacy sector and this could be built on with the introduction of a CPAMS.

1.5 Overview of the Dissertation

This chapter has outlined the study background, the research question, the research objectives, the motivation for the research, and an overview of the research.

Chapter 2 presents the literature review. It first addresses the broad area of anticoagulation and warfarin in particular. It then provides a detailed view of anticoagulation management and models of anticoagulation management service delivery. Finally it covers the area of health information systems which are used in the delivery of community pharmacy anticoagulation management services.

Chapter 3 provides details on how the research was carried out including the research method and research design which outline why a triangulated mixed method approach was used. The questionnaire and case study design is discussed along with the data collection process.

Chapter 4 presents the results of the three case studies. The case studies provide a detailed analysis of each of the services presenting the information assimilated from the available literature and from the interview process. The case studies focus on the background environment which enabled the service development, the operation of the service and the health information systems which are used to support service delivery.

Chapter 5 discusses the results of the case studies and examines what comparisons and implications can be made in the context the current Irish health service.

Chapter 6 concludes the dissertation by examining the potential for a Community Pharmacy Anticoagulation Management Service in Ireland, the limitations of the study and identifies possible future research work in this area.

2 Literature Review

2.1 Introduction

The objectives of the literature review were outlined in section 1.5 where the topics of interest including anticoagulation, warfarin, anticoagulation management, models of anticoagulation management service delivery and health information systems were introduced. The literature review enabled an emergent understanding of the broad subject area and provided an insight into the components required for the delivery an anticoagulation management service.

2.2 Anticoagulation

Anticoagulants are agents used to interfere with the usual process of coagulation or clotting which occurs naturally to blood. Anticoagulants are given in situations where there is a history or a risk of abnormal clotting. The two major classes of anticoagulants are distinguished from each other according to their method of administration, parenteral or enteral. Parenteral agents are administered by injection and are generally used for treatment and short-term prophylaxis of venous thromboembolism (Joint Formulary Committee 2012). Enteral agents are administered orally and this form of treatment is often referred to as oral anticoagulant therapy.

2.2.1 Warfarin

Warfarin is the most commonly prescribed OAT in the world and is used in the prophylaxis of venous and pulmonary embolism (PE) (Wardrop and Keeling 2008). Warfarin is a member of the Coumarin family of anticoagulants, which also includes acenocoumarol and dicoumarol. These agents all target the action of Vitamin K which is involved in the coagulation cascade (Jones 2008). For the purpose of this research the terms OAT, oral anticoagulant and Vitamin K antagonist (VAK) are understood to refer to warfarin.

Warfarin was not developed through the drug discovery process that yields many of the modern drugs in use today. The research that eventually led to the discovery of warfarin was focused on investigating the cause of haemorrhagic events in North American livestock during the 1920's (Wardrop and Keeling 2008). The biochemist Karl Paul Link began to study the phenomenon of uncoagulated blood from cattle who died of sweet clover disease and in 1940, after 5 years of research, the molecule dicoumarol was synthesised which finally proved the structure of the natural anticoagulant (Campbell and Link 1941).

Further work was carried out by the biochemist Link and a number of his researchers into synthesising agents similar to dicoumarol. In 1948, Link and his colleagues produced a potent anticoagulant which they named Warfarin after the sponsors of the research, Wisconsin Alumni Research Foundation and the coumarin family of compounds they were studying (Link 1959). Warfarin immediately began to be used as a rat poison but did not become used in clinical practice for a number of years. The use of warfarin as an anticoagulant could not be justified until a predictable and safe method to reverse its anticoagulant effects could be found (Wardrop and Keeling 2008).

During the 1940's a number of clinical trials demonstrated that predictable reversal of warfarin-induced anticoagulation could be produced in humans by the administration of Vitamin K. One of the main events that helped warfarin to be viewed as a therapeutic agent rather than a rodenticide was when it was given to President Dwight Eisenhower following a myocardial infarction. This helped to change attitudes towards warfarin which then began to be viewed as an important therapeutic agent (Wardrop and Keeling 2008).

2.2.2 Warfarin - Mode of action

Warfarin began to be used as a therapeutic agent in the 1940's however its exact mechanism of action was not proven until 1978. Research carried out by Whitlon et al demonstrated that warfarin inhibits an enzyme which converts oxidised Vitamin K back into the regular form of Vitamin K required for the activation of clotting factors. Without this supply of Vitamin K, the clotting factors cannot be converted to their active forms and the ability of blood to coagulate is reduced. In order to reverse the action of warfarin, Vitamin K is administered which allows the activation of clotting factors thus reducing the risk of haemorrhage (Whitlon *et al* 1978).

It has been shown that warfarin has two desirable characteristics for a clinical anticoagulant, a rapid onset of action and simple method to reverse anticoagulant effect. These characteristics have led to warfarin becoming the most commonly used oral anticoagulant in the world. However, warfarin also has a number of characteristics which make it a very clinically complex agent to manage. Warfarin has a narrow therapeutic range which means that there is only a small dosage range that spans no effect, desired therapeutic effect and undesired adverse effects. If too low a dose is given then the patient will become under-anticoagulated which can lead to the formation of thrombosis which can cause death. If too high a dose is given the will become over-anticoagulated which can cause haemorrhage which can also cause death. This is the reason patients taking warfarin require frequent monitoring to measure their anticoagulation state (Keeling *et al* 2011).

There is considerable variation in the clinical effect of warfarin between individuals. This variability is due to a number of compounding factors including genetic differences, other medication and diet. The largest source of variation in response to warfarin therapy is due to the fact that warfarin has a very large number of drug-drug interactions. Warfarin has more documented number of drug interactions than any other licensed medication (Baxter 2013). These interactions interfere with expected degree of anticoagulation and it has been found that drug interactions have been cited as the most frequent cause of over-anticoagulation in patients receiving warfarin therapy (Ouirke *et al* 2007).

The dietary effects on the action of warfarin within the body are divided into two categories. The first category is foods and herbal products which directly alter on the effect of warfarin within the body. These products can cause clinically significant interactions by either potentiating the effect of warfarin (e.g. Grapefruit, Mango, Fenugreek, Alcohol) or inhibiting the effect of warfarin (e.g. Avocado, Ginseng). The second category is foods which contain a large amount of Vitamin K (e.g. most green leafy vegetables – Broccoli, Cabbage). Vitamin K antagonises the effects of warfarin and therefore eating large quantities of these foods can alter the anticoagulant effect. Clinical guidelines indicate that these products can be consumed by patients on warfarin therapy but that consumption should not vary greatly over time. This is because the interactions will be accounted for when a stable INR is achieved but varying the consumption of one of these products after this could lead to an INR which is outside the therapeutic range (Holbrook *et al* 2005).

The standard method of managing the variation in individual response to warfarin is to carry out regular blood testing to determine the individual pharmacological effect. The initiation of treatment with warfarin is when the patient is at greatest risk of adverse events including under and over-anticoagulation. Therefore, testing is most frequent during the first three months of warfarin treatment (Holbrook *et al* 2012).

2.2.3 Warfarin monitoring

In order to be able to provide the correct level of anticoagulation for a patient, it is necessary to be able to accurately measure the therapeutic effect of warfarin. When warfarin was first used clinically as a therapeutic agent in the 1950's, the prothrombin time (PT) was the laboratory standard to measure the clotting time of blood. Measuring the PT involved the addition of thromboplastin, which is a protein involved in the coagulation cascade, to a blood sample and determining how long the coagulation process took.

The issue with using PT to assess the clinical effect of warfarin is that thromboplastin is a natural agent and considerable variation in PT was seen with the source of the thromboplastin. It was not possible to compare PT measured using thromboplastin produced by different laboratories or even between different batches produced by a single laboratory. The need for a new method of measuring the effect of warfarin was recognised in order to produce the desired level of anticoagulation in a safe and repeatable manner.

The World Health Organisation (WHO) in conjunction with Kirkwood devised a method to standardise the measurement of blood coagulation (Kirkwood 1983). Firstly, they made it possible to compare thromboplastin produced by different manufacturers by introducing a value called the International Sensitivity Index (ISI). The WHO defined an international reference preparation of thromboplastin and defined the ISI of this preparation as 1.0. Manufacturers around the world were then required to calculate the ISI of their individual preparations of thromboplastin to indicate the sensitivity of the thromboplastin relative to the reference preparation.

Secondly, to standardise variations which may occur due to the local testing systems, the prothrombin ratio is calculated. The prothrombin ratio is calculated by testing the blood plasma of people not taking warfarin against the blood plasma of patients taking warfarin in parallel with the local reagent and reference thromboplastin (Hobbs and Fitzmaurice 1999).

$$\text{INR} = [\text{Prothrombin Ratio}]^{\text{ISI}}$$

The result of this equation is known as the International Normalised Ratio (INR) and can be used to reliably compare the degree of anticoagulation from tests conducted anywhere in the world. A person who is not receiving anticoagulant therapy would be expected to have an INR of 1.0. Anticoagulant therapy increases the time it takes for a person's blood to clot and therefore therapeutic goals would often aim for an INR of between 2.0 and 4.0 (World Health Organization Technical Report Series 1983).

2.2.4 New oral anticoagulants (NOAC)

As has been noted earlier, warfarin is the most widely used oral anticoagulant in the world and has been in routine clinical use for almost 60 years. However, warfarin is not without its drawbacks such as genetic variability of effect, drug and dietary interactions and the requirement for frequent monitoring. These limitations have led to the underuse of warfarin in patients where therapy is indicated (Alberts *et al* 2012). These facts prompted the

development of a new generation of anticoagulants which could overcome the limitations presented by warfarin therapy. These new agents specifically target thrombin (Dabigatran) or factor Xa (Rivaroxaban, Apixaban). Targeting these specific elements of the coagulation cascade has led to the creation of agents that have predictable anticoagulation effects with limited drug and dietary interactions. These factors remove the need for regular monitoring of the anticoagulant effect that is being produced on a patient specific basis (Alberts *et al* 2012). However, these agents are also not without their disadvantages.

From a clinical perspective, some of the disadvantages such as the requirement for twice daily dosing with dabigatran versus once daily dosing with warfarin are not very serious. Others such as underdeveloped methods of characterising the anticoagulation produced by these agents and potential for adverse events when used in patients with renal insufficiency are factors which must be considered when deciding on anticoagulant therapy for certain groups of patients. One of the most serious disadvantages is that there is no agent available which will reverse their anticoagulant effects. If serious haemorrhagic events occur with a patient, there is no method to stop the anticoagulant effect other than to wait until their pharmacological effects wear off. This is compared to warfarin where the anticoagulant effect can be easily reversed with the administration of Vitamin K. These newer anticoagulants are also much more expensive than warfarin therapy even when the costs of monitoring are included (Deedwania 2013).

At present there are three new generation anticoagulants which are licensed for use in Ireland; Dabigatran (Pradaxa®), Rivaroxaban (Xarelto®) and Apixaban (Eliquis®) (Irish Pharmaceutical Healthcare Association 2013). Only dabigatran and rivaroxaban are eligible for reimbursement under the community healthcare schemes such as the General Medicines Scheme (GMS) and Drugs Payment Scheme (DPS). Both dabigatran and rivaroxaban were initially given negative assessments for reimbursement by the National Centre for Pharmacoeconomics for the prevention of stroke in atrial fibrillation. Following these initial evaluations the manufacturers of both agents submitted new applications with a reduced price and positive assessments were made (National Centre for Pharmacoeconomics 2012a, 2012b).

2.2.5 Atrial Fibrillation

Warfarin is indicated for the treatment and prophylaxis of venous thromboembolism, which is a blood clot which forms within a vein. Warfarin is primarily used for the prevention of stroke in patients who have been diagnosed with atrial fibrillation and also in patients who have mechanical heart valves (Keeling *et al* 2011). Atrial fibrillation is a condition which is

characterised by a cardiac arrhythmia or irregular heartbeat. There are a number of possible causes for atrial fibrillation including coronary artery disease, atrial fibrosis, valvular disease and hyperthyroidism. The presence of this arrhythmia may not cause any physical symptoms but may disrupt the normal flow of blood through the heart. It is estimated that up to 40,000 Irish people have atrial fibrillation. The prevalence of atrial fibrillation rises from approximately 0.2% under the age of 45 years to 2.5% between 65 and 69 years to almost 10% in those aged 80 years (Mahmud *et al* 2007). Ireland has an ageing population and thus the number of people with atrial fibrillation will increase in the future as the average age of the population increases.

The irregular heartbeat caused by atrial fibrillation results in the incomplete expulsion of blood from the chambers of the heart. The blood which is not expelled then has a greater risk of coagulating due to its increased level of stagnation. If a blood clot occurs in the heart, it can travel through the circulatory system until it reaches a blood vessel which is too small to pass through. This causes the blood vessel to become blocked, cutting off the circulation to the surrounding tissues. When a blood vessel in the brain becomes blocked it is termed a cerebrovascular accident (CVA) or stroke. This can cause permanent neurological damage, which generally affects one side of the body or death (Alberts *et al* 2012).

Treatments targeted at either rhythm or rate control can be used to restore normal cardiac function in patients with atrial fibrillation (Nieuwlaat *et al* 2006; Bajpai *et al* 2008). Stroke prevention is the other main treatment goal and is achieved through the use of anticoagulant and antiplatelet therapy. Warfarin is the most commonly prescribed anticoagulant in atrial fibrillation but the new oral anticoagulants such as Dabigatran, Rivaroxaban and Apixaban have also been licensed for use in atrial fibrillation (National Medicines Information Centre 2006). Antiplatelet therapy involves the use of aspirin to prevent the aggregation of platelets and thus reduces the risk of clot formation. Antiplatelet therapy is generally used where there are contraindications to the use of anticoagulants (Bajpai *et al* 2008).

2.2.6 Stroke Prevention

The proportion of the population with atrial fibrillation has been estimated to be between 0.4 – 1.3% (National Medicines Information Centre 2006; Marsden and Smyth 2012). The overall number of people with atrial fibrillation has increased as the demographics of the country have shifted. However, the number of atrial fibrillation patients being treated with oral anticoagulant therapy has increased significantly in the past three decades. Warfarin has been used since the 1950's for the treatment and prophylaxis of venous thromboembolism but its

significance in the prevention of stroke associated with atrial fibrillation was not completely understood until the 1990's. The Agency for Health Care Policy and Research in the US commissioned the Prevention of Stroke Patient Outcomes Research (PORT) study in 1991 to assess strategies for stroke prevention. They took the unprecedented step of publishing certain findings in 1995, before the study had been completed. The study had found that expanded use of warfarin could halve the 80,000 strokes that were caused every year by atrial fibrillation which would result in an annual saving of $600 million (Agency for Health Care Policy and Research 1995).

Further research has been carried out to quantify the reduction in risk of stroke by prescribing anticoagulants to patients with atrial fibrillation. It was found that warfarin reduced the risk of stroke by 64% compared to placebo (Zabinski and Valley 2009). It has also been shown that the benefit produced by warfarin in patients with atrial fibrillation increased with age (Mant J, Hobbs FD, Fletcher K 2007). The risk of peripheral thromboembolism in atrial fibrillation increases from 1.5% in patients aged under 60 and rises to 24% in patients aged over 80. The risk of the peripheral thromboembolism causing a stroke is dependent on the patients other cardiovascular risk factors and on their history of stroke. People over 80 years old are at the greatest risk of developing atrial fibrillation and also at the greatest risk of developing a peripheral thromboembolism which could lead to a stroke (Wolf PA, Abbott RD 1991).

Despite the clear risk of stroke in atrial fibrillation and the clear benefits of using anticoagulants in these patients, there are still a large proportion of these patients who are not receiving anticoagulation therapy (Department of Health and Children 2010). Data from European and UK studies have found that only between 30-60% of appropriate patients with atrial fibrillation have been prescribed oral anticoagulants. The lowest use of anticoagulants is seen in patients over 80 years of age who are at the greatest risk of stroke (Nieuwlaat *et al* 2006; Jones 2008).

There are a number of compounding factors which may indicate why in the face of such overwhelming evidence anticoagulant therapy is not used to its full extent. As discussed previously, warfarin has a large number of interactions with other medicines. There is a clear link between the number of medicines a patient has been prescribed and their age. Elderly patients with atrial fibrillation are more likely to have been prescribed polypharmacy. Therefore doctors may choose to withhold anticoagulant therapy due to the increased likelihood of interactions with warfarin which could cause adverse bleeding events (Montamat *et al* 1989; Spinewine *et al* 2007). Elderly patients are also intrinsically more sensitive to

warfarin and this can cause difficulties when initiating warfarin therapy when a steady-state dose needs to be achieved (Deedwania 2013).

Patients taking warfarin require access to testing services to ensure they do not experience under-dosing or over-dosing events. It has been seen that warfarin may be underutilised where access to INR monitoring services is not sufficient (Jackson *et al* 2004). The access to anticoagulation management services is vital to ensure that prescribers can confidently commence warfarin therapy where it is clinically necessary. The organisation and operation of anticoagulation management services will be discussed in the next section.

2.3 Anticoagulation Management

It has been seen from the previous section that due to the complex nature of warfarin, patients require regular monitoring and dosage adjustment. This involves a number of distinct processes which are collectively known as an anticoagulation management service (AMS).

2.3.1 Anticoagulation management service

The elements which make up an anticoagulation management service are blood sampling, INR measurement, result analysis, dosage calculation and clinical management. Depending on the setting where the anticoagulation management service takes place, these distinct tasks can be carried out by one healthcare professional or by a number of healthcare professionals and scientists/technicians.

The main differentiation in terms of anticoagulation management services is the process by which the blood samples are collected and analysed. The traditional method relies on phlebotomy to obtain a venous blood sample which is then sent to a laboratory where the INR is calculated and reported back. The more modern method relies on point of care testing where a finger-prick blood sample is obtained and tested in the vicinity of the patient using a portable meter (Jones 2008).

2.3.2 Venous Blood Sampling in Hospital Clinic

Anticoagulation management services in outpatient hospital clinics utilise phlebotomy and laboratory services in the delivery of care. The outpatient anticoagulation clinics were developed to provide a structured and organised service to cater for the needs of patients living in the community setting. Outpatient anticoagulation clinics can be run by a combination of nurses, doctors and pharmacists. The venous blood sample is extracted into sample collection tube containing sodium citrate which prevents the immediate coagulation of the

blood. The sample is then sent to the hospital laboratory where it is centrifuged to separate the plasma. The plasma sample is then placed on the coagulometer and the thromboplastin is added. The time taken for the sample to coagulate is measured and the INR is then calculated (Gardiner *et al* 2005). The patients then wait until the results are delivered to the doctor who calculates any necessary dosage adjustments and writes the warfarin prescription (Potts *et al* 2011).

An important aspect of the laboratory testing process is ensuring that quality assurance measures are strictly adhered to. The potential for variation in test results due to local testing procedures and the particular thromboplastin in use have been outlined in the previous section. In order to ensure that results obtained are consistent within a laboratory and between laboratories there are internal and external quality assurance systems in place. Internal quality assurance is used to verify that the consistent results are produced in the laboratory over a period of time while external quality assurance is used to verify that the results produced by one laboratory are consistent with the results produced by other laboratories. Internal quality assurance involves quality control measures which incorporate checking the laboratory equipment and reagents used in the testing process. External quality assurance schemes are also available such as the National External Quality Assessment Scheme (NEQAS) which operates in England (NEQAS 2013). These schemes involve laboratories testing the same sample and the results are analysed centrally. If the results of one laboratory are outside the mean result achieved by the other laboratories, it is an indication that the testing procedures need to be audited to determine the source of the discrepancy (Ryan *et al* 2010).

Prior to the establishment of dedicated anticoagulation clinics, there was no structured delivery of anticoagulation services in the hospital environment. Due to the lack of knowledge and experience in the clinical effects of warfarin, anticoagulant therapy was only initiated on an in-patient basis (Udall 1962). As doctors became more experienced in the management of anticoagulation, warfarin therapy began to be initiated on an outpatient basis. Patients requiring anticoagulant therapy came under the care of a doctor from an established hospital service such as the general medical clinic or subspecialty clinics often in the area of cardiology. This practice provided a poor standard of anticoagulation management as patients often saw different doctors when they attended the hospital and the organisational structures for dealing with patients on long-term anticoagulation therapy were not available (Chiquette *et al* 1998).

It was recognised as early as the 1950's that in order to provide an optimum standard of care, patients on warfarin should be managed in what were termed Long Term Anticoagulation Clinics. Askey and Cherry stated that successful anticoagulation therapy depended on "an essential triad: a vigilant physician, a cooperative patient and a readily available, reliable laboratory". The goal was to have highly trained physicians providing continuity of anticoagulation management in a uniform manner. However, there were often poor levels of anticoagulation control as it was generally inexperienced doctors who frequently rotated between specialities that were responsible for the calculation and prescription of anticoagulation therapy. Poor adherence to paper-based guidelines and frequent dosage errors provided an unsatisfactory service for patients and caused frustration for senior doctors and hospital authorities (Askey and Cherry 1950; Chiquette *et al* 1998).

As the number of patients on anticoagulation therapy increased, methods to improve the level of anticoagulation control were investigated. The development of clinical decision support systems (CDSS) enabled anticoagulation management clinics to be run in a rigorous and consistent manner. The use of CDSS enabled less experienced practitioners to make informed judgements about anticoagulation therapy as the system would give automatic dose adjustment recommendations based on the patient's target INR, current test results and in-built treatment guidelines. The use of CDSS improved the level of anticoagulation control and has been shown to provide superior INR control when compared with experienced anticoagulation practitioners (Vadher *et al* 1997; Hennessy *et al* 2000).

The success of anticoagulation clinics which utilised CDSS to inform warfarin dosing decisions led to the evolution of the current anticoagulation clinics which are staffed by a range of healthcare professionals. Anticoagulation clinics run by nurses and pharmacists with appropriate training in anticoagulation management and using CDSS have been shown to provide an excellent standard of INR control (Lalonde *et al* 2008; Marsden and Smyth 2012). Patients attend the anticoagulation clinic where they have a consultation with an anticoagulation practitioner and a sample of blood is drawn. The patient is then free to leave the clinic and the results are communicated to the patient by telephone or by posting out their warfarin book which details their dosage until the next appointment. The majority of patients in Ireland are initiated on warfarin by hospital-based prescribers rather than their GP. This is the most common model of anticoagulation management service in Ireland and deals with large numbers of patients on a regular basis. These clinics provide a high standard of care and

are the gold standard against which other services are measured (Mahmud *et al* 2007; Marsden and Smyth 2012).

2.3.3 Venous Blood Sampling in Primary Care

General practitioners also provide anticoagulation management services by obtaining venous blood samples in the primary care setting. Practice nurses generally provide the phlebotomy service and the samples are then sent to a remote laboratory which is often in a nearby hospital where the INR is determined. There is an inevitable time delay in this process due to the fact that the samples must be transported from the GP surgery to the laboratory and then the test results have to be communicated back to the surgery. The GP will then interpret the result with or without the use of CDSS and will communicate the current warfarin dose to the patient. Studies have demonstrated that this method of anticoagulation management tends to deliver poorer therapeutic control with lower time in therapeutic range and greater incidence of thrombotic and bleeding events than dedicated anticoagulation management clinics. This may be due to the fact that the delay introduced by the need to physically transport the blood samples can have potentially serious implications in cases where patients have high INR's (Garwood *et al* 2008). It has also been found that GP's tend to underutilise thromboembolic prophylaxis, including warfarin. This is especially prevalent in elderly patients over 75 years of age and may be due to the fact that these patients are at a greater risk of adverse events with anticoagulation therapy than the general population (Mahmud *et al* 2007). Large numbers of patients are managed in this manner but there may be scope for improved outcomes by providing anticoagulation services through alternate models of care.

2.3.4 Point of Care Testing by Healthcare Professional

The advent of point of care testing meters enabled healthcare professionals to provide anticoagulation management services in community healthcare settings without the need to obtain venous blood samples. The use of point of care testing meters in anticoagulation management services has now expanded beyond community healthcare workers with general practitioners and hospital outpatient clinics now using the devices (Bubner *et al* 2009).

Point of care testing (POCT) involves carrying out testing procedures which would traditionally be confined to the conventional laboratory environment, in the vicinity of the patient to whom the test relates (Irish Medicines Board 2009). Point of care tests are often carried out using a sample of blood obtained from a simple finger prick which dispenses with the need for venepuncture to collect a whole blood sample. Removing the need for venepuncture means that suitably trained healthcare staff or the patient themselves can carry out point of care

testing. For healthcare professionals, the advantage of using point of care testing is that rapid results can be obtained in the vicinity of the patient which can then be acted upon immediately. A single healthcare practitioner is involved in the end-to-end patient consultation and this can facilitate patient education and patient engagement in their own treatment. Point of care testing is in common use for chronic conditions such as diabetes mellitus. Blood glucose levels can be obtained very quickly by obtaining a fingerpick blood sample and applying it to a test strip which is analysed by portable glucometer.

Point of care coagulation monitoring also utilises test strips which are inserted into a portable coagulometer. As with the laboratory INR measurements, thromboplastin forms the basis for the point of care measurement. A drop of blood is drawn from the finger and is placed on the test strip where it is carried by capillary action to the reagent chamber which contains the thromboplastin, stabilisers and preservatives. The blood then begins to clot and this process is analysed by a laser which determines how long this takes to occur. The coagulometer then carries out the necessary calculations and displays the INR on screen. The time taken for this complete process is generally less than one minute (Gosselin *et al* 1997).

Point of care coagulometers have undergone extensive analysis and testing to determine their precision and accuracy compared to traditional laboratory methods. The three most commonly used coagulometers currently on the market are; CoaguChek® XS (Roche Diagnostics), INRatio® (Hemosense), and ProTime®/ProTime 3 (International Technidyne Corporation) (Plüddemann *et al* 2012). These meters were studied in a recent systematic review. It found that the precision and accuracy of these portable meters compared with traditional laboratory methods was adequate for clinical use. Internal and external quality assurance methods can be used to measure accuracy of coagulometers over time. Internal quality control measures involve electronic keys or control solutions provided by the manufacturer with each batch of test strips which calibrates the machine for the specific test strips in use (Christensen and Larsen 2012).

External quality assurance measures involve comparing INR measurements from the point of care coagulometer with measurements from a laboratory or calibrated coagulometer. One of the largest quality assurance schemes for coagulometers in the UK is operated by the National External Quality Assessment Scheme for Blood Coagulation. This involves two samples being sent from the central laboratory that are tested on the local point of care coagulometer and the results returned to NEQAS. Statistical analysis is carried out on the results which compare each individual model of coagulometer to give median result. An individual coagulometer must

be within 15% of this median result to be within consensus (Christensen and Larsen 2012; NEQAS 2013).

By utilising POC testing devices which provide instant results that can be input into the CDSS, dosing decisions can be made during the patient consultation. This service model enables the healthcare practitioner to discuss the results and on-going warfarin therapy with the patient. This conversation can also facilitate patient education dealing with the INR result and warfarin dosage. It has been demonstrated that this model of anticoagulation management can achieve TTR values similar to the gold standard of hospital-based anticoagulation clinics (Holder *et al* 2000).

2.3.5 Patient Self-Testing/Management

The validation of POC meters and web-based CDSS led to the view that a cohort of patients existed who could utilise these technologies to gain an increased level of control in their own anticoagulation management. A number of different models exist for the inclusion of patients in the decision making process including; patient self-testing with healthcare practitioner dosage management (Bradbury *et al* 2008), patient self-testing with online reporting and healthcare practitioner dosage management (Gilmore 2008) and patient self-management with web-based CDSS (Ryan *et al* 2009). This model of anticoagulation management provides high levels of acceptability for suitable patients as it enables them to incorporate the processes of anticoagulation management into their own schedule. Patients are able to travel with their portable coagulometer and still perform the INR measurements when required. Patients who are motivated to have an active role in their anticoagulation management can achieve TTR equivalent to laboratory-based services (Harper and Pollock 2011).

2.4 Health Information Systems and Services

It has been discussed earlier in this chapter that the use of CDSS has enabled a variety of healthcare practitioners to make informed judgements about anticoagulation therapy. The creation of CDSS for anticoagulation management was one of the main drivers behind the expansion of non-medical healthcare practitioners delivering this type of service. This section will explore the role of and CDSS and other health information systems and services in the delivery of community pharmacy anticoagulation management services.

2.4.1 Clinical Decision Support System

Clinical Decision Support Systems are computer programmes which have been designed to provide both knowledge and guidance to healthcare practitioners at appropriate stages in

their workflow. One commonly used definition of CDSS which has been proposed by Hayward is “Clinical Decision Support systems link health observations with health knowledge to influence health choices by clinicians for improved health care” (Hayward 2004). This definition highlights the fact that CDSS utilises information about the current clinical situation regarding a patient together with pre-programmed decision support rules to assist the healthcare practitioners in making real-time treatment decisions. CDSS is ideally suited for use in clinical environments where treatment decisions can be consistently determined by applying a fixed set of rules to the current situation.

The process of warfarin initiation and dose adjustment is clinically complex but is supported by validated guidelines which detail the recommended actions to take in a wide variety of circumstances. When a patient is initiated on warfarin therapy, they are each set a target INR based on a number of factors including therapeutic indication, co-morbidities and age. The target INR is decided upon with reference to current guidelines which are compiled by a number of organisations including the British Committee for Standards in Haematology and American College of Chest Physicians. The target INR is what healthcare professionals will refer to when assessing a patient’s warfarin therapy, although it is generally accepted that INR readings which vary by 0.5 from this target INR are within the target range. Therefore, if a patient has been assigned a target INR of 2.5, their target range will be 2.0-3.0 (Keeling *et al* 2011; Ansell *et al* 2012).

Depending on the target INR and the patient’s physical characteristics, the patient is started on an initial daily dose of between 4 and 6mg of warfarin. The patient takes this initial loading dose for one week and then their INR is tested to determine the clinical anticoagulant effect (Wilson *et al* 2007). This initial dose will establish how the individual patient responds to the warfarin therapy and the first INR measurement will form the starting point for the dosage adjustment process. The process of dosage adjustment is a pivotal part of warfarin-based anticoagulant therapy and whereas the target INR can be straightforward for a clinician to assign and is well supported by guidelines which are regularly updated, the dosage adjustment process is much more complicated. There are published guidelines which specify the broad criteria for a 10% adjustment, a 10-20% adjustment or a temporary withholding of the daily warfarin dose (Kim *et al* 2010).

However, clinicians in anticoagulation management clinics often use their clinical experience to specify the correct dose adjustment (Kim *et al* 2010). These clinicians have a very good understanding of how warfarin interacts with the medication and diet of the individual patient.

