

Developing and Evaluating Primary Care Anticoagulation Services in Practice:

A Randomised Crossover Trial

Thesis submitted in accordance with the requirements of the
University of London for the degree of doctor of Philosophy by

Frances Akinwunmi

School of Pharmacy, University of London
September 2006

ProQuest Number: 10104698

All rights reserved

INFORMATION TO ALL USERS

The quality of this reproduction is dependent upon the quality of the copy submitted.

In the unlikely event that the author did not send a complete manuscript and there are missing pages, these will be noted. Also, if material had to be removed, a note will indicate the deletion.



ProQuest 10104698

Published by ProQuest LLC(2016). Copyright of the Dissertation is held by the Author.

All rights reserved.

This work is protected against unauthorized copying under Title 17, United States Code.
Microform Edition © ProQuest LLC.

ProQuest LLC
789 East Eisenhower Parkway
P.O. Box 1346
Ann Arbor, MI 48106-1346

Plagiarism Statement

This thesis describes research conducted in the School of Pharmacy, University of London Between December 2002 and September 2006 under the supervision of Doctor Catherine Duggan, Doctor Dita Engova, Professor Ian Bates and Doctor Peter MacCallum. I certify that the research described is original and that any parts of the work that have been conducted by collaboration are clearly indicated. I also certify that I have written all text herein and have clearly indicated by suitable citation any part of this dissertation that has already appeared in publications.

A handwritten signature in black ink, appearing to be 'fa' followed by a long horizontal stroke and a small upward tick at the end.

Frances Akinwunmi

08/09/06

This thesis is dedicated to my parents, Olusola and Francis Tunde Akinwunmi, who have been a tower of strength and motivated me to complete this study.

Abstract

Warfarin is a drug with proven effectiveness in the prevention of stroke. Patients on warfarin need their therapy to be monitored by regular blood tests to prevent the occurrence of thrombotic and haemorrhagic events. Traditionally, this anticoagulation service has been provided in secondary care anticoagulation clinics. The National Service Framework (NSF) for Older People (Department of Health 2001a) prioritised reduction in the incidence of stroke, this coupled with the UK's ageing population, has resulted in an expected 10% yearly increase in the demand for anticoagulation services. Current evidence suggests that not all patients who would benefit from warfarin are receiving it and, despite this unmet need, the pressure on the traditional hospital-based service is already becoming unsustainable.

In this study, anticoagulation services at Barts and The London NHS Trust were to be developed and evaluated from a research perspective. Developmental work involved collection and analysis of patient satisfaction data, literature review and multidisciplinary discussions. Evidence from the developmental phase was triangulated and used to develop an intervention study to test the impact of providing anticoagulation services in patients' homes. The intervention was tested in a randomised crossover study comparing two models of domiciliary anticoagulation service for mobility-impaired patients with each other and against the traditional service provision. The first model involved a general phlebotomist obtaining venous samples in the patients' homes. All other aspects of the service were provided by the hospital. In the second model, one-stop testing and dosing in the patients' homes was performed by a trained pharmacist using near patient testing and software-assisted warfarin dosing. The domiciliary models were evaluated in terms of patient satisfaction, anticoagulation control and safety.

The findings included equivalent anticoagulation control achieved by the domiciliary services compared to that achieved by the traditional hospital-based service. The number of adverse events in the domiciliary services was comparable to that observed in the traditional service. Finally, there was a significant improvement in patient satisfaction with the domiciliary services compared to the traditional service. The results suggest that the evidence based domiciliary anticoagulation service models were suitable alternatives to the traditional anticoagulation service model.

Contents

List of Tables.....	14
List of Figures.....	19
Abbreviations.....	22
Acknowledgements.....	23
Preface.....	24
Chapter 1 Introduction.....	26
1.1 Introduction	27
1.2 Part I – Anticoagulation Therapy	28
1.2.1 Thrombosis and anticoagulation therapy.....	28
1.2.2 Increase in demand for anticoagulation therapy and associated services	32
1.3 Part II – Government agenda.....	34
1.4 Part III – Literature Review.....	42
1.4.1 Literature search	42
1.4.2 Findings of literature search	42
1.4.2.1 Near patient testing.....	43
1.4.2.2 Computerised decision support software.....	51
1.4.2.3 GPs' perspectives of providing anticoagulation services	54
1.4.2.4 Nurse-managed anticoagulation services	58
1.4.2.5 Pharmacy and anticoagulation service provision	62
1.4.2.6 Patient self-testing and self-management of anticoagulation therapy	69
1.4.2.7 Domiciliary anticoagulation services for the mobility-impaired	73
1.4.2.8 Feasibility of primary care anticoagulation services	76
1.4.2.9 Developments in anticoagulation services in the UK.....	77
1.4.2.10 Overview.....	79
Chapter 2 Aims and Objectives.....	83
2.1 Development of the research question.....	84
2.2 Main research questions.....	85
2.2.1 Main hypotheses	85
2.3 Aim of the thesis.....	86

2.4	Objectives of the thesis.....	86
Chapter 3	Materials and Methods.....	87
3.1	Introduction	88
3.2	Approach to the research	88
3.2.1	Qualitative versus quantitative methods.....	89
3.3	Quantitative data analysis.....	91
3.3.1	Time series analysis.....	91
3.3.2	Linear regression	93
3.4	Participating Agencies.....	96
3.4.1	Barts and The London NHS Trust.....	96
3.4.2	Tower Hamlets PCT	97
3.4.3	Homerton University Hospital Trust.....	98
3.4.4	City and Hackney PCT	99
3.4.5	Anticoagulation services in BLT.....	100
3.5	Ethical Approval	100
3.6	Administrative support	101
3.7	Academic and Practical Support	101
Chapter 4	Developmental Phase.....	102
4.1	Introduction	103
4.1.1	Aim.....	105
4.1.2	Objectives.....	105
4.1.3	Ethics Approval.....	105
4.2	Patient satisfaction	106
4.2.1	Introduction	106
4.2.1.1	Assessing “satisfaction”	106
4.2.1.2	Satisfaction with service provision.....	108
4.2.1.3	Approaches to measuring patient satisfaction.....	110
4.2.1.4	Measurement of patient satisfaction – survey instrument and administration	110
4.2.2	Aims and objectives of patient satisfaction data collection	114

4.2.3	Methods.....	114
4.2.3.1	Sample.....	118
4.2.3.2	Patient Recruitment.....	119
4.2.3.3	Data processing.....	120
4.2.3.4	Missing values	120
4.2.4	Results	120
4.2.4.1	Data cleaning and quality assurance - BLT data.....	121
4.2.4.2	Data cleaning and quality assurance - HUH data	123
4.2.4.3	Patient background data	125
4.2.4.4	Patient groups and CSQ results.....	129
4.2.4.5	Median CSQ score when item values missing	133
4.2.4.6	Service specific items analysis for BLT and HUH patients	134
4.2.4.7	Multiple linear regression for BLT patients	144
4.2.4.8	Multiple linear regression for HUH patients.....	148
4.2.4.9	Multiple linear regression for postal and transport specific items	152
4.2.4.10	Multiple linear regression summary	154
4.2.4.11	Qualitative data from patients' comments.....	155
4.3	Group interviews.....	179
4.3.1	Background.....	179
4.3.2	Aim.....	180
4.3.3	Objectives.....	180
4.3.4	Discussion with BLT anticoagulation clinic practitioners.....	180
4.3.4.1	Objectives.....	181
4.3.4.2	Method.....	181
4.3.4.3	Results	181
4.3.5	Stakeholder discussion.....	185
4.3.5.1	Objectives.....	185
4.3.5.2	Method.....	185
4.3.5.3	Results	185
4.3.6	City and Hackney pharmacy forum meeting.....	189
4.3.6.1	Objectives.....	190
4.3.6.2	Methods.....	190
4.3.6.3	Results	190
4.3.7	Nominal group session.....	193

4.3.7.1	Objectives	193
4.3.7.2	Method	193
4.3.7.3	Sample	193
4.3.7.4	Results of nominal group session	196
4.4	Literature review	212
4.4.1	Aim and Objectives	212
4.4.2	Methods	212
4.4.3	Results	213
4.4.3.1	Evaluation of the literature	213
4.4.3.2	Summary of literature evaluation	218
4.4.3.3	Models described in the literature	219
4.4.3.4	Section summary	220
4.5	Triangulation	221
4.5.1	Introduction	221
4.5.2	Method	221
4.5.3	Results	221
4.5.3.1	<i>Patient satisfaction</i>	221
4.5.3.2	<i>Stakeholder discussions</i>	222
4.5.3.3	<i>Literature Review</i>	222
4.5.3.4	Selection of models for the trial	223
4.6	The preparatory stage	227
4.6.1	Service Protocol	227
4.6.1.1	Aim/Purpose of the service protocol	227
4.6.1.2	Method of the service protocol development	227
4.6.1.3	Results	228
4.6.2	Risk assessment	229
4.6.2.1	Aim (of the risk assessment)	230
4.6.2.2	Objective (of the process of assessing the risk)	230
4.6.2.3	Method	230
4.6.2.4	Results	233
4.6.3	Checklist for community visits: General and important safety points for community visits 234	
4.6.4	Personnel Training	234

4.6.4.1	Phlebotomy training	235
4.6.4.2	Training in use of the CoaguChek S NPT device.....	235
4.6.4.3	Training in the use of Dawn AC software (4S Dawn Clinical Software).....	235
4.6.4.4	Training on administration of parenteral anticoagulants	236
4.6.4.5	Anticoagulation practitioner training	236
4.6.5	Job descriptions	237
4.7	Discussion of Findings	238
4.7.1	Patient satisfaction	238
4.7.1.1	Background	238
4.7.1.2	CSQ-8	238
4.7.1.3	Service specific items and Qualitative data	239
4.7.1.4	Difficulties during data collection	241
4.7.1.5	Limitations with the satisfaction study.....	241
4.7.1.6	Section summary	244
4.7.2	Group interviews.....	244
4.7.2.1	Introduction	244
4.7.2.2	Recruitment	245
4.7.2.3	Alternatives to nominal group session	246
4.7.2.4	Data collection.....	246
4.7.2.5	GPs' and Pharmacists' roles.....	246
4.7.2.6	Targeting for service development.....	247
4.7.2.7	Study limitations.....	248
4.7.2.8	Validity of interviews.....	248
4.7.3	Literature review	249
4.7.3.1	Findings.....	249
4.7.3.2	Study limitation	250
4.7.4	Pragmatism in model selection.....	250
4.7.5	Other difficulties during the developmental phase.....	250
4.7.6	Overview.....	250
Chapter 5	Intervention phase.....	252
5.1	Introduction	253
5.2	Aims of the study	253

5.3	Objectives	253
5.4	Hypotheses	253
5.5	Intervention Phase Methods	254
5.5.1	Ethics Approval	254
5.5.2	Trial design and description	254
5.5.3	Service model descriptions and procedures	254
5.5.3.1	Equipment for delivery of service models	257
5.5.3.2	Notification of patients' GPs	258
5.5.3.3	Clinic staff notification	258
5.5.3.4	Patients using medicines compliance aids	258
5.5.3.5	Annual and sick leave	258
5.5.3.6	End of trial patient notification	258
5.5.4	Patient sample	259
5.5.5	Trial Recruitment	259
5.5.6	Randomisation	260
5.5.7	Outcome measure: Patient satisfaction	263
5.5.7.1	Development of service specific items	263
5.5.7.2	Piloting the survey tool	264
5.5.8	Outcome measure: Anticoagulation control	266
5.5.8.1	Time in range	267
5.5.8.2	Proportion of tests in range	268
5.5.9	Outcome measure: Number of adverse events (Safety)	268
5.5.10	Patient background data	269
5.5.11	Contents of trial database	270
5.5.12	Data cleaning	270
5.5.12.1	Quality assurance	270
5.5.12.2	Management of outliers	270
5.5.13	Data analysis	271
5.5.13.1	Quantitative data analysis	271
5.5.13.2	Qualitative data analysis	273
5.5.14	Recording of interventions made during the trial	273
5.5.15	Meetings held during the trial	274
5.6	Results	275

5.6.1	Introduction	275
5.6.2	Recruitment	275
5.6.3	Data Cleaning and Quality Assurance.....	276
5.6.4	Sample demographics	277
5.6.5	Randomisation	279
5.6.6	Patient demographics - Crossover stage	280
5.6.7	Patient Satisfaction – Crossover Stage.....	282
5.6.7.1	Missing Values from CSQ – Crossover Stage	283
5.6.7.2	Service specific items analysis – Crossover Stage	284
5.6.7.3	Correlations and multiple linear regression – Crossover Stage	286
5.6.7.4	Patient satisfaction qualitative data – Crossover stage	286
5.6.7.5	Time in Range – Crossover Stage	290
5.6.7.6	Proportion of tests in range – Crossover Stage.....	290
5.6.8	Patient demographics - End of trial stage	291
5.6.9	Risk Factors for warfarin therapy complications	293
5.6.10	Co-morbidities.....	294
5.6.11	Additional drugs.....	294
5.6.12	Patient Satisfaction – End of Trial Stage	295
5.6.12.1	Missing Values from CSQ – End of Trial Stage	296
5.6.12.2	Service specific items analysis – End of Trial Stage	296
5.6.12.3	Additional items on Patient Satisfaction Questionnaire – End of Trial Stage	297
5.6.12.4	Correlations and Multiple Linear Regressions – End of Trial Stage	300
5.6.13	Anticoagulation control – End of Trial Stage	306
5.6.14	Summary of quantitative results from trial period	307
5.6.14.1	Introduction	307
5.6.14.2	Time in range and Proportion of tests in range for entire trial period	309
5.6.14.3	Adverse events	309
5.6.14.4	Dose Changes.....	311
5.6.14.5	Number of appointments	311
5.6.14.6	Time Series Analysis	312
5.6.15	Interventions made during the trial	319
5.6.15.1	Introduction	319
5.6.15.2	Phlebotomist interventions.....	319
5.6.15.3	Pharmacist interventions	319

5.6.16	Practical issues of running the service.....	327
5.6.17	Meetings.....	328
5.7	Discussion of findings.....	331
5.7.1	Introduction	331
5.7.2	Patient recruitment and sample.....	332
5.7.3	Patient satisfaction	333
5.7.3.1	Satisfaction study overview	333
5.7.3.2	CSQ-8 results	334
5.7.3.3	Service specific items and qualitative data.....	335
5.7.3.4	Overview.....	338
5.7.4	Anticoagulation control and Safety	339
5.7.4.1	Anticoagulation control.....	339
5.7.4.2	Time series analysis.....	341
5.7.4.3	Safety	342
5.7.4.4	Pharmacist interventions made during the trial.....	343
5.7.5	Limitations of methodology	344
5.7.6	Section summary.....	345
Chapter 6	Thesis Discussion and Conclusions.....	346
6.1	Preface.....	347
6.2	Study overview.....	347
6.3	Multimethod approach to service evaluation.....	349
6.3.1	Challenges encountered with measuring patient satisfaction	349
6.4	Selecting models for long-term implementation	351
6.5	Aspects of providing model 2.....	351
6.6	Some challenges with conducting research in practice	355
6.7	Implementing research in practice.....	358
6.8	Studying anticoagulation services in primary care	360
6.9	Summary.....	360
6.10	Study Conclusions.....	363

References.....	366
-----------------	-----

Appendices.....	i
-----------------	---

Appendix 1	CSQ-8 questionnaire.....	ii
Appendix 2	Additional questionnaire items.....	iii
Appendix 3	Nominal group session invitation letter to general practitioners.....	vi
Appendix 4	Nominal group session invitation letter to community pharmacists.....	vii
Appendix 5	Nominal group session worksheet.....	viii
Appendix 6	Domiciliary anticoagulation services trial protocol.....	ix
Appendix 7	Checklist for community visits-general and important safety points for community visits.....	xxi
Appendix 8	Patient details check.....	xxiii
Appendix 9	Domiciliary trial information leaflet.....	xxiv
Appendix 10	Domiciliary trial consent form	xxvii

List of Tables

Chapter 1

Table 1.1	Factors affecting response to warfarin.....	31
Table 1.2	Example target INRs and duration of warfarin therapy.....	31
Table 1.3	Summary of key NHS documents in last 10 years - I.....	36
Table 1.4	Summary of key NHS documents in last 10 years - II.....	37
Table 1.5	Summary of key NHS documents in last 10 years - III.....	38
Table 1.6	Summary of key NHS documents in last 10 years - IV.....	39
Table 1.7	Literature search strategy.....	42
Table 1.8	Definitions of near patient testing.....	43
Table 1.9	Near Patient Testing devices available at the time of the literature review.....	44
Table 1.10	Summary of INR NPT evaluations.....	45
Table 1.11	The potential advantages and disadvantages of Near Patient Testing.....	50
Table 1.12	Summary of studies evaluating CDSS use in anticoagulation management.....	52
Table 1.13	Summary of studies of GP-led anticoagulation services.....	56
Table 1.14	Summary of studies exploring nurse involvement in anticoagulation services.....	59
Table 1.15	Summary of studies of pharmacists managing secondary care anticoagulation clinics.....	63
Table 1.16	Summary of studies of pharmacists managing primary care anticoagulation clinics.....	65
Table 1.17	Description of patient self testing and self management in anticoagulation monitoring.....	69
Table 1.18	Summary of studies evaluating self-testing (ST) and self-management (SM) of oral anticoagulation.....	70
Table 1.19	Studies outlining domiciliary anticoagulation services provided for mobility-impaired patients.....	74

Chapter 3

Table 3.1	Main differences between qualitative and quantitative research.....	91
Table 3.6	Fitting independent variables to produce a multiple linear regression model.....	95

Chapter 4

Table 4.1	Some models of patient satisfaction.....	107
Table 4.2	Some assumptions made in the evaluation of patient satisfaction.....	107
Table 4.3	Patient groups attending BLT anticoagulation clinics.....	117
Table 4.4	Comparison of Indication for warfarin in the study sites.....	128
Table 4.5	Comparison of mean ages across patient groups at BLT.....	132
Table 4.6	Median CSQ score of different patient groups in BLT and HUH.....	133
Table 4.7	Comparison of CSQ-8 scores when missing values are replaced and when missing values are not replaced – Developmental Phase.....	133
Table 4.8	Mann Whitney U test for ranks of individual items between HUH and BLT.....	134
Table 4.9	Correlation between additional items, patients' age and CSQ score –BLT patients.....	144
Table 4.10	Model Summary using Stepwise method-BLT patients.....	145
Table 4.11	Categorization of variance effect size – linear regression.....	146
Table 4.12	ANOVA for BLT CSQ data.....	146
Table 4.13	Coefficients for BLT CSQ score Equation.....	146
Table 4.14	Correlations with additional items and CSQ score – HUH patients	148
Table 4.15	Outliers –Casewise Diagnostics.....	149
Table 4.16	Model Summary – HUH.....	149
Table 4.17	ANOVA for CSQ data-HUH.....	149
Table 4.18	Coefficients for HUH data.....	150
Table 4.19	Coefficients for BLT postal patients CSQ score	152
Table 4.20	Coefficients for BLT transport patients CSQ data.....	153
Table 4.21	Coefficients HUH transport patients CSQ data	154
Table 4.22	The in-vivo codes describing the data elicited in the open ended section in the semi-structured questionnaires: BLT.....	155
Table 4.23	Development of themes from the reflective coding process for BLT patients.....	156
Table 4.24	The in-vivo codes describing the data elicited in the open ended section in the semi-structured questionnaires – HUH.....	156

Table 4.25	Development of themes from the reflective coding process - HUH.....	157
Table 4.26	Display of examples of quotes from Theme One – BLT.....	158
Table 4.27	Display of examples of quotes from Theme One - HUH.....	159
Table 4.28	Display of examples of quotes from Theme Two - BLT.....	161
Table 4.29	Display of examples of quotes from Theme Two - HUH.....	162
Table 4.30	Display of examples of quotes from Theme Three - BLT.....	164
Table 4.31	Display of examples of quotes from Theme Three - HUH.....	165
Table 4.32	Display of examples of quotes from Theme Four - BLT.....	167
Table 4.33	Display of examples of quotes from Theme Four - HUH.....	167
Table 4.34	Display of examples of quotes from Theme Five - BLT.....	169
Table 4.35	Display of examples of quotes from Theme Five - HUH.....	170
Table 4.36	Display of examples of quotes from Theme Six - HUH.....	172
Table 4.37	Display of examples of quotes from Theme Six - BLT.....	174
Table 4.38	Display of examples of quotes from Theme Seven - HUH.....	175
Table 4.39	Display of examples of quotes from Theme Seven - BLT.....	177
Table 4.40	Display of examples of quotes from Theme Eight - HUH.....	177
Table 4.41	Stakeholders identified in the literature regarding primary care anticoagulation services development.	179
Table 4.42	BLT Anticoagulation team concerns regarding mobility impaired patients.....	184
Table 4.43	Issues regarding current anticoagulation service provision in Tower Hamlets highlighted by key stakeholders.....	186
Table 4.44	Issues regarding current anticoagulation service provision for BLT anticoagulation patients highlighted by key stakeholders.....	188
Table 4.45	Issues to be addressed for effective implementation of services.....	192
Table 4.46	The proposed models and the traditional model of anticoagulation service provision.....	196
Table 4.47	Participant ranks for anticoagulation service models.....	197
Table 4.48	Summary of key issues highlighted for Model 1 in nominal group session.....	198
Table 4.49	Summary of key issues highlighted for Model 2 in nominal group session.....	199
Table 4.50	Summary of key issues highlighted for Model 3 in nominal group session.....	200
Table 4.51	Summary of key issues highlighted for Model 4 in nominal group session.....	201
Table 4.52	Summary of key issues highlighted for Model 5 in nominal group session.....	202
Table 4.53	Summary of key issues highlighted for Model 6 in nominal group session.....	203
Table 4.54	Summary of key issues highlighted for Model 7 in nominal group session	204

Table 4.55	Summary of key issues highlighted for Model 8 in nominal group session.....	205
Table 4.56	Summary of key issues highlighted for Model 9 in nominal group session.....	206
Table 4.57	Grades of Evidence (NICE – Grading Scheme 2004.....	213
Table 4.58	Evaluation of Literature (I)	214
Table 4.59	Evaluation of Literature (II)	215
Table 4.60	Evaluation of Literature (III)	216
Table 4.61	Evaluation of Literature (IV)	217
Table 4.62	Primary care-based anticoagulation service models identified in the literature.....	220
Table 4.63	Classification of risks (BLT 1997)	232
Table 4.64	Classification of potential hazards identified for domiciliary visits.....	233

Chapter 5

Table 5.1	Example minimisation table.....	262
Table 5.2	Minimisation table with the first patient's details.....	262
Table 5.3	Additional Likert style items administered to domiciliary trial participants at the crossover stage and at the end of the trial.....	265
Table 5.4	Additional Likert style items administered to domiciliary trial participants at the end of the trial	265
Table 5.5	Methods of reporting anticoagulation control.....	267
Table 5.6	Summary of data analyses for the intervention phase.....	274
Table 5.7	Summary of the reasons for loss of participants.....	276
Table 5.8	Primary indication for warfarin – domiciliary anticoagulation service trial patients..	279
Table 5.9	Demographics of patients randomised to domiciliary anticoagulation services...	280
Table 5.10	Demographics of patients randomised to domiciliary anticoagulation services at crossover	282
Table 5.11	Comparison of CSQ score between domiciliary models at crossover and hospital service	283
Table 5.12	Comparison of additional items administered to trial participants and hospital transport patients.....	285
Table 5.13	In-vivo codes from analysis of patients comments at crossover.....	287
Table 5.14	Development of themes from the reflective coding process at crossover.....	287

Table 5.15	Display of examples of quotes from Themes emerging in the crossover satisfaction survey	289
Table 5.16	Demographics of domiciliary trial patients at the end of the trial.....	293
Table 5.17	Trial patients risk factors for complications with warfarin therapy.....	293
Table 5.18	Co-morbidities of trial participants.....	294
Table 5.19	Mann Whitney U test for ranks of individual items in domiciliary trial.....	297
Table 5.20	Friedman test to compare responses for item 12.....	298
Table 5.21	Wilcoxon test to compare responses for item 12.....	298
Table 5.22	Comparison of responses to items 12 a, b and c between groups A and B	298
Table 5.23	Post-hoc analysis of responses for item 13 – patient satisfaction with each service.....	299
Table 5.24	Comparison of responses to items 13 a, b and c between the two service groups.....	299
Table 5.25	Coefficients for linear regression of additional items against CSQ score for Group B Model 1 patients – End of Trial.....	300
Table 5.26	Coefficients for linear regression of additional items against CSQ score for Group A Model 2 patients – End of Trial.....	301
Table 5.27	Display of examples of quotes from Themes emerging in the End of Trial satisfaction survey	305
Table 5.28	Summary of End of Trial results related to anticoagulation control.....	308
Table 5.29	ARIMA regression coefficients for changes in mean INR due to service models: first study period.....	315
Table 5.30	ARIMA regression coefficients for changes in mean INR due to service models: second study period	317
Table 5.31	Interventions made by the pharmacist during the trial.....	324
Table 5.32	Baseline Time in Range readings for patients at different stages of the study	340

Chapter 6

Table 6.1	Models of anticoagulation services and benchmark fees under enhanced services in GMS contract.....	355
-----------	--	-----

List of Figures

Chapter 1

Figure 1.1	Diagrammatic representation of the Introduction chapter	27
Figure 1.2	Vitamin K dependent clotting cascade.....	29
Figure 1.3	Key themes of the Modern NHS.....	41
Figure 1.4	Recent developments in anticoagulation services in the UK.....	78
Figure 1.5	Diagrammatic representation of the introduction chapter and key words.....	82

Chapter 3

Figure 3.1	MRC framework for evaluation of complex health intervention.....	89
Figure 3.2	Illustration of fitted regression line with residuals	94

Chapter 4

Figure 4.1	Diagrammatic representation of Developmental Phase.....	104
Figure 4.2	Historical development of "patient satisfaction"	109
Figure 4.3	Clinic operation at BLT anticoagulation clinic.....	115
Figure 4.4	Clinic operation at HUH anticoagulation clinic.....	116
Figure 4.5	BLT patient satisfaction questionnaires.....	122
Figure 4.6	HUH patient satisfaction questionnaires.....	124
Figure 4.7	Age distribution for BLT anticoagulation patients.....	126
Figure 4.8	Age distribution for HUH anticoagulation patients.....	126
Figure 4.9	Duration of treatment distribution for BLT anticoagulation patients.....	127
Figure 4.10	Duration of treatment distribution for HUH anticoagulation patients.....	127
Figure 4.11	Distribution of CSQ scores – BLT.....	131
Figure 4.12	Distribution of CSQ scores – HUH.....	131
Figure 4.13	Waiting times – BLT patients.....	138
Figure 4.14	Waiting times – HUH patients.....	138
Figure 4.15	Blood sample method – BLT patients.....	139
Figure 4.16	Blood sample method – HUH patients.....	139

Figure 4.17	Satisfaction with staff taking blood – BLT patients.....	140
Figure 4.18	Satisfaction with staff taking blood – HUH patients.....	140
Figure 4.19	Clarity of explanation about what to do between visits – BLT patients.....	141
Figure 4.20	Clarity of explanation about what to do between visits – HUH patients.....	141
Figure 4.21	Length of time for ambulance service to pick patients – BLT patients.....	142
Figure 4.22	Length of time for ambulance service to pick patients – HUH patients.....	142
Figure 4.23	Frequency of failure of transport service to pick patients – BLT patients.....	143
Figure 4.24	Frequency of failure of transport service to pick patients – HUH patients.....	143
Figure 4.25	Distribution of residuals.....	145
Figure 4.26	Diagrammatic representation of multiple linear regression equation linking independent variables to patient satisfaction with BLT anticoagulation services...	147
Figure 4.27	Diagrammatic representation of multiple linear regression equation linking independent variables to patient satisfaction with HUH anticoagulation services.	151
Figure 4.28	Model A of GP-based anticoagulation service described by the BLT anticoagulation clinic staff	183
Figure 4.29	Model B of GP-based anticoagulation service described by the BLT anticoagulation clinic staff	183
Figure 4.30	Diagrammatic representation of triangulation of data sources.....	225
Figure 4.31	Model 1 of the domiciliary anticoagulation service trial.....	226
Figure 4.32	Model 2 of the domiciliary anticoagulation service trial.....	226
Figure 4.33	An example of question b), Frequency of exposure to hazard.....	232
Figure 4.34	An example of question c), Maximum probable loss.....	232

Chapter 5

Figure 5.1	Intervention study protocol.....	256
Figure 5.2	Age distribution for domiciliary anticoagulation service trial patients.....	278
Figure 5.3	Duration of treatment distribution for domiciliary anticoagulation service trial patients.....	278
Figure 5.4	Distribution of Time in Range for domiciliary anticoagulation service trial Patients.....	279
Figure 5.5	Age distribution for domiciliary anticoagulation model 1 service.....	281
Figure 5.6	Age distribution for domiciliary anticoagulation model 2 service.....	281
Figure 5.7	Means and 95% confidence intervals for the CSQ score for the different	

	services.....	283
Figure 5.8	Age distribution of model 1 patients.....	292
Figure 5.9	Age distribution of model 2 patients	292
Figure 5.10	Distribution of the number of additional drugs	295
Figure 5.11	Means and 95% confidence intervals for the CSQ score for the different anticoagulation services	296
Figure 5.12	Autocorrelation Function Plot of Mean INR- Group B.....	313
Figure 5.13	Partial Autocorrelation Function Plot of Mean INR- Group B.....	313
Figure 5.14	Autocorrelation Function Plot of Mean INR- Group A.....	314
Figure 5.15	Partial Autocorrelation Function Plot of Mean INR- Group A.....	314
Figure 5.16	Time series Plot of Group B patients' INRs pre-intervention and post intervention	316
Figure 5.17	Time series Plot of Group A patients' INRs pre-intervention and post intervention	316
Figure 5.18	Time series Plot of Group B patients' INRs during trial	318
Figure 5.19	Time series Plot of Group A patients' INRs during trial	318

Chapter 6

Figure 6.1	Diagrammatic representation of the introduction chapter and key words	348
Figure 6.2	Diagrammatic representation of service model 2.....	353

Abbreviations

a/c	anticoagulation
AF	atrial fibrillation
BLT	Barts and The London Trust
CDSS	computer dosage support software
CP	community pharmacist
GP	general practitioner
HCP	healthcare professional
HUH	Homerton University Hospital
INR	international normalised ratio
MHRA	Medicines and Healthcare Products Regulatory Agency
Neqas	National external quality assurance scheme
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NPT	Near patient testing
NSF	National Service Framework
o/p	outpatient
PCG	primary care group
PCT	primary care trust
POCT	point of care testing
RPSGB	The Royal Pharmaceutical Society of Great Britain
SM	Self Management
ST	Self Testing
TIR	Time in Range

Acknowledgments

Firstly, I would like to thank God for getting me through the past three and a half years! It hasn't always been fun, but I've learnt that experiences shouldn't always be about our comfort; they're much more valuable when they are about our character.

I would like to thank my supervisors Ian Bates, Catherine Duggan, Dita Engova, and Peter MacCallum, for giving me the opportunity to do this PhD, you might have wondered if I was grateful – I am! Also thank you for managing, and motivating me through this challenging process. I would like to thank ELENor for funding the developmental phase of the study and the Multidisciplinary and Health Service Research group (MDHSR) for funding the randomised crossover study.

I would also like to thank the anticoagulation team at Barts and The London, for their support during the developmental and intervention phases of the study. In particular, I would like to thank Kate Ortiz, for agreeing to play the integral role of phlebotomist during the intervention phase, I know it wasn't easy but you did a fantastic job!

To all my friends who feel like they've been doing this PhD with me, thanks for listening to me rant on about anticoagulation service developments in primary care for the last three years. I know you feel like you've had the information forced on you, but remember, knowledge is power!

I would like to thank members of my extended family and my church family whose encouragement and prayers have been uplifting and motivated me to cross the finish line!

Lastly, I would like to thank my parents, Olusola and Francis Tunde Akinwunmi and my siblings, Frederick, Florence and Felix. You were all so unwavering in your belief, encouragement and support of me; you don't know how much it's meant. Thank you.

Preface

The purpose of this thesis was to use a research perspective to conduct an evidence based development and evaluation of a complex healthcare intervention; anticoagulation monitoring. The study focuses on patients attending Barts and The London anticoagulation clinics and is set against the changing environment of the NHS, which requires a patient-centred approach to service redesign and the challenges of practice based research, which requires a pragmatic approach for successful implementation of service developments.

The thesis consists of six chapters. Chapter one, the Introduction, discusses the clinical evidence for the use of anticoagulation therapy in stroke therapy, it outlines the Government's NHS modernisation agenda and reviews the literature on anticoagulation service developments. It clarifies the links between these areas, in terms of the effectiveness of warfarin in the prevention of stroke secondary to atrial fibrillation, the Government's stroke reduction agenda, the resulting increased burden on secondary care anticoagulation services, the Government's call for services to be patient centred, where possible moved to primary care, and the supporting literature on the use of technology and non-medical practitioners to facilitate the move to primary care.

Chapter two is the Aims and Objectives chapter. It describes the development of key questions utilised to direct the study. It goes on further to outline the hypotheses to be tested during the intervention phase along with the overall aim of the thesis; to develop and evaluate two domiciliary anticoagulation services in terms of patient satisfaction, anticoagulation control and safety.

Chapter three, the Materials and Methods chapter, outlines the research methodology used throughout this thesis. In addition, it outlines the organisations involved and the supervisory support given throughout the study. This chapter outlines the rigorous yet pragmatic approach taken to the service development process, utilising a multimethod approach.

Chapter four, the Developmental Phase, describes the three phase approach to the exploratory work that was undertaken; this consisted of, a comparative patient satisfaction survey of anticoagulation patients across Homerton and Barts and The London Hospitals, multidisciplinary discussions with local stakeholders and an evaluation of the literature on anticoagulation service developments to sufficiently evidence the intervention. It describes the triangulation of the data and the selection of two services for evaluation. The chapter goes on to describe the preparatory work done prior to implementation of the intervention; covering risk assessment of the developed

services as well as a variety of training and documentation requirements for the safe implementation of the services.

Chapter five, the Intervention Phase outlines patient recruitment and the randomisation process, the use of a patient satisfaction questionnaire, as well as the implementation of the intervention in a randomised crossover trial. It details the outcomes used to evaluate the effectiveness of the intervention; patient satisfaction as assessed by the client satisfaction questionnaire (quality; access), anticoagulation control as assessed by Rosendaal's Time in range, proportion of tests in range and time series analysis (quality) as well as the incidence and annualised event rate of haemorrhagic and thrombotic events (safety).

Chapter six, the Discussion chapter, discusses the methods used in the developmental phase in the development of a complex pharmaceutical healthcare intervention in practice. It relates the intervention phase back to the developmental phase and back to the introduction. It outlines the limitations of the study and the complexity of the intervention. It explores how the interventions address the areas of overlap between the Government's agendas, the clinical evidence and the available literature on anticoagulation service developments.

This thesis describes the evidence based approach to developing and evaluating a primary care based intervention that aimed to improve patient satisfaction with anticoagulation services and maintain the standards of anticoagulation control and safety achieved by the traditional model.

The thesis concludes that the evidence based anticoagulation services developed are suitable alternatives to the traditional anticoagulation service model.

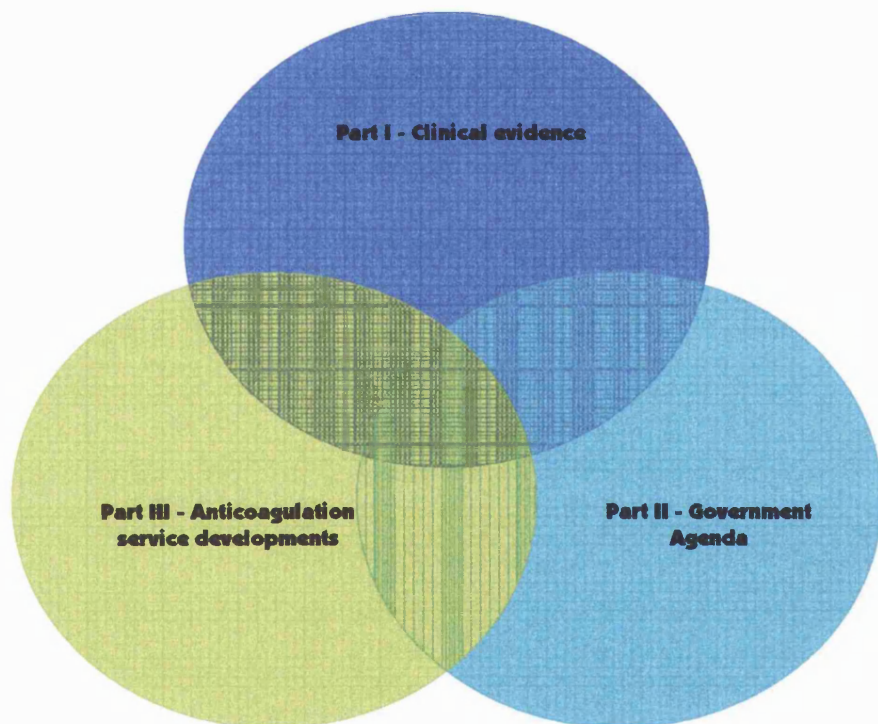
Chapter 1

INTRODUCTION

1.1 Introduction

The introduction chapter is made up of three sections, providing an overview of the clinical need for anticoagulation; the current Government-driven climate within the NHS; and an outline of the development of anticoagulation services (Figure 1.1).

Figure 1.1: Diagrammatic representation of the Introduction chapter



Part I briefly outlines the causes and consequences of thrombosis, together with a description of its treatment in the form of anticoagulation therapy, and goes on to outline the main changes that have led to the necessity for service developments in anticoagulation. Part II outlines a number of Government papers and initiatives that have had an impact on the NHS with regards to its modernisation. Part III describes the literature search method utilised to explore anticoagulation service developments, and goes on to outline the findings in a literature review. Despite the study being UK based, the literature review incorporates international service developments as relevant contributions to the evidence-base. The chapter attempts not only to provide an account of service developments, but also to identify the areas where literature is lacking, in this way the review is utilised as a tool to inform anticoagulation service developments (Chapter 4) in the study site.

1.2 Part I – Anticoagulation Therapy

Thrombosis is a frequent and significant cause of morbidity. Numerous problems in clinical practice are associated with thrombosis, including deep vein thrombosis, pulmonary embolism and ischaemic stroke often as a consequence of atrial fibrillation (Blann *et al.* 2002).

1.2.1 Thrombosis and anticoagulation therapy

Three main factors, known as Virchow's triad, affect the occurrence of thrombosis (Blann *et al.* 2002):

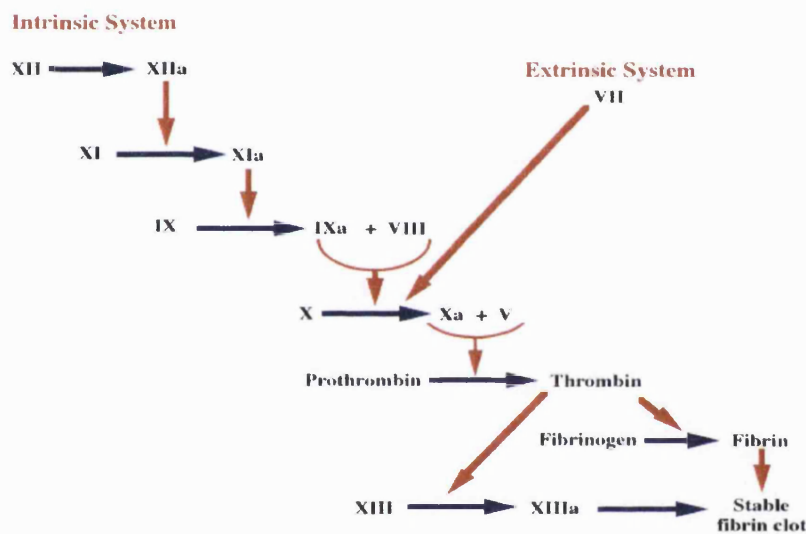
1. Altered blood flow, resulting in areas of stasis.
2. Abnormalities of blood vessel wall.
3. Alterations in blood clotting components, resulting in abnormal coagulability of blood.

Anticoagulants reduce thrombosis by decreasing the clotting ability of the blood. They are indicated for the prevention of thromboembolism in patients at increased risk, and to prevent the extension or embolisation of a thrombus that has already occurred.

Warfarin is an oral anticoagulant, it is the most commonly used oral anticoagulant in the United Kingdom (Adams 1998). Blood coagulation is a complex enzyme cascade, in which a series of clotting factors are sequentially activated and subsequently circulated. Warfarin inhibits the vitamin K - dependent synthesis of clotting factors, II, VII, IX and X (see vitamin K dependent clotting cascade Figure 1.2). Following oral administration, approximately 95% of a dose of warfarin is

absorbed from the gastrointestinal tract, it has a relatively small volume of distribution and is extensively plasma protein bound (circa 97%). Peak plasma concentrations occur around one hour after administration. However its onset of action is delayed until existing clotting factors, already present in the circulation, are eliminated; this can be anywhere from 48 to 96 hours. Warfarin is metabolised in the liver and has a highly variable half life, but it is usually approximately 40 hours and therefore a change in dose may take two days to show its full effect.

Figure 1.2: Vitamin K dependent clotting cascade



Patients' response to warfarin is highly variable and is dependent on numerous factors (Adams 1998; Ansell *et al.* 2001; Table 1.1). The international normalised ratio (INR) is the measure of intensity of anticoagulation. "The INR is an expression of the patient's prothrombin time¹ compared to an internationally standardized thromboplastin²" (Adams 1998). Intensity (target INR) and duration of warfarin treatment is dependent on the condition being treated (Table 1.2).

¹ Prothrombin time is the time in seconds required for a fibrin clot to form; it is a measure of blood clotting ability.

² A thromboplastin is a phospholipid-protein extract of tissue (usually lung, brain or placenta) that contains both tissue factor and phospholipids necessary to promote activation of factor X by factor VII. It is used to perform a prothrombin time assay and to derive an INR (Hirsh *et al.*, 2003).

Warfarin is a drug with a narrow therapeutic range; therefore small changes in dose can result in large changes in INR. It is important to tailor a patient's dose of warfarin to ensure that their INR is kept within the specified therapeutic range. If the dose is too low, the result is under-anticoagulation; and thus increased risk of thrombotic events, if the dose is too high the result is over-anticoagulation and increased risk of haemorrhagic events. Such complications can be life-threatening. With respect to managing anticoagulation therapy, patients require regular INR monitoring by means of a blood test, warfarin dosage is adjusted accordingly, to ensure that their INR is maintained within the narrow therapeutic INR range for their condition. In the UK, this anticoagulation management has traditionally been provided via a secondary care anticoagulation outpatient clinic. Whilst anticoagulation therapy is largely recognised as safe it is also seen as high risk (Building a safer NHS; Department of Health 2004a). The NHS litigation authority reports that oral anticoagulation errors are one of the ten most common errors resulting in claims against NHS Trusts (National Patient Safety Agency 2006). In primary care, anticoagulation therapy is in the top three classes of medicines most commonly associated with fatal medication errors (Green *et al.* for The Medical Defence Union 1996). Further, in secondary care, warfarin is consistently one of the top ten medications associated with dispensing errors (Upton and Cousins. 1998).

Table 1.1: Factors affecting response to warfarin

Factor	Effect	Mechanism	Reference
Age	An increased response to warfarin with increasing age, often necessitating a reduction in dose.	Increased receptor site sensitivity, reduced liver clearance. Note elderly patients tend to have more co-morbidities and increased number of concomitant medication, increasing the potential for interactions.	(O'Malley <i>et al.</i> 1977)
Racial background	Asian or African – Caribbean background: reduced anticoagulant effect	Mechanism unclear, could be cytochrome P450 mediated	(Blann <i>et al.</i> 2002)
Diet	Patients who are malnourished may have increased response, necessitating lower doses of warfarin	Low vitamin K intake and decreased serum albumin concentrations leading to increased bioavailability of warfarin	(Horton and Bushwick 1999)
	High intake of salads: reduced anticoagulant effect: dark green vegetables - spinach, kale, spring greens, cabbage, brussels sprouts, broccoli, asparagus, watercress, parsley	High vitamin K intake antagonises effect of warfarin	(Blann <i>et al.</i> 2002)
Concurrent diseases	Could have multiple effects examples:		
	Liver disease: enhanced anticoagulant effect	Defective synthesis of clotting factors	(Breckenridge 1977)
	Heart Failure: enhanced anticoagulant effect	Reduce clotting factor synthesis	
	Hyperthyroidism: enhanced anticoagulant effect	Increased clotting factor degradation	(O'Reilly and Aggeler 1970)
Interacting drugs	Could have multiple effects examples:		
	Barbiturates – reduce anticoagulant effect, requires higher doses of warfarin	Increased warfarin metabolism through enzyme induction	(Horton and Bushwick 1999)
	Antifungals e.g. Ketoconazole – increased sensitivity, reduced doses required	Decrease warfarin metabolism	
	Alcohol	Inhibit warfarin metabolism	
Alcohol	Acute use: increases sensitivity resulting in INRs above range	Inhibit warfarin metabolism	(Breckenridge 1997)
	Chronic use: reduced sensitivity leading to increased doses required note: when cirrhosis develops sensitivity increased and lower doses required	Chronic alcohol consumption induces liver enzymes note: when cirrhosis develops: reduction in metabolism	
Pregnancy	An increased response to warfarin	Increased blood coagulability	(Breckenridge 1997)

Table 1.2: Example target INRs and duration of warfarin therapy

Indication	Target INR (range)	Length of treatment
Proximal deep vein thrombosis (DVT)	2.5 (2-3)	6 months
Pulmonary embolism	2.5 (2-3)	6 months
Mechanical prosthetic heart valve	3.5 (3-4)	Lifelong
Atrial fibrillation	2.5 (2-3)	Lifelong

1.2.2 Increase in demand for anticoagulation therapy and associated services

Over recent years there has been a substantial increase in the number of patients requiring anticoagulation therapy in England. There have been three main drivers in this increase:

1. Expansion of indications for warfarin
2. Ageing population
3. Government targets to reduce the incidence of stroke in England

These aspects are discussed in more detail below.

Context

Stroke is the third most common cause of death and the single largest cause of severe disability in the United Kingdom (National Service Framework for Older People; Department of Health 2001a). In 1998, the NHS expenditure on stroke was estimated to be £2.3 billion per year in the UK, almost twice the amount spent on coronary heart disease (Rothwell 2001). Stroke not only represents a considerable burden on the NHS, but also on the relatives/carers of those afflicted (Anderson 1987; Van Heugten *et al.* 2006). Atrial fibrillation (AF) is the most common cause of embolic stroke (McCormick *et al.* 2001); nonvalvular AF increases the risk of stroke five-fold and the prevalence of AF increases with age, substantially after the age of 70 (Wheeldon 1995; Akhtar *et al.* 1998). In the UK, five percent of over 65s have AF, this increases to 10% in those over 75 (National Assembly for Wales 2001).

Expansion of indications for warfarin

The list of indications for warfarin has expanded. Previously, warfarin was indicated for deep vein thrombosis, transient ischaemic attacks and prophylaxis of embolisation after insertion of prosthetic heart valves (British Medical Association and Royal Pharmaceutical Society of Great Britain 1988). In addition, it is now also indicated for pulmonary embolism and prophylaxis of embolisation in rheumatic heart disease and atrial fibrillation. The use of warfarin in stroke prevention is as a result of numerous clinical studies that have demonstrated long-term warfarin use is effective for the primary and secondary prevention of ischaemic stroke, reducing the risk of stroke by 68% in patients with nonvalvular AF (Ezekowitz *et al.* 1992).

The UK's ageing population

The results of the 2001 UK Census showed that, for the first time, there were more individuals aged over 60 (21% of the total population) than there were children under 16 (20%). Furthermore, the

number of people aged over 85 had increased more than five-fold since 1951 to 1.1 million (1.9% of the total; Office for National Statistics 2001). The UK's population is getting older and projections predict that this trend will continue (Medicines and Older People; Department of Health 2003). Reduced mortality rates have led to significant decreases in the projected number of future deaths per annum. The result is an increase in the numbers of middle-aged and elderly people; it is expected that this will be counterbalanced by a corresponding decline in the number of children, teenagers and younger people. Therefore, overall there will be a relative and absolute increase in the number of elderly people (Government Actuary 1999)

The incidence of AF increases with age (Stewart *et al.* 2001), this coupled with the UK's ageing population, is likely to result in an increased burden of disability in the UK population. Healthcare professionals and policy makers are addressing these issues in a number of ways. One of the approaches is the use of warfarin for prevention of stroke in those with AF (Medicines and Older People; Department of Health 2003).

Government targets to reduce the incidence of stroke

In 2001, the Government published the National Service Framework (NSF) for Older People (Department of Health 2001a), with the aim of improving the health of the nation's older population. In light of the recognised impact of stroke on individuals and on the population, standard five of the NSF sets the agenda for reducing the incidence of stroke by 40% by the year 2010.

The NSF recognises the role of AF in stroke and states that AF should be actively managed; and includes, where clinically appropriate, warfarin therapy. The NSF builds upon a previous Government White Paper; *Saving Lives: Our Healthier Nation* (1999), which outlines the national strategy for improving health and sets a target for reducing mortality from coronary heart disease (CHD), stroke and related disorders by 40% in people aged under 75 by the year 2010. These are discussed further in the next section.

The resultant increased use and demand for warfarin is expected to continue at a rate of 10% per year (Williams *et al.* 2003). Despite the substantial increase in use of warfarin, there is evidence that approximately only a third of those who would benefit from warfarin therapy are receiving it (Rashid *et al.* 2005; Samsa *et al.* 2000; Sudlow *et al.* 1998). The Venous Thromboembolism Impact Assessment Group in Europe (VITAE) undertook a study which suggests that venous

thromboembolism may be causing between 25,000 - 60,000 deaths in the UK each year and costs the NHS £640 million, but is largely preventable through clinically appropriate and cost effective anticoagulation therapy. These figures have highlighted the need for prophylaxis in the form of anticoagulation for at-risk patients to minimise venous thromboembolism-related deaths (VITAE 2005). Despite the unmet need, the pressure on the traditional hospital-based, venous-sampling service is already becoming unsustainable. There is a need for alternative anticoagulation service models.

Summary

- Thrombosis is a frequent and significant cause of morbidity.
- Stroke is a common consequence of thrombosis, the risk of which increases with age and the presence of atrial fibrillation (Department of Health 2003).
- Anticoagulants such as warfarin reduce thromboses by decreasing the clotting ability of blood. When used appropriately warfarin is safe, however as it has a narrow therapeutic window, it requires monitoring to prevent potentially fatal adverse effects due to inappropriate management, hence it is deemed to be a high risk drug.
- There has been an increased demand for warfarin due to an increase in the number of indications, an ageing population and national stroke reduction targets.
- The traditional service cannot sustain this increased demand, thus there is a need for alternative anticoagulation service models.

1.3 Part II – Government agenda

Over the last 10 years, there has been a Government-initiated climate of modernisation in the English NHS. In an effort to modernise the traditional NHS, the Government has produced numerous reports, initiatives and professional contracts that have cumulatively had a huge impact on health policy and practice. This section briefly outlines some of the White papers, policies and contracts that have influenced the current NHS culture. Although, each publication has its own focus there are many overlapping themes and recurring concepts within them (Table 1.3 to Table 1.6).

Saving lives: Our Healthier Nation (Department of Health 1999)

This white paper outlined incidence reduction targets for accidents and a number of disease areas such as coronary heart disease, stroke and cancer to be achieved by 2010. Achievement of these national targets should minimise many of the health inequalities across the nation.

NSF for Older People (Department of Health 2001a)

The NSF for Older People advocates that patients identified as being at increased risk of stroke (such as smokers and those with hypertension) should be offered support and advice. It emphasises the two most effective interventions in stroke prevention are maintaining blood pressure within recommended limits and ensuring that individuals with atrial fibrillation receive antithrombotic therapy such as warfarin or aspirin. The NSF states that it is not sufficient to simply prescribe antihypertensives and antithrombotics; it recognises that pharmacists have a role in providing advice and answering questions about medication. The NSF sets out a number of stroke-related targets, such as by 2004 Primary Care Trusts should ensure that every general practice can identify their patients at increased risk of stroke because of hypertension, AF or other risk factors.

Building a safer NHS for patients: Improving medication safety (Department of Health 2004a)

published by the Department of Health builds on 'An organisation with a memory' (Department of Health 2000a), with the aim of improving the safety and quality of patient care with regards to medicines. It focuses on the causes and frequency of medication errors and calls for the safer use of medicines. Anticoagulation therapy is highlighted in the paper as a high risk therapeutic area. The rise in numbers of patients requiring anticoagulation therapy and the move to primary care anticoagulation service models is recognised. Authors state that, "Local testing of anticoagulation control may increase the safety of therapy by allowing frequent testing and improved communications between the patient and the primary care team" (Department of Health 2004a). It also recommends that routine audits of under- and over- anticoagulated patients should be undertaken by staff managing anticoagulation clinics.

The new NHS Community Pharmacy contractual framework (2005) implements a system to reward pharmacists providing high quality services, rather than payment solely based on the volume of prescriptions dispensed. In addition, the contract allows PCTs to increase the range of services they provide in the community. The contract offers opportunities for community pharmacists to provide patient-centred, quality-driven services that accurately reflect the needs of the local population. The contract encourages implementation of Pharmacy in the Future (Department of Health 2000b) by encouraging pharmacists to provide specialist services such as hypertension or anticoagulation clinics from general practice or within the community pharmacy setting through locally commissioned local enhanced services.

Table1.3: Summary of key NHS documents in last 10 years – I

THEME	PAPER	SUMMARY	RELEVANCE TO STUDY
VISION	The New NHS: Modern, Dependable (Department of Health 1997)	Ten year NHS modernization plan. Aimed to: improve quality, cost-effectiveness, reduce health inequalities and facilitate use of NHS services by the public . Addressed issues of seamless provision of care across health and social care sectors: service provisions in areas such as nursing homes and domiciliary care to benefit from cross-sector networks. In addition, promoted the coming together of those who provide housing, education and employment services in an effort to reduce inequalities.	Recognition that patients may need help to make the best use of or to access services appropriately.
SERVICES AND DEVELOPMENTS	Pharmacy in the Future: implementing the NHS Plan - a programme for pharmacy in the National Health Service (Department of Health 2000b)	Government showed appreciation of crucial part pharmacy had to play in implementing NHS plan. Pharmacy recognised as underutilised resource. Aim for pharmacy: provide patients with 'right care at the right time in the right way and of the right quality'. Pharmacists to work more flexibly alongside other healthcare professionals , take advantage of modern technologies and use their skills more effectively. Pharmacists given opportunity to extend their role both as dependent and independent prescribers. In addition, calls for multidisciplinary approach to pharmaceutical service developments.	Appreciation of the role of pharmacists in clinical multidisciplinary teams
RISK MANAGEMENT	A First Class Service: Quality in the New NHS (Department of Health 1998)	Introduced concept of clinical governance which addressed issues of providing services with continual focus on resources, risk minimisation and quality across NHS. In addition, it called for transparency and clear lines of accountability and responsibility.	Quality, Risk and Finance management are important in the new NHS and thus relevant to service provision / developments.
CLINICAL MANAGEMENT	Medicines and Older People (Department of Health 2003)	Implemented medicines-related aspects of NSF for older people. Stated that older people should receive more support in using their medicines from pharmacists .	Potential role for increased pharmacist contact with older patients to ensure their pharmaceutical needs are met
PATIENT FOCUS	Commissioning a Patient-led NHS (Department of Health 2005a)	Outlines how commissioning will develop around patients' needs throughout NHS . Primary Care Trusts restructured to minimise administration and management costs and facilitate shift.	Focus service developments around patients

Table 1.4: Summary of key NHS documents in last 10 years - II

THEME	PAPER	SUMMARY	RELEVANCE TO STUDY
VISION	Saving lives: Our Healthier Nation (Department of Health 1999)	Outlined incidence-reduction targets for accidents in a number of disease areas such as coronary heart disease, stroke and cancer to be achieved by 2010. Vision: achievement of these national targets should minimise health inequalities across the nation.	Government policy has a focus on stroke. Prevention strategies include warfarin for patients with AF.
SERVICES AND DEVELOPMENTS	The expert patient: a new approach to chronic disease management for the 21st century (Department of Health 2001b)	Brought together patients and clinical organisations to develop self-management initiatives for long term conditions to be rolled-out on a population scale. Encouraged move towards increased patient involvement in disease management, autonomy and empowerment.	Innovative ways of managing long term conditions.
RISK MANAGEMENT	An organisation with a Memory (Department of Health 2000a)	Called on NHS to adopt an open culture and encourage learning from errors . Promoted implementation of changes in practice to improve standards of quality.	NHS accepts that although a high quality service is a key objective, there is still room for improvement.
CLINICAL MANAGEMENT	New General Medical Services Contract (Department of Health 2004b)	Contract based on concept of providing quality services for practice population. Encouraged GPs to offer their patients more choice . Scope for multidisciplinary working to ensure that GPs meet indicators on Quality and Outcomes Framework, which determines their pay.	Focus on increased patient choice through general practice – based services.
PATIENT FOCUS	Involving Patients and the Public in Healthcare: A Discussion Document (Department of Health 2001c)	Outlined proposals for implementing vision of patient-focused NHS , set out in NHS plan. Recognised that in the past, services were often redesigned without consideration of patients' needs, leading to unnecessary or unacceptable changes to service provision. Appreciated that service users should be involved in development of services.	Focus service developments around patients.

Table: 1.5 Summary of key NHS documents in last 10 years -III

THEME	PAPER	SUMMARY	RELEVANCE TO STUDY
VISION	Our Health, Our Care, Our Say: A New Direction for Community Services (Department of Health 2006a)	Patients at forefront of service developments. Called for redesigning of services to fit around service users needs. Called for better prevention services with earlier intervention, ways of handling inequalities and encouraging equitable access to services. Supports patient choice and involvement in service redesign, through trebling investment in Expert Patient Programme. Pushes for more health services to be provided in primary care, including patients' homes .	Focus service developments around patients; alternative settings such as patients' homes, for service provision.
SERVICES AND DEVELOPMENTS	NHS Improvement Plan: Putting People at the Heart of Public Services (Department of Health 2004c)	Outlined Government's commitments to reducing waiting times, increasing patient choice and managing long term conditions, to transform patients' experience of the NHS.	Focus service developments around patients.
RISK MANAGEMENT	Spoonful of sugar: medicines management in NHS hospitals (Audit Commission 2001)	Built on 'An organisation with a memory'. Recognised role for pharmacists in redesigning services around patients' needs , to ensure optimal use of medication. Appreciated many errors could be eliminated through use of computer technology : electronic transcription of prescriptions, reducing number of illegible handwriting and transcription errors also for clinical decision support, to facilitate management of conditions. Linked medicines management to clinical governance through functions such as prescription monitoring, managing risk and financial planning.	Pharmacists to have a key role in service developments and meeting patients pharmaceutical needs; technology can reduce errors and facilitate developments.
CLINICAL MANAGEMENT	The new NHS Community Pharmacy service contract (Pharmaceutical Services Negotiating Committee 2004)	Implemented system to reward pharmacists providing high quality services , rather than payment solely based on volume of prescriptions dispensed. Contract allows PCTs to increase range of services provided in community . Offers numerous opportunities for pharmacists to provide patient-centred, quality-driven services accurately reflecting needs of local population. Encourages implementation of Pharmacy in the future through encouraging pharmacists to work in GP practices or within community pharmacy setting, for example reviewing repeat prescribing and providing specialist services such as hypertension or anticoagulation clinics.	Role for pharmacists to increase range of services they provide in the community.
PATIENT FOCUS	National Service Framework for Older People (Department of Health 2001a)	Comprehensive ten year strategy setting standards for care of older people across health and social services. Framework called for provision of patient-centred care, extended access to services for this patient group, supporting of patient independence and improving standards of care.	Standard 5: reduce incidence of stroke.

Table 1.6: Summary of key NHS documents in last 10 years - IV

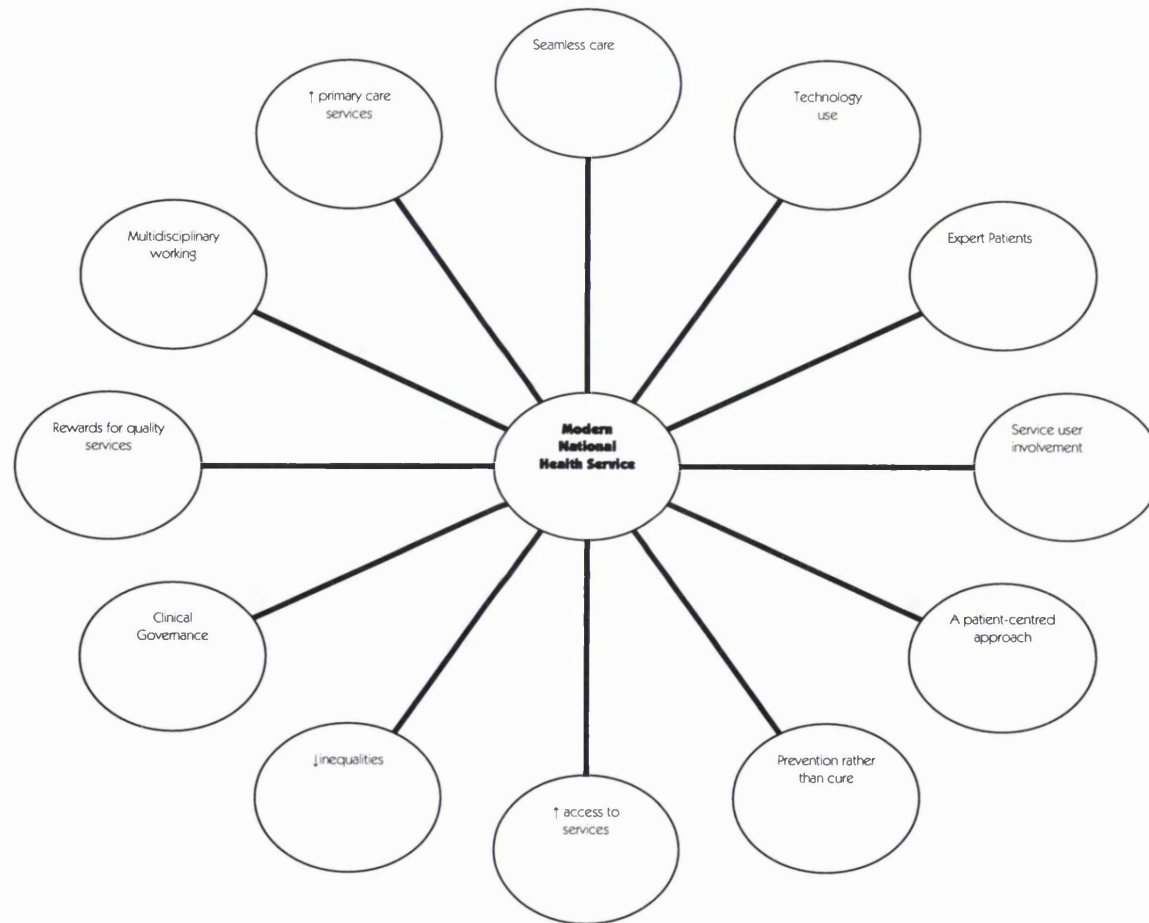
THEME	PAPER	SUMMARY	RELEVANCE TO STUDY
VISION	The NHS plan: a plan for investment (Department of Health 2000c)	Constituted biggest change to healthcare in England since NHS was formed in 1948. Focused on priorities of evolving NHS: reduced waiting times, high quality patient-centred care with emphasis placed on prevention and maintenance of health, and better healthcare delivery. Called for patients to have more influence over way NHS functions. Vision: minimise inequalities in health and access to NHS services so that those most in need of health services are no longer marginalized	Increase patient access to health services; increase patient choice.
SERVICES AND DEVELOPMENTS	Practice-based Commissioning: Engaging Practices in Commissioning (Department of Health 2004d)	Model encourages multidisciplinary and public involvement. Practices given own budget by PCT to tailor services they provide to practice population. Patient choice recognised as key driver to achieving quality in wider range of services. Payment by results, with funds following services patients use.	Focus services around patients.
RISK MANAGEMENT	Building a safer NHS for patients: Improving medication safety (Department of Health 2004 a)	Aim to improve safety and quality of patient medicines-related care. Called for safer use of medicines . Anticoagulation therapy highlighted as high risk therapeutic area.	Anticoagulation therapy (key in implementing stroke reduction strategy) is high risk drug additional systems / services may be required to further minimise potential problems with therapy.
CLINICAL MANAGEMENT	Supporting People with Long Term Conditions, an NHS and social care model (Department of Health 2005b)	Effective management of long term conditions: NHS priority - potential of having huge and positive impacts on effectiveness and efficiency of resource use across health economies. Called for better management of chronic diseases to reduce hospital admissions and hospital stays. Aim: bring benefits to patients through increasing their control over their conditions and reducing unnecessary hospital admissions. A number of chronic disease management models adopted to achieve objectives.	Better management of long term conditions may require service development strategies to be implemented.

Together, these Government papers, professional contracts and initiatives outline a modern NHS that through redesigning services around patients aims to empower the patient. It encourages cross-sector and multidisciplinary working to provide a rich skill-mix for achieving national and local targets and to improve access to services. It focuses on the development and implementation of quality standards and risk minimisation. Figure 1.3 displays some of the key themes in the modern NHS.

Summary

- Numerous Government White Papers, new professional contracts and policies have been introduced in the last decade; producing a climate of change and setting the agenda for NHS modernisation and innovative ways of addressing the health of the nation.
- Within the papers and contracts there are a number of overlapping themes.
- There is a clear role for multidisciplinary working, with a focus on quality rather than volume.
- Patients' input is recognised as integral to the service development process within the call for a patient-centred NHS.
- In line with the concept of clinical governance, strategies to address quality in services and prescribing, risk minimisation and finance must be in place throughout the NHS.

Figure 1.3 Key themes of the Modern NHS



1.4 Part III – Literature Review

This section outlines the findings of a literature review on anticoagulation service developments. The review was to inform anticoagulation service developments for anticoagulation patients attending Barts and The London Trust (BLT) outpatient anticoagulation clinics (see section 3.4.5).

1.4.1 Literature search

The literature search was undertaken using the databases and key words displayed in Table 1.7. The searches were restricted to obtaining literature on transferring services to primary care and identification / evaluation of various models of anticoagulation service, including: exploring delivery of services by a variety of healthcare professionals and the process of developing alternative services. The initial literature search was conducted in January 2003. Subsequently, to ensure the literature review was up-to-date, smaller scale literature searches were conducted on a bi-monthly basis until July 2004. The overall database search covered the period from 1966 to (July) 2004.

Table 1.7: Literature search strategy

Databases	Key words
Medline Embase Cochrane Library British Medical Journal Online Pharmaceutical Journal Online International Pharmaceutical Abstracts CINAHL	Near patient test Point-of-care (testing) Home testing Self-testing Primary care Blood anticoagulation tests Community based Anticoagulation Anticoagulation clinics Coagulometers Computer dosage software support Pharmacist General practitioners Nurses Outreach clinics Domiciliary

1.4.2 Findings of literature search

In total, 163 references were identified during the literature search. These included published papers, relevant reports and policies from the Government (for example, department of health; MHRA), other bodies and narratives. Of these, 121 were deemed by the main and second investigators to be relevant / suitable for the review. Those that were discounted focused on aspects related to the key words that were outside the remit of the review, such as the development of the INR. The findings of the review of the key aspects of anticoagulation service developments are outlined in this section.

1.4.2.1 Near patient testing

In 1999, 470 000 patients were taking warfarin in the UK. With the current growth in patient numbers of 10% per annum expected to continue at least over the next decade, it is expected that this number will eventually double (Murray *et al.* 2004). The subsequent increase in demand for warfarin has led to an increased interest in anticoagulation near patient testing as a way of coping with the substantial rise in work volume in anticoagulation clinics (Fitzmaurice *et al.* 1998). This section evaluates studies of near patient testing for anticoagulation monitoring in terms of the accuracy and suitability of near patient testing devices and the potential advantages and disadvantages of this technology.

Definitions of near patient testing

Near patient testing (NPT) is not an exclusive term for rapid testing technology and as such does not have a universally accepted definition. Other synonymous terms include point of care testing (POCT), bedside testing, extra-laboratory testing, decentralized testing and rapid diagnostics. The majority of definitions in the literature are for POCT and NPT, and are based on location (that is, near the patient), the lack of need for a professional laboratory technician to perform the test, the speed in which the test can be performed and results yielded and the purpose of the paper/document. The other terms (that is other than POCT and NPT) do not appear to have stand alone definitions. There is no consensus on the definitions for specific terms, leading to overlapping or vague definitions and the interchangeable use of terminology within published papers. This adds to the notion that they all in fact mean the same thing. The main definitions are summarised in Table 1.8.

Table 1.8: Definitions of near patient testing

Reference	Term	Definition
Hobbs (1996)	NPT	Any investigation carried out in a clinical setting or the patient's home for which the result is available without reference to a laboratory and perhaps rapidly enough to affect immediate patient management
Jacobs (2001)	POCT	Clinical laboratory testing conducted close to the site of patient care, typically by patients or clinical personnel whose primary training is not in the clinical laboratory sciences. POCT refers to any testing performed outside of the traditional, core or central laboratory.
Medical Devices Agency (2002)	POCT	Any analytical test performed for a patient by a healthcare professional outside the conventional laboratory setting.
Roche Diagnostics Glossary (2004)	Rapid diagnostics	All those tests capable of providing a result in a few seconds or minutes directly at the site of the investigation

There are numerous NPT devices available for INR determination made by a variety of diagnostic companies. At the time of the review there were a number of INR NPT devices on the market, some of these are outlined in Table 1.9. It is widely accepted that validity and reliability tests should be performed on these devices to assess how closely the results they yield correlate with standard laboratory methods. A number of validity evaluations of INR NPT devices have been performed and these are summarised in Table 1.10.

Table 1.9: INR Near Patient Testing devices available at the time of the literature review (Adapted from Murray *et al.* 2004)

System	Manufacturer	IQC	EQA	Test method (ISI, cost per test)	Current availability
CoaguChek S	Roche Diagnostics (Lewes, UK)	Vials supplied by manufacturer	NEQAS	10 μ l capillary blood onto test strip (ISI 1.6, £2.50)	Available from manufacturers; Roche valuated (approved for use by professionals; 2001 and patients; Feb 2004)
Thrombotrak	Thrombotrak (Nicomed, Oslo, Norway)	Supplied by various diagnostic manufacturers	NEQAS	50–100 μ l capillary blood, venous whole blood or plasma*	Axis Shield
KCI	Amelung (Trinity, Biotech, Bray, Eire)	Supplied by various diagnostic manufacturers	NEQAS	50–100 μ l capillary blood, venous whole blood or plasma*	Trinity Biotech
Protime biotrak	International Technidyne Corp (distributed by instrumentation Laboratories, Inc., Warrington, UK)	Integral to test	None	27 μ l capillary blood/test strip (ISI 1.0, £4.20)	MHRA approved in June 2004
Avosure	Avocet Medical	Supplied by manufacturer	None	15 μ l capillary blood/test strip (ISI 1.5)	Currently not available
INRatio	Hemosense distributed by Sysmex, Milton Keynes, UK)	Integral to test	None	15 μ l capillary blood/test strip	Available. Approved by MHRA March 2006
Rapidpoint coagulometer (TAS)	PharmaNectics (distributed by Bayer)	Supplied by manufacturer	NEQAS	30 μ l capillary blood/test card (ISI 1.0, £5.50)	Removed from market

IQC = internal quality control EQA = external quality assurance ISI=International Sensitivity Index is the international sensitivity index and the WHO reference ISI for Warfarin = 1 (Oertel 1999) NEQAS = National External Quality Assessment Service. Table taken from Murray *et al.* 2004

Table 1.10: Summary of INR NPT devices evaluations

Reference	Method	Key findings	Conclusions
McCurdy and White. (1992)	Assessment of performance of a portable anticoagulation monitoring system (Coumatrak) with respect to precision and agreement with a reference laboratory in 43 long-term anticoagulation patients.	Within the range of 2.0 to 3.0 INR units, the monitor yielded values that were on average up to 0.3 units higher than the laboratory values. Seventy-five percent of paired monitor and laboratory values were within 0.7 INR units of each other.	The NPT device is useful for patients requiring anticoagulation monitoring.
Tripodi <i>et al.</i> (1993)	Assessment of the precision of the INR determined by NPT device (Ciba Corning 512 monitor) compared to laboratory method over 12 consecutive days. Twenty healthy individual and 60 patients receiving oral anticoagulation for at least 6 weeks were recruited.	Between-assay reproducibility of the monitor was unacceptably poor when results were converted into INR.	Monitor might be suitable for INR determination if a more sensitive thromboplastin used.
Kaatz <i>et al.</i> (1995)	Agreement evaluated by determining how accurately laboratory and monitor INR determinations matched criterion standard values in designating a sample to be within or outside of currently recommended INR target ranges. 150 long-term anticoagulation patients recruited.	Laboratory methods that used relatively sensitive thromboplastins showed close agreement, those that used less sensitive thromboplastins showed poor agreement. The two coagulometers (NPT devices) evaluated fell between these extremes.	Accuracy of monitor measurements was satisfactory.
Murray <i>et al.</i> (1999)	Parallel INR estimation using 3 NPT devices (Protime, CoaguChek and TAS) and laboratory analysis over a 5-month period. Patients had been receiving warfarin for at least 6 months and attended an inner city general practice-based anticoagulation clinic; 19 patients.	No statistically / clinically significant differences between results from the 3 devices, although all near patient tests showed slightly higher mean readings than the laboratory.	All 3 devices were safe and efficient for producing acceptable and reproducible INR results in a primary care setting. Devices are subject to operator dependent variables at time of blood sampling.
Medical Devices Agency (2001)	Agreement between laboratory methods (Innovin method and PT Fibrinogen HS Plus reagent method) and CoaguChek S NPT device INR results assessed in 93 anticoagulation patients once only.	Acceptable levels of imprecision, reliability and comparability with conventional laboratory techniques. Increased scatter at higher INR values. However, agreement was obtained over the therapeutic range between the CoaguChek S and the laboratory methods.	The CoaguChek S was approved as suitable for professional use in anticoagulation monitoring.
Shiach <i>et al.</i> (2002)	Agreement between laboratory and NPT device (CoaguChek) INR results assessed in 46 patients in a randomised crossover trial with two 6 month-arms. Patient satisfaction with NPT in community and hospital testing was also assessed. All patients had previously been receiving oral anticoagulation treatment, period not specified.	Results with the POCT monitor compared favourably with the hospital coagulometer (NPT). Patients expressed greater satisfaction with community NPT monitoring.	Results suggest it is possible to introduce a reliable and safe community anticoagulation service using NPT INR monitoring.
Lizotte <i>et al.</i> (2002)	Two-visit study in a pharmacist managed anticoagulation clinic assessing agreement between CoaguChek S NPT device and laboratory method. Interater variability was assessed by having two different personnel obtain NPT INR results from same individual, this was also compared to laboratory results. Study had 100 patients who had been receiving warfarin for at least 96 hours.	Test-retest reliability was high (intraclass correlation coefficient; ICC=0.98), as was interrater reliability (ICC=0.97). The device was shown to produce accurate results when compared to the laboratory method (ICC=0.93). However, the device tended to overestimate the INR as the standard laboratory INR increased.	"When used by healthcare professionals in a pharmacist-managed anticoagulation clinic, the CoaguChek S was reliable, valid and easy to use. However its validity tends to decrease with increasing INRs probably due to lack of sensitivity of thromboplastins."
De Miguel <i>et al.</i> (2003)	Parallel INR estimation using AvoSure PT PRO and laboratory analysis.	Correlation was good for INR values for capillary blood and plasma samples by AvoSure PT PRO and laboratory reference method.	AvoSure PT PRO is accurate in determining INR in plasma and capillary blood samples.
MHRA (2004)	Evaluation of patients' ability to obtain accurate INR values whilst self-testing: during clinic appointments INR comparisons were made between the CoaguChek S (patient self-testing; n = 44) and the Innovin-Sysmex CA-1500 method (Laboratory Instrumentation; n= 40). Patients had been receiving warfarin for at least 6 months. Study period was 6 months.	Satisfactory agreement was found between the NPT and laboratory method when INRs were in therapeutic range. Differences of > 1.0 INR unit were obtained when the INR was > 4.5 (determined by laboratory method); these differences were clinically insignificant; that is they would not have resulted in different management of anticoagulation control.	Patient self-testing using the CoaguChek S (Roche Diagnostics, Lewes, UK) was a safe alternative to laboratory INR measurement.
Poller <i>et al.</i> (2003)	Parallel INR estimation using 2 NPT devices (CoaguChek Mini and TAS) and laboratory analysis for one test period (i.e. each patient tested only once). Multicentred study with 600 patients on long term warfarin.	INR results displayed by the two NPT devices differed by 21.3%. One of the NPT devices gave INR results which, on average differed from the true INR value by 15.2%, whilst the other gave INR results which differed on average by 7.1%.	Results not only reflected instrumental error but also the added variation introduced by the different operators. The discrepancies were clinically relevant. In addition, additional steps in calibrating the international sensitivity index and quality control are essential to ensuring the reliability and safety of both of the devices.

This section outlines some of the evaluations displayed in Table 1.10; it is not an exhaustive narrative but provides an overview of studies pertinent to this thesis.

The Medicines and Healthcare Products Regulatory Agency (MHRA; formally medical devices agency) are an executive agency of the Department of Health. The MHRA provides an evaluation service for devices and advice on the safety, reliability and performance of devices, to aid the process of selection for clinicians and purchasers. CoaguChek S has been approved by the MHRA both for use by professionals and for use by patients who are self-testing (Table 1.10). Both evaluations have involved assessing the level of agreement of the CoaguChek S INR determinations with standard laboratory method(s). The first evaluation (use by healthcare professionals) showed that reasonable agreement was obtained over the therapeutic range between the CoaguChek S and two laboratory methods; there was no statistical difference between CoaguChek S results and the Innovin method (using Sysmex CA-1500 machine) however, there was a statistically significant difference in the INR measurements obtained with PT Fibrinogen HS Plus reagent method (using ACL – 7000 machine) though this difference was not clinically significant. In addition, there was increased scatter of CoaguChek S determined INRs at higher INR values as assessed by laboratory methods (Medical Devices Agency 2001).

One benefit of the advance in near patient testing technology is that it offers the potential for patients to self-test and self-manage their INRs. In the evaluation of CoaguChek S for patient self-testing (Williams *et al.* 2003), 84 patients were recruited in a case controlled non-crossover study, 44 were randomised to the self-testing group. Self-testing patients received training in the use of CoaguChek S (Roche Diagnostics, Lewes, UK) and were assessed for competence. These patients tested themselves once a week and recorded the results over a six-month period. They continued to attend the anticoagulation clinic at appropriate intervals, where their anticoagulation therapy was managed. During clinic appointments INR comparisons were made between the CoaguChek S (patient self-testing) and the Innovin-Sysmex CA-1500 laboratory method. Patient acceptability was evaluated using a questionnaire (details of questionnaire development were not given). Time-in-range (Rosendaal *et al.* 1993) during the study period was compared between the control and self-testing group. Satisfactory agreement was found between the NPT and laboratory method when INRs were in therapeutic range. Differences of > 1.0 INR unit were obtained when the INR was > 4.5 (determined by laboratory method); these differences were clinically insignificant; they would not have resulted in different management of anticoagulation control. There was no

significant difference between the groups in the percentage of time patients' INRs were in the therapeutic range.