Patients who are established on warfarin therapy have clinical notes which detail how that patient has responded to previous dose adjustments, as this is another area in which individual patient responses can have an impact on anticoagulation management. This inequality in dose adjustment can mean that increasing or decreasing the warfarin dose by a fixed amount will produce different INR changes in different patients. Experienced clinicians can use their clinical experience along with the patient's dosage history to determine the correct warfarin dose to prescribe (Wilson *et al* 2007). This system based upon the clinical experience of the anticoagulation clinic staff can lead to difficulties when less experienced clinicians such as junior doctors or new members of staff are required to make decisions about warfarin dose adjustment. Without access to new technologies, less experienced practitioners have to rely upon paper-based dosage algorithms or nomograms to determine the most appropriate action for each individual patient. This can lead to over-steering errors, where a practitioner alters the warfarin dose by too great an extent for a particular situation. This can result in reducing the warfarin dose too much in response to an elevated INR, thus leading to an INR level which is then too low, or vice-versa (Potts *et al* 2011).

There are many nomograms available but many of these have only undergone limited evaluation. A number of clinically validated nomograms have been developed in the recent past. These nomograms give detailed directions of what warfarin dose to prescribe and when to repeat the INR measurement for the potential INR values obtained for patients in specific therapeutic INR ranges. These nomograms are not standardised in terms of the INR ranges they cover or INR intervals for which they specify adjustments. The nomogram developed by Wilson et al provides two separate dosage adjustment algorithms for patients with a target INR range of 2.0-3.0 and 3.1-4.0. Specific dosage adjustments are listed for 13 INR ranges which could be seen in each of the above scenarios. These dose adjustments specify what the warfarin dose should be modified by and when to withhold warfarin doses completely. The dosage adjustments are not evenly spaced across the full INR spectrum for these two scenarios. Some dosage adjustments are listed for an INR range of as low as 0.1 while others cover an INR range of up to 1.2 (Wilson *et al* 2007).

The nomogram developed by Kim et al covers two different target INR ranges, 2.0-3.0 and 2.5-3.5 and only lists dosage adjustments for 7 INR ranges from <1.5 to >9.0. This nomogram not only details extent to which the warfarin dose should be modified and the relevant withholding period for high INR's but also when Vitamin K should be administered and what dose it should be administered at. This nomogram lists most dosage adjustments for an INR

range of 1.0 but some are as low as 0.48 and some are as large as 3.99 (Kim *et al* 2010). Other nomograms such as the one developed by Dalere et al have represented the dosage adjustment algorithms in a graphical format. This nomogram is based on a log linear warfarin pharmacodynamic model which represents a number of steady-state warfarin dose-response curves. The current warfarin dose and INR measurement are used to select the appropriate curve. The target INR on this curve is then used to identify the appropriate warfarin dose (Dalere *et al* 1999).

These examples show the wide variation in paper-based dosing models which are available. These nomograms all present the data and provide dose adjustment advice in different formats. This lack of standardisation and the potential confusion these varying nomograms create has led to the development of CDSS for anticoagulation management services. Use of CDSS removes the need for the healthcare practitioner to memorise the information in the paper-based guidelines and also removes the potential for the incorrect interpretation of the guidelines. The use of CDSS has been demonstrated to enable the safe delivery of anticoagulation management services by a wide range of healthcare practitioners including non-consultant hospital doctors, pharmacists and nurses (Vadher *et al* 1997; Fitzmaurice *et al* 1998; Garton and Crosby 2011)

The use of CDSS enables a safe and scalable distributed anticoagulation management service to be delivered as there should be a common interpretation and application of the clinical guidelines. This standardisation of service delivery is facilitated by the fact that anticoagulation CDSS also provides additional features outside of providing guidance on treatment decisions. The majority of anticoagulation CDSS incorporate an electronic patient record (EPR) and this facilitates the management and overview of the anticoagulation management service (Austin, Sun, *et al* 2009). The use of CDSS in the delivery of anticoagulation management services by non-medical staff is recommended by British Committee for Standards in Haematology (BCSH). The BCSH recognise that the use of CDSS can increase TTR but also recognise that features such as appointment scheduling, tracking patients who are overdue and generating reminders regarding anticoagulation end dates contribute to the delivery of a safe anticoagulation management service. The use of CDSS also facilitates governance and oversight through the facility for service audit. This enables service oversight by tracking the TTR, level of patients outside their therapeutic range and enables the comparison of this data across service settings and service providers (Waring and Cooke 2007).

2.4.2 Unique Health Identifier

There are a number of terms such as Unique Health Identifier (UHI), Unique Patient Identifier (UPI) and Individual Health Identifier (IHI) which all describe a single non-transferrable number which is used to identify a patient across all healthcare settings for the duration of their life.

Patients will normally access a variety of different health care services, in a variety of settings over the course of their lives. Patients will often move house, move county or change their name. Irish patients may have a different name on their passport to the one they commonly use and patients not born in Ireland may have multiple names which have the potential to be interpreted in a number of different ways when being entered as a first name and surname. In the absence of a UHI for the Irish healthcare system, service providers have developed different methods of identifying patients in their care which often rely on these changeable demographic details. Pharmacies generally identify patients using their name and address, GP's generally use name and date of birth and hospitals generally use the Medical Record Number (MRN).

The availability of a unique health identifier has been identified as a crucial component for the delivery of high quality patient care. HIQA has stated "*the absence of a UHI for individuals is the single most important deficiency in the health information infrastructure in Ireland*" (Health Information and Quality Authority 2009). The high degree of importance that is placed on the availability of a UHI is due to the fact that it has the potential to impact on many vital areas within the healthcare service. It is vital from a clinical perspective to know that the healthcare professional is dealing with the right patient in the right place at the right time. Using demographic data as the primary method of patient identification introduces an element of risk into the process that may impact on the quality of patient care. In order to strive for the highest quality of care, it is important to ensure that every effort is made to avoid clinical decision making based on inaccurate patient information (Delany 2006). This also is very important when dealing with healthcare data associated with the patient. Fully informed clinical decisions cannot be made unless healthcare professionals have access to complete and consistent patient records. The inability to find vital healthcare information due to records being duplicated or records being filed under different identities prevents the optimal delivery of care (National Patient Safety Agency 2009).

The availability of a unique health identifier also facilitates non-clinical functions within the healthcare system. Healthcare systems without a unique health identifier face a greater administrative burden as there is little potential for sharing information between services. This

results in the duplication of administrative tasks and the need for data maintenance to be carried out at individual sites instead of being carried out at a centralised location (Nicholls 2008). A unique health identifier would also facilitate a greater degree of analysis and research to be carried out on healthcare data. Having a single identifier for individual patients would enable datasets to be linked and would provide much richer data sources for longitudinal and broad scope healthcare research projects. Statistical matching based on multiple demographic details is a method which can be used to link individuals across multiple datasets but this falls victim to the inherent demographic difficulties which were discussed earlier. Difficulties arise even when a patient does not change their demographic details or use different pseudonyms due to the way the demographic details are recorded. One example of this is the format which date of birth is recorded in, such as dd/mm/yy or dd/mm/yyyy. Both of these values represent the same date of birth but the structure of the data fields will present difficulties for interoperability between health information systems (Trapskin *et al* 2006). Unique health identifiers can also be used to provide a greater degree of privacy, confidentiality and security when carrying out analysis and research using electronic patient information. The presence of a unique health identifier allows the demographic details to be removed whilst retaining the ability to accurately determine the individual patient records (Health Information and Quality Authority 2013).

2.4.3 Health Messaging

Healthcare services rely on clinicians being able to access the right information at the right time in order to make treatment decisions which will produce favourable outcomes for patients. The Health Information and Quality Authority (HIQA) have indicated that up to 30% of the total health budget may be spent on the processes of data collection, storage and retrieval (Health Information and Quality Authority 2012). It is also vitally important that information can be safely and securely passed between different areas of the healthcare service for clinical, administrative, financial and audit purposes. The most basic form of health messaging is oral communication which can be carried out face-to-face or via communication channels such as fixed-line telephony, mobile telephony, Voice Over IP (VOIP) or video conferencing. Physical documents such as letters and faxes enable messages to be transmitted, stored and retrieved which provides increased levels of safety and facilitates audit functions. These forms of health messaging are widely used within the Irish healthcare system for communication between healthcare practitioners, healthcare agencies and patients.

However, there are serious deficiencies with these forms of health messaging such as the potential for misinterpretation of information, loss of information or inappropriate access to information. Many healthcare providers now utilise Information and Communications Technology (ICT) solutions in the delivery of patient care and to store information regarding patients and their treatment, although without a connected health strategy many of these systems use proprietary technologies which results in data silos and low levels of interoperability between providers. ICT can provide solutions to revolutionise the area of health messaging in Ireland by utilising standards-based messaging services to deliver a safe, secure and interoperable messaging platform for the exchange of information within the healthcare sector.

The use of standards-based messaging can facilitate a greater integration of healthcare services between primary, secondary and tertiary sectors by enabling providers to collaborate more effectively in the delivery of patient care. Standards increase systems interoperability which is defined by Healthcare Information and Management Systems Society (HIMSS) as "the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged". This definition also includes a broader interpretation of three distinct levels of interoperability: Foundational which enables data exchange but not interpretation; Structural which defines the syntax of the exchanged data and enables individual data fields to be interpreted; and Semantic which defines the structure and content of data giving the highest level of interoperability which enables the exchange of information in a manner which allows the information to be interpreted and used (HIMSS 2013).

When two systems which do not utilise a common messaging standard are required to communicate, an interface must be developed to translate each message passed between the systems. As the number of systems that are communicating with each other increases, so does the number of interfaces which are required. The number of interfaces required for N systems can be calculated using the formula $(N^2-N)/2$. Benson illustrates (Figure 2-1) that 15 interfaces are required (left) to connect 6 systems using incompatible messaging formats compared to one common interface (right) when a common standard is used (Benson 2010).

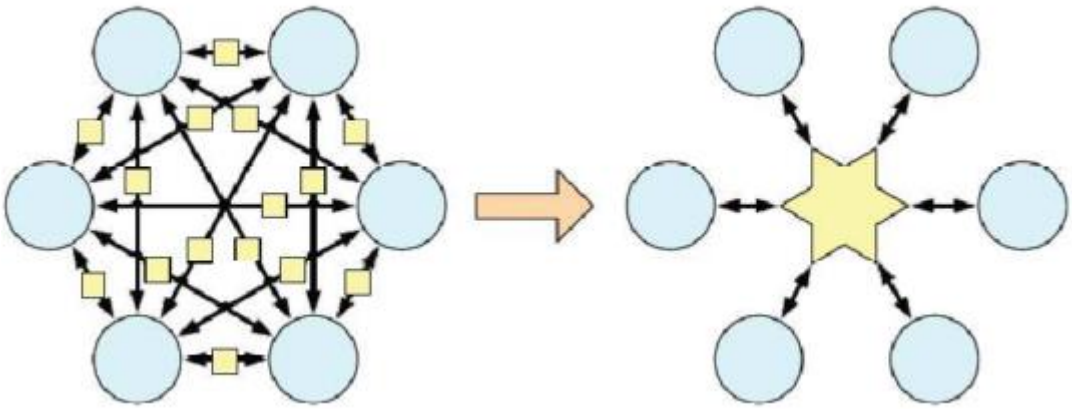


Figure 2-1 Impact of standards on interfaces (Benson 2010)

There are a number of health messaging standards that have been developed by international Standards Development Organisations (SDO) such as International Organization for Standardization (ISO), American National Standards Institute (ANSI), European Committee for Standardization (CEN) and Health Level Seven International (HL7). The most widely used health messaging standards are HL7 V2.x, HL7 V3, CDA and EDIFACT. On an international scale, the HL7 v2.x messaging standard is the most widely implemented standard for health messaging (HL7 International 2013). The HL7 v2.4 messaging standard has been recognised by HIQA as the most commonly used messaging standard in Ireland and has endorsed its continued use (Health Information and Quality Authority 2012).

HL7 v2.x is based on the Electronic Data Interchange (EDI) format and was developed with the aim of enabling point-to-point communication between independent systems. The standard has evolved since the first widely used version, HL7 v2.1 was introduced in 1991. HL7 v2.x provides a degree of flexibility in the implementation of the standard as it defines how messages are to be exchanged but not the message contents. This has provided for a very flexible messaging system with individual implementations able to choose from large number of optional data elements and data segments. The HL7 v2.x standard describes the structure of message with delimiters indicating the message type and the individual elements within message. The messages have a hierarchical structure (Figure 2-2) with chapters indicating the message domain and segments containing data fields ordered into logical groupings (Benson 2010).

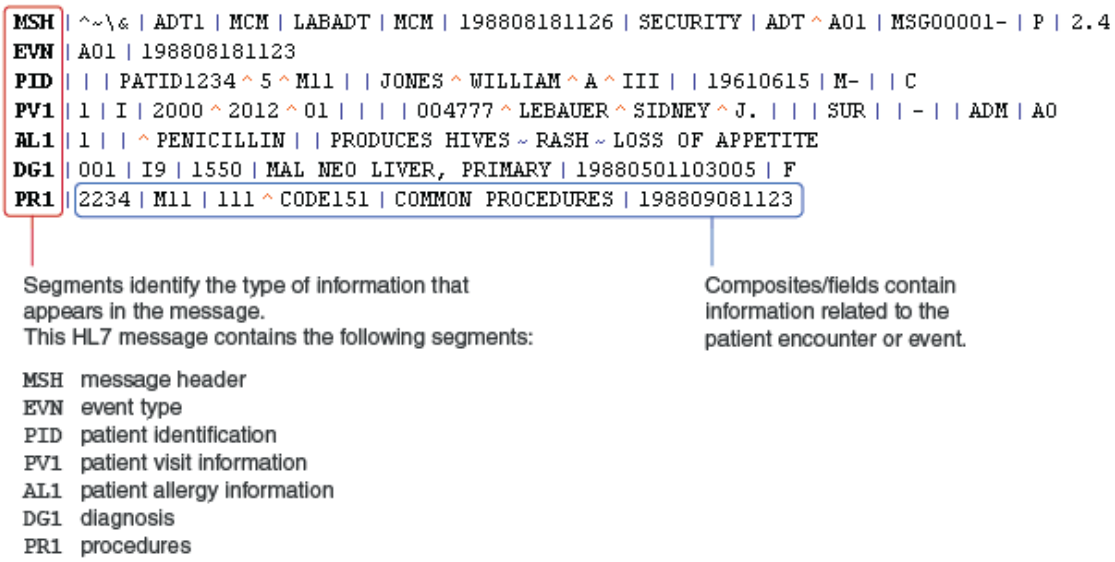


Figure 2-2 HL7 v2.x message structure (Altova 2013)

2.5 Community Pharmacy Services

Community Pharmacies are acknowledged as being the most accessible locations for patients within the healthcare system (Rutter and Newby 2011). In Ireland, there are over 1600 pharmacies where patients can obtain prescription medication, over-the-counter medication, advice and an increasing range of enhanced services. As was discussed in Chapter 1, many pharmacies provide health screening services including blood pressure and cholesterol monitoring. These prove very useful for patients who often choose to avail of these services in community pharmacies rather than GP surgeries due to time and cost factors (O'Flaherty 2009). The health service agencies in many countries are now looking to utilise the knowledge and experience of pharmacists by enabling an enhanced range of services to be delivered through community pharmacies. Many countries including Australia, New Zealand, Canada and the UK are developing point-of-care testing (POCT) services to enable pharmacists play a more active role in the management of chronic disease. Pharmacists in these countries now operate programmes for the screening and management of conditions such as diabetes, asthma and chronic obstructive pulmonary disease (COPD) (St John 2010). Technological advances in POCT technology are enabling diagnostic procedures which previously required laboratory testing, to be carried out in community pharmacy locations. It is precisely this type of technological innovation which has enabled the process of INR measurement to move from a model which was dependent on laboratory services to one which can be provided as part of a community pharmacy anticoagulation management service.

3 Methodology

3.1 Introduction

This chapter will discuss the methodologies used to answer the research question:

> *"What lessons can be learned from the international experience to assist the development of suitable electronic support services for a community pharmacy anticoagulation management service in Ireland?"*

The rationale behind how the study was structured and executed will be discussed. The mixed methods approach of this study provided an opportunity to acquire data from different perspectives. The process for selecting the case studies and interview design will be explained along with how the resulting data was collected and analysed.

3.2 Research Method

The area which was being addressed by the research was one which required the assimilation of knowledge from a wide and varied range of sources. The various research methods which would best allow the collation and analysis of available data sources were studied by the researcher. Quantitative research methods can be seen as embodying a positivist philosophy. According to Johnson and Onwuegbuzie this implies that researchers *"should eliminate their biases, remain emotionally detached and uninvolved with the objects of study, and test or empirically justify their stated hypotheses"* (Johnson and Onwuegbuzie 2004). Quantitative research methods can be seen as embodying an idealist philosophy. Quantitative researchers argue that *"time and context-free generalizations are neither desirable nor possible, that research is value-bound, that it is impossible to differentiate fully causes and effects and that logic flows from specific to general"* (Guba 1990). While there are merits in both qualitative and quantitative research philosophies, neither provided the most accurate and honest method to capture the required depth and breadth of knowledge required for this study. Thus a mixed method study design was chosen which allowed multiple viewpoints, positions and perspectives to be observed (Johnson *et al* 2007).

3.3 Research Design

The process of triangulation was outlined by Denzin who described it as "the combination of methodologies in the study of the same phenomenon" (Denzin 1978). Through the use of methodological triangulation, a number of research methods were used to illuminate the topic

from a number of different angles. This enabled a richer source of data to be obtained and allowed emergent themes to be investigated as the research process was carried out. The research methods utilised in this study were mainly qualitative in nature as this allowed a detailed understanding of the selected services to be developed. The mixed method approach enabled multiple sources of information to be collated which led to an emergent understanding of the area which was refined as the research was continuing. The sources of information which were utilised in the research included an in-depth literature review and semi-structured interviews which enabled the formation of detailed case-studies regarding the most relevant services which were identified.

3.4 Role of Literature Review

The initial objective of the literature review was to investigate the various models of anticoagulation management which were employed on a global scale. This literature review enabled an emergent understanding of the broad subject area and provided an insight into delivery an anticoagulation management service. An in-depth literature review was then carried out to identify the anticoagulation management services which were being operated in the community pharmacy setting. In order to provide an acceptable scope for the research and also acknowledging the limited timeframe which was available, a number of criteria were used to determine the services which would be chosen for further investigation.

Firstly, it was decided to include services where published information in English was available. Secondly, it was decided to include services which were operated by pharmacists with similar levels of education and training to pharmacists in Ireland. Thirdly, it was decided to include services with differing levels of maturity to capture the broadest range of experience. Finally, it was decided to include services which varied in size from small independently operated services to large nationally operated services.

The literature review process resulted in four community pharmacy anticoagulation management services being selected for inclusion in the research process. The relevant stakeholders and domain experts involved with the selected case studies were identified. A key variable in the success of the research is the availability and willingness of the selected stakeholders to participate in the process.

The literature review provided the basis for identifying the main themes related to the delivery of a community pharmacy anticoagulation management service such as processes and

procedures for delivering a safe service, ensuring scalability in a distributed service, use of clinical decision support systems and communication between healthcare practitioners.

3.5 Case Study Design

Research within the realm of healthcare carries with it a number of inevitable influences from the overall system within which a particular service resides. The use of case studies facilitated the study of individual community pharmacy anticoagulation management systems but also provided an opportunity to explore how these services interacted with the broader healthcare system in that location. Case studies normally rely on multiple methods of data collection and facilitate the use of both qualitative and quantitative data (Yin 1999).

Case studies were used to develop an in-depth understanding of the anticoagulation services which being provided by community pharmacists in other countries. These case studies examined all aspects of the anticoagulation management service in place and placed particular emphasis on the health information systems including CDSS and messaging systems used in the delivery of the service. It was envisaged that 2-4 suitable case studies would be identified for this purpose. From the initial work carried out on the literature review the countries of interest for this purpose were Canada, New Zealand, United Kingdom, Ireland and Australia.

3.6 Inclusion Criteria

The inclusion criteria for the study were defined as services that have literature available in the English language, have pharmacists with a comparable standard of education and training as Ireland and have experience in the operation of anticoagulation management services in the community pharmacy setting

3.7 Semi-structured Questionnaire Design

The use of semi-structured interviews provided an opportunity to gain valuable insight into the organisation and operation of successful community pharmacy anticoagulation management services. Structured interviews are often used as a method to produce qualitative data but could not have provided the necessary flexibility to explore the individual nature of the various services. Unstructured interviews are often used in ethnographic research where the researcher gathers data through participant observation and produces an output of field notes which are later analysed. The semi-structured interview is the most widely used interview format for qualitative research. It facilitates dialogue from the basis of a number of open-

ended questions which allow for emergent understanding as the interview progresses (Dicicco-Bloom and Crabtree 2006).

Semi-structured interviews with domain experts selected from the case studies were used to gain an insight into how all aspects of the community pharmacy anticoagulation services were organised and how they operate. Domain experts working in community pharmacy anticoagulation management services, clinical governance boards, national health agencies and pharmacy regulatory bodies were identified as people of interest e.g.: Pharmacy Council New Zealand, Health Workforce New Zealand and National Health Service (NHS).

3.8 Data Collection

Semi structured interviews with domain experts were used to obtain qualitative data regarding the history, organisation and operation of community pharmacy anticoagulation management services. The participants were identified by selecting case studies of community pharmacy anticoagulation management services which have the greatest potential to provide learning outcomes which could influence the development of a similar service in Ireland. The selected participants were sent an email containing the information sheet and given the option to participate in the interview. Following receipt of their consent to participate in the interview process, the list of interview questions were forwarded to the participant by email ahead of the interview to give them an opportunity to reflect on the questions. Four case studies were initially chosen and representatives from all four services initially communicated a willingness to participate in the research. However, one representative failed to respond to further communication and therefore this case study was excluded from the research process.

As the majority of the participants were located in Ireland, the interviews were conducted by telephone and recorded to facilitate subsequent transcription. I acknowledge the fact that as data controller, I have a responsibility to safeguard the audio recordings and to only keep hold of them for as long as necessary (Irish Statute Book 1998). The audio recordings were stored on the local drive of my computer in an encrypted folder and once the audio recordings were transcribed, they were be erased.

3.9 Ethical Considerations

In accordance with the School of Computer Science and Statistics (SCSS) research protocols, ethical approval was sought as my study required human participation. During the reflection process, the main ethical issues associated with the research were identified. These issues

mainly concerned the human aspect of the services involved and the power relationships which could potentially impact the information provided to the researcher. The interview themes for the semi-structured interview (Appendix 1) and research proposal were submitted to the SCSS Research Ethics Committee for review.

4 Research

4.1 Introduction

This chapter presents three case studies detailing community pharmacy anticoagulation management services which are operating in Ireland, England and New Zealand. These case studies present a description of the service history and operation and an in-depth analysis of the Health Information services which are utilised in each case.

4.2 Research Process

As outlined in the previous chapter, the case studies involved integrating the data collected from selected sources to provide a comprehensive and detailed description of the services. This process began with an initial high-level literature review being carried out to establish the background to anticoagulation management services and in particular, services being operated in the community pharmacy setting. The information extracted from this initial literature review enabled the themes for the semi-structured interviews to be developed (Appendix 1). This process also enabled the development of the inclusion criteria for the case studies. This resulted in the identification of suitable services from the list of community pharmacy anticoagulation management services which had been gathered from the initial literature review.

A comprehensive literature review was then carried out to develop an understanding of anticoagulation and anticoagulation management services. A detailed knowledge of each of the three selected services was gained through the literature review process which involved gathering all the available information regarding each service. The key stakeholders involved in the establishment, operation and governance of the three services were identified. These key stakeholders included community pharmacists, hospital pharmacists, haematologists, members of clinical governance boards, members of national health agencies and members of national pharmacy regulatory bodies. These key stakeholders were then initially contacted by email to inform them about the research and to invite them to participate in an interview. Semi-structured telephone interviews were then carried out with stakeholders involved with three services. The early development of the interview themes enabled correlating data to be collected in each interview. The recorded telephone interviews were then transcribed and analysed for content and themes.

The information gathered from the various sources was then integrated to produce three case studies on community pharmacy anticoagulation management services.

4.3 Case Study 1: Cloyne Pharmacy Anticoagulation Clinic, Ireland

4.3.1 Service Background

Cloyne Pharmacy is located in the village of Cloyne in south-west Cork. It is situated about 35km from Cork city where Cork University Hospital (CUH), the major hospital for this area, is located. Cloyne pharmacy has been operating an anticoagulation management service since 2010 and caters for an average of 35-40 patients. The service was designed in conjunction with a consultant haematologist from CUH who also provides medical oversight for the service. Service protocols deal with the correct procedures that must be carried out when: in-range INR results are obtained, when out-of-range INR results are obtained and when extremely out-of-range INR results are obtained. When results <1.5 or >5 are obtained, the pharmacist will contact the consultant haematologist or registrar on duty in CUH to discuss the treatment plan and next test date.

Two pharmacists have been accredited to provide the anticoagulation management service in Cloyne Pharmacy. The training programme for the pharmacists operating the anticoagulation management clinic was developed in conjunction with the consultant haematologist. The pharmacists attended a number of anticoagulation management clinics in CUH and observed the operation of the service. They also attended a number of training courses and anticoagulation conferences in the UK which were run by the National Centre for Anticoagulation Training (NCAT). Initially when the service was started, an entirely paper-based system was used. Paper-based algorithms were used for dose calculation and paper-based records were kept for each patient in a physical file. This paper-based system was replaced by the RAID Express system which was used as a patient management system exclusively for the anticoagulation management service and which also had CDSS functionality.

Appendix 2 contains more comprehensive background information on the establishment and operation of the Cloyne Pharmacy Anticoagulation Clinic.

4.3.2 Health Information Systems

4.3.2.1 CDSS

RAID Express is a software solution from HiruMed® UK that is designed for use in the management of anticoagulant therapy in the primary care environment. RAID stands for Rapid

Anticoagulation Interpretation and Dosing. HiruMed® has two software solutions for the management of anticoagulant therapy, RAID Express and HiruMed® RAID. In the recent warfarin clinic survey it was found that four hospitals in Ireland that use HiruMed® software but it is not stated whether they use the more basic RAID Express system or the more advanced HiruMed® RAID system (Marsden & Smyth, 2012). Three of the major differences between the systems is that HiruMed® RAID allows for up to 100 user defined algorithms, has multiple data export functions to provide real-time reporting to other systems e.g. Laboratory Information Systems and has an in-built statistics package.

In the Cloyne Pharmacy anticoagulation management service, the RAID Express system is used as a patient management system to manage the records of all patients who attend the anticoagulation management service in the pharmacy. It is separate to the software that is used for the dispensing operations in the pharmacy. The system does have an inbuilt CDSS but it is felt that the algorithm behind the CDSS is not flexible enough to cater for all the situations faced in the operation of the service. The RAID Express system was not in use when the anticoagulation management service was initially rolled-out. The pharmacist believes this may be the time when the CDSS functionality of the system would be most beneficial as it would give an indication of the dosage and next test date should be. The CDSS will provide a recommended dosage based upon the recent INR history and current INR result.

The pharmacist has indicated that an important part of anticoagulation management is to investigate whether or not a change in the patient's INR level can be attributed to particular external factors. In situations where the patient has changed their lifestyle, diet or has started on new medication, this would be classified as a 'provoked' change. In situations where the patient has not experienced any of the above alterations significantly, this would be classified as an 'unprovoked' change. With the experience of running the anticoagulation management service for a number of years, the pharmacist can treat 'provoked' and 'unprovoked' situations differently. The patient may be started on a short-term course of antibiotics e.g. Clarithromycin which generally cause a patient's INR level to increase. The pharmacist will deal with this increase in INR as a 'provoked' change. Individual patient reactions to introduced medications can vary greatly and the patient's INR history can provide valuable information for making treatment decisions. If the patient had taken this medication previously, the INR history can be examined to look for trends and can be used to pre-empt the effect of the medication and adjust the warfarin dosage accordingly. A different scenario occurs when a patient is started on long-term medication e.g. amiodarone which interacts with warfarin. This

is also a 'provoked' change but the goal is to adjust the warfarin dosage to take the new interacting medication into account and to achieve a stable INR.

The pharmacist believes that the ability to deal with these scenarios comes with experience and from looking at the patient's anticoagulation history to identify trends. In order for the CDSS to be able to replicate the decision making ability of an experienced practitioner it would have to become a lot more flexible and be able to take into account all the influencing factors. The pharmacist has indicated that improvements could be made to the RAID Express system in terms of the CDSS functionality and the reporting functionality. The ability to share the results electronically or to be able to provide online access to the record for GP's and hospital doctors are features that would improve the communication with the other healthcare professionals involved in the care of the patient. The pharmacist has contacted the software developers in relation to enhancements that would be desirable in future programme upgrades.

There are a number of other systems on the market but after reviewing the different options, the RAID Express system was chosen based upon suitability for use in the pharmacy setting and price.

4.3.2.2 Unique Health Identifier

The absence of a UHI for the Irish healthcare system means that the anticoagulation management service being operated in Ireland cannot utilise a national patient identification service and therefore must rely on a demographic details as a method of identifying patients. The patient identifier that is used in the pharmacy anticoagulation management service is generally the hospital medical record number (MRN) in conjunction with the patient date of birth (DOB). The service has a close association with the warfarin clinic in Cork University Hospital and patients in the hospital setting will always be identified through the use of the MRN and DOB. In order to facilitate communication between the pharmacist and the warfarin clinic staff, the same patient identifier is used in the pharmacy anticoagulation management service.

4.3.2.3 Health Messaging

Ireland does not have a health messaging platform to enable the exchange of information between pharmacies and other service providers. There is a limited deployment of health messaging to facilitate the transmission of reimbursement data from pharmacies to the Primary Care Reimbursement Service (PCRS). This service evolved from the manual claim system which involved pharmacies submitting paper-based records for all prescriptions

dispensed under government-reimbursed schemes which were then manually processed for payment. The PCRS developed the electronic reimbursement standards based on HL7 Clinical Document Architecture (CDA) release 1 standard (Murray 2008).

The RAID Express system used in the operation of the anticoagulation management service is a single-user standalone programme which does not facilitate remote or web-based access. Therefore the pharmacist was not in a position to utilise electronic messaging to communicate details of patient consultations with GP's or clinicians in CUH. The programme has the facility to print out user-defined patient reports which can include their INR and dosage history. These printed reports could then be faxed or posted when the pharmacist wished to review a patient's anticoagulation therapy with the haematologists in CUH. The pharmacist also had phone numbers for the haematologists in CUH which enabled more urgent issues to be discussed with the medical staff who were overseeing the operation of the service. It has been acknowledged that the ability to electronically share patient information and consultation details with the haematologists in CUH would provide a safer model of care as they would always have access to the most recent information and it would eliminate the potential for miscommunication between the parties.

4.3.3 Service Evaluation

An evaluation of the Cloyne Anticoagulation Clinic was carried out which compared the community pharmacy-based service with the hospital based-service provided in CUH. It was found that the community pharmacy-based service was as effective as the secondary care centre of excellence and that it exceeded the international BCSH operating standards. The service also demonstrated high levels of patient satisfaction in a survey of the service users. (Walsh 2012).