Furthermore, 94% of self-testing patients found it acceptable and 77% preferred self-testing to attendance at the hospital anticoagulation clinic.

McCurdy (1993) assessed the accuracy of the Coumatrak NPT device compared to standard laboratory method in 143 samples in 43 patients. Agreement was acceptable and was optimal at around an INR value of 3.0, although the NPT device underestimated results as the INR value increased. This tendency for Coumatrak to underestimate higher INR values was also shown by Kaatz *et al.* (1995). Tripodi *et al.* (2001) evaluated the reliability of the Ciba Corning 512 monitor. Precision was acceptable when results were reported as prothrombin times (CV = 9.7%) but was unacceptable when reported as INRs (CV=18.8%), indicating that the high international sensitivity index (ISI) value of the thromboplastin resulted in poor reproducibility. Similarly to the Coumatrak device, the Ciba Corning 512 monitor also tended to underestimate results as INR values increased, however this did not happen when the INR was calculated using recalibrated ISI. The authors concluded that the instrument should use more sensitive thromboplastin (low ISI) for oral anticoagulation monitoring to be more precise and accurate (Tripodi *et al.* 2001).

Murray *et al.* (1999) compared three INR NPT devices: Protine, CoaguChek and TAS in an urban general practice-based, nurse-led anticoagulation clinic, over six months in 19 patients. There was good agreement between the NPT systems and in comparison with standard laboratory measures (Murray *et al.* 1999). All three devices were simple to operate, however there was an increased risk of inadequate capillary sampling with the Protine device, as it required substantially more blood than the CoaguChek or TAS (65 μ l versus 45 μ l or 30 -35 μ l respectively), therefore improper blood sampling technique was more likely to lead to inadequate quantities of sample for proper INR determination. Authors reported that although all three were acceptable for use in primary care, adequate training of personnel was required to avoid operator – dependent differences in INR determination (e.g. due to poor blood sampling technique).

In a study conducted by Poller *et al.* (2003) there were concerns over the discrepancies between two NPT devices (CoaguChek Mini and TAS PT-NC) being evaluated in 600 patients (each patient was seen once during the study). Authors concluded that better ISI calibration of NPT devices by manufacturers was required along with more robust methods of quality control.

In response to Poller's *et al.* paper (2003), Murray and Greaves (2003) commented that the limitations of INR NPT devices had already been recognised and that the findings needed to be put into context. The authors stated that there was potential for NPT to offer safe and effective anticoagulation therapy efficiently. Murray and Greaves highlighted that, although better standardization and quality assurance methods were needed, clinical studies had already shown that NPT could be effectively introduced into practice. In addition, they emphasised the difference between statistical and clinical significance; and recognised that the differences found in Poller *et al.* (2003) paper could have resulted in different doses being administered, which could have clinical management implications. Murray and Greaves (2003) concluded that larger studies would be needed to exclude important differences in clinical outcomes with confidence. However, the majority of evidence accumulating in this area shows promise for the widespread use of NPT (Table 1.10). Shiach *et al.* (2002) performed a randomised crossover trial comparing the CoaguChek NPT device within a primary care clinic and a hospital laboratory in 46 patients, with two six month study blocks, where dosage was based on the NPT device for six months and then on the laboratory method for six months. Dosage was determined using Dawn AC computer dosage support software. Results of both methods were comparable, however at INRs over 4.0 there were some discrepant results. Lizotte *et al.* (2002) assessed the reliability, validity and ease of use of the CoaguChek S NPT device in a Canadian pharmacist-managed anticoagulation clinic in a prospective cohort study in 100 patients at two clinic visits. When the NPT device was compared with laboratory methods there was acceptable levels of agreement, however at supratherapeutic INR values (classified by authors as INR >3.0), authors found the NPT device tended to overestimate the INR as the standard laboratory INR values increased, although differences were not significantly different (precise details not given). The authors advised that higher INR measurements on the CoaguChek S should be confirmed with results by venous sampling and standard laboratory measurement (Lizotte *et al.* 2002).

Limitations of studies evaluating INR NPT devices

This section outlines the limitations of studies evaluating NPT devices. The majority of studies had a small number of participants; 150 or less. Studies were carried out for short durations; from one visit to twelve months (two 6 month crossover periods); thus a relatively small number of INR measurements were used for analysis. The majority of studies concerned with evaluating the accuracy of NPT devices failed to indicate whether the same lot number of reagent cartridges and laboratory reagents were used throughout the study. It has been shown that variation exists between the responsiveness of thromboplastin reagents (Zimmerman 2000). The majority of

studies focused on the degree of agreement between the NPT devices and laboratory methods. With regards to assessing NPT validity, a number of studies used the correlation coefficient (CC) as a measure of agreement and accuracy. However, if there is a systematic difference between two methods it will not affect the CC; a more appropriate method would be to plot the difference in INR values against the average (Bland and Altman method; 1987). This method enables the investigator to identify whether discrepancies are related to the magnitude of the measurement (Tripodi *et al.* 2003). In addition, rather than simply assessing the validity of NPT devices it would have been beneficial to have assessment of the appropriateness of anticoagulation dosage adjustments based on INR results from NPT and laboratory methods, no papers adequately addressed this. The majority of studies did not address the issues of cost-effectiveness. NPT is more expensive than laboratory coagulation analysis based on supply costs, but it is hoped that if more patients could be managed more frequently using NPT, there would be an improvement in the quality of anticoagulation control, an overall reduction in thrombotic and haemorrhagic events and a resultant reduction in the cost of the treatment of adverse events (Zimmerman 2000). The percentage of patients achieving adequate control tends to be relatively high in the UK, therefore attaining a benefit with the introduction of NPT may be a challenge. Studies are needed to fully assess cost effectiveness of anticoagulation service models involving NPT, as its advantages may be offset by increased implementation and maintenance costs. Although relatively simple to use, training is still required on finger-prick technique, quality control and interpretation of readings. Ansell *et al.* (1991) reported that inadequate samples from finger-prick punctures and traumatic finger-prick punctures contributed to a technical error rate of 14%, this could cause unreliable results through excessive platelet activation.

Advantages and Disadvantages of NPT

The introduction of NPT has implications for primary care service delivery (Delaney *et al.* 1999). The Medical Device Agency's bulletin on the management and use of in vitro diagnostic POCT devices suggested a number of sites for point of care testing in primary care (Medical Devices Agency 2002), including, GP surgeries, community clinics, health centres and pharmacies. The Agency summarises the potential advantages and disadvantages of NPT (Table 1.11).

Table 1.11: The potential advantages and disadvantages of Near Patient Testing

Advantages	Disadvantages
Decreased turnaround time - mainly by shortening the pre and post analytical steps	Unnecessary duplication of equipment
Potential for better monitoring of conditions where frequent testing is desirable	Tests performed by staff with non-analytical background – uncertainty as to who will interpret the results and detect erroneous results
Smaller sample and reagent volumes - POCT methods may be less clinically invasive	The available array of tests may tempt users to perform unnecessary or inappropriate testing
Advantageous in remote geographical areas where access to a laboratory is limited	Data recording may be complex and less robust – potentially less recording of results in patient records
POCT may offer easier access to service, for example for the elderly	Incompatibility with laboratory results - reference ranges and results may differ from those used in laboratories, thus making comparisons difficult
Economic – although POCT is generally more expensive than laboratory testing, it may offer wider economic benefits with a reduced number of clinic visits, reduced length of stay in a hospital and fewer hospital admissions.	If performed on a small scale (i.e. a small number of patients), POCT can be expensive
Greater patient involvement in their own care through self testing / management	

The employment of NPT reduces waiting times at hospital clinics and is less invasive than using a venous sample to determine INRs (MHRA 2004). The proven accuracy of INR NPT devices makes them suitable for patients with poor venous access (Zimmerman 2000). As many NPT devices are portable, this allows for a number of different sites, other than a hospital setting, to operate anticoagulation services, including in patients' homes (Zimmerman 2000). In this way, there is enhanced access to testing for patients with either geographic or physical disabilities that limit their ability to travel to hospital clinics for traditional testing. Near patient testing has the potential to improve the quality of management in primary care (Delaney *et al.* 1999; Murray and Greaves 2003), and aid the progressive move towards patient self-management (Murray and Greaves 2003).

It is thought that the use of NPT can reduce the risk of errors due to multiple stages in the passage of the traditional venous sample process of INR determination. NPT is performed by a single provider, with simple sampling and testing methodology and the sample is analysed and results are available within minutes (Zimmerman 2000). Furthermore, it has been reported that laboratory INR results are not comparable across sites, due to a lack of standardization with some reagents, NPT devices largely control variability among thromboplastin reagents through electronically controlling lot-to-lot variation in reagent sensitivity (Boehringer Mannheim Diagnostic 1995).

In order to ensure the successful and safe utilisation of NPT, in addition to adequate training, robust quality assurance systems have to be in place. Quality assurance should be carried out in

collaboration with the local / hospital pathology department and facilitated by a national external quality assurance scheme such as the National External Quality Assessment Service (NEQAS Chapter 4; see page 194 (Fitzmaurice *et al.* 1996a).

Section Summary

Studies have shown that NPT for anticoagulation monitoring is largely acceptable. NPT could facilitate the devolution of anticoagulation services to primary care. Users need to be aware of the limitations of NPT with regard to determining higher INRs. In addition, internal quality control and external quality assurance must be in place.

1.4.2.2 Computerised decision support software

Computerised decision support has been described as the provision of assessments or prompts specific to the patient and selected from a knowledge base on the basis of individual patient data (Hunt *et al.* 1998). Computerised decision support software (CDSS) has been developed in an attempt to improve the efficiency and quality of anticoagulation services by facilitating clinical decision making (Manotti *et al.* 2003). This section reviews the evaluations of CDSS and its implications with respect to anticoagulation service developments. A number of evaluations of CDSS use in anticoagulation management have been conducted, they are outlined in Table 1.12.

Table 1.12: Summary of studies evaluating CDSS use in anticoagulation management

Authors	Country	Study method	Setting	Key finding	(Main) Limitation(s)
White and Mungall (1991)	USA	RCT CDSS: n= 24 Nurse specialist, n=26 7-42 days	Hospital	Accuracy of dosage adjustments using CDSS was comparable to the skill of an anticoagulation nurse-specialist.	Small study, nurses were also responsible for entering data into CDSS, therefore some learning might have taken place.
Fitzmaurice et al. (1996 b)	UK	Observational in first practice (n=26). Comparison prestudy INR RCT in second practice (intervention, n=14, control=9). 12 months	General practice	Significantly improved INR control in all intervention patients (p<0.001). RCT: INR control increased (p<0.25). Increase recall time compared with control group (p=0.033).	Small study
Vadher et al. (1997a)	UK	RCT CDSS: n=72 Traditional: n=76 Study continued until end points reached.	Hospital	CDSS significantly reduced median time to achieve stable dose for target INR (p=0.001) during a/c initiation. CDSS group spent greater time in range compared to control group (not significant).	Difficult to shield the doctors treating the control group from the CDSS, so there may have been some learning therefore a carry over effect in the treatment of the control group leading to a potential under estimation of the effects of CDSS.
Vadher et al. (1997b)	UK	RCT Nurse led o/p using CDSS versus junior doctor led clinic without CDSS Group A INR range 2-3 nurse, n= 37 doctor, n=44 Group B INR range 3-4.5 nurse, n= 50 doctor, n=46. Study continued until end points reached.	Hospital	CDSS improved quality of control of anticoagulation therapy by a nurse practitioner over that by trainee doctors for therapeutic range 2-3 (Group A). Group B= amount of time spent within therapeutic INR range was slightly longer for junior doctor group. (No p values given).	May have been biased against CDSS. Doctors were not shielded from CDSS, so they may have been some learning and carry-over effect in the decisions made in the doctor group. Unfamiliarity with the CDSS may have contributed to sometimes inappropriate use by nurses.
Poller et al. (1998)	UK (European-wide)	RCT CDSS: n=137 Traditional: n=148 3 months	Hospital	Significant benefit in all INR ranges of CDSS over traditional dosing methods in stable patients (p=0.02).	Non-masked nature of the study may have influenced medical staff dosing decisions if they felt they were in direct competition with CDSS. Short study duration.
Fitzmaurice et al. (2000)	UK	RCT CDSS: n=122 Traditional: n=245. 12 months	Primary care setting and Hospital setting	Employing NPT and CDSS led to significant improvement in INR control for intervention group (p=0.008).	-
Mannotti et al. (2001)	Italy	RCT CDSS: n=603 Traditional: n=648. 12 months	Hospital	Patients in the computer-aided dosing group spent more time within the therapeutic INR range than controls (p<0.001).	-

o/p = outpatient; a/c = anticoagulation; RCT = randomised controlled trial

In summary, the evaluations have been favourable, suggesting that employment of CDSS is at least as good as the traditional method of non-assisted dosing in terms of anticoagulation control. However, a number of studies had methodological limitations, such as small study size, or the possibility of practitioners providing control services learning from the CDSS, where they had access to the system. Considering the limitations of some of these studies, it would be useful to have a large scale, multicentre blinded randomised control trial conducted to obtain conclusive evidence of the scale of the benefits of CDSS. However, it is largely accepted that use of CDSS offers advantages over traditional dosing, including improvement in dosing and recall decisions based on INR results, in both the primary and secondary care settings (Fitzmaurice *et al.* 1996a; Ryan *et al.* 1989). Other benefits of CDSS suggested by the authors of the reviewed studies include, provision of uniform management of anticoagulation and better use of medical and secretarial time as most systems produce letters, labels and copies of patient advice.

In addition, most softwares were able to maintain up-to-date computerized files for each patient and allow audit and statistical analysis of patient data. Through saving medical and nursing time, CDSS allows attention to be focussed on those patients who present with unusual difficulties for anticoagulation control (Poller *et al.* 1998).

Implications of CDSS technology

CDSS technology reduces the dependence on specialist delivery of anticoagulation services and may overcome lack of experience of non-specialist practitioners, permitting other healthcare professionals to manage anticoagulation (Hobbs *et al.* 1997). The use of CDSS has facilitated safe and effective decentralization of anticoagulation management services into primary care settings (Vadher *et al.* 1997a) Furthermore, using CDSS alongside NPT offers the possibility of full devolution of anticoagulation services to primary care (Hobbs 1996).

Summary

Near Patient Testing

- A number of INR NPT devices have been subjected to evaluation with favourable results.
- They have largely been shown to yield INR measurements that either produce results that are not statistically significantly different from laboratory determination or results with no discrepancy in clinical impact on anticoagulation management.
- At higher INR values accuracy of NPT devices is diminished; venous samples may need to be performed to verify results in these instances.
- Results from the studies suggests that their employment is both feasible and practical.
- Studies have shown that near patient determination of INRs can be effectively introduced into primary care clinical practice; with the potential to improve access to anticoagulation services and reduce the workload in secondary care.

Computer Dosage Support Software

- There are a number of good quality studies evaluating the use of CDSS for oral anticoagulation management particularly in primary care.
- CDSS can achieve at least equivalent anticoagulation control when compared with human performance.
- CDSS facilitates the management of anticoagulation clinics by non-medical practitioners and the move of services into primary care based settings.

1.4.2.3 GPs' perspectives of providing anticoagulation services

The traditional role of the GP with regards to anticoagulation services has been limited to prescribing warfarin, with or without knowledge of patients' INRs. In recent years anticoagulation services have increasingly been operating from general practitioners' premises in a variety of models (Fitzmaurice *et al.* 2000; Blann *et al.* 2003). This shift has been prompted by a number of variables such as long waiting times in hospital clinics, with elderly and very ill patients sometimes requiring accompaniment to hospital-based clinics and mobility-impaired patients requiring hospital ambulances to transport them (Macgregor *et al.* 1996; Radley *et al.* 2000). This section provides a review of GP-led anticoagulation clinics together with drivers and barriers to this service model. Table 1.13 summarises the key findings of a number of studies exploring GP-led anticoagulation services and perceptions of GPs towards anticoagulation therapy.

Barriers to GP provision of anticoagulation services

A GP's decision to initiate warfarin therapy in elderly patients with chronic atrial fibrillation is based on a complex and individual interpretation of a number of factors including the evidence base and their own previous experience, but essentially it is a risk assessment (Gross *et al.* 2003; Monette *et al.* 1997). It has been reported that doctors may have concerns about commencing anticoagulation therapy as they perceive the risks associated (such as haemorrhages) with inadequate management to be so great as to negate the potential benefit of stroke prevention

(Bellelli *et al.* 1999; Rozzini *et al.* 1999; Rozzini *et al.* 2001). This finding has been echoed in other studies; in the survey conducted by Rodgers *et al.* (1997), 29% of GPs reported that fear of litigation due to the risk of an anticoagulation related adverse event was a limiting factor on their ability to manage anticoagulation. GPs may feel that the intensive monitoring required for anticoagulation therapy may not be appropriate for elderly, often cognitively-impaired patients and opt for more simple modes of thromboprophylaxis, such as low dose aspirin despite evidence that it is less effective than warfarin in stroke prevention (Rozzini *et al.* 2001; Hart *et al.* 1999; Saxena and Koudstaal 2000).

Table 1.13: Summary of studies of GP-led anticoagulation services

Study	Design	Findings	Limitations
Rodgers <i>et al.</i> (1997) UK	Postal survey on current anticoagulation services and practice including 1° and 2° care services 459 GPs 163 consultants general medicine, care of the elderly, cardiology, haematology, neurology and nephrology in Newcastle	Consultants and GPs felt patients might benefit and prefer a primary care managed anticoagulation service. GPs expressed willingness and enthusiasm to provide anticoagulation services. Potential barriers to GP service provision were identified as: lack of time, lack of knowledge relating to warfarin, lack of training and facilities, need for more finance, fear of litigation. Factors that would influence GPs' use of warfarin were: availability of consultant advice, encouragement by local haematologists, further remuneration, further training	Not generalisable. Response bias - it is likely that clinicians who had interest in anticoagulation services would be more likely to complete the surveys.
Monette <i>et al.</i> (1997) USA	Postal survey for physicians (n=182) structured questionnaire on use of warfarin therapy for stroke prevention in patients with AF in long-term care facilities.	Estimates of the risk of a stroke without warfarin therapy and the risk of an intracranial haemorrhage with therapy varied widely. There were many uncertainties around the decision to prescribe warfarin and questions about the appropriate intensity of treatment. Concerns about the risks of bleeding appear to prevail over stroke prevention when physicians make prescribing decisions.	Response bias it is likely that physicians who had interest in a/c services would be more likely to complete the surveys.
Casey and Hanley (2001) Ireland	Efficacy of 21 Irish general practice anticoagulation services in terms of the quality of a/c control (percentage INRs within the target therapeutic range and the rate of haemorrhagic events): 3 month prospective study 325 patients.	41% of INRs were within the target range and 41% fell below target range. 18% of measurements were above the therapeutic range (over-anticoagulation).	Short study duration.
Holden and Holden (2001) UK	Retrospective observation (pharmacist v GP) 51 patients. Duration of follow-up not clear	The proportion of INR estimations within the prescribed range was greater for pharmacists than for GPs (p=0.03).	Retrospective study, small sample size.
Krass <i>et al.</i> (2002) Australia	Focus groups with Australian clinicians and health consumers discussing the use of anticoagulation for the prevention of stroke in elderly patients with atrial fibrillation, 63 participants.	Although aware of the clinical evidence supporting warfarin, GPs focussed more on the risks of anticoagulation than on the benefits. Consequently, they were often reluctant to prescribe warfarin in this patient population because of the perceived risk of a major haemorrhagic event.	Response bias, it is likely that GPs who had interest in a/c services would be more likely to participate in the focus groups than those who were not interested.
Holm <i>et al.</i> (2002) Denmark	Prospective observation of GP clinic, results compared to retrospective data from hospital outpatient clinic 8 months data collection for each service. 124 patients	The proportion of time spent in therapeutic range was greater for the GP clinic than for the hospital clinic (p<0.001).	Sequential rather than parallel study design. Hawthorne effect, GPs may have been aware that their dosing was being monitored during the trial and this may have had an effect on the quality of anticoagulation control.
Wilson <i>et al.</i> (2003) Canada	RCT (tertiary hospital a/c clinic versus family physician). 221 patients: 112 - a/c clinics; 109 - family physicians 3 months follow up	Anticoagulation clinics provided better oral anticoagulation management than family physicians (p=0.034).	Short study duration.
Gross <i>et al.</i> (2003) USA	Postal survey containing fourteen clinical vignettes was mailed to a cross-section of general internists. The outcome measure was the number of case vignettes for which warfarin was recommended.	142 questionnaires returned out of 426. There was no relationship between the perceived benefits of warfarin and its use in the case vignettes. Perceived risk for warfarin associated haemorrhage was strongly associated with reported warfarin use (P < 0.001). Physicians provided estimates of the annual rate of warfarin-associated intracerebral haemorrhage that were >10-fold higher than literature-based estimates, and physicians providing higher risk estimates tended to use warfarin less often.	Response bias; low response rate (33%).

1° = primary 2° = secondary

This section details some of the studies in Table 1.13. In a study of GP-led anticoagulation clinics there was a high percentage of low INR results, authors reported that this may be an indication of GPs' hesitance to adjust warfarin doses for fear of the occurrence of haemorrhagic events or a lack of training and knowledge with regards to warfarin (Casey and Hanley 2001). The authors concluded that the use of NPT and CDSS (neither of which were presently used) together with general practitioners' enthusiasm could provide optimal anticoagulation management for patients. Similarly, Rodgers *et al.* (1997) reported a high demand for guidelines and Krass *et al.* (2002) stated that GPs felt that there was a lack of practical guidelines, timely education and support for GPs managing anticoagulation.

As an alternative to GP-led anticoagulation clinics, a number of clinics have been set up in a GP setting that are managed by pharmacists (Macgregor *et al.* 1996) or nurses (Fitzmaurice *et al.* 1998). Macgregor (1999a) explored the views of a GP with regards to the affect of including a pharmacist in their general practice team. The GPs highlighted anticoagulation management as an area where pharmacists had made a positive impact, with reference to the substantial improvement in anticoagulation control experienced by patients managed by a pharmacist within the practice when compared to prior hospital management (Macgregor *et al.* 1996). There has been a growth in interest for general practices to undertake anticoagulation management due to increased number of patients requiring oral anticoagulation and a push for more services to be provided in the community. There is a role for general practitioners in the provision of primary care anticoagulation services and GPs are willing to provide such services (Rodgers *et al.* 1997). However, there seems to be certain apprehension due to a perceived lack of knowledge and training of dosing that can result in suboptimal anticoagulation control. In addition, for those GPs that are competent and willing to provide anticoagulation monitoring, there have been reports of frustration due to the large increase in extra work without the corresponding increase in resources (Shakespeare 1994). With the new general practitioners contract (General Medical Services Contract, Department of Health; 2004b), rewarding GPs for provision of enhanced services, these issues have apparently been considered and more GPs may opt to implement anticoagulation management as an enhanced service within their practice. The contract gives GPs greater autonomy to design services around the needs of their local population, encourages greater team work and new roles for allied healthcare professionals.

Section Summary

The evidence currently available does not support GP-led anticoagulation services. However, this may be due to a lack of published literature on this anticoagulation service model. It appears that GPs are apprehensive but willing to provide anticoagulation services as long as support is provided through training, remuneration and ongoing education. It may be appropriate to provide services from GP premises, but with nurses and pharmacists as the primary providers.

1.4.2.4 Nurse-managed anticoagulation services

Over recent years, nurses have been developing roles that were traditionally performed by medical staff, in an attempt to free up medical practitioners' time and reduce costs. Outpatient anticoagulation management is an example of this shift towards nurse-managed services. Following the expansion of available models for anticoagulation service provision, and facilitated by the introduction of CDSS and NPT, the effectiveness and safety of nurse-managed clinics in primary care has been investigated. This section outlines the published evaluations of nurse-led anticoagulation (Table 1.14).

Table 1.14: Summary of studies exploring nurse involvement in anticoagulation services

Authors	Country	Study method	Setting	Key Finding	Main Limitations
Taylor <i>et al.</i> (1997)	UK	Retrospective comparison over two 6 month periods (nurse led versus o/p consultant led). 430 patients: consultant group: 211; nurse group: 219.	Hospital	No significant difference in the mean proportion of time spent in therapeutic range.	Retrospective data collection. Not generalisable.
Vadher <i>et al.</i> (1997b)	UK	RCT Nurse led o/p using CDSS versus junior doctor led (Table 1.12). Nurse group: 87 patients Doctor group: 90 patients.	Hospital	More time was spent in therapeutic range by patients managed by nurses (57.6%) than by patients managed by doctors (43.4%; authors do not give information on statistical significance).	Nurses had CDSS as an advantage over the junior doctors, may have been fairer to equip the doctors with CDSS or compare nurse/CDSS dosing to that of an experienced practitioner. The results give more information about the usefulness of CDSS than the skill of nurses.
Fitzmaurice <i>et al.</i> (2000)	UK	RCT Intervention: 122 patients vs. control: 245. 12 months. (nurse led with NPT and CDSS versus o/p consultant led; Table 1.12).	GP (CDSS and NPT)	Significantly ($p=0.008$) better anticoagulation control achieved by nurse-managed service.	It is not possible to determine which aspect of the nurse-led (nurse, CDSS, NPT) service had the greatest impact on the results.
Hennessy <i>et al.</i> (2000)	UK	Retrospective comparison of a consultant-led and a nurse-led (CDSS) service over two sequential 6-month periods. Patient number increased from 818 – 1170 over study period.	Hospital	No significant difference in the mean proportion of time spent in therapeutic range.	It is not possible to determine which aspect of the nurse-led (nurse, CDSS) service had the greatest impact on the results
Baird (2001)	UK	Development of nurse-led anticoagulation service: 15-20 patients attending the clinic.	GP	A trained nurse can manage anticoagulation therapy in the general practice setting.	Evaluation of services not robust, only two audit parameters reported on at the end of the service, no baseline evaluation.
Connor <i>et al.</i> (2002)	UK	Retrospective comparison of a consultant-led and a nurse-led service over two sequential 18-month periods; 197 patients.	Hospital	No significant difference in the mean proportion of time spent in therapeutic range.	Patient perspective not taken into account.

o/p = outpatient

This is an overview of some of the studies exploring nurse-led anticoagulation services; it is not intended to be exhaustive. Baird (2001) outlined the development of a nurse-led anticoagulation clinic in general practice in the Sheffield area. It was stated that the new contract for GPs placed greater demands on doctors and provided greater incentives for provision of services. This was seen as a potential trigger to the expansion of the role of a nurse practitioner. The anticoagulation service in the general practice developed in response to patient need; a number of patients had requested that the practice take over anticoagulation management as hospital management was inconvenient and time-consuming. Those who were reliant on hospital transport services were particularly dissatisfied with the hospital service as hospital visits often took the whole day. Initially, the nurse's role was a simple phlebotomy role with GPs providing dosing advice (details of quality of anticoagulation control for GPs were not given). Subsequently, the nurse undertook anticoagulation training provided by the local hospital. A protocol for provision of a fully nurse-led service operating from the practice was developed. The practice was a small one; the number of patients varied between 15 and 20 with only a few patients requiring domiciliary visits. The small number of patients meant that the practice decided not to implement NPT and CDSS. For the purposes of auditing the service; authors evaluated the number of INRs within range (as a percentage of the three previous INR readings) and the frequency of testing over six months. The results from the audit performed were regarded as positive (77% of the previous three INR recordings were within the patient's target range and an average of 6.7 tests per patient over six months) and the author stated that "a suitably trained nurse can safely and efficiently manage anticoagulation in general practice"(Baird 2001; page 26). Whilst the small number of patients in the trial prevents definitive conclusions being drawn, the findings suggest that nurse – led anticoagulation services operating from general practice may represent a feasible and acceptable service model.

Murray and Fitzmaurice (1996) investigated the perceptions of patients and nurses of a nurse-led, general practice-based anticoagulation service. Clinical results of the study involving 49 patients at two practices (Practice A, n=26, Practice B, control: n=9; these patients had their venesection carried out in the practice but all other parts of the service were provided by the hospital, intervention: n=14; completely practice-based service) were not reported. A questionnaire comparing the service provided by the practice-based clinics to previously attended hospital-based clinics was administered (manner not specified) to 47 patients involved at the end of the study, a 54% (25/47) response rate was achieved. The results of the questionnaire suggest that the majority of patients felt that, compared to the hospital clinic, they could contact the practice more easily, waiting times were less, waiting facilities better and that they could discuss treatment more easily in the practice clinic. Of the 25 respondents, 22 were happy with the nurse-run clinic. In addition, what emerged from participants responses was the importance

attached to being seen by the same member of staff; they may feel this enhances the continuity of care. The authors concluded that patient satisfaction was high, although it was perceived that the delay in receiving results was a problem (one negative comment). They reported that this problem could be rectified with the introduction of NPT. In addition, the nurses providing the service reported satisfaction in being responsible for provision of a complete package of care. In 2000, Fitzmaurice *et al.* showed that a nurse-led primary care anticoagulation clinic using NPT and CDSS achieved anticoagulation control comparable to that achieved in routine hospital outpatient management. Prior to managing the anticoagulation clinics, the nurses received theoretical and practical training in the management of anticoagulation therapy as well as in the use of NPT and CDSS. Taylor *et al.* (1997) showed that anticoagulation nurses were more thorough in documenting relevant clinical information than consulting physicians; perhaps as a result of nurses having more interaction with patients and better clerking skills, this was important from a risk management and quality control perspective.

Hennesy *et al.* (2000) concluded that a nurse-led outpatient anticoagulation service was able to accommodate the increase in patient demand and improve the quality, efficiency and cost-effectiveness of the service. Evaluations of nurse performance in managing anticoagulation in an outpatient setting suggest that nurses are able to achieve anticoagulation control that is at least as good as that achieved by medical staff (Table 1.14). Further, studies report that nurse involvement in anticoagulation services results in greater job satisfaction as a result of role expansion (Murray and Fitzmaurice 1996).

Summary

General Practitioners

- GPs are providing anticoagulation services, however, with little dissemination of experiences and results
- There is little available data on general practitioner-led anticoagulation services
- Evidence of GPs expertise in monitoring anticoagulation successfully is scarce and adds weight to the reports of the need for further training and support.
- Increased resources and training need to be provided for successful GP-led anticoagulation services to be realised.

Nurses

- Studies suggest that nurses can manage anticoagulation therapy at least as well as medical practitioners
- The literature indicates that when trained to use NPT and CDSS, nurses can have the potential to achieve better anticoagulation control than medical staff
- Nurse-led anticoagulation monitoring may improve nurses' job satisfaction

1.4.2.5 Pharmacy and anticoagulation service provision

Government White papers such as *The New NHS* (Department of Health 1997) and *Pharmacy in the Future* (Department of Health 2000b), require the pharmacy profession to redefine its traditional medicinal supply role within the systems of healthcare delivery, chiefly via provision of timely and effective pharmaceutical care³, in order to achieve national health targets. Pharmacy has emerged as a profession that can play a key role in a number of disease management models, including anticoagulation therapy. Pharmacists have been involved in anticoagulation services in secondary care since the 1970s (Reinders and Steinke 1979). Table 1.15 outlines the studies that have evaluated pharmacist-led secondary care anticoagulation services.

Limitations of studies evaluating pharmacist-led secondary care anticoagulation services

No prospective randomised controlled trials of secondary care pharmacist-led anticoagulation services were identified in the literature search. The majority of studies involved less than 100 patients. Only one study employed any type of randomisation; matched control by randomised sampling (Lee and Schommer 1996). A number of ways of assessing the quality of anticoagulation control were used, including the number of adverse events and the percentage of out-of-range results, the usefulness of these as proxy measures of anticoagulation control compared to percentage of readings in range or time in range is debatable. The differences in measure reflect the lack of consistency among evaluations of anticoagulation services as to which outcome measures should be used. A number of studies have employed designs that made following patients passage through the trial difficult. Lee and Schommer (1996) reported on new and established patients as two separate groups in the methodology but combined their outcomes in the results section. Capturing complete data was not always possible for the control groups in some studies, this was in part due to the retrospective nature and in part due to the lack of completeness of notes in medical records entered in by non-pharmacist personnel (Lee and Schommer 1996).

³ Pharmaceutical care is defined as 'the responsible provision of drug therapy for the purpose of achieving outcomes that improve a patient's quality of life' (Hepler and Strand; page 539).

Table 1.15: Summary of studies of pharmacists managing secondary care anticoagulation clinics

Reference	Method	Findings
Pegg <i>et al.</i> (1985) UK	Pharmacist adjusted warfarin dose as appropriate, all decisions were checked and signed off by a doctor Retrospective comparison of anticoagulation control achieved by a clinic managed by pharmacists and supervised by physicians and a clinic managed solely by physicians. Anticoagulation control assessed by a number of different methods: interval between appointments, the number of occasions patients were out of therapeutic range, the degree of fluctuation in PT Index (PI).	No difference in anticoagulation control between patients managed by the pharmacist (with physician supervision on request) and those managed solely by the doctor.
Garabedian-Ruffalo <i>et al.</i> (1985) USA	Retrospective descriptive study of pharmacist-led anticoagulation service in patients who had been receiving warfarin for at least one year prior to attending the pharmacist-led clinic.	There was a significant reduction in the number of PT measurements that were out of range in the pharmacist-led clinic compared to previous management (preclinic phase; previous treatment at medical centre) 14.4% v 35.8% no p value given.
Cohen (1985) USA	Pharmacist-managed clinic compared retrospectively to physician-managed clinic in terms of anticoagulation control (PT) over a 2-year period.	No statistical difference in anticoagulation control between pharmacist-managed and physician-managed clinics.
Conte <i>et al.</i> (1986) USA	Retrospective descriptive study of nine years of a pharmacist-led anticoagulation clinic.	Over the nine-year period, 59.2% of PT readings were within range. Four major haemorrhagic events occurred in this time (defined as those requiring hospitalisation, cessation of therapy or reversal of anticoagulation).
Radley <i>et al.</i> (1995) UK	Hospital anticoagulation clinic previously run by medical staff, then subsequently managed by pharmacists. Comparison of anticoagulation control in the doctor-managed (doctors from rotating pool of SHOs and registrars) clinic (before change in management) versus pharmacist-managed clinic. Retrospective review. INRs recorded for those patients attending physician-managed clinic. INRs recorded for patients attending pharmacist-managed clinic Quality of anticoagulation control assessed using audit standards developed for the anticoagulation service. Proportion of patients in range at the last two physician appointments compared to proportion of patients in range on the first two pharmacist appointments	No significant difference in anticoagulation control achieved by pharmacists and medical staff. Pharmacists were more likely to return INRs that were out of therapeutic range back into range at the next visit than medical staff were. Based on the four occasions that the INR was looked at, there was no change in the mean overall proportions of patients in range.
Wilt (1995) USA	Retrospective comparison (data collection through chart review, then analysis of INRs and adverse events) of a physician-managed and a pharmacist-managed anticoagulation service.	Patients managed by physicians were 20 times more likely to experience an adverse event than patients managed by pharmacist (patient groups were similar).
Lee and Schommer (1996) USA	Matched control study comparing pharmacist-led anticoagulation clinic with usual care (not defined), over 90-day period following hospital discharge and commencement of warfarin.	Reduced rate of hospital readmissions in patients receiving the pharmacy-led service ($p=0.01$). No data on anticoagulation control in terms of INR given.
Chiquette <i>et al.</i> (1998) USA	Comparison of pharmacist-led anticoagulation clinic with usual medical care, that being care provided by attending physicians and nurses from sub-speciality clinics and family and general medicine.	In patients with a target range between 2.5-4.5, the pharmacist-led service achieved a significantly better quality of anticoagulation control compared to usual care (50.4% v 35.0%; $p<0.001$). Significant reduction in thrombotic events (78%; $p<0.005$) and in significant haemorrhages requiring evaluation or referral (77%; $p<0.001$).

SHOs = senior house officers
PT = Prothrombin time

Summary of findings of studies evaluating secondary care pharmacist-led anticoagulation services

Despite the acknowledged limitations of the studies, the literature shows that, in the secondary care setting, pharmacists are able to achieve anticoagulation control (therapeutic INR range) that is at least as good as that achieved by medical staff (Parekh and Ghee 1987; Pegg *et al.* 1985; Radley *et al.* 1995). Furthermore, pharmacy-led secondary care anticoagulation clinics have been shown to reduce hospitalisations due to adverse events of anticoagulation and the role of pharmacists can be justified in terms of cost-savings due to reduction in hospital admissions (Chiquette *et al.* 1998; Gray *et al.* 1985).

Primary care models involving pharmacists

Following the success of pharmacists in managing secondary care anticoagulation services, the pharmacists' role in the provision of primary care services was subsequently explored. Table 1.16 summarises studies that have explored and investigated pharmacist-led primary care anticoagulation services.

Radley and Hall (1994) conducted a postal survey among hospital practitioners (senior hospital pharmacists and hospital anticoagulation clinic managers) and general practitioners to explore whether there was support for community pharmacists providing anticoagulation management services. The majority of the general practitioners (26/30; 86.7%) and many of the hospital practitioners (pharmacists: 24/46, 52.2%; clinic managers: 12/28, 42.9%) supported this extended role for community pharmacists. In addition, the authors reported findings from a survey exploring patient preferences for the important aspects of a service provided to them. The results suggested that patients wanted a 'personal service', in which they could 'participate' (see Table 1.16).

Table 1.16: Summary of studies of pharmacists managing primary care anticoagulation clinics

Authors	Country	Study method	Setting	Key Finding /Conclusion	Main Limitations
Hall and Radley (1994)	UK	(I) 34 patients (majority long term) presenting at community pharmacy with prescription for anticoagulation therapy surveyed on various aspects of their care. Survey details not given. (II) Surveyed 32 GPs and 78 hospital practitioners on attitude towards community pharmacists being involved in anticoagulation management.	Community pharmacy / General Practice / Hospital	Patients experienced considerable cost and inconvenience in regularly attending anticoagulation clinic for INR monitoring. High reliance (36%) on ambulance transport to attend clinic. In terms of time spent between 0.5 – 1.5 hours in clinic. From leaving home to returning home could take between 1.25 and 4.5 hours. Patient rated having a clinic near their home as most important, other aspects included personal service, patient participation and interval between appointments. GPs and to a lesser extent hospital practitioners welcome an extended role for community pharmacists. Findings support further exploration of extending community pharmacists roles.	Small sample size, surveys used were not described, response bias
Radley and Hall (1994)	UK	Preliminary results of community pharmacy based outreach anticoagulation clinic using Biotrack 512 NPT device. Data presented for 6 months, also retrospective comparison of results for patients when they were receiving the hospital service. 31 anticoagulation patients – described as reasonably stable	Community Pharmacy	Of the 91 results, 83.5% were within ± 0.5 units of the desired therapeutic range. When outreach clinic was compared to the hospital clinic, i.e. before outreach set up there were less (9.1 versus 16.4%) out of range in hospital clinic. Authors suggest that this was due to the fact that the pharmacist service was provided during the winter period, when there is an increased likelihood of intercurrent conditions that can affect anticoagulation control Preliminary results suggest that the outreach clinic is providing an effective and safe alternative to hospital anticoagulation service.	Adequate details of survey not given
Macgregor <i>et al.</i> (1996)	UK	Evaluation of anticoagulation service after 6 months and 1 year of commencement. 36 patients receiving anticoagulation therapy. Testing of patient knowledge and patient preference using a self-administered questionnaire (details of which not given).	General practice	At 6 months: 84% INRs in range $\pm 10\%$ At 12 months: 90% INRs in range $\pm 10\%$ Patient preference questionnaire: patients preferred pharmacist-led, general practice-based management to the hospital clinic.	Small sample size, retrospective comparison for only 14 patients. Inadequate details on questionnaire to assess patient knowledge. No details of how patient preference was assessed

Table 1.16: Summary of studies of pharmacists managing primary care anticoagulation clinics – Continued

Authors	Country	Study method	Setting	Key Finding /Conclusion	Main Limitations
Knowlton <i>et al.</i> (1999)	USA	Evaluation of one-year pilot study of community pharmacist-led anticoagulation service. 26 patients majority new patients with atrial fibrillation	Community Pharmacy	Of the 235 INR values. 75% were within their individualized target range ± 0.2 units. There were no thrombotic events and one cancer related bleed. Community pharmacists can effectively implement anticoagulation monitoring	Short follow – up; up to 8 months, small sample size. Some patients were only in study for 2 -3 months
Holden and Holden (2000)	UK	Control study: retrospective comparison of length of time that patients were within their target therapeutic range over one year was compared for those patients being closed by the pharmacists who had previously been seen by GPs (51 patients; study period unclear).	General practice	Pharmacists more effectively targeted the mid-points of the INR ranges (for example, 2.5 of a target range of 2-3) The mean interval between appointments for patients seen by GPs was 28.6 days compared to 34.1 days for those patients seen by the pharmacist ($p=0.001$). The proportion of INR estimations within the desired range was greater for pharmacists (0.7) than for GPs (0.6).	Small sample size retrospective data collection
Holden and Holden (2001)	UK	Retrospective comparison between GPs and pharmacists of length of time taken to regain anticoagulation control following a deviation from the desired range. Comparative sequential study of community-based anticoagulation patients who had originally received GP management then subsequently received pharmacist management. 51 patients (study period unclear).	General Practice	When pharmacist managed spent less time outside range than when GP managed and mean duration of deviation was lower for pharmacist management as well - though neither were significantly different. Management of patients deviating from their INRs is as least as effective by pharmacists when compared to GPs.	Small sample size, duration of study periods not given. Patient characteristics not given
Coleman <i>et al.</i> (2003)	UK	Study to set quality standards for community pharmacy-based anticoagulation service: involved gathering stakeholder opinion, on standards of care, training of community pharmacist in anticoagulation management and use of NPT and CDSS and a pilot study of the community based anticoagulation service	Community pharmacy	Standards for community pharmacist service provision were identified and service was initiated.	-

Macgregor *et al.* (1996) described the evaluation of an anticoagulation service provided by a pharmacist. The weekly clinic was based in a general practitioner's surgery. The pharmacist used the Biotrack 512 NPT device to measure patients' INRs from capillary blood samples. Patients were dosed according to the British Society of Haematology's recommendations. At one year, 90% of INRs were within the target range plus or minus 10% (The authors offered no definition as to what was acceptable variation. However, the standard has been defined by the BSH as achievement of target INR: 50% of INRs within 0.5 INR units and 80% within 0.75 INR units). Comparison of 14 patients' INRs in the surgery and in the hospital clinic before transfer showed that there was a significant improvement in the percentage of values within the therapeutic range (χ^2 , $p < 0.001$). Patient preferences were explored using a questionnaire (details of development and psychometric properties not given) and showed that there was a preference for surgery management and that travelling time was less for 64% of patients. In addition, the majority of patients preferred a pharmacist to a rotating junior doctor.

Coleman *et al.* (2003) described a pilot community pharmacist-led anticoagulation clinic operated on a weekly basis by two trained pharmacists, using NPT and CDSS. The authors detailed the quality standards required to ensure successful operation of such a service. Issues addressed included, eliciting stakeholder opinion, identifying quality standards of care, which incorporated health and safety and training of the pharmacists. Authors reported that the service had, to date, been operating smoothly with no errors and incidents.

Khan and Rutter (2002) conducted a study to determine the current level of primary care anticoagulation service provision. They aimed to establish which Primary Care Groups⁴ / Primary Care Trusts and which healthcare professionals were providing anticoagulation services and to what extent purchasers were likely to commission anticoagulation services in the future. Authors conducted a postal survey of the clinical governance leads of every PCG/Ts in England ($n=475$) and achieved a response rate of 26% ($n=124$). Of the responding PCG/Ts, 37% ($n=46$) offered an anticoagulation service, over half offered NPT for INR determination. Of those not currently providing a service, 47% ($n=37$) of PCG/Ts were considering establishing a service in the near future to reduce workload for secondary care (20%) and to increase patient convenience (16%). Only one PCT offered a community pharmacy-based model. Of those PCG/Ts considering developing a service, 59% ($n=22$) were likely to include pharmacists in their models. The results of

⁴ Primary Care Groups (PCGs) were the predecessor organisations of PCTs; by 2004 all PCGs had transferred to PCT status; giving them increased responsibility for their local population and decreasing the role of regional health authorities.

this survey showed that there was little community pharmacists' involvement in the current service provision. However, almost 60% of those PCG/Ts considering the implementation of new anticoagulation services were likely to involve community pharmacists. The results of this study were very useful but due to the low response rate, it is unclear how well this picture reflected what is occurring across the UK.

Limitations of studies evaluating primary care based pharmacist-led anticoagulation services

The majority of studies evaluating primary care based pharmacist-led anticoagulation services had small sample sizes and short follow-up durations. Across the studies there was little consistency regarding the extended ranges used to denote anticoagulation control (e.g. target range $\pm 10\%$ versus ± 0.2 units). Most of the studies failed to explore the cost implications and long term viability of primary care pharmacist-led anticoagulation services. In addition, the patient perspective was seldom explored and when it was, adequate details of questionnaires used were not given.

Implications of exploration of the role of pharmacy in anticoagulation monitoring

With the introduction of the new pharmacy contract the profession has a number of opportunities to capitalize on their knowledge, skills and position within their local communities. Under the new contract, pharmacists can commission services to be provided either from a community pharmacy, a health centre or general practice, this could be useful for rolling out primary care anticoagulation services. In addition, by increasing the number of services provided in community pharmacies, there is the potential for patients to have more access to healthcare professionals. Pharmacists have a role in providing support to patients with long-term conditions, through provision of medicines management services such as medicines use review and prescription intervention services, which ensure that patients obtain maximum benefit from their medicines. By making better use of the community pharmacists' clinical skills, community pharmacists have a real opportunity to finally be integrated into the NHS 'family' and work in multidisciplinary teams (De Souza 2005).

Despite the limitations, studies have shown that pharmacists can successfully monitor anticoagulation in primary care, although more work is needed to determine the economic implications of primary care pharmacy-led anticoagulation services.

Summary

- Secondary care pharmacy-led anticoagulation services have been established and are known to achieve anticoagulation control that is at least equivalent to medical practitioner control.
- Studies evaluating primary care anticoagulation services, suggest that pharmacists achieve anticoagulation control that is at least as good as that achieved by routine hospital care.
- At present the use of pharmacists in primary care anticoagulation monitoring is limited.
- Few studies have evaluated the use of pharmacist based primary care anticoagulation services in combination with CDSS and NPT technologies.

1.4.2.6 Patient self-testing and self-management of anticoagulation therapy

Over recent years, there has been a move towards patient self-care (The NHS plan; Department of Health 2000c). The introduction and predominantly positive evaluations of INR near patient testing devices (Medical Devices Agency 2001; Murray *et al.* 1999) has made the move towards patient self-testing and self-management of anticoagulation therapy possible. This section gives an overview of the use of NPT devices for patient self – testing and self – management of anticoagulation therapy. The terms patient self-testing and self-management are not interchangeable; they are described in Table 1.17.

Table 1.17: Description of patient self testing and self management in anticoagulation monitoring

Term	Person testing	Responsibility for determining dosing an frequency	Internal control quality	External control quality	Maintenance of device
Self-testing	Patient	HCP	HCP / Patient as agreed	HCP / Patient as agreed	HCP / Patient as agreed
Self-management	Patient	Patient. Support is available from a HCP clinically responsible according to an agreed contract	HCP / Patient as agreed	HCP / Patient as agreed	HCP / Patient as agreed

HCP = healthcare professional

There are a number of potential advantages of patient self-testing and self-managing their anticoagulation therapy, such as increased convenience for the patient (Sickles *et al.* 1999) and the ability to easily increase the frequency of testing, with minimal disruption to patients' routine (Ansell *et al.* 2001). When patients are trained to effectively manage their therapy, not only is there the potential for better knowledge and awareness of treatment which could improve adherence / compliance (Ansell *et al.* 2001), but also of improved patient outcomes in terms of anticoagulation control and adverse events (Sickles *et al.* 1999). A number of studies have been carried out to evaluate the clinical effectiveness and safety of self-testing and management (Table 1.18).

Table 1.18: Summary of studies evaluating self-testing (ST) and self-management (SM) of oral anticoagulation therapy

Authors / Country	Study method and Patient numbers: Intervention / control	Results / Findings	Conclusions	Main limitation(s)
White <i>et al.</i> (1989) USA	Prospective RCT: nurse led specialist anticoagulation clinic care versus ST managed directly by general internists. 2 months, 23/23, Coumatrak device used. New patients, ST after initiation of warfarin. Inclusion included demonstrated ability to use NPT device and indication requiring at least 8 weeks of therapy. Exclusions, included previous use of warfarin, history of non-compliance during outpatient care.	ST patients had a significantly greater percentage of time in range (93% versus 75%**, p=0.003).	Use of NPT device by ST patients at home feasible. ST patients achieve better anticoagulation control compared to those receiving standard clinical care	Small sample, short duration, Training not well described
Anderson <i>et al.</i> (1993) Canada	Observational. ST versus laboratory measurements 40/(self-control), Biotrack device used 6-24 months. Patients given patient preference survey self-administered, details not described. Patients on long-term warfarin and considered to be reliable and geographically accessible for follow up.	Mean standard level of agreement achieved per patient was 83% (95% confidence interval, 79% to 87%). In terms of therapeutic control, 74%* of INR test results were within therapeutic range (value not stated for matched control group). 97% of patients preferred home testing to clinic management, (assessment not described). No P - values	Patients preferred ST. Use of NPT device as primary method for prothrombin time monitoring can be recommended in selected patients receiving long term anticoagulation therapy	Small sample, variations in patient follow-up from 6 - 24 months. Training and patient selection process not well described. Questionnaire not adequately described
Ansell <i>et al.</i> (1995) USA	Retrospective cohort study of SM patients with matched control patients receiving anticoagulation management from a tertiary medical institute. Patients included "carefully chosen based on the investigators' assessment of their compliance, stability and ability to follow directions as determined by their previous response to instruction, stability of PT on previous visits, and willingness and ability to keep clinic appointments." 20/20. Approx 43 months, Coumatrak device used. Patients were long term, compliant and relatively stable Measurement of patient satisfaction survey	SM group monitored their PT more often than control patients had their PTs monitored (2153 times versus 1608 times; p>0.05). SM group changed their dose significantly less frequently than the control group (11.5 dose changes per patient versus 22.7 dose changes per patient; p<0.001). SM group were within the therapeutic range 88.6% of the time compared to 68.0%** of the time in the control group (p<0.001) There was no significant difference in complication rates experienced by the two groups. Sixteen out of seventeen SM patients who completed a satisfaction survey stated they preferred SM to routine anticoagulation clinic management.	Selected patients capable of testing and adjusting their anticoagulation dose; achieve better anticoagulation control than clinic managed patients.	Satisfaction survey not adequately described. Retrospective.
Horskotte <i>et al.</i> (1996; abstract) Germany	RCT: managed by physician versus SM 75/75 CoaguChek device used 3 month follow up	The SM group's INRs were in range 43.2% compared to 22.3% in routine care* (p<0.001). The SM group had a 4.5% incidence of bleeding and a 0.9% incidence of thrombotic complications compared to a 10.9% bleeding incidence and 3.6% incidence of thrombotic complications in the control group (p=0.038).	SM results in a significant improvement in anticoagulation control when compared to routine care	Short duration, training not well described. Overall anticoagulation control poor
Hasenkam <i>et al.</i> (1997) Denmark	SM, versus control group of patients from the outpatient anticoagulation clinic was matched retrospectively (n=90) to compare time within therapeutic range with the SM group. 9 month follow up. Patients described as compliant. CoaguChek device used, 21/20	The SM patients' INRs were in the therapeutic range 77% of the time, compared to 59%** of the time for the control patients (no p values given).	SM can be recommended to patients who have been properly trained	Small sample, short duration, training not well described
Bernardo (1998) Germany	Observational, SM between 1986 and 1992. 216 / (no control). Criteria for entrance into training programme were ability to participate in patient-orientated (not defined) programme and ability to use an INR NPT device. Hepatoquick device used and later CoaguChek device used. There were further criteria for elderly patients to qualify for inclusion: adequate eyesight, adequate motor coordination, and sufficient manual dexterity. Questionnaire on complications experienced during SM of their anticoagulation therapy given to patients.	During the study period, 83.1%* of the PT determinations were within the target range and no major adverse events occurred. The majority of patients (78.7%) reported no complications, with 13.9% reporting minor complications that did not require medical treatment (e.g. intensified nose bleeding, bleeding gums).	Further trials needed to evaluate whether ST and SM are associated with reduced frequency of adverse events and to assess cost implications.	Poor level of follow up only 216 out of 600 patients reported on. Patients highly selected. Questionnaire not well explained. Cost implications not considered

Table 1.18: Summary of studies evaluating self-testing (ST) and self-management (SM) of oral anticoagulation therapy – Continued

Authors / Country	Study method and Patient numbers: Intervention / control	Results / Findings	Conclusions	Main limitation(s)
Sawicki (1999) Germany	RCT: SM versus Family doctor, 90/89, 6 months follow up CoaguChek device used, patients not previously on warfarin and expected to be on long term anticoagulation, no other preselection. Quality of Life assessed using a 40 – item structured questionnaire developed with the help of an anticoagulation self-help group.	SM group had INR values within target range more often (repeated measurement analysis for categorical data, $p=0.006$), with 53.0% of patients in the SM group achieving INRs within the therapeutic range compared to 43.2%*** of patients in the control group. Fewer patients in the SM group had subtherapeutic INR values (33.7% versus 48.2%). This difference was not statistically significant ($p=0.08$).	An education program for SM improves accuracy of anticoagulation control and treatment – related quality of life measures	Small sample, short duration, overall quality of anticoagulation – poor.
Cromheecke <i>et al.</i> (2000) Netherlands	Randomised crossover study: 50 Long term patients on oral a/c for at least 6 months. SM versus management at a specialised, doctor-led a/c clinic. Randomised to either self- management or clinic management for three months and then subsequently crossed over to the alternative hospital-based strategy. Trial participants asked to complete previously validated questionnaire (details not given) assessing self-perceived quality of care before and after the SM period. Control group for questionnaire = matched clinic managed patients. 48 / matched control for questionnaire, 6 month follow up CoaguChek device used.	Patients were ± 0.5 from the target INR 55% of the time during SM and 49%*** of the time during clinic management ($p=0.06$). No significant difference in incidence of adverse events in SM patients compared to clinic-managed (p values not given). Questionnaire responses from 45 SM patients significantly different from the control group. Scores for the five categories, general treatment satisfaction, self-efficacy, anxieties, distress and strain all favoured SM.	SM feasible, acceptable to patients and able to provide anticoagulation control that was at least as good as clinic management.	Small sample, short duration. Details of questionnaire not given.
Beyth <i>et al.</i> (2000) USA	RCT: SM versus treatment by a doctor who based dosing decisions on venous sampling 163/162, 6 month follow up	SM group in range 56% of the time compared to 32%** of the time with doctor management ($p < 0.001$). Rate of haemorrhage in doctor-led group was 12% compared to just under six per cent in the SM group ($p=0.05$). Less thrombotic events in SM group (9%) compared to doctor-led group (13%; $p=0.2$).	Intervention enhanced safe, effective use of warfarin in older patients. May promote more widespread use of oral anticoagulation in this patient group, who may currently go untreated.	Short duration.
Kortke <i>et al.</i> (2001) Germany	RCT: patients who had had mechanical heart valve replacement surgery: SM versus routine care of a family doctor. CoaguChek Plus device used, 305/295. Follow - up from 25 to 51 months; mean 38.34 months	78.3% of INRs were within the therapeutic range in the SM group, compared with 60.5%* in the control group ($p < 0.001$). Further, there was a significant difference in occurrence of adverse events between the groups (9.5% for SM group, 15% for the control group, $p=0.03$).	All patients for whom long term anticoagulation is indicated are potential candidates for SM.	Control group management not clear. Variations in follow-up duration. Training not adequately described.
Fitzmaurice <i>et al.</i> (2002) UK	RCT: SM versus standard general practice care. CoaguChek S device used, 6 months follow up, 23/26. Patients over 18 year, on anticoagulation therapy for at least six months and sufficient vision and manual dexterity were identified, then subsequently nurses selected according to predefined criteria, including: ability to follow simple instructions, previous treatment adherence, physical well being, cognitive ability, visual ability. Questionnaire to elicit issues with regards anticoagulation services, semi-structured and also a previously validated QoL questionnaire. Costs compared.	Testing frequency: 14.6 for SM group and 5.3 for the control group ($p < 0.001$). No significant difference between pre-study control and study-period control for either group in terms of TIR; patients in the SM group were in range 74% of the time compared to 77%** of the time for the control group. No major adverse events in the SM group and one fatal haemorrhage in the control group. SM- significantly more costly than routine primary care; £425 per patient each year compared to £90 per patient each year. No significant difference in QoL between the groups.	SM safe in terms of anticoagulation control and incidence of adverse events and was feasible in the UK.	Small sample, short duration. large number (28% of patients) unwilling to participate in study - may have positively biased results as patients included tended to be motivated. Questionnaire was cross-sectional rather than longitudinal and done on only 8 control and 8 study patients
McCahon <i>et al.</i> (2003) UK	Multicentred randomised controlled trial: Self management versus treatment by a doctor	Preliminary results: of 2586 patients invited to participate, 608 (24%) consented. 327 SM patients: 85 failed to complete the training mainly due to manual difficulties with procedure. 242 of the 327 (74%) patients completed the training and commenced SM. Of these, 212 (88%) continued SM for the 12-month follow-up. Those who completed training were significantly younger than those who did not (61 years versus 71 years, $p=0.001$). Of those who completed SM, 75% ($n=159$) considered it a convenient and valuable method of controlling their own health.	Careful selection together with training and guidelines are required for SM programmes to be adopted.	-

*% tests in range ** % time in range *** %patients in range

QoL = Quality of Life

Near patient testing devices have been evaluated and have been shown to be reliable, accurate and safe for INR determination by healthcare professionals. With regards to patient self-testing (ST) and patient self-management (SM), the literature suggests that following training, patients with adequate vision, manual dexterity, intelligence, motivation and previous compliance and INR stability, can use NPT devices to test their INRs and can manage their own oral anticoagulation therapy and achieve anticoagulation control that is at least as good as standard care (Ansell *et al.* 1995; Bernado 1995; Fitzmaurice *et al.* 2002). The UK studies (Blann *et al.* 2003; Fitzmaurice *et al.* 2002; McCahon *et al.* 2003) suggest that patient self-management may be more costly, at least at the initial phase, and that a large number of patients on warfarin may not be suitable to undertake self-management.

Patient self-management may have a positive impact on patient empowerment, compliance and satisfaction and in this way improve patient outcomes (Ansell 1999). With Government policy highlighting the active role that patients can play in the NHS, there is recognition that they can have a level of expertise in the management of their long-term conditions: described in the concept of the expert patient (Wilson 2002). A recent national media advertising campaign promoting self-management of anticoagulation using the CoaguChek S device, has resulted in an increased demand by patients for self-management and illustrates the move towards patients wanting to take more control of their health. Fitzmaurice and Machin (2001) have made recommendations for the training requirements and eligibility for patient self-management, that can be used as a guideline for deciding whether it would be appropriate for particular patients.

A major issue in the roll-out of patient self-management is cost. In Germany and America, where health systems are influenced by insurance, companies are willing to fund self-management once patients' competence has been established, and where standards of routine anticoagulation care are not as high as those in the UK, self-management represents a cost effective treatment modality which improves patients' therapeutic control. However, in the UK, it is not clear whether there will be clear improvements in anticoagulation control, due to already high standards of routine management.

Self-management has been shown to achieve anticoagulation control that is at least as good as routine anticoagulation management (that is, hospital anticoagulation management or general practice management in other countries). However, there is a proviso; according to the available UK literature, this model only appears to be suitable for a minority of selected individuals, rather

than a model that could be rolled out for widespread adoption. McCahon *et al.* (2003) showed that of 2586 anticoagulation patients invited to participate, only 25% agreed and 30% dropped out during or following SM training; leaving 17.5% of those that were invited self-managing their anticoagulation therapy. Furthermore, the increased cost of self-management includes cost of the NPT device, cost of the test strips, increased frequency of testing, cost of the training required and the costs of quality control procedures. Whether these costs will be offset by reduced costs due to reduction in hospital admissions and treatment due to adverse events and reduced contact with healthcare professionals remains to be evaluated.

Summary

- Available studies suggest that self-management is a feasible alternative to other models of anticoagulation service.
- It is important to state that in numerous studies, patients were highly selected with regards to dexterity, vision and ability to follow instructions.
- Due to extensive inclusion / exclusion criteria, the number of potential patients for whom this model could be suitable may, in fact be very small.
- The majority of studies were not performed in the UK and thus the results may not be generalisable to the UK settings .
- Standard care provided within the non-UK based studies has been cited as poor compared to that received by patients in the UK (Fitzmaurice *et al.* 1996; Hasenkam *et al.* 1997). Therefore, improvements in anticoagulation control related to self-management may be overstated in comparison to the UK models of care.

1.4.2.7 Domiciliary anticoagulation services for the mobility-impaired

The literature on domiciliary anticoagulation services for the housebound/ mobility-impaired was scarce. No papers were found evaluating domiciliary oral anticoagulation services, apart from the self-management/self-testing evaluations. This may reflect the 'newness' of the application of anticoagulation NPT devices for use by healthcare professionals in patients' homes, specifically for those who would not be able to cope with self-testing or self-management. A number of papers evaluating primary care anticoagulation services briefly discussed domiciliary anticoagulation services either in terms of the structured provision of domiciliary services within trials or in general terms of service developments (Table 1.19). As no papers focused solely on evaluating domiciliary oral anticoagulation services, no outcomes for the patient group receiving the service were measured or evaluated.

Table 1.19: Studies outlining domiciliary anticoagulation services provided for mobility-impaired patients

Reference	Description	Findings / Conclusions	Points related to domiciliary anticoagulation services
Taylor <i>et al.</i> UK (1997)	Retrospective comparison over two 6 month periods (nurse led versus o/p consultant led) Hospital based	No significant difference in the mean proportion of time spent in therapeutic range. Nurse specialist had advantages compared to consultant – led anticoagulation service, including provision of domiciliary service for housebound patients, nurse-led service preferred by newly referred patients.	Primary care nurse specialist anticoagulation service in London, based in GP setting, also able to provide domiciliary care for housebound patients.
Bellingham, Hall and Radley (2001; 1995)	Discussion paper on the role that community pharmacists can play in anticoagulation clinics / Near patient testing in the community: new role for pharmacists	Pharmacy has often taken the lead in hospital anticoagulation clinics, this role can be extended into primary care	Discussed domiciliary service (initially ad hoc, subsequently structured) provided by a community pharmacy-led anticoagulation service in County Durham.
Waring (2005)	Discussion (letter) primary care anticoagulation service operating in 10 GP practices in Sheffield, with pharmacists, GPs and district nurses managing anticoagulation.	Community pharmacy may be ideally placed to provide anticoagulation services. With pharmacists contract and supplementary prescribing there is potential for pharmacists to expand their role.	In Sheffield South East PCT a move towards primary care anticoagulation services: healthcare assistants trained to use CoaguChek S reported that housebound patients benefited from domiciliary service (how they benefited was not specified).
Baird (2001)	Discussion paper on development of a nurse-led general practice-based anticoagulation service	A trained nurse can manage anticoagulation therapy in the general practice setting.	Discussed the implementation of a nurse-led anticoagulation service in a GP setting. Domiciliary visits provided to those having difficulty attending the practice.
Mason (2004)	Discussion paper on near patient testing in the pharmacy	Pharmacists have an important role to play in NPT in the pharmacy, especially in the context of health promotion and medicines management	Recognised availability of 'home testing' to manage anticoagulation therapy.
Sheehan <i>et al.</i> (2000)	Discussion paper on primary care anticoagulation services in Ireland	In comparative studies, anticoagulation control is often better in primary care than in hospital clinics. An anticoagulation clinic operating with the skills and knowledge of a clinical pharmacist working within recognized guidelines and in close liaison with GPs is the ideal.	Portability of NPT device renders them suitable for domiciliary INR measurement.
Radley <i>et al.</i> (2000)	Discussion paper on the role that community pharmacists can play in anticoagulation clinics	Pharmacy has often taken the lead in hospital anticoagulation clinics, this role can be extended into primary care	A community pharmacy anticoagulation clinic has to be able to operate domiciliary visiting.
Acomb (2001)	Explored domiciliary service provision of LMWHs for treatment of DVTs by pharmacists in Bradford in a pilot study.	Authors concluded that the home service resulted in patients experiencing less disruption to their daily routine and having greater independence.	Portability of NPT device renders them suitable for domiciliary INR measurement in housebound patients unable to attend the clinic.
Winter <i>et al.</i> (2003)	Developed guidelines for the outpatient management of deep vein thrombosis (DVT), based on formal levels of published evidence	N/A	Recognised a role for domiciliary care (administered by outreach haemostasis or district nurses or by GPs).

Acomb (2001) and Winter *et al.* (2003) evaluated domiciliary anticoagulation services for patients receiving initial treatment with low molecular weight heparins (LMWHs) alongside initiation of warfarin and subsequent referral to an outpatient anticoagulation GP clinic for maintenance of oral anticoagulation therapy. These services were not tailored to the long-term needs of mobility-impaired patients experiencing difficulty in attending anticoagulation clinics due to medical disabilities. Therefore, the applicability of the findings is limited.

Issues surrounding anticoagulation services for older people

It is recognized that many anticoagulation patients are elderly with multiple co-morbidities and find hospital visits difficult (Hall and Radley 1994; Pell *et al.* 1993).. The logistics of using transport to attend anticoagulation clinics is a potential barrier to commencing patients on anticoagulation therapy; thus transport difficulties may be a barrier to accessing anticoagulation services.

Hall and Radley (1994) recognized the organizational issues that clinic staff have to contend with when large numbers of mobility-impaired patients (usually in wheelchairs) are delivered by the hospital ambulance service to the clinic at the same time. In addition, they stated that anticoagulation clinic waiting times were variable, and that travel costs and inconvenience to patients could largely be removed by employing local or domiciliary services.

The NSF for Older People and the Health Improvement Plan advocate the provision of patient-centred services, including those that allow patients to stay in their own homes (Department of Health 2001a; 2004c). Provision of domiciliary services is discussed in terms of providing a convenient and personalised service.

Section Summary

On a small scale, domiciliary anticoagulation services are in place in pockets across the UK. However, there is a need for an evaluation of domiciliary anticoagulation services in long-term anticoagulation management. Patient satisfaction, patient safety, clinical and cost effectiveness of such domiciliary services need to be addressed before the suitability of the widespread application of this service can be adequately considered.

Summary

- No evaluations of domiciliary anticoagulation services for housebound patients were identified
- A number of studies outlined the option of domiciliary services for mobility-impaired patients
- The Government's agenda supports a move to the appropriate use of domiciliary services

1.4.2.8 Feasibility of primary care anticoagulation services

The Department of Primary Care and General Practice, University of Birmingham has been carrying out research on anticoagulation services for ten years. They have developed a primary care anticoagulation model (The Birmingham model), using near patient testing for INR determination (NPT; section 1.4.2.1) and computerised decision support software for dosing support (CDSS; section 1.1.4.1; The Department of Primary Care and General Practice 2002a). In addition, they have also developed a training programme (validated by The British Society for Haematology) for nurses and GPs to become anticoagulation practitioners and manage primary care anticoagulation clinics. The department outlined the reasons why primary care has become a viable option for the provision of anticoagulation services.

It is clear that secondary care services are overloaded and do not always provide high quality care, patients could receive a more holistic package of care when managed within their own general practices. In addition, primary care can undertake this service with minimal investment or organizational disruption, finally the NSF for Older People (Department of Health 2001a) advises the implementation of local delivery plans based on national standards and service models with representative stakeholders from NHS Trusts, PCTs, users and carers (The Department of Primary Care and General Practice 2002a).

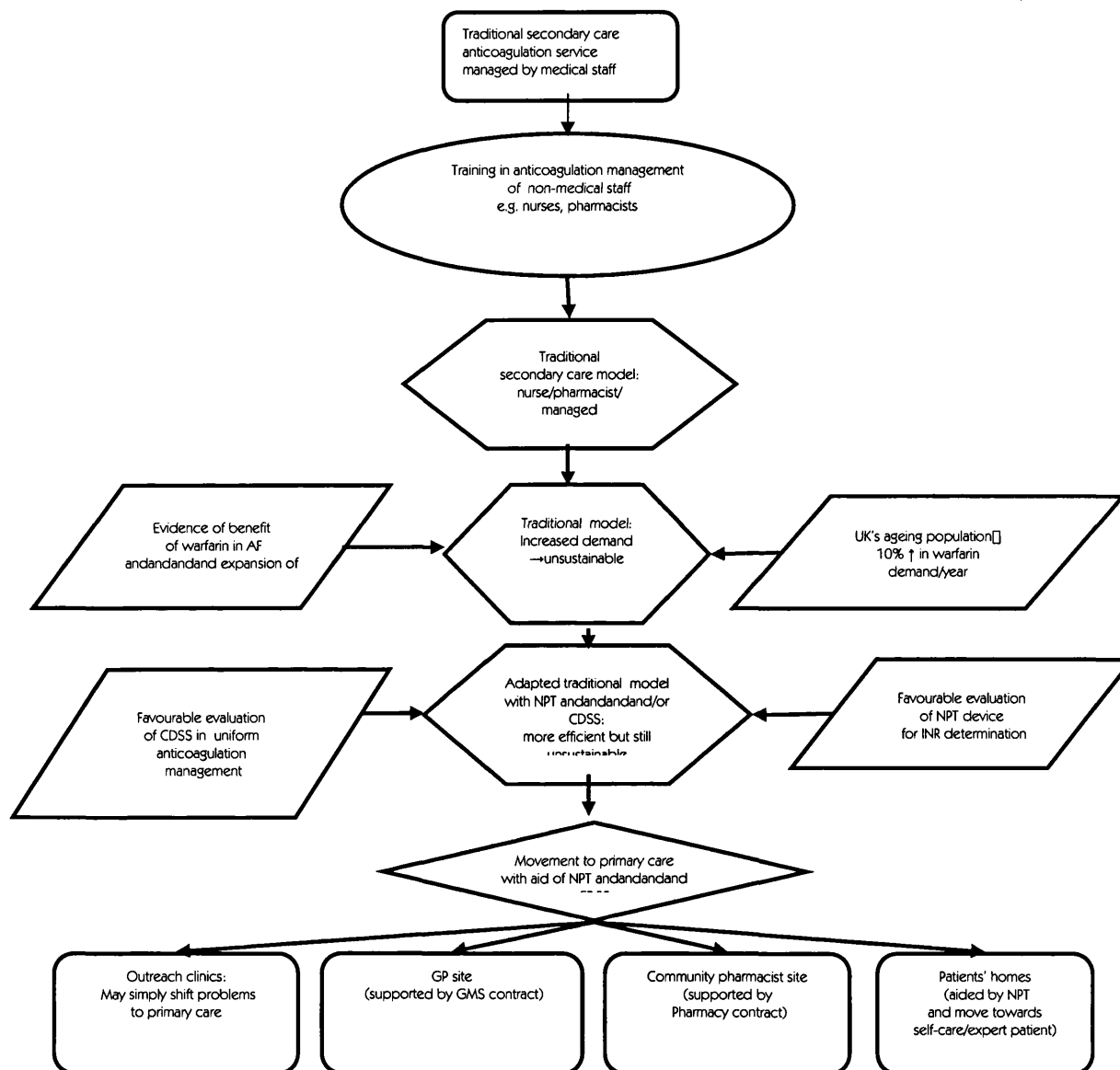
Potential advantages and disadvantages of primary care-based anticoagulation services

Within the literature, primary care-based models were cited as having a number of advantages over the traditional secondary care model; they were seen as able to ameliorate some of the disadvantages of the traditional hospital-based model, described as long waiting times (Coleman *et al.* 2003); difficult visits for elderly and infirm; excessive time off work and loss in productivity of younger patients (Sheehan *et al.* 2000). Primary care based models could involve less travel, reducing travel costs, more convenience for patients (and carers) and enhance seamless provision of care, as primary care practitioners should have a better knowledge of patients' concomitant diseases and drug therapy. In addition, it has been stated that the traditional model has not always performed well, in terms of anticoagulation control, adverse events and patient satisfaction (Rose 1996). The potential advantages of primary care-based anticoagulation services to the NHS include reduction in the pressure on hospital anticoagulation clinics and reduction in the burden on the hospital ambulance service used to deliver patients to and from the clinics (Sheehan *et al.* 2000). A potential disadvantage of developing primary care anticoagulation services could be a loss of contact with the clinical expertise of anticoagulation specialists such as consultant haematologists; primary care clinicians tend to be generalists rather than specialists (Amos 2006).

1.4.2.9 Developments in anticoagulation services in the UK

Figure 1.4 summarises recent anticoagulation service developments in the UK as identified from the available literature.

Figure 1.4: Recent developments in anticoagulation services in the UK



1.4.2.10 Overview

Anticoagulation and the traditional model of service

Warfarin has a narrow therapeutic range and requires regular monitoring of the degree of anticoagulation (measured as the International Normalised Ratio; INR) to achieve the benefit whilst minimising the risk of thrombosis (under-anticoagulation) or bleeding (over-anticoagulation). Consequently, treatment with warfarin entails substantial service resource.

Historically, the traditional hospital-based model of anticoagulation service provision has not always achieved the desired level of anticoagulation control in patients, can involve long waiting times and can be inconvenient, particularly for working patients and mobility-impaired patients requiring hospital transport. In addition, evidence of the benefits of warfarin in the primary and secondary prevention of stroke in patients with atrial fibrillation (Connolly *et al.* 1991; Kalra *et al.* 2000; SPAF Investigators 1996; BAATAF Investigators 1990), alongside an ageing population and Standard Five, Stroke, of the National Service Framework for Older People (Department of Health 2001a), which sets the agenda for reducing the incidence of stroke, has resulted in a substantial increase in the number of patients treated with warfarin. These factors have led to the exploration of alternative models of service provision to cope with the increased demand for services.

Primary care anticoagulation service development

Primary care-based models have been at the forefront of anticoagulation service developments, as they are perceived as representing a potentially more convenient, efficient, patient-centred means of providing anticoagulation care. This move towards primary care models of service has largely been recognised as a consequence of the inability for the hospital-based service to sustain the increased demand (Coleman *et al.* 2004; Fitzmaurice *et al.* 1996b; Khan and Rutter 2002; Macgregor 1999b). The Government agenda supports a move towards provision of health services in primary care. In addition, current clinical demand is for more rapid and accessible coagulation testing, as the clinical diagnostics industry move towards decentralization, with a move to treating the patient in a more timely manner, and as patients seek to regain autonomy over their conditions (Stevens 2003). Primary care has become a more feasible option due to the introduction of near patient testing devices (which allow rapid diagnostic testing and monitoring to be performed at sites other than pathology laboratories) and computerised decision support software (used to aid dosing decisions).

Patient orientated outcomes in the literature

There is now a substantial body of research available on anticoagulation service developments. Much of the data around service provision quality focuses on clinical outcomes such as TIR and incidence of adverse events. There is little on the patients' personal experience such as patient satisfaction with services. When patient satisfaction has been measured, non-validated questionnaires have been devised in an ad-hoc manner, not sufficiently explained. With regards to quality, it is made up of two components; first a quantitative and statistically measurable component and, secondly, a qualitative component related to individuals' value judgements (Calman 1993). Patients' feelings must contribute to the data in order to develop patient-centred services and to assess the full quality of care.

Important factors for successful implementation of anticoagulation service developments

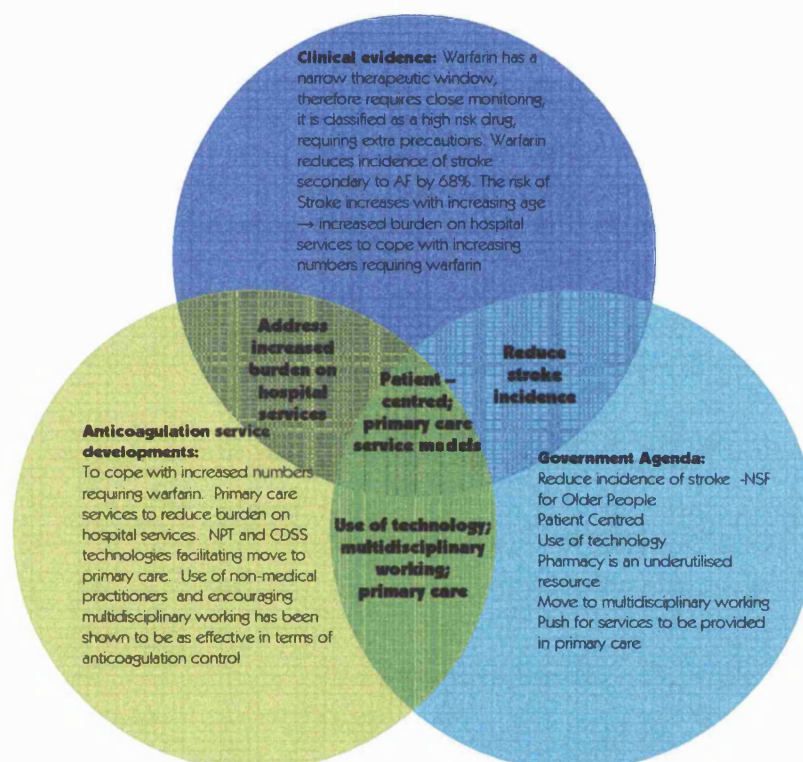
Little is available on the economic implications of NPT, CDSS, self-testing/management and of moving services to primary care. There must be an appreciation of the significance of shifting anticoagulation services to primary care with regards to capacity and resource for implementation of primary care anticoagulation models to be successful. In addition, clinical governance should be at the forefront of anticoagulation service provision. This includes not only the aspects of finance and quality, but also risk assessment, development of audit tools and performance indicators to ensure services are consistently delivered to an acceptable standard.

Gaps in the literature

There are gaps in the evidence base of domiciliary anticoagulation services for mobility-impaired patients. The reasons for this are unclear; it may be that the target population that would benefit from this service is deemed too small for a full evaluation. However, from the data on the under-use of warfarin, it suggests that many patients, particularly those with difficulties attending clinics on a regular basis are not treated with anticoagulation therapy for fear that regular follow-up monitoring and treatment is not feasible. Provision of domiciliary anticoagulation services could reduce marginalisation of these patients, which is of importance as this group of patients, who are often immobile, with multiple co-morbidities stand to benefit most from appropriate anticoagulation therapy. The range of primary care services being developed illustrates that a variety of models are required to suit patients' different needs and to cope with the increased workload, rather than one model being the panacea to the current service delivery issues.

In summary, the introduction to this thesis provides a brief outline of the clinical use of anticoagulation therapy and describes the drivers of the substantial increase in anticoagulation demand. It puts the requirement for anticoagulation service development in the context of the Government's stroke reduction and NHS modernisation agendas. Previous research undertaken in the development of anticoagulation services is described in some detail and along with the gaps identified in the evidence-base, contributes, to informing the development of the intervention described in this thesis. In chapter 3 the study site is introduced; the specific case in point of Barts and The London Trust (BLT) anticoagulation clinic is outlined; rapidly expanding and seeking new ways to provide an anticoagulation service to their patient population. This thesis aims to not only address the need of the BLT anticoagulation patients but also to provide evidence in the areas where it is lacking.

Figure 1.5: Diagrammatic representation of the introduction chapter and key words



Chapter 2

AIMS AND OBJECTIVES OF THE RESEARCH

2.1 Development of the research question

As outlined in Chapter 1, the use of warfarin in the prevention of stroke secondary to atrial fibrillation was shown to have a clear evidence base (Ezekowitz *et al.* 1992) and was promoted by the Government in an effort to reduce the national incidence of stroke (Department of Health 2001a). This coupled with an increased incidence of AF, increased incidence of stroke in older people and an ageing population led to a substantial increase in the demand for anticoagulation services. Consequently, there was a need to explore and evaluate safe alternatives to the traditional model of hospital-based anticoagulation clinics.

Numerous studies were published evaluating different anticoagulation service developments, including the use of non-medical staff as anticoagulation practitioners, alternative settings for clinics such as general practices and community pharmacies and the use of near patient testing and computer dosing support technologies to facilitate the sampling and dosing process (Coleman *et al.* 2003; Fitzmaurice *et al.* 2000; Macgregor *et al.* 1996 Mannotti *et al.* 2001). Services that were evaluated explored anticoagulation control and the incidence of adverse events compared to traditional services. Both were of paramount importance as warfarin was classified as a high risk drug requiring additional precautions when used (Department of Health; 2004a). However, full evaluations of patient satisfaction and domiciliary anticoagulation services were not undertaken, so there was little evidence that could be utilised to address the NHS' call for more services to be provided in the patient's home and to increase patient input into service developments.

It was accepted that service developments should take patients' views into account and that anticoagulation services must achieve adequate anticoagulation control (defined as patients in range 60% of the time; Rose 1996). It is with this knowledge that anticoagulation service development was carried out at BLT. Both of these aspects: anticoagulation control, in the form of time in therapeutic range and patients' views in the form of patient satisfaction data were of prime importance to the service development process. This study used the evidence base but took a pragmatic approach to achieving relevant service developments.

2.2 Main research questions

The scope of the study was developed by preliminary key questions that explored the development of anticoagulation services for the study population, in line with the Government's NHS change agenda. Key questions were reviewed and revised by a second investigator and the consultant haematologist supervisor. The following key questions were selected to guide this study:

- i. Are patients satisfied with the current anticoagulation service?
- ii. Which patient groups could be prioritised for service developments?
- iii. How should BLT anticoagulation services be developed?
- iv. How do service developments affect patient satisfaction?
- v. Are anticoagulation service developments suitable in terms of anticoagulation control (suitable defined as achieving anticoagulation control that is at least equivalent to that achieved by the hospital service)?

The following main hypotheses were identified.

2.2.1 Main hypotheses

- I. An evidence based approach can be integrated with a pragmatic approach to ensure local anticoagulation service developments are relevant, can be implemented and are sustainable.
- II. Service development, incorporating service user and provider feedback and the current evidence base from literature will increase patient satisfaction with anticoagulation services when compared to the traditional anticoagulation service model.
- III. The approach to service developments will ensure that anticoagulation control and safety of the developed domiciliary services for BLT mobility impaired patients will be comparable to that achieved with the traditional service model.

2.3 Aim of the thesis

To develop and evaluate two models of domiciliary anticoagulation service for mobility-impaired patients in their own homes, from a variety of perspectives.

2.4 Objectives of the thesis

- i. To evaluate patients' satisfaction with locally provided hospital-based services
- ii. To identify potential models of primary care-based anticoagulation service (with and without involvement of a pharmacist) through literature review.
- iii. To ascertain Healthcare Professionals' views of the value of proposed potential models of anticoagulation service.
- iv. To select two domiciliary services and evaluate these in a trial in terms of patient satisfaction, anticoagulation control and safety.
- v. To develop documentation to implement the selected domiciliary services prior to trial commencement.
- vi. Following the trial and analysis of data, select an appropriate domiciliary anticoagulation service for ongoing implementation.

In order to achieve these objectives a variety of approaches were used.

- Evaluating the existing evidence on service development based on a comprehensive review of the published literature
- Developing a pragmatic, sustainable intervention from the available evidence and within the allocated resources
- Exploring patient satisfaction at three time points to assess the impact of the intervention on this outcome measure
- Evaluation of the effectiveness of the intervention from a variety of perspectives: patient satisfaction, anticoagulation control and safety

There were two phases to the study; the developmental phase and the intervention phase. The phases are detailed in the relevant chapters.

Chapter 3

MATERIALS AND METHODS

3.1 Introduction

This chapter provides a brief overview of the concept of research in practice and outlines the more complex quantitative analysis methods used within the study. Agencies participating in the study are described, as is administrative and academic support.

3.2 Approach to the research

The theoretical concepts of research can lead one to believe that the processes involved fit easily and discretely into the overall predefined outcome. However, in the real world, the process of research is rarely so simple and orderly. Further, research into the delivery and development of health services presents numerous challenges. The difficulties associated with health services research have been recognised by the medical research council, who, in response have produced guidance on evaluating complex interventions in healthcare (MRC 2000). This publication provides a framework for researchers (Figure 3.1) and was used as a broad guide to facilitate the pragmatic approach to achieving the aims and objectives of this study.

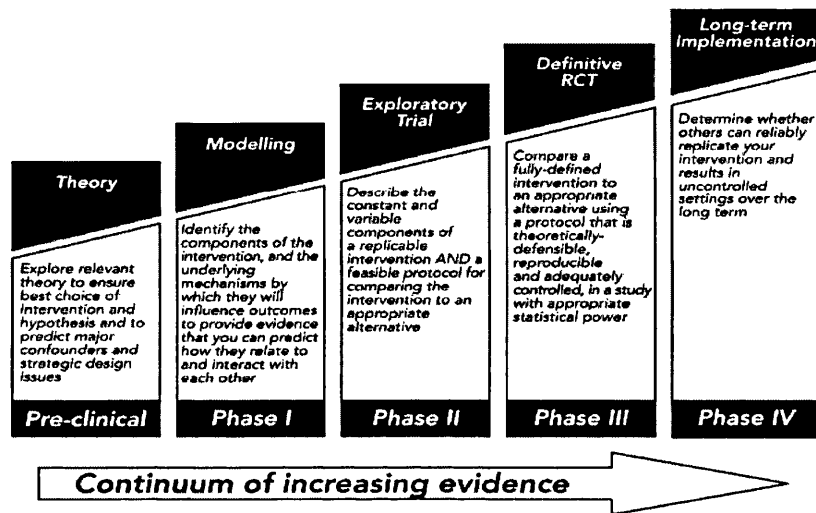
Taking a pragmatic approach ensures that research is not only undertaken in a robust and rigorous manner, but that it is undertaken in real life circumstances as opposed to tightly controlled laboratory conditions. In this way, the process facilitates dissemination of relevant recommendations / findings and the timely implementation of service developments.

In order to fully answer the research questions and to take into account both the service user and provider perspectives, multiple methods are used to complement each other and to produce a complete picture. In keeping with the pragmatic approach, methods were chosen not solely on the basis of their suitability but also taking into account feasibility issues such as time and financial constraints. Within this study, quantitative data were used to describe objective outcomes as well as to quantify subjective concepts (e.g. satisfaction) and qualitative data were used to explore perceptions and derive explanations, the "choice" between quantitative and qualitative data is discussed below.

This multimethod approach lends itself to data triangulation; the process by which different types of research methods / data are combined within one research study in an attempt to fully answer and validate findings (Smith 2005). Triangulation was used to investigate patient satisfaction in the developmental phase of this study; the combination of a validated generic satisfaction

questionnaire, service-specific items and patients' comments were used to ascertain satisfaction and inform service developments in a relevant way.

Figure 3.1: MRC framework for evaluation of complex health intervention (2000; page 3)



3.2.1 Qualitative versus quantitative methods

There has been a long standing debate in research as to whether qualitative or quantitative methods are "better". Some researchers are of the opinion that qualitative research is 'soft' research (Scherer and LaPier 2001). The Epidemiologist, Black (1994) argued that quantified results were more likely to be regarded as fact than qualitative findings. However, qualitative research has gained popularity in biomedical science as it was noted that quantitative research sometimes failed to fully answer questions related to clinical care and service delivery (Greenhalgh and Taylor 1997). Bowling (2002) argues that rather than looking at the two modes of research as opposites, creative ways of combining quantitative and qualitative methodologies in single research studies, should be sought. Clearly in some cases one approach will be more appropriate than another; as Wolfer (1993) proposed, different aspects of reality lend themselves to different methods of inquiry.

A number of ways of combining methods have been outlined in the literature, serving three main functions:

- I. Triangulation: to achieve or ensure substantiation of data, or convergent validation
- II. Complementarity: to elucidate, describe, or otherwise more fully elaborate the results of analyses
- III. Developmental: to guide the use of additional sampling, and data collection and analysis techniques

(Greene et al. 1989)

In addition, data analysis techniques can be combined in a variety of ways. Qualitative and quantitative data can be linked through preserving the words and numbers in each set, another method involves transforming qualitative data into quantitative data through quantifying, the qualitative data or conversion of such data into scales or ranks. In addition, quantitative data can be transformed into qualitative data through qualitzing, for example profiling of cases to create verbal portraits of participants (Sandelowski 2000). Currently, many advocate combining both approaches, where both qualitative and quantitative methods are used to compliment each other and answer research questions.

Qualitative research comprises a number of techniques including in-depth interviews, group discussions (focus groups, surveys, consensus expert panels) and utilizing documentation reports, audio recordings and video clips. Table 3.1 outlines the main differences between qualitative and quantitative research methods.

Table 3.1: Main differences between qualitative and quantitative research

	Quantitative	Qualitative
Associated Concepts	Theory and hypotheses generation is deductive and is tested with data. Subjects are predictable and reasoning is objective.	New hypotheses and grounded theory are generated (inductive), through data collection and field work.
Common study objectives	To test hypotheses, quantify data and extrapolate results from sample to relevant populations. The initial question is pre-specified and the answer is outcome-orientated (objective data e.g. drop in blood pressure)	To investigate and understand reasons that underpin particular behaviours/issues. The initial question is open-ended and the answer is derived through a process-orientated approach (e.g. iterative approach)
Focus	Specific hypotheses: narrow perspective	Exploring the depth and breadth of phenomena of interest: wide perspective
Data collection	Use validated structured instruments (e.g. pre-specified, close ended items) to collect quantitative data. Data consists of variables.	Researcher as main data collection instrument: collection of qualitative data (e.g. in-depth unstructured/semi-structured interview). Data consists of associated words, which are categorised to form themes or 'variables'
Data analysis	Numerical estimation, statistical inference. Findings are reported in a descriptive manner, stating statistically significant differences, correlations etc.	Narrative description, constant comparison, exploration of patterns and themes and holistic features
Findings	Findings should be conclusive Tend to desire a degree of generalisability and wider applicability. A causal relationship can be tested and established. Findings can be used to inform the study and make recommendations.	Findings cannot be represented statistically and are not generalisable. In addition, they are not conclusive. Relationships are suggested, but are not tested. Findings can be used as a foundation for further exploratory work.

(Bowling 2002; Smith 2005)

3.3 Quantitative data analysis

3.3.1 Time series analysis

Time series data is a collection of quantitative observations at regular intervals (SPSS Inc. 1993). Time series analysis can be used to determine trends in the variable of interest and can be formulated into a mathematical model to explain the previous behaviour of the series and predict future behaviours.

Autoregressive Integrated Moving Average (ARIMA) modelling allows one to explore trends through identifying an appropriate model for time series data. ARIMA is often used in the world of finance to assess the impact of an event (such as Hurricane Katrina) or an intervention (such as an advertising campaign) on financial markets. It is often used to devise strategies to deal with foreseeable and unforeseeable events based on previous behaviour to stimuli.

ARIMA models combine up to three types of processes; autoregression (AR), differencing to strip off integration (I) of the series, and moving averages (MA) (SPSS Inc. 1993).

ARIMA is also referred to as the ARIMA (p,d,q,) model, where:

p= Autoregressive parameter –the order of autoregression

d= Difference parameter – the degree of differencing

q= Moving average parameter- the order of moving average involved

The process of time series analysis using ARIMA modelling follows a systematic pattern as there is no quick method and omitting a step could result in an incorrect model being assigned to data.

The approach always follows the same procedure and is made up of three main steps:

- I. The first step is to build a model by determining the values for p, d and q in the ARIMA (p,d,q) process. This is done by creating a sequence graph; visualisation of the data allows step wise changes and other trends in data to be identified. At this stage one can assess whether linear smoothing through differencing (d) of the series is necessary to remove linear trends in the data and make the series stationary; the identification process of the autoregressive (AR) and moving average (MA) components requires a stationary series (SPSS Inc. 1993).
- II. The next step is production of autocorrelation correlograms. Autocorrelation is the correlation of a variable with itself at a given lag (Chatfield 2005). An autocorrelation Function (ACF) plot gives the correlations corrected for uncorrelated data and allows proper interpretation of significance, through identification of the autoregressive order (p). A Partial Autocorrelation Function (PACF) plot gives the moving average (q) by looking at the residuals (error); assessing whether there are any internal errors or lagged shock effects.
- III. When an ARIMA model has been selected, the next step is to fit the model to the data and assess how well the estimated parameters have predicted the observed values. Ideally, there should be no or very few significant ACFs or PACFs at this stage if the model is a good fit. The residuals (error) should have a random normal distribution.

It is imperative that this process is followed to correctly identify the most appropriate model for the data. It may take several rounds of identifying a model, estimating the fit of the model to the data and producing statistics to describe the residuals and series before one knows whether the model can be used with confidence or whether it is necessary to return to the first stage.

Evaluating complex health interventions

One way of evaluating complex health interventions is by performing an interrupted time series (ITS) analysis. The intervention is the interruption in time that changes the normal behaviour of the series. Through interrupted time series analysis, one can assess the impact of an intervention on a given variable, immediately and over time. ITS is useful as it identifies and determines any trends before, as well as after an intervention.

There is no lower limit to the number of observations required for time series analysis, however it is recommended that there are between 40 and 50 observations for analysis. The closer the time points and the greater the number of observations, the more valid the data (England 2005).

During the process of intervention analysis, dummy variables are used to split the data into time frames before and after the intervention. One limitation of intervention analysis is that it is unable to take into account the presence of other factors that may affect the target variable.

Time series analysis was used within the current study to explore the impact of an anticoagulation service intervention on patients' INR (Chapter 5).

3.3.2 Linear regression

Multiple linear regression is useful for exploring the relationships between variables. Correlations between quantitative variables are useful to measure the strength of any association. Regression methods take the analysis further than correlations; they use the presence of an association between two variables to predict the values of one (dependent variable - y) from those of the other (independent variable - x). Simply, two variable regression, the value of the dependent variable can be estimated by the value of an independent variable by a general linear equation of the form:

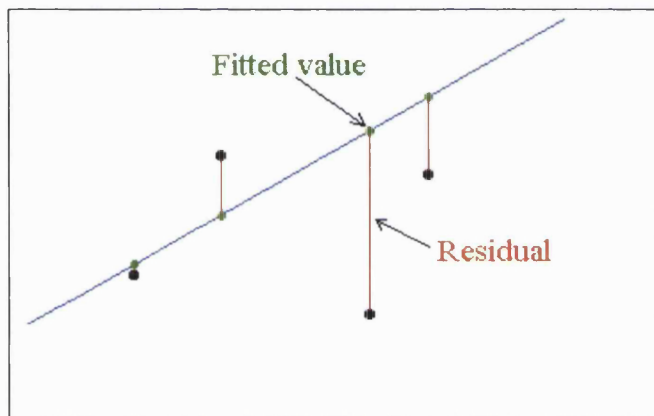
$$y' = b_0 + b_1(x)$$

where:

- y' is the estimated value of the dependent variable, for example CSQ score
- b_1 is the regression coefficient - represents the gradient of the line and the amount the dependent variable changes when the independent changes by one unit
- b_0 is the regression constant - represents the intercept and the amount the dependent y will be when the independent variable is zero
- x is the independent variable, for example clinic environment

The resulting equation should produce a line that fits the data points of the independent and dependent variables when they are plotted on a scatter plot, with minimal deviation from the points. The differences between the line (predicted values) and the data points (observed values) are known as the residuals (Figure 3.2). The residuals are of importance as they allow one to determine how accurate estimates are and how well the regression model represents the data analysed.

Figure 3.2: Illustration of fitted regression line with residuals



Reproduced from: <http://www.le.ac.uk/biology/gat/virtualfc/Stats/regression/regr1.html>

Multiple linear regression allows one to establish whether a set of independent variables explains the variance in a given dependent variable at a significant level (r^2 ; similar to the square of correlation coefficients), and can determine the comparative predictive importance of each independent variable.

The linear multiple regression equation is of the form:

$$y' = b_0 + b_1(x_1) + b_2(x_2) + b_3(x_3) + b_4(x_4) \dots + b_p(x_p)$$

where:

- y' is the estimated value of the dependent variable
- parameters b_1, b_2, \dots, b_n are the partial regression coefficients
- b_0 is the regression constant
- x_1, x_2, \dots, x_n are the independent variables

Analysis of variance (ANOVA) allows one to determine whether the model/equation predicts the dependent variable better than chance, using the significance level of the F of the model; a level of ≤ 0.05 is considered significant.

The following criteria must be met in order to ensure that the multiple linear regression modelling is appropriate.

- i. The distribution of residuals (error) must be normal
- ii. The variance of residual error should be constant for all values of the independent variables : Homoscedasticity
- iii. No outliers; outliers represent large errors and violate the rule of Homoscedasticity and can adversely affect the accuracy of modelling
- iv. Little or no correlation of independent variables (multicollinearity), as it weakens analysis due to reduced reliability of regression coefficients
- v. The sum of the mean values of the residuals for any given value of the dependent variable should equal zero.
- vi. Number of cases: a minimum of 20 cases per independent variable

In addition, ordinal data can be used for regression modelling, with a number of limitations compared with interval data. There are a number of methods for fitting independent variables to produce a model, summarised in Table 3.2.

Table 3.2: Fitting independent variables to produce a multiple linear regression model

Method	Outline
Enter	All variables are entered in a single step
Forward	Variables are entered into the model one by one, the order being determined by the variable's significance in the model, until no more can be entered
Backward	All variables are entered in a single step, then one by one the insignificant variables are removed until, removal results in a significant change in r^2
Stepwise	This is a combination of the forward and backward methods used to produce the best model
Remove	Subsequent to using one of the previous procedures, removes all the variables in the list from the model

The method used depends on whether the purpose of the regression model is to explore data or whether it is to substantiate a theory, and on the presence of related work.

Linear regression formed part of the analysis of patient satisfaction in both the developmental and intervention phases of the study.

3.4 Participating Agencies

3.4.1 Barts and The London NHS Trust

The participation of the Barts and The London Trust, which consists of The Royal London, St Bartholomew's, The London Chest and Queen Elizabeth's Hospitals, in this project was confirmed through meetings with the main investigator, the consultant haematologist, the Director of Academic Pharmacy and the Chief Pharmacist of the Trust. The Trust's Research and Development Department approved the study.

In April 1990, The Royal London Hospital became a NHS Trust in the first wave of Trust formation. In 1994, a merger took place between The Royal London, St Bartholomew's and The London Chest Hospitals and the Trust was renamed The Royal Hospitals NHS Trust. The Queen Elizabeth Hospital for Children merged with the Trust in 1998. In 1999 the Trust was renamed, Barts and The London NHS Trust. At the time of writing, the Trust had 1109 beds. In the year 2004/2005, there were 490,000 outpatient attendances, 85,000 inpatient and day cases admissions and 174,000 patient transport journeys. The Trust has seven clinical directorates, with different service provision requirements. The Barts and The London Trust is one of the largest teaching Trusts in England (Barts and The London Trust 2005). It has a number of key roles including:

- Provision of district general hospital (DGH) service for Tower Hamlets and the City, providing secondary level services to the local population.
- Tertiary centre offering complex specialist services for north east London and the Essex areas.
- Research centre; provision of innovative clinical services for London and the UK.

The pharmacy department provides a number of key services throughout the Trust, including: a medicines information service; dispensing of inpatient and outpatient medication; clinical pharmacy; a production service including preparation of chemotherapy and running of outpatient clinics, including anticoagulation and high risk medicines.

The Academic Department of Pharmacy (ADP) provides the link between the pharmacy service at the Trust and the School of Pharmacy, University of London. This link facilitates a clinical practice foundation for pharmacy undergraduates, the certificate and diploma in pharmacy practice, the MSc in clinical pharmacy and the practice and policy MPhil and PhD programmes. The ADP promotes multidisciplinary working and research projects with aims for measurable impacts on the Trust's patients and pharmacy workforce.

3.4.2 Tower Hamlets PCT

The co-operation of Tower Hamlets PCT was obtained via the Chief Pharmacist of BLT. The Tower Hamlets PCT was formed in April 2001. In April 2003 it became a research PCT. Research PCTs were first introduced in 2002, they were awarded Department of Health funding to take part in a national evaluation of research management and governance. Tower Hamlets is the research PCT for the whole North East London sector. The Trust serves a local population of approximately 200,000 people (Tower Hamlets Primary Care Trust 2005).

Ethnicity

Over fifty percent of Tower Hamlets' population is from non-White British ethnic groups, with a third (33.4%) of the population being Bangladeshi. The total white population, including the ethnic white population is approximately 42% and the African/Caribbean population is approximately seven percent (THPCT 2005).

Deprivation

The Index of Multiple deprivation is utilised as a measure of poverty, it explores deprivation across seven domains: health deprivation and disability; employment; income; education, skills and training; crime; living environment and barriers to housing and services (Department of the Environment, Transport and the Regions 2000).

The residents of THPCT fare badly on this measure in a number of areas, particularly low educational achievement, low income, high unemployment, and poor and overcrowded housing. The Bangladeshi community are particularly affected by overcrowded housing, experiencing twice the rate of the London average. In addition, THPCT has one of the highest population densities in inner London (THPCT 2005). Tower Hamlets PCT is the fourth most deprived borough in the UK, second

most deprived in England and the most deprived in London. (Office of the Deputy Prime Minister 2004).

Infant mortality and Life expectancy

Infant mortality is 6.2 per 1000 live births in THPCT (compared to England average of 3.1 per 1000 live births) and life expectancy is 72.9 years for men (English average 76.6 years), and 78.9 years for women (English average 80.9 years), which is amongst the worst life expectancy in the whole country (THPCT 2005).

Main causes of mortality

Major causes of death in Tower Hamlets include, diabetes, cancers, coronary heart disease and stroke. The number of people living with diabetes is 2-4 times higher than the national average. Ill health and death from cardiovascular disease is significantly higher in Tower Hamlets (THPCT 2005).

3.4.3 Homerton University Hospital Trust

As part of the project Homerton University Hospital's inclusion in the project was confirmed with the Consultant Haematologist, the chief pharmacist and the Research Pharmacist for the Trust. Homerton University Hospital was officially opened in March 1987, although patients were admitted from July of the previous year. From inception, until March 1994 Homerton Hospital was part of the Barts NHS Group of Hospitals. In April, it was established as a directly managed unit of East London and the City Health Authority (ELCHA). Subsequently, Homerton Hospital achieved Trust status in 1995. In 2001, the quality of teaching at the Hospital was recognised and it was renamed the Homerton University Hospital. In April 2004, the Trust became one of the first ten NHS Foundation Trusts in England. Foundation Trusts were introduced to ensure that the needs of the local population could be met through the devolution of power to local managers, in this way they are self-governed (Department of Health 2002a). The Commission for Health Improvement (CHI; now called the Healthcare Commission), regulators for the Trusts awarded the hospital three stars each year between 2002 and 2005 (Homerton 2006), the highest category. At the time of writing the Trust had approximately 500 beds. In the year 2004/2005 there were approximately 174,000 outpatient attendances, 40,200 inpatient attendances and 9,100 day cases in the hospital (Homerton 2005). The Trust has four clinical directorates. Similar to the BLT Trust, the HUH pharmacy department provides a number of key services such as Medicines Information and dispensing of medication for inpatients and outpatients. At this time, the HUH Trust pharmacy department had academic links with the School of Pharmacy, to facilitate undergraduate and

postgraduate learning and research training. In addition, the Trust also has links with London South Bank University, which is involved in the running of non-medical supplementary and independent prescribing courses, whose intake includes pharmacists and nurses.

3.4.4 City and Hackney PCT

The co-operation of the City and Hackney PCT was obtained via the Head of Prescribing and Pharmacy. The City and Hackney PCT was formed in April 2001 and in April 2003 it became a teaching PCT. Teaching PCTs were introduced in 2002 and were implemented in areas where staff recruitment and retention was inadequate, often in deprived areas (Department of Health 2001d). Posts in teaching PCTs provided opportunities for qualified staff to take up prestigious roles with clinical and teaching/development/research responsibilities (Department of Health 2001d). The Trust serves a local population of approximately 260, 000.

Ethnicity

The population supported by HUH and CHtPCT is multicultural and socially diverse, with 40% representing ethnic groups. Within the ethnic population, Black African (12%) and Black Caribbean (10.3%) groups predominate. Even within the white category there is diversity; this population includes the Kurdish and Eastern European communities. The residents of Hackney are young (average age 33 compared to 39 for England) and highly mobile (turnover of 30 – 40% per year). The mobility of residents presents challenges to CHtPCT for keeping track of residents and ensuring that local health targets, such as immunisation programmes are met. (CHtPCT 2005)

Utilising the Index of Multiple deprivation, Hackney compares poorly with the rest of England on a number of key determinants of health and deprivation, including unemployment, poor housing and low educational attainment. Overall it is ranked as the fifth most deprived out of the 354 boroughs in England and the second most deprived in London (Office of the Deputy Prime Minister 2004).

Infant mortality and Life expectancy

Similarly to Tower Hamlets PCT mortality and life expectancy is below average in City and Hackney. Infant mortality is 7.8 per 1000 live births in CHtPCT (compared to England average of 3.1 per 1000 live births) and life expectancy is 73.8 years for men (English average 76.6 years), and 80.1 years for women (English average 80.9 years; (CHtPCT 2005).

The major causes of death in Hackney are coronary heart disease, stroke and cancers. Deaths under the age of 75 from heart disease in Hackney are 31% above the national average (statistically significant). The PCT is amongst the worst fifth nationally of local authorities for circulatory disease in under 75s (CHtPCT 2005).

3.4.5 Anticoagulation services in BLT

The Barts and The London NHS Trust (BLT) hospitals serve the community of the Tower Hamlets Primary Care Trust (PCT). The anticoagulation clinic at BLT has been operating since the early 1970's. The staff team initially consisted of a consultant haematologist, an on-call registrar and an administrator. In 1991 the clinics provided services to approximately 500 patients, almost wholly at St. Bartholomew's Hospital. At present, the anticoagulation team delivers a service to 1490 patients on oral anticoagulants in 6 hospital clinics per week, with over 400 patients attending each week. Provision of the service involves INR testing, dose adjustment, counselling, patient education and audit of clinical standards. In addition, one clinic per week is run in partnership with a general practitioner's surgery, and it is anticipated that this will expand to other general practices shortly. As the number of patients attending the anticoagulation clinics has increased, so the anticoagulation team has expanded. At present, the team includes one consultant haematologist, a senior pharmacist practitioner, two C/D grade pharmacists, a senior nurse practitioner, a nurse practitioner and two administrators. Currently, there are two clinic days at the following Trust sites: The Royal London, St Bartholomew's and The London Chest Hospitals.

Investigation into alternative models of anticoagulation service within the Tower Hamlets service provision area was prompted by BLT anticoagulation practitioners. The practitioners had observed a substantial increase in patient numbers and in their workload and were keen to ensure that the service continued to be patient-centred. In addition, they were aware of developments in technology that could facilitate reconfiguration of the current BLT anticoagulation service.

3.5 Ethical Approval

Ethical approval was sought for and received for the patient satisfaction survey (developmental phase), the group discussions (developmental phase) and the intervention phase of the study.

3.6 Administrative support

A Dell laptop and desktop, installed with Windows 2000 operating software were employed throughout the study. Microsoft Word was used for word processing and the Statistical Package for Social Sciences (SPSS versions 11.0 – 13.0) was used to construct a database and to support statistical analysis of the data. The main investigator was registered as a PhD student at the London School of Pharmacy. Administrative activities required the use of plain paper, envelopes, and labels. In addition, the use of a telephone was required to make calls for arranging multidisciplinary meetings, to communicate with the anticoagulation team and with the study patients. The nominal group session was conducted using pre-printed work books for discussion and a mini-disc recorder. To ensure the security of the investigator and the efficiency of the trial service, a mobile telephone was issued for the duration of the trial. Domiciliary visits were undertaken by car, driven by the main investigator.

3.7 Academic and Practical Support

The investigator was supported academically by the Director of Learning and Teaching (a Professor) and a Senior Clinical Lecturer in Pharmacy Practice and the Academic Director of Pharmacy from BLT. Practical support was obtained from the BLT anticoagulation consultant haematologist. The design of the study, including the intervention phase was agreed by all supervisors. Statistical analysis of data throughout the study was supported by the Director of Learning and Teaching and through the attendance of a research methods course within the University of London.

Chapter 4

DEVELOPMENTAL PHASE

. . .

4.1 Introduction

The developmental phase of the study was conducted to evaluate the need for anticoagulation service developments in the BLT service provision area; to identify which areas of the anticoagulation service provision should be targeted for development; to plan a strategy for this investigation and produce valid documentation for the implementation during the intervention phase (Chapter 5).

The developmental phase consisted of four stages:

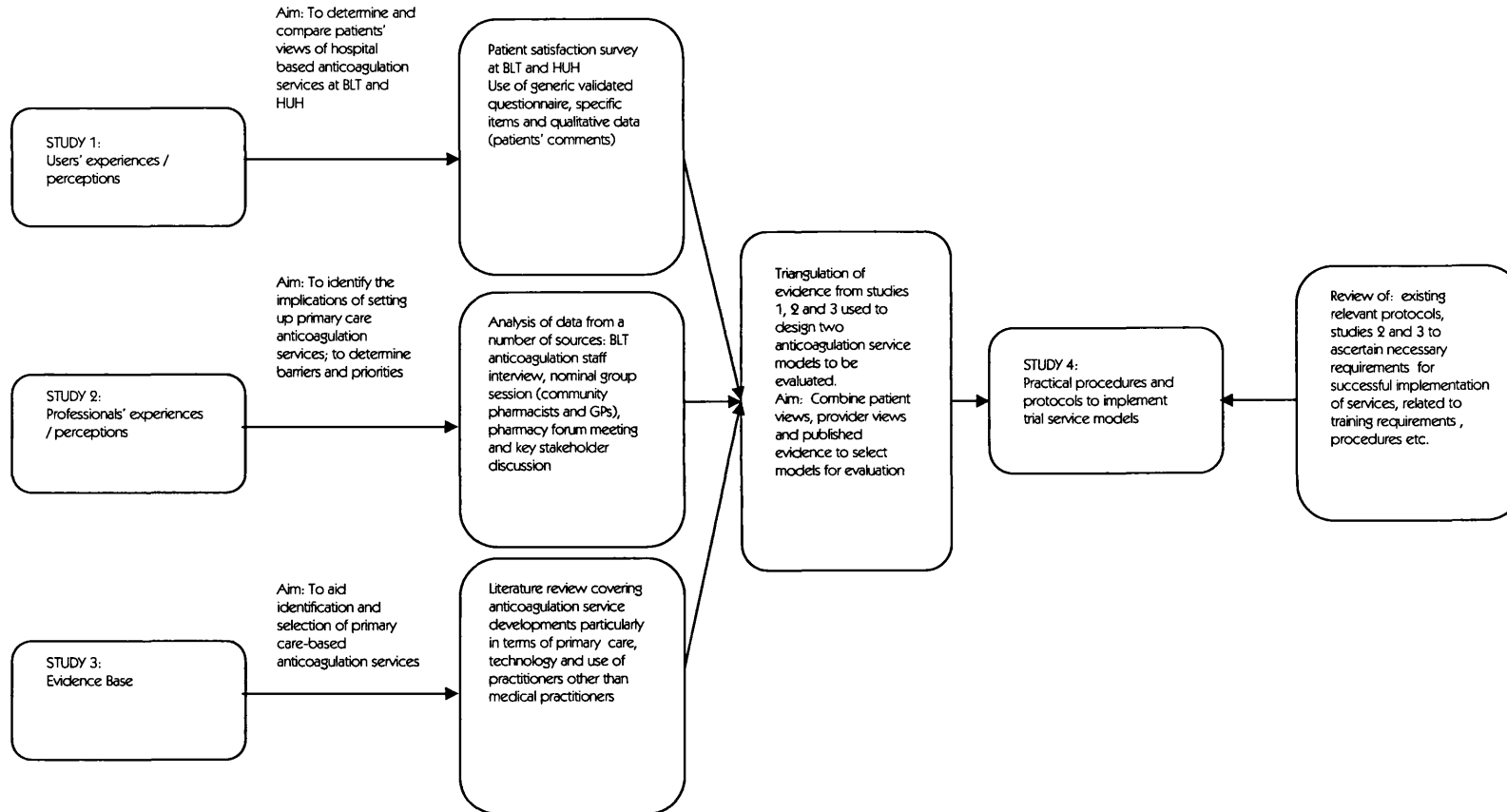
1. patient satisfaction survey;
2. group discussions;
3. literature review;
4. practical procedures for the implementation of selected service models.

This chapter outlines the methods used during the various stages of the developmental phase and goes on to describe how theoretical primary-care based anticoagulation service models were developed by triangulating the evidence from patient satisfaction data, nominal group sessions, stakeholder discussions and the literature on a range of topics including:

- Satisfaction/dissatisfaction with current practice
- Feasibility / employment of a variety of models

The overall objective of this thesis was to develop an intervention that incorporated the current best available evidence with an accurate assessment of the needs of the population, utilising both the service-user and service provider perspectives. A pragmatic approach was taken to designing the intervention. This was appropriate as the evaluation of health interventions in the modern healthcare system is by its very nature a complex task; combining services across primary and secondary care sectors and professionals from different disciplines. Such work cannot be viewed from a purely theoretical perspective, as what is deemed as “best practice” cannot always be achieved in the real world, therefore marrying idealism (theory) with realism (practice-based experience) to obtain a suitable ‘middle way’ offers the best opportunity to deliver interventions that achieve the aim of being meaningful and relevant to a target population. Figure 4.1 describes the content and layout of this chapter.

Figure 4.1: Diagrammatic representation of Developmental Phase



4.1.1 Aim

To develop an evidence-based pragmatic intervention with robust documentation.

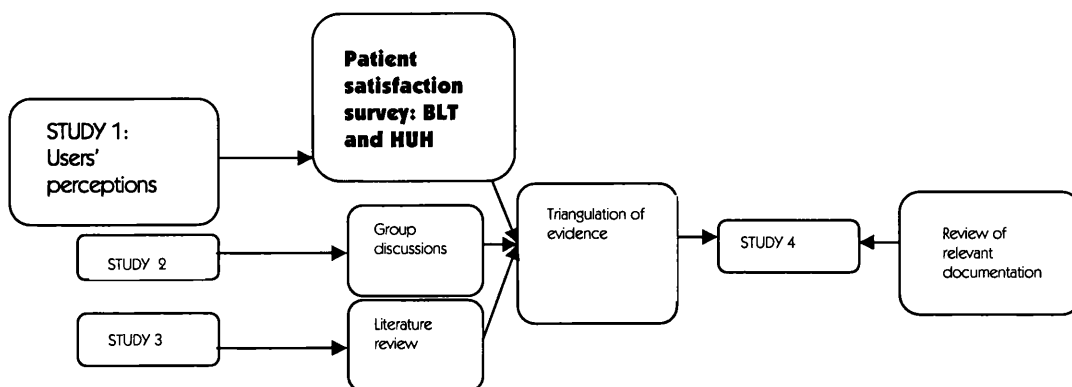
4.1.2 Objectives

- i. To evaluate the perceptions and experiences of service users and professionals with regards to anticoagulation services;
- ii. To evaluate the literature related to the development of anticoagulation services;
- iii. To triangulate the perceptions of users, experiences of professionals and the best available evidence to identify a sub-group of BLT anticoagulation patients in need of prioritisation of service developments;
- iv. To design two appropriate and feasible anticoagulation services for subsequent evaluation in terms of patient satisfaction, anticoagulation control and safety;
- v. To produce appropriate documentation to ensure successful implementation of developed services.

The aim was achieved through operationalisation of the following tools: patient satisfaction survey, literature review, group discussions with relevant professionals, the use of practical procedures (for example anticoagulation training) and development of documentation for the implementation of the models to be evaluated. The detailed aims and objectives of each tool are outlined within the relevant sections.

4.1.3 Ethics Approval

Ethics approval was granted from both Homerton University and Barts and The London Trusts' Ethics Committees to conduct the patient satisfaction surveys and group discussions (Reference: N/02/065).



4.2 Patient satisfaction

4.2.1 Introduction

This study aims to take a patient-centred approach to anticoagulation service development. Patients' satisfaction is associated with the extent to which general healthcare needs and condition-specific needs are met (Asadi-Lari *et al.* 2004), therefore in line with a patient-centred approach, it is appropriate to utilise patient satisfaction as a key outcome. This section gives an overview of the relationship between satisfaction, quality and health service provision, whilst touching upon satisfaction as a concept. This section further goes on to outline various patient satisfaction scales and the rationale for selection of a suitable scale for measurement of patient satisfaction within this study.

4.2.1.1 Assessing "satisfaction"

Schommer and Kucukarslan (1997; page 2721) state that "Satisfaction can be conceptualized as a performance evaluation, disconfirmation of expectations, an affect-based assessment, or an equity-based assessment." Part of the problem of measuring satisfaction is that it is a difficult concept to define. Before one can measure satisfaction effectively, there has to be a clear understanding of what it actually is. What *is* clear is that satisfaction is a complex multi-dimensional concept. A number of authors have developed theories/models to support the concept of satisfaction; some of these models are outlined in Table 4.1. The majority of models place significant importance on patients' expectations and values and make a number of assumptions, which fall down on closer inspection (Table 4.2).

Table 4.1 : Some models of patient satisfaction

Author	Theory/model	Outline of theory
Linder-Pelz (1982)	Value/expectancy	Satisfaction based on belief strength and evaluations of attributes (dimensions) of health care
Lawler (1973)	Discrepancy	Satisfaction is the result of the perceived discrepancy between that which the patient expects and that experienced as a proportion of those expectations
Lawler (1973)	Fulfilment	Satisfaction is the difference between expectations and what is experienced. However, unlike the discrepancy theory does not take proportions into account only views the difference between what occurs and what is expected as salient.
Lawler (1973)	Equity	Satisfaction is perceived equity, that is balance of inputs and outputs
Hunt (from Pascoe 1983 page 187)	Cognitive	Satisfaction is a cognitive response – " an evaluative reaction resulting from the interaction of the product/ situation with the individual's expectation"
Brennan (1995)	Normative Decision Fulfilment	Satisfaction is an appraisal of whether the care provided met the individual's expectations and or preference.
Baker (1997)	Pragmatic	Satisfaction is an evaluative judgement of the care received; it is a continuous and multidimensional variable.

Table 4.2: Some assumptions made in the evaluation of patient satisfaction

Assumptions	Downfall of assumptions
Satisfaction is a function of a prior process such as meeting patients' expectations.	The evidence suggests that although there is a relationship between satisfaction and expectations, it is not a simple one (expectations often accounts for only a small amount of the variance), therefore targeting patients expectations as a way to improve satisfaction may be inadequate.
The expression of satisfaction with an aspect of care/service provision implies that that aspect has in some way been approved by the user.	Expression of satisfaction could be based on reluctance to be critical about aspects of a service. It fails to take fully into account the factors that a patient uses to make their assessment.
Patients do in fact have expectations or values related to aspects of services.	It has been argued that patients may not have expectations. Qualitative work has suggested that at times patients' expectations are unclear.
All patients play the same role (passive recipient versus outspoken consumer) and interpret the data (for example, the experience of a clinic visit) they are given in the same way	The evidence suggests that patients may not play the same role: It has been shown that there is a difference in the satisfaction of patients based on age. And it is proposed that older patients tend to be passive recipients compared to younger patients who are more likely to play the consumer role, this may affect the way they assess their satisfaction.

Adapted from Owens and Batchelor (1996)

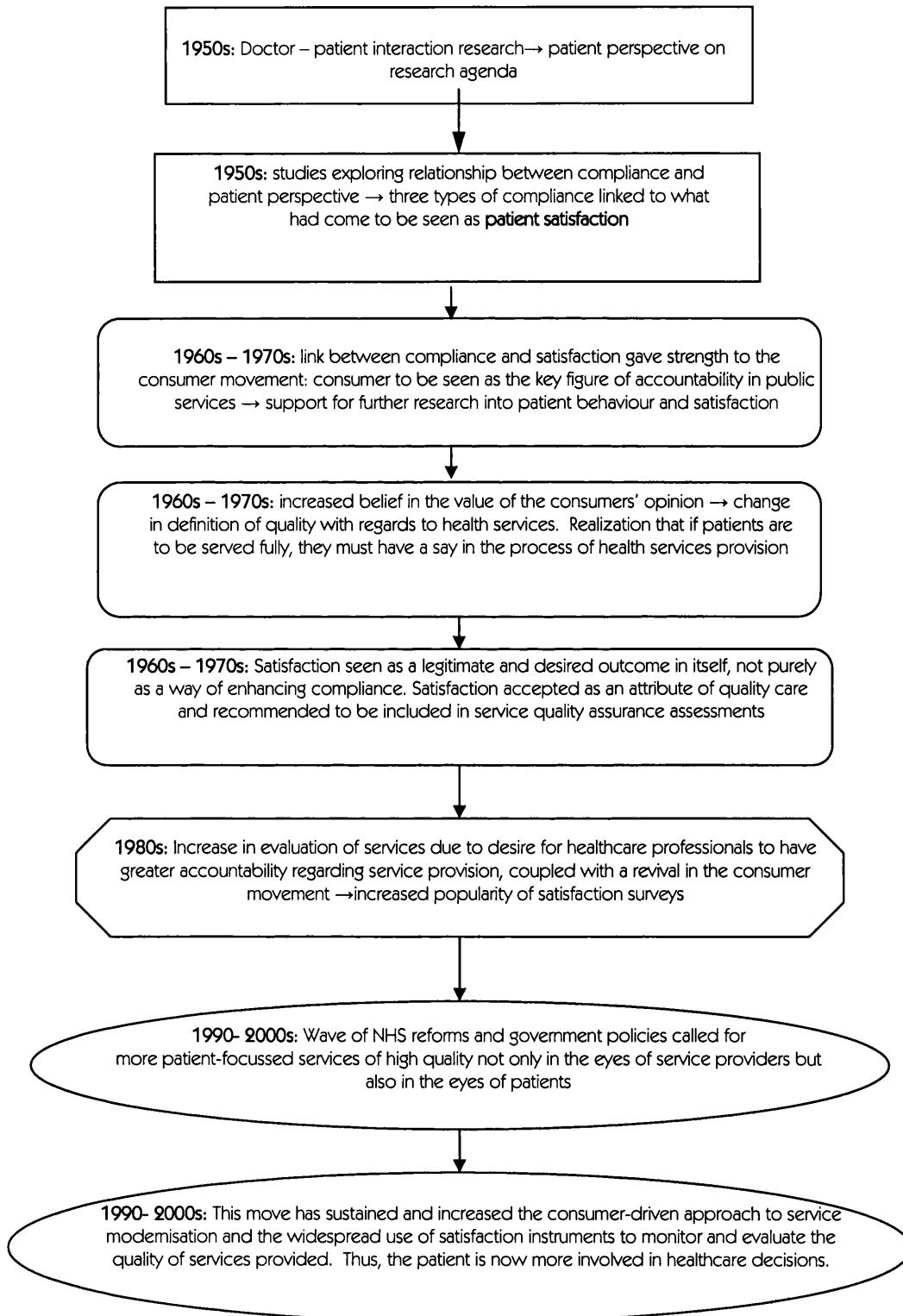
For satisfaction to be measured appropriately one needs to identify not only what is right about any service, but also what is wrong about services and hence find the sources of patient dissatisfaction. Within studies the definition of satisfaction differs, however one thing that is well established is that satisfaction is subjective in nature.

4.2.1.2 Satisfaction with service provision

NHS reforms and government policy have called for more patient-focussed services of high quality not only in the eyes of service providers but also in the eyes of patients (Department of Health 1998; 2001c). This move has led to a more consumer-driven approach to service modernisation and the widespread use of satisfaction instruments to monitor and evaluate the quality of services provided (Williams 1994). Thus, the patient is now more involved in decisions about the provision of healthcare. In this study patient satisfaction is used as a proxy measure of service quality and a tool for service development.

Historically, measures of quality of pharmaceutical and health services were based on objective outcomes such as clinical effectiveness and cost savings. However, this narrow focus on service quality assessment fails to link services to patients' needs, expectations and desires. Since the 1980s the concept of patient satisfaction involving obtaining patients' views to assess and improve the quality of service provisions, has gained favour. Patient satisfaction has become more important as a tool for performance assessment and quality management, in addition it has a role in aiding adequate remuneration of the service provider (Guadagnino 2003). Figure 4.2 outlines the historical development of the concept of patient satisfaction.

Figure 4.2:
Historical development of "patient satisfaction"



4.2.1.3 Approaches to measuring patient satisfaction

In order to identify an appropriate method of measuring patients' satisfaction, the investigator referred to health services research literature. A variety of approaches to explore patient satisfaction were identified (Bauer *et al.* 2001; Salisbury 1997; Tasso *et al.* 2002; Ward and Gordon 1996). These included the use of structured patient satisfaction surveys and structured, semi-structured and unstructured one-to-one and group interviews. Bauer *et al.* (2001) explored patient satisfaction with anaesthesia on the second postoperative day. Authors found that patients' responses were more critical during structured face-to-face interviews than during self-administration of the same items in a questionnaire; suggesting that during interviews patients may explore aspects of service provision with a greater degree of discernment, this would be useful for detailed discussion of aspects of patient dissatisfaction. Whilst interviews offer the advantage of allowing more in-depth exploration of patients' perceptions and experiences (Bowling 2002), in the current context (clinic environment, clinic operation, patient numbers, large numbers of older patients), interviews would pose a range of feasibility issues, including problems with identification of a suitable room, interference with clinic dynamics and time constraints for both one-to-one and group interviews. Therefore a clinic-based patient satisfaction survey was regarded as the most appropriate as larger numbers of patients could be surveyed compared to the number that could be interviewed.

4.2.1.4 Measurement of patient satisfaction – survey instrument and administration

Hudak and Wright (2000) suggest that the two major aspects of patient satisfaction measurement are content (areas of measurement) and method (how the instrument is administered). This section outlines the issues related to the content of satisfaction surveys (for example, validated versus non-validated), the mode of administration and the process of survey selection in the developmental phase.

Content

Following a review of the literature, no validated anticoagulation service-specific satisfaction scales were identified. The use of non-validated questionnaires in research often leads to the validity of results being questioned (Oldridge *et al.* 1998; Thompson *et al.* 1998) and was therefore not regarded as a favourable alternative, however it was suggested that supplementing a validated scale with non-validated service specific items may be acceptable. It was proposed that use of a validated scale would increase the credibility of results, whilst use of service specific items (if

necessary) would aid in the identification of areas for anticoagulation service development. The investigator identified a number of generic validated satisfaction scales that could be used. These measures were developed to measure either general customer satisfaction or specifically for use in health care. The following sections are brief critiques of some of the various scales used to assess satisfaction, including the reasons they were not selected and why the CSQ-8 was selected.

Client Satisfaction Questionnaire - CSQ-8 (Attkisson and Zwick 1982)

The CSQ-8 is a validated, self-administered, eight item, four point rating (Likert) scale designed to assess patients' global satisfaction with services. The CSQ-8 has been widely utilised in the health research arena and has good psychometric properties; demonstrating high levels of internal consistency, reliability and validity (Attkisson and Zwick 1982; Nguyen *et al.* 1983). Due to the generic nature of the scale it is not useful for identifying specific dimensions of satisfaction / dissatisfaction.

*Client Satisfaction Questionnaire - CSQ-18 (LeVois *et al.* 1981)*

The 18 item version of the Client Satisfaction Questionnaire (CSQ-18) has good psychometric properties, including internal consistency and established validity. The investigator and clinic practitioners agreed that, if the CSQ-18 was employed in the present study, it would not be feasible to add additional service-specific items, if this was felt appropriate after preliminary analysis, as the questionnaire would be too lengthy for patients. In addition, the CSQ-8 that is a subset of items from the CSQ-18 scale has performed as well as, and often better than, the CSQ-18 in terms of psychometric properties.

Service satisfaction scale (Greenfield and Attkisson 1989)

The service satisfaction scale (SSS-30) was designed to assess multiple factors of service provision with a focus on conceptual factors identified as most important by service users. It is more specific than the CSQ-8 and is better able to differentiate between service related components with a scale that can measure differential levels of satisfaction with several components of the service delivery process. In addition, it also has good psychometric properties. Factor analysis shows there are two subscales, practitioner manner and perceived outcome. The scale was not selected as it was regarded as too lengthy (30 items) and would preclude the adding of anticoagulation service specific items.

Evaluation ranking scale (Pascoe and Attkisson 1983)

The Evaluation Ranking Scale is a multidimensional instrument that gives more information on specific aspects of satisfaction, rather than a global score. Use of the instrument involves patients ranking and rating six dimensions of satisfaction. Patients are given six cards that represent each dimension and are asked to rank the importance of each dimension by placing the dimension cards on a vertical scale displayed on a poster with anchor statements of *Totally unimportant and Extremely important*. Subsequently, patients are asked to rate the absolute and relative quality of the six dimensions. This scale was viewed as too complex for the target population. In addition, completion of the scale would be time-consuming and not feasible in the clinic waiting areas, which was regarded as the most appropriate time and place for questionnaire completion.

Service Evaluation Questionnaire (Nguyen et al. 1983)

The Service Evaluation Questionnaire combines two previously developed scales, the CSQ-8 and the Symptom Checklist SCL-10. The aim of this scale is to not only assess satisfaction in a global way but also to identify areas where patients may be dissatisfied. However, many of the items forming part of the symptom checklist are not applicable to the anticoagulation patient population.

Whilst all these scales have presented satisfactory psychometric properties, the CSQ-8 was identified as the most suitable. The CSQ-8 is of an appropriate length to allow supplementation by items of special interest to a service program (if required), without undue time demand on clients (Larsen et al. 1979), it is suitable for service evaluation and completion in the clinic environment (Attkisson and Greenfield 1994). The CSQ-8 has been widely used in the health services research arena. In addition, the CSQ-8 has repeatedly shown high levels of internal consistency with Cronbach's alpha greater than 0.8 (Attkisson and Greenfield 1995). It is reportedly useful in identifying cases with differential satisfaction scores (Attkisson and Greenfield 1994). The scale produces a global measure of satisfaction; providing a useful overall assessment of satisfaction, although it was not designed to elicit specific aspects of the service/experience with which patients may be discontent. Its unidimensional nature enables straightforward comparison of results between patient groups and service models (Attkisson and Greenfield 1994).

Mode of administration

Issues such as available resources in terms of time and finance, as well as feasibility were taken into account in the selection of the mode of survey administration. Self-administration of the satisfaction survey during anticoagulation clinics was selected despite a number of potential biases being noted. The mode of questionnaire administration may affect results in a number of ways. For example, when surveys are administered during clinics, patients may react positively to the perceived increased attention from staff during the data collection period (Hawthorne effect; Bowling 2002), potentially promoting positive responses (social desirability; Bowling 2002). Conversely, participants may be more critical as they are being surveyed during receipt of the service; literature has shown that timing of survey administration can affect patient response in both directions (Saal *et al.* 2005; Stevens *et al.* 2006). An alternative is to send the survey by post, however this would require sending at least 1000 questionnaires to each site's patients. As Bowling (2002) notes, postal surveys are notoriously time consuming due to the need for repeat administrations as a consequence of frequently experienced initial low response rates and awaiting return of results. Whilst a number of alternatives, (postal, administration during clinic, distributing during clinic for return at next appointment) and factors (sample size, time constraints, introduction of biases) were taken into account, recruitment and administration of the questionnaire in the clinics was regarded as the most appropriate method of data collection as it was relatively simple, inexpensive, time-efficient, and has been shown to yield generally good response rates (circa 90%; Attkisson and Greenfield 2000; Bowling 2002). The investigator had an eight month time frame in which to conduct the developmental phase prior to commencement of the intervention phase, therefore it was important that techniques used were time-efficient. The next section outlines the patient satisfaction survey study that was conducted at BLT and Homerton University (HUH) Hospitals as a tool for informing anticoagulation service development at BLT.

4.2.2 Aims and objectives of patient satisfaction data collection

The aim of the patient satisfaction survey study was to evaluate and compare patients' views of the hospital-based anticoagulation service provided at Barts and the London Trust and Homerton University Hospitals. This was achieved through the operationalisation of the following objectives:

- Collection of data related to evaluation of patients' satisfaction with the traditional anticoagulation services offered at The Royal London, London Chest and St. Bartholomew's Hospitals (BLT) and at Homerton University Hospital, through completion of a semi-structured, self-administered satisfaction questionnaire by patients.
- Through analysis of data and comparison of data from the different Trusts, key areas of the BLT anticoagulation service to be prioritised for service development were identified.

4.2.3 Methods

A self-completion semi-structured questionnaire measuring patient satisfaction was administered to anticoagulation patients attending outpatient anticoagulation clinics at BLT and HUH. These two hospitals were included to compare levels of patient satisfaction between the traditional service model using venous sampling (BLT) and the more recent model utilising NPT (HUH). The supposition was that the different organisation and operations of the clinics may produce different levels of satisfaction and that different issues may emerge from patients receiving the different services, as the clinics represent both similar and dissimilar experiences for their attendants. These differing experiences and the resultant differing levels of satisfaction could be used to inform service developments.

At the time of data collection, the BLT anticoagulation clinic provided the traditional anticoagulation service model, which involved patients' blood samples being obtained via venous sampling and INR analysis carried out within hospital laboratories. HUH anticoagulation clinic provided a one-stop service, with patients' having a capillary sample obtained by a lancet system and INR analysis using a NPT device. Figure 4.3 and Figure 4.4 summarise operation of clinics.

Figure 4.3: Clinic operation at BLT anticoagulation clinic

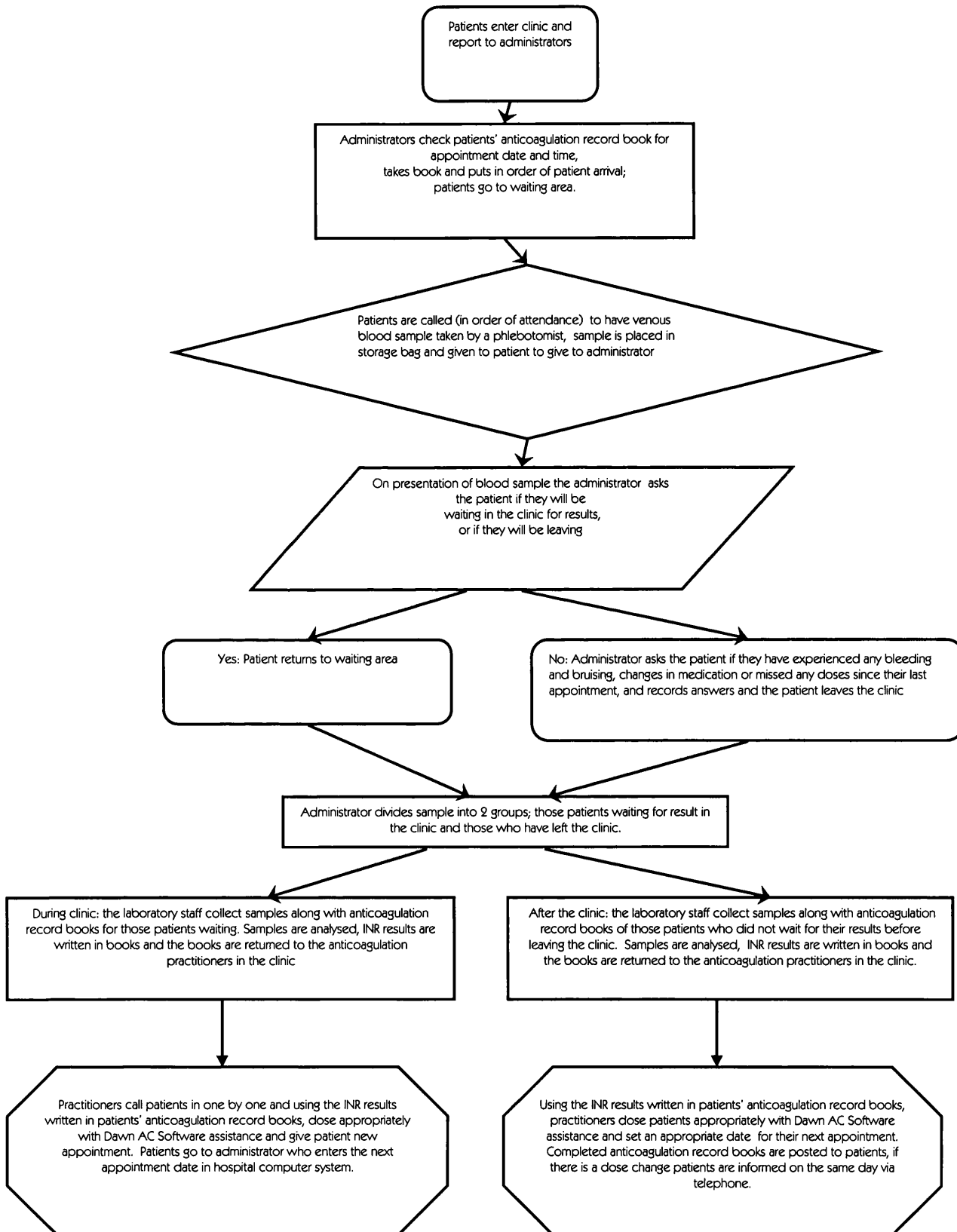
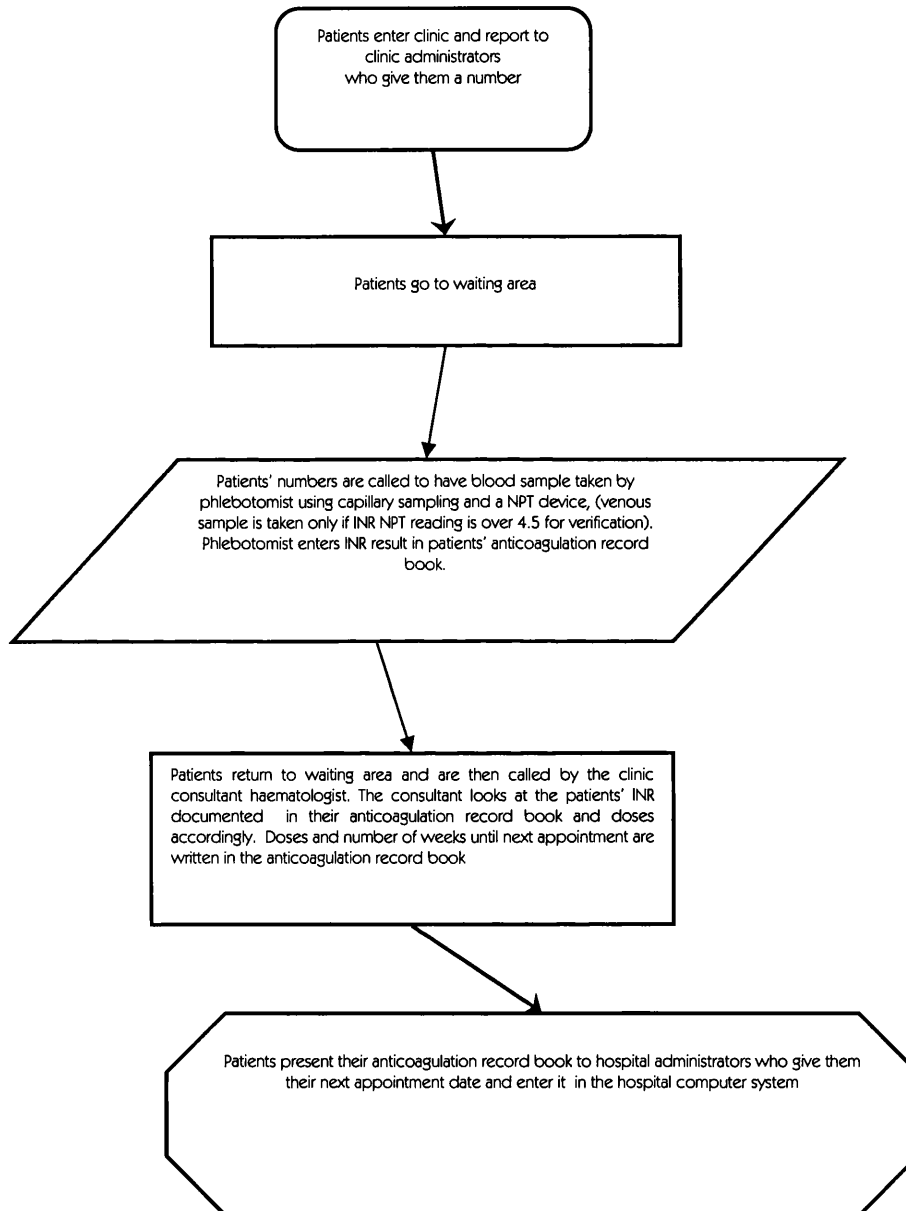


Figure 4.4: Clinic operation at HUH anticoagulation clinic



Development of additional items for the survey

Following preliminary analysis of the CSQ-8 data, it was observed that responses were negatively skewed, suggesting that patients were largely satisfied with the current anticoagulation service without much discrimination. Further, as anticipated due to the generic nature of the CSQ-8 questionnaire it was unable to allow the identification of specific factors or areas of service that were barriers to increasing levels of satisfaction for all patients. In order to identify specific development areas, the investigator and anticoagulation team developed additional items related specifically to the anticoagulation service (Appendix 2 for questionnaire format), using a four point Likert scale, similar to that used in the CSQ-8 questionnaire. Patients' written comments in the optional comments section and the anticoagulation team's experience of working in the clinic were used as sources of evidence for the development of additional items. The CSQ-8 and the additional items were administered at the same time, the concept being that CSQ-8 scores would be used as a global measure of patients' satisfaction, whilst the additional items would be used to pin point and prioritise development areas. Developed items were piloted on a random sample of 30 patients to assess the readability of the items; following pilot analysis and interviews with the respondents no issues were identified, therefore the items were not altered.

Patient groups for administration of satisfaction questionnaire

Patients attending BLT anticoagulation clinics can be divided into three groups; see Table 4.3.

Table 4.3: Patient groups attending BLT anticoagulation clinics

Group	Clinic Activity	Questionnaire Administration
Group 1 - non-transport, non-postal patients	Patients make their own way to the clinic and following INR testing, wait for their results and dosing.	CSQ - 8 Seven additional service specific items Optional comments box
Group 2 - postal patients	Patients make their own way to the clinic, but do not wait for their results; subsequently their results are posted to them.	CSQ - 8 Seven additional service specific items Two extra specific items relating to the postal service Optional comments box
Group 3 - transport patients	Mobility – impaired patients use the hospital ambulance service to make their way to and from the clinic.	CSQ - 8 Seven additional service specific items Three items relating to the hospital ambulance (transport) service Optional comments box

The sample was recruited across the three groups and patients were given the appropriate questionnaire (Table 4.3 and Appendix 2 for details of additional items). There are no postal patients in the HUH clinic as patients receive their INR results within three minutes of being tested, dose consultation happens relatively quickly and there is a fast turnover of patients, therefore only group 1 (non-transport, non-postal) and group 3 (transport) patients attend HUH clinics.

Open section of questionnaire

At the end of the structured section of the questionnaire, respondents were asked to make any additional comments; this open ended section allowed respondents to answer fully and freely. Participants were able to raise any issues that were not addressed in the structured part of the questionnaire. The aim of this qualitative section was to verify and add context to the quantitative data from the structured portion of the survey. A pragmatic approach was utilised, to identify emerging themes. Questionnaires containing respondents' comments were collated and comments were transcribed. The investigator read transcripts and produced brief notes to assist the process of coding emerging topics (inductive analysis). Subsequently, a second investigator also analysed the data, making notes on concepts/categories that became apparent. Due to the small scale of the study and the brevity of the responses, it was not deemed necessary to use qualitative computer software; manual categorisation was employed instead. The computer was utilised to store, identify and manually assign codes to the comments.

The initial processing of data involved the indexing of comments; section labels were applied to patients' transcripts to aid in subsequent identification of sections of texts. Following this, the investigator carried out content analysis of the data and produced further notes on transcripts. Succinct statements were utilised as codes (in-vivo coding) for selected words and phrases that explained participants' feelings as part of the data reduction process. Subsequently, these statements were organised into groups that denoted the emergent themes. Throughout the process, themes were adapted and explanations for attitudes/perceptions/feelings were sought. The process of questionnaire administration, data collection, analysis and interpretation was undertaken in the same manner throughout the study at both BLT and HUH sites; in an attempt to ensure reliability and minimise sources of bias and error. To ensure credibility a second investigator validated the themes, codes and identification indices through conducting a separate content analysis.

4.2.3.1 Sample

At the time of data collection, the estimated clinic caseloads estimated by clinic staff were 1500 patients at the BLT and 1000 patients at the HUH. The sample size was a balance between accuracy and practicality. A third of the population were recruited to the sample as this would give a good level of accuracy and was achievable with the resources available. Therefore, a

convenience sample of the first 500 patients attending the BLT clinic and the first 350 attending the HUH clinic was recruited.

4.2.3.2 Patient Recruitment

CSQ-8 authors recommend that the recruitment period should be at least two standard service weeks, and that this method has the advantage of capturing all cases, except those not attending appointments throughout the period and not accepting the invitation to participate (Attkisson and Greenfield 1994). In addition, authors comment that questionnaire completion rates are often above 90% when this method is employed, compared to approximately 45% when posted even after follow-up, minimising the risk of unknown response bias (Attkisson and Greenfield 1994).

Data were collected at both sites using a standardised procedure to enable comparison. A four week period at each site was used to gain a census sample (that is sample all those attending the clinic in this time frame) at each site as recommended by CSQ – 8 authors (Attkisson and Greenfield 2000); every patient attending the anticoagulation clinics was asked during this period. Posters giving information about the study were displayed in the clinic areas. During clinic times, patients were approached and invited to participate by the investigator whilst they were waiting to have their blood sample taken. They were given verbal and written information about the study by the investigator and asked if they would be willing to complete the questionnaire. Following receipt of patient consent questions to identify which group a patient belonged to (for example a postal patient) were asked, patients agreeing to participate were given the appropriate questionnaire. Patients completed the questionnaire whilst waiting in the clinic area and returned completed questionnaires to the investigator or members of the anticoagulation team. Patients with reading or writing difficulties were helped to complete the questionnaire; the investigator would either read the questionnaire out to the patients and/or circle patients' answers to items. Patients identified as unable to communicate in English were excluded from the survey. The CSQ – 8 has been translated into a number of languages, including French, Spanish and Dutch (Attkisson and Greenfield 2000). However it has not been translated into Kurdish, Bengali or Urdu, some of the dominant languages of the non-English speaking population in East London. Data collection commenced on the 3rd of October 2002 in BLT and on the 18th of March 2003 in HUH.

4.2.3.3 Data processing

Data from questionnaires and background patient data were entered on and analysed with the support of the Statistical Package for Social Sciences (SPSS for Windows 2001) version 11.0. Data was verified through running of frequencies and an accuracy check of a random 10% of cases in the database. There is no widely agreed error rate for quantitative databases; following discussion with investigators, an error rate of less than or equal to one percent was deemed to be acceptable. Data that was normally distributed was analysed using parametric statistics. Data that was not normally distributed was analysed using non-parametric statistics. To explore the predictive power of the specific items (variables) and patients' ages on the global score of satisfaction as assessed by the CSQ scale multiple linear regression was performed.

4.2.3.4 Missing values

It has been suggested for scale measurements that if between 10% and 50% of items are missing (dependent on number of items) the case should be excluded from analysis (Bryman and Cramer 1997). CSQ has 8 items, therefore a more lenient approach than 10% was required, whilst including cases with 50% missing values, would be too lenient as this would result in potential problems with data analysis and reliability of results. Where cases had no more than two missing values they were retained, if more than 2 items (25%) had missing data the case was excluded from the analysis. Following advice from the developer of the CSQ-8, missing values were replaced with the mean value for the entire series (series mean) and retained in the database (see also page 133).

4.2.4 Results

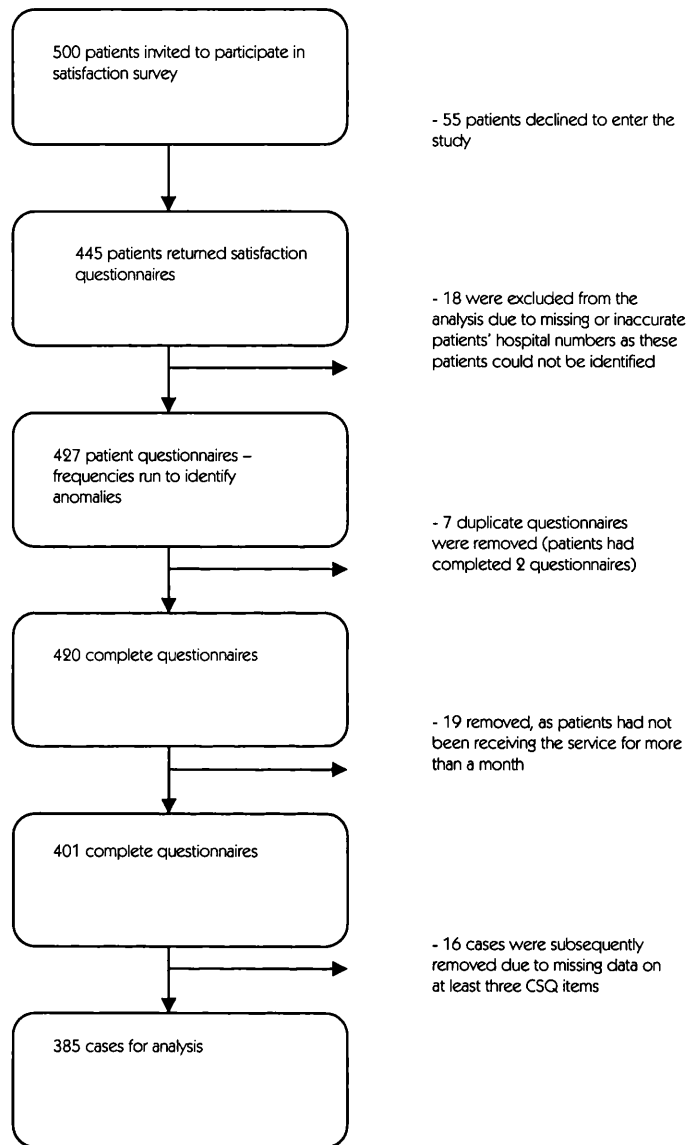
The number of patients invited to participate in the patient satisfaction study at BLT was 500, of these 445 (89.0%) patients accepted. Following a relatively high refusal rate at HUH (22.6%), the investigator continued data collection until approximately a third of the patients at HUH had completed questionnaires, rather than stopping when a third of the patients had been approached. The high refusal rate may have been due to the fast turn around of patients at the HUH clinic. The number of patients invited to participate in the satisfaction survey at HUH was 478, of this 370 (77.4%) patients accepted.

4.2.4.1 Data cleaning and quality assurance - BLT data

Patient background data were accessed using the 4S Dawn Computer dosage support software (CDSS) used by the clinic's practitioners, to ascertain patient date of birth, sex, primary indication for warfarin and the date the patient started warfarin.

Of the 445 returned questionnaires, 18 (4.0%) were excluded from the analysis due to missing or inaccurate hospital numbers as these patients could not be identified. Frequencies identified any outlying values through range checking; two errors were identified at this stage: one CSQ item had been entered as 93 instead of nine and a patient's treatment start date was the same as their date of birth; both were rectified using the original data. Seven patients had "completed" the questionnaire twice, so duplicate questionnaires were removed. This left 420 (94.4%) complete questionnaires. Of the remaining 420, 19 (4.5%) were removed as patients had not been receiving the service for more than a month; it was perceived that these patients had not received the service for long enough before being asked about satisfaction. In addition, 16 (3.8%) cases were subsequently removed due to missing data on at least three CSQ items, which left 385 (86.5%) cases for analysis (Figure 4.5). The final database comprised 17325 entries. Each variable on a random sample of 10% of the cases was verified for accuracy; one error was identified, the CSQ item was entered in as four when it should have stated three, the error was rectified (error rate 0.06%; judged to be acceptable).

Figure 4.5: BLT patient satisfaction questionnaires



4.2.4.2 Data cleaning and quality assurance - HUH data

Patient background data were accessed using individual hand-written patient record cards used by the clinic's consultant haematologists, to ascertain patient date of birth, sex, primary indication for warfarin and the date the patient started warfarin. In many cases, the required data were not present on the cards. When the sex and/or date of birth were missing, these were confirmed using the hospital's electronic patient record. However, other relevant data (i.e. indication, start date) were not available on the electronic records.

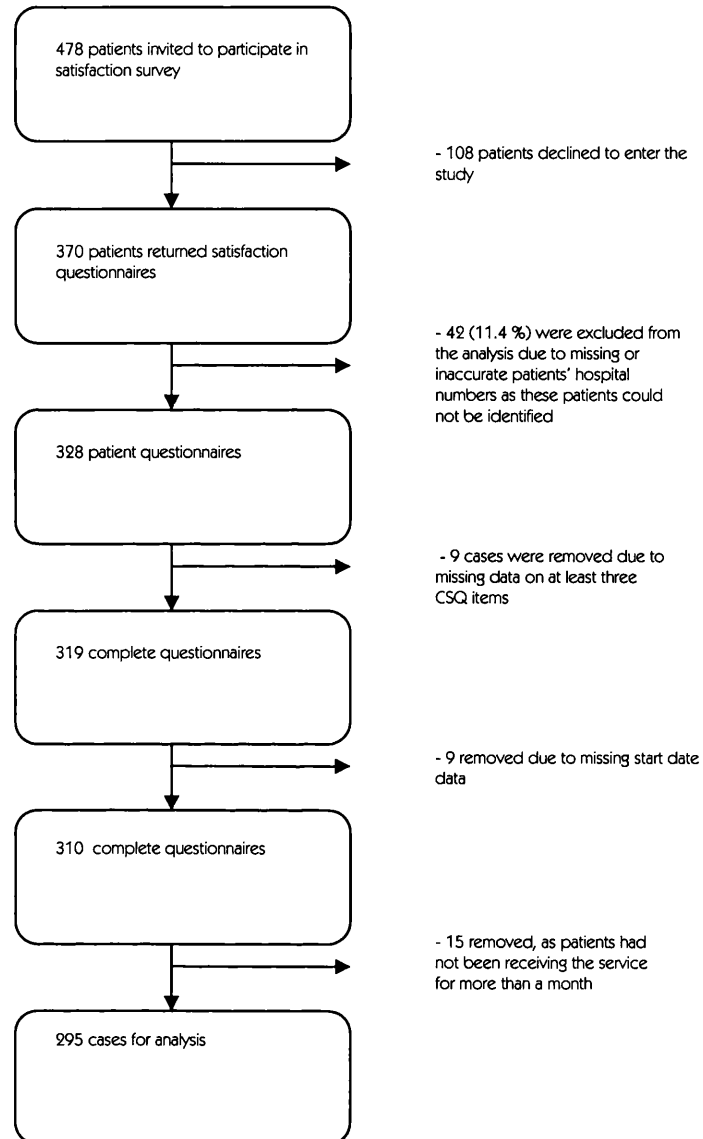
Of the 370 completed questionnaires:

- 42 (11.4%) were excluded due to missing or incorrect hospital numbers
- 9 (2.4%) were removed due to missing patient start date data
- 9 (2.4%) were removed due to non-completion of three or more items
- 15 (4.1%) were removed as patients had been receiving the service for less than a month

This left 295 (79.8%) cases for analysis (Figure 4.6). The final database comprised 13725 cases. The investigator initially verified each variable in the database to identify any obvious errors. Errors in dates of birth were identified, due to the date being entered in a dd/mm/yy format, for instance, 14/03/32 was read as 14/03/2032 instead of 14/03/1932. The investigator corrected these errors by reformatting the date into the dd/mm/yyyy format and correcting each error case individually.

Subsequently, frequency statistics were run to identify any further abnormal or outlying values; none were identified. A random sample of 10% of the cases in the database was taken and double checked for accuracy. One error on date of birth was identified, this was rectified (error rate 0.08%; judged to be acceptable).

Figure 4.6: HUH patient satisfaction questionnaires



4.2.4.3 Patient background data

Data analysis was carried out with 385 cases for BLT data and 295 cases for HUH data. There was a significantly higher proportion of female patients (56.3%, $\chi^2 = 4.641$ df=1 $p=0.031$) than male patients at HUH, compared to 44.7% ($\chi^2 = 4.366$ df=1 $p=0.037$) in the BLT data set; (χ^2 df=1, $p=0.003$, two sided). Reasons for the difference in gender split are unclear, it may be that male patients in the HUH area are not presenting to their GP with relevant health issues or are not receiving anticoagulation therapy when it is indicated. This difference is of importance as the male gender is a risk factor for a number of thrombotic conditions, including stroke (Lip *et al.* 2002)..

Both samples showed negatively skewed age distributions (Figure 4.7 and Figure 4.8) with the overall median age being 69.6 years. There was no significant difference in the median ages of patients between sites (BLT, 70.5 years, range 21.1 – 94.5 years; mean age=66.5 years; HUH, 68.1 years, range 21.5 - 94.6 years; mean age=66.0 years; Mann Whitney U=55084.0; $p=0.502$, two tailed). In addition there was no significant difference in the median duration of treatment of patients at both sites (overall, 3.0 years; BLT, 3.1 years, mean=5.1 years, range 1.1 month to 394.0 months; HUH 3.0 years, mean=4.2 years, range 1.0 month to 241.0 months; Mann Whitney U=53967; $p=0.267$, two tailed; Figure 4.9 and Figure 4.10).