4.4 Case Study 2: North Central London Community Based Anticoagulant and Stroke Prevention Services, UK

4.4.1 Service Background

The North Central London Community Based Anticoagulant and Stroke Prevention Services is an integrated care service that is comprised of hospital outpatient departments and over 30 community sites, including four community pharmacies. The service is centred around Whittington Hospital which is located in North Central London and principally serves the communities of Islington and Haringey. The community pharmacy anticoagulation management service was operated on a pilot basis in one pharmacy during 2002-2003. The service was then rolled out to an additional three pharmacies following the success of this pilot study. These services have a consultant-led service delivery model with medical oversight being provided by the consultant cardiologist in Whittington Hospital.

In order to ensure the safe delivery anticoagulation management services in the community pharmacy setting, a number of procedures and processes were developed. Standard Operating Procedures (SOP) were developed to specify the operation of the service and state the situations where the pharmacist can treat the patient using their own clinical judgement and when they must follow escalation procedures to contact a more experienced anticoagulation practitioner. An education and training programme was developed in Whittington hospital for community pharmacists. This involved compiling a workbook which contained the essential information required for anticoagulation management.

The community pharmacy anticoagulation management service utilises a web-based CDSS which is fully integrated with the Electronic Health Record in Whittington Hospital. The Centre for Health Informatics and Multiprofessional Education (CHIME) worked closely with key personnel at Whittington Hospital to develop and validate the CDSS.

Appendix 3 contains more comprehensive background information on the establishment and operation of the NCLASPS community pharmacy anticoagulation management service.

4.4.2 Health Information Systems

4.4.2.1 Standalone CDSS

As mentioned previously, the consultant cardiologist who was responsible for the operation of the anticoagulation management services sought to improve the delivery of the service by introducing a standalone CDSS. This software was developed by a private software company

who worked with Whittington hospital on a contract basis. This system was used until the 1990's until the software company went out of business and was no longer able to develop or support the software.

4.4.2.2 Standalone CDSS V2

The failure of the software company which designed the original CDSS used in the anticoagulation clinic was taken as an opportunity to develop a completely new system. Whittington hospital initially developed a partnership with the Clinical Operational Research Unit (CORU) at University College London. Work initially began on developing an algorithm for anticoagulant dosing. This work was carried out by a Doctor of Medicine student who developed an algorithm to provide dosage recommendations and also to determine the optimal date for the next clinic appointment. A clinical trial was developed to validate the algorithm developed and it was found that the algorithm performed better than inexperienced clinicians and as well as experienced clinicians for warfarin patients who did not have complicated anticoagulant management issues. This algorithm was also designed to identify patients with potentially complicated anticoagulant management issues and it was found to complete this task better than non-expert clinicians. Analysis of the clinical trial data demonstrated a very close correlation in dosage and test date recommendations between the algorithm and expert decisions (Vadher *et al* 1995). Subsequent studies were then carried out to develop a pharmacokinetic/pharmacodynamic model, which utilised Bayesian parameter estimation to determine daily warfarin doses and the subsequent INR levels during initiation of warfarin therapy (Vadher *et al* 1999).

The Centre for Health Informatics and Multiprofessional Education (CHIME) was established in 1995 as a joint venture between University College London (UCL) and the Whittington Hospital NHS Trust. CHIME was established to deliver undergraduate and postgraduate study programmes as well as to undertake research to support clinical practice (UCL 2013). CHIME worked closely with key personnel at Whittington hospital to develop the algorithms which had been developed and validated, into a fully function CDSS. The reasoning process behind the dosing and scheduling algorithm was implemented using a look-up table methodology.

The initial CDSS utilised an Access™ 2.0 database to store all the tables computed using the look-up methodology. The user interface for this initial version (Figure 4-1) was written using a version of the BASIC programming language which was included in Access™ 2.0 (Austin, Sun, *et al* 2009). This initial version of the CDSS was not available on the networked computers on the hospital wards (Kalra *et al* 2000). An evaluation was carried out to determine whether the

CDSS provided improved levels of anticoagulant control during initiation and on-going treatment when dosing was carried out by inexperienced doctors. It was found that when inexperienced doctors used the CDSS, patients achieved a stable INR in a shorter period of time and had improved therapeutic time in range compared with patients who were managed by inexperienced doctors who did not use the CDSS (Vadher *et al* 1997).

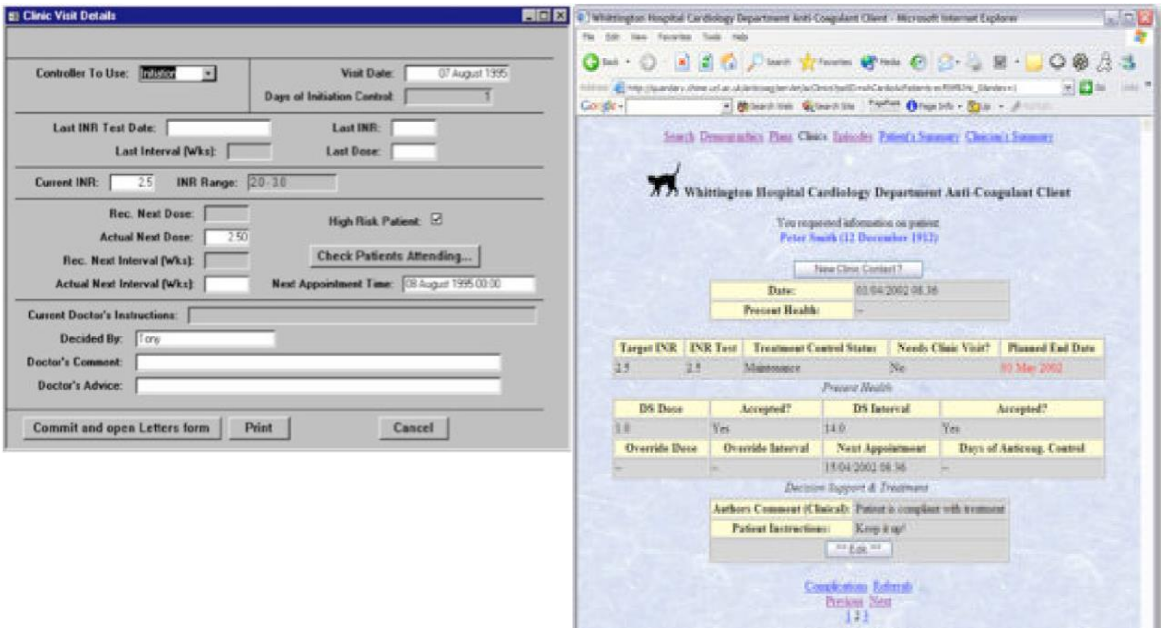


Figure 4-1 Clinic Visit Details screen in Access CDSS (Left) and initial web-based CDSS (Right) Adapted from (Austin, Sun, *et al* 2009)

Due to incompatibilities between the version of BASIC which was included in Access™ 2.0 and subsequent versions of the programme, it became necessary to re-write the entire CDSS software programme. This was viewed as an opportunity to enhance the functionality of the CDSS as well as introducing future-proofing to prevent the programme from becoming obsolete at a later date. The hospital had an existing license for Oracle® 9i and therefore this was the database which the existing Access™ 2.0 database was migrated to. To enable web-based access to the system, a Java-based CDSS was developed to query the Oracle® 9i database which as hosted on Windows™ 2000 Server located in CHIME (Figure 4-1).

4.4.2.3 Web-based CDSS

At the time it became apparent that a re-write of the CDSS software was necessary, CHIME was also participating in the EU-funded Synergy on the Extranet (SynEX) project. The objective of this project was to develop an Electronic Healthcare Record (EHR) to provide practitioners with access to patient information from any computer on the hospital network. The project also looked to facilitate shared care models by providing community-based practitioners with

access to the same patient information. CHIME worked closely with the Whittington hospital cardiology department to develop the EHR and to integrate existing departmental systems. The anticoagulation CDSS was an integral part of the EHR as it demonstrated many of the SynEx objectives such as staff in multiple hospital locations who require access to the shared patient record and the ambition to provide community practitioners with access to the record.

The system utilised Novell® NDS™ to store and authenticate the login details for trained practitioners. This was also used to contain the patient identification information and information on the 30,000+ GP's in the UK. The development of a web-based platform enabled use of the system from multiple locations in Whittington hospital and also by anticoagulant practitioners working in the community setting (Austin, Sun, *et al* 2009). An evaluation of the safety and acceptability of utilising the web-based CDSS to provide an anticoagulation service in a community pharmacy was carried out. The results of this research demonstrated that a safe and effective service could be delivered utilising this service delivery model. The only technological issues that were encountered were due to the fact that the pharmacy did not have access to the secure NHSnet (Coleman *et al* 2004). This obstacle was overcome when the scope of NHSnet was expanded to include secure access from community pharmacies at speeds of up to 256k. NHSnet was then superseded by the National Network for the NHS (N3) which provided increased flexibility.

4.4.2.4 HeartBeat CDSS

Due to the success and experience gained in the deployment of the EHR and embedded CDSS, it was decided to incorporate additional cardiovascular modules into the system. A major software revision was undertaken with the objective of developing three interlinked services for anticoagulation (AC), heart failure (HF) and atrial fibrillation (AF). These cardiovascular modules would all be accessed through the new umbrella portal called HeartBeat (Kalra and Patterson 2010). The anticoagulation CDSS was the first module to be deployed and it utilised the same decision support engine as the previous system. HeartBeat HF is now also operational and HeartBeat AF is undergoing final development. HeartBeat AC provides a more dynamic user experience by utilising Asynchronous JavaScript and XML (AJAX) to deliver the web-based system (Figure 4-2).

The HeartBeat AC system has a number of robust security features to ensure the secure and safe use of the system. User authentication is controlled on an individual basis and was initially handled by CHIME. These functions have since been transferred to an IT administrator at Whittington hospital who assigns the practitioners a username and password. A safety feature

of the system is that a practitioner cannot be assigned username and password until they have passed the OSCE. The individual practitioners can access the records for their own patients but senior anticoagulant practitioners and administrators at Whittington hospital can access the records for all patients on the system. This access control enables the preservation of patient confidentiality but also enables senior anticoagulation practitioners to provide assistance and guidance to community practitioners as well as facilitating Clinical Governance Board (CGB) audits.

An issue with the functioning of the CDSS has been raised in relation to dealing with temporary changes to a patient's INR. Deviations in a patient's INR can be due to provoked or unprovoked reasons. The management of these two situations is different depending on what the practitioner believes is the cause of the deviation. The HeartBeat system is unable to differentiate between these two situations and the practitioner must ignore the CDSS recommendations and use the paper-based algorithms to determine the correct dosage and next test date (Potts *et al* 2011).

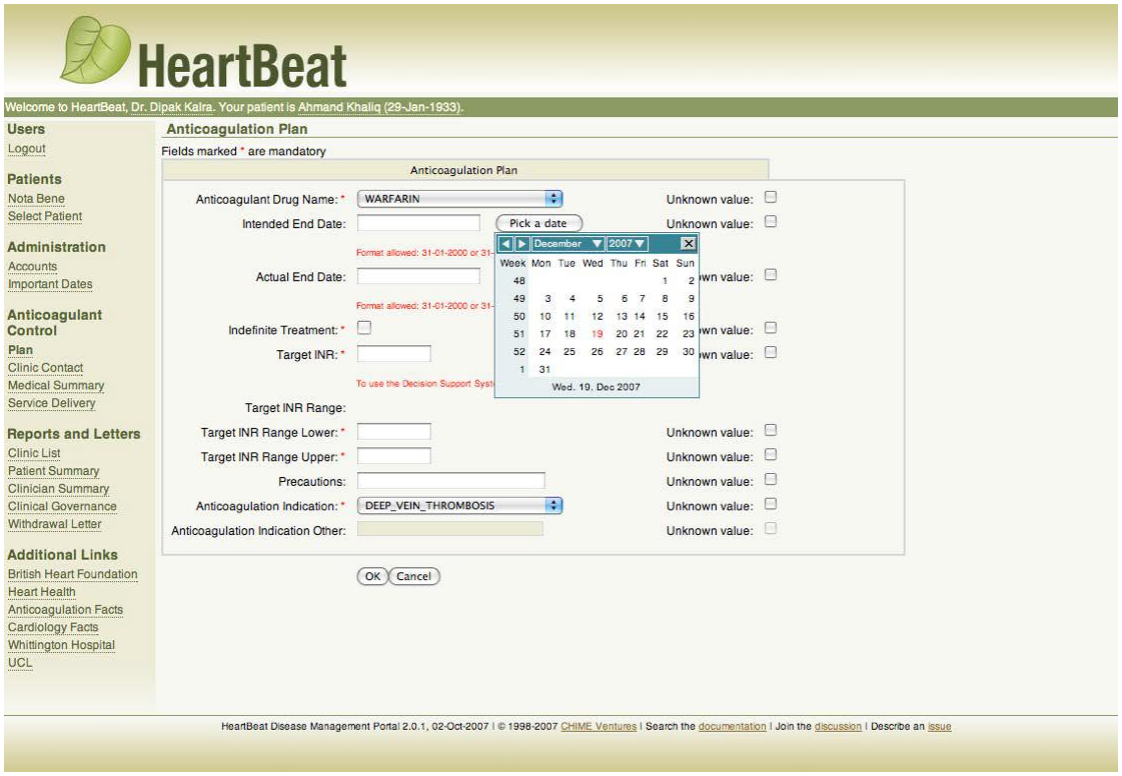


Figure 4-2 HeartBeat Anticoagulation Plan Screen (Patterson and Kalra 2011)

4.4.2.5 Unique Health Identifier

To ensure consistent identification of patients across the range of sites at which anticoagulation management services are delivered, the service has utilised the NHS Number.

The NHS Number is a unique health identifier that can be used within the NHS healthcare services in England and Wales. It is a 10 digit number which is given to all patients registered with the NHS in England and Wales. The number is generally written in the "3-3-4" format for legibility purposes (e.g. 943-476-5919). The NHS number is randomly generated, is never reused and is assigned to the patient for the duration of their life. The 10 digit NHS Number was introduced in 1996 and replaced a number of different health identifiers which existed across the NHS and were comprised of numbers and letters. All patients with an old number were assigned a new 10 digit number. All babies born in England and Wales since 1996 have been assigned an NHS Number at birth and any remaining members of the population who do not have an NHS Number are assigned one when they register with an NHS GP Practice (NHS 2010). Practitioners can also search for patients using demographic details including name and date of birth.

Use of the NHS Number has been selected as a high priority issue within the NHS as a factor which can contribute to safer and higher quality care. Patient awareness campaigns have focused on the positive aspects of identity verification for healthcare providers which enables the complete healthcare record to be matched to the patient. The importance of identity verification when patients are being passed to different parts of the healthcare service has also been highlighted and patients can see their NHS Number on all their healthcare records, prescriptions and correspondence sent to them from the NHS. Four main areas have been indicated to benefit in terms of safety, security and efficiency from routine use of the NHS Number are 1) Facilitating matching of discharge summaries which are sent to a GP or other healthcare practitioner when a patient leaves hospital; 2) Facilitating matching of pathology tests which are sent a GP; 3) Ensuring correct patient identification by pharmacists when they receive a prescription and 4) Facilitating patient referrals between healthcare practitioners in the NHS (NHS 2010).

The main driver behind introducing the NHS Number was to ensure patient safety, especially at the points of interchange within the healthcare system. The number was designed to be patient-centric rather than to fit the needs of any one healthcare organisation. The NHS has also engaged in a process of communication with healthcare practitioners to inform them of the benefits of using the NHS Number and to reinforce the idea that all primary patient identification should be based on the NHS Number (Nicholls 2008). The key message has been "Use The Number" with this tagline and associated logo being used across a range of NHS communications. The National Patient Safety Agency also issued a Safer Practice Notice stating

that patients are being put at risk if the NHS Number is not used in their process of care (National Patient Safety Agency 2009).

The NHS Number is supported by the Personal Demographics Service (PDS) which links the NHS Number with the associated database of personal demographic details. The PDS facilitates patient identification but does not store any clinical information regarding patients. The PDS forms part of the NHS Care Record Spine and can interact with other NHS systems such as Choose and Book through the Transaction and Messaging Service (TMS). HL7 messages between services accessing the Care Record Spine are handled by TMS (Figure 4-3).

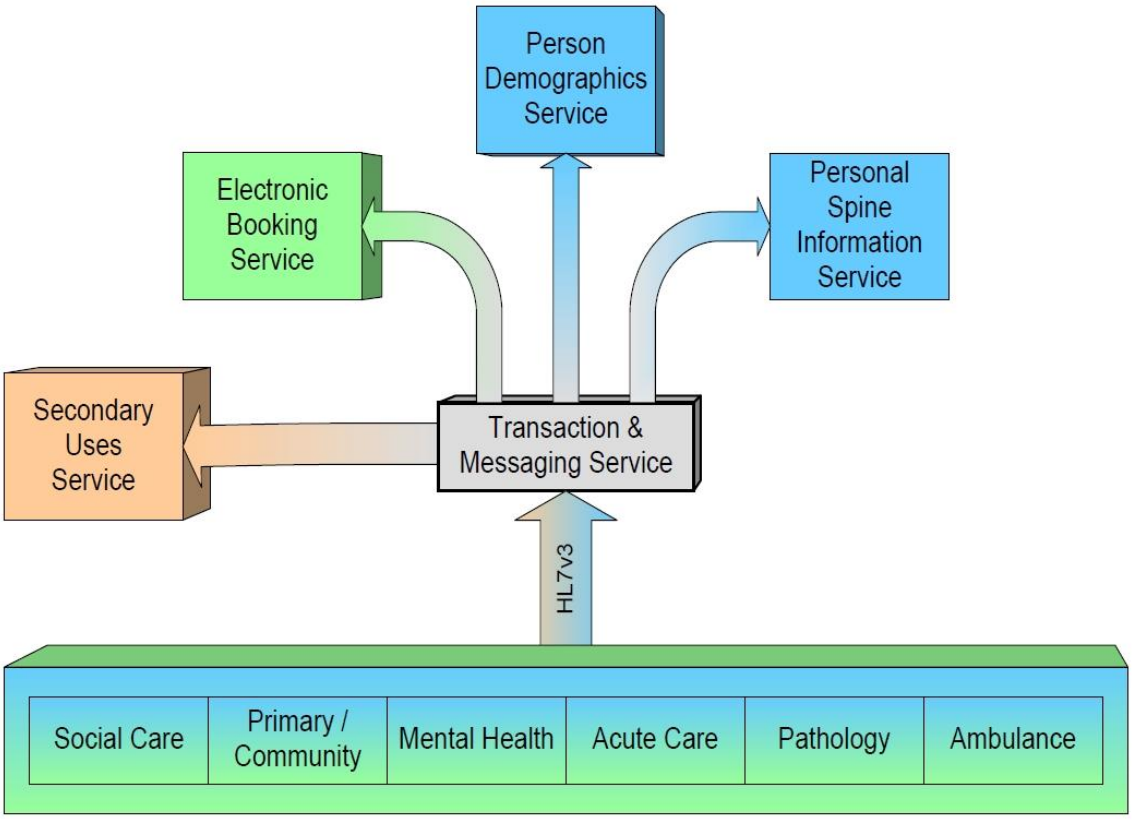


Figure 4-3 Overview of NHS Care Record Spine (NHS Connecting for Health 2005)

The maintenance of patient privacy whilst utilising the NHS Number was an integral part of the design process. A number of steps have been taken to ensure patient privacy including the use of smart cards and associated PIN when healthcare staff are accessing patient records, the level of access to the PDS can be controlled for individual healthcare workers, healthcare records can be provided for audit and research purposed as the NHS Number is content-free and cannot be decoded by members of the public and the system records all user actions which can be audited by designated individuals to verify the purpose for which the records were accessed.

4.4.2.6 Health Messaging

Communication between healthcare practitioners affiliated to Whittington hospital is facilitated by the web-based CDSS. This enables practitioners who respond to the support phone-line to be able to have a real-time view of the patient record and to provide advice accordingly. Patients may also be attending a GP who does not have access to the web-based CDSS and in this situation, local agreements may be in place surrounding the level of information they require. It is often the case where community pharmacists will phone the GP's to inform them of the anticoagulation status of their patients or to enquire about medication which may interact with warfarin therapy.

The hospital clinic and the community pharmacy both utilise the same web-based CDSS and so the patient details and INR history can be viewed by the practitioners in the hospital clinic. If a patient has a suspected bleeding or thrombotic event, the patient must be sent to the Emergency Department (ED) in Whittington hospital. The ED does not have access to the web-based CDSS and thus the protocol is to ensure verbal communication is established with a member of staff in the ED when a patient is being referred.

The development of the anticoagulation CDSS in Whittington Hospital has taken place within the broader context of developing an internationally-interoperable EHR through the SynEx project. The anticoagulation CDSS was the first component to be implemented by UCL as part of this project and was used as a proof of concept site to demonstrate the ability to provide an integrated care service between primary and secondary care by providing seamless interfaces to existing systems. SynEx was a European project which ran from 1998-2000 and built on previous projects such as Good European Health Record (GEHR) and Synapses (Kalra *et al* 2000). The Synapses project was concerned with providing access to the distributed components of a patient record by presenting extracts of individual patient records in a structured manner. The three main concepts that formed the Synapses project were the Synapses object model (SynOM), the Synapses object dictionary (SynOD) and the Synapses record. The Synapses project played an important role in the development of the European EHR Communications pre-standard ENV13606 (Grimson *et al* 2001). The SynEx project built on and integrated the concepts developed by the Synapses project. The SynEx project has implemented the ISO/EN 13606 standard which utilises dual model architecture to provide semantic interoperability in the electronic health record communication. This dual modelling approach has also been adopted by openEHR and HL7 (Austin, Kalra, *et al* 2009).

The SynEx implementation at Whittington Hospital enabled the CDSS to evolve from the standalone system which had been deployed at individual locations in the hospital to a web-based system which interfaced with the EHR and enabled an integrated model of care to be deployed in the North London region. Use of the system outside of Whittington hospital was problematic at the outset for pharmacies as they were required to utilise a dial-up connection and token authentication to access the secure web-based CDSS. This dial-up connection made it difficult to establish and maintain the network connection. After a period of time pharmacies were given access to NHSnet (N2) which was being used to provide secure network connections for hospitals and doctors.

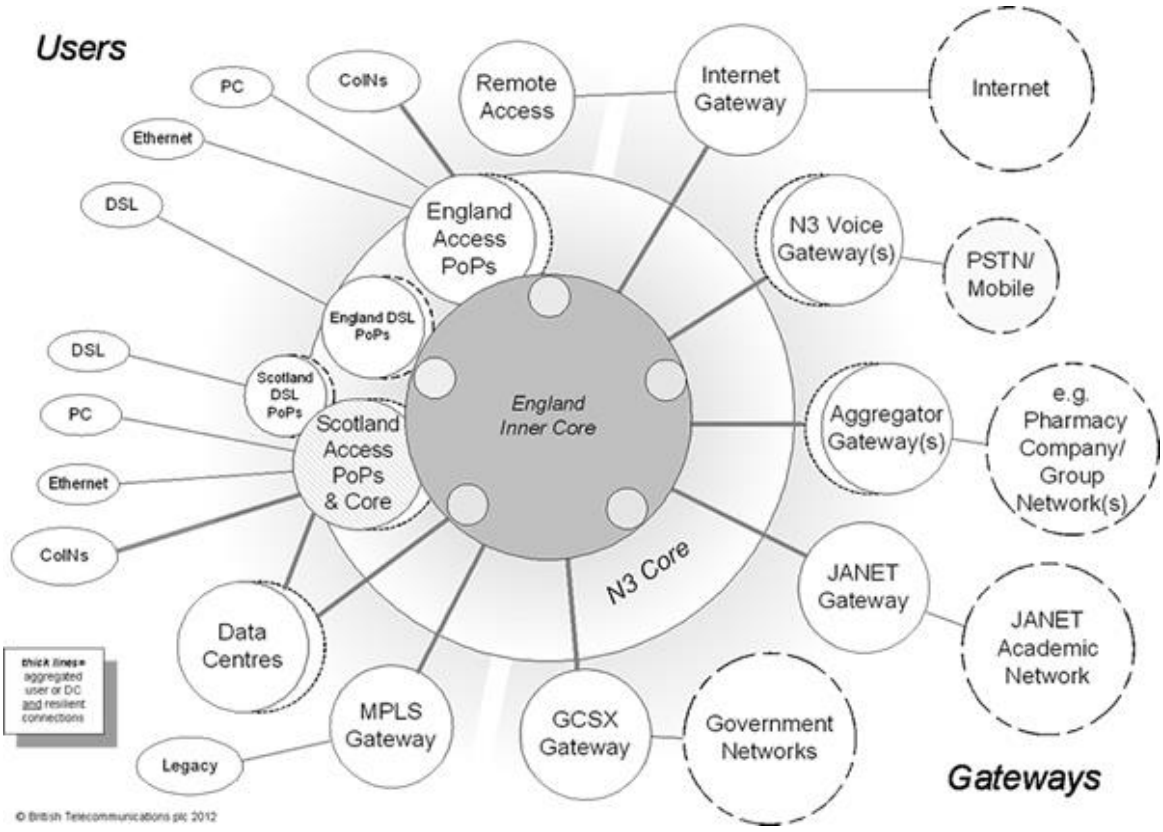


Figure 4-4 Conceptual overview diagram of the N3 network (NHS 2013)

NHSnet was then superseded by N3 which was designed to provide secure broadband connectivity for NHS providers also enabled access for non-NHS providers who are involved in NHS services. N3 provided the platform upon which IT systems and services could be delivered across local, regional and national areas (Figure 4-4). The availability of the N3 network has enabled reliable and secure access to the HeartBeat system from pharmacies and GP practices operating in community locations.

4.4.3 Service Evaluation

The community-based services provided by NCLASPS were deemed to be successful in a service overview conducted by the NHS Service Delivery and Organisation Programme who examined four criteria; clinical outcomes, financial return, service user feedback and commissioner feedback. The clinical outcomes were found to be positive in terms of TTR with respect to international standards and the outcomes achieved in the Whittington Hospital outpatient service. The services were being operated in a manner which provided a financial return for Whittington Hospital. The service user feedback demonstrated that patients were satisfied with the services and had positive user experiences. Health service commissioners also demonstrated positive experiences in dealing with NCLASPS and the number of Primary Care Trusts involved with the service has continued to increase since its inception.(Potts *et al* 2011).

4.5 Case Study 3: Community Pharmacy Anticoagulation Management Service, New Zealand

4.5.1 Service Background

The Community Pharmacist-led Anticoagulation Management Service is a Health Workforce New Zealand (HWNZ) sponsored project which was led by the Pharmaceutical Society of New Zealand (PSNZ). The service has been rolled out to 76 pharmacies across New Zealand and it is envisaged that between 130-140 pharmacies will be operating the service by the end of the 3 year funding model. Approval for a pilot study involving 16 pharmacies was granted in July 2010 and a steering group was established in September 2010. The ability to get the pilot community pharmacy anticoagulation management service approved was due a proactive pharmacist, the diagnostics company looking for new markets, an enabling CDSS and the favourable political climate all coming together at the right time.

The community pharmacy anticoagulation management service operates solely on the basis of GP referrals. This reflects the traditional model of anticoagulant care in New Zealand which is based in the primary care setting and is provided by GP's. The service utilises a mechanism known as a standing order which had been set up by the regulatory bodies which enabled pharmacists to change warfarin doses and to carry out adjustments to the therapy in a GP-led integrated patient care model of service delivery. The model emphasises the collaborative nature of the service with the GP and the pharmacist working together to benefit the health and well-being of the patient. The pharmacist is legally bound to carry out the service in line with the documented policies and procedures which have been specified in the service contract. By utilising the standing order the service operates with the oversight of a GP who will maintain responsibility for the patient once the pharmacist follows these policies and procedures.

Participating pharmacies were chosen based upon: geographical distribution; evidence of support from local primary care providers; accessibility in terms of location, opening hours and population served; ability to provide high quality of care in the service; staffing levels of at least two full-time equivalent pharmacists and the ability to achieve a target service user level of 45 patients. The pre-requisite criteria in relation to pharmacist training were set out by the Pharmaceutical Society of New Zealand. These included sufficient knowledge in the areas of oral anticoagulation and associated risks, pharmacokinetics of warfarin, dose adjustment and emergency procedures. These competencies were delivered and assessed by the New Zealand

College of Pharmacists on a one day training programme which involved theory and demonstration sessions.

INR Online is the CDSS utilised the delivery of the community pharmacy anticoagulation management service. It was initially developed by a consultant haematologist for use within his professional practice. The INR reporting software was initially deployed as standalone software but was later developed into the web-based system INR Online. New Zealand has a well established health information infrastructure which is utilised by INR Online to communicate details such as test results and anticoagulation status to GP's and other healthcare service agencies.

Appendix 4 contains more comprehensive background information on the establishment and operation of the community pharmacy anticoagulation management service.

4.5.2 Health Information Systems

4.5.2.1 CDSS

The core functionality of the CDSS part of INR Online was developed by consultant cardiologist for use in his professional practice prior to the pilot programme being rolled out. The system was then built on and expanded in the years leading up to and during the pilot programme. This involved developing the web-based INR Online and the enhanced communication services. This customisation was carried out by INR Online to fit the system they had into the existing health information infrastructure that existed in New Zealand.

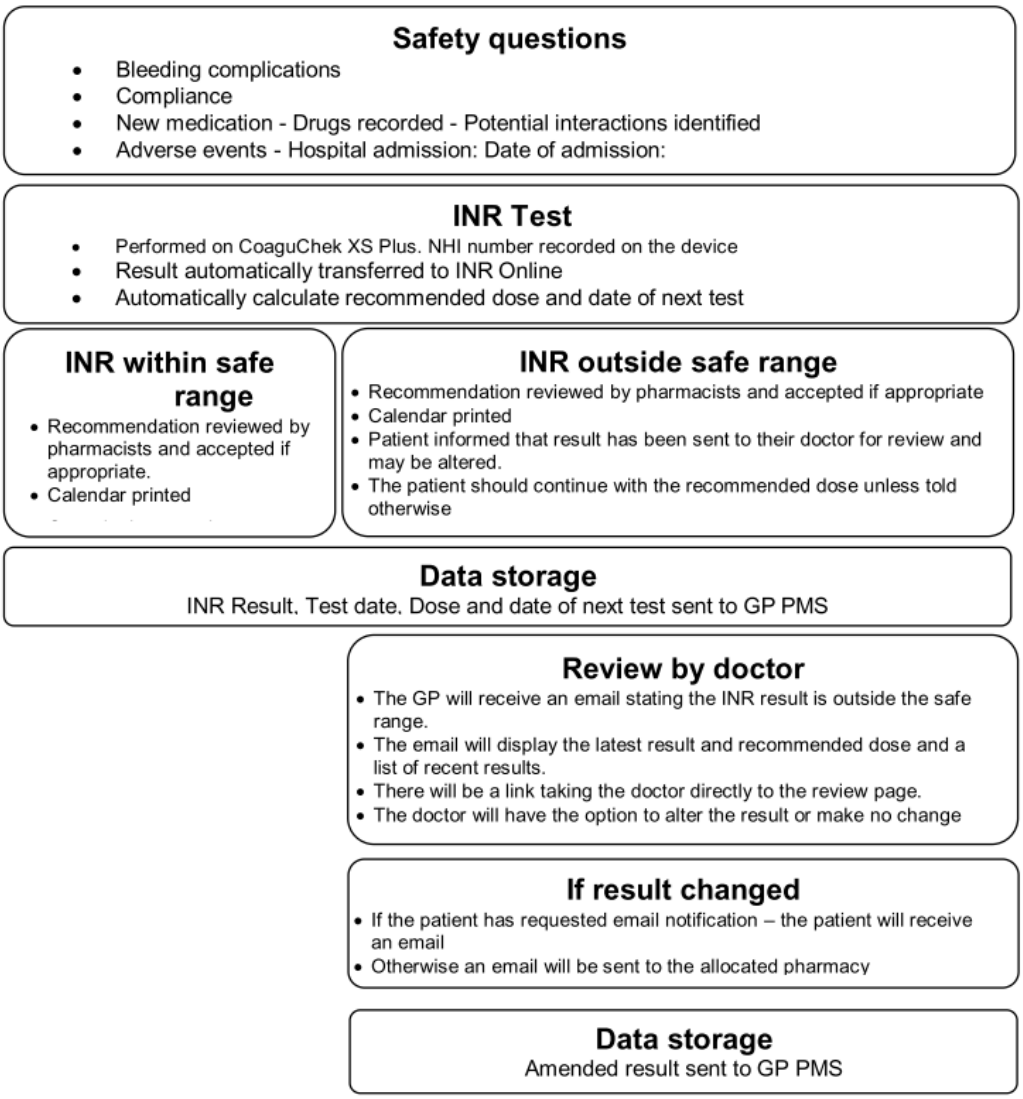


Figure 4-5 Summary of Testing Process (Harper 2012)

The testing procedure involves a number of steps (Figure 4-5) which the pharmacist follows to ensure the quality and safety of the service. Initially, the pharmacist logs onto INR Online using their individual credentials which are supplied by INR Online. Patients are then found by searching for their National Health Index (NHI) number. Access to patient records is controlled by the pharmacist login details but all patients registered on the system can be found by searching for their NHI number. If a patient is transferring from another service or if they temporarily require a test to be carried out in another location, the pharmacist can obtain access to their record and this action will be included in the audit logs for security purposes.

Patients are asked a number of questions in relation to medication compliance, adverse events, new medication and hospital visits since their last test. The patients are asked these questions each time a test is carried out to ensure they are no issues which could compromise

the safety of anticoagulation therapy. The pharmacist then enters the operator ID and the patient's NHI number on the CoaguChek device. Once the finger prick test has been completed, the results are automatically transferred from the CoaguChek device to INR Online along with the operator ID and NHI number which were entered. INR Online then calculates the recommended warfarin dose and the next test date. If the INR result is within the safe range, which is set as 1.5-4.0 by default, the pharmacist can review and accept or reject the CDSS recommendations.

Figure 4-6 INR Online Dose Calendar (INR Online 2012)

A treatment calendar can then be printed for the patient that visually represents the warfarin dose to be taken each day until the next test (Figure 4-6). The traditional method of communicating warfarin doses to the patient was by filling out the details in the "red book" which is also contains general information on warfarin treatment. A number of pharmacists continued to fill out the "red book" as this was a document recognised by other healthcare practitioners and also kept a historic record of their warfarin therapy details.

The INR Online system provides a documented audit trail of all activities carried out on the system. The facility exists to override the recommendations generated by the system and this will be communicated to the GP along with the other information from the consultation. Views

differ as to whether the INR Online software acts as a tool to guide the treatment decisions which are made by the pharmacist or whether the decisions generated by the system are to always be followed unless alterations are first discussed with the GP. It was not indicated that auditing of the frequency or distribution of overrides was carried out on a regular basis.

INR Online presents the graphs of the recent INR history, the individual test results and the previous warfarin dose onscreen during the patient consultation and this can be very beneficial for patient education as it provides a visual method for the patient to understand their therapy. A red line is used to display the most recent test results and the patient can easily see how this compares to their therapeutic range. This can be used to facilitate patient education and can get the patient more involved in the management of their therapy.

4.5.2.2 Unique Health Identifier

The adoption of a unique patient identifier is often referenced as one of the key actions which facilitated the gradual development and expansion of the HIT infrastructure in New Zealand over the subsequent years. A version of the unique patient identifier has been used since the 1970's when the identifier was introduced to enable demographic and other health care data from hospitals to be stored on a central mainframe system. Political decisions then led to the privatisation of parts of the healthcare system and in order to prevent fragmentation of the healthcare information, the New Zealand Health Information Service (NZHIS) was established in 1992. The objective of NZHIS was to develop a repository for key national standards and minimum data which implemented those standards. One of the first tasks the NZHIS carried out was to establish the NHI and the systems which were implemented are largely still in use. An NHI number actually consists of three numbers and four numbers in the format [ABC1234]. The fourth number is a check digit which was used to assess the validity of the number format prior to the advent of widespread internet access (Ministry of Health NZ 2012a).

The NHI number is used as one of the key patient identifiers for hospital admissions and for other hospital events such as emergency department and out-patient visits. The NHI number is also used to index health care user information in primary health care transactions such as laboratory tests, pharmaceutical prescriptions and general practice consultations. Difficulties with administration of the NHI system have come from a number of angles including data protection concerns raised by the Privacy Commissioner and duplication of entries when NHI batches were distributed on CD prior to widespread use of the internet. These issues were largely addressed in 2001 following the publication of the Wave Report which highlighted these concerns. . A team within NZHIS have been working to ensure the integrity of the data

present within the system. Incompatibilities still exist between the application programming interfaces (API) used to connect to NHI Online Access for Health (NOAH) and the GP practice management systems. Work is being carried out on developing a new NHI API that will facilitate the integration of NOAH functionality into the GP practice management systems (Delany 2006).

Data protection concerns have been raised at various stages during the lifetime of the NHI. Two of the most significant developments have been the introduction of the Privacy Act 1993 and the Health Information Privacy Code 1994. These two pieces of legalisation led to the development of use case scenarios for the NHI and created controls over who could access the system once authenticated via the Health Practitioner Index Common Person Number. The NHI is used within the New Zealand healthcare system for patient identification, linking of healthcare records, communication with patients and for research purposes. As part of the on-going NZHIS upgrade process, auditing procedures have been introduced to enable overview as to what actions authorised users are carrying out when the access the system.

4.5.2.3 Health Messaging

New Zealand has a health system which like Ireland's, is a combination of public and private healthcare providers. However, unlike Ireland the utilisation of information technology by these healthcare providers ranks them amongst the world leaders when considered on a global scale. The widespread uptake and acceptance of health information systems in New Zealand is demonstrated by looking at primary care practitioners where 97% of GP's are using patient management systems, 92% have electronic access to patient test results, 94% issue prescriptions electronically and 92% are using advanced electronic health records (Bowden and Coiera 2013). These statistics were demonstrated to be significantly greater that the average amongst 11 OECD countries which were surveyed as part of a Commonwealth Fund report (Sankaran 2008).

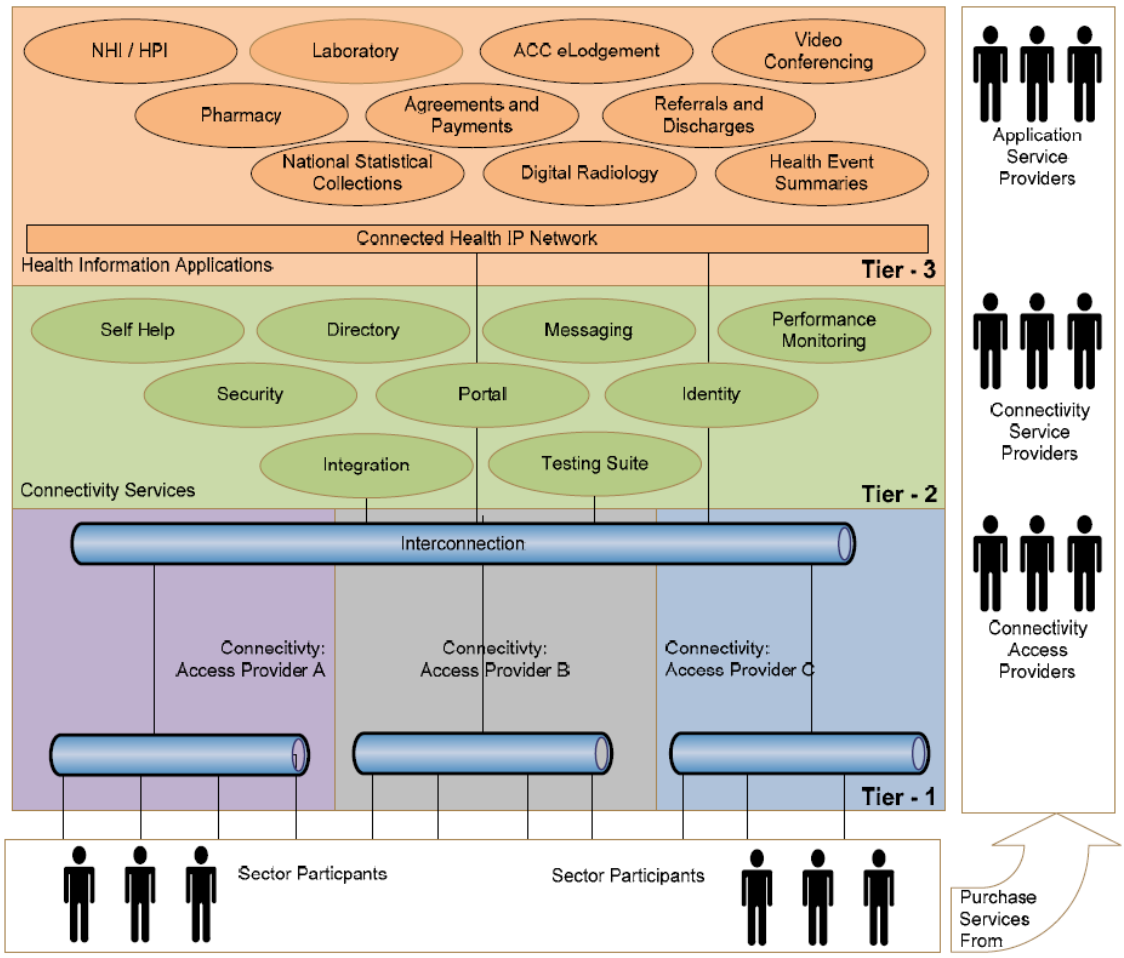


Figure 4-7 Connected Health 3 Tier Model (Huth 2008)

This is mainly due to the highly developed health IT (HIT) infrastructure which is available in New Zealand (Figure 4-7). Components of this infrastructure include a national unique patient identifier, a secure health information network, advanced health messaging systems, current privacy and security legislation and the Health Information Standards Organisation (HISO) which is responsible for setting and implementing national standards for health information (Kerr 2004). This has enabled a high level of interoperability to develop within the national health services. This high level of interoperability has now become part of normal work practices and for example, the average GP exchanges electronic patient information with 58 other healthcare provider organisations for clinical and administrative purposes (Bowden and Coiera 2013). Throughout the entire healthcare service, 50 million items of clinical and administrative information are exchanged annually between the various service providers in the primary and secondary care sectors (Protti and Bowden 2010).

The Wave Report which brought about change in the NHI system was published by the New Zealand Ministry of Health and set out a five-year, broad strategic directive for information

and technology developments. There were a number of initiatives, projects and organisations which were developed or updated following this report such as the HISO which was designed to co-ordinate the development and implementation of standards across the New Zealand healthcare system. New Zealand had adopted HL7 v2.1 for use within the healthcare system in 1993 and HISO endorsed the use of HL7 as the preferred standard for health messaging. New Zealand became the first country in the world implement a widespread HL7-based messaging system for delivery of pathology and radiology information to general practices and for referrals and discharge summaries (Kerr 2004).

HealthLink was established in 1993 in order to develop electronic communication and reporting services targeted at the primary care sector. HealthLink began working with interested parties with the initial goal of developing electronic discharge letters and specialist reports. Healthlink then began to develop an electronic system of claims processing which was facilitated by the launch of the Health Intranet which was a secure network for the interactive exchange of information between health providers in primary care and which would assist the delivery of integrated health services. Following the publication of the Wave Report, the Health Intranet was adopted as the platform for secure health messaging on a national level. In 2005 it was renamed the Health Network and it is now migrating to become the Connected Health Network which will utilise standards, frameworks and network interconnectors to provide a “network of networks”(Huth 2008).

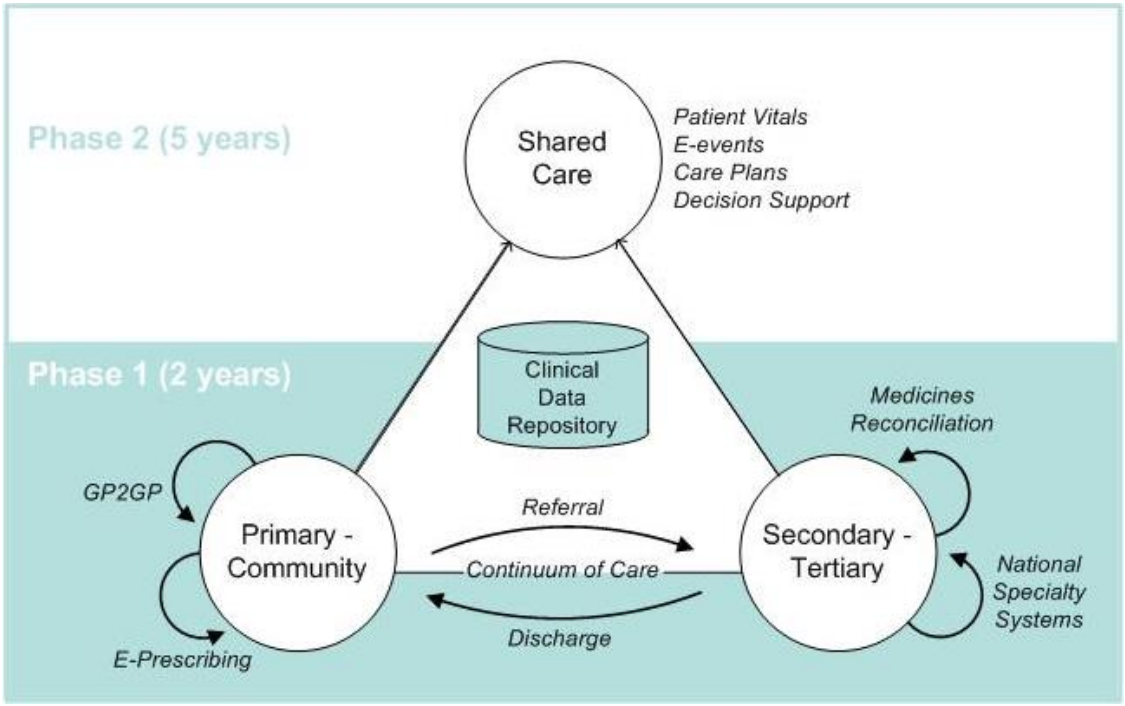


Figure 4-8 Integrated Healthcare Model (National Health IT Board 2010)

This Connected Health Network will facilate the operation of an integrated healthcare model (Figure 4-8) which will promote the use health information soluitions by primary and secondary care providers in the short term and will eventually support a shared care model which will provide access to patient vitals, patient care plans and decision support tools (National Health IT Board 2010).

INR Online was designed with the goal of interoperability in mind. The use of HL7 messaging has enabled integration with GP practice management systems to communicate test result details including latest INR, recommended dose, date of next test, graph of recent control, list of pervious results and a link to INR Online. These details are sent via a secure HL7 messaging service to the GP practice management system via HealthLink where they are accessible in the provider inbox. This operates on the same system that sends traditional laboratory results to the GP patient management system. The test results are also stored in the TestSafe national laboratory repository in Auckland and the Canterbury Health Laboratories repository in Christchurch. The GP can also opt to receive these results by email. The INR result, next test date and dosage calendar can also be sent to the patient if they wish to provide their email address for this purpose. This email is sent over the secure Connected Health network which facilitates electronic communication within the healthcare sector (INR Online 2012).

If results are out of range, an email is sent to the GP but the responsibility is on the pharmacist to actively follow this up to ensure the GP has received it and determine how they would like to act on it. The email is to alert the GP or practice nurse that the result obtained is out of range, what the result was, what the recommend warfarin dose is and when the next appointment has been scheduled for. This email also contains a link to INR Online where the GP can see graphs of the recent INR history, the individual test results and the previous warfarin dose which provides them with the information necessary to make their decision. Common practice is for the pharmacist to either phone the practice nurse or GP directly to confirm that this email has been received and to determine if the GP would like to accept the CDSS advice or if they would like to override the system. It was found that none of the pharmacies relied upon the email alert to inform GPs about out of range results. Pharmacies generally agreed specific protocols with GPs which included specific contact methods such as faxing, phoning, texting and hand-delivery.

4.5.3 Service Evaluation

A formal evaluation of the 16 centre pilot service was carried out by Shaw, Harrison and Shaw from the University of Auckland. The aims of the pilot study were to ascertain whether the community pharmacy anticoagulation management service could provide safe, effective and economical care. The publication of the final report confirmed that these aims were achieved by demonstrating that the mean Time in Therapeutic Range achieved was 78.6%, that there was a low rate of patients having an INR result of 1.0 below their target range, there was a high level of compliance with 83.1% of tests being carried out on or before the due date and that the cost per patient year was approximately 30% less than standard care (Shaw, Harrison and Shaw 2011).

5 Analysis and Evaluation

5.1 Introduction

This chapter analyses the findings from the research which was carried out into the background, organisation and operation of three distinct community pharmacy anticoagulation management services. This analysis will be framed mainly within the enterprise viewpoint but will also include elements from the information viewpoint of the Open Distributed Processing Reference Model (OPD-RM). The ODP-RM architecture provides a method to develop an interoperable framework for distributed systems and for the abstraction of specified domains within the overall system (Raymond and Armstrong 1995). The analysis will initially concentrate on the topics of CDSS, UHI and Health Messaging. These topics will then be used to analyse the readiness of the Irish healthcare system to support a national community pharmacy anticoagulation management service. Finally, a gap analysis will be conducted to identify the additional information that would be required to develop a more complete understanding of how such a service could operate in Ireland.

5.2 Case Study Analysis

5.2.1 CDSS

It has been previously discussed in Chapter 2 that the use of CDSS enables the delivery of a safe and scalable distributed anticoagulation management service through the provision of recommendations on warfarin dosage adjustment and future appointment scheduling. In addition to decision support many systems can also assist in the operation of anticoagulation management services by tracking patient attendance and measuring key performance indicators such as TTR and patients outside therapeutic range. The features available to those operating and overseeing the anticoagulation management service depend on the particular CDSS chosen. There are a number of commercially available anticoagulation CDSS and some organisations also choose to develop their own CDSS to suit their needs. It was seen from the case studies that all three services utilised a different anticoagulation CDSS and there were differences in the platforms and features of each system.

The Cloyne community pharmacy anticoagulation management service initially operated a manual paper-based service before opting to deploy RAID Express system from HiruMed® UK which has both patient management system and CDSS functionality. The pharmacist operating the service has links with CUH and University College Cork (UCC) who have collaborated on

new methods of anticoagulation management including patient self-testing. However, the CoagCare (Zycare Inc., Chapel Hill, NC, USA) web-based CDSS which was used in the delivery of the patient self-testing service is no longer operating. The pharmacist conducted a review of the commercially available CDSS and the RAID Express system was eventually chosen based upon suitability for use in the pharmacy setting and price.

RAID Express is a software programme which is installed on a computer located in the patient consultation area of the pharmacy where the anticoagulation management service is delivered. The patient management functionality of the software enables an individual electronic record to be created for each patient registered with the service. These records are stored on the local computer but there is no facility to share or provide access to these records remotely or via a web-based platform. The software enables the recording and storage of INR results for each patient and the CDSS functionality then provides recommendations on the daily warfarin dose and the next test date. The daily warfarin dose is calculated to one decimal place but in practice patients will be advised to take a warfarin dose which can be achieved using the standard tablet strengths of 1, 3 and 5mg. Therefore if the software returns a recommended daily dose of 7.5mg (total weekly dose of 52.5mg) the pharmacist would instruct the patient to take 7mg for four days and 8mg for three days per week (total weekly dose of 52mg). These calculations have to be carried out by the pharmacist as there is no facility to generate a daily breakdown or dosage calendar. The pharmacist believes that the CDSS can adequately deal with routine maintenance of stable patients but that the ability to differentiate between a provoked and an unprovoked change in INR would make the software more useful in practice.

The CDSS which forms part of the NCLASPS service is one which has been developed through a long standing partnership between Whittington Hospital and CHIME located in UCL. The collaborative efforts of clinicians and the software team have led to the development of a number of systems, each of which has evolved from the previous one. These systems all operate based on the clinically validated algorithms which were developed by a Doctor of Medicine student working with CHIME and the cardiology department of Whittington Hospital. The dosage recommendations and suggested date for the next appointment are still determined using these algorithms. The initial CDSS was designed for use on standalone workstations mainly within the cardiology department. The initial goal of the system was to facilitate the operation of warfarin clinics by doctors who did not have much experience in

anticoagulation management. This initial CDSS was deployed using BASIC programming and an Access™ 2.0 database which became obsolete due to programme upgrades.

The lessons learned from the initial CDSS led to the development of a Java-based CDSS which could be accessed from multiple locations within the hospital and utilised an Oracle® database which would provide enhanced flexibility and future-proofing. The CDSS became a core part of the hospital strategy for utilising health information systems in the delivery of care. The hospital became involved in the SynEx project and began to use the CDSS in the provision community-based anticoagulation management services. The community anticoagulation management service was then expanded and pharmacists were trained and provided with access to the web-based CDSS which enabled them to provide seamless care for patients transferred from the hospital-based service. The latest upgrade to the web-based CDSS saw the roll out of the HeartBeat platform which will be used to manage care across the interlinked services for anticoagulation, heart failure and atrial fibrillation. The new system utilises AJAX to provide a more dynamic user experience. The new system also enables analysis and audit of user actions and clinical performance on an individual or group level.

The CDSS which forms part of the CPAMS in New Zealand was initially developed by a consultant cardiologist for use in his professional practice but has since been developed into a commercially available system. INR Online was developed within New Zealand and was built on and expanded in the period leading up to and during the pilot programme. INR Online was also designed to provide pharmacists with convenient features to enable them communicate details about past trends and future treatment plans to their patients. INR Online presents the graphs of the recent INR history, the individual test results and the previous warfarin dose onscreen during the patient consultation. This can be very beneficial for patient education as it provides a visual method for the patient to understand their therapy. A treatment calendar can then be printed for the patient that visually represents the warfarin dose to be taken each day until the next test. The treatment calendar automatically populates each day with a numerical and pictorial description of the warfarin dose to be taken. Each pharmacist is provided with individual authentication details and this enables audit functions regarding user actions and performance to be carried out at individual or overall service level.

5.2.2 UHI

As discussed in Chapter 2, a Unique Health Identifier is a single non-transferrable number which is used to identify a patient across all healthcare settings for the duration of their life. The availability of a UHI facilitates high quality patient care through the positive identification

of patients, providing access to complete and consistent patient records, reducing duplication of administrative tasks and facilitating added-value analysis and research into healthcare data.

It has been seen that the two community pharmacy anticoagulation management services operating outside Ireland have the facility to identify patients using a national UHI. The NHS Number is used by the North Central London Community Based Anticoagulant and Stroke Prevention Services to identify patients both in the hospital and community-based anticoagulation management services. The NHS Number is a 10 digit number which is given to all patients registered with the NHS in England and Wales. The NHS number is a lifetime number which is randomly generated and is never reused. Use of the NHS Number has been selected as a high priority issue within the NHS as a factor which can contribute to safer and higher quality care by facilitating identity verification at the point of care, facilitating the transfer of patients between different parts of the healthcare service and by facilitating audit within the healthcare system (NHS 2010).

The NHI is used by the national Community Pharmacy Anticoagulation Management Service in New Zealand to identify all patients within the service and also as part of the health messaging service which allows results to be communicated to GP's, hospitals and test result repositories. New Zealand was one of the first countries to recognise the importance of having a unique identifier solely for healthcare purposes. The NHI number does not store any patient information and is used to link with the patient demographics which are located on the central NOAH system.

The absence of a UHI for the Irish healthcare system means that the anticoagulation management service being operated in Ireland cannot utilise a national patient identification service and therefore must rely on a demographic details as a method of identifying patients. The Irish service uses patient name, date of birth and the hospital MRN to identify patients. The service that is being operated in Ireland at present is on a small scale and identification issues are not of great concern at present. However, if a larger service were to be introduced then there would be real concerns as to how patients and results would be identified within the anticoagulation management service and when being transferred outside the service.

5.2.3 Health Messaging

The extent to which health messaging services are implemented within the three services reflects the maturity of the health information infrastructure which exists in each country. Ireland has a very poorly developed health information infrastructure which is required to

enable implementation of health messaging services between providers and has no service which enables the communication of clinical information to or from pharmacies. Therefore the community pharmacy anticoagulation management service being run in Cloyne is not in the position to utilise existing services to share results or consultation details with GP's or hospitals in an electronic format. The parties have agreed written and oral communication protocols to determine what information needs to be communicated and when this needs to occur.

The health information infrastructure in England is more developed and a range of services such as the secure N3 network connection and NHS Number have been utilised in the delivery of the community anticoagulation services coordinated by Whittington Hospital. The NCLASPS service does not facilitate the transmission of messages to other IT systems but provides a range of healthcare professionals with access to the system. The community anticoagulation management service is a consultant-led model with the consultant haematologist in Whittington Hospital assuming overall responsibility for the service. The HeartBeat CDSS system which is integrated with the EHR in Whittington Hospital and can be accessed by experienced anticoagulation practitioners from the pharmacy and haematology departments. This enables the community service providers to access expert advice regarding a particular patient or situation. The healthcare professionals can access the shared record simultaneously to facilitate a discussion about the issue of concern. This ensures patient safety as both parties will be accessing the same record which will display the most current information available and without any delay while waiting to transfer information between physical locations. This approach has also been demonstrated to be a scalable solution as the web-based system can be deployed in any location that has access to the N3 network.

The most advanced health messaging capabilities of the three case studies are seen in the CPAMS in New Zealand. This service utilises the INR Online CDSS which has been developed by a consultant haematologist and his software team. INR Online was customised during the initial deployment phase to enable INR Online integrate with the health information infrastructure that existed in New Zealand. The use of HL7 messaging standards enables INR Online to communicate information regarding patient consultations directly to GP practice management systems and to send test results to the national laboratory repositories via HealthLink over the secure Connected Health network. Patients can also choose to supply their email address to receive details regarding their most recent consultation and future appointments.

5.3 Warfarin services in Ireland

There has been lack of published information regarding anticoagulation management services for patients on warfarin therapy in Ireland. Anticoagulation management services are provided by hospitals and GP's but there is no central register of where and when these services are provided. In order to quantify the warfarin management services provided in Irish hospitals, the National Clinical Programme for Stroke asked the HSE Business Intelligence Unit to provide a list of the warfarin clinics which provided returns to the unit. This report provided details for 20 hospitals that carried out warfarin clinics. In order to ensure a true picture of the warfarin management services being provided, a telephone survey was carried out to contact all acute and non-acute hospitals to capture any warfarin management services that were not reporting to the HSE Business Intelligence unit. A follow up online survey was directed towards all facilities which reported to carry out anticoagulation management services to determine organisation and operation of the warfarin clinics (Marsden and Smyth 2012).

Out of 33 hospitals that were sent the online survey, 29 were identified as suitable candidates for analysis. It was indicated that the departments responsible for the warfarin management services were Haematology, Cardiology, Care of Elderly, General Medicine, Outpatients Department, Pharmacy / Laboratory. The highest percentage of hospitals held the warfarin clinic on one half day per week, the second largest on five full days per week and the third largest on two full days per week. Many of the clinics operated on a half day basis. 42% of hospitals had 200 or more attendances at the warfarin clinics each week, with the top 5 having over 500 attendances per week.

To determine the location of on-going care, the hospitals were asked to quantify the number of patients that entered and left the service during the study period. The number of new patients entering the service ranged from 3 for the lowest and 520 for the highest. It was found that 46% of hospitals registered more than 100 new patients in 2010. The top 5 each registered over 400 new patients. In terms of patients being transferred to other services, it was found that in seven hospitals (26.9%), no patients were discharged back to their GP and in a further six hospitals (23.1%), less than ten patients were discharged. Of particular interest to the researchers was that one of the biggest services in the country with on average 700 patients seen per week only discharged two patients from their warfarin clinic while another with 550 per week did not discharge any patients. When looking at the overall number of patients registered at a warfarin clinic and the number of patients seen per week, the average

frequency of patient visits to the warfarin clinics varied considerably between locations from 2.1 to 4.7 weeks with the average frequency being calculated at every 3.5 weeks.

It was found that one quarter of patients are waiting more than one week to attend their local warfarin clinic from the time of their referral. In 29 hospitals a Consultant refers patients while in 21 hospitals a Non Consultant Hospital Doctor (NCHD) may refer. Sixteen hospitals indicated that a GP may refer with only two hospitals noting that a nurse can refer. It was found that in 93% of the warfarin clinics surveyed it was the referring physician who determined the required INR range for the patient and in 7% of cases it was the warfarin clinic who determined the INR range. Warfarin dosing is determined by NCHD's (51.7%) in the majority of warfarin clinics with consultants (34.5%), nurses (31.0%) and pharmacists (10.3%) also carrying out warfarin dosing activities.

A large majority of the hospitals (86%) use the British Society for Haematology 'Guidelines on oral anticoagulation' to inform the clinical decisions made in the warfarin clinics. A number of hospitals use other sources of information such as the American College of Clinical Pharmacy Guidelines, the British National Formulary or guidelines which have been developed locally.

The personnel carrying out warfarin dosing when a patient is within their therapeutic INR range differs from when the initial warfarin dosing decisions are made. Consultants (17.2%) have a much smaller role in this process with NCHD's (58.6%) and pharmacists (10.3%) providing approximately the same level of service, while nurses carry out this task comparatively more often (44.8%). A multidisciplinary team approach is employed in many hospitals, with combinations of the above healthcare professionals carrying out the warfarin dosing duties (Marsden and Smyth 2012).

An indication of the level of anticoagulation management service provision by GP's was determined by the National Audit of Stroke Care (Irish Heart Foundation 2008). In a survey of 484 GP's with a response rate of 46%, it was found that between 31% and 47% operated a warfarin clinic. A larger proportion of the GP's participating in the Heartwatch programme, which is focused on the secondary prevention of cardiovascular disease, were found to operate warfarin clinics.