Figure 4.7: Age distribution for BLT anticoagulation patients

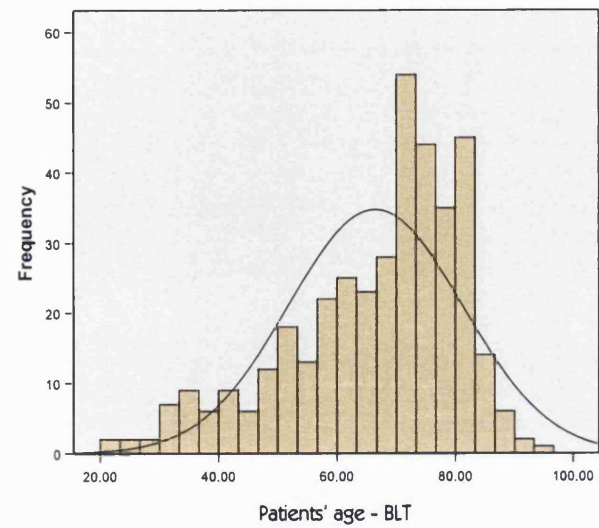


Figure 4.8: Age distribution for HUH anticoagulation patients

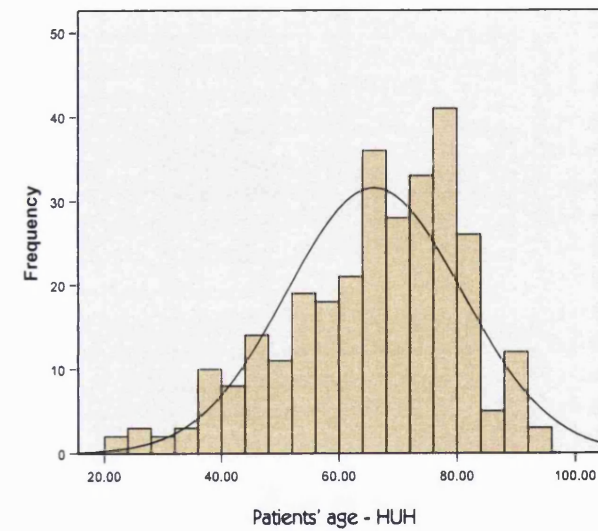


Figure 4.9: Duration of treatment distribution for BLT anticoagulation patients

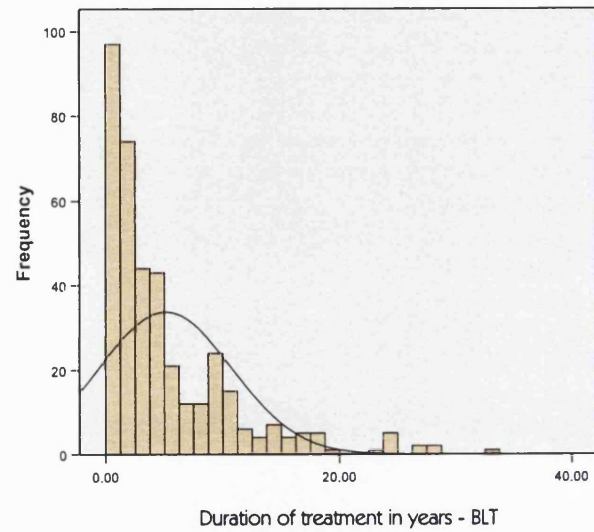
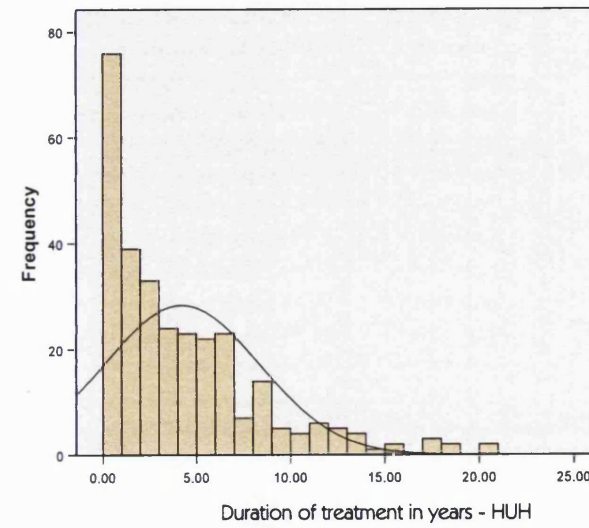


Figure 4.10: Duration of treatment distribution for HUH anticoagulation patients



At BLT, the most common indication for warfarin was AF; 54.8% of patients had this as their primary indication. Valve replacements were the next most common indication (12.2% patients). Details of all remaining indications are in Table 4.4. Similarly, AF was the most common indication at HUH, accounting for 54.9% of cases, followed by Deep Vein Thrombosis (DVT) which accounted for 14.6% of indications. Details of all remaining indications are summarised in Table 4.4. When the primary indication was split into AF or not AF, there was no significant difference in the number of patients receiving warfarin for AF between sites (χ^2 df=1, $p=0.977$, two sided). The similarities seen in age, duration of treatment and indication are not surprising as the Trusts are situated close to each other (neighbouring Trusts) and serve similar populations. Due to the similarities between the groups any differences in the findings are more likely to be due to differences in service provision rather than population differences. The most common indication for anticoagulation for both Trusts was AF, the incidence of which increases with increasing age, therefore the older age of patients was expected. Dichotomisation of the other main indications showed a significant difference in the proportions of patients receiving warfarin for PE and for valve replacements (Table 4.4). These differences may indicate a difference in the incidence of these conditions in residents of the two Trusts, or may be due to differences in prescribing trends and management strategies for conditions between the Trusts.

Table 4.4: Comparison of Indication for warfarin in the study sites

Trust	Indication	No (%)	P value
BLT	Atrial Fibrillation	211 (54.8)	0.977
HUH		162 (54.9)	
BLT	Aortic valve replacement / Mitral valve replacement	47 (12.2)	0.028
HUH		21 (7.1)	
BLT	Deep vein thrombosis	39 (10.1)	0.078
HUH		43 (14.6)	
BLT	Pulmonary embolism	32 (8.3)	0.042
HUH		13 (4.4)	
BLT	Cerebral vascular accident	10 (2.6)	0.722
HUH		9 (3.1)	
BLT	Antiphospholipid syndrome	6 (1.6)	0.828
HUH		4 (1.4)	
BLT	OTHER (including Homozygous V leiden, Myocardial infarction, Protein C deficiency)	40 (10.4)	0.083
HUH		43 (14.6)	
BLT	TOTAL	385 (100)	-
HUH		295 (100)	

4.2.4.4 Patient groups and CSQ results

There was no significant difference in the median CSQ scores for patients at BLT (28.0, mean 27.8, range 14-32) and HUH (29.0; mean 27.8, range 15-32; Mann Whitney U, $p=0.879$, two tailed, Figure 4.11 and Figure 4.12. Of the 385 BLT respondents, 374 (97.1%) scored above the arithmetic median of 20, whilst 220 (57.1%) scored highly when the CSQ score was split around the actual median (28.0). Of the 295 HUH patients, 287 (97.3%) participants were classed as high scorers, when the CSQ score was dichotomised by the arithmetic median of 20, with 148 (50.2%) scoring highly when the CSQ score was split around the actual median (29.0). There was no significant difference between the proportion of high scorers attending HUH and BLT anticoagulation clinics (χ^2 $df=1$, $p=0.889$, two sided). These high scores indicate that both patient populations were largely satisfied with the anticoagulation services provided.

At both sites gender had no affect on CSQ scores (BLT: male 29.0, mean 27.8; female 28.0, mean 27.8; Mann Whitney U $p=0.990$, two sided; HUH: male 29.0, mean 27.9; female 28.8, mean 27.7; Mann Whitney U $p=0.799$, two sided). A weak, but statistically significant correlation between age and CSQ score (Spearman's $\rho=0.183$, $p<0.001$, two tailed), was observed at BLT, suggesting that age had a small affect on patient satisfaction, whereas age did not appear to influence patients' satisfaction with the anticoagulation service at HUH; (Spearman's $\rho=0.108$, $p=0.065$, two tailed), reasons for this difference are unclear.

No significant associations were found between patient satisfaction and the number of years receiving anticoagulation therapy at either site (BLT: Spearman's $\rho=0.097$, $p=0.058$, two tailed; HUH: Spearman's $\rho=0.097$, $p=0.280$, two tailed).

Figure 4.11: Distribution of CSQ scores – BLT patients

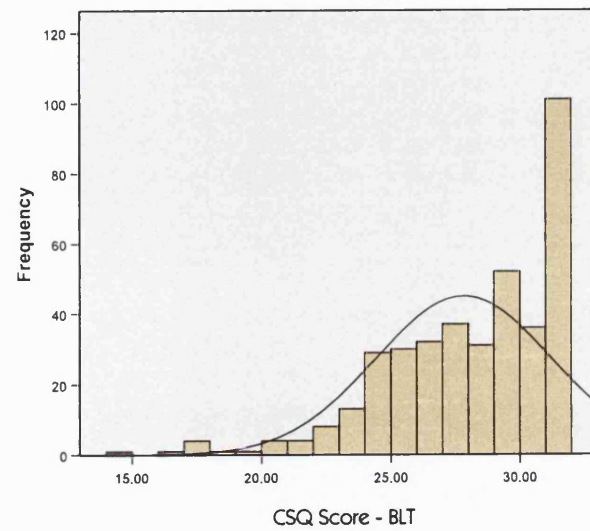
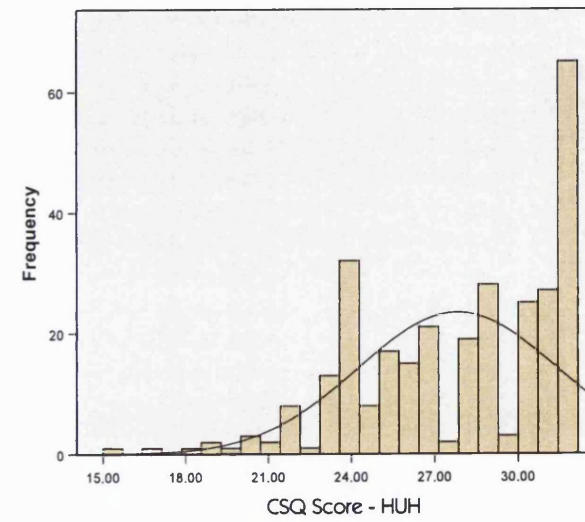


Figure 4.12: Distribution of CSQ scores – HUH patients



Of the 385 BLT patients, 100 (26.0%) were identified as postal patients, 72 (18.7%) as transport patients and 70 (18.1%) as non-transport or non-postal the remaining (143, 37.1%) were unidentified. This was due to the fact that initially the CSQ-8 was administered without the additional items; therefore patient groups were not identified at the time. Where patients' group could not be identified, it was established that they were either non-transport - non-postal patients or postal patients, as all transport patients had been assigned to a special code on the CDSS software for ease of identification by the anticoagulation practitioners. It is also important to note that the non-transport - non-postal and postal groups were not definitive with patients opting to wait for results at times and to leave the clinic after their blood tests at other times. When the three patient groups were compared in terms of age, there was a significant difference (Table 4.5).

Patients not waiting for their results (postal; median age 63.4 years, mean 61.5, range 24.2 to 85.8 years) tended to be the youngest and patients requiring the hospital ambulance service to transport them to the clinic (transport; median age 77.0 years, mean 76.2, range 35.1 to 94.5 years) tended to be the oldest. The median age of non-transport, non-postal patients was 70.9 years (mean 67.3, range 27.3 to 87.1 years).

Table 4.5: Comparison of mean ages across patient groups at BLT

Comparisons	P Value
Three groups	Kruskal Wallis: $\chi^2 = 47.163$, $df=2$, $p < 0.001$
Postal versus Transport	Mann Whitney U, $P < 0.001$
Postal versus Non-transport, non-postal	Mann Whitney U, $P < 0.001$
Transport versus Non-transport, non-postal	Mann Whitney U, $P < 0.001$

Of the 295 HUH patients, 45 (15.3%) were identified as transport and 250 (84.7%) were identified as non-transport. Again, there was a significant difference in the median age of the patient groups, with transport patients tending to be older than non-transport patients (Transport = 75.8 years, mean = 75.6 years range 51.4 to 92.5 years; Non-transport = 66.3 years, mean = 64.3 years range 21.5 to 94.7 years, Mann Whitney U $p < 0.001$).

The older age of the transport patients was not surprising as a reduction in mobility is more likely with increasing age. At BLT there was no significant difference in duration of treatment across the different patient groups (Kruskal Wallis test, $\chi^2 = 0.384$ $df=2$ $p=0.825$). Similarly, at HUH, there was no significant difference in the duration of anticoagulation treatment between the two groups (Mann Whitney U test; $p=0.262$). There was no significant difference between the CSQ scores of

the different patient groups within the two study sites (BLT: Kruskal Wallis test, $\chi^2 = 1.56$ df=2 $p=0.458$; HUH: Mann Whitney U test; $p=0.553$; Table 4.6). This suggests that the differences in service delivery to the various patient groups did not affect the patients' satisfaction. Further, there was no significant difference in CSQ scores of transport patients and non-transport, non-postal patients between the two sites (Table 4.6).

Table 4.6 Median CSQ score of different patient groups in BLT and HUH

Trust	Patient Group	Median CSQ Score	Mann Whitney U (significance two tailed)
BLT	Non-transport, non- postal	29.0 (mean 28.1, range 16-32)	0.578
HUH		28.0 (mean=27.8; range 15-32)	
BLT	Postal	28.0 (mean 27.5, range 17-32)	N/A
BLT	Transport	28.0 (mean 28.2, range 18-32)	0.866
HUH		29.0 (mean=28.2; range 20-32)	

Overall the Cronbach's alpha for the whole CSQ-8 data set was 0.844 (BLT 0.834; HUH 0.858), this compares favourably with that found in other studies (Attkisson and Greenfield 1995), and indicates strong levels of internal consistency of the validated client satisfaction questionnaire. In addition, it suggests that the scale measures patients' global satisfaction with anticoagulation services in the population sampled in a useful way.

4.2.4.5 Median CSQ score when item values missing

Under the advice of the authors of the CSQ questionnaire, a comparison of the median CSQ score without replacing missing items, for those cases that were used for analysis and the median CSQ score when items were replaced was performed (See also page 120, missing values).

There were no changes in the median CSQ scores when they were calculated without replacing missing values (Table 4.7). In addition, when the two median CSQ scores that had not had individual items replaced were compared between HUH and BLT there was no significant difference (Mann Whitney U, $p = 0.667$). In this way replacing missing values did not adversely affect the results of the analysis and increased the number of cases included in the analysis.

Table 4.7: Comparison of CSQ-8 scores when missing values are replaced and when missing values are not replaced – Developmental Phase

Trust	CSQ without replacing missing values	CSQ score with missing values replaced	Mann Whitney U (significance two tailed)
BLT	28 (mean 27.6, n=362)	28 (mean 27.8, n= 385)	0.460
HUH	29 (mean 27.4; n= 267)	29 (mean 27.8, n= 295)	0.411

4.2.4.6 Service specific items analysis for BLT and HUH patients

This section outlines the results for a number of the responses to the additional service specific items developed by the investigator and the BLT anticoagulation team.

The Cronbach's alpha for the first seven individual items (i.e. excluding postal and transport specific items) was 0.552 for the 470 cases that had completed those items, indicating poor internal consistency. When there is poor internal consistency it indicates that the items are not measuring one construct, but may in fact be touching upon a number of different dimensions. Therefore it would be inappropriate to group these items together in the same way as the CSQ items as they are not related, for this reason, the items were analysed separately.

A statistically significant difference was found between the responses of patients at BLT and HUH for the items relating to waiting times in clinic, blood sample method and one of the transport specific items (Table 4.8).

Table 4.8: Mann Whitney U test for ranks of individual items between HUH and BLT

Variable	Which Trust patients are from	N	Mean Rank	U	Significance (two-tailed)
Waiting time in clinic	BLT	145	192.93	17389.500	0.004
	HUH	285	226.98		
How easy to get to clinic	BLT	139	217.87	18227.000	0.268
	HUH	279	205.33		
Blood sample from vein on arm/finger	BLT	142	202.40	18588.000	0.014
	HUH	286	220.51		
Satisfaction with staff taking blood	BLT	144	213.42	20292.000	0.858
	HUH	284	215.05		
Instructions about what to do between visits	BLT	142	214.32	19905.500	0.827
	HUH	283	212.34		
Environment where the service is provided	BLT	143	224.34	18827.500	0.119
	HUH	284	208.79		
How long before transport picks you up	BLT	35	45.64	572.500	0.041
	HUH	44	35.51		
How long does it take them to drop you home	BLT	35	44.03	629.000	0.149
	HUH	44	36.80		
Has the transport ever failed to pick you up	BLT	35	39.63	757.000	0.876
	HUH	44	40.30		

Clinic waiting times

Patients were asked how long they waited in the clinic, the possible responses were, always long, sometimes long, rarely long and never long. Of the 145 BLT respondents, 40.7% stated 'sometimes long' with a further 19.3% reporting 'always long' (Figure 4.13). Of the 285 HUH respondents, 43.2% reported 'sometimes long' with a further 4.6% stating 'always long' (Figure 4.14). The significant difference between BLT and HUH respondents views regarding clinic waiting times was not surprising as the clinics operate differently which leads to differences in the likelihood of long waiting times (Figure 4.3 and Figure 4.4). Patients at BLT who wait for their results have to wait for their blood samples to be taken in bulk to the laboratory, wait for their INR results to be determined in the hospital laboratory, the results to be returned in bulk to clinic staff and then wait for practitioners to advise them of their INR result and the required weekly dose of warfarin. The waiting time is often dependent on the workload of the laboratory, which also deals with the processing of samples for the whole hospital. At HUH, once patients' blood sample has been taken via capillary sampling and immediately tested via an NPT device, results are produced within three minutes. Patients then wait to see the consultant who advises them of their INR result and the required weekly dose of warfarin. The faster processing of the INR results at the HUH clinic leads to a reduction in the average length of time a HUH patient spends in the clinic compared to a BLT patient. It appears that this difference in waiting is reflected in the difference seen between the HUH and BLT patients' response to this item.

Method of blood sampling

Patients were asked how they felt about the way their blood sample was taken, for BLT patients this referred to venous sampling, for HUH patients, this referred to capillary sampling. The possible responses were, 'I definitely dislike this way', 'I quite dislike this way', 'I do not generally mind this way' and 'I do not mind this way at all'. Of the 142 BLT respondents, 81.7% stated that they did not mind the method at all (Figure 4.15). Of the 286 HUH respondents, 89.9% stated that they did not mind the way their blood sample was obtained at all (Figure 4.16). This represented a significant but unsurprising difference between the results. Capillary sampling is a much less invasive method of blood sampling requiring a much smaller volume of blood (10 – 50 μ l) compared to venous sampling, which is more invasive and requires approximately 3 – 5 ml of blood. In addition, many elderly patients have weak veins making venous sampling a more difficult and painful process than capillary sampling (Zimmerman 2000).

Satisfaction with staff taking blood

Patients were asked how satisfied they were with the staff taking the blood samples. Possible responses ranged from always satisfied to always dissatisfied. Of the 144 BLT respondents, 77.1% stated they were always satisfied (Figure 4.17), compared to 78.2% of the 283 HUH respondents (Figure 4.18). There was no significant difference between these results; this suggests that the differences in patients' responses to blood sampling were indeed attributable to the sampling method rather than differences in patients' perceptions of the phlebotomy staff and their technique.

Explanation about what to do between visits

Patients were asked how clear instructions of what to do between appointments were. Possible responses ranged from always clear to never clear. There was no significant difference between the results with 78.9% of the 142 BLT respondents stating that instructions were always clear (Figure 4.19), compared to 77.7% of the 283 HUH respondents (Figure 4.20). This result was interesting, the BLT clinic has on average four practitioners at the clinic seeing patients, whereas the HUH clinic operates with one consultant seeing every patient. This is likely to result in HUH patients getting a shorter amount of time with the consultant to discuss their anticoagulation treatment compared to BLT patients as the workload of dosing and advising patients is spread across four practitioners, however this difference did not appear to impact patients' satisfaction with the dosing instructions they received.

Transport related item – transport collecting patients from home

Transport (mobility-impaired) patients were asked how long they waited for the hospital transport service to pick them up for their outpatient anticoagulation appointment, responses ranged from 'always long' to 'never long'. Of the 35 BLT respondents to this question, 40.0% stated they never waited long, and 31.4% reported that they sometimes waited long (Figure 4.21). Of the 44 HUH respondents, 13.6 % stated they never waited long and 38.6% reported that they sometimes waited long (Figure 4.22). There was a significant difference in these results with HUH patients being less satisfied than their BLT counterparts. The transport service at BLT and HUH operate in the same way, it does not appear that the HUH service operates with more delays than the BLT service. The difference observed in these results may reflect differences in the proportion of time spent waiting for the transport. As the HUH service is a faster service, the wait for the transport to pick patients up may represent a larger proportion of the time involved in the whole appointment

process. At BLT waiting times are longer therefore waits for transport may represent a smaller proportion of the overall time involved in meeting their anticoagulation appointment.

Transport related item – failure of transport to collect patients from their homes

Transport patients were asked if the transport service ever failed to pick them up for their outpatient anticoagulation appointment, responses ranged from 'never' to 'often'. Of the 35 BLT respondents to this question, 68.6% stated never with a further 14.3% stating rarely and another 14.3% reporting sometimes (Figure 4.23). Of the 44 HUH respondents, 68.2% stated never with a further 22.7% stating rarely and 4.5% reporting sometimes (Figure 4.24). These data suggest that while the purpose of providing transport to these patients is to ensure that they do not miss much needed anticoagulation monitoring appointments, at times they are unable to attend the clinic. Reasons for the failure of transport to pick patients up are unclear but it is proposed to be communication issues between the anticoagulation team and the transport service team.

Figure 4.13: Waiting times – BLT patients

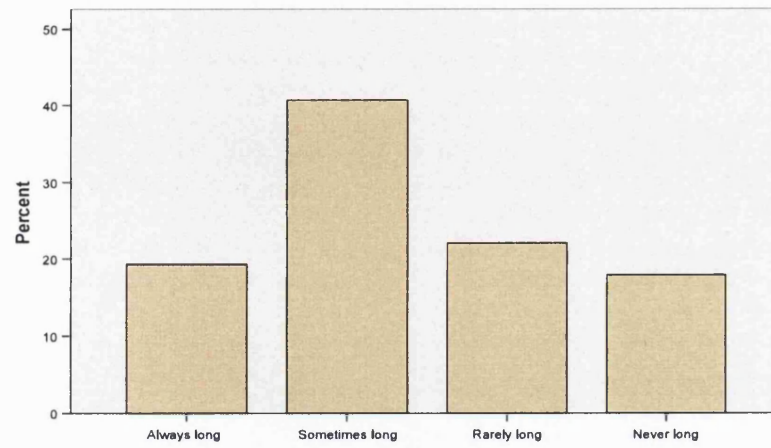


Figure 4.14: Waiting times – HUH patients

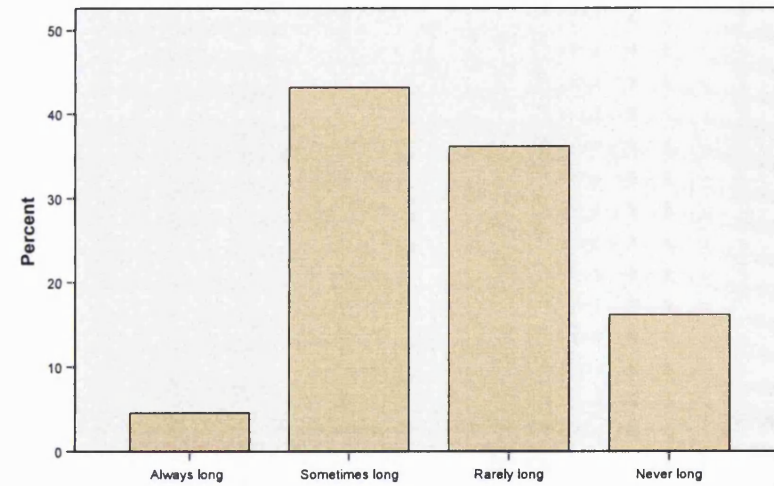


Figure 4.15: Blood sample method – BLT patients

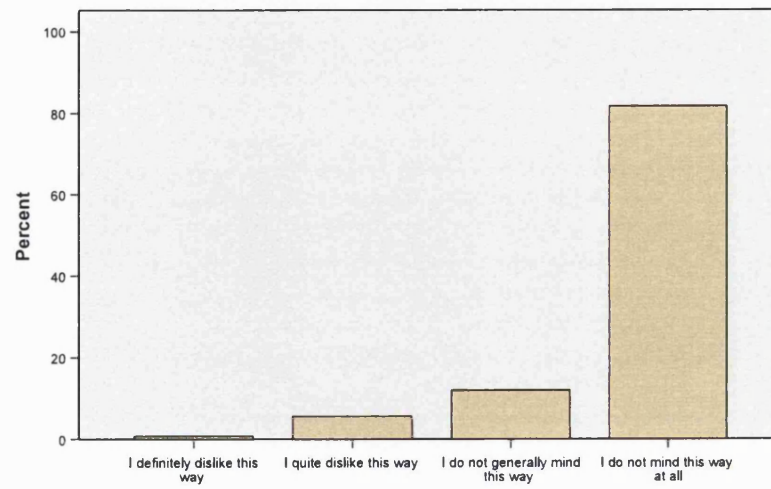


Figure 4.16: Blood sample method – HUH patients

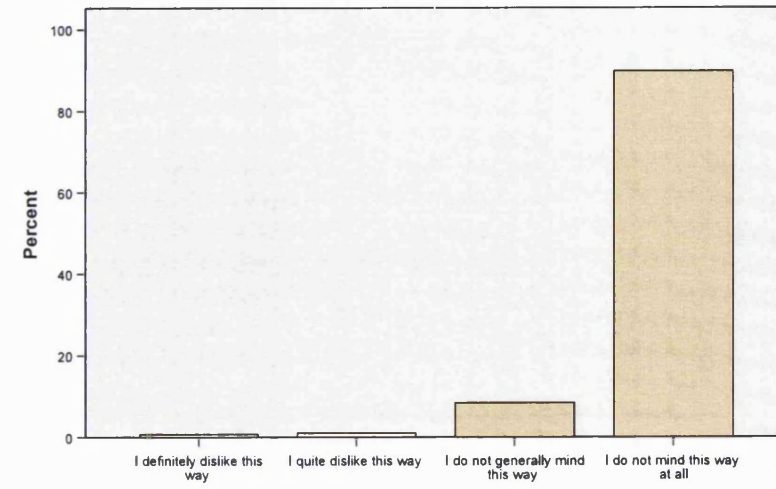


Figure 4.17: Satisfaction with staff taking blood – BLT patients

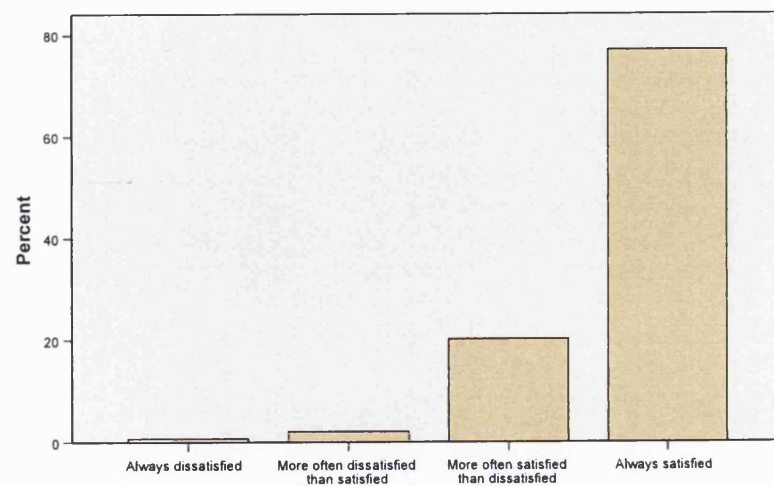


Figure 4.18: Satisfaction with staff taking blood – HUH patients

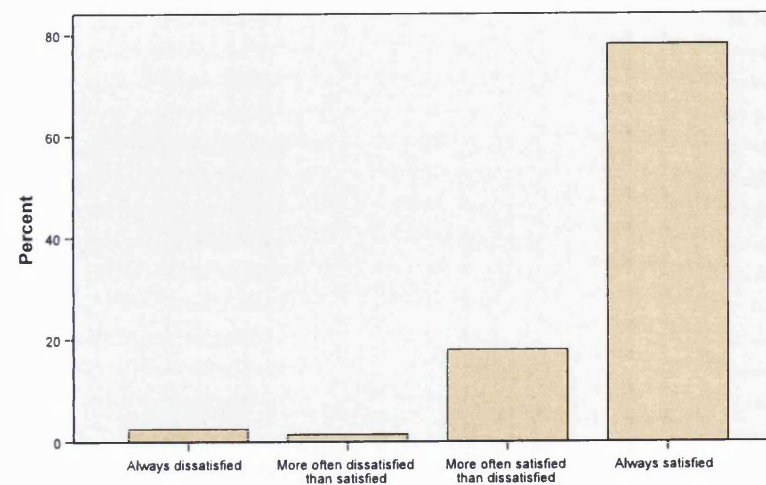


Figure 4.19: Clarity of explanation about what to do between visits – BLT patients

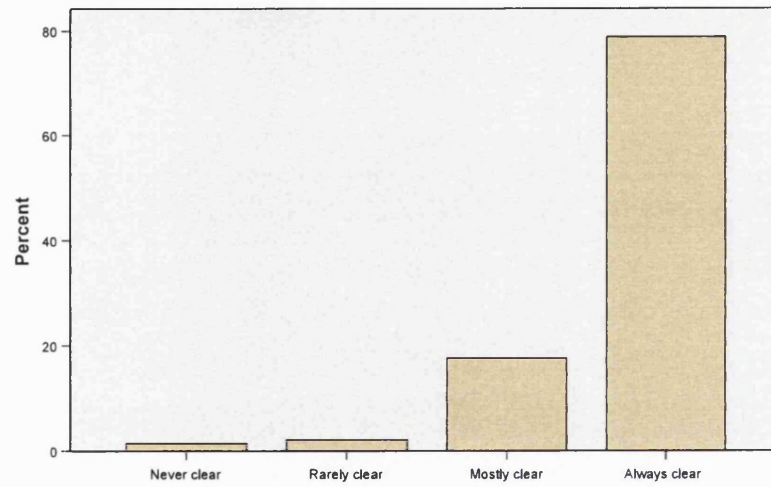


Figure 4.20: Clarity of explanation about what to do between visits – HUH patients

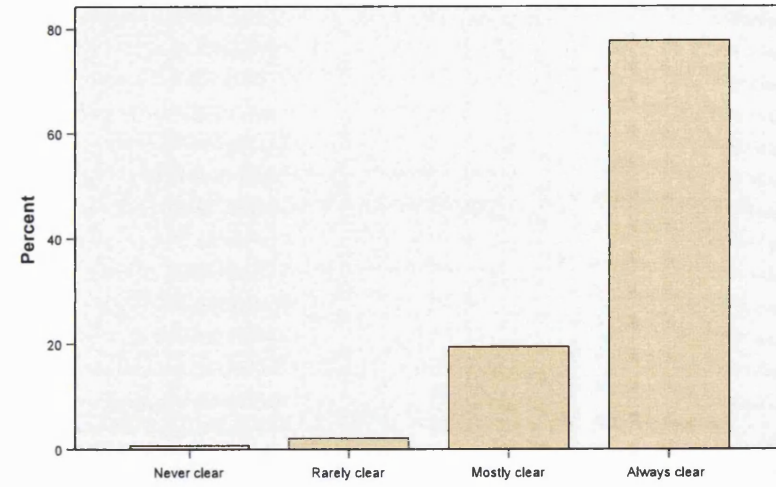


Figure 4.21: Length of time for ambulance service to pick patients – BLT patients

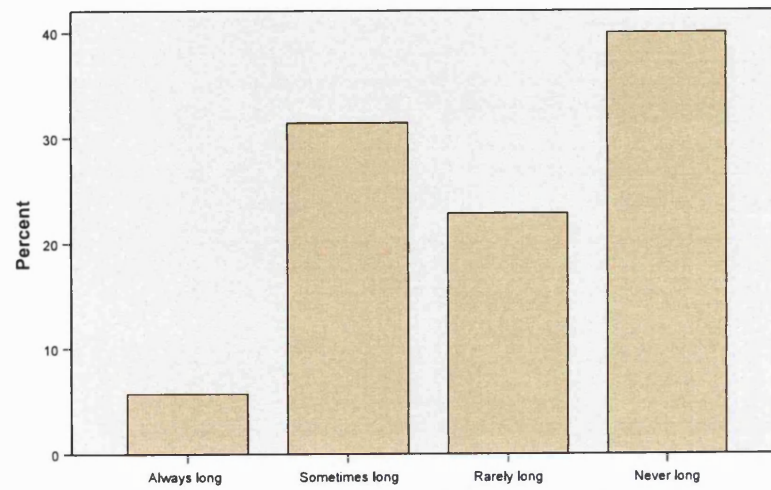


Figure 4.22: Length of time for ambulance service to pick patients – HUH patients

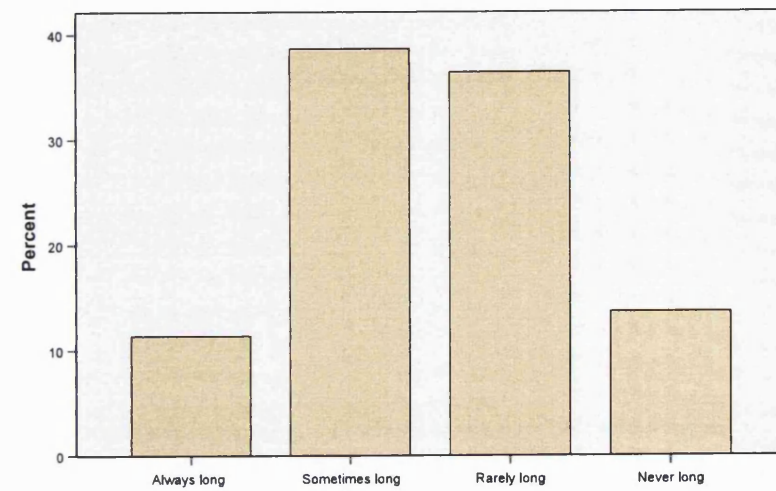


Figure 4.23: Frequency of failure of transport service to pick patients – BLT patients

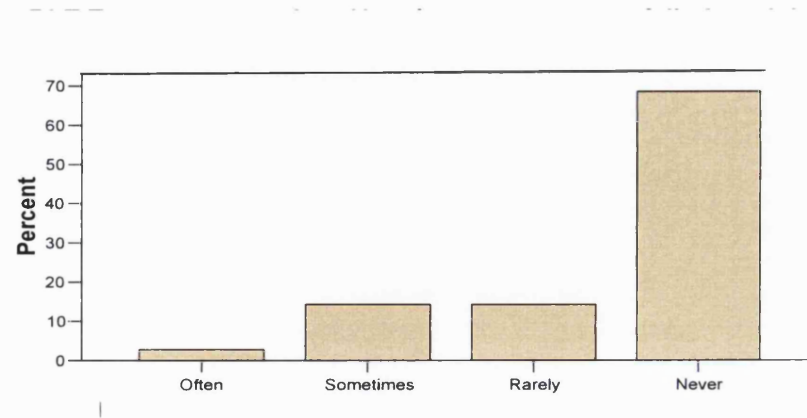
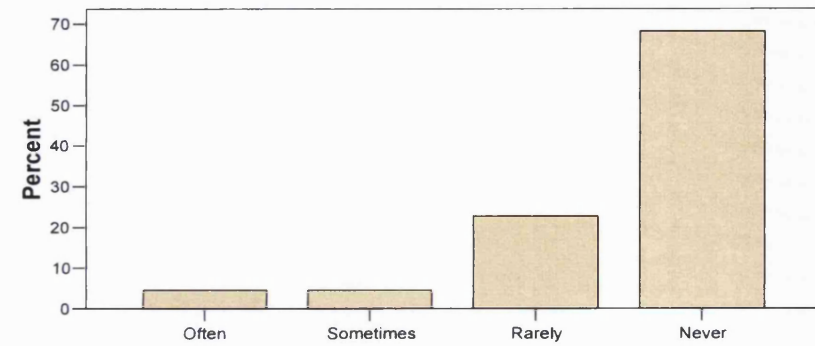


Figure 4.24: Frequency of failure of transport service to pick patients – HUH patients



4.2.4.7 Multiple linear regression for BLT patients

Preliminary analysis of correlations for BLT anticoagulation patients suggested that there were significant correlations between the seven service specific additional items, patients' age and CSQ score (Table 4.9) this suggested that some of these variables contributed in some way to patients' satisfaction and may in fact be able to predict patients' satisfaction. Multiple linear regression was performed for exploration of relationships between the variables.

Table 4.9: Correlation between additional items, patients' age and CSQ score – BLT patients

Independent Variable	Correlation with CSQ Score (Spearman's rho)	
Waiting time in clinic	Correlation Coefficient	0.366
	Sig. (2-tailed)	< 0.01
	N	145
How easy to get to clinic	Correlation Coefficient	0.377
	Sig. (2-tailed)	< 0.01
	N	139
Blood sample from vein on arm	Correlation Coefficient	0.387
	Sig. (2-tailed)	< 0.01
	N	142
Satisfaction with staff taking blood	Correlation Coefficient	0.383
	Sig. (2-tailed)	< 0.01
	N	144
Staff dealing with all other parts of the service	Correlation Coefficient	0.428
	Sig. (2-tailed)	< 0.01
	N	142
Instructions about what to do between visits	Correlation Coefficient	0.311
	Sig. (2-tailed)	< 0.01
	N	142
Environment where the service provided	Correlation Coefficient	0.339
	Sig. (2-tailed)	< 0.01
	N	143
Patient's age	Correlation Coefficient	0.183
	Sig. (2-tailed)	< 0.01
	N	385
Length of treatment in years	Correlation Coefficient	0.097
	Sig. (2-tailed)	0.058
	N	385

Data for participants completing the seven additional items and the CSQ scale was used for this analysis (n=136). All independent variables with significant correlation coefficients (age and additional items) were entered into the modelling procedure using the stepwise approach, the borderline criterion of acceptability was established at $p < 0.05$. The stepwise method was utilised as it is known to be useful for exploratory work and for predicting dependent variables from

independent variables (Garson 1998). In addition, the backward and forward methods were used for validation. All three methods produced the same equation. There were no outliers in the sample; therefore repeat analysis was not necessary. Residuals were normally distributed (Figure 4.25) and multicollinearity was not present. In addition, the other criteria for an acceptable model were met: Homoscedasticity and the sum of residuals was equivalent to zero. The model summary is shown in Table 4.10.

Figure 4.25: Distribution of residuals

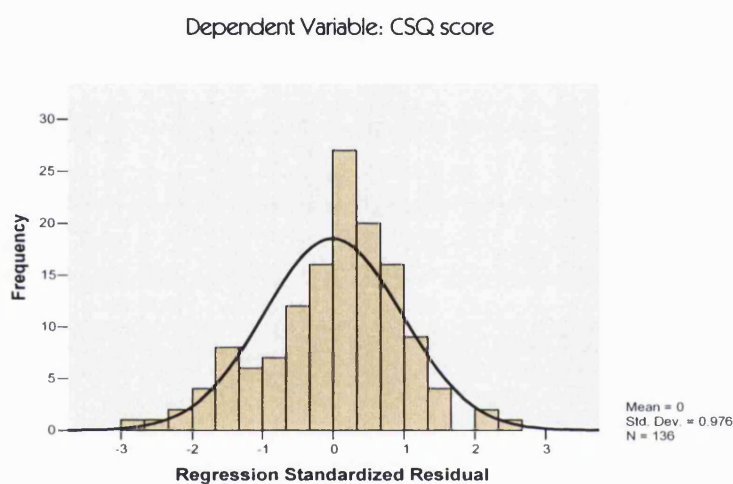


Table 4.10: Model Summary using Stepwise method – BLT patients

					Change Statistics				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change
1	0.635	0.403	0.380	2.75608	0.020	4.260	1	128	0.041

Predictors: (Constant), staff dealing with all other parts of the service, how easy to get to clinic, waiting time in clinic, blood sample from vein on arm, environment where service provided

The independent variables that contributed significantly to levels of satisfaction were, 'staff dealing with all other parts of the service', 'ease of getting to clinic', 'waiting time in clinic', 'blood sample from vein on arm' and 'environment where the service is provided', suggesting that these aspects were the most important measured determinants in the satisfaction of patients attending the BLT anticoagulation clinic. Regression modelling showed that the independent variables contributed to approximately 40% ($r^2=0.403$; Table 4.10) of the variance in the CSQ scores in the sample. Using Kinnear and Gray (2004) categorization of effect size (Table 4.11), to classify the magnitude of the

effect of the independent variables, showed that they had contributory effect on the variance in satisfaction level.

Table 4.11: Categorization of variance effect size – linear regression

Effect size (r^2)	Size of Effect
< 0.001 (<1%)	Small
0.01 to 0.10 (1 – 10%)	Medium
> 0.10 (>10%)	Large

Analysis of Variance (ANOVA) analysis showed that with respect to a linear relationship, this model was statistically significant ($p < 0.01$; Table 4.12), suggesting that there was indeed a linear relationship between the variables and CSQ score.

Table 4.12: ANOVA for BLT CSQ data

Model	Sum of Squares	Df	Mean Square	F	Significance
Regression	656.876	5	131.375	17.295	<0.001
Residual	972.284	128	7.596		
Total	1629.160	133			

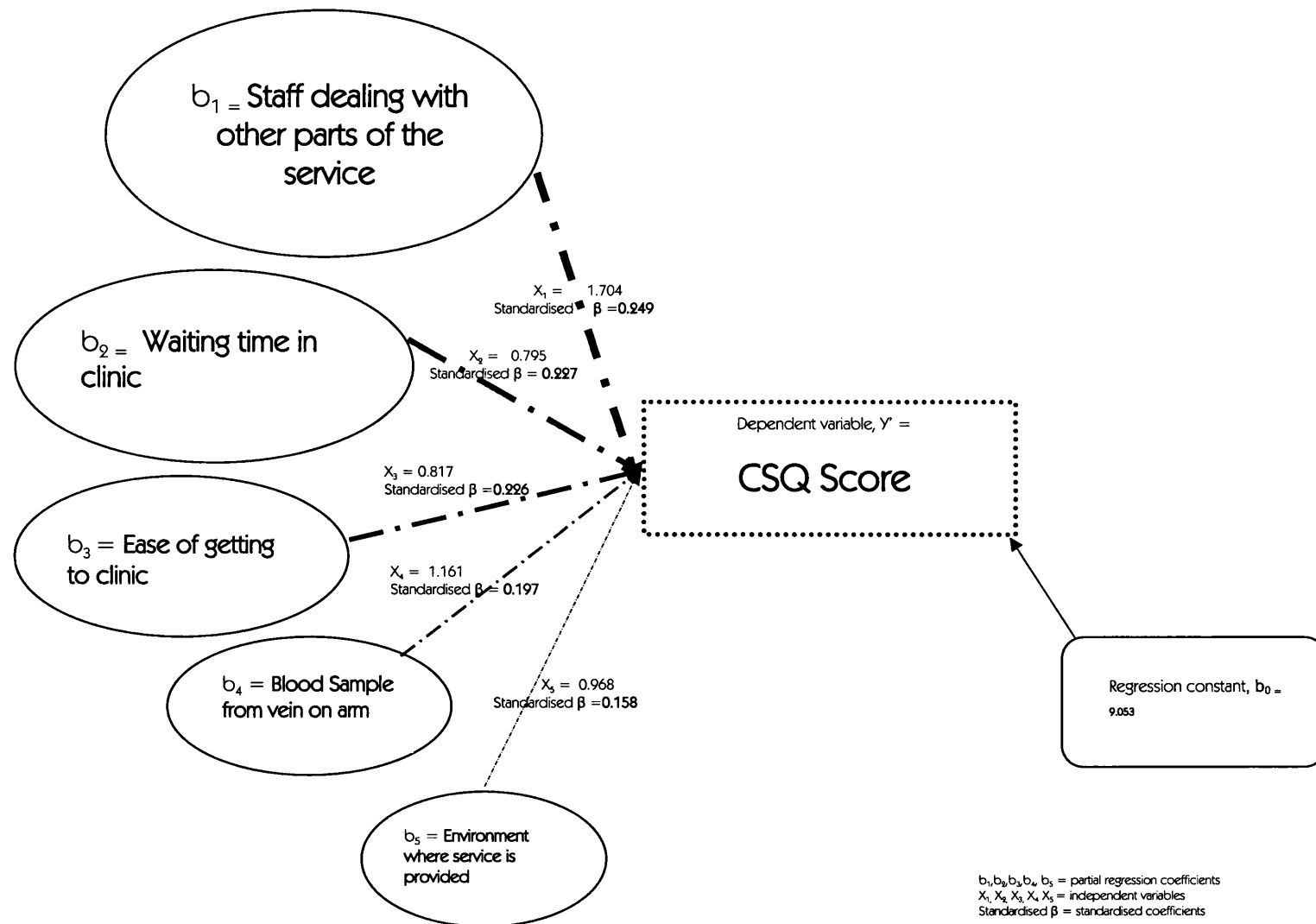
The standardised coefficients give the number of standard deviations change in the CSQ score variable that will be produced by a change of one standard deviation in the given independent variable. Using the standardised coefficients (Beta; Table 4.13), the relative importance of each independent variable was established. The variable 'staff dealing with all other parts of the service' (i.e. all staff patients came in contact with except those taking blood samples) made the greatest contribution to satisfaction levels, followed by waiting time in the clinic, the environment where the service is provided variable made the smallest but still significant contribution to satisfaction levels.

Table 4.13: Coefficients for BLT CSQ score Equation

Model	Unstandardized Coefficients		Standardized coefficients	t	Significance
	B	Std. Error	Beta		
(Constant)	9.053	2.181		4.151	0.000
Staff dealing with all other parts of the service	1.704	0.573	0.249	2.975	0.004
Waiting time clinic	0.795	0.254	0.227	3.129	0.002
How easy to get to clinic	0.817	0.257	0.226	3.178	0.002
Blood sample from vein on arm	1.161	0.476	0.197	2.437	0.016
Environment where the service provided	0.968	0.469	0.158	2.064	0.041

Figure 4.26 illustrates the multiple linear regression and relative importance / weight of the independent variables to the CSQ score at BLT.

Figure 4.26: Diagrammatic representation of multiple linear regression equation linking independent variables to patient satisfaction with BLT anticoagulation services



4.2.4.8 Multiple linear regression for HUH patients

Of the 295 HUH cases, 270 had completed both the service specific additional items and the CSQ scale, these were used for the analysis and for the multiple linear regression modelling. All of the seven additional items were significantly correlated to CSQ score (Table 4.14), however age and duration of treatment were not significantly correlated, perhaps due to a narrow distribution of these variables.

Table 4.14: Correlations with additional items and CSQ score – HUH patients

Independent Variable	Correlation with CSQ Score (Spearman's rho)	
Waiting time in clinic	Correlation Coefficient	0.469
	Sig. (2-tailed)	< 0.01
	N	285
How easy to get to clinic	Correlation Coefficient	0.310
	Sig. (2-tailed)	< 0.01
	N	279
Blood sample from vein on arm	Correlation Coefficient	0.306
	Sig. (2-tailed)	< 0.01
	N	286
Satisfaction with staff taking blood	Correlation Coefficient	0.394
	Sig. (2-tailed)	< 0.01
	N	283
Staff dealing with all other parts of the service	Correlation Coefficient	0.229
	Sig. (2-tailed)	< 0.01
	N	284
Instructions about what to do between visits	Correlation Coefficient	0.423
	Sig. (2-tailed)	< 0.01
	N	283
Environment where the service provided	Correlation Coefficient	0.380
	Sig. (2-tailed)	< 0.01
	N	284
Patient's age	Correlation Coefficient	0.108
	Sig. (2-tailed)	0.065
	N	295
Length of treatment in years	Correlation Coefficient	0.063
	Sig. (2-tailed)	0.280
	N	295

These independent variables were input into a multiple linear regression model using the stepwise technique to explore the predictive power of the variables. During the first analysis three outliers were identified (Table 4.15), these were removed from the analysis, to avoid any disproportionate affect on the resultant regression.

Table 4.15: Outliers –Casewise Diagnostics

Case Number	Std. Residual	CSQ Score	Predicted Value	Residual
178	-4.158	15.00	26.4872	-11.48715
218	-3.196	18.00	26.8279	-8.82786
226	-3.228	17.00	25.9157	-8.91565

Dependent Variable: CSQ Score

The analysis was repeated on the remaining 267 cases, criteria for multiple linear regression was met. The model summary is shown in Table 4.16.

Table 4.16: Model Summary – HUH

					Change Statistics				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change
	0.672	0.452	0.441	2.57158	0.011	5.375	1	261	0.021

Predictors: (Constant), waiting time in clinic, instructions about what to do between visits, environment where the service provided, satisfaction with staff taking blood, how easy to get to clinic

The independent variables that contributed significantly to variance in CSQ scores were, 'satisfaction with staff taking blood', 'ease of getting to clinic', 'waiting time in clinic', 'environment where the service is provided' and 'instructions about what to do between visits'. These independent variables contributed to approximately 45% ($r^2 = 0.452$; Table 4.16) of the variance in the CSQ scores in the sample, representing a large contributory effect on the variance in satisfaction, as assessed by Kinnear and Gray (2004) categorization of effect. Analysis of Variance (ANOVA) analysis showed the model was statistically significant ($p < 0.01$; Table 4.17).

Table 4.17: ANOVA for CSQ data-HUH

Model	Sum of Squares	Df	Mean Square	F	Significance
Regression	154.440	2	77.220	24.025	<0.001
Residual	199.277	62	3.214		
Total	3147.650	266			

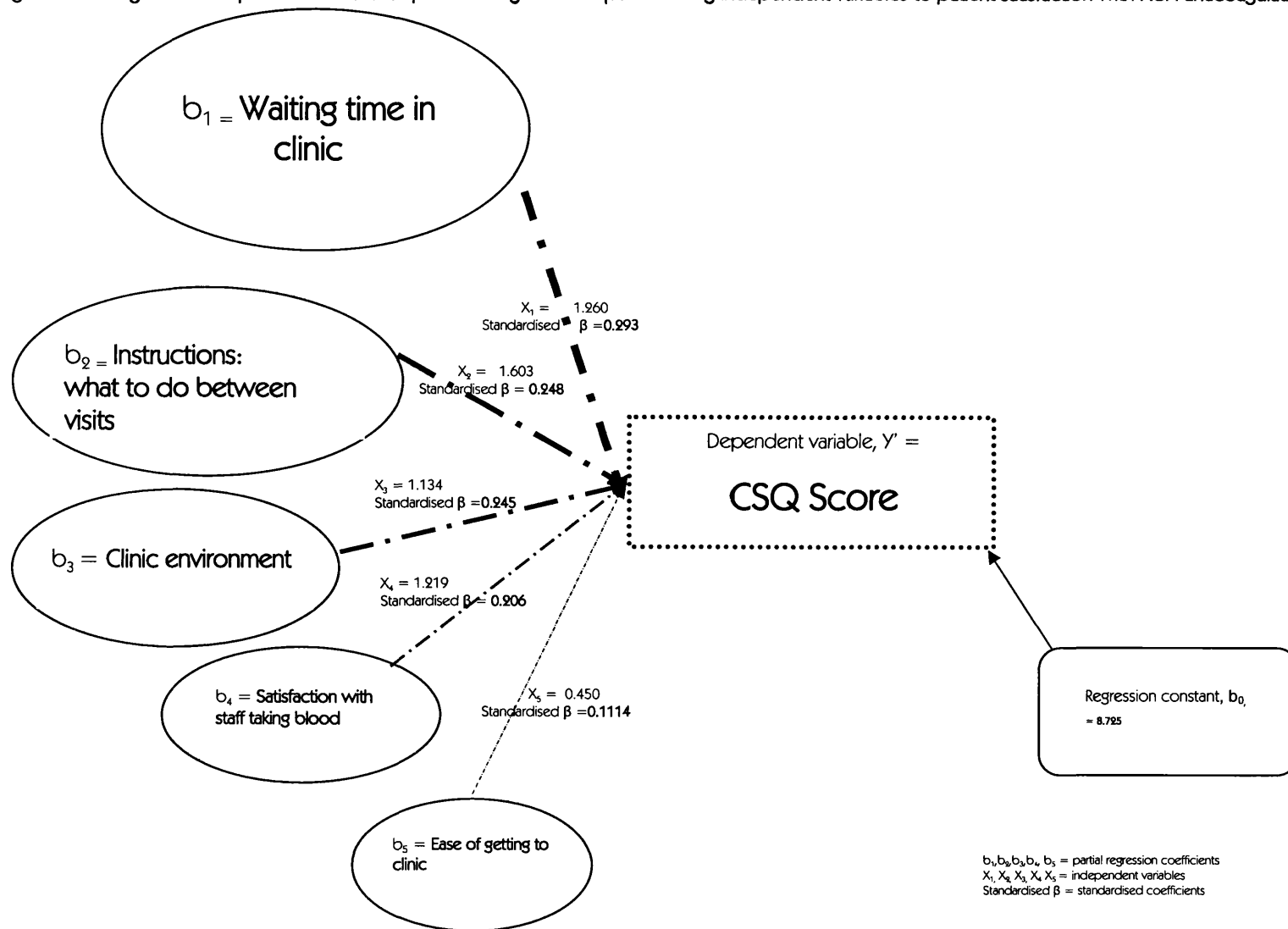
The standardised coefficients (Table 4.18) were used to determine the relative importance of each independent variable. The waiting time variable made the greatest contribution to variance in satisfaction levels, followed by instructions about what to do between visits (Table 4.18).

Table 4.18: Coefficients for HUH data

Model	Unstandardized Coefficients		Standardized coefficients	T	Significance
	B	Std. Error	Beta		
(Constant)	8.725	1.439		6.063	<0.01
Waiting time in clinic	1.260	0.214	0.293	5.881	<0.01
instructions about what to do between visits	1.603	0.324	0.248	4.943	<0.01
environment where the service provided	1.134	0.227	0.245	5.001	<0.01
satisfaction with staff taking blood	1.219	0.294	0.206	4.144	<0.01
How easy to get to clinic	0.450	0.194	0.114	2.318	0.021

Figure 4.27 illustrates the multiple linear regression and relative importance of the independent variables to the CSQ score at HUH.

Figure 4.27: Diagrammatic representation of multiple linear regression equation linking independent variables to patient satisfaction with HUH anticoagulation services



4.2.4.9 Multiple linear regression for postal and transport specific items

This section briefly outlines multiple linear regression modelling that was undertaken to determine whether the items developed specifically for postal and transport patients were predictive of patient satisfaction as assessed by the CSQ questionnaire for these groups of patients.

Multiple linear regression for BLT postal patients

Correlations for the independent variables (the seven general additional items, the two postal service specific items, age and duration of treatment) and the CSQ score were explored for postal patients (n=58). All items, except one of the postal - specific items, 'contacting the clinic by telephone' and duration of treatment correlated significantly with CSQ score. Using the stepwise procedure to assess the predictive power of the correlating variables, three independent variables explained 50.6% of the variance in CSQ score ($r^2 = 0.506$), these were, 'blood sample from vein on arm', 'staff dealing with all other parts of the service' and 'waiting time in clinic'. ANOVA analysis showed that the linear regression model was statistically significant (F 17.381, $p < 0.01$). Blood sampling method contributed the most to the variance in satisfaction, followed by staff dealing with other parts of the service and waiting time in the clinic (Table 4.19).

Table 4.19: Coefficients for BLT postal patients CSQ score

Model	Unstandardized Coefficients		Standardized coefficients	T	Significance
	B	Std. Error	Beta		
(Constant)	5.361	3.143		1.706	0.094
Blood sample from vein on arm	2.683	0.755	0.393	3.555	0.001
Staff dealing with all other parts of the service	2.684	0.879	0.348	3.055	0.004
Waiting time in clinic	1.005	0.413	0.249	2.436	0.018

Multiple linear regression for BLT Transport patients

For BLT transport patients that completed the additional items (n = 33), the independent variables that were significantly correlated to CSQ score were, 'waiting time in clinic', 'ease of getting to the clinic', 'blood sample with vein from arm' and 'staff dealing with all other parts of the service'. Interestingly, none of the transport specific items were correlated significantly to CSQ score, suggesting either that transport related aspects of the service did not affect patients' satisfaction with the service, or that these transport-specific items were not sensitive enough to predict changes in CSQ score.

When these four correlated independent variables were entered using the stepwise method into a multiple linear regression model, 'waiting time in clinic' and 'staff dealing with all other parts of the service' contributed significantly to the variance, accounting for 43.5% ($r^2 = 0.435$) of the variance in the satisfaction for transport patients. Cross validation of the model was performed by conducting the regression analysis with forward and backward methods of independent variable entry, these produced the same results. ANOVA analysis showed that the linear regression model was statistically significant ($F = 11.556$, $p < 0.01$). Clinic waiting time contributed the most to the variance in satisfaction (Table 4.20).

Table 4.20: Coefficients for BLT transport patients CSQ data

Model	Unstandardized Coefficients		Standardized coefficients	T	Significance
	B	Std. Error	Beta		
(Constant)	5.535	6.214		0.891	0.380
Waiting time in clinic	1.823	0.486	0.515	3.752	0.001
Staff dealing with all other parts of the service	4.501	1.559	0.396	2.888	0.007

Multiple linear regression model for HUH Transport patients

For HUH transport patients ($n=43$) the independent variables that were significantly correlated to CSQ score were, 'waiting time in clinic', 'satisfaction with staff taking blood', instructions about what to do between visits', 'environment where service is provided' and 'duration of time spent waiting for transport to collect them'. Using the stepwise method to undertake the linear regression procedure, three of the independent variables were identified as contributing significantly to the satisfaction levels of transport patients, 'satisfaction with staff taking blood', instructions about what to do between visits' and 'environment where service is provided', contributing approximately 54% ($r^2 = 0.543$) of variance in the satisfaction of transport patients. Analysis of variance showed that the combination of independent variables had a significant linear relationship with the CSQ score ($p < 0.001$). With regards to the relative importance of the independent variables, exploring the standardised Beta coefficient (Table 4.21) indicated that, for transport patients the variable that was of the greatest relative importance with regards to satisfaction, was satisfaction with staff taking blood, perhaps due to the relationship between patients and staff.

Table 4.21: Coefficients HUH transport patients CSQ data

Model HUH transport patients	Unstandardized Coefficients		Standardized coefficients	T	Significance
	B	Std. Error	Beta		
(Constant)	3.052	3.853		0.792	0.433
Satisfaction with staff taking blood	2.059	0.580	0.403	3.550	0.001
Environment where service is provided	2.585	0.732	0.381	3.530	0.001
Instructions about what to do between visits	2.114	0.780	0.307	2.711	0.010

4.2.4.10 Multiple linear regression summary

Multiple linear regression was a useful tool for establishing whether the items devised by the investigator contributed to patients' satisfaction. On average, approximately 40% of the variance of the CSQ scores was explained by a combination of the additional items. Interestingly within the postal and transport groups items designed to specifically address those services were not predictive of patients' satisfaction as assessed by the CSQ score. This may suggest that these aspects of the service did not influence patients' satisfaction, or that the items were not appropriate for the services. Clearly, the additional items were not exhaustive and there were other elements that the additional items did not pick up on. Interestingly, age did not contribute greatly to CSQ variance, a number of studies have shown that older patients tend to be more satisfied with services, the lack of this finding may be due to the fact that the population were an older population therefore only a very small proportion of the sample were under 60. For BLT non-transport, non-postal patients the two most important factors were staff dealing with all other parts of the service and clinic waiting time, these were also the two factors contributing most to patients' satisfaction for the transport patients. This indicates that service developments should focus on ensuring that staffs dealing with anticoagulation services are appropriately trained in managing patients and there should be a reduction in waiting times at BLT. Interestingly, at HUH the most important determinant was waiting time; this may be as a consequence of the recent change from venous sampling to a NPT service, reducing the waiting time and potentially increasing patients' satisfaction with regards to length of waiting time. The next section outlines the qualitative portion of the questionnaire.

4.2.4.11 Qualitative data from patients' comments

The CSQ-8 portion of the survey produced a largely positive response but was unable to differentiate between potential sources of satisfaction and dissatisfaction across both sites. Regression modelling with the additional items demonstrated that a number of the aspects of service highlighted in the items were predictive of patients' overall satisfaction with the service. In depth qualitative data collection was not deemed appropriate for this population of patients who were largely elderly, in addition it was not feasible due to time constraints. However the inclusion of a patients' comments box proved to be a useful addition to the questionnaire. The semi-structured format of the questionnaire was useful in not only eliciting sources of satisfaction but also specific sources of dissatisfaction that were not apparent from the responses in the structured portion of the questionnaire. Many respondents did not make additional comments, and those that did generally kept them brief. The brevity of responses limited the usefulness of data in providing a complete perspective of aspects relating to patient satisfaction with anticoagulation services. In spite of this, the qualitative portion did add another dimension to assessing levels of patient satisfaction. The in-vivo codes for BLT respondents are displayed in Table 4.22 and in Table 4.24 for HUH respondents. Codes were then grouped under themes in a reflective coding process (BLT, Table 4.23; HUH, Table 4.25). Despite the small number of responses, a number of themes were identified, however in-depth refined reflective coding was unfeasible.

Table 4.22: The in-vivo codes describing the data elicited in the open ended section in the semi-structured questionnaires: BLT

Code	Description
1	Direct negative comments regarding environment at RLH in comparison to BLT
2	Negative comments regarding RLH environment- no comparisons used
3	Describing staff as rude
4	Need more staff
5	Empathise with staff (they are doing the best they can)
6	Staff are helpful
7	Staff are informal –this is good
8	Staff are informal- this is not good
9	Transport service system is inadequate
10	Negatively expressing time-related issues regarding using the hospital transport
11	Too much time spent waiting in clinic
12	Long wait for laboratory to process results
13	Dissatisfaction with appointment times - not enough / not adhered to
14	Describe satisfaction with service
15	Suggestions of ways of improving service
16	Feeling of lack of flexibility of appointment times for those that work
17	Describing the clinic as overcrowded
18	Service has improved
19	Service has worsened
20	Long wait to have blood sample taken by phlebotomists

Table 4.23: Development of themes from the reflective coding process for BLT patients

THEMES (REFLECTIVE CODES)	SUB-THEMES (IN-VIVO CODES)
Theme One Negative feelings about RLH clinic environment	1 Direct negative comments regarding environment at RLH in comparison to BLT 2 Negative comments regarding RLH environment - no comparisons used 17 Describing the clinic as overcrowded
Theme Two Positive feelings regarding staff and staffing	5 Empathise with staff (they are doing the best they can) 6 Staff are helpful 7 Staff are informal -this is good
Theme Three Negative feelings regarding staff and staffing	3 Describing staff as rude 4 Need more staff 8 Staff are informal- this is not good
Theme Four Transport problems	9 Transport service system is inadequate 10 Negatively expressing time-related issues regarding using the hospital transport
Theme Five Negative feelings regarding time and waiting	11 Too much time spent waiting in clinic 20 Long wait to have blood sample taken by phlebotomists 12 Long wait for laboratory to process results. 13 Dissatisfaction with appointment times- not enough / not adhered to 16 Feeling of lack of flexibility of appointment times for those that work
Theme Six Current service could be better	19 Service has worsened 15 Suggestions of ways of improving service
Theme Seven Positive with regard to current service	14 Describe satisfaction with service 18 Service has improved

Table 4.24 The in-vivo codes describing the data elicited in the open ended section in the semi-structured questionnaires: HUH

Code	Description
1	Describes dissatisfaction with having to move around clinic area during appointments
2	Pleased with general improvement in waiting times
3	Staff would benefit from training
4	Negatively expressing time-related issues regarding the hospital transport
5	Too much time spent waiting in clinic
6	Dissatisfaction with appointment times- not enough / not adhered to
7	Satisfied with service in general
8	Service has worsened
9	Pleased with improvement in waiting times, since introduction of new blood testing system
10	Suggested improvements to service
11	Feeling of lack of flexibility of appointment times for those that work
12	Empathise with staff (they are doing the best they can)
13	Describing the clinic as overcrowded
14	Clinic area badly designed
15	Satisfied with staff
16	Describing staff as rude and / or impatient
17	Transport failing to pick patients up
18	Positive feelings regarding the new blood testing service

Table 4.25: Development of themes from the reflective coding process for HUH patients

THEMES (REFLECTIVE CODES)	SUB-THEMES (IN-VIVO CODES)
Theme One Negative feelings about clinic environment	1 Describes dissatisfaction with having to move around clinic area during appointments 13 Describing the clinic as overcrowded 14 Clinic area badly designed
Theme Two Positive feelings regarding staff and staffing	15 Satisfied with staff 12 Empathise with staff (they are doing the best they can)
Theme Three Negative feelings regarding staff and staffing	16 Describing staff as rude and / or impatient 3 Staff would benefit from training
Theme Four Transport problems	4 Negatively expressing time-related issues regarding the hospital transport 17 Transport failing to pick patients up
Theme Five Negative feelings regarding time and waiting	5 Too much time spent waiting in clinic 6 Dissatisfaction with appointment times - not enough/ not adhered to 11 Feeling of lack of flexibility of appointment times for those that work
Theme Six Positive feelings regarding time and waiting	9 Pleased with improvement in waiting times, since introduction of new blood testing system 2 Pleased with general improvement in waiting times
Theme Seven Current service could be better	8 Service has worsened 10 Suggested improvements to service
Theme Eight Positive with regard to current service	7 Satisfied with service in general 18 Positive feelings regarding the new blood testing service

The themes and example quotes are summarised in Tables 4.26 - 4.40. Despite the differences between HUH and BLT clinics, there were seven key themes similar to both patient populations. This section provides a brief outline of the themes that emerged during content analysis of patients' comments.

Theme one described patients' dissatisfaction with the clinic environment. BLT patients who had attended clinics at both St. Bartholomew's and at Royal London made comparisons between the two and described the RLH clinic environment as unsatisfactory, with particular reference made to the lack of cleanliness of the clinic and crowding of the clinic area.

At the HUH clinic, the waiting area consists of a long corridor with chairs for patients on either side, the phlebotomy room and consultant room are situated along the corridor, patients are instructed to move up one chair as each successive patient is seen until they get to the phlebotomy room and then subsequently the consultant room. Content analysis highlighted that HUH patients were primarily concerned with the crowding at the clinic and described their displeasure with this system of moving from chair to chair 'as though playing a game of musical chairs' (pt id 68 – HUH).

Table 4.26: Display of examples of quotes from Theme One – BLT

Theme One	Sub theme	Patient details	Quote
Negative feelings about RLH clinic environment	Direct negative comments regarding environment at RLH in comparison to BLT	<p>Patient id: 9975, male, aged 30.7 years, receiving treatment for 4.1 months for AF</p> <p>Patient id: 8972 WH, male, aged 36.3 years, receiving treatment for 9.8 years for AVR</p>	<p>I have also been to the RLH anticoagulation clinic and it is stuck away in a horrible dingy basement. The service here at BLT is always very good and the environment is great.</p> <p>The clinic environment in WC is dark, dirty and dismal. The clinic environment at Barts is clean, bright and spacious.</p>
	Negative comments regarding RLH environment- no comparisons used	<p>Patient id: 4020, male, aged 35.6 years, receiving treatment for 1.5 years for AF</p> <p>Patient id: 4231, female, aged 66.6 years, receiving treatment for 1.6 months for DVT.</p>	<p>The surroundings are a disgrace. I'm surprised this part of the hospital hasn't been condemned. People forced to stand who really shouldn't be forced to do so. Overall service great, amenities dire.</p> <p>The parts of the hospital we have seen are scruffy and not clean enough (ever thought of having a matron?)</p>
	Describing the clinic as overcrowded	Patient id: 6318, female, aged 62.4 years, receiving treatment for 7.9 months for PE	I would like to have a proper environment, insufficient room, crowding , insufficient seats

Table 4.27: Display of examples of quotes from Theme One - HUH

Theme One	Sub theme	Patient details	Quote
Negative feelings about clinic environment	Describing the clinic as overcrowded	<p>Patient id: 314, female, aged 61.2 years, receiving treatment for 6.5 years for recurrent TED</p> <p>Patient id: 290, male, aged 82.9 years, receiving treatment for 1.1 years for AF</p> <p>Patient id: 249, female, aged 36.6 years, receiving treatment for 1.7 months for PE</p>	<p>Sadly we have to sit about in cramped conditions, the time of the appointment is never correct and we wait far too long for such a brief chat to the doctor.</p> <p>I am delighted by how clean the hospital is but the service needs more room, it gets very crowded</p> <p>I think there needs to be more room for wheelchair users and a facility for people who are housebound</p>
	Describes dissatisfaction with having to move around clinic area during appointments	<p>Patient id: 381, female, aged 50.7 years, receiving treatment for 6.6 years for Lupus</p> <p>Patient id: 68, male, aged 67.8 years, receiving treatment for 1.3 months for DVT</p> <p>Patient id: 6, female, aged 39.9 years, receiving treatment for 6.3 months for DVT</p>	<p>Quite squashed and lots of moves from chair to chair</p> <p>Appalling, crowded in a narrow corridor with people treading on your feet and wheelchairs wheeled over them. A serious flaw in the design of this new hospital. Woefully insufficient waiting areas for the number of specialist clinics operating. Also a childish system of constantly moving up one seat as though playing a game of musical chairs is extremely painful for those like myself who have great difficulty in raising and lowering the body.</p> <p>Sit there, sit here, move there, move there</p>
	Clinic area badly designed	<p>Patient id: 68, male, aged 67.8 years, receiving treatment for 1.3 months for DVT</p>	<p>Appalling crowded in a narrow corridor with people treading on your feet and wheelchairs wheeled over them. A serious flaw in the design of this new hospital. Woefully insufficient waiting areas for the number of specialist clinics operating.</p>

The second theme described patients' positive feelings with regards to staff and staffing. Both patient samples felt that staff were doing their best in less than perfect work conditions, namely struggling with high workload and cramped clinic conditions. Both sets of patients used positive adjectives to describe the clinic staff including friendly, warm, polite (BLT), kind and courteous (HUH).

Table 4.28: Display of examples of quotes from Theme Two - BLT

Theme Two	Sub theme	Patient details	Quote
Positive feelings regarding staff and staffing	Empathise with staff (they are doing the best they can)	<p>Patient id: 8878, female, aged 31.7 years, receiving treatment for 7.9 months for APS</p> <p>Patient id: 9159, male, aged 54.0 years, receiving treatment for 4.6 months for PE</p>	<p>I think the staff do the best they can considering the amount of people they have to deal with.</p> <p>I attended the WC site on Thurs Oct 31st as a first time patient. The environment in the basement is awful and full marks to the staff and doctors who have to cope with such awful conditions. For the patients the service becomes disjointed and the area is badly congested and there are not enough consultation rooms. Please improve the conditions as both staff and patients deserve better.</p>
	Staff are helpful	<p>Patient id: 3069, female, aged 47.4 years, receiving treatment for 4.9 years for DVT.</p> <p>Patient id: 5246, female, aged 88.3 years, receiving treatment for 2.0 years for AF</p> <p>Patient id: 7120, female aged 34.0 years, receiving treatment for 6.1 months for Lupus</p>	<p>All members of anticoagulation team I have met during my treatment have been polite and helpful</p> <p>Excellent service, very helpful staff, very dedicated.</p> <p>Thus far I am very happy with the service. The staff are very helpful and polite a credit to this anticoagulation clinic.</p>
	Staff are informal –this is good	<p>Patient id: 7444, female, aged 53.9 years, receiving treatment for 1.5 months for AF</p>	<p>I attended another hospital where the systems were so formal that you felt like another number. Here even though the staff are very busy, they are warm and friendly to all patients and have a joke with them. This means that attending clinic is less traumatic than it might be. I appreciate the staff's help a lot.</p>

Table 4.29: Display of examples of quotes from Theme Two - HUH

Theme Two	Sub theme	Patient details	Quote
Positive feelings regarding staff and staffing	Satisfied with staff	<p>Patient id: 281, female, aged 64.7 years, receiving treatment for 6.3 years for MI</p> <p>Patient id: 272, male, aged 58.6 years, receiving treatment for 10.1 years for AF</p> <p>Patient id: 345, male, aged 75.4 years, receiving treatment for 2.6 years for atrial flutter</p> <p>Patient id: 5, female, aged 80.6 years, receiving treatment for 7.0 months for AF</p>	<p>I have always found everybody kind and courteous</p> <p>I hope in future there would be allocated a larger place to accommodate all patients. Everything is ok with the staff and Dr. Amos. For all doing a good job God bless you all.</p> <p>I have no comments to make but praise for the hospital staff.</p> <p>I find the Homerton hospital and all the staff excellent in every way.</p>
	Empathise with staff (they are doing the best they can)	<p>Patient id: 238, male, aged 65.1 years, receiving treatment for 9.2 years for AF</p> <p>Patient id: 32, male, aged 53.1 years, receiving treatment for 2.3 years for AF</p>	<p>Dr. Amos needs an assistant it's too much for one doctor he tries his best but he is only human. Diabetic patients should not wait so long and disabled people in wheelchairs should not wait so long please give the doctor some help.</p> <p>Staff try but limited resources and long waiting times add to stress of an already stressful situation. More staff needed to assist with taking of blood.</p>

Theme three highlighted some of the negative views patients had towards staff and staffing. In contrast to the jocular nature of BLT staff being viewed as positive, at times it was also viewed negatively. Furthermore, BLT patients described the ambulance drivers and some of the phlebotomists as rude. HUH patients felt that some of the clinic staff were rude and unhelpful and that the consultant was inpatient. Further, HUH patients felt that staff needed further training, in contrast BLT patients stated that more trained staff were needed suggesting that they believed that current staff were adequately trained but were insufficient in number. This finding may reflect the different clinic operations. At HUH the clinic team consists of only two regular members of staff, the nurse, who only sees new patients and the consultant who sees all patients to give dosing instructions. The receptionists, phlebotomists and nursing assistants rotate on a regular basis; therefore the consultant is the only member of staff that patients see on a regular basis. At BLT all members of staff apart from the phlebotomists are regular members of staff; the consultant, three pharmacist practitioners, two nurse practitioners and the receptionist, therefore they all know their roles and responsibilities within the clinic well.

Table 4.30: Display of examples of quotes from Theme Three - BLT

Theme Three	Sub theme	Patient details	Quote
Negative feelings regarding staff and staffing	Describing staff as rude	<p>Patient id: 6367, male, aged 84.4 years, receiving treatment for 8.9 years for AF</p> <p>Patient id: 4460, male, 71.3 years, receiving treatment for 10.1 months for DVT</p>	<p>Service is good but drivers are not, some drivers are very rude, sometimes do not want to help. Most are pleasant but some are not. Most of the staff in the hospital are very good. Very happy about the NHS it does an excellent job! (T)</p> <p>Since I have problems and pains each time when a normal type of needle is used, I asked a staff taking blood to use a smaller needle, his answer was 'why? It's expensive, we don't apply it to everybody'. I find his answer rude and unkind.</p>
	Need more staff	<p>Patient id: 5600, male, aged 77.9 years, receiving treatment for 8.3 years for AF</p> <p>Patient id: 8972, male, aged 36.3 years, receiving treatment for 9.8 years for AVR</p> <p>Patient id: 5689, male, aged 78.9 years, receiving treatment for 10.0 years for AF</p> <p>Patient id: 3571, male, aged 73.1 years, receiving treatment for 5.8 years for DVT</p>	<p>Staff are wonderful. Not enough phlebotomists to take the blood.</p> <p>The ratio of staff to patients is too low</p> <p>I suspect that more trained staff would be a distinct improvement.</p> <p>I would recruit more staff</p>
	Staff are informal - this is not good	Patient id: 8055, male, aged 63.2 years, receiving treatment for 2.3 months for AF	The staff are sometimes too jocular it would be better if they were more sober and the information relating to patients' treatment was more clearly said.

Table 4.31: Display of examples of quotes from Theme Three - HUH

Theme	Sub theme	Patient details	Quote
Theme Three Negative feelings regarding staff and staffing	Describing staff as rude and/or impatient	Patient id: 211, female, aged 38.5 years, receiving treatment for 5.1 months for PE Patient id: 25T, male, aged 67.0 years, receiving treatment for 3.4 years for atrial flutter	Couple of the staff are rude and unhelpful and I found it very hard the first time that I came and I found one staff very rude and unhelpful. Also the clinic needs a bigger waiting area. Find the doctor in the anticoagulant clinic to be rather hard and impatient and not very helpful. I feel that I'm just a number. I am sorry about that but that's the way I feel.
	Staff would benefit from training	Patient id: 347, female, aged 77.5 years, receiving treatment for 1.3 years for AF Patient id: 136, female aged 50.6 years receiving treatment for 1.8 years for AF	Staff need further training Some of them (staff) don't know what they are doing, why don't they get training?

The fourth theme highlighted issues with the transport service. The primary cause of dissatisfaction at both sites was the time spent waiting for transport to take patients to and from the clinics. Whilst the HUH patients were significantly less satisfied with the transport service according to the service specific item, in this qualitative portion BLT patients tended to be more vocal than HUH patients in their dissatisfaction, calling the service 'pathetic' (pt 4321 – BLT).

Table 4.32: Display of examples of quotes from Theme Four - BLT

Theme Four	Sub theme	Patient details	Quote
Transport problems	Transport service system is inadequate	Patient id: 4231, female, aged 66.6 years, receiving treatment for 1.6 months for DVT.	The absolute failure in the overall system is the transportation services –that are pathetic. Not an equipment problem – the ambulances are good but purely the management which is inept. No matter how much extra money is pumped into the NHS it will always go to waste if management of the performance of the transportation department is to be taken as acceptable.
	Negatively expressing time-related issues regarding using the hospital transport	<p>Patient id: 1504, female, aged 35.1 years, receiving treatment for 1.1 years for atrial septal defect</p> <p>Patient id: 0122, female, aged 80.4 years, receiving treatment for 3.3 years for AF</p> <p>Patient id: 4234, female, aged 66.1 years, receiving treatment for 1.8 years for DVT</p> <p>Patient id: 3086, female, aged 83.5 years, receiving treatment for 8.8 years for AF</p> <p>Patient id: 5705, female, aged 68.4 years, receiving treatment for 5.0 years for Antiphospholipid syndrome</p>	<p>I am not happy at all with the transport system. This week my husband has taken me to the clinic himself.</p> <p>Air conditioner in the hot weather. Transport takes a long time to bring and to bring back home.</p> <p>Waiting for the ambulance to come here and to go back home is quite bad.</p> <p>If possible I would like to get here a bit quicker.</p> <p>Sometimes I have to wait too long to go back home.</p>

Table 4.33: Display of examples of quotes from Theme Four - HUH

Theme Four	Sub theme	Patient details	Quote
Transport problems	Negatively expressing time-related issues regarding using the hospital transport	<p>Patient id: 64T, female, aged 85.7 years, receiving treatment for 7.2 years for recurrent DVT</p> <p>Patient id: 56T, male, aged 52.3 years, receiving treatment for 1.4 years for AF</p>	<p>I am generally satisfied except waiting for transport-takes my day away</p> <p>I'm happy with transport picking me up but not taking me home. I wait too long</p>
	Transport failing to pick them up	Patient id: 51T, female, aged 75.7 years, receiving treatment for 5.3 months for LV dilatation	Transport has failed to pick me up

Theme five outlined patients' negative feelings towards waiting times in the clinics. Both sets of patients expressed dissatisfaction with the lengthy waiting times. BLT patients were able to cite reasons for the delay as the low numbers and (lack of) ability of phlebotomists, as well as the wait for results to come from the laboratory. HUH patients offered no reasons as to the long waiting times, but complained that they waited for a long time for a brief chat with the doctor. In addition, HUH patients felt that there was a lack of flexibility with appointment times for working patients.

Table 4.34: Display of examples of quotes from Theme Five - BLT

Theme	Subtheme	Patient details	Quote
Theme Five Negative feelings regarding time and waiting	Too much time spent waiting in clinic	<p>Patient id: 0591, female, aged 35.1 years, receiving treatment for 9.8 years for lupus</p> <p>Patient id: 3849, male aged 55.8 years, receiving treatment for 2.3 years for Homozygous V leiden.</p> <p>Patient id: 7727, female, aged 51.4 years, receiving treatment for 14.7 years for AVR.</p>	<p>Everyone is always very helpful but the usual foul up is the waiting and back-log which everyone is aware of and trying to solve.</p> <p>I am tempted to purchase CoaguChek Sin order to avoid lengthy waiting times. The advice and guidance received from Dr. XXX (consultant) and XXX (senior pharmacist) is always much appreciated</p> <p>The only problem on some occasions is the waiting time, although I do appreciate the difficulties in running a department of this nature and realise sometimes such delays are unavoidable.</p>
	Long wait to have blood sample taken by phlebotomists	<p>Patient id: 2611, female, aged 72.3 years, receiving treatment for 1.8 years for AF</p> <p>Patient id: 4211, male, aged 62.0 years, receiving treatment for 1.8 years MI (left ventricular clot)</p>	<p>Just put one more person here taking blood to reduce waiting.</p> <p>The efficiency of the service is erratic; in short the time taken for the outpatient process is critically dependent on the ability of the phlebotomist to take the samples quickly. Sometimes this part of the process is very laborious.</p>
	Long wait for laboratory to process results.	<p>Patient id: 4730, male, aged 75.4 years, receiving treatment for 14.8 years for DVT</p> <p>Patient id: 6850, male, aged 72.7 years, receiving treatment for 9.3 years for CVA</p> <p>Patient id: 3069, female, aged 47.4 years, receiving treatment for 4.9 years for DVT</p>	<p>Occasional delays of awaiting results on the day</p> <p>Waiting for the results sometimes seems interminable. But then I remember when the analysis was done downstairs. My satisfaction with the overall level of service is high given the problems of the NHS</p> <p>Waiting time for results could be improved. Sometimes I can wait up to 2 hours</p>
	Dissatisfaction with appointment times - not enough/ not adhered to	<p>Patient id: 8893, male, aged 56.1 years, receiving treatment for 15.8 years for AF</p>	<p>Sometimes clinic waiting times can be excessive. Also appointment times do not coincide with the arrival of the phlebotomists –they are often late and the commencements of the tests often starts 10-15 minutes after the 1st appointment times. But that said overall it is quite good.</p>
	Feeling of lack of flexibility of appointment times for those that work	<p>Patient id: 8764, male, aged 30.3 years, receiving treatment for 5.8 years for AVR</p> <p>Patient id: 8686, male, aged 33.6 years, receiving treatment for 2.4 months for DVT.</p>	<p>It would be ideal for the clinic to start at 8am. I work and have to be at work by a certain time; sometimes it is not possible to get an 8.30 appointment.</p> <p>It would be good if earlier or later appointments so it would be possible like the rapid response unit, I work and attending clinics on a regular basis is inconvenient</p>

Table 4.35: Display of examples of quotes from Theme Five - HUH

Theme	Sub theme	Patient details	Quote
Five Negative feelings regarding time and waiting	Too much time spent waiting in clinic	<p>Patient id: 314, female, aged 61.2 years, receiving treatment for 6.5 years for recurrent TED</p> <p>Patient id: 6, female, aged 39.9 years, receiving treatment for 6.3 months for DVT</p> <p>Patient id: 213, female, aged 35.2 years, receiving treatment for 2.4 months for antiphospholipid syndrome</p>	<p>Sadly we have to sit about in cramped conditions, the time of the appointment is never correct and we wait far too long for such a brief chat to the doctor.</p> <p>Sometimes waiting times is very poor never seen at the time allocated</p> <p>There is a clear problem of the waiting time to be seen. Disabled parking is also a problem. I think that most staff try there best in a bad situation (clinic space is too small). Patients waiting in three different areas.</p>
	Dissatisfaction with appointment times- not enough/ not adhered to	<p>Patient id: 268, female, aged 58.8 years, receiving treatment for 14.8 years for MVR</p> <p>Patient id: 314, female, aged 61.2 years, receiving treatment for 6.5 years for recurrent TED</p>	<p>My main problem is that it is very hard to book a very early appointment (9 or soon after). By the time you have been seen by the doctor, all the early appointments for 6 or 8 weeks time have been taken. I have to have a very early slot in order to get to work on time this part of the present system does not work at all well for me.</p> <p>Sadly we have to sit about in cramped conditions, the time of the appointment is never correct and we wait far too long for such a brief chat to the doctor.</p>
	Feeling of lack of flexibility of appointment times for those that work	<p>Patient id: 25, male, aged 44 years, receiving treatment for 1.0 month for AF</p> <p>Patient id: 171, male aged 54 years, receiving treatment for 1.5 years for AF</p>	<p>It would be helpful if people who are working could be given the early appointments as it is possible to spend the morning at the clinic.</p> <p>As I have to go to work afterwards, I find I cannot get early appointments, even 4 - 6 weeks in advance</p>

In contrast to BLT patients, who only expressed negative feelings with regards to waiting times, HUH patients also expressed positive feelings with regards to the duration of wait (Theme six – HUH). HUH patients praised the capillary – NPT system and noted that there had been an improvement in waiting times since it had been implemented.

Table 4.36: Display of examples of quotes from Theme Six - HUH

Theme	Sub theme	Patient details	Quote
Six Positive feelings regarding time and waiting	Pleased with improvement in waiting times, since introduction new system of blood testing.	Patient id: 353, female, aged 51.2 years, receiving treatment for 6.9 years for MVR Patient id: 331, female, aged 46.4 years, receiving treatment for 5.0 years for AF	All in all I believe the new system with the finger-pricking is better and faster for all of us as we used to hang around for hours with the old system, so I am grateful for the change. Since the change in the way the blood sample is being taken i.e. from the finger there is a huge improvement in the waiting time for which I am grateful.
	Pleased with general improvement in waiting times	Patient id: 161, male, aged 59.4 years, receiving treatment for 7.3 years for AF Patient id: 12, male, aged 54.8 years, receiving treatment for 2.6 years for AF	12 months ago I did wait 2-3 hours and now it is so much better . I give it 10 out of 10. Keep up the good work. There is a great improvement regarding this service. Specially the waiting time period. The clinic staff generally are also good and friendly.

The next theme (BLT theme six, HUH theme seven) outlined patients' feelings that there was room for improvement with regards to the services. Both sets of patients felt that the service had worsened and offered solutions to improve the service. BLT patients suggested that NPT be introduced to the clinic and more staff be recruited. In addition, both patient groups commented that a more flexible appointment system for working patients would be helpful.

Table 4.37: Display of examples of quotes from Theme Six - BLT

Theme Six	Sub theme	Patient details	Quote
Current service could be better	Service has worsened	<p>Patient id: 6944, male, aged 36. 8 years, receiving treatment for 2.2 years for AVR</p> <p>Patient id: 2694, male, aged 55.9 years, receiving treatment for 15.8 years for AF</p>	<p>Could improve, was better before - I suppose I'll have to make do with the service that is being provided</p> <ul style="list-style-type: none"> • Two people taking the blood. • The service seems to be worse over the last two years. • More staff
	Suggestions of ways of improving service	<p>Patient id: 7265, female, aged 77.0 years, receiving treatment for 28.7 months for MVR</p> <p>Patient id: 8764, male, aged 30.3 years, receiving treatment for 5.8 years for AVR</p> <p>Patient id: 7443, female, aged 38.0 years, receiving treatment for 1.8 months, for DVT</p> <p>Patient id: 5689, male, aged 78.9 years, receiving treatment for 10.0 years, for AF</p> <p>Patient id: 1554 , male, aged 56.7years, receiving treatment for 9.6 years, for coronary artery disease</p>	<p>It would be better if everything was in the same place: doctors, technicians, everybody. You were able to see the process.</p> <p>A ticket system may be the way forward. I have heard about self testing machines could information be provided about this?</p> <p>System would be improved with new 'instant' results if this was found to be accurate.</p> <p>I suspect that more trained staff would be a distinct improvement.</p> <p>Fast track for people who go to work. Blood processed for each appointment time</p>

Table 4.38: Display of examples of quotes from Theme Seven - HUH

Theme	Sub theme	Patient details	Quote
Seven Current service could be better	Service has worsened	Patient id: 317, female, aged 65.6 years, receiving treatment for 5.5 years for AF	Initially new service was running well but recently it's been messing up new staff each time. I've been coming here for years but things don't appear to be improving. Staff always changing waiting area too congested.
	Suggested improvements to service	<p>Patient id: 112, female, aged 71.6 years, receiving treatment for 1.2 years for AF</p> <p>Patient id: 197, female, aged 49.4 years, receiving treatment for 5.7 months for DVT</p> <p>Patient id: 25, male, aged 44 years, receiving treatment for 1.0 month for AF</p>	<p>Instead of keep getting up and down off the chairs, I think that having some sort of light showing your number when it is your turn to see someone</p> <p>It would help if they had an on-site GP to help with any other questions regarding DVTs rather than having to go back to your own GP (appointments not easy to get).</p> <p>It would be helpful if people who are working could be given the early appointments as it is possible to spend the morning at the clinic</p>

The last theme (BLT theme seven, HUH theme eight) highlighted patients' positive feelings with the current service. Both patient groups expressed satisfaction with the service and remarked that the service had improved.

In summary, despite the very different clinic operations, patients' comments were similar, highlighting that the main issues regardless of how the service was provided remained the same. The main difference was that HUH patients expressed positive feelings towards clinic waiting times in light of the NPT system. This difference in view of waiting times was echoed in the difference in results between BLT and HUH patients in the waiting time specific item.

Table 4.39: Display of examples of quotes from Theme Seven - BLT

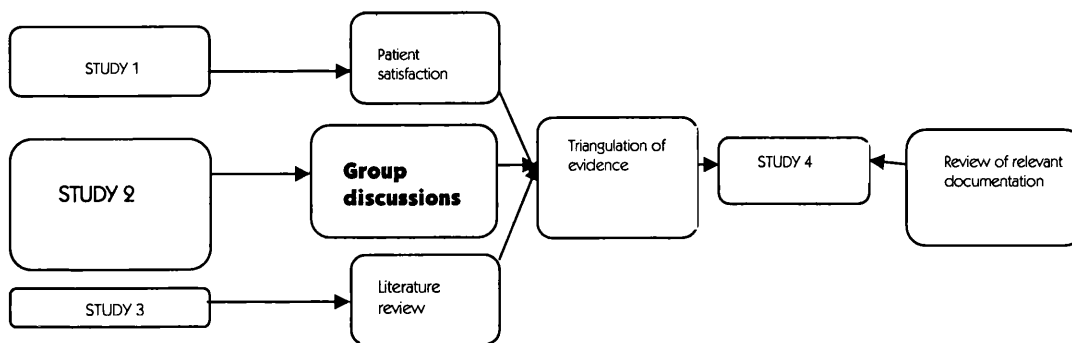
Theme	Subtheme	Patient details	Quote
Theme Seven Positive with regards current service	Satisfaction with service	<p>Patient id: 4070, male, aged 83.6 years, receiving treatment for 4.3 years for AF</p> <p>Patient id: 8846, male, aged 71.2 years, receiving treatment for 3.1 years for AF</p> <p>Patient id: 4106, female, aged 70.5 years, receiving treatment for 2.3 years for TIA</p>	<p>Very satisfied</p> <p>Service is very good I am satisfied with all aspects.</p> <p>Good service I am pleased that Barts is here.</p>
	Service has improved	Patient id: 0122, female, aged 80.4 years, receiving treatment for 3.3 years for AF	I have been attending the Royal London clinic for three years and have been happy with things getting better every time, staff are always helpful

Table 4.40: Display of examples of quotes from Theme Eight - HUH

Theme	Sub theme	Patient details	Quote
Theme Eight Positive with regards current service	Satisfied with service in general	<p>Patient id: 288, male, aged 68.6 years, receiving treatment for 1.0 years for atrial flutter</p> <p>Patient id: 380, male, aged 79.0 years, receiving treatment for 5.0 years for AF</p> <p>Patient id: 356, female, aged 89.4 years, receiving treatment for 1.4 years for AF</p> <p>Patient id: 340, female, aged 75.2 years, receiving treatment for 1.4 years for AF</p> <p>Patient id: 335, male, aged 75.8 years, receiving treatment for 20.1 years for MVR.</p>	<p>Overall this is a well run service and everything is always well explained</p> <p>I'm always satisfied</p> <p>Well satisfied</p> <p>I have no complaints about the service or treatment I get.</p> <p>I think it is very good</p>
	Positive feelings regarding the new blood testing service	<p>Patient id: 331, female, aged 46.4 years, receiving treatment for 5.0 years for AF</p> <p>Patient id: 132, male, aged 61.2 years, receiving treatment for 4.7 years for AF</p> <p>Patient id: 238, male, aged 65.1 years, receiving treatment for 9.2 years for AF</p>	<p>Since the change in the way the blood sample is being taken i.e. from the finger there is a huge improvement in the waiting time for which I am grateful.</p> <p>Service is better now that the new way of taking blood has been introduced.</p> <p>The new way of taking blood from finger is much better than the old way</p>

Summary

- There was no significant difference in the CSQ scores of anticoagulation patients at BLT and HUH.
- The CSQ scores represented high levels of satisfaction without much discrimination.
- Analysis of anticoagulation service specific items across the sites suggested that there was room for improvement with regards to waiting times, method of blood sampling and the transport service for mobility- impaired patients.
- Multiple linear regressions showed that five of the seven specific items accounted for 40% of the variance in patient satisfaction as assessed by the CSQ -8.
- Whilst the patients' comments were not in-depth they gave specific points for service improvement. A content analysis of patients' comments revealed a number of themes, including: the impact of clinic environment, patients' positive/negative feelings towards staff, perceptions of transport services and waiting times.
- The integrated approach produced not only clear, measurable indices of satisfaction across the sites, but also revealed specific areas of priority for service development.



4.3 Group interviews

This section describes the group interviews that were conducted to further inform the selection of domiciliary trial anticoagulation service models for evaluation.

4.3.1 Background

When developing services, it is important that stakeholders are approached, to offer advice and support for informing and implementation of service developments (Sheehan *et al.* 2000). Stakeholders are defined as persons with an interest or concern in something (Oxford University Press 2001). Stakeholders should be involved at an early stage of service developments to ensure that implementation, roll out and maintenance of such services is successful. Information regarding stakeholders that should be involved in the development of anticoagulation services was located in the literature (Table 4.41).

Table 4.41: Stakeholders identified in the literature regarding primary care anticoagulation services development.

Reference	Stakeholders/Groups that should be involved in service developments
Radley <i>et al.</i> (2000)	Links with lead physician (not specified whether primary or secondary-care based physician) Links with local pathology department
Sheehan <i>et al.</i> (2000)	Support from local health board (English equivalent PCT) Co-operation of local anticoagulation laboratory (pathology department) Working party to include: Consultant from local anticoagulation clinic Laboratory technicians Practice nurse Clinically orientated pharmacist
Coleman <i>et al.</i> (2003)	Specifically for community pharmacy anticoagulation service: Representatives from: The hospital anticoagulation service, The haematology department Hospital and community pharmacy Local pharmaceutical committee Primary care trust (PCT) Academic pharmacy. Elicit patient opinion

Following the literature review, key stakeholders (including patients), were identified. Stakeholders were clinic practitioners (nurse and pharmacist practitioners), PCT prescribing leads, consultant haematologists, general practitioners in the locality, community pharmacists in the locality and community pharmacists providing anticoagulation services, pathology managers and the Academic Pharmacy Department at BLT. Obtaining the opinions of these groups allowed for a multidisciplinary approach to anticoagulation service development.

4.3.2 Aim

To discuss various options for anticoagulation services and reach a consensus with regards service development.

4.3.3 Objectives

- To aid selection of primary care-based anticoagulation services for evaluation, through group interviews.
- To identify the implications of setting up primary care-based services.
- To identify the essential requirements and practical considerations for implementation of individual services including training, standards of care, protocol development, documentation requirements, and defining staff roles and responsibilities.
- To identify and highlight stakeholder concerns and perceived potential barriers to service development.
- Discuss the suitability and acceptability of primary care provision of anticoagulation services, with consideration of identified models.
- Explore individuals' interpretation of the need and value of such services.

4.3.4 Discussion with BLT anticoagulation clinic practitioners

Anticoagulation practitioners were identified as being well placed to make suggestions regarding anticoagulation service developments as they were monitoring patients within the hospital anticoagulation clinics on a daily basis and so were aware of a number of the issues with regards to the service.

4.3.4.1 Objectives

In addition to the objectives of the group interviews, the objective of the discussion with BLT anticoagulation practitioners was to investigate the opinions of the anticoagulation team, with regards to current provision of anticoagulation services at BLT.

4.3.4.2 Method

A group discussion was held on the 20th of February 2003 with members of the anticoagulation team during a staff meeting. The discussion involved the chief anticoagulation administrator, the senior pharmacist practitioner, a pharmacist practitioner (on clinical rotation), the senior nurse practitioner, the junior nurse practitioner and the consultant haematologist. The investigator outlined the objectives of the discussion and guided the discussion through the following topics:

- I. Views on current anticoagulation services.
- II. Perceived requirements for taking anticoagulation service developments forward.
- III. Targeting service developments for particular patient groups.

The only room available for the meeting was not conducive for audio-recording, so the investigator made detailed notes during the discussion.

4.3.4.3 Results

This section outlines the main points highlighted during the discussion.

Current service provision

A large increase in the number of patients had been observed over the previous ten years. It was reported that although the team had expanded, services were still inadequate to deal with the ever-increasing numbers of patients. Practitioners agreed that although they managed to run an efficient clinic, changes in service delivery would allow them to more easily take on an increased number of patients.

Patient and Practitioner complaints

Practitioners stated the main complaint of patients was the long waiting times. They reported that patients sometimes waited up to two hours to receive their dose information following INR testing. This was as a consequence of having to wait for INR results to come from the laboratory. The practitioners suggested that the majority of patients opted to leave after the blood sample had been taken and have their anticoagulation record book with the INR results and updated dosage posted to them. The practitioners felt that this system was extremely time consuming and costly

because it involved posting anticoagulation record books back to patients and telephoning all those who needed immediate dose changes.

Developments in service provision

Computer dosing software support

The practitioners commented that the introduction of the CDSS, Dawn AC software (4s Dawn Clinical Software) in 2002 had greatly helped them to keep a record of all patients' INRs, identify patients that had not attended their clinic appointments, provide dosing support (although it was not a replacement for a practitioner) and had helped the auditing process.

Near patient testing

Participants believed a move to using NPT devices, as in the HUH anticoagulation clinic, (Figure 4.4) would be most welcome, they felt it would save time during and after the clinic and improve the flow of patients through the appointment process; patients would obtain their INR results within minutes of blood sampling, receive dosing instructions soon after and be able to take their anticoagulation record books with them.

Current community-based services in the BLT service area

The practitioners felt that a move to services in primary care would please many patients and would lighten the load for the hospital clinics. They would be willing to support and advise community-based services, as this role was within their remit, they described some of the satellite type services that were currently in existence. They supported a GP practice-based service described in Figure 4.28; model A.

Figure 4.28: Model A of GP-based anticoagulation service described by the BLT anticoagulation clinic staff

Mobile patients visit their general practice, where their blood is obtained via venous sampling. The blood sample is sent to and analysed in the local hospital laboratory. The INR determinations are then sent to hospital-based anticoagulation clinic staff, who dose patients according to the laboratory INR results. The hospital practitioners contact the patients either via post or telephone depending on the urgency, with their INR result, the required dose of warfarin and the date of their next blood test at their general practice surgery.

Another GP practice-based service was described, this was completely run by the GP practice with no involvement from the hospital anticoagulation team (Figure 4.28).

Figure 4.29: Model B of GP-based anticoagulation service described by the BLT anticoagulation clinic staff

Mobile patients visit their general practice, where their blood is obtained via venous sampling. The blood sample is sent to and analysed in the local Hospital laboratory. The INR determinations are then sent back to the general practice-based anticoagulation practitioners, who dose patients according to the laboratory INR results using CDSS. The general practice practitioners contact the patients either via post or telephone depending on the urgency, with their INR result, the required dose of warfarin and the date of their next blood test at the general practice surgery.

The team believed that these services were safe, effective in maintaining INR control and good for patients who did not want to make the sometimes long journeys to the hospital clinic and endure long waiting times. They stated that these services were good for those patients who had busy schedules and wanted minimum disruption. They agreed that a move to community – based services that ran out of working hours either from a community pharmacy, GP practice or a healthcare centre would be a “step in the right direction”.

Prioritisation of service developments

Practitioners stated that initial development of services should be targeted at mobility-impaired patients and then to those patients who worked and wanted more flexibility with their INR monitoring. Mobility-impaired patients were routinely brought to the clinic using hospital ambulance services and the team expressed a number of concerns regarding this patient group as summarised in Table 4.42.

Table 4.42: BLT Anticoagulation team concerns regarding mobility-impaired patients

Issues	Participant views
Patient health and time	Lengthy process of transporting patients to and from the hospital on a regular basis for a blood test that takes 5 minutes is highly unsatisfactory; these patients are often very weak and frail, with multiple co-morbidities.
Marginalization of patients	Some patients who would benefit from warfarin are denied it as they are too frail and elderly to travel regularly to hospital for the essential monitoring.
Transportation problems and Practitioner time	Much staff time taken up during clinics ascertaining whether transport patients had been visited by the ambulance service and recalling patients unable to attend the clinic in which they were expected.
	Transport patients delivered to clinic in large groups in wheelchairs were they present a health and safety concern as they often obstructed much of the clinic area.
	Staff spend considerable time inquiring as to the whereabouts of transport patients and moving wheelchairs around within the clinic area instead of focussing on their clinical roles.

Taking anticoagulation services development forward

The practitioners suggested that the way forward was NPT monitoring of INRs in the hospital clinic and a domiciliary service for mobility-impaired patients to address the highlighted issues. In addition, they stated that community-based services should be set up particularly for those with busy working schedules.

Important issues regarding service development

Staff believed that one of the most important issues was clinical governance and that this should be at the forefront as they tried to improve the convenience and accessibility of the service for patients. In addition, good communication links within the hospital departments (particularly between practitioners and the pathology staff) and between secondary and primary care was regarded as fundamental to future service developments. Cost was identified as a further key component as funding for primary care services would be required from the Primary Care Trust, which may not view primary care anticoagulation services as a priority service to be commissioned.

Service models

The practitioners recognized that there were a number of models of delivery of care that had been described and used elsewhere but with little comparative evaluation. Furthermore, one model that may work well in some places or for some patients may not be as effective in other settings. Therefore, they were of the opinion that a number of different service models may have to be established to meet the majority of patients' needs.

4.3.5 Stakeholder discussion

A meeting involving representatives from the pathology department, academic pharmacy, and the PCT, including general practice was arranged to discuss anticoagulation service developments in the Tower Hamlets locality. The date of the meeting was the 9th of July 2003.

4.3.5.1 Objectives

In addition to the objectives of the group interviews, the objective of the stakeholder discussion was to investigate stakeholders' opinions with regards to current provision of anticoagulation services in Tower Hamlets PCT.

4.3.5.2 Method

A meeting organised by the investigator to discuss anticoagulation services in the BLT service provision area was attended by the BLT anticoagulation clinic consultant haematologist, clinic nurse practitioner, pathology department manager and pharmacy research lead (BLT's Academic Director of Pharmacy) and, from Tower Hamlets PCT, the commissioner, prescribing lead and anticoagulation services general practitioner lead. The investigator outlined the objectives of the discussion and guided the discussion through the following topics:

- I. Participants' views on current anticoagulation services
- II. Perceived requirements to improve anticoagulation services for patients and service development issues

The discussion was recorded using a minidisk recorder and the investigator also made detailed notes during the discussion.

4.3.5.3 Results

Current service provision at BLT

An overview of the main points made by participants regarding current service provision is shown in Table 4.43.

Table 4.43: Issues regarding current anticoagulation service provision in Tower Hamlets highlighted by key stakeholders

Issues	Participant views
Overstretched staff	Growing number of patients without sufficient growth in anticoagulation staff was leading to difficulties in maintaining standards of service provision.
Logistics of clinic operation	Although the service took place in one site, there was a feeling of fragmentation as the majority of patients had little to no contact with practitioners during clinic visits (postal patients), increasing the likelihood that some patients may be getting lost to follow up
Prescribing of warfarin	GPs were expected to prescribe warfarin to patients with very little patient information and sometimes without knowledge of patients' INRs.
Transport patient dissatisfaction	Transport patients had expressed dissatisfaction to GPs at protracted waits before and after clinic appointments
Transport problems	Unsatisfactory system for patients who were often frail and needed to be assisted to get to and from the clinic. Transporting such patients was deemed to be an irrational expense, as locally based services might be better.

Primary care anticoagulation services

The GP lead for anticoagulation services commented that usage of the anticoagulation service had outstripped initial estimates from primary care on the basis of practice surveys of warfarin use at the time; this was thought to be due to the increase in indications for warfarin including AF and stroke risk. A number of GPs expressed dissatisfaction with their role as prescribers of warfarin; in general practice, they had the problem of either having a consultation with a patient to check their anticoagulation record book result prior to issuing a prescription, or hoping that safe monitoring had taken place, as there were not systems in place to provide on line notification of patients results and doses:

"As with many other medicines I prescribe for my patients, I have to take it on trust that the prescribing and dose of warfarin requested by my hospital colleagues is appropriate. Many times patients come without their record books and expect me to prescribe, in these cases the best I can do is prescribe a box of 'ones', 'threes' and 'fives', but it's not best practice to be prescribing warfarin blind." GP anticoagulation lead.

Both the pharmacy lead and anticoagulation services GP-lead pointed out that there was a general view that prescribing of anticoagulation by GPs was unsafe territory:

"The Medical Defence Union (MDU) say litigation related to anticoagulant prescribing is one of the most common drug complaints plus inappropriate warfarin prescribing leads to increased hospital admissions when it goes wrong; it's easier for GPs to opt for aspirin." Pharmacy lead

Participants were aware that two general practices ran anticoagulation clinics (see anticoagulation team discussion), through practice funded phlebotomy, they thought that these services operated well. They recognized that anticoagulation in general practice was listed as an enhanced service in the new GP contract (DoH), but felt that overall there was a shortage of funding and interest for widespread implementation of these services; so it would be some time before such services made an impact:

"yes, (name) service runs well and he says patients are satisfied, but he has an interest in anticoagulation, that's why he started, he's using INRStar (CDSS), that's different from what you're (hospital practitioners) using isn't it?.....I don't see every GP setting up anticoagulation monitoring even with the new contract! It's not priority" GP lead

Secondary care

The consultant and nurse practitioner gave estimates of the BLT anticoagulation clinics workload; approximately 450 patients were seen each week, and approximately 20,000 dose changes made every year. The majority of patients had phlebotomy done at the anticoagulation clinic, left after the sample had been obtained and waited to receive letters from the clinic with details of results and dose changes. The consultant estimated that use of anticoagulation was preventing 50 strokes due to AF per annum in Tower Hamlets. However, operating the anticoagulation service was difficult because the anticoagulation team was small in number and often stretched due to the large number of patients:

"We're spreading ourselves thin, when there's a busy clinic or annual leave and sickness you really feel it. It's too much at the moment and we need to plan how we're going to cope in the future: it won't get better. I've been with the clinic for seven years and in that time I've seen a huge rise in our work load." Nurse practitioner

Transport (mobility-impaired) patients

Participants highlighted the issue of transport (mobility-impaired) patients. The consultant stated that it was not unusual to hear of mobility-impaired patients spending four hours in the hospital to get their blood taken and to be taken home. On occasion, the failure of patients to attend the clinic was due to transportation problems, or the patient being too ill to attend the clinic, giving rise to concerns about patient safety. In addition, there was an ongoing health and safety concern because of a lack of space within the clinic areas due to the large numbers of patients in wheelchairs being delivered at the same time.

Participants commented that use of NPT and dosing support software, could reduce waiting times in the hospital clinics and also allow for more local access to anticoagulation services for this group of patients.

Issues to be addressed

A number of issues were highlighted by the participants as important to address (Table 4.44).

Table 4.44: Issues regarding current anticoagulation service provision for BLT anticoagulation patients highlighted by key stakeholders

Issues	Points made
Provision of patient centred care	Patient care must be of paramount importance in quality service provision
Safety/risk management issues in the clinic	Space within clinics is an issue for patients in Wheelchairs
Housebound/mobility impaired patients	High risk patients: as immobility increases risk of blood clots, also they often have multiple co-morbidities
Governance issues around safe drug monitoring services for mobility-impaired patients	Patient non-attendance at clinic leaves them vulnerable to adverse effects of anticoagulation, a domiciliary service could address some governance issues and improve patient care
GP management of anticoagulation	Protocols, guidelines, training and support from BLT clinic practitioners would have to be provided to remove GPs fears and to make such a service safe.

Service developments

Some participants questioned the wisdom of resourcing service developments for anticoagulation monitoring with the advent of a new oral thrombin inhibitor, ximelagatran by AstraZeneca. Other participants pointed out that although this new medication would not require monitoring, it was still at trial stage and would not be a consideration for approximately five years, so it was wise and prudent to develop current anticoagulation services to ensure that they were of an acceptable standard for all patients:

"Ximelagatran is a long way off. Although study results are looking good, it is still in development and it probably won't be on the market for at least another four years. Even then, it will be vastly more expensive than warfarin plus INR monitoring and so will probably only be recommended for patients who have suffered from or are at high risk of adverse effects or where warfarin is inappropriate, so in the first instance we still have to deal with these issues here and now". Consultant haematologist.

All participants agreed that anticoagulation services were in need of development. The pathology manager, PCT commissioner and pharmacy lead were all keen to have NPT evaluated in BLT and if found to be feasible, accurate and safe, supported the roll out of near patient testing to the primary care-based setting. The consultant and nurse practitioner reported that they would be piloting NPT in 100 patients at the London Chest hospital imminently, to provide comparison between NPT and the standard laboratory method. Participants were aware that HUH anticoagulation clinic used NPT to determine INRs and thought that incorporating this at BLT would reduce waiting times at the clinic

and would hopefully negate the need for patients to leave the clinic before being given their results and dosage.

Participants stated that service developments should initially focus on housebound patients, as they classified them as high-risk patients as they tended to be older, with multiple co-morbidities, on a number of concomitant medications and at increased risk of thrombotic events due to immobility. They supported the idea of an evaluation of pilot models of domiciliary service for this group of patients; but emphasised that they did not want the study to purely be a research project and that findings at the end of any trial should lead to rapid implementation of an appropriate domiciliary service, with minimal lag time between the end of the trial and permanent service implementation. To ensure that this happened funding should be secured as soon as possible to allow the roll-out of the service, the pathology manager expressed a willingness to plan a domiciliary service into the pathology budget for the year following the trial. Anticoagulation service development was a priority for Tower Hamlets, as current anticoagulation service provision was not as advanced as current good practice in the active management of other chronic diseases such as heart failure and diabetes, where drugs and disease also needed to be monitored.

Requirements for personnel directly involved in anticoagulation service delivery

Participants highlighted the needs for updated job descriptions, service protocols, competency-based training, personal insurance and indemnity for those directly involved in the provision of any domiciliary services.

At the close of the meeting, the anticoagulation services GP lead drew together the points made during the discussions. It was agreed that anticoagulation service developments should aim to improve quality and maintain safety as well as increase patient convenience and access to the service. The three major considerations for anticoagulation service development highlighted were; maintenance of patient-centred care, including management of mobility-impaired patients, risk management and clinic space. In addition, participants were strongly in support of piloting and, if appropriate, implementing models of domiciliary service for mobility-impaired patients.

4.3.6 City and Hackney pharmacy forum meeting

Community pharmacists working within City and Hackney PCT hold regular bimonthly pharmacy forum meetings. The meetings are routinely open to community pharmacy contractors, employees, locums and pre-registration pharmacists. During forum meetings topics such as provision of

community pharmacy services (e.g. smoking cessation clinics, minor ailments schemes) and the influence of Government policies on community pharmacy are discussed. The forum is also used to explore the views of pharmacists about service developments; the pharmacists attending the meetings are part of a community pharmacy working group. The investigator attended a pharmacy forum meeting on the 23rd of September 2003 where the provision of anticoagulation services by community pharmacists was under discussion as part of an agenda of topics to be covered during the meeting.

4.3.6.1 Objectives

In addition to the objectives of the group interviews, the objectives of the pharmacy forum discussion were:

- To explore community pharmacists' views on the potential roles of community pharmacists in primary care anticoagulation service.
- To identify issues that should be addressed before such a service could be implemented.

4.3.6.2 Methods

The discussion was facilitated by the City and Hackney PCT Head of Prescribing (responsible for securing the funding to commission community pharmacy services) and a City and Hackney PCT employee, who was reviewing various models of anticoagulation service provision that could potentially be employed in the City and Hackney PCT. As the discussion was just one part of the agenda for the pharmacy forum meeting, time dedicated to the topic was limited to 20 minutes. During this discussion the investigator acted as an observer, did not contribute to the discussion and made detailed notes.

4.3.6.3 Results

There were 16 pharmacists in attendance at the meeting out of a possible 74 (21.6%). The discussion of anticoagulation service models exceeded the allocated 20 minutes and took 30 minutes. The data are summarised below.

Management of stable and unstable patients

Pharmacists felt that an anticoagulation service from a community pharmacy (CP) would be best suited to those patients whose INRs are stable; initiation and management of unstable patients should still take place in secondary care.

Role of community pharmacists

I. Reduce waiting times

The facilitator described anticoagulation service development at the HUH. Although the HUH service had improved over the years, the large numbers of patients attending the clinics contributed to sometimes extremely long waiting times with overbooked clinics and with only one consultant seeing every patient, the waiting times could exceed one hour. Participants of the forum meeting stated that with appropriate appointment scheduling, in the CP setting, this time could be reduced to a 10 minute session (using NPT) for each patient, improving acceptability of the service for patients.

II. Improve patient accessibility to services

Pharmacists believed that CPs were more accessible than GPs, and they were open for longer hours than outpatient clinics, affording patients more flexibility. Participants commented that, even with the new contract for GPs rewarding doctors for provision of enhanced services, they expected many would be reluctant to manage such a clinic as they may not have the knowledge or skills to maintain the stability of all their patients.

III. Understanding of drug interactions

Participants felt that it would be easier for pharmacists to provide such a service than GPs, as pharmacists have a clearer understanding of the potential for interactions between warfarin and other drugs. Further, with regards to policy documents outlining the future of pharmacy, for example, Pharmacy in the Future (Department of Health 2000b) and A Spoonful of Sugar (Audit Commission 2001), it appears that provision of new services is the way forward for community pharmacy.

IV. Identifying unmet need

Participants were aware of the literature suggesting that warfarin was underutilised. Participants suggested that there might be a role for CPs in screening for AF (for example flagging up prescriptions for digoxin) to identify those patients that would benefit from anticoagulation therapy that were not being treated.

V. Supporting self-testing and self-management

With increasing numbers of patients buying NPT devices for self-testing and self-management participants felt that there might be a role for pharmacists in supporting such patients.

Alternatives to community pharmacy anticoagulation model

For the purposes of organising and co-ordinating the delivery of health and social care at a local level, the area covered by the City and Hackney PCT is divided into four geographical patches (Northeast, Northwest, Southeast and Southwest). Patches are defined as areas lying in only one PCT and only one Council with Social Services Responsibilities (CSSR). The facilitator discussed the option of one major health centre in each patch providing a number of services / clinics (including anticoagulation services) for the community. This option was identified as a feasible alternative to the service being provided from community pharmacies, again improving patient access to the service.

Issues to be addressed for implementation of community pharmacy service

Participants highlighted a number of issues they felt needed to be addressed before community pharmacy-based services were widely implemented. These are summarised in Table 4.45.

Table 4.45: Issues to be addressed for effective implementation of services

Identified issues	Comments
Communication	Good communication essential between HCPs within primary care and between primary and secondary care, to ensure quality care
Access to records	Access to hospital and GP records via NHSnet ⁵ would facilitate such a service
Clinical Governance	Logistics: would pharmacists have to be supplementary prescribers, or would they have to be employees (have honorary contract) with the hospital where the patient had been referred from and work to an agreed protocol before they could provide such a service?
Resources	Some would have to put substantial resources into renovating pharmacy premises. Any consultation room built within the premises would have to be utilised fully to ensure good return on investment; this would involve running other clinics such as smoking cessation or glucose monitoring, in addition to INR monitoring. Further, if a domiciliary service was to be provided, locum cover may be required. To make visits economically viable other services should be provided during visits such as medication review. In addition to cost of premise renovations, cost of NPT devices and strips would have to be factored in.
Quality Assurance	Internal and external QA should be routinely performed and documented.
Remuneration	Uncertainty as to where payment for service provision would come from.

Overall, participants felt that community pharmacists providing such services was a positive move and one that they, as healthcare professionals, would largely welcome, however there were a number of grey areas that would have to be resolved before they saw such services being rolled out.

⁵ NHSnet is a national private internet network, which allows the transfer of patient-identifiable confidential data to and between GPs, hospitals and other specified NHS contractors without using paper.

4.3.7 Nominal group session

This section outlines the objectives of the nominal group session, the methods and results of the multidisciplinary session.

4.3.7.1 Objectives

In addition to the objectives of the group interviews, the objectives of the nominal group session were:

- To investigate the perceptions of GPs and CPs, with regards to the provision of anticoagulation services in primary care.
- To reach consensus on the favourability of a range of potential primary care models.

4.3.7.2 Method

A nominal group technique was chosen to select the anticoagulation service model as it would enable participants to produce a comprehensive topic-related list of issues and, through discussion and ranking, allows participants to reach a consensus.

4.3.7.3 Sample

Two sessions were to be held, one for GPs and one for pharmacists. Single discipline meetings rather than a multidisciplinary session were opted for as it was suggested by practitioners (from the anticoagulation clinic) that a multidisciplinary meeting may inhibit conversation as the two professions would be coming from potentially very different perspectives. The sessions were to be attended by the GPs and pharmacists from City and Hackney and Tower Hamlets PCTs. In addition, practitioners from the Greater London area with experience of providing a community-based anticoagulation service were to be invited. The practitioners from the City and Hackney and Tower Hamlets areas were expected to be able to contribute their experiences and opinions with respect to their locality. The practitioners from the Greater London area were expected to contribute their experiences and insights of providing anticoagulation services in primary care. The aim was for the session to be attended by 12 to 16 of those that accepted the initial invitation (16 practitioners were to be invited to ensure at least 12 practitioners were in attendance at each session); this would include approximately six GPs/pharmacists from City and Hackney and Tower Hamlets PCTs each and two to four GPs/pharmacists London-wide.

Recruitment

To identify those providing a community-based service London-wide, the National External Quality Assessment Service (NEQAS) was contacted. NEQAS is a UK-based service that aims to advise and assist clinical laboratories in producing precise, consistent and comparable test results (including results from NPT devices) irrespective of the site of the test (i.e. community pharmacy, general practice). This is achieved through external quality assessment involving the issuing out of samples to all NEQAS registered laboratories. Laboratories results are subsequently compared to each other and performance is rated. It was hoped that NEQAS would be able to provide information/contact details for those providing primary care anticoagulation services. However, due to confidentiality issues they were unable to divulge the names or details of their clients and were unable to act as intermediates, by sending invitation letters devised by the investigator to their registered laboratories.

Through various professional contacts, one community pharmacist and one GP providing a primary care anticoagulation service as part of their practice were identified and invited to participate in a session, alongside practitioners not providing an anticoagulation service.

Letters outlining the project and inviting GPs and pharmacists to participate in the session were sent to all GP practices and pharmacies in the City and Hackney and Tower Hamlets PCT areas on the 2nd of June 2003, (Appendix 3 and Appendix 4). A further two rounds of letters were posted on the 16th and 30th June respectively, to serve as a reminder. Healthcare professionals were asked to register their interest by returning a reply slip in a freepost envelope provided. Letters were posted in two rounds to those who had not responded to the initial invitation, in an attempt to increase the response rate.

Practitioners were given two dates to choose from so that the session could be organized to suit the majority of participants. Those who expressed an interest were subsequently contacted by telephone to confirm their participation. Prior to attending the session (via post, on the 22nd of July 2003), participants were sent a pack which contained a brief description of the models to be discussed, a programme for the session and an explanation of the nominal group process.

Nominal group session instruments

Three instruments were used to facilitate the nominal group session process:

- i. A session plan was developed to aid session management.
- ii. A worksheet that outlined each model to be discussed during the session was developed (Appendix 5). The worksheet allowed participants to list potential advantages and disadvantages, together with additional comments and rank for each model.
- iii. A discussion guide was developed to be used by the investigator, to ensure that all pertinent aspects, such as training and logistics related to provision of the models of service delivery were discussed during the session.

Nominal group session description

At the start of the session, the investigator gave a brief (5 minute) presentation, which included an introduction to provide the context of the research and a description of nine potential anticoagulation models to be discussed (Table 4.46). With the participants' consent, the session was recorded using a minidisk recorder and microtelephone. Participants were given the worksheets, and were asked to complete the sections pertaining to the nine models individually. Of the nine models, two represented current hospital-based services for ambulatory and mobility-impaired patients. The remaining seven were primary care models identified from the literature review. Following this, each model was discussed in turn by the whole group. The potential advantages and disadvantages of each model as cited by the group were listed on a flip chart, along with individuals' rankings for each model. The group was then asked to arrange the advantages and disadvantages in order of importance with explanation. Following group discussion, the advantages and disadvantages were ordered in such a way that the majority of the group were in agreement. This process was followed for each model. Once each model was discussed, the practitioners were asked to agree on a rank for each model and rank them in order of preference. The topic guide was used to prompt the group discussion to include the sustainability of each model in the current framework of healthcare in East London, training and support requirements and ways of addressing potential barriers. At the end of the session, the practitioners were asked what their ideal model would be.

Table 4.46: The proposed models and the traditional model of anticoagulation service provision

Patients	Model	Sample site	Type of sample	Test site	Dosing site	Patient contacted by
<i>Mobile</i>	<i>Model 1 (Traditional)</i>	Hospital	Venous	Hospital	Hospital	Hospital
	<i>Model 2</i>	General practice	Capillary	General practice	General practice	General practice (one stop)
	<i>Model 3</i>	General practice	Venous	Hospital	Hospital	Hospital
	<i>Model 4</i>	General practice	Venous	Hospital	General practice	General practice
	<i>Model 5</i>	Community pharmacy	Capillary	Community pharmacy	Community pharmacy	Community pharmacist (one stop)
<i>Immobile</i>	<i>Model 6</i>	Patient's home	Capillary	Patient's home	Patient's home	Nurse or healthcare assistant or community pharmacist (one stop)
	<i>Model 7</i>	Patient's home	Venous (general phlebotomist)	Hospital	Hospital	Hospital
	<i>Model 8</i>	Patient's home	Venous (general phlebotomist)	Hospital	General practice	General practice
	<i>Model 9 (Traditional)</i>	Hospital (via hospital transport service)	Venous	Hospital	Hospital	Hospital

4.3.7.4 Results of nominal group session

The nominal group session was held on the 30th of July 2003.

Pharmacies

Seventy-four pharmacies were contacted in City and Hackney and 40 in Tower Hamlets. Following two rounds of letters and telephone calls to follow-up displays of interest, two pharmacists attended, both from the Tower Hamlets area (response rate 1.8%).

General Practices

Forty-eight General Practices in City and Hackney and 42 in Tower Hamlets were contacted with an invitation to participate in the session. Following two rounds of letters and telephone calls to follow-up displays of interest, two attended, one working in the City and Hackney area and one working in Tower Hamlet's PCT (response rate 2.2%).

In addition, the community pharmacist (London-based) identified as providing a community pharmacy-based anticoagulation service also participated. Finally, a haematologist from Whittington hospital who was interested in contributing to the discussion on primary care anticoagulation services also attended. The individual ranking and consensus ranking for each model is detailed in Table 4.47.

Table 4.47: Participant ranks for anticoagulation service models

Model	Participant 1 (consultant haematologist)	Participant 2 (CP)	Participant 3 (CP)	Participant 4 (GP)	Participant 5 (GP)	Participant 6 (CP providing service)	Consensus rank
				Ranks			
1	5	3	5	5	4	5	5
2	1	2	2	2	2	2	2
3	3	4	4	4	3	4	4
4	4	5	3	3	1	3	3
5	2	1	1	1	5	1	1
6	1	1	1	1	2	1	1
7	2	3	2	3	3	3	3
8	3	2	3	2	1	2	2
9	4	4	4	4	4	4	4

Table 4.48 to Table 4.56 outline the key issues that were highlighted for the various models.

MODEL 1	
Mobile patients visit the hospital anticoagulation clinic, where their blood is obtained via venous sampling. The blood sample is sent to and analysed in the hospital laboratory. The INR determinations are then sent to anticoagulation clinic staff, who dose patients according to the laboratory INR results. If the patient decides not to wait for their result, the hospital contacts them either via post or telephone depending on the urgency with their INR result, the required dose of warfarin and the date of the next appointment. This model is the one employed at BLT anticoagulation clinic for their mobile patients.	

Table 4.48: Summary of key issues highlighted for Model 1 in nominal group session

Theme	Participants' perceptions
Resources required for service model; not only financial	Potentially most expensive model for ambulatory patients; involves use of consultant time, laboratory time, nurse time, administrator time and patient time. Several departments involved in provision of this model. Participants felt model wasted time and other resources.
Training standards of practitioners providing the service	Training of practitioners within hospital setting is of a high standard and appropriate .
Logistics of the service model	Advantages: Presence of consultant haematologist on site to answer queries or handle difficult cases In addition, dedicated expert advice available for patients at point of contact. All parts of service carried out on site , results and dose adjustments done the same day: important factor in ensuring consistency and minimizing the risk of errors in blood handling Hospital-based: access to patients' medical histories more readily available. Disadvantages: Results often received slowly Venous method of blood sampling: negative: relatively large amount of blood is required to yield an INR result. Positive: results deemed accurate
Communication between practitioners	Disadvantages: Lack of communication between hospitals and general practices: General Practitioners expected to supply warfarin. However, often not told what dose a patient is on, rarely given anticoagulation record book. Often prescribe blindly- could put GPs in a vulnerable position, with regards to provision of quality patient care.
Time related issues for the service model, predominantly focussing on patient time	Disadvantage: Long time spent waiting in clinics , patients sometimes wait up to two hours for the result, dose and follow-up appointment date. Potentially long travel times , particularly difficult for weaker patients: perceived as a major downside. Some expressed the opinion: as clinics tend to be busy, even with experts on site, often little or no quality discussion between clinicians and patients . Patients who work and attend clinic regularly, might have to consider impact of their illness on their work, as frequent clinic visits could result in a significant loss of working hours.
Environment of where the service is held and ease of access to the service	For small minority of patients, clinic appointments serve as a social activity; day out for those who might be lonely. With hospitals becoming more saturated with patients, more patients receiving this service need to be directed away from hospitals to primary care to free up space so that expertise could be utilized in other ways.
With whom does the responsibility for provision of the service and any service-related issues lie?	Overall responsibility and accountability with consultant haematologist . Other practitioners would be held accountable and would be expected to defend their dosage decisions if they had not followed an agreed protocol.

MODEL 2

Mobile patients visit the general practice-based anticoagulation clinic, where their blood is obtained via capillary sampling. The blood sample is analysed using an NPT device, to determine the patient's INR while they wait. The anticoagulation practitioner (GP/ Pharmacist/Nurse) doses the patients using the INR results at the same appointment, the patient is advised of the result, the dose of warfarin required and the date of the next appointment. This service is a 'one stop shop', as all aspects of the service take place at one site.

Table 4.49: Summary of key issues highlighted for Model 2 in nominal group session

Theme	Participants' perceptions
Resources required for service model; not only financial	Question mark as to cost-effectiveness and where funding would come from. Expecting GPs to find the money could result in overstretching of GP resources. PCT should pay for service , however benefits would have to be clearly established through pilot studies. Costs including cost of NPT device. Responsibility for quality assurance and maintaining supply of consumables would have to be accurately evaluated before service could be implemented and sustained.
Training standards of practitioners providing the service	Questions: how to ensure consistency in the level of knowledge by eliminating disparity in training between practices. Training particularly important as person making dosing decision must be able to elicit relevant information from patient to inform dosing decision especially when INR results are out of range. GPs at the very least must have basic anticoagulation training irrespective of whether they were directly involved in provision of the service. GPs to be used as a source of advice when more complex dosing required.
Logistics of the service model	Quick results and dosing. Capillary method- represents easy blood withdrawal. Patients receive relevant and tailored advice as HCPs have access to full medical records, seen as aid to patient care. Potentially unwelcome load on GPs. Questions over reliability of NPT devices versus conventional laboratory methods of analysis. Rather than a GP led service, more likely nurse/pharmacist-led service within General Practice. Protocols needed to ensure service runs in accordance with the best practice.
Communication between practitioners	GPs would need close support from affiliated hospital anticoagulation team to prevent isolation Advantage: GPs, nurses and healthcare technicians have more regular contact with patients than hospital clinicians, so might be better able to interpret patients' INR results.
Time related issues for the service model, predominantly focussing on patient time	"One stop shop", quick results, believed to reduce waiting times compared to model 1.
Environment of where the service is held and ease of access to the service	Advantage: based in easily accessible 'Local Doctor's Surgery', more convenient for patients , who avoid making sometimes long trips to Hospital. General practice: familiar surroundings for patients, may enhance communication between HCPs and patients as may reduce patients' anxiety compared to attending the hospital outpatient clinic.
With whom does the responsibility for provision of the service and any service-related issues lie?	Overall responsibility, irrespective of whether the GP was directly involved in the service provision, lies with the GP .

MODEL 3	
Mobile patients visit their general practice, where their blood is obtained via venous sampling. The blood sample is sent to and analysed in the local Hospital laboratory. The INR determinations are then sent to hospital-based anticoagulation clinic staff, who dose patients according to the laboratory INR results. The hospital practitioners contact the patients either via post or telephone depending on the urgency, with their INR result, the required dose of warfarin and the date of their next blood test at the general practice surgery.	

Table 4.50: Summary of key issues highlighted for Model 3 in nominal group session

Theme	Participants' perceptions
Resources required for service model; not only financial	This service was seen as reducing GP service to a simple phlebotomy service.
Training standards of practitioners providing the service	Training issues were as for model 1. Training of practitioners within hospital setting: a high standard and appropriate.
Logistics of the service model	Disadvantage: numerous steps -GP practice → hospital lab → hospital anticoagulation clinic for dosing, leading to increased risk of errors, and increase in time the patients wait to receive the results.
Communication between practitioners	Disadvantage: Number of staff involved in the model → increased potential for communication errors , particularly as faceless interaction between practitioner and patient. There is no direct communication with GP with regards to dosing, GP expected to prescribe blind. System should not bypass the GPs.
Time related issues for the service model, predominantly focussing on patient time	Patients wait for sample to be delivered to hospital and either a letter or telephone call from the hospital team: a lengthy process.
Environment of where the service is held and ease of access to the service	Easy access, local and familiar surroundings.
With whom does the responsibility for provision of the service and any service-related issues lie?	Hospital satellite service, therefore, consultant haematologist has overall responsibility (GP = blood test site only).

MODEL 4

Mobile patients visit their general practice, where their blood is obtained via venous sampling. The blood sample is sent to and analysed in the local Hospital laboratory. The INR determinations are then sent back to the general practice-based anticoagulation practitioners, who dose patients according to the laboratory INR results. The general practice practitioners contact the patients either via post or telephone depending on the urgency, with their INR result, the required dose of warfarin and the date of their next blood test at the general practice surgery.

Table 4.51: Summary of key issues highlighted for Model 4 in nominal group session

Theme	Participants' perceptions
Resources required for service model; not only financial	Expensive: involves more specific use of primary care resources.
Training standards of practitioners providing the service	Training needs to be of a sufficient standard to ensure decision maker able to interpret INR results and dose appropriately. Development of a service protocol would aid decision making processes.
Logistics of the service model	Scheduling of appointments more flexible and hence more convenient for patients versus hospital service. Disadvantage: venous sample requires relatively large volume of blood (3-5ml) compared to samples using capillary blood with an NPT device (10 µl). Error prone as involves a number of steps and communications between different departments across different sectors.
Communication between practitioners	Dosing may not be done by expert practitioner, impersonal approach as patients telephoned by practice to advise them of the dose changes. Model would be better if patients asked back to see a practitioner but patients may not like this. GPs may feel isolated and may lack knowledge regarding safe and effective use of anticoagulants to effectively run such a service.
Time related issues for the service model, predominantly focussing on patient time	Reduce long waiting times in hospital clinics. Long wait for INR results and dosing as practice would have to wait for sample to be analysed by hospital laboratory then sent back to a GP practice before anything could be done. Transfer of long waiting times: instead of patients waiting for long amounts of time when receiving the hospital service, the long waiting times are shifted to the general practice setting.
Environment of where the service is held and ease of access to the service	As with model 3: GP practice, often a better site for patients to travel to, probably more accessible than a hospital.
With whom does the responsibility for provision of the service and any service-related issues lie?	As much of service taking place in GP premises, even if not GP-led service, the GP would hold overall accountability for ensuring the service ran safely and staff were adhering to agreed protocols.

MODEL 5

Mobile patients visit a community pharmacy based anticoagulation clinic, where their blood is obtained via capillary sampling. The blood sample is analysed using an NPT device, to determine the patient's INR while they wait. The pharmacist doses the patients using the INR results at the same appointment. The patient is advised of the result, the dose of warfarin required and the date of the next appointment. This service is a 'one stop shop', as all aspects of the service take place at one site.

Table 4.52: Summary of key issues highlighted for Model 5 in nominal group session

Theme	Participants' perceptions
Resources required for service model; not only financial	<p>If community pharmacy had enough anticoagulation patients, this model would be cost-effective.</p> <p>Does not use hospital practitioners' or GPs' time.</p> <p>Financial arrangement unclear; who should be expected to fund the service? Potentially the PCT: Before a PCT would pay for such a service, they would need evidence of benefit to patients following pilot studies in their area.</p>
Training standards of practitioners providing the service	<p>Standardized training needed to ensure consistency amongst pharmacist practitioners. Agreed training objectives alongside protocol would help to achieve this.</p>
Logistics of the service model	<p>Personalized service alongside professional dosing. One stop: risk of errors minimised.</p> <p>Scheduling of appointments: fast and flexible.</p> <p>Protocols should be set up: appropriate referral to hospital should be time efficient</p> <p>Efficient quality control system needs to be in place</p> <p>Pharmacists may be in danger of isolation, if no close links with GPs and Hospital, as form of back up, especially with regards to medical knowledge.</p> <p>Advantage: Pharmacists knowledge of local patients helps with OTC medication, compliance issues, communication issues, knowledge of diet and drinking habits etc; benefits dosing process.</p> <p>Less stigma attached to attending local pharmacy, than to hospital or GP practice (i.e. less likely to be seen as ill) -</p> <p>Working patients: appointments out of working hours to fit patients' lifestyle.</p> <p>Potential disadvantages: pharmacists may recall patients too quickly, due to uncertainty about NPT device test results (irrespective of proven accuracy) as likely to have small number of patients and because the method of sampling, analysing and dosing-very quick. This might offset benefit to patients with regards to travel time, might make service more expensive.</p> <p>For pharmacists to be able to provide this service more effectively- would have to be on the NHSnet to access the most up-to-date medical information regarding patients.</p> <p>Emphasis on support from GPs and Hospital staff.</p> <p>If GPs and pharmacists were able to forge and maintain close links, this service would be a truly multidisciplinary approach to anticoagulation service provision.</p>
Communication between practitioners	<p>Pharmacists well placed to provide service; compared to hospital or general practice staff-better able to elicit information to aid in dosing of individual patients.</p> <p>Pharmacy service provides a more personal touch. Pharmacists should maintain contact with GPs to ensure doctors aware of monitoring situation and so that GPs could let pharmacists know of changes to prescribed drugs and diagnosis of illnesses.</p>
Time related issues for the service model, predominantly focussing on patient time	<p>Patients able to arrange appointments out of working hours as many pharmacies are open in the evening.</p> <p>Reduces amount of time patients would have to take off work for appointments. Quick results and dosing, alongside local location minimises time spent by patients to receive the anticoagulation monitoring service.</p>
Environment of where the service is held and ease of access to the service	<p>Local environment and ease of access</p>
With whom does the responsibility for provision of the service and any service-related issues lie?	<p>Service provided in community pharmacy, however GPs would have some responsibility as they would be responsible for signing prescriptions for warfarin.</p> <p>Based on pharmacists advice</p> <p>Community pharmacist and GP.</p>

MODEL 6

Immobile anticoagulation patients are visited at home by a pharmacist / nurse, where a capillary sample along with an INR determination using an NPT device is carried out. The patient is dosed according to the INR result and informed of the INR result, the required dose and the date of the next visit by the visiting practitioner. All aspects of the service take place in the patient's home; therefore this is a 'one stop shop' model.

Table 4.53: Summary of key issues highlighted for Model 6 in nominal group session

Theme	Participants' perceptions
Resources required for service model; not only financial	Most expensive of those provided for the immobile patients; involves dedicated time of a healthcare practitioner and involves travel. Financial arrangement unclear; who should be expected to fund the service?
Training standards of practitioners providing the service	Training and working within agreed protocols important. HCPs expected to be able to defend any dosing decision; important that they are assessed as competent anticoagulation practitioners prior to service provision
Logistics of the service model	Advantages: "Eliminates long tortuous journeys to hospital and long waits at hospital". Quick results and dosing. Capillary sample viewed as more appropriate for this group of patients who are often elderly and frail and may have weak veins. Model perceived as providing good patient care, improving convenience to patients and minimal disruption to their routine.
Communication between practitioners	Advantage: One to one time between patient and the practitioner in patients' own home: practitioners perceived to be better able to elicit relevant information to ensure dosing appropriate.
Time related issues for the service model, predominantly focussing on patient time	Time efficient for patients: no need to go to a hospital and endure variable waiting times. Testing and dosing completed within 10 minutes at patients' homes. Service-very time consuming for HCP
Environment of where the service is held and ease of access to the service	Patients: comfortable as no need to worry about getting ready long in advance of their scheduled appointment.
With whom does the responsibility for provision of the service and any service-related issues lie?	Overall responsibility for service with HCP who doses.

<p style="text-align: center;">MODEL 7</p> <p>Immobile anticoagulation patients are visited at home by a general phlebotomist, who obtains blood via venous sampling. The blood sample is sent to and analysed in the local Hospital laboratory. The INR determinations are then sent to hospital-based anticoagulation clinic staff, who dose patients according to the laboratory INR results. The hospital practitioners contact the patients either via post or telephone depending on the urgency, with their INR result, the required dose of warfarin and the date of the next visit</p>

Table 4.54: Summary of key issues highlighted for Model 7 in nominal group session

Theme	Participants' perceptions
Resources required for service model; not only financial	Perceived as less costly than model 6: utilizes general phlebotomist's time instead of a more expensive healthcare professional such as a nurse or pharmacist.
Training standards of practitioners providing the service	Training issues were as for model 1: Training of practitioners within hospital setting: a high standard and appropriate.
Logistics of the service model	Venous sampling not ideal in this group of patients as often poorly and have weak veins. Model represents "a multi-participant service channel:" may be an increased risk of errors.
Communication between practitioners	Communication issues raised as for model 3: Disadvantage: Number of staff involved in the model \square increased potential for communication errors , particularly as faceless interaction between practitioner and patient. There is no direct communication with GP with regards to dosing, GP expected to prescribe blind. System should not bypass the GPs.
Time related issues for the service model, predominantly focussing on patient time	Service could be too time-consuming as venous sample sent to hospital for analysis before patients are dosed
Environment of where the service is held and ease of access to the service	Advantage: Elimination of patient travel and provision of service in patients' home.
With whom does the responsibility for provision of the service and any service-related issues lie?	Responsibility and accountability for provision of service lies with the hospital haematology consultant.

MODEL 8
Immobile anticoagulation patients are visited at home by a general phlebotomist, who obtains blood via venous sampling. The blood sample is sent to and analysed in the local Hospital laboratory. The INR determinations are then sent back to the general practice-based anticoagulation practitioners, who dose patients according to the laboratory INR results. The general practice practitioners contact the patients either via post or telephone depending on the urgency, with their INR result, the required dose of warfarin and the date of the next visit.

Table 4.55: Summary of key issues highlighted for Model 8 in nominal group session

Theme	Participants' perceptions
Resources required for service model; not only financial	As for model 4: expensive , involves more specific use of primary care resources.
Training standards of practitioners providing the service	As for model 4: Of a sufficient standard to ensure decision maker able to interpret INR and dose appropriately. Development of service protocol would aid decision making processes.
Logistics of the service model	Convenient for patients: do not have to travel. Service is not a one-stop service. Venous sampling not ideal for this patient group.
Communication between practitioners	Advantage: General practitioner involved in dosing: promotes good relationship between patient and GP practice. Better than model 7, as dosing being performed by patients' GP practice staff.
Time related issues for the service model, predominantly focussing on patient time	Process involves 3 different sites (patient's home, hospital and GP practice): time consuming.
Environment of where the service is held and ease of access to the service	Advantage: similarly, to model 6 and 7 provision of a domiciliary service for mobility-impaired patients advantage over traditional method of transporting patients to hospital.
With whom does the responsibility for provision of the service and any service-related issues lie?	General practitioner has overall responsibility for provision of model.

MODEL 9	
<p>Immobile anticoagulation patients are taken to the hospital anticoagulation clinic by the hospital ambulance service. Patient's blood is obtained via venous sampling. The blood sample is sent to and analysed in the Hospital laboratory. The INR determinations are then sent to anticoagulation clinic staff, who dose patients according to the laboratory INR results. Patients are then taken to the departure suite, where they wait for the ambulance service to transport them home. The hospital practitioners contact them either via post or telephone depending on the urgency with their INR result, the required dose of warfarin and the date of the next appointment. This model is the one employed at BLT anticoagulation clinic for their immobile patients.</p>	

Table 4.56: Summary of key issues highlighted for Model 9 in nominal group session

Theme	Participants' perceptions
Resources required for service model; not only financial	Service expensive as involves hospital ambulance service to deliver patients to the hospital.
Training standards of practitioners providing the service	As for model 1 and 3. Training of practitioners within hospital setting: a high standard and appropriate .
Logistics of the service model	From start to finish the appointment could take the best part of a day. Venous sampling not ideal for the patient group.
Communication between practitioners	Sometimes communication problems between the anticoagulation clinic staff and hospital ambulance service staff .
Time related issues for the service model, predominantly focussing on patient time	Time consuming for patients ; they wait for ambulance service to pick them up one by one and deliver them to hospital in a group, then wait for the whole group to be seen by a practitioner and then wait for the ambulance service to take them home one by one.
Environment of where the service is held and ease of access to the service	Some patients like waiting in the hospital, it gives them a social life
With whom does the responsibility for provision of the service and any service-related issues lie?	As the service was provided by the hospital the hospital consultant would have overall responsibility of the service.

Barriers to service provision identified by participants

The main barriers to primary care anticoagulation service developments identified by participants were GP reluctance, a lack of clarity regarding funding, communication (transfer of information) issues, including a lack of access to records for pharmacists and a perceived lack of time to provide services and go for training.

GP reluctance

GPs were apparently reluctant to increase their involvement in anticoagulation service provision. Indeed, data indicated that GPs were, at times uncomfortable with the choice of warfarin and had fears over prescribing in primary care with monitoring in secondary care because they felt there was inadequate transfer of information, as illustrated in this nominal group participant's comments:

"The main thing that I see from a logistic point of view is that there has always traditionally been quite poor communication between hospital and community, and the hospital though they provide the warfarin dose - the patient comes to the GP for their follow-up. They lose their book, they lose their tablets, they go on holiday, there's a lot of issues, I'm sure you've all come across it. So they come to me, they want more tablets, I don't get to see their yellow book, I don't know what dose they're supposed to be on, they say something, or they say 'Doc I don't know', so I end up trying to find more information, there always seems to be this poor communication so it puts me in a very vulnerable state, it puts the patient in a vulnerable state. Now I don't prescribe until they show me the yellow book after a significant event happened.....a life threatening bleed." (Nominal group session GP participant-4)

Participants also felt that GPs lacked time, and confidence to provide anticoagulation services:

"Talking logistically, I'm unsure there will be enough GPs to soak up the patients of other GPs who I'm pretty sure would be very unwilling to take this up, probably because they are not confident, not prepared to go for training and haven't got the time." (Nominal group session GP participant-4)

Funding

Issues over who should fund service developments were identified and it was recognised as a source of frustration for the community pharmacist providing an anticoagulation service:

"Who bears the cost? – Hospital? GPs? Pharmacists?" (Nominal group GP participant-5)

"You tell me – I can't sell the service. Getting it (community pharmacy service) sold as a service is light years away; we're getting nowhere in XXX, so don't get excited. I can't see it happening unless you've got a very good PCT that can see it's an advantage to the hospital." (Nominal group pharmacist participant-6)

There was a feeling of despondence and frustration, that service developments were piloted and rolled out but not supported financially in the long term, this was regarded as a problem with the NHS and the Government's modernisation agenda:

"Politicians only want money from you, but when they want to pay you, you are the beggar! It's not just a matter of money it's a matter of equilibrium. The most important thing is patient care, it's not just about money; there are easier ways to make money! But I have bills to pay, I can't provide everything for free; the tax collector doesn't say tax free!" (Nominal group pharmacist participant-3)

Communication – transfer of information

Repeatedly, improved communication was stated as key to future service developments. It appeared the role of effective communication could not be overstated:

"I think XXXX (community pharmacist model) system is really wonderful, but it's not just about taking time away from a busy clinic and making use of important knowledge. It's also important to link everything together; it's not as if pharmacy is there - GP there - patient there or patient with GP or patient with pharmacy. It would be good if it's a channel and we all work together. The Community pharmacist must ensure that links are maintained with the GP." (Nominal group pharmacist participant-3)

"Communication needs to work both ways. The GP needs to inform the prescriber – 'I have dosed patient X with this or I've added this new drug otherwise that automatically puts the prescriber in a vulnerable position.'" (Nominal group GP participant-4)

The lack of access to patients' records for pharmacists was perceived to be a huge barrier to the effective and safe implementation of community pharmacy based anticoagulation services. It was felt that access to patients' records would optimise pharmacists' ability to provide a range of services including anticoagulation monitoring to the public:

"I feel pharmacists put themselves in a vulnerable position if they prescribe without access to patients' records. Pharmacists are not on NHSnet, which is a big disadvantage. Once they are included they'll know that there making decisions on current clinical information, until then it's risky" (Nominal group GP participant-4)

Lack of time

Whilst some participants were in favour of primary care anticoagulation services, others felt that they were under pressure to provide more and more services with minimal support. Participants felt that with more services coming to primary care they would have to prioritise; there was neither time to provide or train for every service. They were aware that service provision did not only involve attending some training sessions, it also involved time to develop and familiarise themselves with service protocols and systems, time to provide the service efficiently within current practice / pharmacy set-up and time to keep up-to-date with any further clinical or service developments:

"The GPs are not going to do it (provide anticoagulation services)...are they? They're too busy doing other things. They want us to do minor ailments, emergency hormonal contraception, smoking cessation, obesity clinics, cholesterol testing, dispensing for residential homes...I really do wish I could do it all but...where's the time! It's not just finding time to provide the service safely, it's training and keeping up to date and if we mess up our career could be on the line...I know others are keen, I'm definitely interested but I'm not sure. I would need a locum pharmacist to help cover the pharmacy if I was doing all this and I'm not sure if it makes economic sense." (Nominal group session Pharmacist participant – 5).

I know. There's so much to do... I struggle to get to grips with all that they want from us. (Nominal group session GP participant-1)

Participants also questioned whether the risks to themselves (litigation) of providing anticoagulation services outweighed the benefits to patients and whether provision of a high risk service would be the best use of their time.

Traditional models

Models 1 and 9 (traditional for mobile and immobile patients) were viewed as out-dated and no longer sufficient as the sole models of anticoagulation service provision. They were ranked the lowest when compared to alternative services and seen as wasteful:

"Conventional services use consultant time, lab time patient time, nursing time, some patients require transport don't they? A few of my patients do. I have a feeling it's probably the most wasteful. The time arranged is usually not suitable for the patients. Patients end up spending one day there for a 20 minute job." (Nominal group GP participant-4)

Perceived ideal anticoagulation service model

The group dynamics of the session resulted in participants being asked to clarify their views and in some cases challenge their perceptions. Indeed, one GP's view of community pharmacy led – anticoagulation services, changed from negative to positive over the course of the session:

"The ideal model would be a pharmacist-led one – I know I'm changing my mind now! But I think it should really be a non – doctor led service". (Nominal group GP participant-4)

All the presented models, apart from the domiciliary / pharmacist service, were viewed as relatively easy to sustain, this model involved large costs and was perceived to involve more dedicated HCPs' time compared to the other models. However, the participants felt that, if cost was not an issue, the ideal model would involve a trained pharmacist or nurse practitioner-led service for both ambulatory and mobility-impaired patients. It was agreed that the pharmacist/nurse would have to have close links with the patients' GPs. Where pharmacists were providing the service they should also have some medication review role alongside their anticoagulation duties. Whilst GPs may be responsible for supporting the service, it would not be a GP-led service. It was largely felt that a GP-led service would not be appropriate as many GPs would be reluctant to take the lead due to lack

of remuneration, time and training. A hospital anticoagulation team was suggested as an alternative to GP support. It was highlighted that in the community nurses tended to take short term positions which would necessitate re-training each time a new nurse was employed into a nurse-led anticoagulation service. It was generally agreed that pharmacists (particularly in independent pharmacies) tended to stay in their posts for some time. Participants felt that this was an advantage as patients would probably feel more comfortable seeing the same person / team each time.

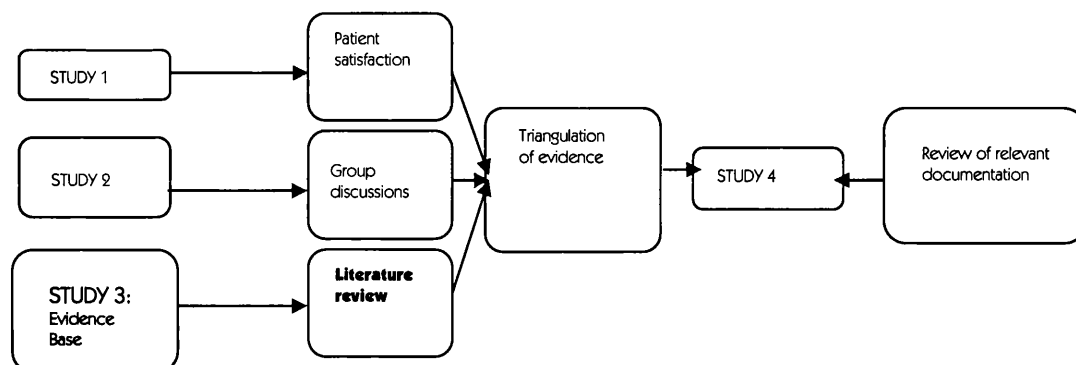
Ways forward for local anticoagulation services

The participants all agreed that a move to community-based anticoagulation services was the way forward. They agreed that, although one of the objectives of community-based services would be to reduce workload for hospital services, patient care was of paramount importance. Participants felt that ideally initial service developments should focus on domiciliary services for the mobility-impaired, as such patients were currently spending much of their day commuting to and from the clinic for a simple blood test. Further, they stated that implementation of NPT at BLT anticoagulation clinics to reduce waiting times would be appropriate until primary care anticoagulation service models were in widespread use.

It was noted that not all healthcare professionals would be prepared to take on this role, and that it would not be necessary for every single pharmacist and GP to do so. Participants repeatedly stated that issues that would have to be carefully considered before any of the primary care models could be implemented long-term included, finances (assessment of cost effectiveness and who would bear the costs), practitioner support systems, IT systems (dosage support, access to NHSnet), and incentives for practitioners to provide such services. Further, training and up-to-date protocols were viewed as key in the provision of safe and effective community services. It was agreed that a decision-maker must be able to defend (for instance in a court of law) any decisions that were not included in a protocol. Where incidents occurred and practitioners had acted appropriately within the protocol, those responsible for developing the protocol could be asked to defend it.

Summary

- There was recognition of the recent increase in demand for local anticoagulation services which had not been offset by an increase in capacity of anticoagulation services.
- Professionals agreed that local anticoagulation services were in need of development, particularly with regards to a move towards primary-care based settings and the potential use of near patient testing.
- Issues such as, clinical governance, mobility - impaired patients, health and safety (in clinics), training, funding, practitioner support systems, IT systems (dosage support, access to NHSnet) and protocols were highlighted as requiring particular attention in current services and in future service developments.
- The mobility-impaired were recognised as a patient group that would benefit from being the focus of initial service developments.
- A domiciliary service involving a trained anticoagulation practitioner and the use of NPT and CDSS was regarded as the ideal model for mobility impaired patients.



4.4 Literature review

This section describes the findings of a literature review conducted to assess the level of the evidence base and as a tool for informing anticoagulation service developments at BLT. Whilst it is presented as “study 3”, it was in fact the starting point of the study.

4.4.1 Aim and Objectives

The aim of the study was to aid selection and identification of primary care-based anticoagulation services for evaluation, through a review of the literature. This was achieved through the following objectives:

- To identify relevant evidence on anticoagulation service developments, including literature related to primary care models.
- To evaluate the identified studies using pre-defined criteria.
- To utilise the evidence to inform service developments at the study site, including identification of the requirements for and implications of setting up primary care-based services.

4.4.2 Methods

Evaluation of the Literature

The literature search strategy has previously been outlined in Chapter 1 together with a review of the papers. This section outlines the evaluation of key papers developing new models of care in terms of validity and rigour. Studies identified during the search process were compiled and subsequently evaluated in terms of validity and rigour utilising the National Institute for Health and Clinical Excellence (NICE) criteria (outlined in Table 4.57). From the inception of the study it was

accepted that any development of anticoagulation services had to fit into the current climate of the NHS. In addition to evaluating the studies against a hierarchy of evidence, the main investigator utilised the NHS modernisation agenda (see Chapter 1, section 1.3) to elicit the key aspects required for service modernisation and development that were directly applicable to the study, these were validated by a second investigator as directly relevant to the study. Four key aspects were identified and validated:

- Primary care-based service provision (Department of Health 2006a; 2004b)
- Utilising Non-medical practitioners (Department of Health 2000b; 2004d)
- Utilising technology to assist in modernisation (Audit Commission 2001)
- Patient centred services (Department of Health 2005a; 2001c)

During the review of the literature the investigator focused on the aforementioned key aspects to inform potential anticoagulation service developments for the BLT anticoagulation patient population.

Table 4.57: Grades of Evidence (NICE – Grading Scheme from Eccles and Mason 2001)

Grade of Evidence	Type of evidence
I	Evidence obtained from a single randomised controlled trial or a meta-analysis of randomised controlled trials
IIa	Evidence obtained from at least one well-designed controlled study without randomisation
IIb	Evidence obtained from at least one other well-designed quasi-experimental study
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

4.4.3 Results

4.4.3.1 Evaluation of the literature

An outline of the key anticoagulation service papers along with the grade of evidence rating and the identified relevant key aspects addressed is presented in Tables 4.58 to 4.61.