The operation of a community pharmacy anticoagulation management service is in line with a number of government strategy documents which set out the future direction of service delivery in Ireland. In the National Service Plan 2013, the HSE reaffirmed its commitment to

introducing new models of care which will enable care to be delivered at the least complex level in the most cost effective manner (HSE 2013b). The goal is to increase the delivery of care within the primary care sector and to decrease the reliance on the secondary care sector. Routine chronic care has been identified as an area which can be managed to a greater extent in the primary care sector with will enable the secondary care sector to focus on the delivery of acute care services. The HSE have established a number of National Clinical Programmes (NCP) to improve the delivery, quality and patent safety of services through the establishment of optimal care pathways. One of the deliverables of the NCP for Stroke is to increase anticoagulation in known atrial fibrillation (HSE 2012b). It has been demonstrated that OAT is frequently underused in AF patients, with the levels of warfarin therapy in this cohort of patients varying between 30 and 60%. One of the prerequisites for initiating patients on warfarin is the availability of suitable anticoagulation management services to ensure the safe and effective delivery of anticoagulation therapy (Nieuwlaat *et al* 2006). The HSE have also committed to providing the health information systems required for the operation of a community pharmacy anticoagulation management service including the roll-out of a secure health service communications platform to enable health messaging between healthcare practitioners, supporting ICT infrastructure across the primary and secondary domains and a unique health identifier (Department of Health and Children 2004).

5.4 Health Information Systems and Services in Ireland

5.4.1 CDSS

The use of CDSS in the delivery of anticoagulation management services is recommended by the BCSH Guidelines on Oral Anticoagulation with Warfarin (Keeling *et al* 2011). The BCSH state that computer assisted dosing is superior to manual dosing and can increase TTR but also recognise that features such as appointment scheduling, tracking patients who are overdue and generating reminders regarding anticoagulation end dates contribute to the delivery of a safe anticoagulation management service. In Ireland, anticoagulation management services are delivered by GP's and hospitals but there is no nationally recommended or preferred CDSS. The warfarin clinic survey which was carried out in 2012 found that 12 out of 27 hospital warfarin clinics utilised CDSS in the delivery of their anticoagulation management service. These hospitals used commercially available CDSS from four vendors: DAWN, RAID, Apex iSoft/iLab and BAP-PC. There are no figures available to indicate the prevalence of CDSS in the provision of anticoagulation management services by GP's in Ireland (Marsden and Smyth 2012).

The warfarin clinic survey also found that data collection in relation to operation of the services was inconsistent and this made accurate audit at a national level impossible. The recommendations included that CDSS should be a minimum requirement for anticoagulation management services being operated by hospitals. It was noted that the widespread use of CDSS would result in the standardisation of anticoagulation management, enable a wider range of healthcare practitioners to deliver the service and would provide valuable data to enable credible audit of the services provided. The use of CDSS would also lead to the provision of a safer service as it has been proven to reduce the risks of bleeding and thrombotic events (Marsden and Smyth 2012).

5.4.2 Unique Health Identifier

As was previously discussed in Chapter 2, HIQA have stated that "*the absence of a UHI for individuals is the single most important deficiency in the health information infrastructure in Ireland*" (Health Information and Quality Authority 2009). This is due to the fact that the availability of a UHI is one of the fundamental building blocks needed to implement high quality services that utilise best practice health informatics principles to safely and securely provide services to patients within a modern health system. A common requirement for all such services is that the healthcare professional can be confident that they are dealing with the right patient in the right place at the right time.

The need for a unique health identifier has been identified in a number of reports and publications stretching back over a decade such as "Building a Culture of Patient Safety: Report of the Commission of Patient Safety and Quality Assurance" (Department of Health and Children 2008) "Building Healthier Hearts – Introduction to the Report of the Cardiovascular Health Strategy Group" (Wiley and Shelley 1998) and "Quality and Fairness: A Health System for You" (Department of Health and Children 2001).

The Department of Health and Children recognised the necessity of introducing a unique health identifier and put forward the position that the PPS number should be repurposed for this use in their policy document "Health Information: A National Strategy" (Department of Health and Children 2004). Following on from this policy document, the government began a public consultation process on the Health Information Bill in 2008 where it accepted submissions from interested parties. The Data Protection Commissioner made a submission to the Department of Health which contained the statement "*this Office cannot in any way support the use of the PPSN as a unique health identifier (UHI) in the health system*" (Data Protectition Commissioner of Ireland 2008). In 2009 HIQA published "Recommendations for a

Unique Health Identifier for Individuals in Ireland" in which they also rejected the use of the PPSN for use as a unique health identifier. A number of other recommendations were also made in the report including the fact that a new healthcare-focused number should be created, that the required infrastructure and governance should be put in place to support the UHI and that this should all be done as soon as possible (Health Information and Quality Authority 2009).

HIQA published another report in 2010 entitled "International Review of Unique Health Identifiers for Individuals" which examined the unique health identifiers in England, Canada, New Zealand, Australia and Germany assessing the features of each system and detailing what lessons could be learned from the experience in each country. This work was then built on for a dissertation entitled "Implementing an Individual Health Identifier in Ireland" which recommended that the Australian model should be used as the basis for a unique health identifier in Ireland (Figure 5-1) (Harney 2012). It was found that the Australian Individual Health Identifier (IHI) scored highest in the evaluation method set out in "Standard Guide for Properties of a Universal Healthcare Identifier" (The American Society for Testing and Materials 1995). It was also noted that the Australian Individual Health Identifier was introduced in 2010 and managed to learn from the positive and negative experiences in other countries.

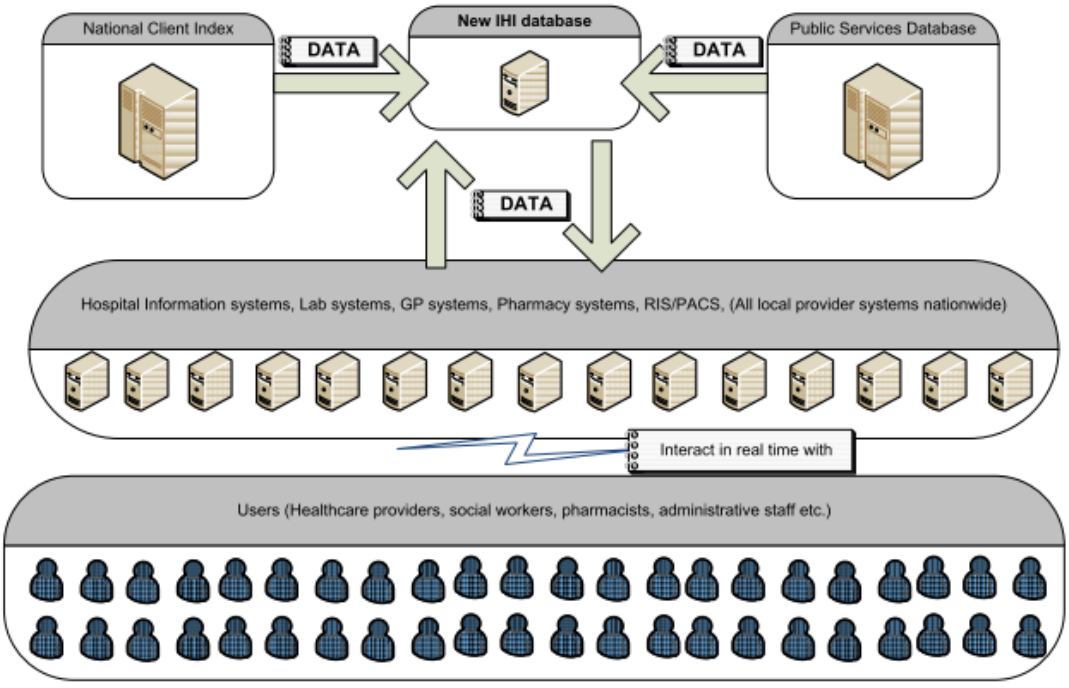


Figure 5-1 Example of how IHI service could be structured (Harney 2012)

The absolute details of the unique health identifier for Ireland will not be known until the Health Information Bill has been published. There have been many false starts and publication deadlines set for the Health Information Bill which has been in a draft state since 2008. At the beginning of this dissertation the date of publication of the bill was scheduled for late 2013 but has since been pushed out to early 2014 (Department of the Taoiseach 2013).

5.4.3 Health Messaging

As was discussed in Chapter 2, the use of standards-based messaging can facilitate a greater integration of healthcare services between secondary, primary and tertiary sectors by enabling providers to collaborate more effectively in the delivery of patient care. However, the lack of funding and investment which has been provided for the development of the health services IT infrastructure means that implementing any wide scale health information service can be very difficult. These difficulties include the lack of a dedicated health information network, the lack of a unique health identifier and the lack of information about what types of health information systems have been deployed by public and private healthcare providers. One large-scale project which had to overcome these difficulties was the National Integrated Medical Imaging System (NIMIS).

The aim of the NIMIS project was to develop a standardised national solution for Picture Archive and Communication System (PACS). A study was carried out in 2010 that found that only 16 out of 50 publically funded hospitals had PACS. These systems had been sourced and installed by the individual boards of management at each hospital and had resulted in a wide range of systems with varying capabilities being installed. NIMIS took the approach of installing the same solution in each hospital to enable them to become filmless in radiology, to improve efficiency in radiology and to improve patient safety. Key goals of the system were to enable studies to be performed at one location and for the reporting to take place at any other location where the NIMIS solution had been deployed. The vendor solution that was implemented provided for a centralised data repository which archived a copy of each study from each individual location which could then be accessed as required. In order to deploy this system the issues of network connectivity, identity and systems interoperability had to be addressed. An initial site survey of 35 hospitals was carried out and it was found that the majority of the hospital systems in the target sites were HL7 v2.x compliant. This fact reinforced the use of HL7 v2.x as one of the core standards for the NIMIS project (Harney 2012).

NIMIS operates on the Government Virtual Private Network (VPN) which enables the transfer of information across public networks in a secure and managed fashion. The government VPN is not a dedicated system for the transfer of health information but it does provide the required levels of security and management for the operation of such a service. The lack of a national UHI meant that the NIMIS project had to identify individuals within the system using the local hospital MRN. This means that patients who have examinations in a number of different hospitals will have a number of different records associated with the individual MRN's. The project team began to investigate the possibility of linking the records for an individual patient by querying the National Client Index (NCI) which is operated by the PCRS. This statistical matching service would determine the probability of a match by comparing key demographic details and then the verified identity details would be stored on the centralised data repository. Much of the technical details required to operate this matching service had been worked out before this approach had to be abandoned due to guidance from the Data Protection Commissioner. It was judged that the hospitals had not obtained consent from the patients for their data to be used in this manner. NIMIS has been deployed in over 60% of the target locations to date (O'Hare 2013). The HSE has also increased the scope of the NIMIS project and has increased the number of sites in which it will be deployed to 41 (Cahill 2013a).

Healthlink is another large-scale project within the Irish healthcare sector and is designed to facilitate the operation of health messaging services. The National Healthlink Project began in 1995 within the Mater Hospital and has since evolved into the national HealthlinkOnline project which is funded by the HSE. Healthlink has established itself as the national messaging broker for the exchange of health information between the primary and secondary healthcare sectors. These messages are all specified in HL7 v2.4 and formatted in XML 2.0. The latest statistics indicate that 34 hospitals and 2958 individual GP's are now using Healthlink. Both inbound and outbound messages are facilitated by Healthlink and the system is used by hospitals to send results and notifications to GP's and to send referrals from GP's to hospitals. There is a wide variation in health messaging capabilities between hospitals with some only able to send laboratory results while some of the larger hospitals have reached the stage where they are now sending electronic discharge summaries to the GP's (Lalor 2013). The three major General Practice Information systems (Health One, Socrates and Complete GP) in Ireland all support HL7 as the standard for health messaging (Harney 2012). These systems have all been certified by the General Practice Information Technology (GPIT) group within the Irish College of General Practitioners (ICPG) (ICPG 2013).

5.5 Potential for Community Pharmacy Anticoagulation Management Service in Ireland

In order to develop a safe and scalable community pharmacy anticoagulation management service for deployment on a national scale in Ireland, a framework needs to be put in place to facilitate the operation of such a service. A number of vital components such as a unique health identifier, CDSS, health messaging and clinical governance have been identified but they interact and rely upon a much broader range of systems and services to function effectively. This broad service layout has been represented in the diagram below (Figure 5-2). This diagram demonstrates the interplay between infrastructure and clinical services which are necessary for the large scale deployment of a community pharmacy anticoagulation management service.

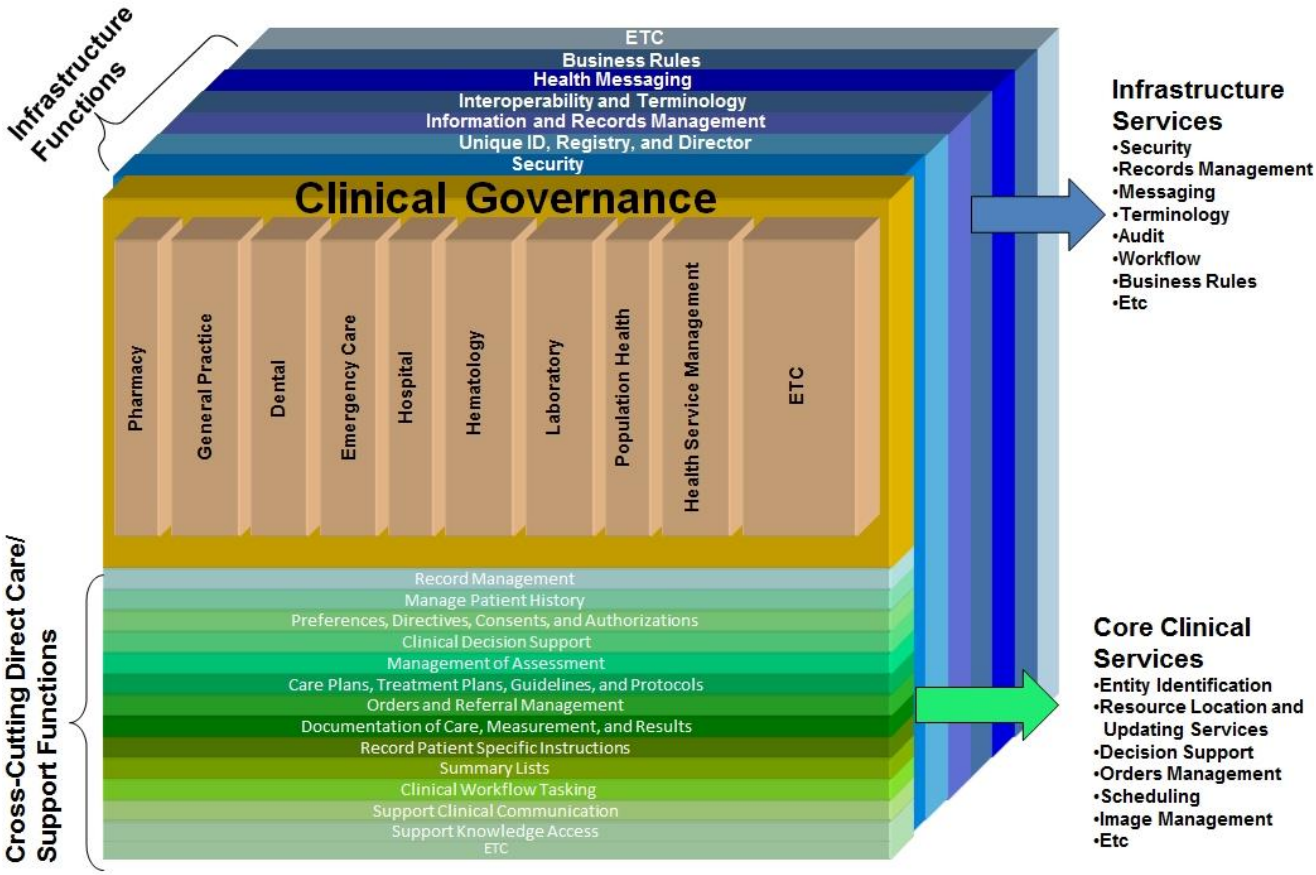


Figure 5-2 Service Model Diagram Adapted from (Hufnagel 2010)

The proposed solution for the implementation of a community pharmacy anticoagulation management service in Ireland is based on an integrated model of care. This recognises that no single model of care can accommodate the needs of all patients at all times. Therefore there will be a number of parties involved in the care of the patient during their

anticoagulation therapy including pharmacists, GP's and secondary care providers. The solution that is put in place must enable these healthcare practitioners to safely make treatment decisions regarding the patient whilst being fully informed of their anticoagulation status. There may also be a case for facilitating the self-care of patients and the solution should provide the flexibility to integrate this type of care also.

As has been seen in the case studies, there are two main forms of medical oversight that can be utilised in the delivery of a community pharmacy anticoagulation management service i.e. a consultant-led service (Cloyne, NCLASPS) and a GP-led service (New Zealand). In the case of Cloyne and NCLASPS, the consultants who acted as the service leads were heavily involved in the design and specification of the services and thus were the clear choice to provide medical oversight for the service. Both of these services operate over a limited geographical area and have a relatively stable number of enrolled patients which enables a single consultant haematologist to provide the required level of medical oversight. The New Zealand service relies upon each pharmacy to identify a local GP who then assumes medical oversight for the operation of the service in that particular pharmacy. This model is a reflection of the fact that prior to the commencement of the community pharmacy service, the vast majority of anticoagulation management functions were carried out by GP's. The pharmacies that operate the anticoagulation management service are also located in geographically diverse locations and GP-led model means that medical oversight is provided by a GP in the same locality as the pharmacy. The choice of service lead for a national community pharmacy anticoagulation management service in Ireland is difficult due to the fact that anticoagulation management services are currently provided by both hospital-based clinics and GP's. The choice of service lead would be likely to require discussions between representatives for pharmacists, GP's and consultants in conjunction with the HSE, Department of Health and regulatory bodies.

The inclusion of CDSS for a national community pharmacy anticoagulation management service in Ireland is vital for the operation of a safe and scalable service. It has been seen that the use of CDSS enables non-expert practitioners to deliver a service which is comparable in terms of safety to the gold standard of hospital-based anticoagulation management clinics. As was seen with the NIMIS project, the adoption of a standardised solution for all participants in the service would provide a common platform which would simplify training, support and systems interoperability. The computerised solution should support a wide range of clinical functions in addition to providing decision support. These functions include user

authentication, record management, patient history management, clinical communication and audit.

The identification of patients within any anticoagulation management service is necessary to ensure the safety of the patients during service delivery and when communicating information with outside parties. It has been seen from the case studies that it is possible to operate a small-scale service utilising demographic details but the services operating at a larger scale utilise a unique health identifier. The availability of a unique health identifier for the Irish healthcare system is long overdue but there are strong indications that enabling legislation for the introduction of the IHI will be passed within the next six months. As an interim measure, the NIMIS project has demonstrated that the technical capabilities exist to link episodes of care from different healthcare providers but this solution would not be as robust as utilising the IHI.

In order to facilitate integrated care and medical oversight, the system should enable other healthcare practitioners to be made aware of the anticoagulation status of patients being managed in the pharmacy setting through the use of health messaging and/or a web-based system. The Healthlink system currently facilitates the exchange of HL7 v2.x messages between GP's and hospitals. HL7 v2.x is the health messaging standard which has been endorsed by HIQA and the majority of hospital systems identified during the NIMIS survey are capable of handling messages in this format. Thus a CDSS solution capable of sending and receiving messages in the HL7 v2.x format would have the potential to communicate with GP and hospital systems. This would be advantageous as it would be able to send routine messages such as INR results which would be available to the other healthcare providers should they need to consult them. The use of a web-based CDSS solution would enable a more in-depth level of access to the anticoagulation record for other healthcare practitioners. If these healthcare practitioners were provided with secure authentication details, they could review the detailed anticoagulation history including clinical notes, graphs and anticoagulation control statistics.

The operation of a distributed service provided by individual anticoagulation practitioners introduces certain challenges regarding the standards that are set for the service and how these standards are reviewed and enforced. The establishment of a Clinical Governance Board would provide a forum for representative stakeholders from all aspects to come together and review and reflect upon the operation of the service. This group would potentially be comprised of representatives for patients, pharmacists, GP's, secondary care providers, the

HSE, the CDSS provider, regulatory bodies and other experts. This group would provide the necessary oversight to ensure that a safe and scalable service was being provided and their functions would include reviewing service operation, service performance (TTR, % in range), clinical incidents and quality assurance measures. The clinical governance board would also oversee the training programme for pharmacists who wish to provide the service and the on-going continuing professional development for pharmacists actively providing the service.

5.6 Evaluation

An evaluation of the approach which was proposed in the Potential for Community Pharmacy Anticoagulation Management Service in Ireland was carried out by approaching two domain experts for their opinions. These two domain experts are a doctor and pharmacist who are involved in the delivery of anticoagulation management services in the hospital and community pharmacy settings respectively. They were provided with section 5.5 and asked to submit feedback regarding this proposal and any other information which they felt would benefit the study.

The feedback which was received indicated that CDSS would potentially be of greatest benefit when a pharmacist is just beginning to deliver the service. This would give these inexperienced practitioners an opportunity to evaluate the recommendations given by the CDSS using the knowledge they received during their training and decide on the most appropriate course of action. It was also felt that this initial period of service delivery could be further supported by the use of solutions which enable input from more experienced clinicians. Suggestions include the facility to electronically share details of patient consultations with experienced clinicians who are required to digitally sign off on treatment decisions before they are communicated to the patient. Should this prove to disrupt the process of patient care, experienced clinicians could review the treatment decisions on a daily, weekly or monthly basis to ensure the correct decisions are being made and to provide feedback/learning outcomes to pharmacists. It was suggested that it would be beneficial to be able to share results and/or patient records with other healthcare professionals to facilitate the highest standard of patient care. It was indicated that the CDSS could be used for auditing the performance of the service and that this would be a vital requirement for a broader community pharmacy anticoagulation management service. It was felt that the various funding models including state-funded, patient-funded and co-payment would have to be investigated to determine what the optimal solution would be.

6 Conclusions and Future Work

6.1 Introduction

The primary objective of this research was to carry out a detailed examination of a number of community pharmacy anticoagulation management services in order to identify the necessary supports and services that would be needed to establish and run a CPAMS on a nationwide basis in Ireland. The research question posed was "What lessons can be learned from the international experience to assist the development of suitable health information support services for a community pharmacy anticoagulation management service in Ireland?" The research process provided for a thorough understanding of each service and enabled the common and unique elements to be identified. An examination of the current state of anticoagulation management services and health information systems and services in Ireland provided the basis for understanding what future work would need to be carried out to support the operation of a nationwide CPAMS.

6.2 Research Findings

The research identified the main components required for the establishment of a community pharmacy anticoagulation service in Ireland. The readiness of the Irish health information infrastructure to support these components demonstrated that significant work and investment would be required to enable a state-of-the-art community pharmacy anticoagulation management service to be delivered in Ireland.

6.3 Gap Analysis

There are a number of areas which were outside the scope of this dissertation but that would have to be investigated in order to develop a complete understanding of the potential for a community pharmacy anticoagulation management service in Ireland. One area is the level of current anticoagulation management service provision by GP's in Ireland. The Warfarin Clinic Survey which was carried out under the supervision of the NCP for Stroke provided detailed information on the anticoagulation management services being provided at 31 hospital locations around the country (Marsden and Smyth 2012). However, there are no clear figures available at a national level which indicate the number of GP's that are providing anticoagulation management services. The type of service that GP's are providing would also provide an insight into expected level of anticoagulation control as the variation between the various models of care were discussed in Chapter 2. The HSE have stated that geographic

inequalities exist in terms of access to anticoagulation management services and that the services provided by GP do not operate in a standardised or integrated manner. The HSE recognise that a significant investment in the provision of anticoagulation management services is required (Cahill 2013b).

An economic viability study would also be required to be carried out to determine the costs associated with the delivery of a community pharmacy anticoagulation management service including the cost of equipment, software licenses, staff and training. The various funding models including state-funded, patient-funded and co-payment would have to be investigated to determine what the optimal solution would be. The cost and benefits of providing the service would be very important information for both the state and the pharmacists. The state would need to be able to compare the cost and potential benefits of funding a community pharmacy anticoagulation management service compared to the current system which is provided by hospitals and GP's. The HSE have stated that significant investment into the provision of anticoagulation management services is required and an assessment would have to look at how to achieve the greatest return on this investment. Funding a community pharmacy anticoagulation management service would eliminate the need for the HSE to employ additional healthcare staff and to acquire or equip additional premises in which to deliver the services.

The economic assessment would also have to look at the alternative course of events which may arise from not providing a comprehensive nationwide anticoagulation management programme. This includes the potential cost of morbidity and mortality arising from thrombotic and haemorrhagic events due to the underuse or sub-optimal use of warfarin therapy. Potential costs also exist if patients are switched from the relatively inexpensive warfarin to the much more expensive new oral anticoagulants.

6.4 Limitations of the Study

Examining healthcare services which have been implemented in international locations can give great insight into how these services have been developed and deployed. However, the overall healthcare environments that these services operate in may vary greatly and thus it can be difficult to make direct comparisons as to how such a service could operate in another country. The evaluation criteria which were outlined in section 3.4 could also be viewed as limitations of the study as available time, suitable healthcare environments and a necessity for English language literature to be available may have impacted on the scope of the study. The

willingness of representatives from identified case studies to be interviewed also served as a limitation of the study. The author of the research is a pharmacist and while an impartial research viewpoint was aspired to, it is a factor which should be noted by the reader.

6.5 Recommendations for Future Work

In order to implement a safe and scalable community pharmacy anticoagulation management service in Ireland, a number of health information systems and services need to be available for utilisation. The provision of these systems and services has the potential to benefit the healthcare service as a whole as most service providers will be able to leverage an IHI, secure network and secure messaging platform to deliver safe healthcare. It is recommended the following areas should be investigated during future work:

- Investigate implementation of IHI
- Investigate economic potential for service provision
- Investigate the potential for a secure, dedicated healthcare network
- Investigate the potential for pharmacies utilise a secure messaging platform (e.g. Healthlink)
- Investigate CDSS solutions available or need to develop bespoke system
- Investigate potential members of CGB and education/training requirements
- Potentially carry out a small scale pilot
- Roll out national service if pilot scheme proves a success

6.6 Reflections on the Study

This research focused on the delivery of anticoagulation care through the network of community pharmacies in Ireland. However, there are a range of chronic conditions such as diabetes, asthma and heart failure which could have elements of care delivered through community pharmacies. There are many commonalities in the requirements for delivering anticoagulation care and delivering care for these chronic conditions. Elements such as CDSS, UHI and health messaging along with medical oversight from a GP or consultant would all be required for the delivery of a broader range of services in community pharmacies. The successful operation of a community pharmacy anticoagulation management service could provide valuable experience to enable expanded service delivery in the primary care setting through integrated care models.

7 References

Agency for Health Care Policy and Research (1995) Life-Saving Treatments to Prevent Stroke Underused [online], available: http://archive.ahrq.gov/news/press/stroke.htm [accessed 28 Feb 2013].

Alberts, M.J., Eikelboom, J.W., Hankey, G.J. (2012) "Antithrombotic therapy for stroke prevention in non-valvular atrial fibrillation.," *Lancet Neurology*, 11(12), 1066–81, available: http://www.ncbi.nlm.nih.gov/pubmed/23153406 [accessed 10 Feb 2013].

Altova (2013) HL7 Technology Overview [online], *Altova.com*, available: http://www.altova.com/HL7_technology_primer.html [accessed 29 Jul 2013].

Amruso, N.A. (2013) "Ability of clinical pharmacists in a community pharmacy setting to manage anticoagulation therapy.," *Journal of the American Pharmacists Association*, 44(4), 467–71, available: http://www.ncbi.nlm.nih.gov/pubmed/15372867.

Ansell, J., Hirsh, J., Hylek, E., Jacobson, A., Crowther, M., Palareti, G. (2012) "Evidence-based management of anticoagulant therapy: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines," *Chest*, available: http://www.ncbi.nlm.nih.gov/pubmed/22315266 [accessed 6 Mar 2013].

Askey, J.M., Cherry, C.B. (1950) "Thromboembolism associated with auricular fibrillation," *Journal of the American Medical Association*, 144(2), 97–100.

Austin, T., Kalra, D., Lea, N.C., Patterson, D.L.H., Ingram, D. (2009) "Analysis of Clinical Record Data for Anticoagulation Management within an EHR System.," *The open medical informatics journal*, 3, 54–64, available: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2737130&tool=pmcentrez&rendertype=abstract.

Austin, T., Sun, S., Lea, N., Iliffe, S., Kalra, D., Ingram, D., Patterson, D. (2009) "Clinical Benefits of an Embedded Decision Support System in Anticoagulant Control," *World Academy of Science, Engineering and Technology*, (53), 1057–1063.

Bajpai, A., Savelieva, I., Camm, a J. (2008) “Treatment of atrial fibrillation,” *British Medical Bulletin*, 88(1), 75–94, available: http://www.ncbi.nlm.nih.gov/pubmed/19059992 [accessed 2 Mar 2013].

Baxter, K. (2013) Stockley’s Drug Interactions [online], *Pharmaceutical Press*, available: www.medicinescomplete.com [accessed 12 Feb 2013].

Benson, T. (2010) *Principles of Health Interoperability HL7 and SNOMED*, Springer.

Best Practice Journal (2009) “INR point of care testing in community pharmacies – is this the future?,” *Best Practice Journal*, (31).

Bowden, T., Coiera, E. (2013) “Comparing New Zealand’s ‘Middle Out’ health information technology strategy with other OECD nations.,” *International Journal Of Medical Informatics*, 82(5), e87–95, available: http://www.ncbi.nlm.nih.gov/pubmed/23287413 [accessed 3 Jun 2013].

Bradbury, M.J.E., Taylor, G., Short, P., Williams, M.D. (2008) “A comparative study of anticoagulant control in patients on long-term warfarin using home and hospital monitoring of the international normalised ratio.,” *Archives of Disease in Childhood*, 93(4), 303–6, available: http://www.ncbi.nlm.nih.gov/pubmed/17675359 [accessed 12 Aug 2013].

Bubner, T.K., Laurence, C.O., Gialamas, A., Yelland, L.N., Ryan, P., Willson, K.J., Tideman, P., Worley, P., Beilby, J.J. (2009) “Effectiveness of point-of-care testing for therapeutic control of chronic conditions: results from the PoCT in General Practice Trial.,” *The Medical Journal of Australia*, 190(11), 624–6, available: http://www.ncbi.nlm.nih.gov/pubmed/19485840.

Byrne, S. (2012) *The Role of Pharmacists – Achieving International Best Practice Standards and Realising Key Opportunities*, School of Pharmacy, University College Cork, available: http://www.thepsi.ie/Libraries/Pharmacy_Practice/Stephen_Byrne.sflb.ashx.

Cahill, N. (2013a) HSE Extends NIMIS Deadline Once Again [online], *Irish Medical News*, available: http://www.imn.ie/index.php?option=com_content&view=article&id=5206:hse-extends-nimis-deadline-once-again&catid=61:news&Itemid=28 [accessed 12 Aug 2013].

Cahill, N. (2013b) Warfarin Clinic Investment Needed [online], *Irish Medical News*, available: http://www.imn.ie/index.php?option=com_content&view=article&id=5299:warfarin-clinic-investment-needed&catid=61:news&Itemid=28 [accessed 28 Jul 2013].

Campbell, H., Link, K. (1941) "Studies on the haemorrhagic sweet clover disease. The isolation and crystallization of the haemorrhagic agent," *Journal of Biological Chemistry*, 138(21).

Chiquette, E., Amato, M.G., Bussey, H.I. (1998) "Comparison of an Anticoagulation Clinic With Usual Medical Care," *Archives of Internal Medicine*, 158, 1641–1647, available: http://50.22.56.132-static.reverse.softlayer.com/data/Journals/INTEMED/22506/ioi71070.pdf [accessed 22 Apr 2013].

Christensen, T.D., Larsen, T.B. (2012) "Precision and accuracy of point-of-care testing coagulometers used for self-testing and self-management of oral anticoagulation therapy.," *Journal of Thrombosis and Haemostasis*, 10(2), 251–60, available: http://www.ncbi.nlm.nih.gov/pubmed/22118602 [accessed 11 Feb 2013].

Coleman, B.B., Martin, C., Barber, N., Patterson, D. (2004) "An evaluation of the safety and acceptability of an anticoagulation clinic in a community pharmacy setting: a pilot study," *Pharmaceutical Journal*, 822–824, available: http://cat.inist.fr/?aModele=afficheN&cpsidt=16328846 [accessed 9 Dec 2012].

Cousins, D., Harris, W. (2006) *Risk Assessment of Anticoagulant Therapy*, National Patient Safety Agency, available: http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60022&...

Dalere, G.M., Coleman, R.W., Lum, B.L. (1999) "A graphic nomogram for warfarin dosage adjustment.," *Pharmacotherapy*, 19(4), 461–7, available: http://www.ncbi.nlm.nih.gov/pubmed/10212019.

Data Protectition Commissioner of Ireland (2008) "Submission of the Office of the Data Protection Commissioner in relation to the proposed Health Information Bill," available: http://www.dataprotection.ie/docs/Submission-of-the-Office-of-the-Data-Protection-Commissioner-in-relation-to-the-proposed-Health-Information-Bill/900.htm [accessed 16 Jul 2013].

Deedwania, P.C. (2013) “New Oral Anticoagulants in Elderly Patients with Atrial Fibrillation,” *The American Journal of Medicine*, available: http://www.ncbi.nlm.nih.gov/pubmed/23369212 [accessed 10 Feb 2013].

Delany, R. (2006) Fourteen Years Young: A Review of the National Health Index in New Zealand [online], available: http://www.hinz.org.nz/journal/2006/06/Fourteen-Years-Young-A-Review-of-the-National-Health-Index-in-New-Zealand/936 [accessed 3 Jun 2013].

Denzin, N.K. (1978) *The Research Act: A Theoretical Introduction to Sociological Methods*, Praeger: New York.

Department of Health and Children (2001) *Quality and Fairness: A Health System for You*, available: http://www.dohc.ie/publications/pdf/strategy.pdf?direct=1 [accessed 22 Jul 2013].

Department of Health and Children (2004) *Health Information: A National Strategy*, available: http://www.dohc.ie/publications/pdf/nhis.pdf?direct=1.

Department of Health and Children (2008) *Building a Culture of Patient Safety - Report of the Commission on Patient Safety and Quality Assurance* [online], available: http://www.dohc.ie/publications/pdf/en_patientsafety.pdf?direct=1.

Department of Health and Children (2010) *Changing Cardiovascular Health - National Cardiovascular Health Policy*, Dublin, Ireland, available: http://www.dohc.ie/publications/pdf/changing_cardiovascular_health.pdf.

Department of the Taoiseach (2013) Government Legislation Programme [online], *taoiseach.gov.ie*, available: http://www.taoiseach.gov.ie/eng/Taoiseach_and_Government/Government_Legislation_Programme/SECTION_B1.html [accessed 22 Jul 2013].

DHB New Zealand (2007) *New Zealand National Pharmacist Services Framework*, available: http://www.dhbsharedservices.health.nz/site/sig/npsf/.

DHB Shared Services (2012) “Expression of Interest to Undertake Community Pharmacy Anticoagulation Management Services,” available:

http://www.pharmacytoday.co.nz/media/403996/cp_-_cpams_expression_of_interest__5_sept_2012.doc.

DHB Shared Services (2013) *Community Pharmacy Anti-coagulation Management Service - Information for General Practice*, Wellington, New Zealand, available: http://www.healthworkforce.govt.nz/sites/all/files/Pharmacy AMS demonstration final evaluation report.pdf.

Dicicco-Bloom, B., Crabtree, B.F. (2006) "The qualitative research interview," *Medical Education*, 40(4), 314–21, available: http://www.ncbi.nlm.nih.gov/pubmed/16573666 [accessed 27 Feb 2013].

Fitzmaurice, D. a, Hobbs, F.D., Murray, E.T. (1998) "Primary care anticoagulant clinic management using computerized decision support and near patient International Normalized Ratio (INR) testing: routine data from a practice nurse-led clinic.," *Family Practice*, 15(2), 144–6, available: http://www.ncbi.nlm.nih.gov/pubmed/9613482.

Gardiner, C., Williams, K., Mackie, I.J., Machin, S.J., Cohen, H. (2005) "Patient self-testing is a reliable and acceptable alternative to laboratory INR monitoring.," *British journal of haematology*, 128(2), 242–7, available: http://www.ncbi.nlm.nih.gov/pubmed/15638860 [accessed 10 Feb 2013].

Garton, L., Crosby, J.F. (2011) "A retrospective assessment comparing pharmacist-managed anticoagulation clinic with physician management using international normalized ratio stability.," *Journal of Thrombosis and Thrombolysis*, 32(4), 426–30, available: http://www.ncbi.nlm.nih.gov/pubmed/21710189 [accessed 10 Dec 2012].

Garwood, C.L., Pharm, D., Dumo, P., Baringhaus, S.N., Laban, K.M., Of, Q., Care, P.A. (2008) "Quality of anticoagulation care in patients discharged from a pharmacist-managed anticoagulation clinic after stabilization of warfarin therapy.," *Pharmacotherapy*, 28(1), 20–6, available: http://www.ncbi.nlm.nih.gov/pubmed/18154470.

Gilmore, R.M. (2008) "Towards an integrated web-based service for the management of patients requiring oral anticoagulation in Ireland."

Gosselin, R.C., Owings, J.T., Larkin, E., White, R.H., Hutchinson, R., Branch, J. (1997) "Monitoring Oral Anticoagulant Therapy with Point-of-Care Devices: Correlations and

Caveats.," *Clin. Chem.*, 43(9), 1785–1786, available: http://www.clinchem.org.elib.tcd.ie/content/43/9/1785.full [accessed 11 Feb 2013].

Grimson, J., Stephens, G., Jung, B., Grimson, W., Berry, D., Pardon, S. (2001) "Sharing health-care records over the Internet," *IEEE Internet Computing*, 5(3), 49–58, available: http://ieeexplore.ieee.org/lpdocs/epic03/wrapper.htm?arnumber=935177.

Guba, E.G. (1990) *The Paradigm Dialog*, Sage: Newbury Park, CA.

Harney, C. (2012) "Implementing an Individual Health Identifier in Ireland," available: https://www.scss.tcd.ie/postgraduate/health-informatics/assets/pdfs/Clare Harney FINAL SUBMISSION.pdf.

Harper, P. (2012) *Standing Orders for the Management of Warfarin*, available: http://www.inronline.net/wp-content/uploads/2012/12/Pharmacy-warfarin-standing-order-Signed.pdf.

Harper, P., Pollock, D. (2011) "Improved anticoagulant control in patients using home international normalized ratio testing and decision support provided through the Internet.," *Internal medicine journal*, 41(4), 332–7, available: http://www.ncbi.nlm.nih.gov/pubmed/20546057 [accessed 2 Jun 2013].

Hayward, R. (2004) "Clinical decision support tools : Do they support clinicians," *Future Practice*, 66–68, available: http://www.cche.net/about/files/clinical_decision_support_tools.pdf.

Health Information and Quality Authority (2009) *Recommendations for a Unique Health Identifier for Individuals in Ireland*, available: http://www.hiqa.ie/system/files/Unique_Health_Identifier_Report_0.pdf.

Health Information and Quality Authority (2012) *Guidance on Messaging Standards for Ireland*, available: http://www.hiqa.ie/system/files/Guidance-on-Messaging-Standards.pdf.

Health Information and Quality Authority (2013) Unique Identifiers [online], *HIQA.ie*, available: http://www.hiqa.ie/healthcare/informing-decision-making/unique-identifiers [accessed 16 Jul 2013].

Health Workforce New Zealand (2011) “Pharmacy Anticoagulation Management Services,” available: http://www.healthworkforce.govt.nz/new-roles-and-scopes/pharmacy-anticoagulation-management-services.

Hennessy, B.J., Vyas, M., Duncan, B., Allard, S. a (2000) “Evaluation of an alternative model of anticoagulant care.,” *Irish Journal of Medical Science*, 169(1), 34–6, available: http://www.ncbi.nlm.nih.gov/pubmed/10846855.

Hill, H. (2013) “Our Developing Community based and Hospital supported Cardiovascular Services including Anticoagulant and Stroke Prevention Services,” 1–9, available: system.improvement.nhs.uk/ImprovementSystem/ViewDocument.aspx?path=Cardiac%2fNational%2fAF Uploads%2fAnticoagulation%2fAnticoagulation Resources%2fExamples of anticoagulation services%2fThe Whittington Anticoagulation Service%2f2011 Service Concept Overview.pdf.

HIMSS (2013) “Definition of Interoperability,” available: http://himss.files.cms-plus.com/FileDownloads/HIMSS Interoperability Definition FINAL.pdf [accessed 29 Jul 2013].

HL7 International (2013) Introduction to HL7 Standards [online], *HL7.org*, available: http://www.hl7.org/implement/standards/index.cfm?ref=nav [accessed 28 Jul 2013].

Hobbs, F., Fitzmaurice, D. (1999) “Is the international normalised ratio (INR) reliable? A trial of comparative measurements in hospital laboratory and primary care settings.,” *Journal of Clinical Pathology*, 494–497, available: http://jcp.bmj.com/content/52/7/494.short [accessed 10 Feb 2013].

Holbrook, A., Schulman, S., Witt, D.M., Vandvik, P.O., Fish, J., Kovacs, M.J., Svensson, P.J., Veenstra, D.L., Crowther, M., Guyatt, G.H. (2012) “Evidence-based management of anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines.,” *Chest*, 141(2 Suppl), e152S–84S, available: http://www.ncbi.nlm.nih.gov/pubmed/22315259 [accessed 29 Jan 2013].

Holbrook, A.M., Pereira, J. a, Labiris, R., McDonald, H., Douketis, J.D., Crowther, M., Wells, P.S. (2005) “Systematic overview of warfarin and its drug and food interactions.,” *Archives of*

Internal Medicine, 165(10), 1095–106, available: http://www.ncbi.nlm.nih.gov/pubmed/15911722.

Holder, R.L., Allan, T.F., Rose, P.E. (2000) "Oral Anticoagulation Management in Primary Care With the Use of Computerized Decision Support and Near-Patient Testing," *Arch Intern Med*, 160, 2343–2348, available: http://www.ncbi.nlm.nih.gov/pubmed/10927732.

HSE (2011) Get the Vaccine – Not the Flu [online], *HSE.ie*, available: http://www.hse.ie/eng/services/News/newsarchive/2011archive/Oct2011/FLU 2011.html [accessed 15 Jul 2013].

HSE (2012a) Stroke Programme - National Clinical Care Programme [online], *HSE.ie*, available: http://www.hse.ie/eng/about/Who/clinical/natclinprog/strokeprog.html [accessed 20 Nov 2012].

HSE (2012b) National Clinical Care Programme - Stroke [online], available: http://www.hse.ie/eng/about/Who/clinical/natclinprog/strokeprog.html.

HSE (2013a) Emergency Contraceptive Pill [online], *HSE.ie*, available: http://www.hse.ie/eng/health/az/M/Morning-after-pill/ [accessed 15 Jul 2013].

HSE (2013b) *National Service Plan 2013*, available: http://www.hse.ie/eng/services/Publications/corporate/NSP2013.pdf.

Hufnagel, S. (2010) "HSSP Practitioners Guide Volume II," in *HL7 Rio Workgroup Meeting*, Rio de Janeiro, Brazil, available: http://hssp.wikispaces.com/file/view/HSSP+Practitioners+Guide+Volume+II+by+EHR+SD +RM+Project+20100526.ppt.

Huth, M. (2008) "Connected Health Architectural Framework," available: http://www.ithealthboard.health.nz/sites/all/files/10037.1 Connected Health Architectural Framework v2.pdf.

ICPG (2013) GPIT Group [online], *ICPG.ie*, available: http://www.icgp.ie/go/in_the_practice/information_technology [accessed 12 Aug 2013].

INR Online (2012) *Using INR Online*, available: http://www.inronline.net/index.php/information/using-inr-online/.

IPU (2011) "Pharmacist of the Year 2011," *IPU Review*, (6), available: http://91.197.228.177/~phar/ipu.ie/images/stories/publications/IPU Review/IPU Review DEC-JAN 2011.pdf.

Irish Heart Foundation (2008) "National Audit of Stroke Care," (April), available: http://www.irishheart.ie/media/pub/strokereports/stroke_report.pdf.

Irish Medicines Board (2009) *Guidelines for Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care*, available: http://www.imb.ie/EN/Publications/Publications/Guidelines-for-Safe-and-Effective-Management-and-Use-of-Point-of-Care-Testing-in-Primary-and-Community-Care.aspx.

Irish Pharmaceutical Healthcare Association (2013) Medicines.ie [online], *www.medicines.ie*, available: http://www.medicines.ie/default.aspx [accessed 10 Feb 2013].

Irish Statute Book (1998) *Data Protection Act, 1998* [online], Irish Statute Book, available: http://www.irishstatutebook.ie/1988/en/act/pub/0025/print.html [accessed 8 Jan 2013].

Jackson, S.L., Peterson, G.M., Bereznicki, L.R., Misan, G.M., Jupe, D.M.L., Vial, J.H. (2005) "Improving the outcomes of anticoagulation in rural Australia: an evaluation of pharmacist-assisted monitoring of warfarin therapy.," *Journal of Clinical Pharmacy and Therapeutics*, 30(4), 345–53, available: http://www.ncbi.nlm.nih.gov/pubmed/15985048.

Jackson, S.L., Peterson, G.M., House, M., Bartlett, T. (2004) "Point-of-care monitoring of anticoagulant therapy by rural community pharmacists : Description of successful outcomes Case studies," *Australian Journal of Rural Health*, 2, 197–200.

Johnson, R.B., Onwuegbuzie, a. J. (2004) "Mixed Methods Research: A Research Paradigm Whose Time Has Come," *Educational Researcher*, 33(7), 14–26, available: http://edr.sagepub.com/cgi/doi/10.3102/0013189X033007014 [accessed 27 Feb 2013].

Johnson, R.B., Onwuegbuzie, a. J., Turner, L. a. (2007) "Toward a Definition of Mixed Methods Research," *Journal of Mixed Methods Research*, 1(2), 112–133, available: http://mmr.sagepub.com/cgi/doi/10.1177/1558689806298224 [accessed 27 Feb 2013].

Joint Formulary Committee (2012) *British National Formulary*, 64th ed, BMJ Group and Pharmaceutical Press: London.

Jones, C. (2008) *Anticoagulation - Managing Patients, Prescribing and Problems*, University of Manchester, available: http://www.cppe.ac.uk/learning/Details.asp?TemplateID=ANTICOAG-D-03&Format=D&ID=0&EventID=41947.

Kalra, D., Austin, A., O'Connor, A., Patterson, D., Ingram, D., Lloyd, D. (2000) *London Demonstrator Site*, available: http://discovery.ucl.ac.uk/1600/1/R1.pdf.

Kalra, D., Patterson, D. (2010) "Sharing patient records across Primary and Secondary Care," (February), available: http://www.ucl.ac.uk/slms/domains/population-health/eHealth/patterson.

Keeling, D., Baglin, T., Tait, C., Watson, H., Perry, D., Baglin, C., Kitchen, S., Makris, M. (2011) "Guidelines on oral anticoagulation with warfarin - fourth edition.," *British Journal of Haematology*, 154(3), 311–24, available: http://www.ncbi.nlm.nih.gov/pubmed/21671894 [accessed 4 Nov 2012].

Kerr, K. (2004) The Electronic Health Record in New Zealand [online], available: http://www.hinz.org.nz/journal/2004/03/The-Electronic-Health-Record-in-New-Zealand---Part-1/892#NZ [accessed 3 Jun 2013].

Kim, Y.-K., Nieuwlaat, R., Connolly, S.J., Schulman, S., Meijer, K., Raju, N., Kaatz, S., Eikelboom, J.W. (2010) "Effect of a simple two-step warfarin dosing algorithm on anticoagulant control as measured by time in therapeutic range: a pilot study.," *Journal of Thrombosis and Haemostasis*, 8(1), 101–6, available: http://www.ncbi.nlm.nih.gov/pubmed/19840361 [accessed 9 Mar 2013].

Kirkwood, T. (1983) "Calibration of reference thromboplastins and standardization of the prothrombin time ratio," *Thrombosis and Haemostasis*, 49, 238–244.

Lalonde, L., Martineau, J., Blais, N., Montigny, M., Ginsberg, J., Fournier, M., Berbiche, D., Vanier, M.-C., Blais, L., Perreault, S., Rodrigues, I. (2008) "Is long-term pharmacist-managed anticoagulation service efficient? A pragmatic randomized controlled trial.,"

American Heart Journal, 156(1), 148–54, available: http://www.ncbi.nlm.nih.gov/pubmed/18585510 [accessed 29 Nov 2012].

Lalor, M. (2013) *Healthlink Newsletter*, available: http://www.healthlink.ie/newsletterJune2013.pdf.

Link, K. (1959) "The discovery of dicoumarol and its sequels," *Circulation*, 19(97).

Mahmud, A., Bennett, K., Okechukwu, I., Feely, J. (2007) "National underuse of anti-thrombotic therapy in chronic atrial fibrillation identified from digoxin prescribing.," *British Journal of Clinical Pharmacology*, 64(5), 706–9, available: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2203268&tool=pmcentrez&rendertype=abstract [accessed 23 Nov 2012].

Mant J, Hobbs FD, Fletcher K, et al. (2007) "Warfarin versus aspirin for stroke prevention in an elderly community population with atrial fibrillation (the Birmingham Atrial Fibrillation Treatment of the Aged Study, BAFTA): a randomised controlled trial," *Lancet*, 370(9586), 493– 503.

Marsden, P., Smyth, D.B. (2012) *Warfarin Clinic Survey*, available: http://hse.ie/eng/about/Who/clinical/natclinprog/strokeprogramme/SProgWarclinsur.pdf.

Ministry of Health NZ (2012a) National Health Index Questions and Answers [online], available: http://www.health.govt.nz/our-work/health-identity/national-health-index/nhi-information-health-consumers/national-health-index-questions-and-answers#background [accessed 3 Jun 2013].

Ministry of Health NZ (2012b) National Health Index [online], available: http://www.health.govt.nz/our-work/health-identity/national-health-index [accessed 2 Jun 2013].

Ministry of Health NZ (2013) Overview of the Health System [online], available: http://www.health.govt.nz/new-zealand-health-system/overview-health-system [accessed 11 Apr 2013].

Montamat, S.C., Cusack, B.J., Vestal, R.E. (1989) “Management of Drug Therapy in the Elderly,” *New England Journal of Medicine*, 321(5), 303–309, available: http://dx.doi.org/10.1056/NEJM198908033210507.

Murray, F. (2008) *The Development of Electronic Health Messaging Services in Denmark, and Lessons for Ireland*, available: http://lenus.ie/hse/bitstream/10147/55193/1/Development of Electronic Health Messaging Services in Denmark, and Lessons for Ireland.pdf.

National Centre for Anticoagulation Training (2013) National Centre for Anticoagulation Training (NCAT) - University of Birmingham [online], available: http://www.birmingham.ac.uk/research/activity/mds/projects/HaPS/PCCS/anticoagulation/index.aspx [accessed 1 Jun 2013].

National Centre for Pharmacoeconomics (2012a) NCPE Rivaroxaban (Xarelto®) spAF Assessment | National Centre for Pharmacoeconomics [online], *www.ncpe.ie*, available: http://www.ncpe.ie/drugs/rivaroxaban-xarelto-for-spaf-2/ [accessed 10 Feb 2013].

National Centre for Pharmacoeconomics (2012b) Dabigatran Etexilate (Pradaxa®) – for the Prevention of Stroke and Systematic Embolisom in Atrial Fibrillation [online], *www.ncpe.ie*, available: http://www.ncpe.ie/drugs/dabigatran-etexilate-pradaxa-for-the-prevention-of-stroke-and-systematic-embolisom-in-atrial-fibrillation/ [accessed 10 Feb 2013].

National Health IT Board (2010) *National Health IT Plan*, Wellington, New Zealand, available: http://www.ithealthboard.health.nz/sites/all/files/National Health IT Plan v11_1.pdf.

National Medicines Information Centre (2006) *The Contemporary Management of Atrial Fibrillation*, Dublin, Ireland, available: http://www.stjames.ie/GPsHealthcareProfessionals/Newsletters/NMICBulletins/NMICBulletins2006/The Contemporary Management of Atrial Fibrillation Vol.12 No.3 2006.pdf.

National Patient Safety Agency (2009) *Risk to Patient Safety of Not Using the NHS Number as the National Identifier for All Patients*, available: http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=61409&type=full&servicetype=Attachment.

NEQAS (2013) UK NEQAS for Blood Coagulation Point of Care Testing (POCT) / Near Patient Testing (NPT) [online], *www.ukneqasbc.org*, available: http://www.ukneqasbc.org/content/PageServer.asp?S=551702&C=1252&ID=29 [accessed 11 Feb 2013].

NHS (2010) *NHS Number FAQ For Patient*, available: http://www.connectingforhealth.nhs.uk/systemsandservices/nhsnumber/patientfaqs.pdf .

NHS (2013) N3 Network Overview [online], available: http://n3.nhs.uk/technicalinformation/n3networkoverview.cfm [accessed 31 May 2013].

NHS Connecting for Health (2005) "SNOMED CT in the NHS Care Records Service Norway," available: http://www.kith.no/upload/2585/SNOMED CT in the NHS Care Records Service Norway Nov 2005.ppt.

Nicholls, M. (2008) *NHS Number Programme Implementation Guidance*, available: http://www.isb.nhs.uk/documents/isb-0149-02/dscn-32-2008/014902322008guidance.pdf.

Nieuwlaat, R., Capucci, A., Lip, G.Y.H., Olsson, S.B., Prins, M.H., Nieman, F.H., López-Sendón, J., Vardas, P.E., Aliot, E., Santini, M., Crijns, H.J.G.M. (2006) "Antithrombotic treatment in real-life atrial fibrillation patients: a report from the Euro Heart Survey on Atrial Fibrillation.," *European heart journal*, 27(24), 3018–26, available: http://www.ncbi.nlm.nih.gov/pubmed/16731536 [accessed 3 Nov 2012].

O'Flaherty, K. (2009) "Pharmacy Point-of-Care Testing - IPJ," *The Irish Pharmacy Journal*, (December), available: http://www.thepsi.ie/Libraries/Irish_Pharmacy_Journal/IPJ_Nov-Dec_2009_Vol_87_Nos_11-12.sflb.ashx?download=true.

O'Hare, N. (2013) "The National Integrated Medical Imaging System (NIMIS)," in *HISI*, available: http://hisi.ie/pdfs/HISI 6 Neil O%27Hare.pdf.

Ouirke, W., Cahill, M., Perera, K., Sargent, J., Conway, J. (2007) "Warfarin prevalence, indications for use and haemorrhagic events.," *Irish Medical Journal*, 100(3), 402–4, available: http://www.ncbi.nlm.nih.gov/pubmed/17491542.

Papastergiou, J., Rajan, A., Diamantouros, A., Zervas, J., Chow, J., Tolios, P. (2012) “HbA1c testing in the community pharmacy: A new strategy to improve care for patients with diabetes,” *Canadian Pharmacists Journal*, 145(4), 165–167, available: http://www.cpjournal.ca/doi/abs/10.3821/145.4.cpj165.

Patterson, D., Kalra, D. (2011) “Continuing development of the community based anticoagulant and stroke Progressing towards Electronic Health Record (EHR),” available: http://www.ucl.ac.uk/slms/domains/population-health/eHealth/patterson.

Pharmaceutical Society of Australia (2011) “Review of anticoagulation therapies in atrial fibrillation.,” (January), 2–3, available: http://www.pbs.gov.au/reviews/atrial-fibrillation-files/42-pharmaceutical-society-of-australia.pdf.

Pharmaceutical Society of New Zealand (2011) *Pharmacy-led Anticoagulation Service Pre-requistes*, available: http://www.centraltas.co.nz/LinkClick.aspx?fileticket=dvE1sxz0wJY%3D&tabid=278&mid=971.

Plüddemann, A., Thompson, M., Wolstenholme, J., Price, C.P., Heneghan, C. (2012) “Point-of-care INR coagulometers for self-management of oral anticoagulation: primary care diagnostic technology update.,” *The British journal of general practice*, 62(604), e798–800, available: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3481522&tool=pmcentrez&rendertype=abstract [accessed 11 Feb 2013].

Potts, H.W.W., Keen, J., Denby, T., Featherstone, I., Patterson, D., Greenhalgh, T., Colligan, L., Nicholls, J., Shah, A., Wong, G., Martin, C. (2011) “Towards a better understanding of delivering e-health systems : a systematic review using the meta-narrative method and two case studies,” available: http://www.sdo.nihr.ac.uk/files/project/SDO_FR_08-1602-131_V01.pdf.

Protti, D., Bowden, T. (2010) “Electronic Medical Record Adoption in New Zealand,” *Issues in International Health Policy*, 96(August), 1–14, available: http://www.commonwealthfund.org/~/media/Files/Publications/Issue Brief/2010/Aug/1434_Protti_electronic_med_record_adoption_New_Zealand_intl_brief.pdf.

Radley, A., Hall, J., Dixon, N. (2000) “Primary care group anticoagulant clinics,” *Primary Care Pharmacy*, (1), 70–2, available: http://www.pjonline.com/PrimaryCarePharmacy/200006/disease/anticoagulant.html.

Raymond, K., Armstrong, L. (Eds.) (1995) *Open Distributed Processing*, Springer.

Roche Diagnostics (2006) “CoaguChek XS Plus,” available: http://www.coaguchek.com/resource.php?id=Resourcefile-113184501270fd75cf&f=UkZJTEUxMTMxODQ1MDEyNzBmZDVlNWEucGRm&W=uk&l=en&mc=professionals.

Rutter, P., Newby, D. (2011) *Community Pharmacy: Symptoms, Diagnosis and Treatment*, 2nd ed, Elsevier Health Sciences: Chatswood, Australia.

Ryan, F., Byrne, S., O’Shea, S. (2008) “Managing oral anticoagulation therapy: improving clinical outcomes. A review.,” *Journal of Clinical Pharmacy and Therapeutics*, 33(6), 581–90, available: http://www.ncbi.nlm.nih.gov/pubmed/19138235.

Ryan, F., Byrne, S., O’Shea, S. (2009) “Randomized controlled trial of supervised patient self-testing of warfarin therapy using an internet-based expert system.,” *Journal of Thrombosis and Haemostasis*, 7(8), 1284–90, available: http://www.ncbi.nlm.nih.gov/pubmed/19496921 [accessed 28 Nov 2012].

Ryan, F., O’Shea, S., Byrne, S., Shea, S.O. (2010) “The reliability of point-of-care prothrombin time testing. A comparison of CoaguChek S and XS INR measurements with hospital laboratory monitoring.,” *International Journal of Laboratory Hematology*, 32(1 Pt 1), e26–33, available: http://www.ncbi.nlm.nih.gov/pubmed/19032373 [accessed 28 Nov 2012].

Sankaran, S. (2008) “Incorporating systems thinking in organizational change projects using action research by practitioners conducting academic research,” *Proceedings of the 52nd Annual Meeting of the ISSS*, 1–17, available: http://journals.isss.org/index.php/proceedings52nd/article/view/1003 [accessed 3 Jun 2013].

Shaw, J., Harrison, J., Harrison, J. (2011) *Community Pharmacist-led Anticoagulation Management Service Final Report - Appendices*, Auckland, New Zealand, available:

http://www.healthworkforce.govt.nz/sites/all/files/Pharmacy AMS demonstration final evaluation report appendices.pdf.

Shaw, J., Harrison, J.J., Shaw, P.J. (2011) *Community Pharmacist-led Anticoagulation Management Service Final Report*, Auckland, New Zealand, available: http://www.healthworkforce.govt.nz/sites/all/files/Pharmacy AMS demonstration final evaluation report.pdf.

Spinewine, A., Schmader, K., Barber, N. (2007) "Appropriate prescribing in elderly people: how well can it be measured and optimised," *Lancet*, 370, 173–184, available: http://www.farm.ucl.ac.be/cfcl/Full-papers-cfcl/Spinewine-2007-2.pdf [accessed 5 Mar 2013].

St John, A. (2010) "The evidence to support point-of-care testing," *The Clinical Biochemist Reviews*, 31(August), 111–119, available: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2924123/ [accessed 21 Feb 2013].

Stafford, L., Peterson, G.M., Bereznicki, L.R.E., Jackson, S.L., van Tienen, E.C., Angley, M.T., Bajorek, B. V, McLachlan, A.J., Mullan, J.R., Misan, G.M.H., Gaetani, L. (2011) "Clinical outcomes of a collaborative, home-based postdischarge warfarin management service.," *The Annals of Pharmacotherapy*, 45(3), 325–34, available: http://www.ncbi.nlm.nih.gov/pubmed/21386021 [accessed 28 Nov 2012].

The American Society for Testing and Materials (1995) *ASTM International: Standard Guide for Properties of a Universal Healthcare Identifier (UHID)*, available: http://www.astm.org/Standards/E1714.htm.

Trapskin, J.P., White, L., Amistead, A. (2006) "Improving the Accuracy of Patient Identification in the Medication Use Process," *American Journal of Health-System Pharmacy*, 63(3), 218–222, available: http://www.ncbi.nlm.nih.gov/pubmed/16434780.

UCL (2013) University College London CHIME [online], available: http://www.ucl.ac.uk/chime [accessed 30 May 2013].

Udall, J. (1962) "The establishment and operation of a long term anticoagulation clinic," *The American Journal of the Medical Sciences*, 244(2), 1–2, available:

http://journals.lww.com/amjmedsci/Abstract/1962/08000/The_Establishment_and_Operation_of_A_Long_Term.11.aspx [accessed 22 Apr 2013].