Table 4.58: Evaluation of Literature (I)

Study	Design	Sample	Outcome measure	Method	Discussion	Quality grading	Key aspect
Medical Devices Agency (2001)	Comparative study: quasi experimental	93 patients receiving oral anticoagulation (details on patients not given)	Agreement between NPT and laboratory method; reliability of CoaguChek S	Compared prothrombin time readings of CoaguChek S with laboratory methods.	Acceptable levels of imprecision, reliability and comparability with conventional laboratory techniques: CoaguChek S was suitable for professional NPT in anticoagulation monitoring.	IIb	Technology: NPT
Williams <i>et al.</i> (2003)	Intervention (controlled study)	84 patients receiving long term oral anticoagulation therapy	Agreement between NPT and laboratory method; patient acceptability; ease of use	Patients randomised to self-testing (with laboratory tests as control) or clinic testing	INR results obtained by CoaguChek S in good agreement with laboratory results: Patient safe-testing with CoaguChek S appeared to be safe alternative to laboratory INR testing.	IIa	Technology: NPT,
McCurdy and White. (1992)	Comparative study: quasi experimental	43 long term anticoagulation patients	Agreement between Coumatrak NPT and laboratory method	Compared prothrombin time readings of CoaguChek S with laboratory methods.	Seventy-five percent of paired monitor and laboratory values were within 0.7 INR units: The NPT device was useful for patients requiring anticoagulation monitoring.	IIb	Technology: NPT

Table 4.59: Evaluation of Literature (II)

Study	Design	Sample	Outcome measure	Method	Discussion	Quality grading	Key aspect
Lizotte <i>et al.</i> (2002)	Comparative study: quasi experimental	100 patients receiving oral anticoagulation therapy for at least 96 hours	Test-retest reliability of CoaguChek S and standard laboratory method utilised in pharmacist-led anticoagulation clinic	Determination of the agreement between INR measurements from CoaguChek S and standard laboratory results	Test-retest reliability was high (Intraclass device produced accurate results when compared to the laboratory method: CoaguChek S was reliable, valid and a good alternative to standard laboratory technique for managing anticoagulation in a pharmacist-led clinic	IIb	Non-medical practitioner; Technology: NPT
Mannotti <i>et al.</i> (2001)	Intervention (controlled) study	1251 patients 2 sets of patients: Set 1: receiving a/c therapy < 3 months. Set 2: receiving > 3 months	Percentage of patients reaching stable state of anticoagulation within first 3 months of treatment; percentage of time individuals spent in desired therapeutic range	603 patients randomised to service involving dosing by CDSS (parma software) and 648 patients randomised to an arm where CDSS was not used to assist dosing decisions	Patients in the computer-aided dosing group spent more time within the therapeutic range than controls ($p < 0.001$): Use of CDSS resulted in better quality of treatment	I	Technology: CDSS
Fitzmaurice <i>et al.</i> (2000)	Intervention (controlled) study	224 patients receiving a/c therapy new and established patients	Proportion of patents that achieved appropriate INR control and mean percentage of time each patient spent within desired therapeutic INR range	Intervention: 122 patients allocated to nurse care in general practice using CDSS (softop information systems) and NPT (Thrombotrak); Control: 102 patients allocated to hospital based care at 3 different physician managed/supervised clinic sites, one using CDSS; anticoagulation control was measured	No significant difference in proportion of patients who achieved appropriate INR control, patients in nurse led group had a higher percentage of time spent in therapeutic range ($p < 0.001$): care provided by the intervention service was at least as good as routine hospital-based care.	I	Non-medical; Technology, CDSS, NPT; Primary care setting

Table 4.60: Evaluation of Literature (III)

Study	Design	Sample	Outcome measure	Method	Discussion	Quality grading	Key aspect
Macgregor <i>et al.</i> (1996)	Non-experimental comparative study	30 patients at 6 month follow up 36 patients at 12 month follow up 14 patients that had previously received a/c monitoring in hospital were in comparison with practice service	Percentage of INRs within target range $\pm 10\%$ and costs of service	Evaluation of weekly practice-based pharmacist-led anticoagulation clinic (intervention) and comparison of previous hospital based care for those previously receiving hospital-based service	The percentage of values within the desired range improved significantly during pharmacist-led service, patients preferred practice based management (method of questioning not specified): Good therapeutic control was achieved in the practice	III	Primary care setting; non-medical practitioner; Technology: NPT; Patient-centred
McCahon <i>et al.</i> (2003)	Description of set up of intervention (controlled) study	No final number given; patients recruited from 49 general practices; had been receiving warfarin for over 6 months, had previously been receiving either hospital managed care or practice based service.	Therapeutic INR control in terms of percentage of time spent within therapeutic range; incidence of major bleeding, thrombotic complications and associated deaths.	Patients randomised to self treatment received training, patients tested themselves every 2 weeks. Control patients continued with their prestudy clinics	25% of patients invited to participate accepted, 30% of patients in the self-management group dropped out immediately after treatment. Clarity is required to establish which patients would benefit from this type of treatment	III	Primary care; Technology: NPT, patient-centred

Table 4.61: Evaluation of Literature (IV)

Study	Design	Sample	Outcome measure	Method	Discussion	Quality grading	Key aspect
Coleman <i>et al.</i> (2003)	Pilot descriptive study	18 patients originally receiving hospital a/c service	Setting quality standards for a community pharmacist-led anticoagulation clinic	Working group examined feasibility of community pharmacy service. Hospital patients asked in a semi-structured questionnaire how they felt about Community Pharmacist-led anticoagulation service; 9 month pilot study assessing whether provision of a community pharmacy anticoagulation service could complement existing hospital and primary care models	Working group identified standards of care for a Community Pharmacist-led anticoagulation service, 52% of patients were interested in CP service. Interested patients were recruited to a pilot service; with appropriate quality standards: A Community Pharmacist-led anticoagulation service appears feasible, such a service has the potential to increase patient access to service.	III	Non-medical; Primary care; Technology, NPT, CDSS, patient-centred
Shiach <i>et al.</i> (2002)	Intervention (uncontrolled) study	46 patients on long term warfarin therapy previously receiving a/c service from hospital a/c clinic.	Patient satisfaction, baseline and end of trial; percentage of time patients were in therapeutic range; agreement between NPT and laboratory INR determinations	Randomised crossover study, 23 patients randomised to receive INR testing using NPT (CoaguChek) in a community clinic, at this time venous sample was also taken and the INR determined in the hospital laboratory – dosing decisions were based on NPT INR determinations. 23 patients randomised to receive laboratory INR determinations only: the groups were crossed over after 6 months. Both arms used CDSS (DAWN AC) to assist dosing	There was no significant difference in the mean percentage of time spent in therapeutic range. Satisfaction questionnaires showed there was greater satisfaction with community NPT monitoring: Results suggest that it is possible to introduce a reliable safe primary-care based anticoagulation service.	IIb	Primary care; patient-centred; technology: NPT, CDSS

4.4.3.2 Summary of literature evaluation

The evaluation tables summarise the key papers which spanned the grades of evidence from levels I to III, with the several of the studies receiving a level IIb grading, classified as quasi-experimental (Eccles and Mason 2001; Shiach *et al.* 2002; Medical Devices Agency 2001; McCurdy and White 1992; Lizotte *et al.* 2002). There were two grade I papers, one explored the affect of CDSS on anticoagulation control in a randomised controlled trial involving 1251 patients (Mannotti *et al.* 2001) and the other compared a general practitioner based anticoagulation service (*nurse led with NPT and CDSS*) with routine hospital management in a randomised controlled trial involving 224 patients (Fitzmaurice *et al.* 2000). The majority of papers utilised a sample size of less than 100 patients, which provides less definitive results (Medical Devices Agency 2001; Williams *et al.* 2003; McCurdy and White 1992; Macgregor *et al.* 1996; Coleman *et al.* 2003; Shiach *et al.* 2002). A number of the key aspects related to the NHS were explored in the studies; the majority explored the use of NPT with regards to either the accuracy and reliability of devices (Medical Devices Agency 2001; Williams *et al.* 2003; McCurdy and White 1992; Lizotte *et al.* 2002), or the use of such devices as part of anticoagulation services evaluation (Fitzmaurice *et al.* 2000; Macgregor *et al.* 1996; McCahon *et al.* 2003; Coleman *et al.* 2003; Shiach *et al.* 2002). A variety of methods were employed to answer the research questions; with regards to assessing NPT, agreement of the device with laboratory measurements was the method most commonly used (Medical Devices Agency 2001; Williams *et al.* 2003; McCurdy and White 1992; Lizotte *et al.* 2002). Similarly, CDSS services were compared to those where CDSS was not used and compared in terms of the anticoagulation control achieved (Mannotti *et al.* 2001; Fitzmaurice *et al.* 2000; Shiach *et al.* 2002), which in turn was assessed in a number of different ways, including proportion of patients in range at one time and percentage of time patients spent in therapeutic range (Mannotti *et al.* 2001; Fitzmaurice *et al.* 2000).

A variety of different objective outcome measures, such as accuracy (e.g. NPT devices) and anticoagulation control (e.g. in use of non-medical practitioners and services using CDSS) were utilised, very few studies explored the patient perspective with regards to satisfaction with evaluated services, opting to focus on objective outcomes (Shiach *et al.* 2002). With regards to studies exploring service provision in the primary care setting, none evaluated the domiciliary service provision to any formal extent. The evaluation suggests that, although there is a wealth of literature on the development of anticoagulation services, evaluation of domiciliary anticoagulation services and evidence relating to the patient experience of the service is scarce. In addition, very few studies utilise a large enough sample size and the “gold standard” randomised control trial

design, which suggests that large scale studies have not been feasible, and also indicates that further large scale work may be required utilising robust methodology in a wider patient population.

The patient groups sampled were largely those patients receiving anticoagulation services for long term indications, in order to ensure that follow-up was for an appropriate duration (Williams *et al.* 2003; McCurdy and White 1992; McCahon *et al.* 2003; Coleman *et al.* 2003; Shiach *et al.* 2002). This frequently used exclusion criterion results in a lack of knowledge of the impact of service developments for short term service users. This may be deemed appropriate as these patients do not attend the service for a long duration, therefore service developments may not impact them to the same extent as those receiving the service for a longer duration of time.

It was interesting that in the trial exploring patient self-management (McCahon *et al.* 2003) that only 25% of those invited to participate accepted, indicating that the majority of patients would not like to maintain their treatment themselves. Thus it appears that although primary care-based services receive favourable reports from recipients, apparently offering improved convenience and access, patients still value practitioner input into the provision of their care. This may be reflective of the patient demographics; with numerous studies evaluating aspects of anticoagulation services, suggesting that the majority of patients receiving long term anticoagulation therapy are of an older age (over 55; Amruson 2004; Conte *et al.* 1986; Sawicki 1999; Vadher *et al.* 1997a); older patients may feel unable to manage their condition independently. Overall, the studies provided useful information on a variety of key aspects relating to service developments, but due to the largely small numbers the findings of studies were rarely generalisable. Despite this, the studies did impact on different aspects of the design of the intervention, from the feasibility and potential barriers of setting up anticoagulation services (Coleman *et al.* 2003) to the anticipated affect of utilising non-medical practitioners (Lizotte *et al.* 2002; Macgregor *et al.* 1996) and technology in a primary care setting (Shiach *et al.* 2002).

4.4.3.3 Models described in the literature

Primary care based service models were evaluated to inform the design of an intervention. Moving services into primary care has become an integral part of the modern NHS (The NHS plan; Department of Health 2000c). A number of primary-care based anticoagulation service models have been proposed and described in the literature (Table 4.62). These data, along with the

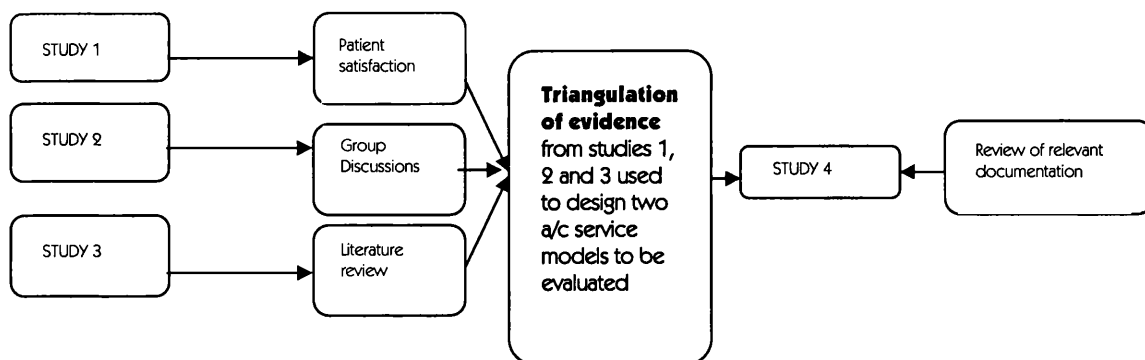
evaluation of the literature, patient satisfaction data and group discussions involving practitioners were triangulated to design a feasible intervention.

Table 4.62: Primary care-based anticoagulation service models identified in the literature

Model			
Led by:	Sample site	Provision	Reference
GP/ Pharmacist/ Nurse	General Practice	NPT in GP practice with dosing (with or without CDSS) and management by GP practice (dosing and informing patient); minimal input from the hospital, although hospital practitioner support available if required.	Fitzmaurice <i>et al.</i> (2000)
		Phlebotomy in GP practice, sample sent to hospital laboratory. Dosing by hospital staff that communicate with patients.	Blann <i>et al.</i> (2003)
		Phlebotomy in practice, sample sent to hospital laboratory, result returned to GP practice. Dosing by GP practice staff who also communicate with patients.	Blann <i>et al.</i> (2003)
Community pharmacist	Community Pharmacy	NPT in pharmacy with dosing assisted by CDSS; pharmacy-led service (pharmacist responsible for dosing and informing the patient). Minimal input from the hospital, although hospital practitioner support available if required.	Coleman <i>et al.</i> (2003)
Pharmacist	Patients' home	NPT in patients' homes with dosing assisted by CDSS; pharmacy-led service. Minimal input from the hospital, although hospital practitioner support if required.	Coleman <i>et al.</i> (2003)
Hospital clinic		Phlebotomy in patients' homes, sample sent to hospital laboratory. Dosing by hospital staff that communicate with patients.	Blann <i>et al.</i> (2003)
GP/ Pharmacist/ Nurse		Phlebotomy in patients' homes, sample sent to hospital laboratory. Results returned to patients' practice. Dosing by practice staff that communicate with patients.	Blann <i>et al.</i> (2003)
Patient/carer		NPT in patients' homes by patients/carers. I. Anticoagulation practitioner contacted to give advice on appropriate dose, or II. Trained patients / carers dose according to algorithm. Hospital practitioner support is available if required.	The Department of Primary Care, Birmingham University (2002 b) Blann <i>et al.</i> (2003)

4.4.3.4 Section summary

From the review it is apparent that a number of anticoagulation service developments are taking place to cope with an increasing workload in the management of these patients. The NHS agenda, coupled with NPT and CDSS technologies have moved services from secondary care into primary care. The success of non-medical practitioners in secondary care anticoagulation clinics has made the transition of these practitioners into primary care acceptable. The next section summarises the key points from each of the exploratory studies of the developmental phase and describes the triangulation of this data to aid in the selection of models to be evaluated in a trial.



4.5 Triangulation

4.5.1 Introduction

The combining of methods, approaches and different types of data in a single study, a process known as triangulation has become an established tool in health services and pharmacy practice research (Smith 2005; Chapter 3). Through combining methods results are confirmed, validated or refuted and the 'truth' can be more accurately identified. This section outlines the selection of models for evaluation through triangulation of the data.

4.5.2 Method

Selection of models for the trial was based on combining (triangulation) the results from the patient satisfaction questionnaires administered to anticoagulation patients at BLT and HUH, the group interviews and review of the literature.

4.5.3 Results

The following key points were used to inform model selection:

4.5.3.1 Patient satisfaction

- Patients at BLT were less satisfied than their HUH counterparts with the method of blood sampling and waiting times at the clinic.
- The majority of transport (mobility-impaired) patients at BLT and HUH expressed dissatisfaction with aspects of the ambulance service (items 16 and 17).

4.5.3.2 Stakeholder discussions

a) Anticoagulation team

The anticoagulation team highlighted the following points:

- A move towards NPT testing rather than venous sampling.
- Positive results with CDSS (Dawn AC - 4s Dawn Clinical Software).
- General support for a move towards primary care anticoagulation services.
- Mobility-impaired patients to be the focus of initial service developments.
- Support for domiciliary service for mobility-impaired patients.

b) Stakeholder discussion (GP lead; Academic Director of Pharmacy etc.)

- Anticoagulation services need to be patient-centred.
- Initial service developments should focus on the mobility-impaired.
- Prior to implementation, updated job descriptions for direct service providers, a service protocol and competency-based training is required.

c) Community pharmacy forum

- There is a role for pharmacists in the development of anticoagulation services.

d) Nominal group session

- Current secondary care service provision viewed as inadequate. Primary care services viewed as the way forward.
- An ideal model would be either nurse or pharmacist-led for both ambulatory and mobility-impaired patients.
- A community pharmacy-based model using NPT ranked as the most favourable model for ambulant patients, followed by a general practice-based model using NPT.
- For mobility-impaired patients, a domiciliary service involving home visits by a healthcare professional using NPT was seen as the best model, followed by a domiciliary service involving venous sampling with dosing carried out in general practice.

4.5.3.3 Literature Review

- The Government is keen to make health services more accessible for patients, with services being provided in patients' homes where appropriate.
- The increase in demand for anticoagulation monitoring services has led to the development and exploration of primary care models.

- Primary care-based models have been found to have a number of advantages over secondary care-based models.
- NPT for anticoagulation patients has been shown to be reliable, accurate and safe.
- NPT facilitates the move of services to primary care.
- NPT can be useful for INR determination in patients' homes (either as part of self-testing/management or potentially for the housebound). In addition, it is less invasive than venous sampling and may be of benefit to those patients who have poor venous access.
- CDSS has been shown to improve anticoagulation control (over traditional dosing) and aids the devolution of anticoagulation services to primary care.
- It has been shown that healthcare professionals other than doctors (such as pharmacists and nurses) can achieve acceptable levels of anticoagulation control in the secondary and primary care setting.

A number of primary care models have been described in the literature; settings include general practices, community pharmacies and patients' homes (Blann *et al.* 2003; Coleman *et al.* 2003; Fitzmaurice *et al.* 2000).

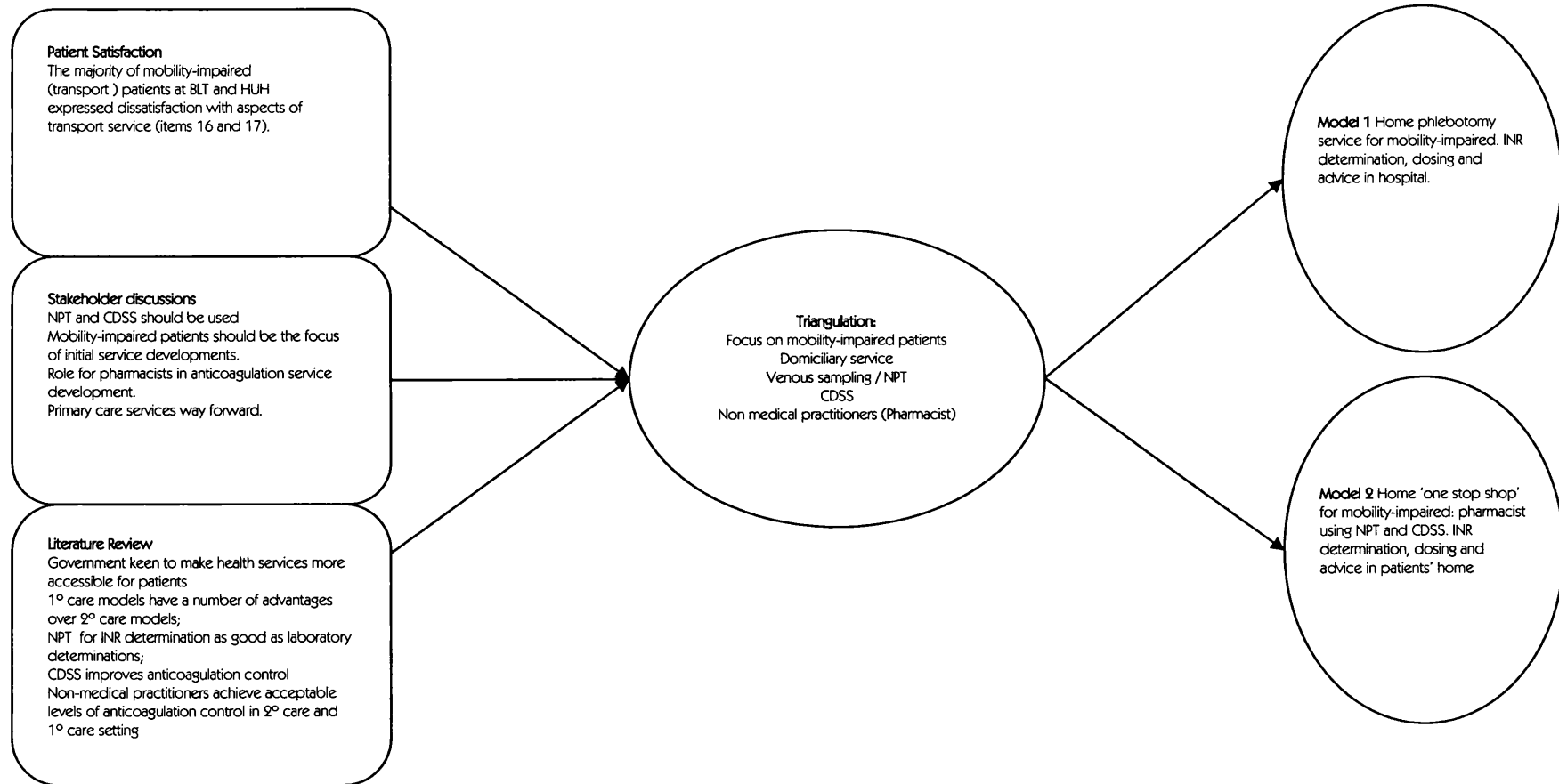
4.5.3.4 Selection of models for the trial

Figure 4.30 is a diagrammatic representation outlining the process of triangulating and selecting the models. The findings confirmed that focussing on mobility-impaired patients as a target group for service developments was appropriate as the importance of safe and convenient care for this group of patients was an issue that was repeatedly highlighted. Therefore initial service development and evaluation would be of domiciliary services for mobility-impaired patients.

The concept of home phlebotomy was well received in the nominal group session and was highlighted as an option by anticoagulation practitioners. The investigator chose a domiciliary model for the trial where mobility-impaired patients would be seen by a phlebotomist at home and all other parts of the service would be carried out by the hospital (Figures 4.30 and 4.31; model 1). This option was ranked as number three out of the four models for mobility-impaired patients presented to stakeholders at the nominal group session. The investigator in collaboration with the BLT anticoagulation team, opted for this model, rather than the model ranked second, as the model ranked second required general practitioner involvement; using this model would involve finding a willing and suitable general practice, providing funding/remuneration for the service provision and assessing and meeting the training needs of the general practitioner and the staff in the general

practice surgery. Due to a limited amount of resources, the model involving the hospital practitioners was selected for the trial in preference to the general practice-involved service model.

Figure 4.30: Diagrammatic representation of triangulation of data sources



1° = primary
2° = secondary

Figure 4.31: Model 1 of the domiciliary anticoagulation service trial

MODEL 1

Immobile anticoagulation patients are visited at home by a general phlebotomist, who obtains blood via venous sampling. The blood sample is sent to and analysed in the local hospital laboratory. The INR results are then sent to hospital-based anticoagulation clinic staff, who dose patients according to the laboratory INR results with the aid of CDSS. The hospital practitioners contact the patients either via post or telephone depending on the urgency, with their INR result, the required dose of warfarin and the date of the next visit.

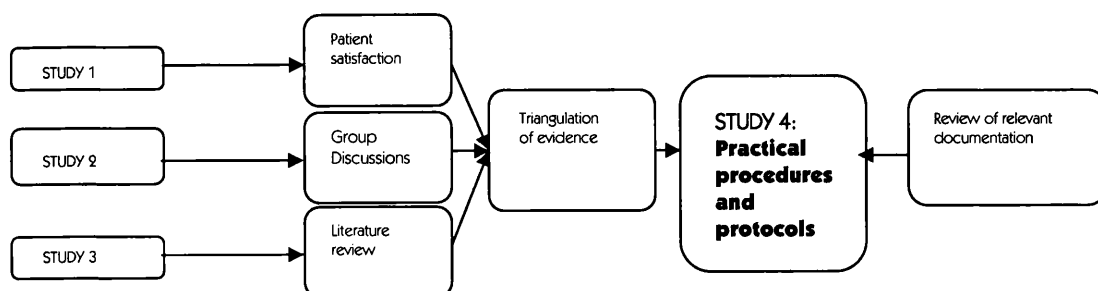
The introduction and successful use of NPT (at HUH and literature review) and CDSS (at BLT and literature review) and the nominal group session, that ranked the domiciliary service using NPT (Figures 4.30 and 4.32, model 2) as the most favourable option for mobility-impaired patients prompted the investigator and the anticoagulation team to select this as the other model to be piloted.

Figure 4.32: Model 2 of the domiciliary anticoagulation service trial

MODEL 2

Immobile anticoagulation patients are visited at home by a pharmacist, where a capillary sample along with an INR determination using an NPT device is carried out. The patient is dosed according to the INR result with the aid of CDSS and informed of the INR result, the required dose and the date of the next visit by the visiting pharmacist. All aspects of the service take place in the patient's home, therefore this is a 'one stop shop' model.

The preparation for implementing and evaluating the two domiciliary services is described in the next section.



4.6 The preparatory stage

This section outlines the preparatory stage of the developmental phase. The preparatory stage aimed to ensure safe and standardized provision of the domiciliary services during the anticoagulation services trial and consisted of service protocol development, risk assessment and personnel training.

4.6.1 Service Protocol

This section describes the development of the service protocol. Protocols are important for outlining the operational procedures and standards a service should adhere to. The importance of protocol development was highlighted not only in the literature (Coleman *et al.* 2003), but also in professional stakeholder discussions.

4.6.1.1 Aim/Purpose of the service protocol

The protocol was developed to provide detailed guidelines for the operation of the domiciliary services and to outline service evaluation criteria.

4.6.1.2 Method of the service protocol development

A request for protocols for provision of community anticoagulation services was made to hospital anticoagulation pharmacists from the Greater London area. Occupational therapist leads and district nurse leads within the Tower Hamlets PCT were contacted via telephone and email to obtain protocols for provision of domiciliary services; as domiciliary patient visits are within their remit. An Internet search was also carried out to identify any procedural documentation on such services in the public domain. The identified protocols and documents relating to all aspects of service provision, such as phlebotomy, were reviewed by the investigator and used to inform the development of the service protocol specific to the present project.

4.6.1.3 Results

The following sources of information were identified and applied by the investigator to develop the protocol:

- i. A standard operating procedure (SOP) for a primary care anticoagulation service, produced by a hospital anticoagulation pharmacist in the Greater London area (Whittington Hospital 2003) who had set up a community pharmacy-based anticoagulation service. This SOP included information on documentation requirements, use of the CoaguChek S (Roche Diagnostics, Lewes, UK) NPT device, management of out-of-range INRs, complaints and incident reporting.
- ii. A protocol produced by a clinical scientist of a Cornish hospital haematology department involved in setting up anticoagulation services in local GP surgeries (Royal Cornwall Hospital 2000). The protocol covered maintenance of records, discussed the need for designated and trained individuals to provide the service and discussed weekly analysis of manufacturer's control sample to ensure proper operation of NPT devices. In addition, the protocol advised that all INRs above 4.5 should be verified using a venous sample.
- iii. The BLT phlebotomy handbook (2000) provided information on the technical procedure for taking a blood sample, including needle positioning, equipment required and the policy for the safe handling of body fluid spillages.

Information regarding training requirements, practitioner responsibilities and boundaries were obtained from:

- I. The BLT anticoagulation team training programme for practitioners (1998), along with the anticoagulation clinic training manual that gave specific information on the management of patients with in-range and out-of-range INRs,
- II. BLT's 'Patient Group Direction for the supply, administration and dosing of anticoagulants by the authorised pharmacists and nurse practitioners working in the anticoagulant clinic' (2003a), this document contained clinical information including warfarin-drug interactions and warfarin-food interactions and the guidelines for managing warfarinised patients requiring dental procedures,
- III. BLT's SOP for the use of the CoaguChek S NPT device (Roche Diagnostics, Lewes, UK) in the anticoagulation clinic (2003b),
- IV. Sheehan *et al.* (2000) described establishing a primary care-based anticoagulation clinic and discussed practical issues such as setting up a working party and the need and

importance of service audit.

A draft protocol was produced by the investigator and presented to the BLT anticoagulation team practitioners: following feedback (reference to supporting pre-approved documents (for example anticoagulation dosing PGD) as appendices instead of inclusion of content within the protocol), the draft protocol was revised. Subsequently, the final version of the protocol (Appendix 6) with the appropriate appendices was produced and approved by the senior members of the BLT anticoagulation team

The final version of the protocol outlined:

- i. the aims and objectives of the service,
- ii. the two models of service to be employed,
- iii. the training requirements for the phlebotomist (for model 1) and the pharmacist (investigator; for model 2) in providing the trial services,
- iv. use of near patient testing and computer decision support software technology,
- v. procedure for managing out-of-range INR results,
- vi. quality assurance processes,
- vii. documentation and record keeping requirements,
- viii. capillary sample and venesection as methods of collecting blood samples,
- ix. handling of blood samples,
- x. procedure for handling patient complaints,
- xi. procedures to be followed in case of incidents and errors, and
- xii. clinical audit standards for deviations from target therapeutic range and for adverse events.

The protocol was supported by other procedures, policies and Patient Group Directions being used by the anticoagulation team.

4.6.2 Risk assessment

The domiciliary service models involved the investigator and phlebotomist leaving the hospital premises, travelling to patients' homes and obtaining and evaluating blood samples. Therefore, it was necessary to undertake risk assessment of the services to ensure that 'best working practices' for delivery of the domiciliary anticoagulation services were adhered to and to fulfil the requirements of the 'Management of Health and Safety at Work Regulations' (Management of health and safety 1999).

Within the process of risk assessment, a hazard is defined as “something with the potential to cause harm (this can include substances, plant or machines, methods of work, the working environment and other aspects of work organisation”; Health and Safety Executive; 1997; page 76). Risk is defined as “the likelihood of potential harm from that hazard being realised” (Health and Safety Executive; 1997; page 76). The extent of risk will depend on:

- i. The likelihood of that harm occurring;
- ii. The potential severity of that harm, i.e. of any resultant injury or adverse health effect; and
- iii. The population which might be affected by the hazard, i.e. the number of people who might be exposed.

4.6.2.1 Aim (of the risk assessment)

The aim of the risk assessment was to ensure that potentially hazardous operations were carried out safely and to minimise accidents and illness caused as a direct result of domiciliary anticoagulation service provision

4.6.2.2 Objective (of the process of assessing the risk)

The objectives of the process of risk assessment were:

- i. To identify hazards relating to the relevant task(s) - Hazard Identification
- ii. To evaluate the degree of risk to personnel and identify structures and procedures to eliminate, reduce and/or control the risk - Hazard Assessment
- iii. To develop procedures by which risks to health and safety may be effectively controlled - Risk Management

4.6.2.3 Method

In accordance with the specific requirement of the ‘Management of Health and Safety at Work Regulations’ (Management of health and safety at work 1999), general risk assessment of the trial was performed using BLT general risk assessment forms (1997).

The process of risk assessment involved three procedures:

- Hazard Identification,
- Hazard Assessment, and
- Risk Management.

Steps involved in the risk assessment:

Hazard Identification

1. The first stage involved identifying any possible hazards by reviewing each step of a home visit; this was from the moment the investigator/phlebotomist entered a vehicle to leave for the patients' homes to the moment they returned to the hospital having completed their home visits. Following charting of all activities undertaken by the investigator/phlebotomist during a visit and discussion with the anticoagulation team and the assistant general manager of the Cancer Services and Pathology Directorate (the phlebotomist's line manager), the investigator identified the following hazards:
 - a) Road traffic accident
 - b) Theft of equipment
 - c) Needle stick injury
 - d) Slips, trips and falls
 - e) Attack from domestic animals in patients' homes
 - f) Assault by a patient/carer/relative/member of public
2. For each identified hazard, any current control measures such as local policies and procedures and training were documented.

Hazard Assessment

3. Four questions about each hazard were then answered:
 - a) Contact with the hazard,
 - b) Frequency of exposure to the hazard,
 - c) Maximum probable loss, and
 - d) Number of people at risk.

Figure 4.33 and Figure 4.34 present examples of question b) and question c).

4. Answers to each question had a corresponding score (Figure 4.33 and Figure 4.34). For each identified hazard, the scores of the answers to the four questions were multiplied by each other. The result yielded the hazard rating number $[a) \times b) \times c) \times d) = \text{hazard rating number}]$ and enabled the risk of each potential hazard to be classified (Table 4.63).

Figure 4.33: An example of question b), Frequency of exposure to hazard (BLT 1997)

How often is a person (s) likely to be exposed to the hazard?	
Frequency	Score
In Frequent	0.1
Annually	0.2
Monthly	1.0
Weekly	1.5
Daily	2.5
Hourly	4.0
Constantly	5.0

Figure 4.34: An example of question c), Maximum probable loss (BLT 1997)

If a person does come into contact with the hazard what is the worst that can happen?	
Loss	Score
A person could die	15
A person could lose both limbs, both eyes, or sustain a serious permanent injury/illness/condition	8
A person could lose one limb, one eye, or sustain a temporary serious injury/illness/condition	4
A person could break a major bone or sustain a permanent major injury/illness/condition	2
A person could break a minor bone or sustain a temporary minor injury/illness/condition	1
A person could sustain a laceration or minor ill health effect	0.5
A person could sustain a scratch or bruise	0.1

Table 4.63: Classification of risks (BLT 1997)

Hazard Rating	Classification	Hazard Rating	Classification
0 – 10	Low	101-500	Very High
11- 50	Medium	501-1000	Extreme
51 –100	High	1000+	Unacceptable

5. Low risk hazards do not require any remedial action. Activities given a medium hazard rating are deemed safe to undertake, so long as remedial and control measures, such as an awareness of the number to telephone and advice on what to do in case of a needle stick injury, have been implemented.

Risk Management

6. For each hazard, remedial measures in the event of the hazard occurring were discussed between the investigator and the anticoagulation team and documented.

4.6.2.4 Results

Table 4.64 summarizes classification of each identified potential hazard. The overall risk of providing the domiciliary anticoagulation service was assessed as medium. The 'needle stick injury' hazard rating number was different for the investigator and phlebotomist as frequency of exposure to the potential hazard differed; in the NPT model, the investigator was only expected to obtain a venous sample if the NPT monitor displayed a reading above 4.5, compared to the phlebotomist who would be taking venous samples at every domiciliary visit.

Table 4.64: Classification of potential hazards identified for domiciliary visits

Potential Hazard	Hazard rating Number		Hazard Classification
Road traffic accident	37.5		Medium
Theft of equipment	2.5		Low
Needle stick injury	Pharmacist: 22.5	Phlebotomist 37.5	Medium
Slips, trips and falls	25		Medium
Attack from domestic animals in patients' homes	30		Medium
Assault by a member of public/patient/carer/relative	3		Low

Remedial measures

To minimise the risk of road traffic accidents the administrator and investigator were advised not to drive aggressively, but defensively with a constant awareness of pedestrians and motorcycles. They were also told to park in an appropriate place when using their telephones in the car and when searching for their destinations; it was agreed that as much as possible they should plan their routes before setting off on their visits to minimise stops on their journeys. With regards to needle stick injuries, they were advised to ensure that patients' home conditions were suitable for venous

sampling, in the case of the investigator who was not taking blood samples during every visit, advice was given that if a refresher course of phlebotomy techniques was required, she should make necessary arrangements to attend a course. The investigator and phlebotomist were asked to wear sensible foot wear to avoid slips trips and falls. In addition, it was recommended that patients' pets (cats and dogs) should be kept away from the room where the test was taking place during the visit, as the pet may be protective of the patient and may become aggressive.

4.6.3 Checklist for community visits: General and important safety points for community visits

In addition to the service protocol and risk assessment, a safety and general points checklist for community visits related to lone-working and home visiting was compiled to ensure that personnel had an efficient way of remembering the logistical aspects of service provision (Appendix 7). Similar documents were located within the BLT, neighbouring Primary Care Trust and via an internet search. The following sources were reviewed and used to compile the safety checklist:

- I. St. Bartholomew's Hospital internal publication: Barts and The London Trust. Occupational Therapy Service: Safety on Community Visits Policy (Barts and The London Trust 1999).
- II. Tower Hamlets Primary Care Trust. Code of Safe Practice: Helpful advice for staff working alone in the community (Tower Hamlets Primary Care Trust. 2001).
- III. St. Bartholomew's Hospital internal publication: Barts and the London Trust. Safe working procedure for lone workers within the peritoneal dialysis department (Barts and the London Trust 2001).
- IV. Tower Hamlets Primary Care Trust. Musculoskeletal team: Home Assessment Policy, Standards for Practice (Tower Hamlets Primary Care Trust 2002).
- V. Southport and Formby Primary Care Trust: Lone Workers Policy (Southport and Formby Primary Care Trust 2002).

A draft checklist was reviewed by the anticoagulation team, and, following a discussion between the investigator and the team, was revised. The final version of the checklist is in Appendix 8.

4.6.4 Personnel Training

This section of the developmental phase describes the training provided to the investigator and anticoagulation clinic administrator responsible for providing the domiciliary anticoagulation services. The administrator's training pertains to provision of model 1, the investigator's training pertains to provision of model 2.

4.6.4.1 Phlebotomy training

Phlebotomy training, i.e. the procedure and technique involved in obtaining a venous sample, was given to both the investigator and the anticoagulation clinic administrator. The investigator received phlebotomy training so that venous samples could be obtained if patients had INR readings of above 4.5 on the NPT device. It has been shown that at higher INR values (specifically above 4.5), NPT devices accuracy may be impaired (Medical Devices Agency 2001). Furthermore, INRs above 5 have been linked to an increased risk of bleeding (Hylek *et al.* 1996). The anticoagulation clinic administrator was trained as a phlebotomist, so that service model 1 could be provided.

Training was provided by BLT phlebotomy team. The training involved self-study of the BLT Phlebotomy Handbook (2000) and practical training. The handbook provided information on equipment required, use of protective clothing, documentation requirements, handling of a needle-stick injury and body fluid spillages, management of sharp equipment and disposal of waste materials.

In addition, the administrator and the investigator attended a one week long practical training course, which included training in assembling the equipment, correct holding and positioning of the needle and obtaining of a blood sample. Final assessment of competency as a phlebotomist was by a consultant haematologist.

4.6.4.2 Training in use of the CoaguChek S NPT device

For those patients receiving the model 2, one-stop service, the CoaguChek S NPT device (Roche Diagnostics Lewes, UK) was used as it had received favourable reports (Medical Devices Agency 2001; Williams *et al.* 2003). The investigator was provided with training that consisted of three sessions focusing on technique for obtaining a capillary sample, strip insertion and deposition of a suitable blood sample for the purpose of INR monitoring. Use of the CoaguChek S was assessed by a senior nurse practitioner within the BLT anticoagulation team, to ensure that the investigator used the device correctly and in accordance with the relevant SOP.

4.6.4.3 Training in the use of Dawn AC software (4S Dawn Clinical Software)

The Dawn AC computer dosing support software (4S Dawn Clinical Software) was used in conjunction with the NPT technology for the provision of model 2. Training provided by an anticoagulation nurse practitioner on the use of the Dawn AC software basics took place in a one

half-day session. Training included accessing a patient's computerised file and clinic files, the system used to dose patients, and how to override the software's dosing suggestions. The investigator practiced using Dawn AC software during visits to the anticoagulation clinic. After two weeks of using Dawn AC, the investigator's competence in using the software was assessed by the senior pharmacist practitioner of the anticoagulation team. Later training needs regarding Dawn AC were fulfilled on an ad-hoc basis either by members of the anticoagulation team or by the Dawn AC software system support staff via the telephone and email.

4.6.4.4 Training on administration of parenteral anticoagulants

The investigator undertook training in the administration of parenteral anticoagulants, as it was anticipated that it would be necessary to provide parenteral anticoagulation to patients who may be temporarily taken off warfarin for surgical procedures. A parenteral anticoagulant is often used in these circumstances to provide anticoagulation cover until warfarin is effectively restarted. This training would not normally be a part of a pharmacist's training to be an anticoagulation practitioner and was specific to the domiciliary service.

Training on administration of parenteral anticoagulants was provided in a half-day one-to-one session by a nurse experienced in the administration of parenteral anticoagulants. Training covered:

- i. areas of the body that could be injected;
- ii. hygiene requirements;
- iii. use of alternating sites for injection;
- iv. correct positioning of the syringe;
- v. handling of the injection site;
- vi. insertion of the needle into the skin fold;
- vii. insertion of medicament;
- viii. removal of the needle and prevention of bruising;
- ix. appropriate disposal of used syringe.

4.6.4.5 Anticoagulation practitioner training

For the purposes of the trial, the investigator was trained to competence in the provision of anticoagulation management. The role of a BLT anticoagulation practitioner is to provide successful therapeutic control of the patients' INRs. The anticoagulation pharmacist practitioner is expected to have knowledge of a range of topics, including:

- I. The mechanism of action of warfarin as the main oral anticoagulant;

- II. Diet and lifestyle issues, for example alcohol intake, and vitamin K intake related to vegetable consumption;
- III. Co-morbidity issues as these may necessitate extra anticoagulation monitoring;
- IV. Patients at increased risk of haemorrhagic events, for example those with history of gastrointestinal bleeds; and
- V. Drug interactions of warfarin with short and long term therapy.

The investigator completed the BLT anticoagulation team training programme for nurse and pharmacist practitioners (Barts and The London Trust: Anticoagulation Team 1998), and the BLT anticoagulation clinic training manual for clinical pharmacists (Barts and The London Trust 2003c) under the supervision of a senior pharmacist and nurse practitioners. The training consisted of self-study using an 'Essential Reading' list, shadowing practitioners in clinics, structured teaching, supervised clinic activities (for example counselling and dosing of patients), practice-based sessions, where the investigator and practitioners discussed specific patients and their individualised management, case studies for the investigator to complete and gain an awareness of the range of issues pertaining to anticoagulation management, and assessments.

At the end of the training programme, the senior pharmacist practitioner supervising the training assessed the investigator. The assessment included marking the completed questions within the training manuals, shadowing the investigator whilst counselling and dosing patients in the clinic and evaluating the investigator's answers to scenario-style questions. The assessment confirmed that the investigator had fulfilled the training requirements and was competent to manage anticoagulation therapy.

4.6.5 Job descriptions

The investigator held an honorary contract with BLT. In order for both the investigator (pharmacist) and phlebotomist to carry out the tasks related to the trial, their job descriptions were updated with their additional roles and responsibilities.

Summary

- Following a risk assessment of the proposed services; the overall risk of providing the domiciliary anticoagulation services was assessed as medium, remedial measures to minimise the risks were put in place.
- Training for the investigator covered phlebotomy, the use of the CoaguChek S NPT device, the use of 4S Dawn AC CDSS, administration of parenteral anticoagulants and anticoagulation practitioner training.
- Personnel job descriptions were updated to cover the new responsibilities associated with delivery of the two models of domiciliary anticoagulation service.

4.7 Discussion of Findings

The developmental phase comprised a patient satisfaction survey across BLT and HUH hospitals; group interviews; a literature evaluation; and preparatory work for implementation of the evidence-based intervention (chapter 5). The multimethod approach was useful in not only elaborating on findings (complementarity) but also in substantiating findings (triangulation) for model selection. The findings of the developmental phase are discussed in this section alongside methodological difficulties and limitations of the study.

4.7.1 Patient satisfaction

4.7.1.1 Background

The present study used a cross-sectional survey design, applying a combination of validated (CSQ-8) and non-validated instruments to measure satisfaction in a specific population. This has not been the traditional approach to measuring satisfaction with anticoagulation services; the majority of studies identified have employed non-validated scales only, making comparison of results difficult (Coleman *et al.* 2004; MHRA 2004; Chaudry *et al.* 2004). There is an awareness of the widespread use of non-validated scales and lack of a standardised approach in the measurement of satisfaction (Oldridge *et al.* 1998; Thompson *et al.* 1998), leading to the significance of results being overlooked (Asadi-Lari *et al.* 2004). Furthermore, there is a shortage of information available on the reliability of scales (Asadi-Lari *et al.* 2004).

4.7.1.2 CSQ-8

Overall, patients at both sites expressed equivalent and high levels of satisfaction as assessed by the CSQ-8. The high score was not surprising. Authors report that the CSQ scale, similar to other patient satisfaction scales, tends to produce negatively skewed (long left tail) distributions as participants report high levels of satisfaction with services (Nguyen *et al.* 1983; Owens and Batchelor 1996). Further, previous studies have established that older patients tend to report higher levels of satisfaction (Pascoe 1983); therefore due to the distribution of patients' ages, the high satisfaction scores were not unexpected. Gender has also consistently been shown to be a predictor of satisfaction levels, with females tending to report higher levels of satisfaction (Pascoe 1983). However, there was no correlation between gender and satisfaction scores in the present study. Pascoe (1983) remarks that where this trend is not seen it is generally as a result of a unique mode of operational settings, how much this explains the equity in the results of this study is unclear.

It was surprising that both HUH and BLT patients were 'equally satisfied' with two different modes of anticoagulation service delivery. One might intuitively expect patients at HUH to display higher levels of satisfaction than patients at BLT due to the employment of less invasive NPT over venous sampling and the resultant reduction in waiting times. There could be a number of reasons for the equity in satisfaction scores. If satisfaction is a function of expectations and experiences as suggested in a number of models identified by Lawler (1973) then patients at BLT and HUH may have become accustomed to the service they received. As one becomes accustomed to a service it may no longer exceed their expectations, as their expectations have been shaped by additional experience, suggesting that satisfaction is a dynamic attitude. It is hard to assess whether the high CSQ scores are in part due to low or non-existent expectations, whether they are an accurate function of service quality, or whether it indicates that the CSQ-8 is an insensitive tool. Patient satisfaction surveys, particularly in elderly patients are known to produce positive results; it is likely that this would be the main factor (Owens and Batchelor 1996).

CSQ-8 results from the developmental phase are comparable to those in the literature which range from 26.35 to 27.80 (Attkisson and Greenfield 2004), however the CSQ-8 has not been used to assess patients' satisfaction with anticoagulation, so the usefulness of this comparison is debateable.

4.7.1.3 Service specific items and Qualitative data

Despite the high reports of satisfaction from the CSQ-8 scale, responses to the specific items showed that there was room for improvement in the service at BLT. Multiple linear regression analysis showed that the service specific items had a large impact on the variance in satisfaction for both BLT and HUH patients. These sections of the questionnaire were useful in revealing the importance of blood sampling method, waiting times, interactions with staff, including clarity of dosing instructions as well as clinic environment for patients.

Waiting times

Qualitative statements supported the significant difference in expressed satisfaction with waiting times (service-specific item) with HUH patients reporting higher levels of satisfaction, largely thought to be a consequence of the use of NPT at HUH compared to venous sampling at BLT:

Patient ID: 0517BT - When there are two phlebotomists things are speeded up. But then time is wasted by blood having to be taken up to the path lab and results returned to the clinic where staff and patients are often kept waiting. (BLT)

Patient ID: 353 - All in all I believe the new system with the finger pricking is better and faster for all of us as we used to hang around for hours with the old system, so I am grateful for the change. (HUH)

Transport patients

Both hospitals provided mobility-impaired patients with a hospital ambulance transport service to enable them to attend the clinic with minimal discomfort. However, many of those who used the service were still dissatisfied. From the specific items, the majority of patients stated that at times they waited a long time for transport to pick them up and take them home. The dissatisfaction of transport patients at waiting time and accessing the clinic was echoed in the qualitative portion of the questionnaire, by comments such as this:

Patient ID: 5502 - If one is depending on transport to get here, as I am, one can spend a whole morning getting a blood sample done. I find that the most frustrating thing (BLT)

Worryingly, just over 25% of patients (BLT =28.6%, HUH=27.2%) claimed that transport had failed to pick them up on occasion (service specific item). These results are cause for concern as it is imperative that patients' INRs are regularly monitored to ensure that they are within therapeutic range and are not at risk of anticoagulation related adverse events (Blann *et al.* 2002). On commencement of therapy, patients are counselled on the importance of attending all clinic appointments and about the increased risk they are exposing themselves to if they fail to attend. Immobile patients tend to be frail and often have co-morbidities, which together with their lack of mobility put them at increased risk of adverse events (Froom *et al.* 2003), thus failure of the transport service to undertake its responsibility to deliver patients to the clinic could be extremely dangerous.

For the majority of transport patients, the transport service resolved the issue of adequate access to the clinic, however it created an alternative source of dissatisfaction with regards to the inconvenience of waiting for the service. By providing a domiciliary anticoagulation service, these problems might be resolved (Hall and Radley 1994).

The approach to measuring patient satisfaction was useful in producing an overall measure of satisfaction (CSQ-8) and unmasking specific causes for concern with respect to service provision (waiting time, blood sampling, interactions with staff, dissatisfaction with the transport service). Whilst the approach was appropriate, a number of difficulties during the data collection period and study limitations were identified, these are summarised below.

4.7.1.4 Difficulties during data collection

Patient demographics

Demographic data for BLT patients was obtained from electronic patient files stored on the anticoagulation clinics CDSS (Dawn 4S) package, this allowed easy retrieval of the relevant data. At HUH, patients' files were not computerised. Instead, patients' data were kept on individual cards and unfortunately there was a lack of consistency with regards the data that was recorded, this resulted in a number of cases being excluded from the data analysis due to lack of required data.

Assisting patients to complete satisfaction survey

A large proportion of patients at both HUH and BLT (including mobility-impaired patients) were frail and required assistance when completing the questionnaire. Whilst the investigator was assisting some patients, others who needed assistance to complete the questionnaire left the clinic before the investigator had the opportunity to help them. A second investigator to assist patients would have been useful; this may have increased the number of patients sampled.

4.7.1.5 Limitations with the satisfaction study

Selection bias

Sample

Patients with unstable INRs tend to return to the clinic frequently to have their dose and INR assessed, therefore such patients were seen on a number of occasions at clinics during data collection, but were only permitted to complete the survey once. Patients with stable INRs return to clinics on average every 8 to 12 weeks, and were therefore less likely to be captured during the study period. Increasing the length of the study period to allow inclusion of more patients would have been preferable, however this was not feasible with the available resources. As a way of increasing the sample size and minimising this sampling bias patients not seen during the four week period could have been sent the satisfaction questionnaire by post.

Exclusion of Non-English speaking patients

Non-English speaking patients were excluded from the sample. The satisfaction survey used was not available in other relevant languages and translation of the survey was not feasible within the allotted time and resources. Translation of an instrument is a task that not only involves the translation and back translation of phrases, but also involves ensuring that in different cultural contexts the instrument loses none of its meaning, that topics of the instrument do not change in the weighting of their importance and that the psychometric properties of the instrument are maintained (Bowling 2002). Related to this exclusion, ethnicity may have been a factor, this could result in non-response bias and artificially inflate the satisfaction of the population. It is possible that such patients may have been less pleased with the service, (Larsen *et al.* 1979) perhaps due to communication issues. Carrasquillo *et al.* (1999) showed that non-English speaking (Hispanic) patients were significantly less satisfied than English speaking patients with services provided during emergency visits at 5 teaching hospitals in North East America. Findings showed that a perceived lack of staff courtesy was a key determinant in the lower levels of satisfaction amongst the non-English speaking patients. This exclusion is a major limitation as it means that the views of the patient population are not fully represented which is important in a population with such ethnic diversity.

Lack of demographic data on patients not participating in the study

A large number of patients invited to participate at HUH declined (22.6%); however detailed exploration of the reasons or comparison of demographic characteristics was not possible. It is possible that these patients were less satisfied, again leading to over inflated levels of satisfaction. This type of positive bias has been documented in literature (Nguyen *et al.* 1983). Non-responders may have required more assurance that completing the questionnaire would not affect their receipt of the service.

Social desirability bias

The administration procedure may have introduced a number of social-psychological consequences, such as social desirability bias, where participants give what they perceive to be the expected responses (Bowling 2002). In addition, the differences in the operations of the clinics may have potentiated these biases to different extents. In the BLT clinic, patients are seen by the same team of staff apart from the phlebotomists who may vary whereas at the HUH clinic the nurse assistants, administrators as well as the phlebotomists are subject to regular change. The affect of associating the service with a group of well-known service providers versus a less consistent approach would be difficult to quantify, however it is reasonable to expect BLT patients to have built up more of a relationship with service providers than HUH patients. The majority of

patients at both trusts were receiving anticoagulation therapy for AF, a long-term indication. Owens and Batchelor (1996) suggested that patients receiving services for chronic conditions (such as AF) may have built up affective relationships with service providers and this may make it difficult in eliciting levels of dissatisfaction. Further, Williams (1994) argued that patients' views regarding service provision were in part constructed by their relationships with healthcare professionals; therefore a comparatively impersonal operation such as HUH may be subject to more criticism than a more personal service operation such as BLT.

Experimenter bias

There is possibility of experimenter bias in analysing qualitative data as the investigator was affiliated with both clinics and it has been shown that service evaluations are more likely to be positive when analysis is performed by an affiliated investigator (Gordon and Morse 1975). Review of qualitative analysis by a second investigator not affiliated with the services or clinics was performed to minimise the potential for this bias.

Validation of service specific items

Whilst the service specific items were developed following analysis of patients' comments, further work such as qualitative interviews to support the content of the service specific items and to provide further insight into potential sources of satisfaction or dissatisfaction would have been useful in validating the content of the questionnaire and may have provided other data which might have been useful for developing further service specific items.

This study was subject to a number of limitations, it is impossible to fully quantify the impact that they had on the findings.

4.7.1.6 Section summary

Despite the difficulties faced during the patient satisfaction study and the methodological limitations, the satisfaction questionnaire provided useful insight into patients' perceptions and was a valuable tool for BLT anticoagulation service development.

Collecting data at HUH as well as BLT enabled the results from BLT to be put into some form of context; this was a useful way to assess how the respective services performed (according to patients) and to identify service development objectives. Findings suggested that *perceived negative interactions with staff, long waiting times, difficulty getting to the clinic and dissatisfaction with the mode of blood sampling* contributed largely to lower levels of satisfaction at BLT.

Patient satisfaction with services is becoming more important especially with regards to service redesign (Larson *et al.* 2002). Current literature accepts the role of patient satisfaction in evaluating health services; it provides a patient perspective that can contribute to a complete, balanced evaluation of the structure, process and outcome of services. One proviso is, that patient satisfaction data by itself gives an incomplete picture. It is important to note that patient satisfaction is a subjective measure, and as demonstrated in this study, findings may be affected by numerous factors. It is one source of information necessary for service planning, development and evaluation and should be coupled with measures that seek to explore clinical outcomes as well as risk and financial management, ideally taking a longitudinal approach.

4.7.2 Group interviews

4.7.2.1 Introduction

This section discusses the group interviews held during the developmental phase, giving a brief overview of the methodology and findings. Difficulties encountered and limitations of the study are discussed in the relevant sections.

The multidisciplinary discussions comprised a BLT anticoagulation team meeting, a pharmacy forum meeting, a meeting with professional stakeholders in strategic positions, for example the Academic Director of Pharmacy and lastly, a nominal group session. In the study, stakeholder opinion was used, not only to aid in the selection of models for evaluation, but also to highlight requirements, potential issues and the perceived need and value of such services.

4.7.2.2 Recruitment

The focus of the study was anticoagulation service developments in a specific East London locality; generalisability of the findings was not an aim. The BLT anticoagulation team and professional key stakeholders meetings were small in size, despite full representation as they covered the Tower Hamlets area only.

The Pharmacy forum is open to all pharmacists working in the City and Hackney area, however only a small percentage (approximately 22%; 16 / 74) of pharmacies were represented at the meeting. In addition, there was a very low response rate to the nominal group session, despite two mail outs and subsequent telephone calls to those that had shown interest in attending the session. The low response rate may reflect a lack of interest or motivation to develop such services. Alternatively, GPs and pharmacists may not have felt qualified to contribute to the service development process.

Arranging the nominal group session at a time convenient for all participants proved difficult. Due to limited resources there was no possibility of paying for locum cover for pharmacists and GPs. Therefore the meeting had to be held in the evening and although there was much interest in the meeting, many were reluctant to give up their own time to participate or had other commitments. Further, the session was held in summer (July 2003), a time when many take annual leave. Due to time constraints, it was not possible to arrange another nominal group session later in the year, as the service was scheduled to start in November 2003. Smith (2005) suggests that incentives for participants may increase response rate; an incentive such as issuing of continued education certificates to participants could have been offered. There is no evidence that this would have improved attendance.

It would have been useful to have more than one practitioner providing primary care anticoagulation services attend the nominal group session. However, it proved difficult to identify such practitioners, other than through networking.

The poor response rate of the nominal group and pharmacy forum sessions, may have reduced the representativeness of the findings. The result is likely to have caused response bias due to self-selection of participants. It is likely that pharmacists and GPs taking part in the meetings were highly motivated and had a personal interest in anticoagulation services, possibly not shared by the majority of clinicians. One could question how the perceptions of practitioners that did not attend

the meetings differed from those that did and how if incorporated into the study the results may have differed.

4.7.2.3 Alternatives to nominal group session

The nominal group session was a useful method to reach a clear quantitative consensus regarding anticoagulation service models in a relatively short amount of time. Possible alternatives include the Delphi method or administration of a one-off questionnaire exploring primary care clinicians' perceptions. A drawback of these methods is that they do not allow interaction between participants. Smith (2005) reports that the opportunity for participants to discuss issues can result in views being altered, indeed participants' views changed over the course of the nominal group session.

In addition, to lack of group dynamics, the Delphi is a more time consuming process than the nominal group technique. Carley *et al.* (1999) used a Delphi method to "identify and improve areas of concern in the planning of care for children in major incidents." The Delphi involved 22 multidisciplinary experts and was conducted in three rounds over eight months (from February 1996 to October 1996). To ensure that the study time frame was adhered to in the present study, the nominal group session was a more appropriate method. Administration of one-off questionnaires to those unable to attend meetings should have been explored, this may have produced wider coverage of stakeholder perceptions and may have yielded more representative results.

4.7.2.4 Data collection

Whilst the practitioner meeting and pharmacy forum meetings were not audio recorded the investigator was able to make detailed notes throughout the meetings and able to write up points fully after the meetings. Independent repeat analysis of the formally recorded stakeholders and the nominal group session meetings ensured accuracy and validity of findings, and is a recognised method for testing the reliability of initial content analysis (Bowling 2002).

Key findings

4.7.2.5 GPs' and Pharmacists' roles

Despite the new GMS contract, the general consensus was that the majority of GPs would not be eager to start anticoagulation services. Participants felt that this might be due to an already overstretched work load, fear of litigation and feeling that they were not adequately trained. A

literature review of GPs perceptions with regards to anticoagulation services (section 1.4.2.3) supports this finding. Rogers *et al.* (1997) showed that a number (22%) of GPs were fearful of litigation when surveyed about issues related to anticoagulation therapy. Further, it has been shown that GPs are reluctant to prescribe warfarin and may over exaggerate the risks of anticoagulation, whilst minimising the potential benefits (Monette *et al.* 1997).

Whilst it is important to remember that the findings may not be representative, results from the pharmacy forum indicated that pharmacists were more keen and confident to utilise their skills to manage anticoagulation patients than GPs (NG and stakeholder session). Further, community pharmacists wanted to play an integral part in anticoagulation services, including the screening of patients for anticoagulation therapy. A community pharmacy-based anticoagulation service is plausible; Coleman *et al.* (2004) showed that anticoagulation control achieved by a community-pharmacy based anticoagulation clinic was at least as good as that achieved in the (previous) hospital setting. Chapter six discusses the role of pharmacists in anticoagulation services and in the modern NHS (sections 6.5; 6.9).

4.7.2.6 Targeting for service development

Mobility-impaired patients were repeatedly identified as a priority group for service development, primarily due to the unfavourable logistics of service provision for this patient group. Hall and Radley (1994) were also aware of the logistical issues, with large numbers of mobility-impaired patients arriving in anticoagulation clinics at the same time and advocated either a local or domiciliary service for such patients. Further, a number of primary care-based anticoagulation service developments have incorporated domiciliary services albeit in an ad-hoc fashion to facilitate the monitoring process for mobility-impaired patients (Coleman *et al.* 2004; Baird 2001). The study findings suggested participants' concerns were legitimate as they were echoed in the literature.

A domiciliary service for the mobility-impaired could address a number of concerns raised during the group discussions, such as risks of missing appointments due to patient illness or transport issues and health and safety concerns in the clinics. It is apparent that perceptions of the logistics of the monitoring service alongside the risks of inadequate monitoring come in to play when GPs are deciding to initiate anticoagulation therapy (York *et al.* 2003; Lipman *et al.* 2004). If the monitoring service was more favourable for this group of patients, GPs may be more willing to prescribe warfarin.

Stroke is the third most common cause of death and the single largest cause of disability in the UK (NSF for Older People; 2001), warfarin has been shown to reduce the incidence of stroke secondary to AF by 68% (Ezekowitz *et al.* 1992). Ensuring all those most at risk of thrombotic disease receive appropriate therapy would go some way to meeting the Government's stroke reduction targets (Department of Health 2001a; Livingston 2003) and would potentially produce cost savings through reduction in hospital admissions and rehabilitation costs.

4.7.2.7 Study limitations

The limitations of the poor response rates of the pharmacy forum and nominal group session have been previously discussed (section 4.7.2.2)

Heterogeneous group for nominal group session

The original plan for the nominal group session was to have two sessions consisting of homogeneous groups (GPs in one group, pharmacists in another), however due to the poor response rate, a heterogeneous group of GPs and pharmacists was used. Homogeneous groups are regarded as more productive in the data they yield, due to more in-depth discussions (Smith 2005). However within the study, the heterogeneous group was useful in giving both GPs and pharmacists insight into each others perspectives. With the move to more multidisciplinary working this approach may gain increased favour as when appropriately facilitated, it promotes candid discussion between the professions about their views and concerns.

Pharmacy Forum

Investigator attendance at the pharmacy forum was a simple way of collecting data from a pre-established group of pharmacists. This method could be regarded as a strength as the group was already in existence, therefore participants were less likely to be inhibited during discussions than they may have been discussing amongst strangers (Smith 2005). However, the limitations of the method include a lack of investigator control (Smith 2005), the meeting was organised by the group and the topic guide was developed by another investigator exploring various anticoagulation models. Further, the investigator was not permitted to record the session.

4.7.2.8 Validity of interviews

Smith (2005; page 155) describes validity during group discussions, as ensuring participants "feel able to express their views and influence the direction of the discussion regarding the topic of research." Through the use of open questions, allowing adequate time for all participants to speak

and creating a comfortable environment with refreshments during the discussions, this was achieved. Whilst the opinions of service providers are important, they are not a replacement for the scientific published literature; that the available literature substantiated the findings from the group discussions further suggests despite the identified limitations, the findings were valid (cumulative validity; Smith 2005; Jones and Hunter 1995).

Despite study limitations, the analysis of the group discussions gave an important insight into the perceptions of local healthcare professionals with regards to developing anticoagulation services.

4.7.3 Literature review

The investigator conducted a thorough review and evaluation of the literature by using a clear process for identifying, retrieving and managing literature.

4.7.3.1 Findings

The literature review of developments in anticoagulation service was useful in, identifying alternative models; outlining the evidence supporting use of technology to facilitate developments; exploring requirements and implications of establishing primary care-based services and identifying gaps in service development knowledge and research.

The low number of randomised controlled trials identified suggests that the majority of the research was done in 'real world' conditions. Rather than a weakness, the 'real world' conditions of the evidence base should be viewed as a strength with regards to the relevance and applicability to the 'real life' situation at the BLT anticoagulation clinics.

The approach of using literature to inform service developments has not been specifically or widely reported on, however a literature review is widely accepted to be one of the first steps in the decision making process on topics for investigation (Bowling 2002). Further, this approach to service development is descriptive of evidence based practice, where the best available evidence from the literature is used to inform decisions about the provision of healthcare. Jones (2003) recognised the importance of conducting a literature review and referring to the published evidence base when developing pharmaceutical services.

4.7.3.2 Study limitation

Within the current study, literature was found from database searches. A limitation of the literature review was the potential for publication bias; with the inclusion of only published data. A criticism of this approach is that published literature tends to be positive in nature; papers reporting perceived negative or insignificant findings are often not published (Bowling 2002); this could potentially result in an unreliable evidence base. Attempts should have been made to locate unpublished data, either through networking with others investigating anticoagulation service provision or sourcing relevant abstracts through conference attendance (Bowling 2002).

4.7.4 Pragmatism in model selection

Model selection for the intervention phase was a balance between evidence and feasibility. Together with the patient satisfaction and multidisciplinary discussions the literature review was able to inform the design of the intervention and the direction of service developments. A GP based model was selected during the nominal group session (ranked 2 in the nominal group session), however with the overall GP reluctance that was vocalised throughout the discussions, and difficulty in identifying interested GPs, an alternative domiciliary service (ranked 3) was selected in addition to the pharmacist / NPT service (ranked 1).

4.7.5 Other difficulties during the developmental phase

Following satisfaction data collection at BLT and HUH, the investigator attended the BLT clinic for approximately six months to receive training and reach competence as an anticoagulation practitioner. Over this time the investigator became accepted as part of the anticoagulation team such that, when the clinic was short staffed the investigator's regular assistance in the clinic was requested. This presented challenges in maintaining good relationships with the team and ensuring that the study schedule was not affected due to work pressures on the investigator. The investigator had to ensure that there was a clear understanding of her role amongst the anticoagulation team.

4.7.6 Overview

The developmental phase was useful not only in assessing developments in a number of aspects of anticoagulation service delivery but also in ensuring that developments were relevant for the local population. Further, with the selection of two models of service for evaluation using technology and non-medical practitioners in a primary care based setting, the work was in line with the Government's NHS modernisation agenda.

Whilst an aim of the study was to ensure that developed services were evidence based the limitations and challenges (for example, selection bias; poor response rates) of the methods used calls into question how feasible this is in practice; challenges of undertaking research in practice are discussed in Chapter 6.

This chapter has outlined the developmental work, including the exploratory research and the practical preparatory work required to select two evidence-based anticoagulation service models and prepare for them. The next chapter describes the implementation and the evaluation of these services in a randomised crossover study.

Chapter 5

INTERVENTION PHASE

5.1 Introduction

Exploratory work into the development of anticoagulation services across the primary and secondary care interface underpinned the development of the intervention phase. This evidence-based approach was used to inform the design of the service models, i.e. two different domiciliary anticoagulation service models for mobility-impaired patients. This chapter describes the evaluation of the two service models, with respect to patient satisfaction, anticoagulation control and safety in a randomised crossover study. In addition, the chapter gives an overview of the recruitment, randomisation process and results.

5.2 Aims of the study

The aim of the intervention phase was to implement and evaluate two evidence-based service models in terms of defined patient-specific, objective and subjective outcomes. To achieve this aim the following objectives were operationalised.

5.3 Objectives

- i. To implement two previously selected domiciliary anticoagulation services for BLT mobility-impaired patients in a pilot study
- ii. To evaluate and compare the anticoagulation service models in terms of:
 - a. Patient satisfaction (Quality) (Access)
 - b. Anticoagulation control (Quality)
 - c. Number of adverse events (Safety)
- iii. To compare the service models with the traditional hospital-based service with respect to the aforementioned outcomes
- iv. To identify the practical issues associated with delivery of these service models

5.4 Hypotheses

- i. An evidence based approach can be integrated with a pragmatic approach to ensure local anticoagulation service developments are relevant, can be implemented and are sustainable.
- ii. Service development, incorporating service user and provider feedback and the current evidence base from literature will increase patient satisfaction with anticoagulation services when compared to the traditional anticoagulation service model.

- iii. The approach to service developments will ensure that anticoagulation control and safety of the developed domiciliary services for BLT mobility-impaired patients will be comparable to that achieved with the traditional service model.

5.5 Intervention Phase Methods

5.5.1 Ethics Approval

Barts and The London Trusts Ethics Committee granted approval for the study to be undertaken (Reference: N/02/094).

5.5.2 Trial design and description

The study was a randomised crossover trial of the two domiciliary anticoagulation service models for mobility-impaired patients. Mobility-impaired patients were recruited and randomised to receive either service model 1 or model 2 first. Each patient received their first service for five months before being crossed over to receive the alternative service model for a further five months (Figure 5.1).

5.5.3 Service model descriptions and procedures

Model 1

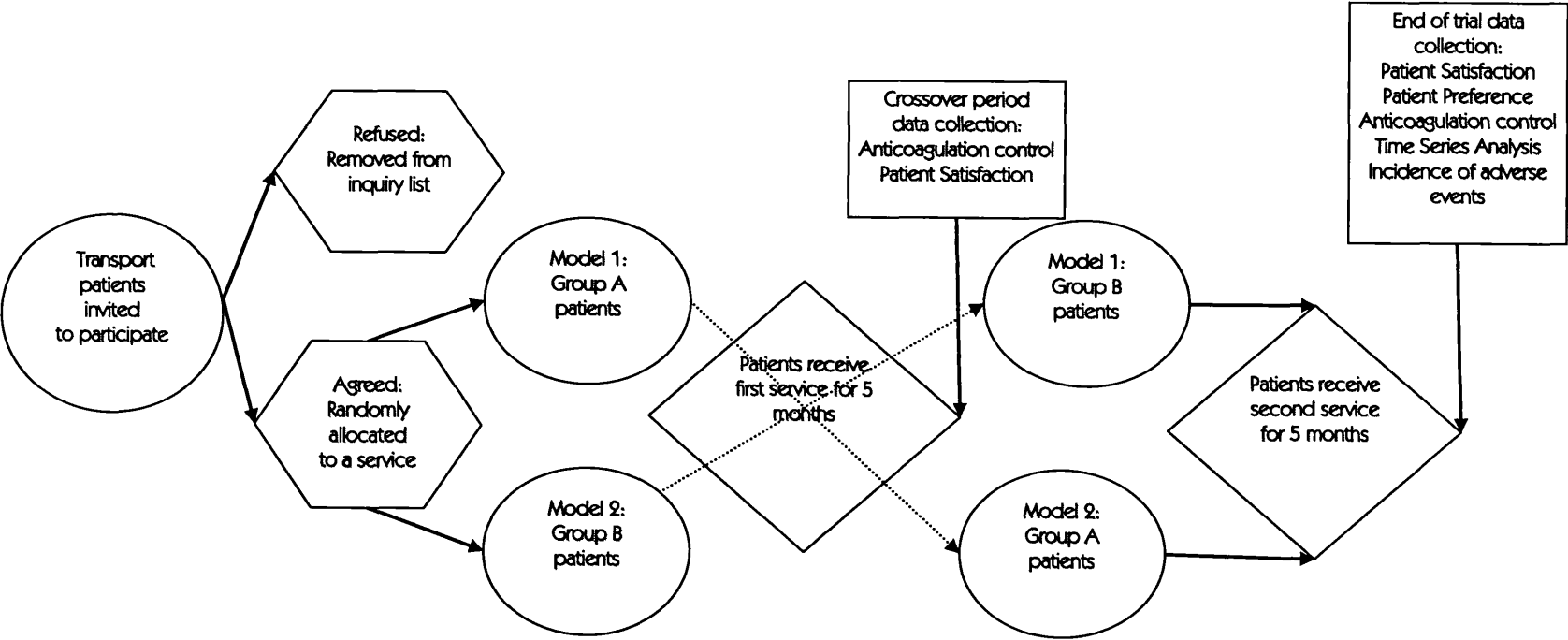
A phlebotomist, the chief administrator of the current anticoagulation team at BLT, carried out domiciliary visits to mobility-impaired patients. In this model, standard venous blood sample collection was performed. Following venous sampling, the phlebotomist would ascertain from the patients (or their carers) whether they were on any new medication (yes/no response) and if they had experienced any bleeding or bruising since their last appointment. Patients' or carers' responses were recorded on the Patient Details Checklist (Appendix 8). Once the phlebotomist had completed all visits for the day, the samples were transported to the BLT pathology laboratory for analysis and the checklist was given to the hospital anticoagulation practitioners. Once available, the results were reviewed by the hospital anticoagulation practitioners who dosed patients accordingly, with the aid of Dawn AC software (CDSS) and the Patient Details Checklist. If INR results were cause for concern, practitioners telephoned patients and asked further questions to aid the dosing decisions, such as details of new medication, general well-being and any changes in diet and/or alcohol intake.

The phlebotomist was responsible for contacting those patients whose INR was cause for concern by telephone and advising them of their INR results, required doses and dates of follow-up appointments. Patients (or their carers) were expected to document results and dosing advice in their anticoagulation record books. In addition, letters with results, dosing advice and dates of follow-up were sent to patients on the day of the phlebotomist's visit. Phlebotomists would not normally discuss INR results with patients; however the phlebotomist was acting in her capacity as the chief administrator, where she had been trained to perform this function. It is of note that this model would not operate in exactly the same way if a phlebotomist other than the chief administrator was involved and thus calls into question how sustainable such a model would be with an alternative phlebotomist in post.

Model 2

The investigator (a pharmacist) linked to the BLT anticoagulation clinic team, performed domiciliary visits to mobility-impaired patients utilising a one-stop anticoagulation service model. INR testing was performed from capillary blood using an NPT device and lancet system. Following the INR test the investigator asked some initial questions to aid in the assessment of the dose required, such as whether any doses of warfarin had been missed and whether they had experienced any bleeding or bruising since their last appointment. Depending on the responses and the INR results, further questions such as inquiring about changes to medication, general well being and any changes in diet and/or alcohol intake were asked. When the INR value was obtained, the investigator entered this into the Dawn AC software system (CDSS; on a portable computer) for a recommended dose to be calculated. The investigator either accepted or rejected the suggested dose, depending on the information that had been elicited from the patient and/or carer. The investigator recorded the INR result, the dose and follow-up appointment date in the patient's anticoagulation record book and advised the patient / carer of the dose, ensuring that the advice was understood. If the NPT device gave an INR reading of over 4.5, the investigator took a venous sample to verify the NPT reading. Venous samples were transported to the hospital pathology laboratory, where they were analysed and the final INR results confirmed. Based on the laboratory INR result, the investigator selected an appropriate dose (with the aid of CDSS) and informed the patient of the result, dose and the next appointment date over the telephone. A letter detailing dosing advice was posted to these patients on the same day by the investigator. In these cases, patients and/or carers were expected to enter advice given over the telephone in the patient-held anticoagulation record books.

Figure 5.1: Intervention study protocol



5.5.3.1 Equipment for delivery of service models

Model 1

Venous blood samples (4.5 ml) were collected in blue vacuum tubes (Becton Dickinson Vacutainer System) containing the anticoagulant sodium citrate. These tubes are used for obtaining venous samples in the hospital anticoagulation clinic. The samples were processed in the BLT pathology laboratory using either a Sysmex® CA1000 or Sysmex® CA7000 (Sysmex, Milton Keynes, UK) optical density coagulometer with a thromboplastin reagent to determine the INR.

Model 2

For model 2, the CoaguChek S (Roche Diagnostics, Lewes, UK) NPT device was used for near-patient INR testing. The CoaguChek S was selected as it is the most widely used anticoagulation NPT device in the UK, primarily due to its proven reliability, small volume requirements (10 µl) and ease of use (Gardiner 2003; personal communication; Dept of Health Evaluation Centre; MHRA). Furthermore, it has received Medical Device Agency (MDA) approval (Medical Devices Agency 01026; 2001). The softclix lancet system (Roche Diagnostics, Lewes, UK) was used to obtain capillary blood samples (finger prick) from trial participants as, with this system, the depth of lancet entry can be varied according to skin type (Roche Diagnostics, Lewes, UK).

Dawn AC software (4S Dawn Clinical Software)

The dosing decisions in both models were supported by the computerised decision support software, Dawn AC software (4S Dawn Clinical Software). In model 1 CDSS was used by the hospital anticoagulation practitioners in BLT to dose patients once their results had been determined in the hospital laboratory. In model 2, Dawn AC software was downloaded to a portable computer that was taken to the domiciliary visits to aid the investigator in making dosing decisions in the patients' homes. Computer-assisted dosing aids interpretation of results although computer-generated dosing suggestions can be over-ridden if the dose is not clinically indicated or as the practitioner sees appropriate in their professional opinion (Vadher *et al.* 1997a). Dosing supported by the Dawn AC software has been shown to give better anticoagulation control when compared to dosing by medical staff alone (Poller *et al.* 1998). In addition, the use of CDSS aids clinical audit and hence quality assessment to ensure reliable performance of anticoagulation services (Oppenkowski *et al.* 2003).

5.5.3.2 Notification of patients' GPs

All patients' GPs were notified that their patients were participating in the trial. It was agreed with GPs that patients needing additional blood tests, for example fasting glucose measurement, would have these taken during the home visit where patients presented the investigator or the phlebotomist with the request form.

5.5.3.3 Clinic staff notification

So that hospital anticoagulation staff could ensure that all patients were seen on their appointment dates and to follow-up patients who were not available when the investigator or phlebotomist visited, the trial patients were entered into a 'community visits' clinic in the computerised Dawn AC software system. Every time their files were accessed, a box containing the words 'community visits' appeared on the computer screen.

5.5.3.4 Patients using medicines compliance aids

Some patients had their warfarin supplied, along with other medicines, on a weekly basis in a medicines compliance aid, such as a dosette box. Dosette boxes accommodate seven days of patients' medication in 28 compartments, four for each day: morning, lunchtime, evening and bedtime. They are particularly useful for those patients taking high numbers of medicines, as they allow patients' medicines to be placed in daily compartments according to the appropriate time and can aid as a reminder for patients. The medicines compliance aids are prepared and dispensed by community dispensing technicians and checked for appropriateness and accuracy by community pharmacists. For the trial patients using medicines compliance aids, a dosing advice letter was created and faxed to the relevant community pharmacist. In model 1, letters were produced and faxed by the BLT anticoagulation clinic practitioners, in model 2, letters were produced and faxed by the investigator.

5.5.3.5 Annual and sick leave

On the occasions when the investigator and phlebotomist were absent from work (annual leave or sick leave), their patients were seen in the conventional way in the hospital anticoagulation clinic, using the hospital ambulance service.

5.5.3.6 End of trial patient notification

Patients were given six weeks notice of the date that the domiciliary service trial ended.

5.5.4 Patient sample

The target population for the domiciliary services trial were the mobility-impaired patients attending the BLT outpatient anticoagulation clinics (St. Bartholomew's, Royal London and The London Chest Hospitals). For the purpose of this study, mobility-impaired patients were defined as those requiring the ambulance service to transport them to and from the hospital for anticoagulation monitoring. The whole eligible population was sampled; therefore no sample size calculations were required.

5.5.5 Trial Recruitment

To maximise feasibility we limited the study to eligible BLT mobility-impaired anticoagulation patients; this provided a population of approximately 200 (precise: 193 of the 227 mobility-impaired patients attending BLT anticoagulation outpatient clinics; see exclusion criteria below). A previous study conducted on a similar population yielded 82% response to invitation to participate (Engova *et al.* 2002). Therefore, for the present study, the investigator expected to recruit at least 150 patients, i.e. 75 patients into each service model. This sample size was adequate for the descriptive nature of the study and the comparative analysis that was to be performed (bivariate and basic multivariate calculations).

Mobility-impaired patients were invited to participate in the trial by the investigator and the BLT anticoagulation administrator during their attendance at an anticoagulation clinic. A checklist was devised to ensure that each patient was given the same information regarding the service and the trial, irrespective of who spoke to him or her. In addition to the verbal information, the patients were also given an information leaflet (Appendix 9) with information about the domiciliary services and the trial. Those wishing to participate signed a written consent form (Appendix 10).

Exclusion criteria

The following exclusion criteria were applied:

- o Patients under 18 years - the investigator had not been trained to deliver an anticoagulation service to younger patients. In addition, the ethics committee approval was obtained for patients over 18 years of age only.
- o Patients not receiving warfarin as anticoagulation therapy - the investigator had not received training in adjusting the dose of any other oral anticoagulant apart from warfarin.

- o Patients receiving warfarin for short-term treatment - patients entered into the trial would be expected to receive both services for five months each; this would not be possible if they were receiving warfarin for short-term indications for a maximum of six months.
- o Patients with no telephone – without telephone contact, there was no immediate means of contacting patients with dose changes in model 1.
- o Patients living outside of the BLT service provision area - it was not deemed feasible or time-efficient to visit patients living outside of the service provision area.

5.5.6 Randomisation

For the purposes of this study, randomisation was used to allocate each recruited patient to a domiciliary service model. Minimisation was the randomisation method of choice for the present study as the participant number was small (<200 patients) and participants had a number of important prognostic variables, which could be used as factors to minimise potential imbalance between the groups (Roberts and Togerson 1998). Randomisation was carried out in three steps:

Step 1

The investigator identified four factors that could affect results of the trial if they differed significantly between the two groups. These were discussed with and approved by the consultant haematologist. The four factors were age, sex, anticoagulation control and indication for anticoagulation treatment.

Anticoagulation control was expressed as the percentage of time spent in therapeutic range (TIR; Rosendaal *et al.* 1993). When patients are initiated on anticoagulation therapy, the initial titration phase necessitates more frequent visits to the clinic to establish the correct maintenance dose for the patient. Furthermore, patients are more likely to be out of their therapeutic range during these initial monitoring visits before the correct dose is established. This could affect the measurement of anticoagulation control. Therefore, recruited patients were divided into two groups; 'new' patients, defined by the BLT consultant haematologist as those that had been receiving warfarin for less than three months, and 'follow up' patients as those receiving warfarin for more than three months. The 'new' patients were randomised using the remaining 3 factors only; excluding anticoagulation control as assessed by the TIR.

Step 2

An SPSS (SPSS for Windows, 2001; version 11.0) database was developed of data on the four minimisation factors of all mobility-impaired patients attending the BLT anticoagulation clinics. Patients' time in range (TIR) was calculated using a Time in Range Calculator Software (4S Dawn Clinical Software) for a period of one year; 30th September 2002 to 30 September 2003. The data for individual factors were analysed to establish medians and means to identify suitable cut-off points. Medians were used for non-parametric distributions and means for normally distributed data. The median age of the target group of patients was 79.1 years with a range of 30.6 to 95.8 years (n=193, the age of the patients was calculated as the difference between the date of data collection and their date of birth). The median age was used as the cut-off point. For patients who had been attending the clinic for more than 3 months, the mean time in range was 60.9% and this value was used as a cut-off point. The most frequent indication for warfarin was atrial fibrillation (AF, 136, 70.4%). Therefore, for pragmatic reasons the patients were divided into indication groups according to whether their indication was atrial fibrillation or not.