Vadher, B., Patterson, D., Leaning, M. (1997) “Evaluation of a decision support system for initiation and control of oral anticoagulation in a randomised trial,” *BMJ*, 314(April), available: http://www.bmj.com/content/314/7089/1252.abstract [accessed 5 Jan 2013].

Vadher, B., Patterson, D.L., Leaning, M. (1999) “Prediction of the international normalized ratio and maintenance dose during the initiation of warfarin therapy.,” *British Journal of Clinical Pharmacology*, 48(1), 63–70, available: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2014877&tool=pmcentrez&rendertype=abstract.

Vadher, B.D., Patterson, D.L., Leaning, M.S. (1995) “Validation of an algorithm for oral anticoagulant dosing and appointment scheduling,” *Clin Lab Haematol*, 17(4), 339–45, available: http://www.ncbi.nlm.nih.gov/pubmed/8697730.

Walsh, K. (2012) *Evaluation And Analysis Of Coagulation Management Services And Therapeutic Time In Range For Patients Attending Both Primary And Secondary Care Anticoagulant Clinics*, available: http://www.scribd.com/doc/104427445/EVALUATION-AND-ANALYSIS-OF-COAGULATION-MANAGEMENT-SERVICES-AND-THERAPEUTIC-TIME-IN-RANGE-FOR-PATIENTS-ATTENDING-BOTH-PRIMARY-AND-SECONDARY-CARE-ANTI-C.

Wardrop, D., Keeling, D. (2008) “The story of the discovery of heparin and warfarin.,” *British Journal of Haematology*, 141(6), 757–63, available: http://www.ncbi.nlm.nih.gov/pubmed/18355382 [accessed 8 Feb 2013].

Waring, B., Cooke, T. (2007) “Oral Anticoagulation Management,” *Pharmacy Magazine*, available: http://www.pm-modules.co.uk/pm_modules/ora_pm0707.pdf.

Wensing, M., Wollersheim, H., Grol, R. (2006) “Organizational interventions to implement improvements in patient care: a structured review of reviews.,” *Implementation Science*, 1, 2, available: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1436010&tool=pmcentrez&rendertype=abstract [accessed 28 May 2013].

Whitlon, D., Sadowski, J., Suttie, J. (1978) “Mechanism of coumarin action: significance of vitamin K epoxide reductase inhibition,” *Biochemistry*, 17(8), 1371–7.

Whittington Health NHS (2013) Whittington NHS Trust Website: About Us [online], available: http://www.whittington.nhs.uk/default.asp?c=3920 [accessed 28 May 2013].

Wiley, J., Shelley, E. (1998) *Building Healthier Hearts: The Report of the Cardiovascular Health Strategy Group*, available: http://hdl.handle.net/10147/45832.

Wilson, S.E., Costantini, L., Crowther, M. a (2007) “Paper-based dosing algorithms for maintenance of warfarin anticoagulation.,” *Journal of Thrombosis and Thrombolysis*, 23(3), 195–8, available: http://www.ncbi.nlm.nih.gov/pubmed/17186393 [accessed 6 Mar 2013].

Wolf PA, Abbott RD, K.W. (1991) “Atrial fibrillation as an independent risk factor for stroke: The Framingham Study,” *Stroke*, (22), 983–988, available: http://stroke.ahajournals.org/content/22/8/983.full.pdf.

Wolfram Alpha (2013) Ireland Vs New Zealand Health [online], available: http://www.wolframalpha.com/input/?i=ireland+vs+new+zealand+health [accessed 2 Jun 2013].

World Health Organization Technical Report Series (1983) *WHO Expert Committee on Biological Standardization. Thirty Third Report.*, World Health Organization technical report series, available: http://www.ncbi.nlm.nih.gov/pubmed/22900409.

Yin, R.K. (1999) “Enhancing the quality of case studies in health services research,” *Health Services Research*, 34(5 Pt 2), 1209–24, available: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1089060&tool=pmcentrez&rendertype=abstract.

Zabinski, R., Valley, G. (2009) “Meta-Analysis to Assess the Quality of Warfarin Control in Atrial Fibrillation Patients in the United States,” *Journal of Managed Care Pharmacy*, 15(3), 244–252, available: http://www.amcp.org/JMCP/2009/April/April_PDFs/8115/1033.html [accessed 5 Mar 2013].

Appendix 1 – Interview Themes for Semi-structured Interviews

An investigation into international community pharmacy anticoagulation management services

Interview Questions

1. Briefly describe your role in relation to the development/operation of the community pharmacy anticoagulation management service, in order to outline your perspective.

2. What drivers led to the establishment of the community pharmacy anticoagulation management service, and how was the programme developed and rolled-out?

3. What strategy/approach was taken in terms of safety with regards to;
    - Patients
    - Healthcare professionals
    - Confidential data

4. Was a pilot programme initially rolled out and if so, what were the main lessons learned?

5. What steps were taken to ensure the scalability of this type of multi-centre service e.g. standards, terminologies, data coding, patient identifiers?

6. What models of service delivery e.g. consultant-led and GP-led were considered and what was the rationale behind choosing the eventual model?

7. What health information systems are used to support the operation of the service?
    - What computerised decision support system is used and how was this system chosen?
    - Has the operation of the clinical decision support system been evaluated in practice?
    - Are any electronic messaging services used to communicate results and patient information from the pharmacy to the doctor or hospital?
    - Are there any plans to upgrade or add functionality to the health information systems used to support the operation of the service?

8. What impact has the community pharmacy anticoagulation management service had on the delivery of anticoagulation services in your area?

9. Do you believe that the service delivery model for the community pharmacy anticoagulation management service could be used in the delivery of services for other chronic illnesses e.g. Diabetes management?

10. In your opinion, what do you believe are the key aspects that need to be considered in order for a community pharmacy anticoagulation management service to be developed in Ireland, such as;
    - Governance
    - Education
    - Health information systems

- Evaluation

11. Are there any other topics that you believe we should discuss?

Appendix 2 – Cloyne Pharmacy Anticoagulation Clinic, Ireland

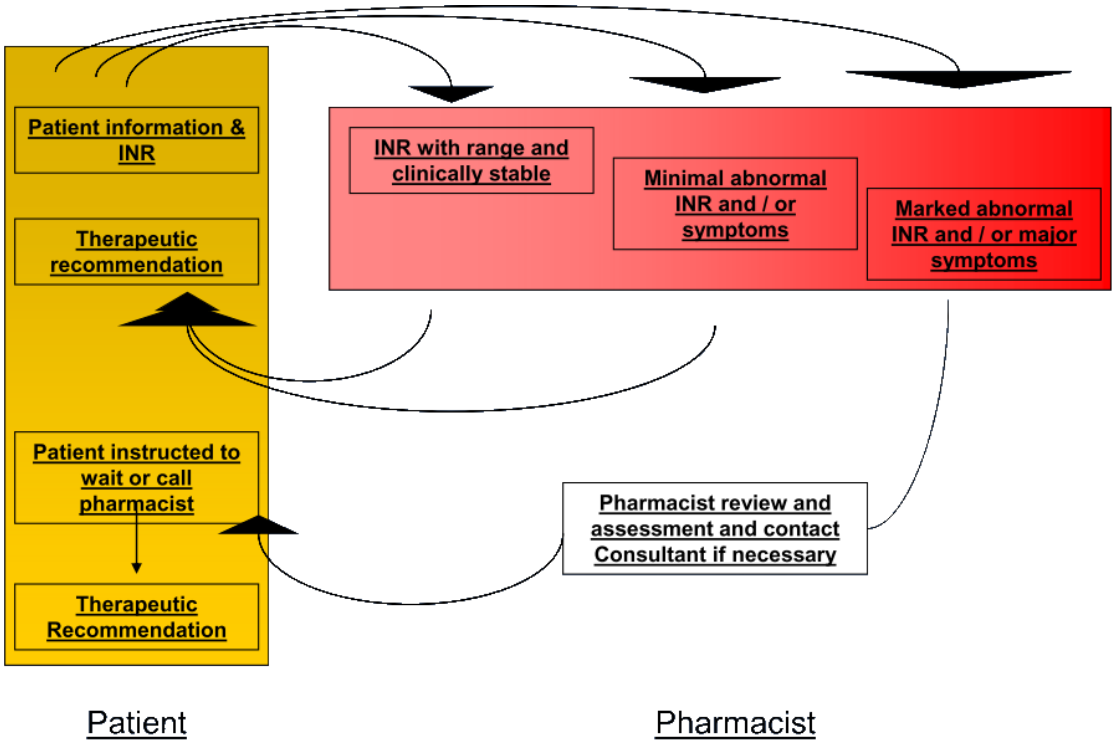
Cloyne Pharmacy is located in the village of Cloyne in south-west Cork. It is situated about 35km from Cork city where CUH, the major hospital for this area, is located. The pharmacist who owns and runs Cloyne Pharmacy has had a long-running interest in the development of community pharmacy services. The pharmacist and another colleague had previously researched the possibility of developing a medication optimisation service for patients with heart failure (IPU 2011).

The pharmacist was approached by one of the patients attending the pharmacy and asked if there was any other option available to him other than attending the anticoagulation management service in CUH. This was the main centre for warfarin management services in the Cork region but was located 30-45 minutes away from the homes of most warfarin patients who attended Cloyne Pharmacy. Specific appointments were not given for the anticoagulation management service in CUH and the patient in question used to wake at 4am in order to be one of the first patients in the queue. The anticoagulation management clinic carried out up to 90 consultations during each clinic and patients who did not arrive early could be waiting for up to four or five hours. The INR measurement would take place at 8am with the results being available at 9am. The patient would then leave CUH and arrive back to his house at 10am.

In order to assess the potential demand for a community pharmacy anticoagulation management service in the area, the pharmacist carried out a survey of the patients who were dispensed warfarin in Cloyne Pharmacy. The results demonstrated that the majority of patients were attending the anticoagulation management service in CUH, the majority of patients would prefer to attend an anticoagulation management service in the community setting and that between 60-65% of the patients would be willing to pay for the service themselves. Responses indicated that a local service would save time and money for patients and carers. Transport issues in terms of cost and time were cited as issues of concern because CUH was at least half an hour each way from Cloyne and further if patients lived outside the town. Carers and patients had to take time off work to attend the anticoagulation management service in CUH. The results of the patient survey demonstrated that there was the demand for an anticoagulation management service to operate at a local level but that was none available. GP's in Ireland were not being paid to provide an anticoagulation management service and no GP in the local area was providing an anticoagulation management service. The results of the survey proved to the pharmacist that there was a gap

in the local service provision and the potential avenues for providing a community pharmacy anticoagulation management service were then investigated.

The Department of Haematology in CUH and Pharmaceutical Care Research Group in UCC had carried out considerable research in the area of oral anticoagulation therapy. These studies included a review of strategies to achieve optimal anticoagulation control and improve the outcomes with oral anticoagulation therapy (Ryan *et al* 2008) and the reliability of portable coagulometers (Ryan *et al* 2010). The teams also carried out a randomised controlled trial of supervised patient self-testing using an web-based expert system (Ryan *et al* 2009). This study involved the novel use of a web-based platform to provide access to the CoagCare CDSS. The pilot project involved patients testing their INR using the CoaguChek XS portable coagulometer. The patients then input their INR results into the CoagCare system which they accessed using their personal login details and were required to input information regarding their recent health status, lifestyle changes or missed doses. The system categorised the results and provided three different levels of response. If the INR level was within normal the normal therapeutic range or slightly outside range, the system provided the patient with their recommended warfarin dose and details of their next scheduled test. INR results which were far outside the target range for the patient prompted the patient to take an additional dose of warfarin if <1.5 or to skip a dose of warfarin if >5.0 and to log back in later that day. These results were reviewed daily by a clinical pharmacist and additional information was provided to the patient upon their next login. If the patient's INR result was extremely out of range of if they provided information suggestive of a thrombotic or haemorrhagic event, they were advised to urgently seek medical attention (as shown in the image following). These out of range results were then discussed at regular meetings between the research pharmacist and a consultant haematologist.



Model of Patient Self-Testing service (Byrne 2012)

Community Pharmacy Anticoagulation Management Service

The close collaboration between the pharmacists in the Pharmaceutical Care Research Group, UCC and the consultants in the Department of Haematology, CUH provided a basis for the pharmacist in Cloyne Pharmacy to initiate discussions on the possibility of setting up a community pharmacy anticoagulation clinic. In January 2009 the pharmacist contacted the anticoagulation management service in CUH, who proved very receptive to the idea of managing patients on oral anticoagulant therapy in the community pharmacy setting. The hospital was looking to reduce the number of patients attending the anticoagulation management service and had commissioned a patient survey to assess patient attitudes to being managed in the community setting. The consultant haematologist believed that a range of healthcare professionals including consultants, non-consultant hospital doctors, GP's, nurses and pharmacists were able to develop the necessary skills to operate an anticoagulation management service. The consultant haematologist believed there were a number of key factors necessary for the operation of a successful anticoagulation management service: the same healthcare professionals provided the service on an on-going basis, the healthcare professionals focused on gaining experience, the healthcare professionals participated in on-going training and that service participated in quality assurance schemes.

With the support of the consultant haematologist, the pharmacist began to plan how the community pharmacy anticoagulation management service would operate. A consultant-led community anticoagulation management service model was adopted. It was envisaged that the community pharmacist would emulate the role of a hospital pharmacist in a hospital-based anticoagulation management service. In April 2009 the pharmacist began to develop the main service protocols in conjunction with the consultant haematologist. The protocols deal with the correct procedures that must be carried out when: in-range INR results are obtained, when out-of-range INR results are obtained and when extremely out-of-range INR results are obtained. The protocol states that for results <1.5 or >5 the consultant haematologist or registrar on duty in CUH must be contacted. The pharmacist will outline the background situation with the particular patient and their recent INR control. The pharmacist will outline the treatment plan and the reasoning behind this and when they plan to carry out the next test. The doctor can then agree to this plan or suggest an alternative plan that would see the pharmacist giving a different warfarin dose or carrying out the next test on a different date. The details of all communication regarding these out of range results are logged including what pharmacist made the contact, who they spoke to, when they spoke to them and what treatment plan was agreed upon. The channels of communication had to be defined and the pharmacist will first contact the anticoagulation management service to speak with the doctor on duty. The pharmacist also obtained the direct contact details of a number of the doctors who work in the anticoagulation management service to facilitate urgent communication when no response is obtained through the primary phone line. The GP will be notified that the patient has had an out of range result and this may be done by email or by phone. This is done to keep the GP updated with the patient's status and to ensure that the GP has up-to-date information when prescribing medication for the patient and so that this information can be provided to out-of-hours services if required. It is the hospital doctors rather than the GP's that will provide guidance on the treatment plan.

Education and Training

A training programme for the community pharmacist was also developed in conjunction with the consultant haematologist. The pharmacist attended a number of anticoagulation management clinics in CUH and observed the operation of the service. The pharmacist also attended a number of training courses and anticoagulation conferences in the UK. Courses are run by the NCAT which operates out of the University of Birmingham (National Centre for Anticoagulation Training 2013). These training courses aim to enable autonomous practice in a community pharmacy anticoagulation management clinic. The course participants are required

to complete a multiple choice question exam and a practical assessment during the course. A summative assessment is carried out six months after the completion of the course and accreditation is provided at this stage. At this stage the Pharmaceutical Society of Ireland (PSI) notified the pharmacist to say they would be in contact regarding service but they did not follow up on this. The pharmacist contacted PSI subsequently, once the success of the scheme was proven with positive data.

Service Roll-out

The service began to operate in February 2010 and ran on an appointment basis on Thursday mornings. A second pharmacist also worked in the pharmacy during this period to ensure the pharmacist running the anticoagulation management service did not have to carry out dispensing duties also. This second pharmacist was subsequently trained to provide the anticoagulation management service to ensure continuity if the main pharmacist was not available. Occasionally when a patient could not attend during the scheduled clinic times a consultation would be carried out on an alternative day during a quiet period. The initial patient selection process was partly an opportunistic selection in that any patient who gets a prescription for warfarin dispensed in the pharmacy was informed about the anticoagulation management service. Many of these patients were also under the care of the anticoagulation management service in CUH and were referred by the consultant haematologist. The pharmacist did not require the approval of the patient's GP before beginning to care for them in the community pharmacy anticoagulation management service. However, the pharmacist did contact the patient's GP to inform them of the change in anticoagulation management service provider. The GP's were informed that the service was being run under the supervision of a consultant haematologist from CUH and that robust protocols were in place to ensure the safety of the service. The response from GP's was variable with a number of the closest GP's fully supporting the service and who began to refer patients to the pharmacy for anticoagulation management, a number of GP's did not express any opinion but did not refer to patients to the service and a small number of GP's expressed opposition to the service and some of these GP's began to provide their own anticoagulation management services. As the service progressed, the pharmacist kept in contact with GP's and the number of GP's who referred patients to the service increased.

No robust referral procedure has been put in place and the information on the patient's history that is presented to the pharmacy can be very variable. It can be the case that the referring healthcare professional will phone the pharmacy to say the patient is being

discharged from hospital and will be attending the service in the pharmacy in the next few days. These patients may have a discharge letter that outlines the indication for warfarin, the target INR, the INR range, the duration of therapy and the referring healthcare professional. It can be the case that these patients are being initiated on warfarin therapy and therefore will have no INR history. They will often receive the first dose of warfarin in hospital and will be told to attend the pharmacy the next day where the pharmacist will then have to start process of stabilising the patient's INR. The pharmacist has indicated that a structured referral process would be beneficial and that the more information that the pharmacist had on the patient and their anticoagulation management history, the better informed they would be in making treatment decisions. Long term warfarin patients who have had a bleeding incident may be referred to the service. These patients may have received non-oral anticoagulants which will require the pharmacist stabilise these patients on warfarin in the same manner as is carried out with new patients. In this situation, an INR history would not provide very much insight into current warfarin dosing.

Initially when the service was started an entirely paper-based system was used. Paper-based algorithms were used for dose calculation and paper-based records were kept for each patient in a physical file. This paper-based system was replaced by the RAID Express system which was used as a patient management system exclusively for the anticoagulation management service and which also had CDSS functionality. The paper-based files were regularly sent to the consultant haematologist for review during the initial phase of the service. This provided the consultant with the opportunity to review the treatment decisions and to ensure that a safe service was being delivered. This also provided learning opportunities for the pharmacist as these records formed the basis for discussions on the most appropriate course of action in various scenarios. The pharmacist also communicated by fax and phone with the anticoagulation management service in CUH to obtain a second opinion on how particular patients and situations were being managed. There could be a delay in contacting one of the doctors in the warfarin clinic and patients were sometimes contacted later in the day to communicate the warfarin dose. This enabled a safe service to be provided while also providing the pharmacist with back-up from experienced practitioners. The frequency of contact began to decrease as the experience and confidence of the pharmacist began to increase. Initially contact would take place every week regarding the latest consultations, then the contact decreased to possibly every other week and then every month. When the pharmacist received formal accreditation from the UK-based training course, it was felt that the pharmacist had the knowledge and experience to manage patients in the INR range of 1.5

to 5. The pharmacist was only required to contact the anticoagulation management clinic in CUH if INR results outside this range were obtained. The pharmacist felt the service was running in a routine manner after 7-8 months of operation.

The number of patients enrolled in the community pharmacy anticoagulation management service has stayed relatively stable at around 35-40 patients. The service has cared for over 70 people since the service began. Some of these are patients who are on long-term warfarin therapy while others are patients who will be on warfarin for a short period of time and may be replaced by other patients when their therapy concludes. Some patients who have their warfarin dispensed in Cloyne Pharmacy continue to attend the anticoagulation clinic in CUH. Some patients are not prepared to pay for the service and would prefer to attend the free service provided in CUH. There are a number of patients who have expressed the opinion that they prefer to attend the clinic in CUH for the social reasons. These patients are most likely to be elderly patients who have been on warfarin therapy for a significant length of time and enjoy the social aspect of going into Cork city by bus and meeting the regular patients and staff they have gotten to know over the years.

The INR results and the dosage decisions for the individual patients were initially recorded in the paper-based records but the RAID Express system then began to be used to keep a record of these details. The results were communicated to the patients verbally and when the RAID Express system was introduced, patients could be shown a graph of their INR control and they could be given a printout if necessary. The routine method of providing the patient with their warfarin dose for the period of time until their next INR test was to write the daily dose in the yellow warfarin book. The dosage information could potentially be printed off using the RAID Express system but this was not carried out routinely. Opportunities for patient education exist through one-to-one consultation based nature of the service. This area was examined by a final year pharmacy student from UCC who carried out a project to assess the anticoagulation management service in Cloyne Pharmacy. He found that patients were very happy with the service that was being provided. The patients were then given various scenarios to test their knowledge of the correct practices that should be adhered to while on warfarin. This found that patients would benefit from further education in relation to their warfarin therapy (Walsh 2012).

The service is paid for by the patients who attend the community pharmacy anticoagulation management service. Anticoagulation management services are funded in various ways in different parts of Ireland. Services which operate on a clinic basis in large hospitals are funded

by the HSE and the patient does not pay. Services which are operated by GP's are not funded by the HSE and patients are often required to pay for the service. The pharmacist believes that a co-payment model involving the state and the patient both contributing to the cost of the service would provide the most benefits. Introducing a payment for the patients can increase their level of awareness and ownership of their medical condition and can lead to them becoming more involved with their treatment decisions.

Some patients are reviewed by the consultant on a six-monthly or yearly basis. This review process is carried out particularly in cases where the patient has had Deep Vein Thrombosis (DVT) or PE. These patients may not need to be on lifelong warfarin therapy and the consultant will assess their treatment at regular intervals to assess the extent of INR control and also whether the patient is required to continue on warfarin therapy. The review date for DVT and PE patients is routinely recorded on the RAID Express patient management system. To facilitate these treatment reviews the pharmacist can generate a report of the patient's recent INR control. The report displays a graphical representation of the most recent INR results as well as the Time in Therapeutic Range, Time Below Range and Time Above Range. This report can be emailed to the consultant or can be printed off and given to the patient to bring to the hospital. The hospital consultants have reported favourable views on the ability to view the recent INR control in this manner as the standard method of gaining insight about INR control is by reviewing the yellow book into which the INR results and warfarin doses are manually written. The majority of atrial fibrillation patients will be on warfarin therapy for life and thus they will generally not require the same level of treatment review.

The pharmacist has informed the GP's that in all cases where the patient's INR is consistently outside range or if INR readings of <1.5 or >5 are obtained that contact will be made to notify them and that contact will be made with the consultant haematologist to discuss the treatment options. It is important that this communication is recorded by the GP as the information will then be available to the out-of-hours GP service should the patient require emergency treatment. The GP's have also been informed that they can contact the pharmacist by phone or by email should they require any information on a patient's warfarin therapy. The RAID Express system can be used to produce statistics on Time in Therapeutic Range, % of results outside range, % of results <1.5 or >5, % of results >8. This information can be used to inform doctors of the reliability of the service. Up until now there have been over 2000 tests carried out and there have been no adverse bleeding events or event related to anticoagulant therapy requiring a patient to be hospitalised.

The ability of the community pharmacy anticoagulation management service to provide tight control of a patient's INR level can also have benefits for other areas of the health service. Cardioversion is a procedure which is carried out on patients who have an irregular heart rhythm. The procedure involves delivering a controlled electrical shock to the patient's chest and is carried out under anaesthesia or sedation. In order for atrial fibrillation patients to undergo cardioversion, they must have 3-4 weeks of stable INR readings. The appointments for cardioversion are generally made a number of weeks in advance but if the INR readings are not acceptable then the procedure cannot go ahead. This leads losses in both time and revenue for the hospital due to missed appointments. In order to be eligible for cardioversion, the patient's INR must be 2 or above and the aim for dosing is to try and keep the patient at the upper end of their target range to prevent them falling below the minimum INR value. The location of the anticoagulation management clinic in the community setting means that it can be easier to increase the frequency of INR testing compared with patients who are managed in a central hospital clinic. This has meant than all patients who are managed by the anticoagulation management service in the pharmacy have had their cardioversion procedures carried out on the scheduled date. The pharmacist communicated the weekly INR results to the cardioversion nurse by email to keep them informed of the patient progress which assisted with resource planning in the hospital.

Quality Assurance

The pharmacist chose to use a CoaguChek XS Plus to carry out the point-of-care INR tests. The pharmacy participates in the external quality assurance scheme operated by NEQAS. This involves NEQAS sending out two samples to be tested every quarter. One sample is generally in the lower INR ranges while the other is in the high INR ranges. Very specific protocols have to be followed when preparing and testing the samples with the CoaguChek XS Plus machine. The results are then submitted to NEQAS within two weeks of receipt, where they are compared to the test results of the other CoaguChek XS Plus machines. A median result is calculated for each instrument group and the percentage deviation of your device from this value will be calculated. In order to pass the external quality assurance, the results must not deviate by more than 15% from the 'consensus' of the other CoaguChek XS Plus machines. If on three occasions results are not submitted or the results are 'outwith consensus' the participating centre will be contacted by the scheme director. The results are forwarded to the pharmacy one week after the closing date or they can be accessed online via a secure website (NEQAS 2013).

Appendix 3 – North Central London Community Based Anticoagulant and Stroke Prevention Services, UK

Whittington Hospital is located in North Central London and principally serves the communities of Islington and Haringey. The hospital is part of the Whittington Health organisation that is currently being operated by The Whittington Hospital NHS Trust. Medical services have been delivered on the site of Whittington Hospital since 1473. A number of institutions amalgamated in 1946 to form Whittington Hospital which now has 360 beds and serves a catchment area of approximately 440,000 people. Whittington Hospital is a centre for medical education and also has a high level of involvement in community care services (Whittington Health NHS 2013).

The anticoagulation management clinic in Whittington Hospital started as a small service but became larger over time. Initially, the hospital clinic was staffed by junior doctors who rotated between specialities on a frequent basis. Thus these doctors did not have a great deal of experience with the pharmacodynamics or dosing decisions concerning warfarin therapy. This lead to sub-optimal INR control for patients due to over-steering errors where the inexperienced doctors increased or decreased the warfarin dose incorrectly. The junior doctors were making these decisions based on their limited experience and by consulting paper-based dosing algorithms (Potts *et al* 2011).

In the early 1980's the consultant cardiologist who was responsible for the operation of the anticoagulation management services sought to improve the delivery of the service by introducing a stand-alone CDSS. This was the beginning of the use of technological solutions which would enable the delivery of anticoagulation management services by a wide variety of healthcare professionals in a wide variety of healthcare settings. The initial stand-alone CDSS has since evolved into a web-based CDSS which is fully integrated with the Electronic Health Record in Whittington Hospital (Potts *et al* 2011).

Community Anticoagulation Management Service

The consultant cardiologist who drove the introduction of the CDSS within the Whittington anticoagulation management services was committed to the idea of integrated services. This involved empowering a range of healthcare professionals with the knowledge, skills and tools required to deliver anticoagulation management services. Nurses from Whittington hospital were trained as anticoagulation practitioners and became involved in the operation of the hospital clinics. The initial community service model involved outreach clinics in GP surgeries

which were run by an anticoagulation nurse from the Whittington hospital. This model of service involved the nurse using the CDSS to perform the dosing and the GP writing the prescription. However, due to difficulties involving GP contracts, a decision was taken not to pursue this model any further.

In order to continue to provide community services, the possibility of providing anticoagulation management services in community pharmacies was explored. This process began in 2000 and involved pharmacists from Whittington hospital. This involved the process of identifying key stakeholders and holding discussions to facilitate the expansion of the service. An existing community pharmacy anticoagulation management service in Durham was visited to gather information on how this service was being operated (Radley *et al* 2000). A patient survey was carried out by University College London at this time to investigate patient views on warfarin testing in community pharmacies. The results of this survey demonstrated that patients were in favour of this type of service.

Education and Training

An education and training programme was developed in Whittington hospital for community pharmacists. This involved compiling a workbook which contained the essential information required for anticoagulation management. This workbook was given to the community pharmacists to be used as an on-going reference source. The pharmacists attended face-to-face training sessions in Whittington hospital. The pharmacists were required to attend at least one anticoagulation clinic in Whittington hospital where they worked alongside experienced anticoagulation practitioners. At the end of the training sessions, the pharmacists were required to sit an objective structured clinical examination (OSCE) which was designed to test their knowledge and understanding of anticoagulation management processes and their ability to competently carry out the service.

The pharmacists also attended a full day training session which involved use of the CDSS and INR testing procedure. The pharmacists learned the correct technique to draw a finger-tip blood sample and how to operate the CoaguChek XS Plus portable coagulometer. As part of the training, the quality assurance techniques for validating the coagulometer were demonstrated. The CoaguChek XS Plus features a number of technologies to provide automatic on-going quality assurance. The on-board integrated system control performs an integrity check on the functioning of the device and test strips as part of every test. Each pack of test strips comes with a code chip which is inserted into the coagulometer. The strips are automatically checked to ensure they have not been used and that they are in date (Roche

Diagnostics 2006). Each community pharmacy service also performs external quality assurance which is run by NEQAS. This involves testing two samples which are sent to the community pharmacy on a quarterly basis and sending the results back to NEQAS within two weeks. The results of the external quality assurance are analysed by the clinical governance board.

Detailed Standard Operating Procedures were also developed which detailed the actions the pharmacist must carry out in various situations. These included what actions were to be taken if out of range results were recorded and who to contact if they required further assistance. Health and Safety specifications for the pharmacy premises were also drawn up which included access requirements to facilitate people with a disability and equipment standards which included the provision of running hot and cold water to facilitate hand warming and hand washing.

Pilot Scheme

A pilot scheme was then carried out in a community pharmacy from January 2002 to February 2003. The aim of this pilot study was to determine the quality, safety and patient acceptability of the community pharmacy anticoagulation management service. This pilot study was a vital part of the process as a number of community pharmacy anticoagulation management services were in operation at the time, none of these services had been evaluated in practice. The results of the pilot study demonstrated that patient satisfaction with the service was listed as high, with the majority of patients indicating that it produced less disruption in their lives than the hospital clinic and that they would prefer to attend the pharmacy clinic rather than the hospital clinic. The quality of the service was demonstrated by the fact that 56% of INR measurements were within 0.5 units of the target INR, exceeding the British Haematological Society goal that 50% of measured INRs should be within 0.5 units of the target INR. This also exceeded the results seen for the same cohort of patients when being managed in the hospital clinic the preceding year where 50% of the measured INRs were within 0.5 units of the target INR. The safety of the service was demonstrated by the fact that 3% of the total recorded INRs were below 1.0 and 3% were above 6.0, with no patient having a recorded thrombotic or bleeding event.