Step 3

Step 3 involved balancing of the key characteristics for patients in the two groups to minimise any imbalance. The first patient to be randomised was a 77 year old female with a TIR of 67.2% and AF as an indication for warfarin. She was randomly allocated to model 2 using a sequence of random numbers from a statistical textbook (Altman 1991) where even numbers denoted model 1 and odd numbers denoted model 2. The first number on the top left hand corner of the page was 47, so the patient was randomised to receive model 2 first (group B). Table 5.1 is an example of a minimisation table used in the present study. The first patient's details were entered in the minimisation table (Table 5.2).

Table 5.1: Example minimisation table

	model 1	model 2
Age ≤ 79		
Age > 79		
Male		
Female		
AF		
Not AF		
TIR ≤ 60.9		
TIR > 60.9		

Table 5.2: Minimisation table with the first patient's details

	model 1	model 2
Age ≤ 79		1
Age > 79		
Male		
Female		1
AF		1
Not AF		
TIR ≤ 60.9		
TIR > 60.9		1

The next patient was an 84 year old male with AF and a TIR of 78.4%. The frequency of occurrence of his characteristics for both services was calculated and totalled.

In model 1:

> 79	=	0
Male	=	0
AF	=	0
> 60.9	=	0
Total	=	0

In model 2:

> 79	=	0
Male	=	0
AF	=	1
> 60.9	=	1
Total	=	2

As the total was 0 for model 1 and 2 for model 2, to minimise imbalance, this patient was assigned to receive model 1 first (group A). This process was continued for each patient. Where totals were the same for each service for an individual's factors, the patient was allocated randomly using the sequence of random numbers (Altman 1991).

'New' patients (those attending the clinic for less than 3 months) were randomised on a separate table which did not include the TIR variable.

5.5.7 Outcome measure: Patient satisfaction

The client satisfaction questionnaire described previously in section 4.2.1.3 (CSQ-8; Attkisson and Greenfield 1995) was employed to evaluate patient satisfaction with the developed services at the crossover and end of trial stages.

5.5.7.1 Development of service specific items

Previous experience of using the CSQ-8 in the developmental phase had suggested that results tended to be negatively skewed. In addition, although the CSQ-8 is useful as a global measure of satisfaction it is unable to assess patients' satisfaction with specific aspects of service delivery. To ensure that key aspects of the service were assessed, the investigator developed additional service-specific items to complement the CSQ-8 questionnaire to explore aspects of the domiciliary service that contributed significantly to a patient's satisfaction. Following a review of published literature, no relevant validated tools were identified. The investigator used the results of the linear regression modelling that explored factors determining patient satisfaction in the developmental phase of the study to select relevant items. The results of HUH and BLT patients revealed that method of blood sampling (BLT and HUH), satisfaction with staff taking the blood (HUH) and clarity of instructions (HUH) were important aspects of overall satisfaction with the service, therefore the investigator selected these items to be asked at both the crossover and end of trial stages of the study (Table 5.3). Other items shown to be important to patients' satisfaction in the developmental phase were not transferable to the domiciliary service (for example, waiting time in clinic) and were therefore not used. For the purposes of comparing patients' views regarding the traditional, model 1 and model 2 services, the investigator developed three extra items to be administered at the end of the trial, (in addition to the CSQ-8 and the aforementioned additional items). These were developed after the BLT anticoagulation practitioners had described what information was important for them to know to move the anticoagulation service forward in line with patients' needs. These items are outlined in Table 5.4; the first of these was a preference item to rank the three services, patients were asked, which service they would like to use least, less or most out of the three services they had received (hospital, model 1 and model 2). In this way they were ranking each service in order of preference. The second was a visual analogue scale to rate patients' satisfaction with each service, with an open ended section for participants associated comments on this item, the final two items were open ended and asked the participants to outline their 'likes and dislikes' for each service model.

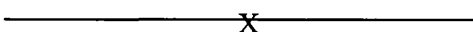
5.5.7.2 Piloting the survey tool

To ensure the developed items were understandable and valid, the surveys were given to a random sample of 20 mobility-impaired anticoagulation patients that weren't recruited to the trial (prior to crossover and end of trial administration to trial patients). Pilot analysis and respondent interviews indicated that the wording of the items was appropriate, therefore the items remained unaltered. The questionnaire was sent to the participants by post for self-completion to be returned in an enclosed envelope to the School of Pharmacy.

Table 5.3: Additional Likert style items administered to domiciliary trial participants at the crossover stage and at the end of the trial

Item number	Item	Likert Statement Responses			
		1	2	3	4
9	How did you feel about the way your blood sample is taken, i.e. from a vein on your arm (model 1)/ from your finger (model 2)?	I definitely dislike this way	I quite dislike this way	I do not generally mind this way	I do not at all mind this way
10	How satisfied were you with the staff taking blood?	Always dissatisfied	More often dissatisfied than satisfied	More often satisfied than dissatisfied	Always satisfied
11	Normally, how clear was the explanation of what to do between the visits, i.e. what dose to take?	Never clear	Rarely clear	Mostly clear	Always clear

Table 5.4: Additional Likert style items administered to domiciliary trial participants at the end of the trial

Item number	Item	Response options		
12	Over the last 18 months you have received three different services to monitor your warfarin. Please rank them in order of preference of each service: Which service would you like to use most (3), which one less (2) and which one least (1). Please circle your response	Hospital service. I would like to use this service: (1)least, (2) less, (3) most	Home service with blood taken from vein. I would like to use this service: (1)least, (2) less, (3) most	Home service with blood taken from finger. I would like to use this service: (1)least, (2) less, (3) most
13	Visual analogue scale item: In general, how satisfied were you with each service? Please tell us how satisfied you were with each service by making an X mark anywhere on the line between Not at all satisfied and Completely satisfied. Example Not at all satisfied  Completely satisfied	Hospital service.	Home service with blood taken from vein.	Home service with blood taken from finger.
Qualitative non optional items				
14	Please write the main thing you liked LEAST about each service:	Hospital service:	Home service with blood taken from vein:	Home service with blood taken from finger:
15	Please write the main thing you liked MOST about each service:	Hospital service:	Home service with blood taken from vein:	Home service with blood taken from finger:

5.5.8 Outcome measure: Anticoagulation control

The most appropriate measure of anticoagulation control has not been universally agreed. This is a salient issue as the achieved intensity of anticoagulation control is related to the benefit one receives from the therapy (Fitzmaurice *et al.* 2003). In this way, anticoagulation control can be used as a proxy measure for clinical outcomes; improved anticoagulation control should yield improved clinical outcome (such as reduced incidence of adverse events). A number of issues surround the assessment of anticoagulation control:

- o There are methodological issues with reporting data on the quality of anticoagulation control as INRs are measured at distinct time points.
- o The use of different measures of control has been shown to produce different results on the same data sets (Fitzmaurice *et al.* 2001).
- o It has proved difficult to accurately measure the percentage of time that the INR is within the prescribed therapeutic range (Rosendaal *et al.* 1993).

Prior to commencement of the trial, the investigator explored possible anticoagulation control measures for use as outcome measures in the trial. Information in the literature for the rationale, potential advantages and disadvantages of using particular measures was scarce. It is apparent that there is no perfect measure, hence the array of measures that has been utilised by different authors in an attempt to measure, as accurately as possible, the quality of anticoagulation control. Table 5.5 outlines some of these methods.

Fitzmaurice *et al.* (2003) conducted a systematic review of outcome measures reported for the therapeutic effectiveness of oral anticoagulation in published literature. The authors recommended that at least two of the four most widely used measures below should be reported on:

- Percentage of time spent in range (Rosendaal *et al.* 1993)
- Mean INR
- Proportion of tests in range
- Mean warfarin dose.

Table 5.5: Methods of reporting anticoagulation control (Fitzmaurice *et al.* 2003)

Measure	Brief Description	Advantages	Disadvantages
Point Prevalence	Proportion of patients with INR results that are within the therapeutic range at any given time	Unbiased; utilises cross-section of data at a particular time-point and easy to generate	Inefficient, does not consider results between follow-up dates
Mean INR	Mean INR of sample population	Easy to generate	Cases have to have the same target INR range; in small studies this may reduce the usefulness of data
Proportion of tests in range	Number of INRs in range divided by the total number of INR tests	Easy to generate	Method may be biased: tests are done more frequently on unstable patients, therefore may underestimate control
Percentage of time spent in range (Rosendaal <i>et al.</i>)	Estimates the amount of time a patient is in the therapeutic range based on the actual INRs measured, assuming a linear relationship between consecutive INRs	Takes into account the time between the tests	Requires software for calculation and the assumption of linearity may not be applicable, particularly for unstable patients
Dose changes each month	Number of dose changes in a given month	Can provide information on the skill of the practitioner in providing anticoagulation	This monitors dosing rather than anticoagulation control
Mean warfarin dose	Average dose of warfarin for sample population	Provides information for the monitoring of dosing advice, easy to generate	In an ageing population intra-individual variation in warfarin dose response may increase over time due to increased sensitivity with increasing age, therefore may not be an accurate measure of standards of control or dosing

The two most popular methods (Fitzmaurice *et al.* 2003); time in range (Rosendaal *et al.* 1993) and the proportion of tests in range were used in the present study. For both methods anticoagulation stability was calculated not only in terms of patients' actual specified range but also for an extended range. The extended range was ± 0.75 units of the target INR (as recommended by the British Committee for Standards in Haematology (BCSH; 5.5.8.2), for instance an INR actual range of 2- 3, is equivalent to a target INR of 2.5 and would have an extended range of 1.75 – 3.25. An extended range was used as it is more reflective of clinical practice; INRs within the extended range would not prompt a dose change in normal practice. Taylor *et al.* (1997) and Connor *et al.* (2002) used an extended range of ± 0.7 units when evaluating nurse specialist anticoagulation services.

5.5.8.1 Time in range

The Rosendaal percentage of time spent in therapeutic range (TIR) method is outlined in Table 5.5. The TIR during each service provision period was calculated using a Time in Range Calculator software developed by 4S Dawn Clinical Software, which calculates the TIR using Rosendaal's assumption that there is a linear relationship between INRs. INR measurements and associated dates for each patient were recorded retrospectively (baseline data; 12 months between 30th September 2002 and 30th September 2003) for the traditional model (Figure 4.2, Chapter 4) and

prospectively over a period of 5 months for the service model 1 and model 2 for each patient for both the first and second service periods. Fitzmaurice *et al.* (1996a) suggest that, on the basis of data from the United Kingdom, patients should expect to be within their own therapeutic INR range at least 60% of the time. The authors recommend that this is the standard that anticoagulation services (traditional and alternative) should be audited against. Therefore, in the current study patients were considered to be adequately controlled if they spent at least 60% of time within their therapeutic range (Fitzmaurice *et al.* 1996a; Fitzmaurice and Ketstevan 2003). At the end of the trial further calculations were performed to calculate the percentage of time each model kept patients within, above and below range over the entire trial period.

5.5.8.2 Proportion of tests in range

The calculation of the proportion of tests in range is outlined in Table 5.5. At the crossover stage the proportion of tests in range was calculated. At the end of the trial the total number of appointments each patient had in each service model (including the hospital service model for the year prior to the trial), along with the number of appointments that were within, above or below the range was obtained from the Dawn AC Software and used to calculate the proportion of tests within, above and below range over the entire trial period. The British Committee for Standards in Haematology (BCSH) outlines standards for audit in their guidelines on oral anticoagulation (Winter *et al.* 1998). BCSH uses target INRs, rather than INR ranges. Therefore a patient with an INR range of 2-3 has a target INR of 2.5. They recommend that at least 50% of INRs should be within 0.5 INR units of the target INR and that at least 80% of INRs should be within 0.75 INR units of the target INR.

5.5.9 Outcome measure: Number of adverse events (Safety)

With regards to monitoring anticoagulation services there is no universally accepted definition of adverse events. The majority of research studies evaluating anticoagulation services focus on haemorrhagic and thrombotic events when discussing adverse events (Ansell *et al.* 2001). The majority of definitions are concerned with categorising haemorrhagic events, with most opting for a two-tier denotation of minor/major event. Again, what constitutes a minor or major event has not been agreed and so papers tend to give their own definition. For the purposes of this study, a haemorrhagic event was defined as major if it caused death, stroke, or operation, or if it necessitated hospitalisation, blood transfusion, or both; all others were considered minor (Pellegrini *et al.* 1991). Thrombotic events are not subject to classification of minor or major, instead it is usual to simply record the occurrence of an event.

To assess the impact of anticoagulation services on the rate of adverse events such as haemorrhage and thrombosis, a large sample size is required, as it is known that although well documented, these events occur infrequently (Vadher *et al.* 1997a). Therefore, although recorded and reported on, these were not the main outcome measures of the present study, which was small in size. Published literature has employed a variety of ways of reporting on adverse events. Some trials state the numbers of adverse events occurring during the study; (Sawicki 1999). Others have used annualised event rates to account for the rarity of events; stating events in terms of the number of events per 100 patient years or per patient year; (Alonso *et al.* 1995). In addition, Kaplan-Meier survival analysis has been used to determine the time to a primary outcome adverse event of major haemorrhage, non fatal thrombotic event or vascular death (Walling 2000). In this study, for ease of comparison the number, type of adverse events and the rate of occurrence of the adverse events in terms of number per 100 patient years were used.

5.5.10 Patient background data

Background and demographic data were collected from 4s Dawn CDSS using patients' hospital numbers to identify them. The following data were recorded: patients' sex, date of birth, length of treatment and the primary indication for warfarin treatment.

There are certain factors such as the presence of co-morbidities that affect anticoagulation control and the incidence of adverse events (Ansell *et al.* 2001). To explore the extent to which some of these factors affected trial participants, the following data was extracted from the 4S Dawn software for further data analyses:

- i. Details of risk factors for complications with warfarin therapy
- ii. Number of additional drugs
- iii. Details of patients' co-morbidities
- iv. Number of dose changes for each service model including the hospital service (baseline data)
- v. The number of INRs over 4.5 and 6.0 in each service model and for baseline data
- vi. The number of INRs under 1.5 in each domiciliary service and for baseline data

Following discussion with the consultant haematologist, all identified factors were regarded as having the potential to affect both anticoagulation control and the incidence of adverse events. The occurrence of items (v) and (vi) were indicative of poor anticoagulation control; the consultant explained that poor control during the baseline year was seen as predictive for future poor

anticoagulation control. The consultant further stipulated that this list should not be regarded as exhaustive with regards to factors affecting anticoagulation control.

Other data

Data on the number of appointments and dose changes each patient had during each service model were recorded.

5.5.11 Contents of trial database

Patients' TIR, proportion of tests in range, quantitative data from the satisfaction survey, demographic, background data, number of appointments and number of dose changes during each service model (i.e. all data apart from participants' descriptive comments) were entered into the Statistical Package for Social Sciences (SPSS) for Windows, version 11.0 (2001), which was used to support quantitative analysis.

5.5.12 Data cleaning

5.5.12.1 Quality assurance

Data entered on to the databases were checked for accuracy. This process involved scanning of the database for obvious errors and producing descriptive tables and graphs to identify any anomalies in the data. Following this, a random sample of 10% of the cases on the database was compared against the original data (for example, the satisfaction survey) for accuracy of data entry. An error rate of not more than one percent was regarded as acceptable.

5.5.12.2 Management of outliers

Following consultation with the Director of Learning and Teaching (one of the project supervisors), The School of Pharmacy, where appropriate, outliers were removed from datasets, to minimise the effect of unusual results on the rest of the dataset.

5.5.13 Data analysis

5.5.13.1 Quantitative data analysis

To avoid systematic bias during analysis, the investigator was blinded to allocation of models for cases in the database through use of a patient group identifier code unknown to the investigator.

The distribution of data was assessed by plotting histograms with superimposed normal curves and where necessary, using the Kolmogorov-Smirnov test, which tests for normality of distribution by estimating the significance of fit of data with a theoretical normal distribution. When comparing the models for each treatment period only [for example, treatment period 1: model 1 (group A) versus model 2 (group B)] participants were regarded as independent samples; that is two samples receiving two different services. For data found to be normally distributed, the independent sample t-test and the one-way ANOVA were used. When data were non-parametric, Mann Whitney U test and Kruskal- Wallis tests were used. When comparing data from the entire trial population the patients were seen as one sample (that is, all trial patients), with differences in the order of receiving the two services. In these cases, normally distributed data was analysed using paired t-test and one factor within subjects ANOVA (repeated measures analysis). When data were non-parametric, Wilcoxon rank sum paired and Friedman tests were used. To determine whether there was correlation between factors, Pearson's correlation coefficient was used for normally distributed data and Spearman's rho was used for non-parametric data. For nominal data Chi² tests were performed to assess associations between variables. The tests were two sided and values of $p < 0.05$ were taken to be statistically significant. When appropriate, multiple linear regression was conducted to determine whether patients' characteristics or the additional items contributed significantly to patients' satisfaction as assessed by the CSQ-8, with domiciliary anticoagulation services.

Time Series Analysis

The data on patients' INR results were available as multiple INR measurements at given dates, therefore in addition to TIR and proportion of tests in range, interrupted time series analysis (ITS) using Autoregressive Integrated Moving Averages (ARIMA) modelling was conducted. This analysis was undertaken to add another dimension to the study of anticoagulation control. TIR and proportion of tests in range are useful measures of anticoagulation control, however they only yield average values, which give only a limited indication of what is occurring, whilst ITS analysis can be used to explore in detail the impact of an intervention, for example a domiciliary anticoagulation

service, on a given variable, such as INR value, over time. ITS analysis was used to compare anticoagulation control between the two domiciliary services and between the domiciliary services and the traditional service using the available baseline data.

Time series methods and data manipulation

Data analysis was performed for patients whose INR range was between 2.0 and 3.0; three patients had an INR range that was outside these limits; two patients with ranges of 3.0 to 4.0 and one patient with a range between 1.5 to 2.0. These patients were removed from analysis to avoid the data being affected by their INR results. Patients' INR values for the baseline and trial period along with the corresponding dates were entered into a SPSS database. For the purpose of the service model analyses, the trial patients were divided into two groups; Group A patients received the home venous sampling service (model 1) first followed by the home NPT service (model 2) and group B patients received the home NPT service (model 2) first, followed by the home venous sampling service (model 1).

A variable was created to denote the week that the INR tests were performed. Data were then sorted by week and aggregated to give mean INR values for each available week of data for both groups. The resulting aggregated databases were used to perform the service model time series analysis using ARIMA modelling with the support of SPSS (11.0; 2001).

Two analyses were performed; the first compared anticoagulation control during the baseline year (30th September 2002 and 30th September 2003) to anticoagulation control during the trial year for each group. The second analysis explored differences in control between the two domiciliary service models over the trial period.

The baseline year ran from 30th September 2002 to 30th September 2003. The trial began on 10th November 2003, which left five weeks of data that were not available for analysis. In order to preserve the spacing interval between the weeks, these weeks were entered into the database and the cases left as empty observations. It has been reported that ARIMA modelling is able to handle missing imbedded data appropriately (SPSS Inc. 1993).

Baseline year versus Trial year

To assess differences in anticoagulation control over the two time frames, a dummy variable was inserted to denote the introduction of the service model, i.e. domiciliary services provision. The

dummy variable had a value of zero at the pre-service model stage (from week 0 to week 57; 30th September 2002 - 7th November 2003; note week 53 to 57 were empty cases) and 1 at the service model stage (from week 58 to week 108; 10th November 2003 -5th November 2004).

Model 1 versus Model 2

To assess differences in anticoagulation control between the two trial models, an additional dummy variable was inserted to denote the crossover period. The crossover period ran for five weeks (due to differences in patients entry date to the trial); during week 23 to week 27 of the trial or week 79 to week 84 of the entire time series period (week 0 to 108). For the purpose of analysis and creation of a dummy variable, week 81 was taken as the crossover time. The dummy variable was 0 (from week 58 – week 81; 10th November 2003 – 30th April 2004) for the first domiciliary service model period, then it was 1 for the second domiciliary service model period (from week 82 to week 108; 3rd May 2004 -5th November 2004).

The main analysis compares the three service models (traditional model, model 1 and model 2) in terms of patient satisfaction and quality of anticoagulation control. A summary of main quantitative (including descriptive) analyses is in Table 5.6.

5.5.13.2 Qualitative data analysis

Methods for content analysis of patients' qualitative data from the patient satisfaction questionnaire were the same as in the developmental phase and have been described previously (section 4.2.3).

5.5.14 Recording of interventions made during the trial

During the course of the trial, both the investigator (a pharmacist) and the phlebotomist kept a record of interventions they made that impacted on the health and medicines management of the study patients. Short verbal medication counselling was not recorded by the investigator. The purpose of recording interventions was to assess whether there was any additional benefit of a pharmacist providing the domiciliary service over having a general phlebotomy service as in model 1. At the end of the trial the interventions were collated and reported.

Table 5.6: Summary of data analyses for the intervention phase

<p><i>Demographics</i></p> <p>Following recruitment and randomisation, patients' demographics were compared between the two trial groups, to assess whether there were any significant differences between the groups that could bias results of outcome analysis.</p> <p>Crossover stage</p> <p><i>Patient satisfaction</i></p> <p>Data from patient satisfaction questionnaires completed by patients at the crossover stage were compared for service models 1 and 2. In addition, trial satisfaction data were compared with satisfaction data from mobility-impaired (transport) patients that had completed satisfaction questionnaires during the developmental phase of the study.</p> <p>Analysis of anticoagulation service specific items was performed. Correlation of independent variables with CSQ-8 performed.</p> <p><i>Time in range and Proportion of tests in range</i></p> <p>Time in range data for the domiciliary service models were compared with one another for the first service period. In addition, TIR data were compared between the domiciliary service models and the traditional hospital service, using the retrospectively collected baseline data for the patients in the trial at crossover stage.</p> <p>Proportion of tests in range data for both domiciliary service models were compared for the first service period. In addition, proportion of tests data were compared between the domiciliary service models and the traditional hospital service, using the retrospectively collected baseline data for the patients in the trial at crossover stage.</p> <p>End of trial stage</p> <p><i>Patient satisfaction</i></p> <p>Data from patient satisfaction questionnaires completed by patients at the end of the second service provision period were compared for service models 1 and 2. In addition, trial satisfaction data were compared with satisfaction data from mobility-impaired patients that had completed satisfaction questionnaires during the developmental phase of the study.</p> <p>Analysis of anticoagulation service specific items was performed.</p> <p>Correlation of independent variables with CSQ-8 performed. Linear regression for patient characteristics and additional items to ascertain to what extent variance in patient satisfaction due to these aspects.</p> <p><i>Time in range and Proportion of tests in range</i></p> <p>TIR data for service models 1 and 2 in the second service provision period was compared.</p> <p>TIR data for each service model in the second service provision period was compared with baseline TIR data for the patients that had reached the end of the trial.</p> <p>TIR data over the entire trial period for both domiciliary service models was compared for each domiciliary model</p> <p>TIR data over the entire trial period was compared for all three service models (i.e. including traditional hospital service)</p> <p>Proportion of tests in range was compared for the two domiciliary service models over the trial period</p> <p>Proportion of tests in range was compared for all three service models.</p> <p><i>Time series analysis</i></p> <p>Comparing anticoagulation control between the two domiciliary service models.</p> <p>Comparison of time series data between each domiciliary service model and the traditional service model.</p>

5.5.15 Meetings held during the trial

Throughout the course of the trial a number of meetings took place:

- i. The investigator and consultant haematologist met every four weeks, to monitor patients' INRs and assess any specific patient issues such as non-compliance.
- ii. Two months before the end of the trial the anticoagulation team held a meeting to discuss the impact of the domiciliary services on their workload and after preliminary analysis of the

data, decide which of the two domiciliary services would be preferable for long term implementation.

- iii. Two months before the end of the trial the BLT anticoagulation team met with BLT pathology manager to discuss the long term future of a domiciliary service in terms of funding.
- iv. Towards the end of the trial the investigator, phlebotomist and the BLT anticoagulation team had a discussion about the practical issues encountered in providing the domiciliary services.

5.6 Results

5.6.1 Introduction

The first part of this section outlines patient recruitment and data cleaning processes undertaken prior to data analysis. The section then goes on to describe the demographics of the trial patients and the outcome of the randomisation (minimisation method) process. The findings of the trial in terms of the two main outcome measures; patient satisfaction and anticoagulation control at crossover and at the end of the trial are described. In addition, data on aspects of patient safety are outlined. Interventions made by the phlebotomist and pharmacist during the trial along with a review of these interventions by the BLT senior anticoagulation pharmacist practitioner are detailed. Key meetings related to monitoring of patients, the BLT anticoagulation team's views on the interventions and funding of a domiciliary service model are outlined. The section concludes with a summary of the key findings.

5.6.2 Recruitment

Recruitment took place from July 2003 to January 2004. One hundred and twenty-one patients agreed to participate in the study. The number of patients recruited was lower than expected and was anecdotally thought to be due to the fact that for many patients the clinic appointments were viewed as their only opportunity to get out of their homes. In addition, there may have been doubts over the safety of an alternative service in comparison to the hospital-based service. It was identified before randomization that the administrator assisting in recruiting had recruited patients that were on the exclusion list. Therefore, prior to commencement of the trial, ten patients were excluded as they lived outside the BLT service provision area, a further three patients were excluded because they were on short-term warfarin treatment and one patient was identified as having no telephone. In addition, one patient died and two patients withdrew prior to commencement of the trial. Therefore, 104 patients were randomised to each service model. By

the end of the trial, 12 months later, 63 patients were participating, 41 of the original patients were no longer in the trial. Table 5.7 summarises the reasons for loss of participants.

The trial commenced in November 2003 and ended in November 2004, to allow for those patients who had been recruited in January to receive both service models for five months each.

Table 5.7: Summary of the reasons for loss of participants

Reason for loss of participants during the trial		Frequency
Death		10
Excluded from trial:		17
Due to non-compliance with appointment dates/times	3	
Moved abroad	1	
Moved out of Tower Hamlets service provision area	2	
Long-term inpatients	3	
Moved anticoagulation management to a different hospital	1	
Opted out of receiving domiciliary visits:		
After one appointment	1	
After difficulty obtaining venous blood sample due to weak veins	1	
Removed by phlebotomist due to weak veins	2	
Short-term indication	1	
Discharged from the clinic	2	
Warfarin discontinued by GP or hospital clinicians:		14
Reason not specified	7	
Due to falls and nose bleeds	1	
Due to lung cancer	1	
Due to gastric bleed	1	
Due to reported side effects of malaise	1	
Due to non-compliance	2	
Due to failure of oral anticoagulation to effectively manage DVT treatment	1	
Total		41

5.6.3 Data Cleaning and Quality Assurance

Initial database

The initial database consisted of patients' demographics and their TIR over the previous trial year for the 104 cases at the start of the trial. Following a random 10% verification of the variables no errors were detected; therefore there was a zero percent error rate. The database contained 1456 entries.

Crossover database

The database devised at crossover consisted of 84 cases and 1596 entries. When frequencies were run, one error was identified regarding the incorrect input of a CSQ item number (6 instead of 4), this error was amended. Following a check on a random 10% of the database, one additional error was identified regarding incorrect input of a CSQ item number (3 instead of 4), which was rectified. When frequencies were run again, no further errors were detected. The error rate was 0.6% and was judged acceptable.

Final database

The database devised at the end of the trial consisted of patients' demographics, CSQ data, anticoagulation service specific items data, TIR data (calculated using the 4S TIR calculator), the number of appointments, number of INRs in range, dose changes and proportion of tests in range (number of INR tests in range / total number of INR tests). There were 63 cases and 3410 entries.

No errors were identified when frequencies were run. Following accuracy checks on a 10% random sample of cases, one error was identified. In one case the number of dose changes stated was incorrect; instead of 6 it stated 8. This was corrected. Secondary checks (running descriptive statistics) identified no further errors. The error rate was 0.29% and was judged to be acceptable.

5.6.4 Sample demographics

Forty-five males (43.3%) and 59 females (56.7%) were recruited to the trial. There was no significant difference in the number of males and females in the trial ($\chi^2 = 1.885$, $df=1$, $p=0.17$). The median age of the group was 79.5 years with a range of 30.8 to 95.7 years (mean = 77.4 years; Figure 5.2), as expected, patient's age was negatively skewed.

The median length of treatment was 2.7 years, (Figure 5.3; mean = 3.8 years, range 0.79 to 300.4 months). Seventy one percent (71.2%) of patients had atrial fibrillation as their primary indication. Deep vein thrombosis was the next most common indication (11.5 %). Details of all remaining indications are in Table 5.8. During the baseline year, 99 of the 104 recruited patients had received warfarin for more than three months. INRs were in desired therapeutic range 60.1% of the time (Figure 5.4, median = 62.2%; range: 0.0% - 100.0%; Kolmogorov-Smirnov; $Z= 0.979$, $df= 99$, $p=0.293$).

Figure 5.2: Age distribution for domiciliary anticoagulation service trial patients

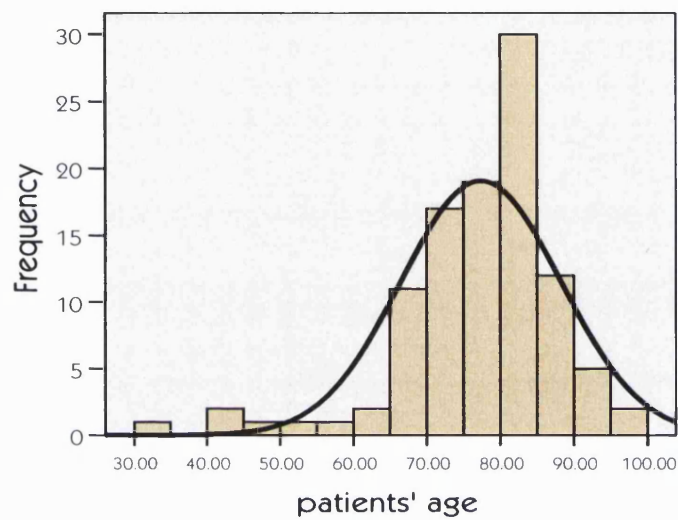


Figure 5.3: Duration of treatment distribution for domiciliary anticoagulation service trial patients

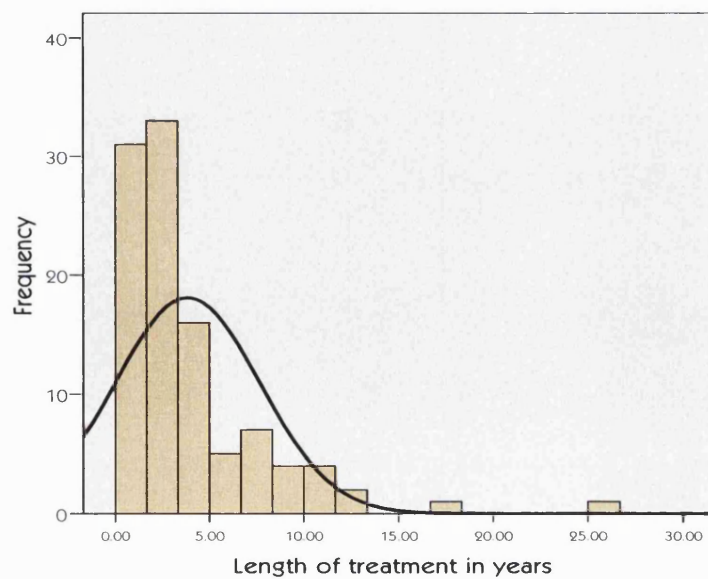
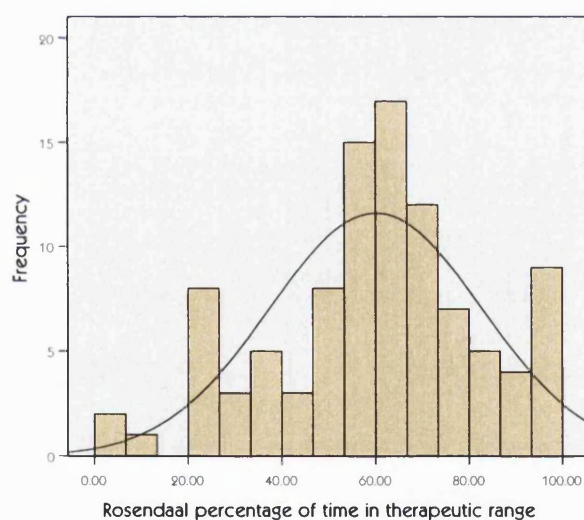


Table 5.8: Primary indication for warfarin – domiciliary anticoagulation service trial patients

Indication	Frequency	Percent
Atrial fibrillation (AF)	74	71.2
Deep vein thrombosis (DVT)	12	11.5
Pulmonary embolism (PE)	7	6.7
Cerebral vascular accident (CVA)	3	2.9
Aortic / Mitral valve replacement (AVR/MVR)	2	1.9
Other (aneurysm, mitral thrombus, transient ischaemic attack)	6	5.8
Total	104	100

Figure 5.4: Distribution of Time in Range for domiciliary anticoagulation service trial patients



5.6.5 Randomisation

In the minimisation process, 53 patients were recruited to model 1 and 51 patients to model 2. In addition to there being no difference in gender split between the two groups, there was no significant difference between the groups with respect to age, primary indication, proportion of tests in range and TIR (Table 5.9).

Table 5.9: Demographics of patients randomised to domiciliary anticoagulation services

Variable	Categories	model 1 (n=53)			model 2 (n=51)			Statistical test and p value
		Frequency	Percent		Frequency	Percent		
Gender	Male	23	43.4		22	43.1		Chi ² =0.001, df=1, p=0.979, two tailed
	Female	30	56.6		29	56.9		
Primary Indication (% with AF)	AF	67.9			74.5			Chi ² =0.549, df=1, p=0.459, two tailed
	Not AF	32.1			25.5			
Duration of treatment (years)	N/A	Mean	Median	Range	Mean	Median	Range	Mann Whitney U p=0.535, two tailed
		3.3	2.7	0.07-11.8	4.4	2.8	0.15-25.0	
Median age (years)	N/A	79.7 (mean=76.9; range: 40.3-95.7)			79.5 (mean=77.9; range 30.8-94.9)			Mann Whitney U p=0.532, two tailed
Median TIR (%)	N/A	61.2 (mean=59.7 ; range: 3.7-100.0) Kolmogorov-Smirnov; Z= 0.090, df= 50, p=0.200			63.2 (mean= 60.4; range 0.0 - 100) Kolmogorov-Smirnov; Z= 0.121, df= 49, p=0.070			Independent samples t- test - 0.159, p=0.874, two tailed
Median proportion of tests in range	N/A	56.1 (mean=54.2; range: 1.4-100.0) Kolmogorov-Smirnov; Z= 0.087, df= 50, p=0.101			58.0 (mean =55.4 ; range 0.0 - 100) Kolmogorov-Smirnov; Z= 0.121, df= 49, p=0.093			Independent samples t- test - 0.095, p=0.65174, two tailed

5.6.6 Patient demographics - Crossover stage

Eighty four patients reached the crossover stage, 41 receiving model 1 and 43 receiving model 2.

There was no significant difference between the number of male (33; 39.3%) and female patients (51; 60.7%; Chi² =3.857, df=1, p=0.050). The mean age of the whole sample was 77.5 years (range 31.2–94.5); age distribution was negatively skewed for patients receiving both domiciliary service Figure 5.5 and Figure 5.6.

Figure 5.5: Age distribution for domiciliary anticoagulation model 1 service

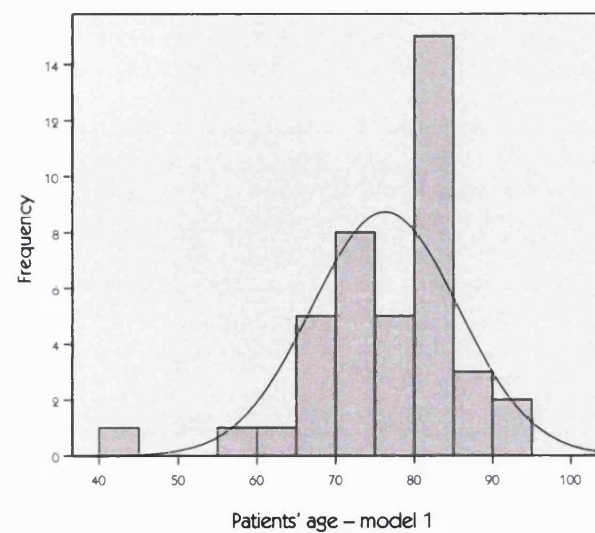
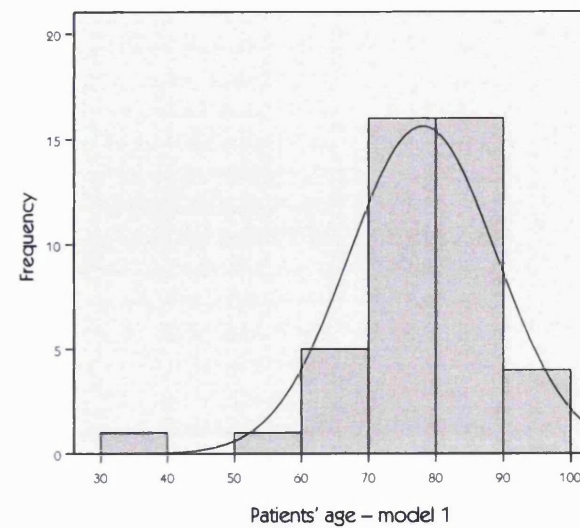


Figure 5.6: Age distribution for domiciliary anticoagulation model 2 service



There was no significant difference between the groups, with respect to age, sex and primary indication (atrial fibrillation for 72.6%; Table 5.10).

Table 5.10: Demographics of patients randomised to domiciliary anticoagulation services at crossover

Variables	Categories	model 1 (n=41)		model 2 (n =43)		Significance (2-tailed)
		Frequency	Percent	Frequency	Percent	
Gender	Male	17	41.5	16	37.2	Chi ² =0.159, df=1, p=0.690
	Female	24	58.5	27	62.8	
Primary Indication (% with AF)	AF	70.7		74.4		Chi ² =0.143, df=1, p=0.705
	Not AF	29.3		25.6		
Mean age	N/A	76.3 (range: 43.4 – 94.5 years, median age= 79.0 years) Kolmogorov-Smirnov; Z= 0.812, p=0.524		78.1 (range: 31.2 – 93.5 years, median age= 79.0 years) Kolmogorov-Smirnov; Z= 1.105, p=0.174		Independent samples t-test, t = -0.807, p=0.422

5.6.7 Patient Satisfaction – Crossover Stage

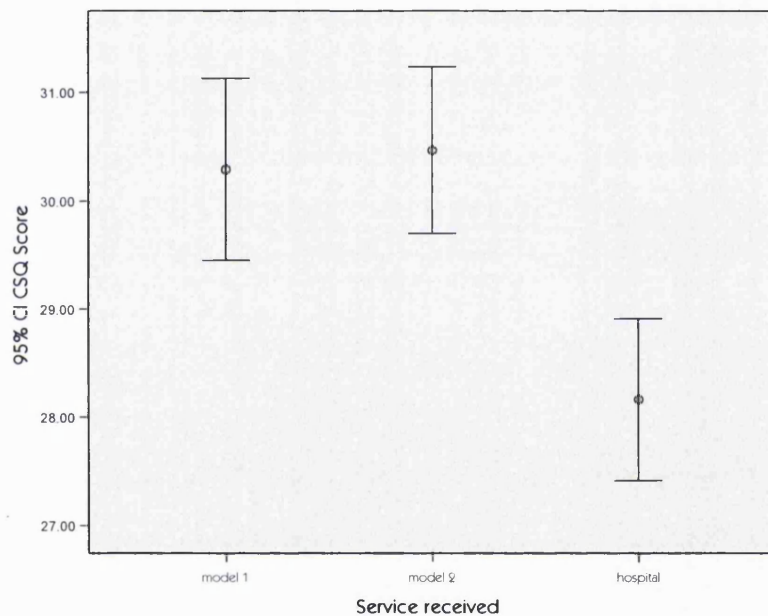
Seventy-two mobility-impaired patients in the developmental phase (hospital service) completed the CSQ questionnaire. Following two rounds of postal administration of the questionnaire (to maximise the response rate), 71 (84.5%) domiciliary trial participants (n=34 model 1; n=37 model 2) completed the CSQ-8 at the crossover stage. Two participants failed to complete more than two items, therefore these cases were eliminated from analysis. Eight cases had at least two missing items, which were replaced with the mean value for the entire series and were kept for analysis. Sixty-nine domiciliary trial cases were analysed: data for 33 patients receiving model 1 and 36 patients receiving model 2 are presented.

Overall, the Cronbach's alpha for the CSQ-8 administered to the trial participants was 0.77, indicating a good level of internal reliability and that the questionnaire was a useful measure of patient satisfaction in this group of patients. The overall median CSQ for the domiciliary services was 31.0 (Kolmogorov-Smirnov; Z= 2.167, df= 81, p <0.001; mean = 30.38, range 23 – 32; arithmetic median = 20), suggesting patients were highly satisfied. Comparing the CSQ scores of the groups (model 1, model 2 and hospital service; Kruskal Wallis test), there was a significant difference between the groups (Table 5.11; Figure 5.7). There was no difference in satisfaction between the two domiciliary services (Table 5.11), however, there was a significant difference in satisfaction between the service model domiciliary groups compared to the hospital group (Table 5.11).

Table 5.11: Comparison of CSQ score between domiciliary models at crossover and hospital service

	Model 1	Model 2	Hospital	Comparisons p values
N	33	36	72	
Median CSQ	31.0	31.0	28.0	Comparing the 3 models: Kruskal Wallis test, $\chi^2 = 19.8$, $df=2$, $p<0.001$ Comparing model 1 and model 2: Mann Whitney U, $p=0.925$, two-tailed. Comparing domiciliary with hospital, Mann Whitney U, $p<0.001$, two-tailed
Mean CSQ	30.29	30.47	28.16	
Range	24 – 32	23 - 32	18 – 32	
Kolmogorov-Smirnov	Z= 1.461, p = 0.028	Z= 1.730, p = 0.005	Z= 1.246, p = 0.090	

Figure 5.7: Means and 95% confidence intervals for the CSQ score for the different services



5.6.7.1 Missing Values from CSQ – Crossover Stage

On the advice of the authors of the CSQ questionnaire, a comparison of the median CSQ scores without replacing the missing items (for those cases that were used for analysis) and the median CSQ score when items were replaced, was performed. The median CSQ score for the domiciliary service when the CSQ items were not replaced was 31.0 (mean 30.30) for 61 cases ($n(\text{model 1}) = 31$, $n(\text{model 2}) = 30$), compared to 31.0 (mean 30.38) for 69 cases ($n(\text{model 1}) = 33$, $n(\text{model 2}) = 36$) when items were replaced. There was no significant difference in the mean CSQ scores that had the individual missing items replaced and those that did not have the

individual missing items replaced (Mann Whitney U, $p=0.837$, two-tailed), indicating that replacing the missing values did not adversely affect the observed results.

5.6.7.2 Service specific items analysis – Crossover Stage

This section outlines the results for the responses to the additional service specific items developed by the investigator and the anticoagulation team.

The Cronbach's alpha for the three additional items was 0.404 for the 66 cases that had completed those items. Therefore, items were analysed separately. No statistically significant difference was found between the responses of patients receiving service model 1 and those receiving service model 2 for the additional items (Table 5.12). Furthermore, there was no significant difference in the additional items when the domiciliary service responses were compared with the BLT hospital service 'transport' patients' responses, both collectively (that is model 1 and model 2 together; Table 5.12) and individually (that is comparing model 1 responses to BLT responses and comparing model 2 responses to BLT responses; Table 5.12), indicating that the additional items were not key factors with regards to service provision and patient satisfaction.

Table 5.12: Comparisons of additional items administered to trial participants and hospital transport patients

Mann-Whitney U Test: Comparison of model 1 and model 2 responses						
Variable	Which service are patients receiving	N	Mean Rank	U	Significance tailed	two
Blood sample from vein on arm/finger	model 1	31	31.18	470.500	0.207	
	model 2	35	35.56			
Satisfaction with staff taking blood	model 1	33	34.00	561.000	0.751	
	model 2	35	34.97			
Instructions about what to do between visits	model 1	32	32.16	501.000	0.281	
	model 2	35	35.69			
Mann-Whitney U Test: comparison of all domiciliary and BLT transport patients responses						
Variable	Which service are patients receiving	N	Mean Rank	U	Significance tailed	two
Blood sample from vein on arm/finger	Domiciliary	67	49.90	1065.000	0.273	
	BLT transport	35	54.57			
Satisfaction with staff taking blood	Domiciliary	69	52.01	1173.500	0.245	
	BLT transport	37	56.28			
Instructions about what to do between visits	Domiciliary	68	52.25	1207.000	0.868	
	BLT transport	36	52.97			
Mann-Whitney U Test: comparison of model 1 and BLT transport patients responses						
Variable	Which service are patients receiving	N	Mean Rank	U	Significance tailed	two
Blood sample from vein on arm/finger	model 1	32	31.27	472.500	0.122	
	BLT transport	35	36.50			
Satisfaction with staff taking blood	model 1	34	34.24	569.000	0.231	
	BLT transport	37	37.62			
Instructions about what to do between visits	model 1	33	33.52	545.000	0.423	
	BLT transport	36	36.36			
Mann-Whitney U Test: comparison between model 2 and BLT transport patients responses						
Variable	Which service are patients receiving	N	Mean Rank	U	Significance tailed	two
Blood sample from vein on arm/finger	model 2	35	34.93	592.500	0.710	
	BLT transport	35	36.07			
Satisfaction with staff taking blood	model 2	35	35.27	604.500	0.374	
	BLT transport	37	37.66			
Instructions about what to do between visits	model 2	35	36.91	598.000	0.572	
	BLT transport	36	35.11			

5.6.7.3 Correlations and multiple linear regression – Crossover Stage

Patient satisfaction as assessed by the CSQ-8 score was not influenced by patients' age (Spearman's $\rho = -0.033$, $p = 0.854$, two tailed) or the length of time a patient had been receiving warfarin (Spearman's $\rho = 0.140$, $p = 0.436$, two tailed).

When correlations were performed between the CSQ – 8 score and the additional questionnaire items, the items related to satisfaction with staff taking blood samples (Spearman's $\rho = 0.409$, $p = 0.018$, two tailed) and instructions about what to do between visits (Spearman's $\rho = 0.574$, $p = 0.001$, two tailed) were significantly correlated to the CSQ score. The criteria for linear regression were met and the stepwise method with validation using both the forward and backward methods produced the same results.

Linear regression revealed that for group A patients receiving model 1, the variable regarding instructions about what to do between visits accounted for 27.9% ($r^2 = 0.279$) of the variance in the CSQ scores. For group B patients receiving model 2, linear regression showed that the variable regarding instructions about what to do between visits accounted for 48.6% ($r^2 = 0.486$) of the variance in the CSQ scores.

These were regarded as large effects (Kinnear and Gray 2004), Analysis of Variance (ANOVA) analysis showed that the models were statistically significant (group A; $p = 0.02$; group B; $p < 0.001$), suggesting that there was indeed a linear relationship between the variables and CSQ score.

The instruction variable had a bigger impact on satisfaction for patients receiving instructions in their homes (model 2); this may be as a result to the different mode of instruction delivery. Patients receiving model 2 received dosage instructions during their home appointments with the investigator. Model 1 patients had to wait for results to be communicated to them via the telephone, by the phlebotomist.

5.6.7.4 Patient satisfaction qualitative data – Crossover stage

Similar to the results of the satisfaction survey performed in the developmental phase, the results of the survey undertaken at the crossover stage were largely positive. Whilst there was a significant increase in the CSQ score with respect to the domiciliary services compared to the hospital based service, the comments section was still regarded as useful in informing the investigator of aspects of

the service not covered in the additional service specific items that may have contributed to the increase in satisfaction.

The in-vivo codes for trial participants are displayed in Table 5.13. Codes were grouped under themes in a reflective coding process (Table 5.14). Due to the small number of responses and the lack of detail, in-depth refined reflective coding was not appropriate, instead the quotes could be considered illustrative.

Table 5.13: In-vivo codes from analysis of patients comments at crossover

Code	Description
1	Expression of satisfaction with service being provided at home (increased convenience)
2	Expression of preference of having service provided in home over service in the clinic (Better service access)
3	Satisfaction with service
4	Expression of desire for service to continue
5	Mode of obtaining blood sample in home service
6	Express that service is good for them as they are mobility-impaired (increased convenience)
7	Expression of satisfaction with staff providing home service
8	Happy that waiting for transport has been eliminated (increased convenience)

Table 5.14: Development of themes from the reflective coding process at crossover

THEMES (REFLECTIVE CODES)	SUB-THEMES (IN-VIVO CODES)
Theme One Satisfied with service provided in home environment (Increased convenience)	1 Expression of satisfaction with service being provided at home (Increased convenience) 2 Expression of preference of having service provided in home over service in the clinic (Better service access)
Theme Two Positive feelings regarding service	3 Satisfaction with service 4 Expression of desire for service to continue 5 Mode of obtaining blood sample in home service 6 Express that service is good for them as they are mobility-impaired (increased convenience)
Theme Three Positive feelings regarding staff	7 Expression of satisfaction with staff providing home service
Theme Four Satisfaction with no waiting for transport (Increased convenience)	8 Happy that waiting for transport has been eliminated (increased convenience)

The themes and example quotes are summarized in Table 5.15. A small number of the trial participants gave responses. There was little difference between the responses of both model 1 and model 2 patients. The themes related to: satisfaction with home environment of the service; positive feelings regarding service and staff and satisfaction with no waiting for transport services. A

number of the codes were related to increased convenience with aspects of the domiciliary services compared to the traditional service.

Theme one was concerned with the environment where the service was provided i.e. the patients' homes. Patients expressed satisfaction with the home setting of the service. Further, patients expressed a preference for having the service provided at home over having a service provided at the hospital, reporting increased convenience and access to services.

Theme two described patients' positive feelings towards the service. Echoing patients' satisfaction with the service being provided in their homes, the majority of patients were extremely pleased with the domiciliary service. Wheelchair bound patients no longer had to wait for the ambulance to arrive to attend the clinic (increased convenience and better access). In addition, numerous respondents expressed a strong desire for the service to continue after the trial indicating that they did not want to return to the previous hospital transport service. Model 2 patients expressed a preference for capillary sampling stating that it caused less discomfort.

Theme three outlines the patients' positive feelings towards the staff providing the service; patients felt that the staff were "excellent", "kind" and "helpful."

Theme four described the patients' positive feelings with regards to not having to wait for the ambulance to take them to and from the hospital (increased convenience and better access). All comments regarding the service were positive indicating that patients were satisfied with the domiciliary services.

Table 5.15: Display of examples of quotes from Themes emerging in the Crossover satisfaction survey

Theme One	Sub themes	Patient details	Quote
Home environment	Expression of satisfaction with service being provided at home	Patient id: 4, service received: NPT, female, aged 68.7 years, receiving treatment for 8.0 months for AF Patient id: 31, service received: NPT, male, aged 31.2 years, receiving treatment for 7.4 years for AF	I am very grateful that I can have this done at home. I am often unable to go out due to my illness so home visits are ideal . Also in cold or wet weather I am not able to go out either.
	Expression of preference of having service provided in home over service in the clinic	Patient id: 21, service received: NPT, female, aged 78.0 years, receiving treatment for 5.9 years for AF Patient id: 54, service received: NPT, female, aged 86.5 years, receiving treatment for 1.5 years for recurrent PE	In the past I used to suffer quite a lot because my veins are too thin but nowadays I have less problems and I am very happy that they that come to my home; saves the waiting trips by ambulance to the hospital I would recommend this service to everyone I know who needs it!! Excellent work Team!! Many thanks congratulations!! I am delighted with the home visiting service and pray that it will continue indefinitely. Previously attendance at the clinic caused me a great deal of stress and anxiety and to be free of the visits in cold wet weather was an added bonus. The pharmacist was not only skilled, but friendly and kind and I looked forward to her visits. Please continue this service. It is a godsend to elderly, disabled homebound patients such as myself.
Theme Two Positive feelings regarding the service	Satisfaction with service	Patient id: 39, service received, NPT, female, aged 83.5 years receiving treatment for 1.0 years for AF.	I was very satisfied with the service as I cannot get to hospital, the staff was always very kind.
	Expression of desire for service to continue	Patient id: 74, service received NPT, male, aged 69.0 years, receiving treatment for 4.0 years for femoral aneurysm.	I think the service was excellent and the staff worth every penny and I look forward to having the service for as long as possible because it suits my needs down to the letter.
	Mode of obtaining blood sample in home service	Patient id: 43, service received: NPT, male, aged 74.4 years, receiving treatment for 1.5 years for AF	I dislike the needle it makes my arm sore. More so if they miss the vein. I like the scratch system better it is a lot quicker and cleaner.
	express that service is good for them as they are mobility-impaired	Patient id: 31, service received: NPT, male, aged 31.2 years, receiving treatment for 7.4 years for AF Patient id: 15, service received: venous, female, aged 67.7 years, receiving treatment for 3.3 years for bilateral DVT	I am often unable to go out due to my illness so home visits are ideal. Also in cold or wet weather I am not able to go out either. Being unable to walk and wheelchair dependant it is also better to have blood taken via my finger as transferring to the chair or moving about after blood is taken via the vein can sometimes cause excessive bleeding and discomfort. I hope this service will be available again as soon as possible. It helps me a lot having it done at home because I am in a wheelchair and it's so quick and no waiting for ambulance which sometimes can be a very long wait before you get home.
Theme Three Positive feelings regarding staff	Expression of satisfaction with staff providing home service	Patient id: 3, service received: NPT, female, aged 89.9 years, receiving treatment for 3.6 years for AF	The home service provided is excellent. It saves me from starting my day waiting for an ambulance to arrive in the past, I have often missed my lunch due to the wait for my lift home, as I am diabetic and 90 years old this new service is excellent and the staff are excellent too . Please keep up this excellent service. I am also wheelchair bound and this service has been a great benefit in keeping not stressed.
Theme Four No Waiting for transport	Happy that waiting for transport has been eliminated	Patient id: 15, service received: venous, female, aged 67.7 years, receiving treatment for 3.3 years for bilateral DVT	It helps me a lot having it done at home because I am in a wheelchair and it's so quick and no waiting for ambulance which sometimes can be a very long wait before you get home. I think it is a wonderful idea and Kate has been coming to me is excellent and I don't feel hardly anything when the needle has gone in sometimes nothing at all.

5.6.7.5 Time in Range – Crossover Stage

Baseline data was for 81 patients; three patients were new (receiving treatment for less than three months) at the time of commencement of the trial therefore baseline data were not available for them. At baseline, the trial patients that reached the crossover stage of the trial had a mean TIR of 61.3% (median 63.4%, range 0.0-100.0%; Kolmogorov-Smirnov; $Z = 1.099$, $df = 81$, $p = 0.178$) over the year prior to commencement of the trial (30th September 2002 to 30th September 2003). During the first five months of the trial, the overall TIR for the trial patients was 60.2% (Kolmogorov-Smirnov; $Z = 1.035$, $n = 81$, $p = 0.235$). Model 1 patients were in range 61.4% (Kolmogorov-Smirnov; $Z = 0.137$, $df = 42$, $p = 0.068$). of the time, and model 2 patients were in range 58.7% of the time (Kolmogorov-Smirnov; $Z = 0.134$, $df = 39$, $p = 0.059$). There was no significant difference between these values (paired samples t-test comparing baseline and trial; $t = 0.240$, $p = 0.811$; independent samples t-test comparing models 1 and 2; $t = 0.429$, $p = 0.669$). There was no significant difference in TIR variance for these services (One way ANOVA $df = 2$, $F = 0.171$, $p = 0.843$), indicating that the domiciliary anticoagulation services had not compromised anticoagulation control during the first treatment period of the trial.

5.6.7.6 Proportion of tests in range – Crossover Stage

At baseline, the trial patients that reached the crossover stage of the trial had a mean proportion of tests in range of 56.6% (median 59.1% range 0.0 – 100%; Kolmogorov-Smirnov; $Z = 1.267$, $df = 81$, $p = 0.241$). During the first five months of the trial, the overall proportion of tests in range for the trial patients was 55.3% (Kolmogorov-Smirnov; $Z = 1.212$, $df = 81$, $p = 0.254$) Not surprisingly, there was no significant difference in the proportion of tests in range when the domiciliary services were compared collectively with baseline (hospital; 56.8%; Kolmogorov-Smirnov; $Z = 0.217$, $df = 81$, $p = 0.217$) data and between the domiciliary service models (model 1 56.9% [Kolmogorov-Smirnov; $Z = 0.185$, $df = 81$, $p = 0.137$]; model 2 54.4% [Kolmogorov-Smirnov; $Z = 0.263$, $df = 81$, $p = 0.101$]; paired samples t-test comparing baseline and trial; $t = 0.346$, $p = 0.761$; independent samples t-test comparing models 1 and 2; $t = 0.542$, $p = 0.556$). Further, there was no significant difference in variance for proportion of tests in range between all three models (One way ANOVA $df = 2$, $F = 0.234$, $p = 0.743$).

Summary

- Minimisation was an effective method of randomising the patient sample. There was no significant difference in demographics of the group at commencement and throughout the trial.
- 104 patients were recruited to the trial, 84 reached the crossover stage.
- CSQ-8 scores were significantly higher for the domiciliary services than the hospital service; however there was no significant difference in scores between the domiciliary services.
- Satisfaction with instructions about what to do between visits was the key independent variable in affecting the variance of CSQ-8 scores.
- Analysis of qualitative data revealed patients were positive with regards to the: service models; staff delivering the services; having the appointments in their homes (increased access) and no longer having to wait for transport to collect them or bring them home (increased convenience).
- There was no significant difference in anticoagulation control between the domiciliary services and the hospital service, indicating that the high quality (circa 60% TIR) of anticoagulation control achieved by the hospital service was maintained during the study.

5.6.8 Patient demographics - End of trial stage

Sixty three patients reached the end of the trial, 30 patients receiving model 1 (group B) and 33 receiving model 2 (group A). There were 29 male (46.0%) and 34 (54%) female patients, there was no significant difference in the number of men and women at this stage ($\chi^2 = 0.397$, $df=1$, $p=0.529$). The mean age of the whole sample was 78.5 years (range 31.6 – 94.0 years); age distribution was negatively skewed for patients receiving both domiciliary services (Table 5.16). There was no significant difference between the groups, with respect to age, sex and primary indication (atrial fibrillation for 69.8% for the whole group; Table 5.16; Figure 5.8 and Figure 5.9).

Figure 5.8: Age distribution of model 1 patients

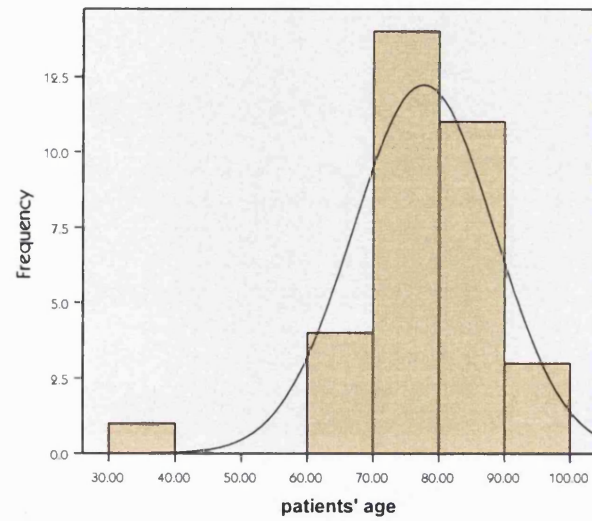


Figure 5.9: Age distribution for model 2 patients

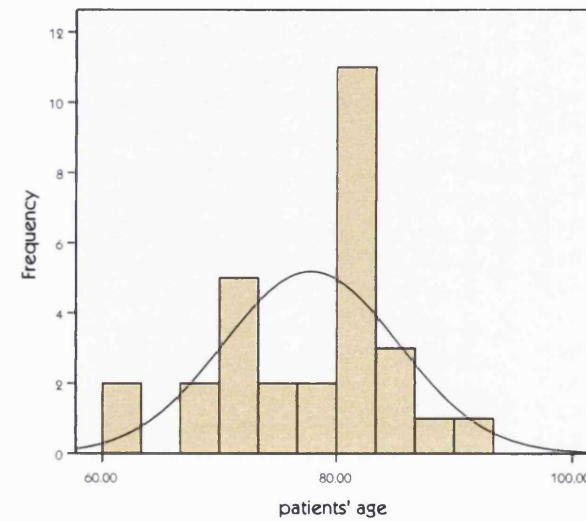


Table 5.16: Demographics of domiciliary trial patients at the end of the trial

Variables	Categories	model 1 n= 30		model 2 n= 33		Significance (2-tailed)
		Frequency	Percent	Frequency	Percent	
Gender	Male	13	43.3	16	48.5	Chi ² =0.168, df=1, p=0.682
	Female	17	56.7	17	51.5%	
Primary indication (% with AF)	AF	73.3		66.7		Chi ² =0.332, df=1, p=0.565
	Not AF	26.7		33.3		
Mean age	N/A	78.9 (range: 31.6 – 92.1 years, median age= 80.0 years) Kolmogorov-Smirnov; Z= 0.890, p=0.406		78.2 (range: 60.8 – 94.0 years, median age= 80.5 years) Kolmogorov-Smirnov; Z= 0.983, p=0.289		Independent samples t-test; t = -0.080, p=0.936

5.6.9 Risk Factors for warfarin therapy complications

At the end of the trial, 14 patients (22.2%) were identified as having risk factors for complications with warfarin therapy during the trial; eight of these patients were in group A and six in group B. Of the 14 patients identified as having risk factors, three had two risk factors, and one patient had three risk factors. The patient who had three risk factors, had the lowest TIR result for the trial year of 27.9% (proportion of tests in range =25.0%), this patient was in group A. In the year prior to the trial, this patient's TIR was 26.7% (proportion of tests in range 24.3%); one of the lowest baseline readings. A list of risk factors and their frequencies are given in Table 5.17.

Table 5.17: Trial patients risk factors for complications with warfarin therapy

Risk Factor	Number
Interacting drugs including (ibuprofen, amiodarone, antibiotics)	7
Operation	5
Compliance issues (as assessed by BLT Team)	4
High alcohol consumption / Binge drinking (as assessed by BLT Team)	2
Previous GI bleed	1

Patients identified as having risk factors were in range 58.4% of the time compared to those patients who did not have risk factors who were in range 69.4% of the time throughout the trial, this was a significant difference (Mann Whitney U p<0.001, 2 tailed), suggesting that the presence of risk factors had a negative effect on anticoagulation control. A statistically significant, but weak association was found between the presence of risk factors and the collective (that is for both domiciliary modalities) proportion of tests in range (Spearman's rho; -0.276: p=0.030). When TIR was used, a significant correlation was not observed (Spearman's rho, -0.241, p=0.059).

5.6.10 Co-morbidities

Sixty-one (96.8%) of the trial participants were identified as having co-morbidities. Twenty-one (33.3%) patients had at least two co-morbidities. The most common co-morbidity was hypertension (46, 56.0%), followed by respiratory problems - asthma and COPD (9, 11%). Details of the remaining conditions are in Table 5.18.

Table 5.18: Co-morbidities of trial participants

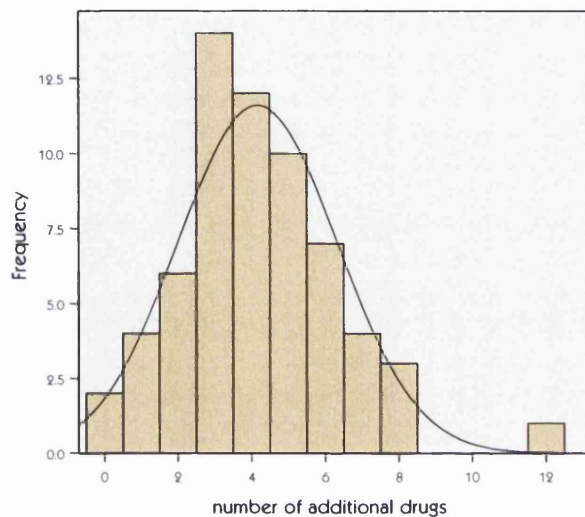
Co-morbidity	Number (%)
Hypertension	46 (56.0%)
Respiratory dysfunction (asthma and COPD)	9 (11.0%)
Diabetes	5 (6.2%)
Other (including depression, epilepsy, pain, hypothyroidism)	22 (26.8%)

5.6.11 Additional drugs

The majority of patients were taking additional drugs (57; 90.4%). The mean number of additional drugs taken by patients was 4.2, ranging from zero to 12 (Figure 5.10). No correlation was found between the number of additional drugs and measures of anticoagulation control (TIR; Pearson's correlation = -0.173, $p=0.178$ two-tailed, proportion of tests in range; Pearson's correlation = -0.132, $p=0.307$; two-tailed), indicating that the number of additional drugs a patient was prescribed had no impact on anticoagulation control.

Two patients had no additional drugs, co-morbidities or risk factors and were in (actual) range 94.5% and 83.4% of the time during the trial year. This suggests that the factors explored do affect anticoagulation control (as the consultant haematologist stated) in this patient group. Therefore it follows that patients who are free from these factors should be relatively stable and easy to manage with respect to anticoagulation control. However this is not definitive and it is well known that the reasons for fluctuations are not always clear (consultant haematologist, personal communication; MacCallum 2004); these patients TIR in the previous year were 56.1% and 71.1%, these are reasonable, but not particularly high.

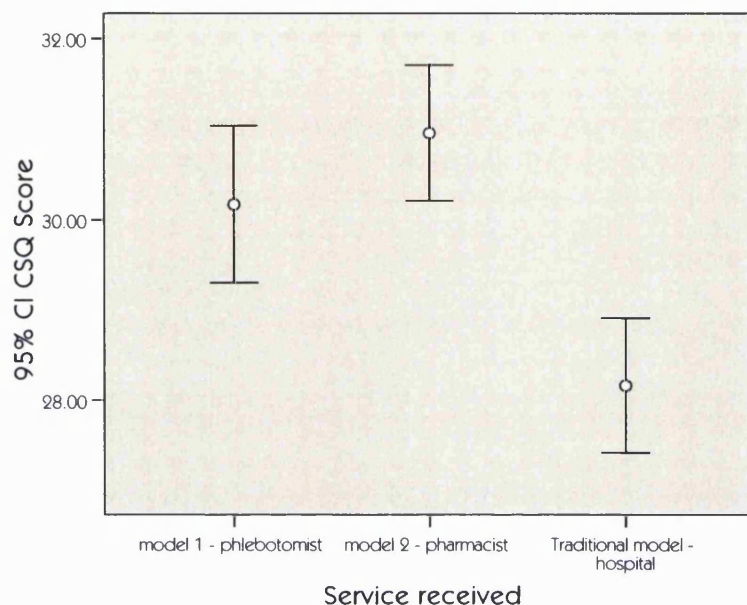
Figure 5.10: Distribution of the number of additional drugs



5.6.12 Patient Satisfaction – End of Trial Stage

Following three rounds of postal administration, 62 patients returned the CSQ-8 questionnaires at the end of the trial, a response rate of 98.4%. One questionnaire had more than two items missing and was therefore, eliminated from the analysis. Four questionnaires had up to two items missing; these items were replaced using the series mean, as advised by the authors of the CSQ questionnaire. Data for 61 cases, $n(\text{model 1})=29$, $n(\text{model 2})=32$ are presented here. The overall median CSQ score for the domiciliary services was 32.00 (mean 30.55 range 25 – 32) and the Cronbach's alpha was 0.82, indicating that the CSQ-8 displayed high levels of internal reliability and measured the construct of patient satisfaction in a useful way. There was a significant difference in CSQ-8 scores between all three services at the end of trial (Kruskal-Wallis test, $\chi^2=25.2$, $df=2$, $p<0.001$, median CSQ (model 1)=31.36 (mean 30.19; range 25 – 32) median CSQ (model 2)=32.00 (mean =30.87; range 25.82 – 32) median CSQ (hospital service)= 28 .00 mean; 28.16 range 18 - 32). No significant differences in CSQ-8 scores were found when the two domiciliary services were compared (Mann Whitney U, $p=0.08$, two-tailed). However, there was a significant difference in satisfaction between the service model domiciliary groups compared to the hospital service model (Mann Whitney U, $p<0.001$, two-tailed; Figure 5.11).

Figure 5.11: Means and 95% confidence intervals for the CSQ score for the different anticoagulation services



5.6.12.1 Missing Values from CSQ – End of Trial Stage

There was no significant difference in the median CSQ scores that had the individual missing items replaced and those that did not have the individual missing items replaced (missing values for 57 cases ($n(\text{model } 1) = 27$, $n(\text{model } 2) = 30$; median = 32.00; mean = 30.39 versus values replaced for 61 cases ($n(\text{model } 1) = 29$, $n(\text{model } 2) = 32$; median = 32.00; mean = 30.55), Mann Whitney U, $p=0.827$, two-tailed).

5.6.12.2 Service specific items analysis – End of Trial Stage

This section outlines the results for the responses to the additional service specific items developed by the investigator and the anticoagulation team. The Cronbach's alpha for the three additional items was 0.124 for the 59 cases who had completed these items. Therefore, they could not be viewed as a scale measuring one dimension, so items were analysed separately.

A statistically significant difference was found between the responses of patients receiving model 1 and patients receiving model 2 for the item relating to blood sample method (Table 5.19) indicating that patients preferred the capillary method of sampling over the venous sampling method. There was no significant difference between the responses of the items related to staff and instructions. In addition there were no significant differences in these items, when the domiciliary service responses were compared with the BLT hospital service 'transport' patients

responses, both collectively (that is model 1 and model 2 together; Table 5.21) and individually (that is comparing model 1 responses to BLT responses and comparing model 2 responses to BLT responses).

Table 5.19: Mann Whitney U test for ranks of individual items in domiciliary trial

Mann-Whitney U Test: Comparison of model 1 and model 2 responses					
Variable	Which service are patients receiving	N	Mean Rank	U	Significance tailed (p)
blood sample from vein on arm/finger	model 1	26	25.50	308.000	0.005
	model 2	32	34.88		
satisfaction with staff taking blood	model 1	29	30.97	436.000	0.597
	model 2	31	30.06		
instructions about what to do between visits	model 1	29	30.95	4365000	0.730
	model 2	31	30.08		
Mann-Whitney U Test: comparison of all domiciliary and BLT transport patients responses					
Variable	Which service are patients receiving	N	Mean Rank	U	Significance tailed
blood sample from vein on arm/finger	Domiciliary	66	51.48	1259.00	0.117
	BLT transport	35	47.52		
satisfaction with staff taking blood	Domiciliary	68	54.57	1185500	0.119
	BLT transport	37	49.57		
instructions about what to do between visits	Domiciliary	67	54.08	1105.000	0.103
	BLT transport	36	47.81		
Mann-Whitney U Test: comparison of model 1 and BLT transport patients responses					
Variable	Which service are patients receiving	N	Mean Rank	U	Significance tailed
blood sample from vein on arm/finger	model 1	26	33.58	545.000	0.142
	BLT transport	35	39.52		
satisfaction with staff taking blood	model 1	29	40.19	618.000	0.183
	BLT transport	37	36.37		
instructions about what to do between visits	model 1	29	40.00	592.000	0.199
	BLT transport	36	35.60		
Mann-Whitney U Test: comparison between model 2 and BLT transport patients responses					
Variable	Which service are patients receiving	N	Mean Rank	U	Significance tailed
blood sample from vein on arm/finger	model 2	32	39.62	504.00	0.059
	BLT transport	35	33.50		
satisfaction with staff taking blood	model 2	31	38.43	567.500	0.262
	BLT transport	37	35.20		
instructions about what to do between visits	model 2	31	38.18	513.000	0.184
	BLT transport	36	33.71		

5.6.12.3 Additional items on Patient Satisfaction Questionnaire – End of Trial Stage

Item 12 a, b and c

Trial patients were asked to rank services in terms of preference, with the number three denoting the most preferable and the number one denoting the least preferable service. Unfortunately, a number of patients ranked more than one service equally, for the purpose of analysis all responses were included, as it was felt that the ranking of two services as equivalent was valid and provided an unbiased insight into patients' views regarding services. When the Friedman test was used, a significant difference was found between the responses of the 48 participants that had completed

all three items (Table 5.20). Further exploration using the Wilcoxon test established that all services differed significantly from each other (Table 5.21), model 2 was ranked the most favourable.

Table 5.20: Friedman test to compare responses for item 12.

	Mean Rank	Chi ²	Degrees of Freedom	P
Hospital service	1.20	61.248	2	<0.001
Model 1*	1.96			
Model 2	2.84			

*Domiciliary venous service

Domiciliary NPT service

Table 5.21: Wilcoxon test to compare responses for item 12.

Variable	Comparing which services	N	Mean Ranks Positive, Negative	Z	Significance (two-tailed)
Which service would you like to receive: most, less, least, ?	Hospital service	42	Negative: 18.67	-4.351	< 0.001
	model 1*		Positive: 17.39		
	Hospital service	42	Negative: 0.00	-5.826	< 0.001
	model 2#		Positive: 20.50		
	model 1*	45	Negative: 16.00	-4.867	< 0.001
	model 2#		Positive: 18.73		

*Domiciliary venous service

Domiciliary NPT service

The trial participants were split into service provision groups for the purpose of further analysis. No significant differences were found between the groups' responses to the items relating to the hospital and home NPT services, that is both groups A and B responded similarly to the items relating to the hospital and domiciliary NPT services. However, a significant difference was found between the groups' responses to the item related to the home venous service (Table 5.22). Of the 27 respondents who had been receiving the home venous service in the second service provision period, 44.4% (12) said they would like to use the service most, compared to 9.5% (2/21) of the patients who had been receiving the NPT service, suggesting that there may have been a degree of recall bias.

Table 5.22: Comparison of responses to items 12 a, b and c between groups A and B

Evaluated service model	Which model patients were receiving before evaluation	N	Mean Rank	U	Significance (two-tailed)
Hospital service	Home Venous (model 1; group B)	23	22.80	234.500	0.796
	Home NPT (model 2; group A)	21	22.17		
Home Venous service	Home Venous (model 1; group B)	27	29.20	156.500	0.003
	Home NPT (model 2; group A)	21	18.45		
Home NPT service	Home Venous (model 1; group B)	27	27.00	729.000	0.642
	Home NPT (model 2; group A)	27	28.00		

Item 13 a, b and c patient satisfaction with each service – visual analogue scale

Patients were asked to indicate their satisfaction with each service on a 100 mm visual analogue scale. The median score for the hospital service was 43.0 (mean 44.9 range 0 to 100), for model 1 it was 81.5 (mean 75.4, range 0 to 100) and for model 2 it was 97.0 (mean 90.1 range 15.0 to 100mm). There was a significant difference between the scores for the three services (Friedman test, $\chi^2=48.47$, $df = 2$ $p < 0.001$). Post-hoc analysis to identify where the significant difference occurred showed that there were significant differences between all the values (Table 5.23).

Table 5.23: Post-hoc analysis of responses for item 13 - patient satisfaction with each service

Compared services	N	Mean Ranks Positive, Negative	Z	Significance (two-tailed)
Hospital service	37	Negative: 10.63	-4.361	< 0.001
Venous service		Positive: 18.42		
Hospital service	38	Negative: 12.00	-4.963	< 0.001
NPT service		Positive: 18.18		
Venous service	44	Negative: 22.13	-3.574	< 0.001
NPT service		Positive: 16.88		

When the participants were divided into service provision groups according to which service they received as the second, i.e. immediately before the evaluation, no significant differences were found between responses to the three items (13 a, b and c; Table 5.24), indicating that both groups had similar opinions of the services. The results suggest that patients were least satisfied with the hospital based service and most satisfied with service model 2.

Table 5.24: Comparison of responses to items 13 a, b and c between the two service groups

Evaluated service model	Which model patients were receiving	N	Mean Rank	U	Significance (two-tailed)
Hospital service	Home Venous (model 1; group B)	21	19.26	173.500	0.883
	Home NPT (model 2; group A)	17	19.79		
Home Venous service	Home Venous (model 1; group B)	26	25.38	159.000	0.072
	Home NPT (model 2; group A)	18	18.33		
Home NPT service	Home Venous (model 1; group B)	26	24.56	284.500	0.975
	Home NPT (model 2; group A)	22	24.43		

5.6.12.4 Correlations and Multiple Linear Regressions – End of Trial Stage

Following assessment of variables including age, duration of treatment, all anticoagulation control and risk factor variables as well as additional questionnaire items for correlation with the CSQ-8 score, it was found that instructions about what to do between visits, method of blood sampling and satisfaction with service model 2 (VAS) were significantly correlated with CSQ-8 score.

Group B patients

Multiple linear regression using the stepwise method showed that the variables instructions about what to do between visits, method of blood sampling and satisfaction with service model 2 (VAS) accounted for 47.1% of the variance in patient satisfaction, using Kinnear and Gray (2004) classification; this is recognised as a large effect, with satisfaction with model 2 on the VAS being of greatest importance (Table 5.25).

Table 5.25: Coefficients for linear regression of additional items against CSQ score for Group B Model 1 patients – End of Trial

Model 1 patients	Unstandardized Coefficients		Standardized Coefficients	T	Sig.
	B	Std. Error	Beta		
(Constant)	17.713	5.326		3.326	0.003
VAS score for Model 2	0.487	0.218	0.438	2.227	0.037
How do you feel about the way your blood sample was taken	1.461	0.668	0.407	2.189	0.040
Instructions about what to do between visits	0.652	1.313	0.095	0.497	0.625

Group A patients

Multiple linear regression (stepwise method) showed that the two variables, way in which blood sample is taken and instructions about what to do between visits accounted for 74.0% of the variance in CSQ scores, representing a large effect, with mode of blood sampling being of greater importance than the instruction variable; see Table 5.26 for model coefficients. The results suggest that satisfaction with capillary sampling and perceived clarity of dosage advice and recommendations were the most important (measured) aspects of satisfaction in this group.

Table 5.26: Coefficients for linear regression of additional items against CSQ score for Group A model 2 patients – End of Trial

Model 2 patients	Unstandardized Coefficients		Standardized Coefficients	T	Sig.
	B	Std. Error	Beta		
(Constant)	9.050	4.008		2.258	0.036
how do you feel about the way your blood sample was taken	5.944	0.416	0.829	14.306	<0.001
instructions about what to do between visits	2.944	0.301	0.566	9.767	<0.001

5.6.12.5 Qualitative data from Patient Satisfaction Questionnaire – End of Trial Stage

As in the developmental phase and the crossover stage of the trial, the CSQ scores for patients were negatively skewed. When comparing the end of trial CSQ scores with the CSQ scores in the developmental phase there was a significant difference in favour of the domiciliary services, indicating that patients were more satisfied with the domiciliary service. The inclusion of a number of open ended items in the 'end of trial' satisfaction survey in addition to the structured additional items, explored patients' perceptions of the hospital service, service model 1 and service model 2 and helped explain the reasons for any preferences. This section describes the responses of trial participants to the open-ended items of the questionnaire.