The success of the pilot scheme validated the service model which had been developed and allowed for further expansion of the service to be discussed. A number of issues were identified during the pilot programme which was fed back into the service planning of future services. One of the major operational challenges was the network connection to enable the use of the web-based CDSS. At the time, pharmacies were not part of the private wide area

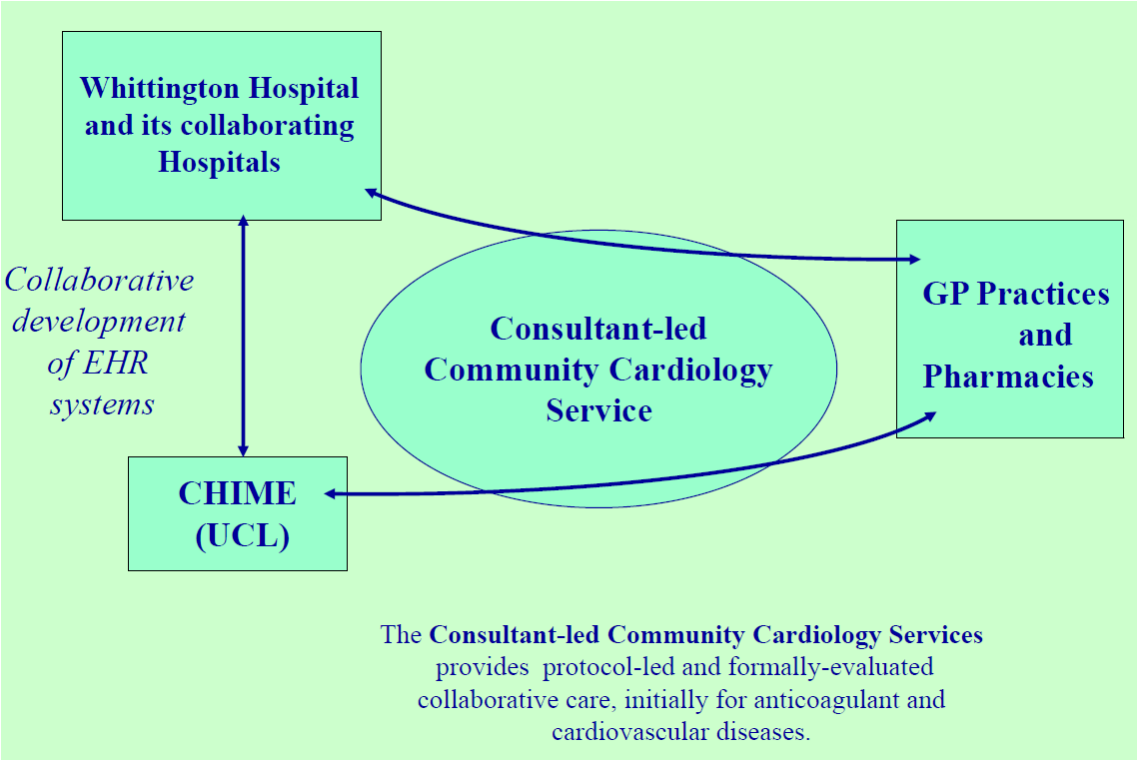
network, NHSnet (which is retrospectively known as N2). The pharmacy was therefore required to utilise a dial-up connection and token authentication to access the secure web-based CDSS. This dial-up connection made it difficult to establish and maintain the network connection and the pharmacist regularly had to perform the consultation "off-line" using paper-based records and to update the system at a later date. After the pilot programme had ended the pharmacy was given access to NHSnet which improved the reliability of the connection.

A number of barriers to the roll-out of the scheme were identified during this pilot phase. One barrier which was unexpected from a service delivery point of view was a social barrier. Patients generally indicated a preference for the community-based anticoagulation management services as they were more convenient and provided greater flexibility. However, a cohort of patients did not wish to move despite the fact that the community-based services may have been more convenient. These patients were generally older patients who were used to the routine to visiting the hospital clinic on certain days and meeting certain other patients and staff. These patients valued the social aspect of the service and viewed the visit to the hospital clinic as an occasion they would miss out on if they attended a community-based service. Another barrier to the roll-out of the scheme is funding. The pharmacist who participated in the initial pilot scheme did not receive any funding from the health services. This pharmacist was very enthusiastic about providing anticoagulation management services in the community pharmacy setting and was prepared to offer the service without a clear funding model being put in place. After a number of years in operation, the local PCT agreed to fund the service in the pharmacy.

Service Roll-out

The service was then rolled out to an additional three pharmacies, with one of these pharmacies being located in a polyclinic. These services have maintained the same consultant-led service delivery model as the pilot pharmacy service (as shown in the image following). The consultant cardiologist with overall responsibility for the hospital and community anticoagulation management clinics has the view that there should be increasing levels of empowerment in relation to healthcare professionals and patients when managing anticoagulation therapy. In terms of patients this encompasses a spectrum from providing patient education to enable the patients become involved in their treatment decisions to facilitating patient self-testing and patient self-management. For healthcare professionals this means community healthcare practitioners caring for the least complicated patients in the

community setting. As the level of treatment complexity increases, patients move to being cared for by nurses and pharmacists in the hospital setting and finally to being cared for by doctors and consultants in the hospital setting.



Consultant-led Community Cardiology Services Model (Patterson and Kalra 2011)

The referral of patients from the Whittington hospital clinic to the community pharmacy anticoagulation management services was originally carried out by the consultant cardiologist. When a new service began, the most stable and easily managed patients were transferred to the community service. This was to enable the community pharmacist to build up their confidence and expertise. The anticoagulation pharmacists then began to refer patients within suitable postcodes to the community services. The clinical indication for warfarin therapy, target INR, INR range, start and end dates for each patient were all determined in the hospital clinic prior to referral. As all sites use the same web-based CDSS, this information was already populated when the community pharmacist accessed the patient record. Previous INR history and any other patient history which had been recorded on the system were also then available to the community pharmacist. A paper-based copy of the referral form was also sent to the pharmacist to keep in the patient file.

Determining who has overall responsibility for the care of patients in the community anticoagulation management services is a difficult task and has been studied by an academic

lawyer from University College London. No definitive findings were obtained from this brief review as the determination of overall responsibility relies on medico-legal issues which have never been tested in a court of law. It is felt that the consultant cardiologist has overall responsibility provided there was no liability on behalf of an individual healthcare practitioner. Each healthcare practitioner has a duty of care to the patients in their service and is required to exercise their own clinical judgement but they also have a degree of protection provided they follow the advice of the validated CDSS, the SOP and the escalation procedures. While the pharmacists carry out the anticoagulation management services, GP's still write the prescriptions for warfarin. GP's may not be fully aware of the patient's state of anticoagulation management but the act of prescribing could mean that the GP has taken on some legal liability in relation to anticoagulation management. This is a complex legal area and there are plans to carry out medico-legal scenario testing to determine the likely outcome of a number of different scenarios.

In order to ensure the safe delivery anticoagulation management services in the community setting, a number of procedures and processes were put in place for when unexpected situations arise. The SOPs which were developed to specify the operation of the service state the situations where the pharmacist can treat the patient using their own clinical judgement and when they must follow escalation procedures to contact a more experienced anticoagulation practitioner. To facilitate this escalation procedure, a dedicated phone line was set up which was manned by a member of the anticoagulation clinic in Whittington hospital. The phone line was usually manned by an anticoagulation pharmacist who could advise on the situation and how the community pharmacist should proceed. If the anticoagulation pharmacist could not deal with the issue, they could escalate the issue to one of the doctors in the hospital or to the consultant cardiologist who oversees the service. This phone line was used most frequently by pharmacists during the initial stages of service provision. They tended to use the service less and less as time went on and they became more experienced in managing anticoagulant therapy.

The emergency procedures also include guidance on situations which cannot be managed by the pharmacist. The CoaguChek XS Plus device is only capable of measuring to an INR value of 8.0 and results which are greater than this are not displayed. In this situation, the patient must be referred to the Whittington hospital anticoagulation clinic for a venous INR sample to be obtained. The community pharmacist can print off a consultation record which contains the patient demographics and last five INR results to provide information to the ED staff. These

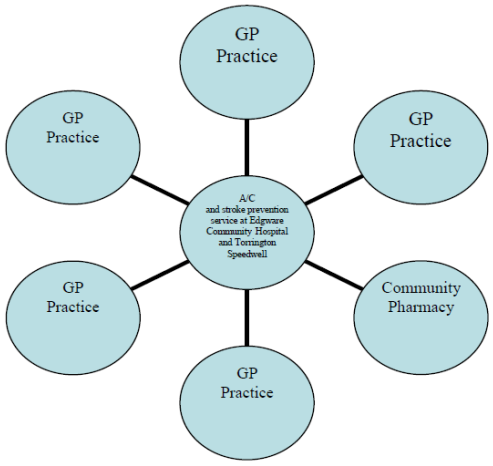
consultation records are regularly printed off and kept in the patient file to cater for situations where the web-based service is temporarily unavailable. Paper-based dosing algorithms are also available in the community pharmacy clinics for this reason.

Patient education is also key to ensure all relevant information is provided to the various healthcare practitioners they might attend such as the doctor, dentist etc. The initial patient education regarding warfarin therapy will usually be delivered in the Whittington hospital clinic but it can also be delivered in the community pharmacy. A vital part of patient education is to ensure patients let the community pharmacist know if medication has been changed, if any new medication has been started, if there is a change in health status or any other major change which may affect anticoagulation control. The patient is provided with a Yellow Book but this is for reference purposes rather than for recording the warfarin dose. A Patient Information Sheet printed out at the end of each clinic contact which contains patient demographics, therapeutic indication, INR range, narrative instructions for dose to be taken and the last 5 INR results. This is given to the patient and the bottom of the sheet contains a text box where the patient can write in changes in medication, lifestyle or health status since the last consultation. The patient brings this sheet back to the pharmacy at the next consultation to enable the recording of any information the patient has written on the sheet. This sheet is then stored in the patient's physical file.

Clinical Governance Board

The establishment of the CGB in 2009-2010 was a major milestone in the development of anticoagulation management services run by Whittington hospital. The CGB was not a part of the service during the pilot or early years of service roll-out. The decision to establish the CGB was a local one as the distributed service was growing rapidly and there was a need to examine how quality standards could be maintained across the service. Around the same time as the decision to establish the CGB was taken, an alert was issued by the National Patient Safety Association (NPSA) which provided a detailed risk assessment of anticoagulant therapy (Cousins and Harris 2006). This NPSA alert helped to structure the quality criteria which the CGB use to analyse the quality and safety of the service. The CGB is comprised of approximately 20 individuals from a diverse range of backgrounds. The membership of the CGB includes anticoagulation practitioners from the hospital and community-based services, patient representatives, clinical leads from the Whittington and North Middlesex Hospitals, senior pharmacists, Primary Care Trust Commissioners, an IT representative from Whittington Hospital, an academic health informatist and an academic legal advisor.

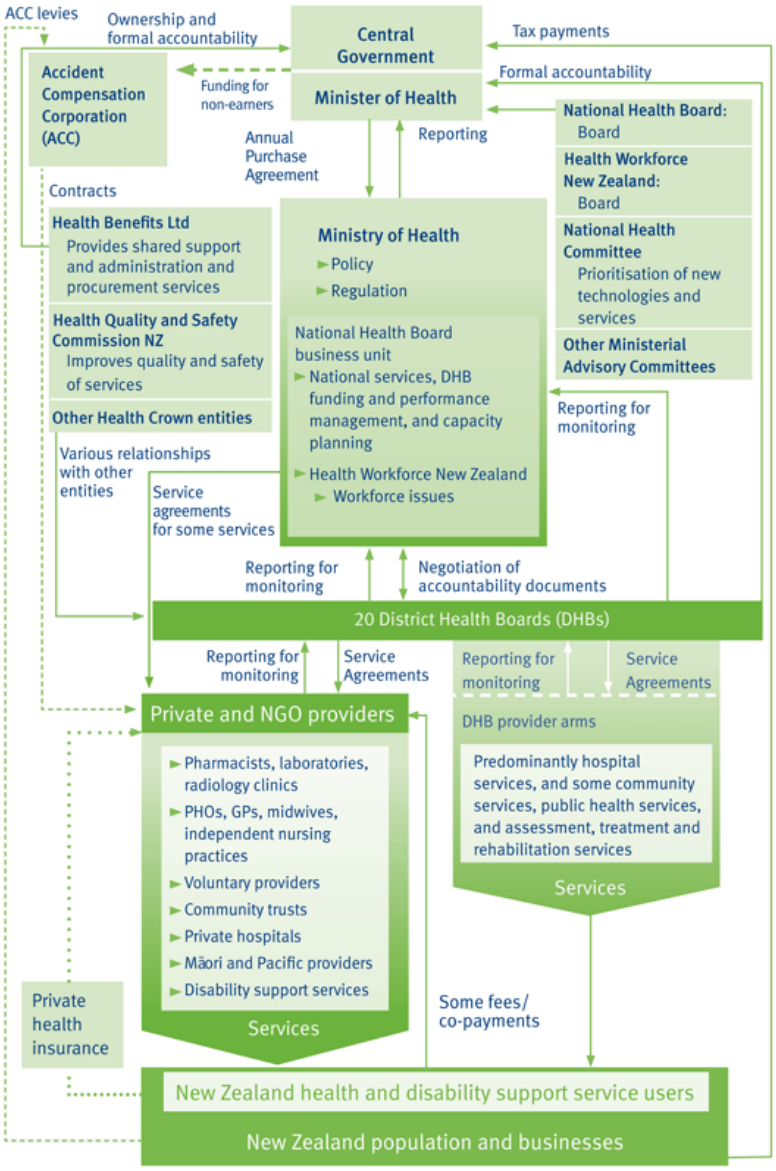
There are a number of key areas which the CGB review to determine the quality and safety of service delivery. These areas include: Patient education and patient satisfaction surveys; Training and education of anticoagulant practitioners; Time in Therapeutic Range by practice site, by local area and for the total service; Quality assurance testing of equipment and Quality control of premises where the services are delivered. All healthcare practitioners who utilise the CoaguChek device for the provision of anticoagulation management services must participate in the NEQAS quality assurance scheme. The CGB jointly review the audit data and develop action points arising from their findings. It also looks at service development and attempts to anticipate future demands to provide services where they are required. The ability to provide distance learning opportunities for anticoagulation practitioners has been identified by the CGB as an area for future development. This will work alongside the twice yearly education events which form part of the continuing professional development and re-validation requirements for the anticoagulation practitioners. Another area of service development is in the area of patient self-testing and patient self-management. The CGB are investigating the possibility of providing patients with access to the web-based CDSS so they can play a greater role in the management of their therapy. The CGB hopes to be able to include annual review of the patients in the service which they hope will be carried out by GP's in the near future. At present, all annual reviews are carried out by the consultant cardiologist in Whittington hospital. It is hoped that information from the web-based CDSS, the GP information system and personal knowledge will be incorporated into a report (as shown below) which could then be reviewed by the GP (Hill 2013).



Hub and Spoke model for annual reviews (Hill 2013)

Appendix 4 – Community Pharmacy Anticoagulation Management Service, New Zealand

New Zealand is a country that has a very similar population to Ireland but a much lower population density due to its much larger size. Both countries have similar numbers of inpatient beds per capita but Ireland has a larger number of physicians per capita and also has an overall health expenditure that is approximately 40% higher than New Zealand (Wolfram Alpha 2013). A conceptual overview of the New Zealand health service is shown below.



Overview of New Zealand's Health System (Ministry of Health NZ 2013)

The traditional model of anticoagulant care in New Zealand is based in the primary care setting and is usually managed by GP's. Patients attend the GP surgery or a local blood collection centre where a blood sample is taken by venepuncture and sent to a laboratory for testing. The results are then sent to the GP Practice Management System (PMS) electronically utilising New Zealand's highly developed electronic health information systems such as HealthLink and TestSafe. The doctor then reviews the test results and records the daily warfarin dose which should be taken by the patient and the next test date. The patient then contacts the GP surgery and is informed of their latest INR result and their warfarin dosing details. Practice nurses are often delegated the responsibility of administering the anticoagulation management service. It has been acknowledged and demonstrated in international studies that this model of anticoagulation management may produce sub-optimal results with Time in Therapeutic Range often below 60% (Zabinski and Valley 2009). This is possibly due to the fragmented nature of the service with a range of healthcare practitioners involved and the process taking place over an extended timeframe. There are a number of dedicated hospital-based anticoagulation management services which are operated by doctors and nurses but these are not widespread in New Zealand. The vast majority of patients are managed in the primary care setting by GP's and practice nurses.

Community Pharmacy Anticoagulation Management Service

In 2009, two pharmacists working in a community pharmacy in Hamilton which is located just south of Auckland, developed an interest in setting up a community pharmacy anticoagulation management service. They saw the opportunity for this type of service with the proven reliability and accuracy of portable coagulometers. The CoaguChek XS Plus device was identified as the preferred coagulometer and Roche Diagnostics NZ came on board to support the pilot project. Roche Diagnostics NZ also had a working relationship with a consultant haematologist who was supportive in the innovation around anticoagulation management services. The consultant haematologist had developed INR reporting software for use within his professional practice and had professional and altruistic interests in supporting the extension of anticoagulation management services into the community setting. The INR reporting software was initially deployed as standalone software but was later developed into the web-based system INR Online. The pharmacists, Roche Diagnostics NZ and the consultant haematologist came together to set up a six month community pharmacy anticoagulation management service trial. The pharmacists reported that the trial was well received with patients and that utilising the CoaguChek point-of-care device and INR Online CDSS produced favourable results for Time in Therapeutic Range.

Pilot Scheme

At the end of the trial in early 2010, the pharmacists had to decide whether to stop the service or to secure funding from the health authorities to continue the service. The pharmacists approached the local District Health Board but they did not have an interest in pursuing the service. The pharmacists and Roche Diagnostics NZ then separately approached the Pharmaceutical Society of New Zealand to see if they would be interested in supporting the operation or expansion of the service. At the time, the New Zealand government and Department of Health were proactively trying to develop new models of care and the political climate was conducive to developing additional pharmacy services. Public policy in New Zealand at the time was that the government wanted to see services that were better, could be delivered quicker and in the most convenient manner for the patient. The authorities were looking to further utilise the pharmacist workforce to alleviate pressure on the GP workforce. To support innovation in the area, they created a demonstration funding pool that groups could apply for. The Pharmaceutical Society of New Zealand had been consulting with the Ministry of Health and the District Health Boards (DHB) on how to better utilise pharmacist knowledge and training through the National Pharmacist Services Framework (DHB New Zealand 2007).

The pharmacists from the Hamilton trial and the representative from Roche Diagnostics NZ made the case that the community pharmacy anticoagulation management services model could fit in with the aim of developing pharmacy services for the future. The Pharmaceutical Society of New Zealand put together a business case and presented it to Health Workforce New Zealand which is a division of the National Health Board business unit within the Department of Health. Health Workforce New Zealand were interested in the proposal and held talks with the Pharmaceutical Society of New Zealand, Roche Diagnostics NZ, the developers of INR Online and the University of Auckland in early 2010. Approval for a pilot study involving 16 pharmacies was granted in July 2010 and a steering group was established in September 2010. The ability to get the pilot community pharmacy anticoagulation management service approved was due the proactive pharmacist, the diagnostics company looking for new markets, the enabling CDSS and the favourable political climate all coming together at the right time.

Expressions of interest were invited from pharmacists to take part in the pilot programme. Over 100 expressions of interest were received and the PSNZ made the decision on the 16 pharmacies that were invited to participate in the pilot scheme. The decisions were based on

the desire to obtain a spread of pharmacies which represented different geographic and demographic areas and the sixteen chosen pharmacies consisted of a mix of urban, suburban and rural populations and a variety of socio-demographic and ethnic profiles. The criteria stated that the pharmacists should be reasonably experienced and have a good working relationship with a local GP. The pilot utilised a mechanism known as a standing order which had been set up by the regulatory bodies which enabled pharmacists to change warfarin doses and to carry out adjustments to the therapy in a GP-led integrated patient care model of service delivery. The model emphasises the collaborative nature of the service with the GP and the pharmacist working together to benefit the health and well-being of the patient (Harper 2012). The legal liability for the operation of the community pharmacy anticoagulation management service is an untested legal area in New Zealand. The pharmacist is legally bound to carry out the service in line with the documented policies and procedures which have been specified in the service contract. By utilising the standing order the service operates with the oversight of a GP who will maintain responsibility for the patient once the pharmacist follows these policies and procedures. Therefore, pharmacists who already had a close working relationship with a GP in their area were thought to be the best candidates to trial this shared model of care.

The pilot was set up with the position of it being evaluated by the University of Auckland from the very beginning and the planning of the pilot included ethics approval to enable this study to be conducted. This was done to enable a rigorous assessment and evaluation of the service to be carried out and to enable a report into the operation of the service to be made available as soon as possible after the pilot phase of the study had been completed. It was envisaged that the pilot would be used to validate the service model but also to validate the operational aspects of the service. The report produced by the University of Auckland demonstrated very favourable outcomes such as time in therapeutic range from the 16 centre pilot programme. Radical changes could not be made to the service after the pilot was completed as they would not form part of the validated study but a number of small changes were made including increasing the number of previous INR records which were imported into INR Online, improved reporting capabilities within INR Online and introducing a greater level of central audit.

In order to be able to roll this service out on a wider basis, achievement of the service model aims had to be demonstrated in the final report. The pilot programme ran for 12 months in 16 pharmacies across New Zealand. The pilot programme continued on past the initial 12 month time period while the final report was being drafted. The aims of the pilot study were to

ascertain whether the community pharmacy anticoagulation management service could provide safe, effective and economical care. The publication of the final report confirmed that these aims were achieved by demonstrating that the mean Time in Therapeutic Range achieved was 78.6%, that there was a low rate of patients having an INR result of 1.0 below their target range, there was a high level of compliance with 83.1% of tests being carried out on or before the due date and that the cost per patient year was approximately 30% less than standard care.

With the publication of the final report, the Department of Health were sufficiently confident in the success of the programme and could see the opportunity to expand the service on a nationwide basis. The Department of Health directed the District Health Boards to fund the service through the new community pharmacy contract. The District Health Boards allocated €7.5M split over three years for the nationwide roll-out of the service. The funding model is what determines the number of pharmacies that can be accepted into the service at the various stages with the allocated funds being split up as $1.5m for year 1, $2.5m for year 2 and $3.5m for year 3. The funding for year 1 allowed for an extra 60 pharmacies to be added to the scheme in addition to the 16 pharmacies that were operating the pilot scheme, to give a total of 76 pharmacies providing the service from 1st July 2012. The total number of pharmacies that are hoped to be offering the service is in the region of 130-140 pharmacies under the current funding model. This funding model runs for three years after which a decision on whether to continue the service will be taken. It is hoped that if the service is continued past this time, the number of pharmacies operating the service could be even greater than this.

Education and Training

The service specifications, standard operating procedures and details of service operation all were developed prior to the pilot phase of the project. The pre-requisite criteria in relation to pharmacist training were set out by the PSNZ. These included sufficient knowledge in the areas of oral anticoagulation and associated risks, pharmacokinetics of warfarin, dose adjustment and emergency procedures. These competencies were delivered and assessed by the New Zealand College of Pharmacists on a one day training programme which involved theory and demonstration sessions. This programme also included training on using the CoaguChek XS Plus and INR Online. The pharmacists had to complete written and practical assessments on all aspects of service delivery in order to be qualified to deliver the community pharmacy anticoagulation management service. Qualifying criteria were also developed for the participating pharmacies. Health and Safety included the presence of a consultation room

including a sink with running hot and cold water and having the computer used to access INR Online in the consultation room (Pharmaceutical Society of New Zealand 2011).

Service Roll-out

The criteria used to select the additional pharmacies were outlined in the expression of interest forms which were distributed to the 950 pharmacies in New Zealand (DHB Shared Services 2012). They stipulated that the pharmacies would be chosen based upon: geographical distribution; evidence of support from local primary care providers; accessibility in terms of location, opening hours and population served; ability to provide high quality of care in the service; staffing levels of at least two full-time equivalent pharmacists and the ability to achieve a target service user level of 45 patients. The final decision on what pharmacies were to be included in the extended roll-out was made by the local DHB's who evaluated the submissions that were received from the individual pharmacies. The funding was allocated to the individual DHB's according to the size of the population that they served. Some smaller DHB's did not represent a sufficiently large population to provide the level of funding to run any service during year 1. The increase in allocated funds for year 2 and 3 of the service should enable the smaller DHB's to fund a community pharmacy anticoagulation management service in their area. The pilot operated on a fee for service model where each consultation attracted a fee for the pharmacist. However, for the extended roll-out the funding model was changed to a fee per month for each patient that is managed by the service. The funding model will be reviewed in 2014 as there are concerns that the service may be under-priced. The service is priced at 1.6 patient tests per month being carried out by the pharmacist. The number of tests being carried out when the pharmacist starts will generally be higher as patients will need to be tested more frequently until their INR's stabilise. The service is operated in 17 out of the 20 DHB's across New Zealand with 3 choosing not to fund services in their areas.

One of the greatest barriers to service roll-out was securing the co-operation of GPs with the pharmacists at local level. The innovative service model that was developed for the community pharmacy anticoagulation management service was described as an agent of change by the Department of Health and therefore had the potential be a service model which GP's would not agree with. A key success factor of the service was identifying a GP who supported the service and that they believed the service would benefit the patient. The pharmacist cannot carry out the service if they cannot find a GP who agrees to participate in the standing order arrangement. The pharmacists who expressed interest in operating this service were required

to have a working relationship with a GP in their area. These relationships are based on a level of trust that both parties had a shared focus of providing services that benefited the patients. In order to complete the expression of interest, the pharmacist was required to approach their local GP to determine their willingness to participate in the service. However, pharmacists had not been provided with much of the required information when they were discussing the service with the GP's. Much of the information which the GP's had requested was not provided to the pharmacists until the training sessions (Shaw, Harrison and Harrison 2011). This information has since been updated and is now much more readily available to GP's (DHB Shared Services 2013).

Providing the GP's with background information on the community pharmacy anticoagulation management service was essential to enable them to make an informed decision on whether to participate or not. Improving communication about the service to GP's through increased contact between national bodies may have facilitated the discussions between individual pharmacist and GP's. On a local level, the GP were generally supportive of the service and this was likely due to the working relationship they had with the pharmacist. On a national level, the organisations representing the GP's take positions to defend the services that their members carry out. The operation of the community pharmacy anticoagulation management service could have the potential to reduce the level of patient income and elements of patient control for GP's. This has been seen in other areas where the opposition to the expansion of community pharmacy services such as influenza vaccinations has been opposed on a national level by many GP representative organisations. This can be at odds with the opinion of local GP's who often support the services especially when they have a good working relationship with the pharmacist.

The referral pathway for the community pharmacy anticoagulation management service is directly from the GP to the community pharmacist. This pathway mirrors the fact that the majority of patients on warfarin are managed in GP practices. Some pharmacies have met with the GP's and decided on suitable patients to refer in a collaborative process. Each pharmacy can only accept a maximum of 45 patients, so generally the more stable patients will be selected for management in the community pharmacy anticoagulation management service. The local DHB has the power to increase the maximum number of patients a pharmacy can accept on a case by case basis. Some pharmacies are now managing up to 60 or 70 patients. Some pharmacies that have a very close relationship with their local GP get the service running at close to maximum capacity within a few months. Other pharmacies experience a much

slower roll-out of the service. This can be down to the fact that the GP initially declared support for the service but subsequently refers a small number of patients. It was also seen that some GP's required the practice nurse to discuss the service with the patients before they were referred. Appointments were not specifically scheduled for this purpose and the discussion took place at the next designated appointment. For some patients this was a number of weeks or months after the pharmacy began to operate the service and referral only took place after this period of time.

It has also been seen that some GP's refer patients who are very difficult to manage and this is potentially a strategy by the GP to see how well the pharmacist can manage to deliver the service. This can be very difficult for the pharmacist but can provide the GP with a level of confidence in the pharmacist's abilities. Patients who the GP's feel are unsuitable or unwilling to be referred to the pharmacy service can continue to be managed in the GP practice. It was generally seen during the pilot that the initial patients referred to the community pharmacy anticoagulation management services were the less complicated, stable patients. However, often after a short period of time the GP's began to refer their most difficult to manage patients to the pharmacist. The GP referral form was designed to capture all necessary demographic data including the NHI number which is the unique patient identifier within the New Zealand health system (Ministry of Health NZ 2012b). The NHI is used to identify patients during the operation of the service and is used for the reporting functionality of the INR Online system. The referral form also contains information regarding the therapeutic indication for warfarin, the target INR, the date warfarin therapy was started, the anticipated duration of therapy, pertinent patient notes and the three most recent INR results and warfarin doses. The potential of importing a larger number of INR results into the INR Online system is being investigated as it would improve the quality of the recommendations the CDSS would be able to provide. Some pharmacists also expressed the opinion that an electronic referral form would reduce the time and complexity of enrolling patients in the service (Shaw, Harrison and Shaw 2011).

Some pharmacists proactively approached and informed patients who they believed were suitable for referral about their new service. Many pharmacists were found to be wary of this method of patient recruitment due to concerns about overstepping the traditional boundary between pharmacists and GP's. The community pharmacy anticoagulation management service operates solely on the basis of GP referrals. In situations where a patient was being managed in a hospital clinic, referral would not take place until the patient was seen by their

GP who would then assess the suitability of the patient for community management. This process was not found to be ideal as there was not a robust method of communication between the GP, the hospital and the pharmacist. It was seen that sometimes patients were being transferred to the pharmacy service without the knowledge of the hospital clinic which then caused tension between the parties. It was also found that communication between the pharmacy-based services and regular hospital services were sub-optimal. The communication difficulties were two-way, with hospitals finding it difficult to gather information about the patient's anticoagulation management status and pharmacists finding it difficult to gather information on hospital admissions and discharges. Communication was often directed through the GP with both sides becoming frustrated at the inconsistent flow of information. The possibility of introducing structured channels of communication between healthcare professionals or making the community pharmacy anticoagulation management service results available on TestSafe, the national test results database were raised by a number of pharmacists (Shaw, Harrison and Shaw 2011).

The pharmacists did not have any centralised information resource to provide assistance during the roll-out of the service, however the 16 pharmacists from the pilot phase put themselves forward as points of contact for the new pharmacists who were beginning to operate the service. These 16 pharmacists had one and a half years' experience in running the community pharmacy anticoagulation management systems at that stage and could provide valuable guidance and assistance if needed. It was found that the workload was greatest during the initial phase of service-roll out as all patients were required to have INR tests on a weekly basis. The workload then gradually decreased as patients began to require testing on a less frequent basis.

It was found that the community pharmacy anticoagulation management service worked better than the fragmented model of the previous service. This involved the patient having a consultation in the GP surgery, the samples being sent off to the laboratory, the results being communicated back to the GP and then the patient attending the pharmacy to get the prescription dispensed. Having the pharmacist as the single point of contact provided a much simpler and more flexible service model that could better accommodate the needs of unstable patients. The community pharmacy anticoagulation management service also facilitated patient education due to the frequent contact. Initiatives such as the printed dosage calendar provided a simple method to communicate the often complicated warfarin dosage regimens which was designed to improve patient understanding and compliance.