Although the overall response rate to the questionnaire was reasonable, the qualitative sections of the survey were often not completed, therefore there was not a substantial amount of data to analyse; due to the small number of responses computer software to support qualitative analysis was not used.

In items 14 and 15; patients were asked, 'what did you like least / most about each service?'

Hospital Service

With regards to the hospital service, issues regarding waiting and the transport service were reported. The transport service was regarded as unreliable and the process of getting to and from the clinic was too time-consuming and inconvenient. There were no negative comments with regards the actual service provided by the hospital anticoagulation practitioners, indicating that the issues with regards to the hospital service were solely associated with transport problems, suggesting that access and convenience were an issue. This is reflected in one patient's comments:

"It wasn't the service at the hospital that was unsatisfactory but the journey by hospital transport and the inevitable wait for the hospital transport to collect me. The journey is too stressful, both physically and emotionally for elderly people especially in our now totally unpredictable weather, both summer and winter." (Patient ID no 54; model 1)

Patients enjoyed the opportunity the hospital service gave them to interact with others (social aspect of the service). When asked, "Please write one thing you liked most about each service – Hospital service", patients said:

"Meeting my friend on the ambulance" (Patient id no 47 model 1)
"Meeting friends" (Patient id no 52 model 1)

Some patients were satisfied with the hospital service, whilst others indicated that they liked nothing about the hospital service.

Question: Please write one thing you liked **most** about each service - *Hospital service*

"Good" (Patient id no 22 model 1):
"Mostly satisfactory" (Patient id no 2 model 2)
"Nothing" (Patient id no 3 model 1)
"I didn't !" (Patient id no 54 model 1)

Model 1 Home venous sampling service

The majority of comments regarding model 1 were positive:

Question: Please write one thing you liked **least** about each service – *Model 1*

"Nothing I disliked" (Patient id no 3 model 1)
"I cannot fault this service" (Patient id no 24 model 1)

Question: Please write one thing you liked most about each service – Model 1

"Done in comfort in my own home" (Patient id no 62 model 1)

Unlike the crossover stage, the mode of blood sampling in model 1 was the focus of comments of dissatisfaction with the service. Interestingly negative comments of this type were made solely by those patients receiving model 2 (Home pharmacist/ NPT), suggesting recall bias and a temporal affect due to timing of questionnaire administration in relation to service receipt:

Question: Please write one thing you liked least about each service – Model 1

"Too much messing about" (Patient id no 35 model 2)

"I hated blood taken from vein with a needle" (Patient id no 43 model 2)

"I got a lot of bruises because they had a job finding the veins" (Patient id no 61 model 2)

Model 2 Home NPT service

Patients receiving model 2 were largely satisfied, expressing positive feelings with regard to the service being provided at home, not having to wait for transport to take them to and from the clinic, the one-to-one contact of the service, the mode of blood sampling and receiving the results in their homes:

Question: Please write one thing you liked least about each service – Model 2

"Nothing I disliked" (Patient id no 3 model 1)

Question: Please write one thing you liked most about each service – Model 2

"I was in my own home and didn't have to wait for a result." (Patient id no 63 model 2)

"Most convenient no waiting for transport" (Patient ID no 14 model 2)

"Very very good no pain no waiting in hospital one and a half hours for transport to go home" (Patient id no 15 model 2)

"Results instantly" (Patient id no 26 model 1)

"One to one contact and no travelling" (Patient ID no 6 model 2)

"Very excellent service, quick, efficient, convenient, with excellent staff. A service which has greatly improved our lifestyle." (Patient id no 79 model 2)

Patients' supporting comments regarding their marking of the rating of each service on a VAS (item number 13) and their service preferences (item no 12), were similar to their responses on their likes and dislikes, with patients stating that they preferred the domiciliary services over the hospital services, and some going further to say they preferred the home NPT service over the home venous service.

"I am 80 years old with bad arthritis and partially blind and deaf so the home service is best for me." (Patient ID no 37 model 1)

"Staff excellent in all services but home service was 100% superior as the service was quick, efficient and excellent." (Patient id no 79 model 2)

"Prefer blood taken from finger- much quicker for me. I have small veins." (Patient ID no 3 model 1)

"Can't find any reason to not having blood from finger excellent." (Patient id no 15 model 2)

"I am very very pleased that I no longer have to go to hospital for my blood test and I love having the sample taken from my finger thanks a lot" (Patient ID no 20 model 1)

In addition to improving the quality of the service for the patients, the service appeared to have a positive impact on the relatives and carers of trial participants, as illustrated by this comment from a trial participant's daughter:

"My parents are elderly and my father has to be checked on a regular basis. Going to hospital caused them many problems:

1. Travelling to and from hospital, in different weather etc.
2. waiting, discomfort, inconvenient
3. stress for both my parents
4. being at the hospital for the whole day for something that can be done in minutes
5. preparing my father and his wheelchair etc.

The home service has made life much easier and simpler for both of them, and improved their lifestyle. The home-based warfarin monitoring service has made a large difference to my parents and myself and we would like to thank everyone involved in this service and hope it continues for many years to come." (Patient id no 79 model 2: From daughter of patient)

Patients were extremely satisfied with the home services, wanting them to continue after the trial. They preferred having the service provided at home over the hospital service; they were pleased they no longer had long waits for the ambulance service to take them to and from the clinic, feeling that because they were mobility-impaired the domiciliary services were much more appropriate for them. Data suggests that the domiciliary services improved patient access to the service and convenience of the service when compared to the traditional hospital model. Patients were also satisfied with the staff providing the service feeling that they had been adequately trained to perform the service. Table 5.27 outlines the themes that emerged from the qualitative data along with example quotes.

Table 5.27: Display of examples of quotes from Themes emerging in the End of Trial satisfaction survey

Theme	Sub themes	Patient details	Quote
Home Environment (Increased convenience)	Expression of satisfaction with service being provided at home	Patient id: 4, service received: NPT, female, aged 68.7 years, receiving treatment for 8.0 months for AF Patient id: 31, service received: NPT, male, aged 31.2 years, receiving treatment for 7.4 years for AF	I am very grateful that I can have this done at home. I am often unable to go out due to my illness so home visits are ideal. Also in cold or wet weather I am not able to go out either.
	Expression of preference of having service provided in home over service in the clinic	Patient id: 75, service received: venous, female, aged 93.6 years, receiving treatment for 4.7 years for AF Patient id: 21, service received: NPT, female, aged 78.0 years, receiving treatment for 5.9 years for AF	Home visit easier for me than going to clinic In the past I used to suffer quite a lot because my veins are too thin but nowadays I have less problems and I am very happy that they that come to my home; saves the waiting trips by ambulance to the hospital I would recommend this service to everyone I know who needs it!! Excellent work Team!! Many thanks congratulations!!
Theme Two Positive feelings regarding the service	Satisfaction with service	Patient id: 3, service received: NPT, female, aged 89.9 years, receiving treatment for 3.6 years for AF Patient id: 9, service received: venous, male, aged 74.8 years, receiving treatment for 2.8 years for AF	The home service provided is excellent. It saves me from starting my day waiting for an ambulance to arrive in the past, I have often missed my lunch due to the wait for my lift home, as I am diabetic and 90 years old this new service is excellent and the staff are excellent too. Please keep up this excellent service. I am also wheelchair bound and this service has been a great benefit in keeping not stressed. No way can I fault this service: I am an emphysemic as time has gone by my breathing has become a problem, so this service has helped me. Like a lot more things people's needs are under-funded.
	Expression of desire for service to continue	Patient id: 54, service received: NPT, female, aged 86.5 years, receiving treatment for 1.5 years for recurrent PE Patient id: 74, service received: NPT, male, aged 69.7 years, receiving treatment for 4.0 years for femoral aneurysm	I am delighted with the home visiting service and pray that it will continue indefinitely. Previously attendance at the clinic caused me a great deal of stress and anxiety and to be free of the visits in cold wet weather was an added bonus. The phlebotomist was not only skilled, but friendly and kind and I looked forward to her visits. Please continue this service. It is a godsend to elderly, disabled homebound patients such as myself. I think the service was excellent and the staff worth every penny and I look forward to having the service for as long as possible because it suits my needs down to the letter.
	Express that service is good for them as they are mobility-impaired	Patient id: 15, service received: venous, female, aged 67.7 years, receiving treatment for 3.3 years for bilateral DVT	It helps me a lot having it done at home because I am in a wheelchair and it's so quick and no waiting for ambulance which sometimes can be a very long wait before you get home.

Table 5.27: Display of examples of quotes from Themes emerging in the End of Trial satisfaction survey
- Continued

Theme	Sub themes	Patient details	Quote
Theme Three Positive feelings regarding staff	Feel that staff are adequately trained	Patient id: 54, service received: NPT, female, aged 86.5 years, receiving treatment for 1.5 years for recurrent PE	I am delighted with the home visiting service and pray that it will continue indefinitely. Previously attendance at the clinic caused me a great deal of stress and anxiety and to be free of the visits in cold wet weather was an added bonus. The pharmacist was not only skilled, but friendly and kind and I looked forward to her visits. Please continue this service. It is a godsend to elderly, disabled homebound patients such as myself.
	Expression of satisfaction with staff providing home service	Patient id: 3, service received: NPT, female, aged 89.9 years, receiving treatment for 3.6 years for AF	The home service provided is excellent. It saves me from starting my day waiting for an ambulance to arrive in the past, I have often missed my lunch due to the wait for my lift home, as I am diabetic and 90 years old this new service is excellent and the staff are excellent too. Please keep up this excellent service. I am also wheelchair bound and this service has been a great benefit in keeping not stressed.
Theme four No waiting for transport (Increased convenience)	Happy that waiting times have been eliminated	Patient id: 21, service received: NPT, female, aged 78.0 years, receiving treatment for 5.9 years for AF	In the past I used to suffer quite a lot because my veins are too thin but nowadays I have less problems and I am very happy that they that come to my home; saves the waiting trips by ambulance to the hospital I would recommend this service to everyone I know who needs it!! Excellent work Team!! Many thanks congratulations!!
		Patient id: 15, service received: venous, female, aged 67.7 years, receiving treatment for 3.3 years for bilateral DVT	It helps me a lot having it done at home because I am in a wheelchair and it's so quick and no waiting for ambulance which sometimes can be a very long wait before you get home.

5.6.13 Anticoagulation control – End of Trial Stage

One patient was excluded from data analysis as the patient's target INR range was altered by the haematologist three times during the trial period. Data are presented for the remaining 62 patients. Baseline data are for 60 patients; two patients participating at the end of the trial were new (receiving treatment for less than three months) at the time of commencement of the trial and, therefore, baseline data were not available for them.

5.6.13.1.1 Time in range and Proportion of tests in range – End of Trial Stage

At baseline, the 60 patients that completed the trial had a mean time-in-range of 65.6% (median 64.8%, range 22.5%- 100.0%; Kolmogorov-Smirnov; $Z = 0.726$, $p = 0.667$) over the year prior to commencement of the trial. During the second 5-month period of the trial, model 1 (group B) patients were in range 67.1% (Kolmogorov-Smirnov; $Z = 0.664$, $n = 30$, $p = 0.771$) of the time, compared to model 2 patients (group A), who were in range 67.5% of the time (Kolmogorov-Smirnov; $Z = 0.581$, $n = 33$, $p = 0.888$). There was no significant difference between the TIR for both models (t-test; $t = 0.490$; $p = 0.890$) and there was no significant difference in the mean TIRs of the domiciliary services (TIR = 67.28% overall for the domiciliary services) and the TIR for the

year prior to commencement (paired t-test; $t=0.565$, $p=0.574$). Comparing all three models individually using ANOVA ($F=0.281$, $p=0.756$), again no significant difference was identified. Similar to the time in range results, when the proportion of tests in range was calculated for this time period, no difference was found between the domiciliary models and baseline data (baseline=62.9; model 1=64.8; model 2 = 65.4; ANOVA [$F= 0.346$, $p = 0.683$]).

5.6.14 Summary of quantitative results from trial period

5.6.14.1 Introduction

This section outlines anticoagulation control and patient safety related to the number of adverse events throughout the trial period, making comparisons between the domiciliary services and between the domiciliary services and the traditional hospital service. In addition, comparisons are made between the number of dose changes and appointments in the various service models. The main findings for the entire trial period are summarised in Table 5.28 and explained below. The section also describes the findings from the time series analysis of the INR variable in the hospital service (baseline) and the two domiciliary services.

Table 5.28: Summary of End of Trial results related to anticoagulation control

	Frequency				Comparing trial year with hospital service P value
	model 1	model 2	Trial year	Baseline year	
TIR	66.1%	66.8	67.0	65.6	model 1 versus model 2 Paired sample t test $t = 0.163$, $p=0.876$ Repeated measures analysis (including baseline): One factor within subjects ANOVA $F=0.050$, $p=0.952$
Time spent in extended range***	83.3% (SD= 16.49)	83.0% (SD=16.21)	83.7%	81.5% (SD= 14.85)	Model 1 versus model 2 Paired sample t test $t = 0.140$, $p=0.889$ Domiciliary versus hospital REPEATED MEASURES ANALYSIS one factor within subjects ANOVA $F= 0.840$, $p=0.434$
Time spent below extended range***	6.5% (SD = 9.25)	8.0% (SD=11.91)	N/A	5.3 % (SD= 6.46)	Model 1 versus model 2 Wilcoxon signed ranks $Z= -0.875$, $p= 0.381$ Domiciliary versus hospital Friedman test , $\chi^2 =1.298$, $df=2$, $p=0.523$
Time spent above extended range***	10.2% (SD =14.03)	9.0% (SD=12.27)	N/A	13.2% (SD= 12.69)	Model 1 versus model 2 Wilcoxon signed ranks $Z= -0.461$, $p= 0.645$ Domiciliary versus hospital Friedman test , $\chi^2 =6.266$, $df=2$, $p=0.056$
Proportion of tests in range	60.5%	62.7%	59.8%	59.9%	model 1 versus model 2 Paired sample t-test -0.758 , $p= 0.451$ Comparison of models and baseline Repeated measures analysis: One factor within subjects ANOVA $F 0.402$, $p=0.670$
Proportion of tests in extended range	77%	76.9%	N/A	75.0%	Model 1 versus model 2 Paired sample t test $t = 0.213$, $p=0.678$ Domiciliary versus hospital REPEATED MEASURES ANALYSIS one factor within subjects ANOVA $F= 0.690$, $p=0.313$
Proportion of tests below extended range***	11.8 (SD=13.18)	12.1 (SD= 14.29)	N/A	9.8 (SD = 10)	Model1 versus model 2 Wilcoxon signed ranks $Z= -0.276$, $p= 0.783$ Comparison of models and baseline Friedman test , $\chi^2 =1.819$, $df=2$, $p=0.403$
Proportion of tests above extended range***	11.2 (SD=13.44)	11.0 (SD=11.39)	N/A	15.2 (SD= 12.46)	Wilcoxon signed ranks $Z= -0.047$, $p= 0.963$ Comparison of models and baseline Friedman test , $\chi^2 =9.643$, $df=2$, $p=0.008$
INR > 4.5*	10	10	20	18	Trial year versus baseline Wilcoxon $Z= -0.404$, $p = 0.686$
INR > 6.0**	1	2	3	1	Trial year versus baseline Wilcoxon $Z= -0.816$, $p = 0.414$
INR <1.5	15	20	35	32	Trial year versus baseline Wilcoxon $Z= -0.031$, $p = 0.9751$
Mean number of dose changes	5.88 for whole trial period 2.94 for five month period	5.90 for whole trial period 3.06 for five month period	5.72	4.59	model 1 versus model 2 Paired t -test -0.279 , $p= 0.781$ trial year versus baseline year: Paired sample t-test 1.597 , $p= 0.116$
Mean number of appointments	15.46	16.00	15.67	14.73	model 1 versus model 2 Paired sample t test $t = -0.940$, $df = 62$, $p=0.351$ Trial year versus baseline year paired sample t test $t = 0.720$ $df =59$, $p=0.474$

* patients with target therapeutic ranges of 3-4 and patients that had been newly initiated on warfarin at the start of the trial were excluded from analysis

** patients that had been newly initiated on warfarin at the start of the trial were excluded from analysis

*** extended range = 1.75-3.25 or 2.75-4.25

Note: Wilcoxon and Friedman tests used for non-parametric data

5.6.14.2 Time in range and Proportion of tests in range for entire trial period

Results are summarised in Table 5.28. During the entire trial period patients' time in range was 67.0%. When model 1 (66.1%), model 2 (66.8%) and baseline TIR (65.6%) were compared, no significant difference was found. When the extended range of within 0.75 units of the target INR was used (proportion of tests in range), model 1 patients achieved 77.0% and model 2 patients achieved 76.9%. The extended range was more relevant to the clinical situation, as minor departures from the range that would not result in a dose change or put patients at increased risk of adverse events were accounted for. When comparing models 1 and 2, there was no significant difference between the percentage of time spent in range (actual and extended range). Baseline time in extended range was 81.5%; there was no significant difference between this value and that of the domiciliary models (model 1, 83.3%; model 2, 83.0%). Using the proportion of tests in range as a measure, no difference was found between the domiciliary models and baseline data (actual and extended ranges; Table 5.28).

5.6.14.3 Adverse events

Data on adverse events were accessed for both patients who reached the end of the trial as well as those patients who did not complete the trial as some of the patients were removed from the trial due to adverse events. The following section outlines the incidence and annualised serious adverse event rate. The entire trial represented 77.3 patient years of data; 37.9 years for model 1 and 39.4 years for model 2.

Baseline year

Three trial patients who reached the end of the trial experienced minor bleeds during the year prior to the trial. There were two major haemorrhagic events in the baseline year. One patient who was removed from the trial following departure from the BLT service provision area, experienced a major bleed in the year prior to the trial. The patient experienced melaena and was hospitalised and received vitamin K whilst in hospital, the patient's INR on this occasion could not be located in the relevant notes. The second patient experienced a GI bleed with an INR of 10.0. No trial patients experienced any thrombotic events during the year prior to the trial. The annualised serious adverse event rate during the baseline year was 2.13 events per 100 years (baseline data for original 104 trial participants represented 94 years of data)

Model 1

One patient experienced a minor bleed (epistaxis) on two occasions whilst receiving model 1 in the first trial period, in both instances the patient's INRs were in therapeutic range. In the second trial period this patient was taken off warfarin and removed from the trial due to a high number of falls. This patient was not included in any further analysis. One patient experienced a major bleed associated with a gastrointestinal ulcer and an INR >10 whilst receiving service model 1. This incident required hospitalisation. This patient was taken off warfarin and removed from the trial, and was not included in any further analysis. One patient experienced a major bleed from a previously split lip whilst receiving model 1 in the second trial period, the patient's INR was 9.1. The patient was treated with vitamin K and warfarin was withheld for four days. Following review of the case by the consultant haematologist, the patient resumed warfarin. No thrombotic events occurred during model 1. The annualised serious haemorrhagic event rate was 2.59 events per 100 years.

Model 2

One trial patient with an INR of 5.8 experienced a minor bleed (haematuria) that did not require hospitalisation or treatment whilst receiving model 2 service. This patient had a risk factor for experiencing complications (previous gastrointestinal bleed). On discussion with the consultant haematologist the patient's warfarin dose was reduced, the patient was maintained on warfarin and stayed in the trial. One patient experienced post-thrombotic syndrome (classified as a major adverse event) in the fifth week of the trial after receiving 11 weeks of warfarin treatment for DVT. This patient was put on a parenteral anticoagulant and taken off the trial. The annualised thrombotic event rate was 1.29 events per 100 years.

Out-of-range INRs

Data on out of range patients is presented for the 63 patients who reached the end of the trial.

INRs under 1.5

In the year preceding the trial, 18 (28.6%) of the trial participants had 32 INRs under 1.5, five of these patients had risk factors for complications with warfarin therapy. During the trial, there were 35 cases of INRs under 1.5 occurring in 24 (40%) patients. Fifteen cases occurred in model 1 and 20 cases occurred in model 2. Of the 24 patients, nine had risk factors for warfarin therapy complications. There was no significant difference in the number of INRs under 1.5 during the trial and in the year prior to the trial (Table 5.28).

INRs over 4.5

Two patients' with a target INR range between 3 and 4, were excluded from this analysis. In the year preceding the trial, there were 18 INRs over 4.5 in 14 patients. Of the 14 patients experiencing INRs over 4.5 during the year prior to the trial, seven had 12 risk factors for complications. One patient was initiated on warfarin therapy during the trial, therefore the initial INRs were unstable; this patient was removed from the analysis. During the trial there were 20 cases of INRs over 4.5 during the trial period for all patients who reached the end of the trial (involved 14 patients, 23.3%). Ten cases occurred in the model 1 service and 10 in the model 2 service. There was no significant difference in these values (Table 5.28). Of the 14 patients experiencing INRs over 4.5 during the trial period, eight had 12 risk factors for complications. The data suggest that the presence of risk factors played a role in the occurrence of INRs over 4.5.

INRs over 6.0

In the year preceding the trial, there was one case of an INR over 6.0 in a trial participant, this patient had two risk factors for complications with warfarin. During the trial there were three cases of INRs over 6.0. Two cases occurred in model 1 and one case occurred in model 2. The patient who experienced an INR over 6.0 in the model 2 service had a target INR range of 3.0 - 4.0. None of these patients had risk factors for complications.

5.6.14.4 Dose Changes

During the trial period, there were a total of 173 dose changes made during service model 1 and 190 dose changes made during service model 2. The mean number of dose changes per patient throughout the trial period was 5.88 (range 0 to 10) for model 1 and 5.90 (range 0 to 15) for model 2. There was no significant difference between these values (Table 5.28). There was no significant difference in the number of dose changes throughout the entire trial period and the baseline year (Table 5.28).

5.6.14.5 Number of appointments

There were a total of 987 domiciliary appointments (model 1 = 479, model 2 = 508). There was no difference in the mean number of appointments per patient between model 1 and model 2 [7.60 (range 3 to 16) versus 8.06 (range 3 to 21); Table 5.28.] Converting this data to appointment intervals, the mean number of days between appointments was 20.0 for model 1 patients and 18.9 days for model 2 patients. In addition, there was no significant difference between the number of domiciliary appointments made in the entire trial year and the number of appointments patients had

when they were attending the hospital anticoagulation clinic, in the year preceding the trial (Trial year 987, Baseline 928; Table 5.28). In the baseline year patients were seen on average every 24.8 days.

5.6.14.6 Time Series Analysis

The purpose of this experiment was to quantify the effect of the domiciliary anticoagulation services on the INR variable. Preliminary Autocorrelation Function (ACF) and Partial Autocorrelation Function (PACF) plots showed that the series for both groups did not attenuate rapidly (due to changes in the mean INR), indicating that the series was not stationary. Therefore, non-seasonal differencing was performed to remove a linear trend, and lagging shock effects by 1. Subsequent ACFs showed a spike at lag 1 and the PACFs died out rapidly from lag 1 (Figures 5.12 - 5.15). This suggested an MA (1) process, as the series had been differenced once, the ARIMA (0,1,1) model offered the best solution for the INR time series data for both groups. Identifying the correct model was necessary to ensure that the analysis yielded accurate results.

Figure 5.12: Autocorrelation Function Plot of Mean INR- Group B

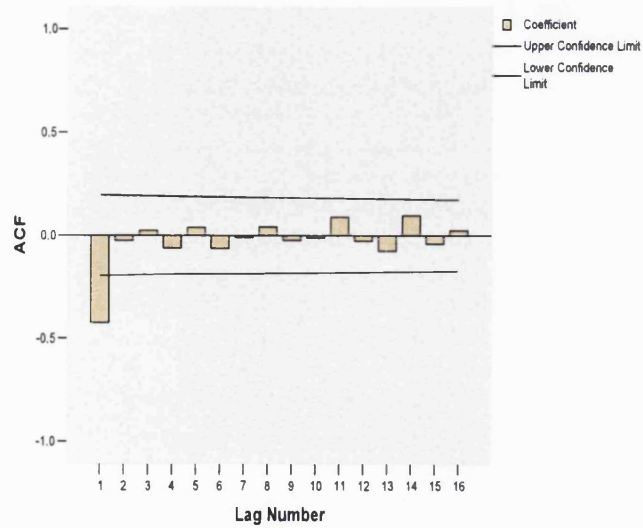


Figure 5.13: Partial Autocorrelation Function Plot of Mean INR- Group B

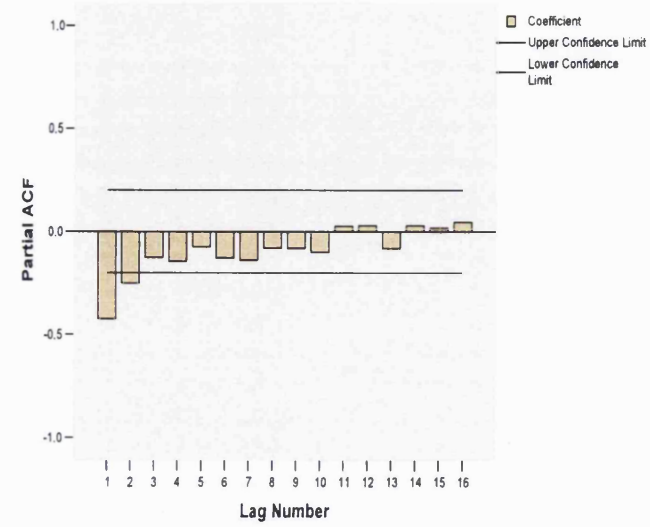


Figure 5.14: Autocorrelation Function Plot of Mean INR- Group A

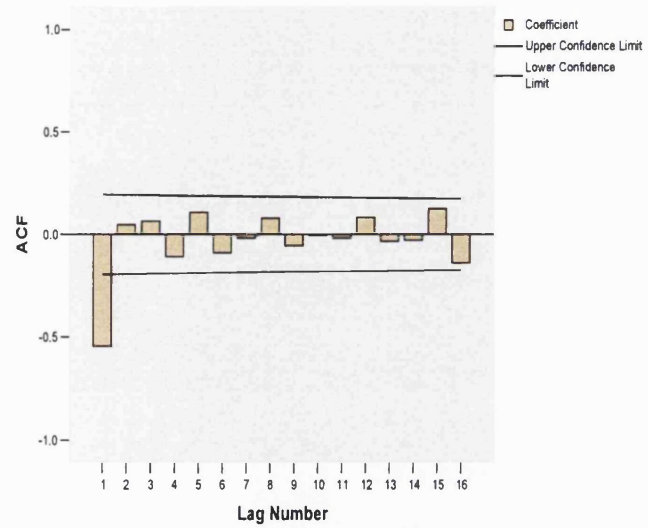
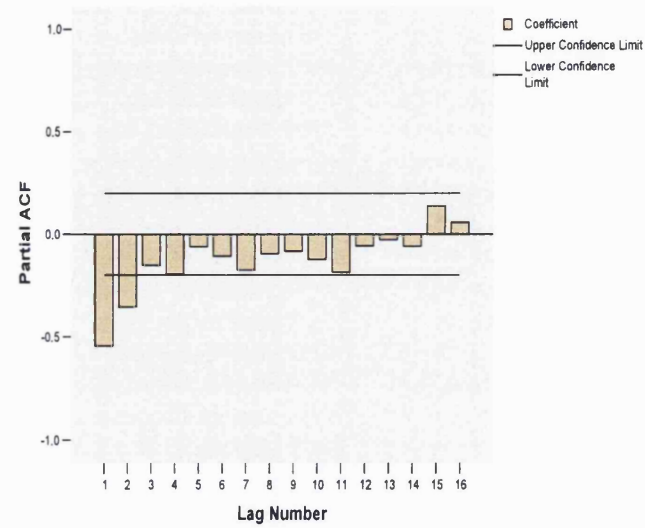


Figure 5.15: Partial Autocorrelation Function Plot of Mean INR- Group A



According to the service model analysis calculations, the mean INR for group B (home NPT service first) dropped by 0.256 of an INR unit as a result of the introduction of the service model (model 2), this represented a significant difference in the mean INR value (Table 5.29). From the time series plots it was evident that group B patients experienced fewer INRs over 3.0 during the trial period compared to the hospital service model period (Figure 5.16). The time series plots also suggest that group B patients were more likely to experience lower INRs during the trial compared to when they received the hospital service (Figure 5.16).

The mean INR for group A (home venous sampling service first) dropped by 0.107 of an INR unit as a result of the service model (model 1), this was not a significant drop in INR value (Table 5.29). Exploration of the time sequence plot for group A suggested that patients in this group were less likely to experience INRs over 3.0 during the trial than during the hospital service (Figure 5.17).

Table 5.29: ARIMA regression coefficients for changes in mean INR due to service models first study period

		Estimates		Std Error		T		Approx Sig	
		Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
Non-seasonal lags	MA1	1.000	0.944	4.305	0.043	0.232	21.892	0.817	< 0.001
Regression Coefficients	Dummy variable 1	-0.107	-0.256	0.065	0.113	-1.656	-2.269	0.101	0.025

Figure 5.16: Time series Plot of Group B patients' INRs pre-intervention and post intervention

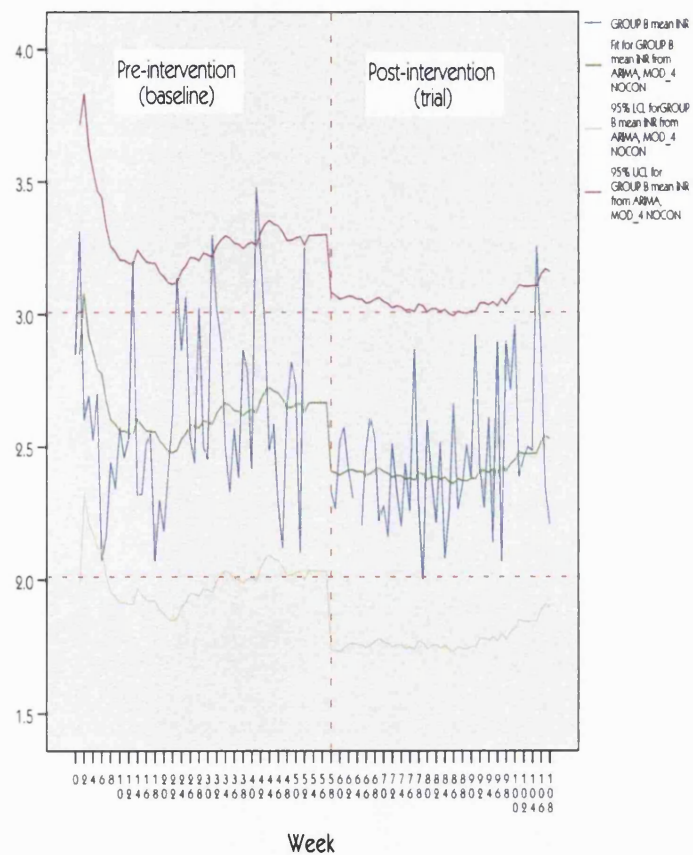
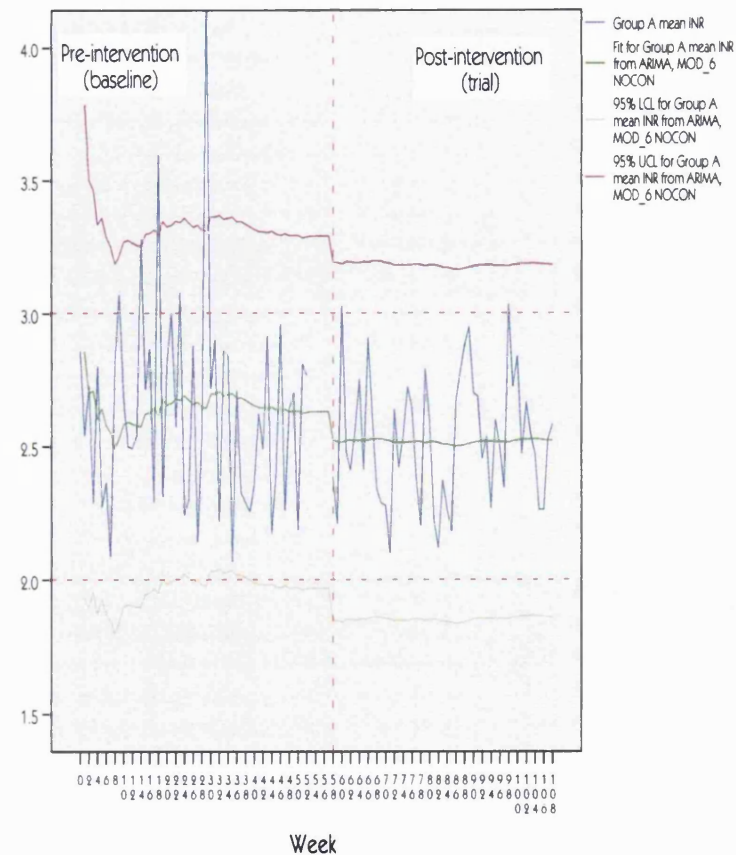


Figure 5.17: Time series Plot of Group A patients' INRs pre-intervention and post intervention



Changes to INR at crossover stage

Group B (Figure 5.18)

According to the service model analysis calculations during the trial, the mean INR for group B (home NPT service first; model 2) increased by 0.108 of an INR unit after patients began receiving model 1. This was not a significant difference (Table 5.30). The time sequence plot with 95% confidence intervals suggests that model 2 maintained a tighter control of patients' INRs within the therapeutic range.

Group A (Figure 5.19)

The mean INR for group A (home venous sampling service first; model 1) dropped by 0.266 of an INR unit after patients began receiving model 2, this was not a significant change (Table 5.30). Although this represented a relatively large change in INR, the mean INR rose after a few weeks to levels that were higher than in the previous service period, which may explain why the difference was not significant. Group A patients were less likely to have subtherapeutic INRs, but more likely to have INRs over 3.0 when receiving the model 2 service in the second service period. From the time series plots group A patients' INRs appear to have fluctuated to a greater extent than group B patients' INRs, this may be as more patients in this group had risk factors for complications (group A = 8 versus group B = 6). In addition, group A had two patients with variable alcohol drinking patterns, whilst group B had no such patients. Misuse of alcohol is known to be one of the biggest risk factors for complications with anticoagulation therapy as alcohol interacts with warfarin and periodic binges are known to result in fluctuating INRs (British Heart Foundation 2006), necessitating frequent changes in dose. Maintaining these patients' INRs in range was a constant struggle; one of these patients had 14 dose changes over the course of the trial, whilst the other had 13; this is compared to the average number of dose changes during the trial year of 5.72. This may go some way to explaining the erratic time series plots for group A.

Table 5.30:ARIMA regression coefficients for changes in mean INR due to service models: second study period

		Estimates		Std Error		T		Approx Sig	
		Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
Non-seasonal lags	MA1	0.967	0.665	0.073	0.106	13.175	6.276	< 0.001	< 0.001
Regression Coefficients	Dummy variable 2	0.108	-0.266	0.082	0.188	1.319	-1.412	0.193	0.164

Figure 5.18: Time series Plot of Group B patients' INRs during trial

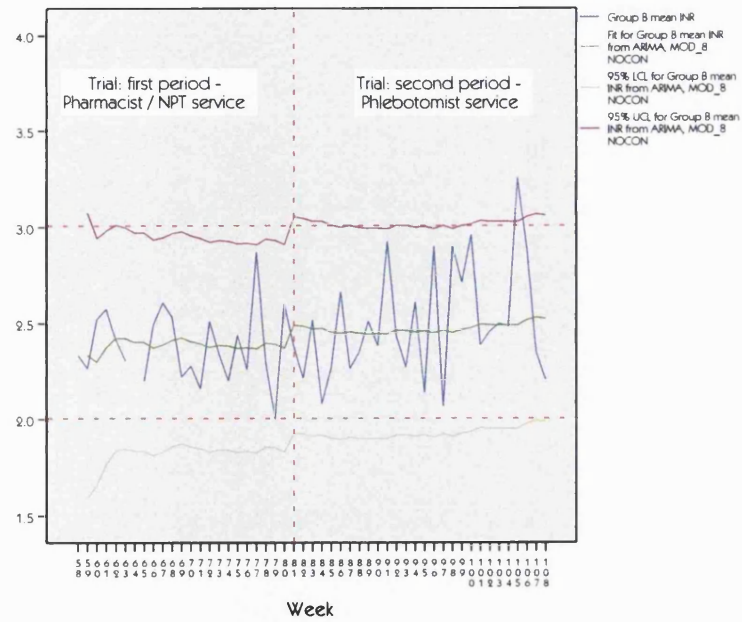
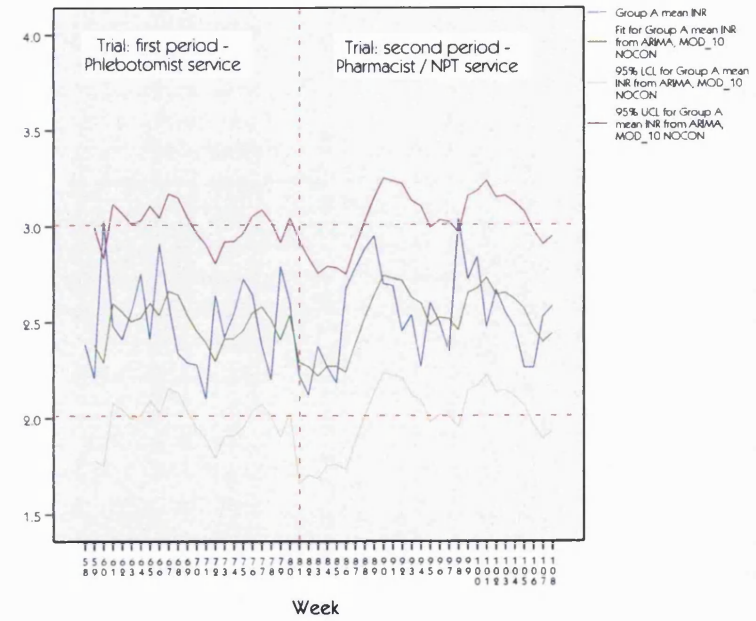


Figure 5.19: Time series Plot of Group A patients' INRs during trial



5.6.15 Interventions made during the trial

5.6.15.1 Introduction

This section outlines some of the interventions made by the phlebotomist and the pharmacist during the course of the study along with reviews of the interventions made by the senior pharmacist anticoagulation practitioner of the BLT anticoagulation team.

5.6.15.2 Phlebotomist interventions

At the end of the study the phlebotomist reported one intervention made during the provision of model 1. A patient had appeared unwell, the phlebotomist had called the patient's GP and arranged for the GP to visit the patient. The patient's GP prescribed asthma inhalers for breathlessness. The senior anticoagulation pharmacist felt that the phlebotomist's intervention was significant and that appropriate action had been taken under the circumstances. The senior pharmacist further commented that the phlebotomist who was also the chief administrator had an advantage over other phlebotomists in that she knew the anticoagulation patients well as she had worked for the clinic for 12 years, the senior pharmacist was unsure whether a phlebotomist not accustomed to the anticoagulation patients would have responded in the same way, the senior pharmacist stated that training and an operational policy for the service would be needed if an alternative phlebotomist continued to conduct visits.

5.6.15.3 Pharmacist interventions

The pharmacist did not record short verbal medication counselling as interventions. Throughout the course of the trial the pharmacist identified two cases where medication had been prescribed inappropriately; one case involved duplication of medication for dyspepsia and the other co-administration of warfarin with high dose aspirin (300 mg). In addition, there was one case of incorrectly dispensed medication a patient should have received Amitriptyline 25mg, a tricyclic antidepressant but was issued Amoxicillin 250mg, an antibiotic instead. The pharmacist was in a rare position of being able to determine what the barriers to patients getting the most out of their anticoagulation treatment were. These barriers included:

- I. Compliance issues, as a result of forgetfulness and / or confusion
- II. Lack of support in taking medicines, such as someone to deliver them or remind them to take their medicines
- III. Lack of understanding of the importance of taking warfarin at the same time of day
- IV. Unwillingness and / or inability to change lifestyle factors such as alcohol intake

- V. Manual dexterity problems, affecting the handling of tablets in bottles with child resistant caps, tablets in blister strips and tablets dispensed in dosette boxes.

Four of the interventions made by the pharmacist during the trial are detailed below.

Patient with sight problems - 15.12.03

The pharmacist had visited the patient's home to provide the anticoagulation service. When the NPT device was used to determine the patient's INR, the reading was 4.6, whilst the desired therapeutic range was 2-3. In addition, the patient's previous INR reading had been slightly over range, at 3.4 and the pharmacist had reduced the patient's warfarin dose as a consequence. It had previously been noted (when the patient was attending the anticoagulation clinic at BLT) that the patient had poor eyesight and for this reason doses were always recorded in the patient's anticoagulation record book in large print using black felt tip pens. During the visit, the pharmacist asked questions to explore reasons why the patient's INR was high. As part of the questioning the patient was asked to explain how he took his medicines. The patient showed the pharmacist a container that contained all the patient's tablets; that is, all strengths of warfarin, diuretics and blood pressure tablets were all mixed together in one container. On further questioning, the patient assured the pharmacist that he knew which tablets were which. The container contained brown (1mg), blue (3mg) and pink (5mg) warfarin tablets, the pharmacist asked the patient to name the colour of the tablets and the corresponding strengths, at this point it became apparent that the patient was unable to differentiate between pink and brown tablets and may have been taking pink tablets (5mg) at times when he was required to take brown tablets (1mg), resulting in the patient being over-anticoagulated and at risk of haemorrhage. The patient was instructed to miss one day's dose of warfarin.

The pharmacist spoke to the anticoagulation team and the patient's community pharmacist regarding the suitability and the feasibility of dispensing the patient's medication in a dosette box. The community pharmacist was willing to make up a dosette box on a weekly basis if he received a weekly prescription regarding the patient's dosage.

The pharmacist returned to the patient and explained the concept of a dosette box to the patient and asked him how he would feel about using a dosette box, the patient admitted that he had been struggling and that a dosette box might assist him in taking his medication.

After further discussions with both the GP and the anticoagulation team it was agreed that the community pharmacist would assume that the patient's weekly warfarin requirements were the

same unless notified via fax and a telephone call from the pharmacist (investigator). Every week the community pharmacist would fax the patient's GP, with the last fax received from the pharmacist (investigator). Based on this fax the GP would write a prescription for the dosage to last for the period of a week. This prescription would be sent to the community pharmacist who would make a dosette box based on the prescription. This dosette box would then be delivered to the patient's home on the same day each week.

The dosette box was delivered for the first time on the subsequent day (day after missed dose; containing all the patient's medication). Following the arrangement of delivered dosette boxes, the patient's INR stabilized within two weeks. In addition, through communicating with the GP, the patient was referred to Moorfield's eye hospital and was also subsequently provided with home help.

The senior pharmacist practitioner reviewed the intervention as a significant one, potentially averting a haemorrhage. The pharmacist was able to identify the issue and deal with it in the immediate and long term; liaise with the community pharmacist, GP, the anticoagulation team and explain and agree arrangements with the patient. An anticoagulation practitioner would be expected to do this in the hospital setting, however such an issue might not be picked up in the hospital or by a nurse or phlebotomist in the patient's home. The pharmacist did not focus solely on anticoagulation management but dealt with the whole pharmaceutical issue.

Patient unusually ill 28.04.04

During one visit, a patient with a therapeutic INR range of 2-3 had an INR of 4.7. In addition the pharmacist noted that the patient, who was known to have a cheerful disposition, seemed extremely low in mood. On questioning about general well-being the patient complained of nausea, chest pain and a thumping headache. The pharmacist informed the patient that she wanted to telephone the ambulance service so that the patient could be seen by doctors, at this, the patient appeared distressed and said she definitely did not want to go into hospital. The pharmacist inquired as to whether she would be happy to see her GP, the patient said that if the GP was prepared to visit her at home that would be fine. The pharmacist called the GP and explained the symptoms. Approximately 45 minutes later the GP arrived and after examining the patient, agreed that the patient needed to go into hospital. After some initial reluctance the patient was taken to hospital where she suffered a myocardial infarction on arrival to the Accident and Emergency department. She received prompt treatment and was kept in hospital for 21 days.

The senior pharmacist classified this as a significant intervention. Whilst the intervention was not related to anticoagulation therapy, a potential major health problem was identified. Whether a

phlebotomist would be able to deal with the issue in a similar way is debatable, when the patient refused to go to the hospital the pharmacist telephoned the patient's GP, suggesting that the pharmacist was aware of the potential severity of the problem. The senior pharmacist commented that at the very least the pharmacist was instrumental in ensuring that the patient received appropriate treatment in a timely manner and that at the very most, the pharmacist saved the patient's life.

Rationalising medications 26.05.04

At one of the pharmacist's visits the patient explained they had been feeling unwell two nights before and that an on-call doctor had visited and prescribed him some tablets for an unsettled stomach, he was now taking these tablets but complained that he wasn't feeling any better. The pharmacist asked him to show her all his medication. During this time the pharmacist identified that the patient was taking a number of medicines including:

Esomeprazole	40mg one each day (ulcer healing dose)
Omeprazole	20mg one each morning (maintenance dose)
Pantoprazole	40mg one each day (ulcer healing dose)

These medications belong to the class of medicines called proton pump inhibitors, they are used to reduce the amount of acid in the stomach. Patients should be on no more than one of these; this patient was on three. The pharmacist contacted the patient's GP to discuss the issue, the GP explained that these would have been prescribed by different GPs at different times, including the on – call GP. The GP said she would telephone the patient and speak to him directly about taking him off at least two of the PPIs. The senior pharmacist classified this as a significant intervention that would not have been picked up by a phlebotomist. Again, this pharmaceutical issue would probably not have been picked up in the outpatient clinic.

Side effects due to warfarin 26.03 04

This patient reported that in August of the previous year when she had been on warfarin she had found that it did not 'agree' with her; she became lethargic, weak, lost her appetite and was unable to sleep at night. When warfarin was stopped she began to feel better and regained her appetite. However, when warfarin was restarted on 15.01.04 and as the dose had been increased to obtain a therapeutic range of 2 – 3, the same symptoms had reappeared. On the 23rd of February 2004, during a home visit, she and her son inquired about stopping the warfarin and starting aspirin. The pharmacist explained to the patient and her son, that she was on warfarin because she had an

irregular heart beat (AF) and because of this she was at increased risk of a stroke. The pharmacist continued to go into some detail about the risk of inadequate protection against blood clots, in addition, the pharmacist explained to them that warfarin was more effective than aspirin at reducing the risk of stroke. The patient's son told the pharmacist that she had been on aspirin before and had had two heart attacks during that time. They were asked if they had any questions and advised to take some time to think about their decision. The pharmacist discussed the issue with the anticoagulation team, who advised that the pharmacist's course of action had been appropriate and asked the pharmacist to report back at the family's decision on the subsequent visit. Subsequently at the following visit, the patient had not made up her mind. At the next visit, a month after the initial conversation, the son reported that his main concern was that his mother was not eating and about the associated weight loss, based on this, they decided to stop the warfarin. Following this the pharmacist liaised with the consultant haematologist and the patient's GP to discuss the issue, it was agreed that the patient's GP would commence treatment with aspirin.

The senior pharmacist classified the intervention as significant as it had the potential to have a great impact on the prognosis of the patient. The pharmacist helped the patient arrive at an informed decision with regards discontinuation of warfarin.

Table 5.31 outlines the interventions made by the pharmacist during the trial including whether, in the senior pharmacist's clinical opinion, the interventions were significant.

Table 5.31: Interventions made by the pharmacist during the trial

Issue	Intervention	Outcome	Significant? (senior anticoagulation pharmacist practitioner's comments)
Erratic INR	Checking of compliance with medication box checks showed that patient was not taking warfarin as advised. Pharmacist undertook close monitoring of INR and communicated with family with regards to supporting the patient in taking warfarin	Over the next four weeks the patient's INR did not stabilise, compliance issues/ lack of support were identified as a key factor. He was taken off warfarin and removed from trial	Yes: Patient had been previously identified as unstable when attending outpatient visits and was regarded as a high risk for adverse events. Within the home setting the pharmacist was able to decipher what the issues were and make an informed decision about the risks and benefits of anticoagulation therapy in this patient. The decision to take patient off warfarin was the correct one.
Management of side-effects	Monitored side effects and attempted to reduce dose to a point where side effects minimised and INR still in therapeutic range. Patient was given information about the risks of coming off warfarin and given time to make a decision	Taken off warfarin due to unmanageable side effects. Patient put on aspirin	Yes: The patient was unable to tolerate warfarin, however had had two heart attacks whilst on aspirin. The pharmacist played an instrumental role in providing the patient with information to make an informed decision about antithrombotic therapy, which could have a big impact on the prognosis of the patient.
Patient suffering from leg pain	Examined area and observed swelling, discussed with consultant that it might be an extension of a recent leg DVT, this was investigated with a Doppler scan	Scan confirmed extension of DVT. Patient was taken off warfarin and commenced management with parenteral anticoagulation	Yes: prompt diagnosis ensured that the patient received the right treatment quickly and averted additional problems from inadequate management of anticoagulation therapy (i.e. extension of thrombus). May have produced indirect cost saving through reduction in scale of medical care required.
Erratic INR	Investigated how patient took tablets, discovered patient was colour blind	Arranged for patient's medicine to be dispensed in a dosette box by community pharmacist	Yes: patient was at risk of haemorrhage if he continued taking 5mg tablets instead of 1mg tablets. This patient had been previously identified as an unstable high risk patient. The pharmacist was able to identify the issues and provide a whole package of pharmaceutical care. May have produced an indirect cost-saving through prevention of haemorrhage.
Medication review	Patient was on three drugs from the same class, PPI for dyspepsia, GP was telephoned and informed	Patient was taken off two of the PPIs.	Yes: minimising polypharmacy increases compliance and reduces the risk of medication interactions. May also produce a direct cost saving due to reduction in drug use.
Checking patient's medication revealed patient was on warfarin and 300mg aspirin concomitantly	Patient's GP was contacted to verify that this was intended.	After checking patient's records the GP saw that the patient should not have been on aspirin long term and took it off patient's prescription	Yes: concurrent administration of high dose aspirin and warfarin put this patient at increased risk of a haemorrhage. At the least the pharmacist rationalised the patient's pharmacotherapy (note: reduced medicines has been shown to increase patient compliance), at the most the pharmacist minimised the risk of a haemorrhage.
Usually stable patient presented with high INR	The pharmacist reviewed patient's medication for any changes. One item had been dispensed incorrectly: Amoxicillin 250 mg issued instead of Amitriptyline 25mg. The community pharmacist was contacted and patient asked to miss one dose of warfarin.	After verifying error the community pharmacist dispensed Amitriptyline, after two weeks the patient's INR was within range	Yes: The patient was unaware of the dispensing error so in her view was not on any other medication, however through asking appropriate questions the pharmacist was able to identify the error and rectify it without causing alarm to the patient. This error is unlikely to be identified in the clinic; based on the minimal information available to us in the outpatient setting, clinic practitioner's would probably have assumed it was an unexplainable blip in patient's anticoagulation control.

Table 5.31: Interventions made by the pharmacist during the trial – Continued

Issue	Intervention	Outcome	Significant?
Patient having difficulty managing diabetes through diet alone	Discussed the management of diabetes with her including targets, ensuring advice was in line with GPs recommendations, after a month of little improvement, discussed the issues with her GP and problems patient expressing.	Patient was put on medication (metformin) for diabetes.	Yes: diabetes is now recognised as a cardiovascular disease appropriate management reduces the risk of cardiovascular events such as stroke
Patient with consistently low INRs despite large increases in the dose	Pharmacist asked patient to explain how they took their medicines: It became clear that the patient had not been taking warfarin consistently, there were unused boxes of warfarin in the patient's home that had been dispensed 3 years earlier.	After discussion with the patient's family and the anticoagulation team the patient was taken off warfarin	Yes: This patient was not taking any of his medication appropriately, this went unknown by the anticoagulation team and the patient's GP. Through the pharmacist, the anticoagulation team and patients' GP were able to identify the reasons why the patient's medication related targets weren't being achieved and better able to rationalise his medication regime.
Erratic INR	Pharmacist asked patient to explain how they took their medicines: Patient had been receiving a dosette box. Every week the patient would take all of the medication out of the dosette box and place it into pieces of tissue, which he would take at later date. The patient was advised of the dangers of this practice and asked to only take the medication out of the dosette box when required	The patient's INR stabilised over the next 3 weeks	Yes: This patient had been identified as an unstable patient when attending the clinic, reasons were unclear. The pharmacist was able to identify that the patient's medication – taking practice was the cause of the difficulty in maintaining control, which was putting the patient at risk of adverse events. Through education the pharmacist was able to change the patient's practices and the anticoagulation control improved and risk of adverse events decreased. May have produced an indirect cost-saving through prevention of adverse events.
Patient complaining of rash	After inspection of the rash, hydrocortisone cream was recommended	Patient reported that the rash had cleared subsequent to use of hydrocortisone	No: whilst the advice offered by the pharmacist was useful to the patient, it is not perceived to be of great significance to the health of the patient, although depending on the severity of the rash one could argue that the intervention made a significant and positive impact on the patient's quality of life.
Patient unwell with INR of 4.7	Investigator attempted to call ambulance services, however patient was unhappy with this. Therefore the pharmacist contacted the patient's GP to come for a home visit.	The GP called the ambulance services after examining the patient, on arrival to RLH A and E the patient suffered a Myocardial Infarction and was able to receive prompt treatment.	Yes: at very least ensured patient received appropriate treatment promptly, at the most may have saved the patient's life. May have produced a cost saving with a reduction in the scale of medical care required

Table 5.31: Interventions made by the pharmacist during the trial – Continued

Issue	Intervention	Outcome	Significant?
Patient developed a tremor and complained of balance problems	The patient's GP was notified	The GP monitored the patient, after 10 weeks the patient was commenced on medication for Parkinson' disease and depression	Yes: Through multidisciplinary communication the pharmacist was able to ensure that the patient received appropriate treatment for these conditions. Further, through the pharmacist's links with the anticoagulation clinic this information and additional drugs prescribed was entered promptly into the patient's records. The pharmacist provided a useful interface link and facilitated communication of issues across the primary / secondary care interface.
Patient told pharmacist that she had Type 2 diabetes and was concerned	The pharmacist outlined the importance of healthy eating ensuring compliance with other medication for lowering of blood pressure and cholesterol as well as monitoring of glucose levels.	Patient was reassured	No: whilst the intervention was important it is not perceived to be clinically significant in this case as the patient had already been given this advice by her general practice's nurse and reported that she was complying with the advice. Nevertheless, that the pharmacist's reiteration reassured her was a positive outcome.
Patient complained of bleeding gums, INR was in range	The patient was asked to contact her dentist	She was put on a mouthwash for gingivitis (gum infection)	No: This particular patient had been complaining of bleeding gums for some time (whilst attending the outpatient clinic) and even reported that she suffered from this occasionally prior to starting warfarin. Her good anticoagulation control (in addition to other factors) meant that she was not at high risk of serious haemorrhage. Nevertheless, it was good that she finally took a practitioner's advice and went to the dentist.
Patient wanted to stop smoking	Pharmacist gave the patient and patient's son smoking cessation advice	The patient commenced smoking cessation treatment with nicotine patches, after four months the patient reported that she had reduced the number although she had not been able to stop completely.	Yes: this patient had smoked for over 50 years and had severe respiratory problems. In addition, smoking is a risk factor for stroke. The pharmacist informed the patient that smoking cessation was available by prescription and free for her, which was an additional motivator. Whilst, the patient did not give up completely reduction is a step in the right direction.

Whilst no formal framework was used to assess the impact of the pharmacist's interventions, the senior pharmacist was of the opinion that the majority (13 / 16) of interventions made were of key value to the health of the patient irrespective of whether they were directly related to the patient's anticoagulation therapy. The pharmacist was in a unique position of being able to give valuable information to other healthcare professionals to positively affect patients' health. Further, a number of the pharmaceutical issues addressed by the pharmacist were only identified because the pharmacist was conducting domiciliary visits.

5.6.16 Practical issues of running the service

This section outlines some of the difficulties encountered by the investigator and phlebotomist while providing the two domiciliary services.

Parking and transport

The main problems for both the investigator and the phlebotomist during the domiciliary services trial had been finding reasonable parking not too far away from patients' homes, as many nearby roads had only residential parking. The consultant haematologist had applied for a Health Emergency Badge (HEB) for both the investigator and the phlebotomist. This badge allows healthcare professionals to park on meters or in pay and display bays without paying. In addition, badge users may park in residents' bays and, if no alternative parking spaces exist, users can park on yellow lines when visiting patients in their homes. However the visiting of anticoagulation patients for checking INR values was not regarded as sufficiently urgent for HEBs to be issued, therefore both the phlebotomist and the pharmacist had to find suitable places to park including pay and display. They sometimes paid for parking, used visitors' parking permits given to them by patients or put notes in the service car to give notification that they were carrying out a health service. Both the investigator and the phlebotomist had to be mindful of the time spent at visits to avoid the service car receiving a parking ticket or being clamped. During the period of the trial, the phlebotomist received one parking ticket and the investigator's car was clamped once. Parking issues continued to be a problem for provision of the domiciliary services throughout the trial period.

Carrying service equipment

The investigator had to carry the CoaguChek S, a laptop and a bag of equipment for phlebotomy during visits, this was sometimes a problem when parking had not been found near to the patients' homes. A rucksack specifically for laptops was purchased for the purpose of the home visits, this

was also able to carry the CoaguChek S making it easier for the investigator to walk around. Further, as less items were being carried individually and the laptop was no longer exposed, the investigator felt less vulnerable. It was hoped that in the future the CDSS information would be available in a handheld personal computer to reduce the weight of the load carried.

Obtaining venous blood samples

At times both the phlebotomist and investigator experienced difficulty in obtaining venous blood samples. The phlebotomist found that a number of trial patients had weak veins, which made the process of obtaining blood samples challenging. Phlebotomists are advised to attempt to obtain a blood sample from a patient no more than twice; if the second attempt is unsuccessful, another phlebotomist is to attempt to obtain a sample. When the phlebotomist was unable to obtain a venous sample during domiciliary visits the investigator would have to attend; this situation was reversed if the investigator was unsuccessful in obtaining a venous sample. At times this arrangement caused difficulties for the investigator and phlebotomist in managing appointment times due to extra patients being visited and a disruption of planned appointments. During the first few months of the trial, three participants were identified as having weak veins and removed from the trial due to the difficulties of obtaining blood samples.

Whilst these issues were troublesome, neither the phlebotomist nor the investigator felt they warranted discontinuation of the domiciliary services.

5.6.17 Meetings

This section outlines meetings relevant to service delivery that were conducted throughout the trial.

Review meetings

Monthly review meetings held between the consultant haematologist and the investigator were useful in monitoring each trial participant's INR and agreeing decisions about patient continuation on anticoagulation management and trial inclusion.

Staff meeting

Two months before the end of the trial the anticoagulation team met; they were asked about their views regarding the domiciliary service in terms of impact on workload, and to state whether there were any preferences between the evaluated domiciliary services. Whilst, the meeting was not formally recorded the investigator made detailed notes and wrote up findings subsequently.

Administrator's role

Provision of the domiciliary service allowed the anticoagulation administrator, to be trained as a phlebotomist. This enabled the administrator to develop a new role as an anticoagulation technician. The administrator positively welcomed this new opportunity and challenge and as a result of the service development, reported a considerable anecdotal improvement in job satisfaction.

Impact of domiciliary service on anticoagulation team

The team stated that they were pleased the domiciliary service would be continuing, as it freed up time that was previously spent on sorting out transport administration issues. Therefore, more time could be devoted to providing the clinical and educational aspects of care. They also stated that the clinic area was much less congested than prior to domiciliary service implementation, with a reduction in the number of patients in wheelchairs attending the clinic, this had gone some way to addressing previous health and safety concerns (Section 4.3.4.3).

Future of domiciliary services

The team felt that the domiciliary services were appropriate for mobility-impaired patients, and reported that a number of mobility-impaired patients currently attending the clinic had started making inquiries as to when they could start having domiciliary service provision. The team were worried that funding would be inadequate after the trial to provide the service for all those who required it. They questioned whether they had adequately resolved the issue of marginalization of the mobility-impaired if the service would not be open to all requiring it, due to demand outstripping capacity.

Selection of domiciliary service models

With respect to the domiciliary service models, data had shown that they were equivalent in terms of patient satisfaction, anticoagulation control and safety. It was clear that the pharmacist led service would be more costly to maintain, however the team believed that service model 2 had produced cost savings in terms of reduction in the amount of time hospital practitioners spent dosing patients, in postage costs and making telephone calls. Further, the savings produced by the pharmacist's interventions would have to be taken into account; they stated that there was an added benefit in having a pharmacist visit patients over the phlebotomist, in terms of provision of

pharmaceutical care and medicines management interventions. Based on this, the BLT anticoagulation team preferred model 2.

Long-term domiciliary service model

The meeting between the anticoagulation team and pathology management is outlined below; funding offered for the domiciliary service was sufficient only to cover costs for a part-time administrator, precluding long-term implementation of service model 2.

In preparation for the end of the trial and as an interim solution, a hybrid of the two domiciliary service models was believed to be the way forward. The phlebotomist would be trained to use the NPT device for use during visits (which preliminary data had shown was preferred over venous sampling) and BLT practitioners would continue dosing (as in model 1) in order to keep providing a domiciliary service. The team believed that with the hybrid service they had maintained the key aspects of the intervention: service provision in the home and patients' preference for NPT, although it was unfortunate that patients would no longer benefit from the on-site provision of pharmaceutical care provided by the pharmacist. They suggested that one of the team's pharmacists might be able to visit patients at agreed intervals (for instance every 6 months to a year) to identify medicines management issues. After some discussion, this was perceived to be an unrealistic option.

Service development experience

Developing and implementing the service was viewed as a team effort, throughout the trial communication and efficient working links were not only increased and strengthened within the anticoagulation team but also between secondary and primary care. Furthermore, the team gained invaluable experience that they planned to use in developing other models of primary care-based services, such as domiciliary phlebotomy.

Meeting with pathology manager

Two months before the end of the trial a meeting was held, between BLT's pathology management and the anticoagulation team to ensure there were no gaps in the provision of the home services, not only in terms of service provision but also with regards to financial support.

Following discussion, it became apparent that whilst modernising anticoagulation services was a priority, funding was not available for provision of service model 2. It was concluded that whilst the initial outlay costs for model 2 would be greater than for model 1, there were likely to be

savings in other areas such as hospital admissions due to a reduction in interactions and other adverse events. However these savings would not be realised as cash put back into pathology services and the pathology department reported that they were under numerous cost pressures. The final agreement was that monies allocated for service modernisation, would be sufficient to enable the team to provide the hybrid domiciliary anticoagulation service and continue with the phased implementation of NPT within the outpatient clinics; the team reported that they were satisfied with this outcome.

Summary

- 63 patients reached the end of the trial.
- CSQ-8 scores were significantly higher for the domiciliary services than the hospital service; however there was no significant difference in scores between the domiciliary services.
- The preference item and VAS satisfaction item suggests that patients were more satisfied with model 2 than model 1.
- For patients, instructions about what to do between visits, feelings with regards to mode of blood sampling and response to VAS satisfaction for model 2 (group B only) contributed to a large amount of the variance in CSQ-8 score.
- Qualitative data confirmed that patients were more satisfied with the domiciliary services than the hospital services.
- Using time in range and proportion of tests in range, there was no significant difference in anticoagulation control between the domiciliary services and the hospital service, indicating that the high quality (circa 60% TIR) of anticoagulation control was maintained during the home visits.
- Time series analysis suggested that the domiciliary services resulted in tighter control of patients' INRs and lower INR levels when compared to the hospital service.
- The rate of adverse events was comparable between the domiciliary services and the hospital service.
- The pharmacist made a number of interventions throughout the trial, the majority of which were judged to have had a significant positive impact on the health of the patient and would not have otherwise been identified.
- Whilst service model 2 was the preferred option, lack of resources suggested that a more pragmatic approach to sustaining the domiciliary service such as a hybrid of the two evaluated service models would be the most appropriate option for the patient group.

5.7 Discussion of findings

5.7.1 Introduction

The intervention phase evaluated two alternative models (domiciliary services) of anticoagulation service for BLT mobility-impaired patients in a randomised crossover study. The findings of the intervention phase are discussed in this section in relation to the study and in the context of other research. The limitations of the study and the practical considerations are also highlighted in the relevant sections.

5.7.2 Patient recruitment and sample

As the purpose of the study was to develop services for BLT anticoagulation patients, the study was limited to one site, this also ensured feasibility. Sample calculations were not performed as all eligible mobility-impaired patients attending BLT anticoagulation clinics were invited to participate in the trial. Differences between patients that accepted the invitation to participate and those that did not were not fully explored, however anecdotally, a number of patients declining to be part of the study, stated that the clinic visits were their only opportunity to go out and interact with others. Indeed, a number of clinicians commented during the group interviews (developmental phase) that some of their patients enjoyed the social aspect of outpatient appointments. Written consent was requested before patients were accepted on to the trial and patients were under no obligation to take part in the trial even once consent was received.

The minimisation method of randomising patients proved effective in ensuring that the patient groups were evenly matched in terms of age, gender split, indication and anticoagulation control despite the small number of patients recruited to the trial. Recruited patients were significantly older than all patients attending BLT anticoagulation clinics (median age: transport patients 79.5 years versus 70.5 years) and there was a significantly higher proportion of patients with AF than compared to those attending the hospital (72.6% versus 54.8%) and in published data (Mediplus analysis 1999 - 60% of patients taking warfarin have AF). This difference is not surprising as mobility problems present as an issue that increases with increasing age and a number of prevalence studies have shown that prevalence of AF is higher in older patients (Majeed *et al.* 2001; Stewart *et al.* 2001).

Despite the loss of 41 patients (approximately 40%) during the trial, due to deaths and the difficulties of managing anticoagulation therapy, such as compliance issues the patient groups continued to be evenly matched with respect to key characteristics throughout the trial. Patient loss during trials is inevitable, due to the characteristics of the patient group (older age, multiple co-morbidities and concurrent medication) the high number of patients lost was not a surprise. Bowling (2002) described the problem of having a sample of predominantly elderly individuals in longitudinal studies, recognising death as a large source of attrition. The full impact of the attrition rate on the results of the study are unknown, but is outlined briefly in section 5.7.4.1.

A large sample size is valued in research studies, however when the sample size of the present study was compared with other relevant research papers, small sample size was a common theme.

In Coleman's *et al.* (2004) evaluation of a community pharmacy based anticoagulation service in terms of patient acceptability and anticoagulation control the sample size was 22. Both of the MDA's evaluations of the CoaguChek S for professional use (2001) and self-testing (MHRA 2004) also had relatively small sample sizes (professional use: 93; self-testing: 84). Whilst large sample sizes are the ideal, real world research issues such as resources and feasibility sometimes makes this impractical (Keech and Gebbski 2002).

Patient recruitment was more time consuming than had originally been expected, as there was a very small window of opportunity for recruitment at each anticoagulation clinic. During clinics, transport patients were brought into the clinic at the same time by the hospital ambulance service and were taken to the departure lounge soon after their blood sample was obtained. It was not deemed appropriate for the investigator to recruit patients in the departure lounge as there was a risk of confusion with distinguishing which patients had attended the anticoagulation clinic. This issue presented logistic problems in the recruitment process as the investigator was solely responsible for recruiting each patient. After discussion with the anticoagulation team, it was agreed that the anticoagulation administrator would also recruit patients during the clinics. The administrator was trained in what to say to patients, in issuing a patient information leaflet (Appendix 9) and was also given a list of eligible patients. The rate of recruitment increased, however, the list of eligible patients was not adhered to, therefore, a number of patients that did not meet the inclusion criteria were recruited to the study. Relevant patients had to be informed subsequently that they were not eligible for inclusion. This highlights an issue of research in practice; support was needed to ensure that the trial could be started on schedule however, the administrator lacked the rigour of the investigator in ensuring that the recruitment list was followed.

5.7.3 Patient satisfaction

5.7.3.1 Satisfaction study overview

Similarly to the developmental phase, a satisfaction questionnaire comprising the CSQ-8, service specific items and qualitative portion(s) was administered to trial patients at the crossover and end of trial stages of the study. During the trial, administration was via post, data was not collected at the beginning of the trial as patient satisfaction data collected during the developmental phase of the study served as an adequate baseline measure and minimised response fatigue bias.

The approach to measurement of satisfaction provided the basis of a longitudinal measurement of the impact of different anticoagulation services on patient satisfaction. The development of the survey tool is described in sections 5.9. The response rates at crossover (84.5%) and end of trial (98.4%) stages were good and were achieved through the posting of the survey twice at crossover and three times at the end of the trial. Repeating mail outs is a recognised way of increasing the response rate of postal surveys (Bowling 2002). Whilst it was time-consuming, it was more appropriate for the questionnaires to be sent via post than for the investigator / phlebotomist to administer them during visits as this may have resulted in patients feeling that they should give certain types of responses in the presence of the service-provider. By posting the surveys, the investigator and phlebotomist were able to distance themselves from the patients' service evaluation process.

5.7.3.2 CSQ-8 results

A Cronbach's alpha of not less than 0.7 is generally regarded as acceptable (Smith 2005). Cronbach's alpha for the CSQ-8 questionnaire during the crossover (0.77) and end of trial (0.82) stage indicated that the CSQ-8 measured satisfaction in a useful way in this patient group and that the scale had tapped into one dimension. Previous research had established that the internal consistency of the CSQ-8 was high, with alpha coefficients ranging from 0.84 to 0.93 (Gaston and Sabourin 1992).

For patients in groups A and B, patient satisfaction increased from baseline to the end of the trial, suggesting that patients were more satisfied with the domiciliary services than the hospital service, irrespective of which domiciliary service was provided.

At the crossover stage, there was no difference in the satisfaction levels of patients receiving the two different domiciliary service models. However there was a significant increase when satisfaction scores were compared to the hospital service. This indicated that increased access of the service and increased convenience (not having to use transport and having the test at home) were the key factors in patients' satisfaction over specific aspects of the delivery of the individual domiciliary service models.

Similarly, at the end of the trial, there was a significant increase in satisfaction when the domiciliary models were compared to the hospital models. Whilst there was no significant difference in satisfaction scores between patients receiving model 1 and patients receiving model 2 the

differential between the CSQ scores for the two domiciliary services was wider at the end of the trial, (model 1 versus model 2; $p=0.008$), than at the crossover stage (model 1 versus model 2; $p = 0.925$) suggesting that having experienced both domiciliary models patients were more discerning in their assessment as they were now able to use both models as points of reference.

Patients reported high levels of satisfaction with the domiciliary services, whilst there was no directly comparable literature, as outlined in Chapter 4 (section 4.7.1.2) it has been shown that CSQ-8 produces largely positive results. Therefore the results were in line with previous research (Nguyen *et al.* 1983). More useful than comparison with the available literature, was using the hospital service as a baseline comparator for the domiciliary services.

5.7.3.3 Service specific items and qualitative data

The Cronbach's alpha for the service specific items at crossover (0.404) and at the end of the trial (0.124) were less than 0.7 indicating that the items were not measuring one dimension, therefore it was more appropriate to consider the items separately than to group them together as for the CSQ-8. Indeed, the aim of the service specific items was to assess a variety of aspects of the service, rather than focus on one facet. The qualitative sections of the domiciliary satisfaction questionnaires were often not completed, however when they were, they reinforced the results (triangulation) and also provided new insight (complementarity) into patients' perceptions.

At the end of the trial there was a significant difference in responses to the mode of blood sampling item between the domiciliary models, with patients preferring model 2's capillary sampling over model 1's venous sampling. This finding was supported by patients' comments. This may explain why patients were marginally more satisfied with model 2 (30.87) than model 1 (30.19). Increased satisfaction with model 2 was supported by the service specific items 12 and 13. The significant differences between model 1 and model 2 for the rank and VAS items, suggest that there was a wider difference in patients' satisfaction with the domiciliary services than indicated by the CSQ-8 results. However it is important to state, that the CSQ – 8 is a validated tool whereas the rank and VAS items are not, this may go some way to explaining the observed difference in significance of the results. Ideally, the VAS should have been administered at crossover so that a longitudinal, rather than cross-sectional comparison could have been undertaken, this may have provided more useful data.

Correlation and multiple linear regression analysis of the independent items and CSQ-8, showed the importance of instructions about what to do between visits and mode of blood sampling in patients' satisfaction.

Instruction variable

Whether the investigator being a pharmacist had an impact on the instruction variable is unclear. Further, it is unclear whether the setting of dosage information exchange, that is, during the appointment at home (model 2) or after the appointment over the telephone and / or via post (model 1), was an important aspect of the instruction variable. Salisbury (1997) reported that a general practice out of hours telephone-based service resulted in reduced satisfaction compared to GP domiciliary visits; this suggests that patients valued face-to-face contact with a healthcare professional over telephone contact. Unfortunately patients did not elicit specific information regarding information setting, so definitive conclusions on this aspect of service provision cannot be made. Literature has shown that interactions with healthcare professionals/service staff can have a large impact on patient-assessed quality of services (Owens and Batchelor 1996). Further, studies have shown that patient-provider interactions, in terms of clarity of explanation and perceived interest of practitioner in patient, can affect levels of satisfaction (Lipkin and Schwartz 2000). Norris and Roswell (2003) explored interactional issues in the provision of counselling by community pharmacists to their clients. Authors found that a number of interactional issues were important to clients such as wanting to understand the counselling, wanting to feel confident in the quality of counselling and privacy issues. Authors concluded that quality interactions were essential for provision of adequate counselling; it could be said that the one-to-one domiciliary visits provided by the investigator promoted positive interactions that might not always be achievable within the outpatient clinic setting, however as this aspect of service provision was not explored there is no firm data to verify this supposition. In a review of determinants affecting patient satisfaction, Crow *et al.* (2002) found that patient-practitioner interaction, including information giving was the most important factor in patient satisfaction. Clearly, literature supports the finding that the instruction variable was a key factor with respect to patient satisfaction.

Mode of blood sampling

When compared to other research, trial patients' increased satisfaction with NPT anticoagulation monitoring over venous sampling is not surprising. Ninety-four percent (15/16) of patients expressed a preference for capillary blood sampling and NPT over venous sampling in an evaluation of a community pharmacy-based anticoagulation service (Coleman *et al.* 2004). Chaudry *et al.* (2004) investigated patients' satisfaction with a nurse-led anticoagulation service utilising NPT over a previous service using venous sampling in a US community medicine practice. With regards to service preference, 79% (143/ 187) stated they preferred the NPT system. Literature has shown that anticoagulation monitoring with NPT can improve the quality of care with regards to access, timeliness (reduce appointment / consultation times), communication (on-site communication of results) and continuity of care (immediate dosing; Chaudry *et al.* 2004). Further, the use of NPT is recommended for patients with poor access to anticoagulation clinics, requiring frequent monitoring due to interacting drugs and in patients with weak veins (Zimmerman 2000).

The themes identified following content analysis of patients' comments at crossover and end of trial were satisfaction with home environment of the service, positive feelings regarding the service, positive feelings regarding the staff and elimination of waiting times for transport service. Patients were vocal at both stages in stating that they wanted the services to continue.

Gaston and Sabourin (1992) identified eight dimensions in the full length Client Satisfaction Questionnaire, these were (a) *physical surroundings*, (b) kind/type of treatment, (c) *treatment staff*, (d) *quality of service*, (e) *amount, length, or quantity of service*, (f) outcome of service, (g) general satisfaction, and (h) procedures. Parallels can be found between the themes of the full length CSQ and the themes elicited from the qualitative portions and the service specific items used in the current study, suggesting that the multimethod approach was successful in drawing out the key aspects related to patient satisfaction. The strength of the study method is that use of the CSQ-8 remained constant throughout the study (that is, baseline, crossover and end of trial stages); if the CSQ-18 had been used it would have had to be adapted due to the difference in services at each stage. For instance one of the items on the CSQ-18 asks, "How convenient is the location of our building?" This would not be relevant for the home service and would have to be excluded; therefore, it would not have been possible to produce a single satisfaction score for simple comparison.

Domiciliary setting

Whilst there were no equivalent evaluations of domiciliary anticoagulation services to compare patients' experience, one paper was identified in which a domiciliary phlebotomy service for elderly psychiatric patients was evaluated (Darley *et al.* 2004). Results of a patient satisfaction survey, showed that all patients were equally or more satisfied with domiciliary visits than with outpatient appointments. Authors stated that patients appreciated the convenience of being seen at home, compared with the difficulties encountered in attending out-patient appointments. It would be unwise to directly extrapolate the findings of this evaluation to the mobility-impaired anticoagulation patient group at BLT, however there appear to be some general themes of commonality between the two groups of patients: elderly, housebound, and difficulties in attending clinic. Therefore the report of increased patient satisfaction with domiciliary services over outpatient attendance in this study appears to be in line with published evidence.

Convenience and access

Warner (2005) recognised that increased access and convenience alongside choice were key to pathology service developments. Warner advocates increased convenience through the use of more convenient testing sites (such as patients' homes) and better access, again through a variety of testing sites and a reduction in turn around times for blood tests; near patient testing plays a key role here. These aspects of service development were addressed in this study and patients' qualitative responses suggest that the developed services did indeed improve convenience and access to the anticoagulation monitoring service.

5.7.3.4 Overview

Previous studies supported the finding that NPT was the preferred mode of sampling and that patients' homes were the preferred location. Provision of domiciliary services successfully increased patients' satisfaction with anticoagulation services. The importance of patient satisfaction should not be understated; increasing patients' satisfaction has been shown to improve patient medication compliance which should ultimately improve patient outcomes (Guldvog 1999). Patient satisfaction was used as a proxy measure of quality; one could say that the domiciliary services were of a higher quality than the hospital based service for this patient group.

5.7.4 Anticoagulation control and Safety

There would be little point in providing an alternative anticoagulation service that patients were more satisfied with in terms of the logistics of how the service was operated, but that failed to ensure at least an equivalent level of anticoagulation control and safety when compared to the traditional service model. The quality of anticoagulation control and rate of adverse events for patients throughout the trial was explored.

5.7.4.1 Anticoagulation control

In line with Fitzmaurice *et al.* (2003) suggestion, two measures of anticoagulation control were used to evaluate the performance of the anticoagulation services. Accepted standards were used to assess the quality of anticoagulation control, however their use has not been widely reported on in the literature, with different authors using different standards as proof of the quality of anticoagulation control (Macgregor *et al.* 1996) or simply comparing with previous literature (Garabedian-Ruffalo *et al.* 1985).

Outline of results

The domiciliary services achieved the target of at least 60% TIR (Fitzmaurice and Ketstevan 2003) during the study. Whilst results showed that both domiciliary anticoagulation service models achieved BCSH standards of $50\% \pm 0.5$ INR units of the target, control fell short of $80\% \pm 0.75$ INR units of the target. The BCSH have recently altered their recommendations on standards for anticoagulation therapy. Their recommendations are now the same as Fitzmaurice and Ketstevan TIR standard (2003). They state the reason for the change is that 'TIR is now considered to be more relevant than simply the proportion of INRs within target range (Rosendaal *et al.* 1993) and clinical experience has shown that this target is achievable' (Baglin *et al.* 2006; page 283). This suggests that their previous standard may have been difficult to attain in some instances.

Literature comparison

A variety of measures were used in the literature, therefore using two measures in the study facilitated more widespread comparison with a number of papers. The lower standards of anticoagulation control outside the UK have been recognised (McCahon *et al.* 2003), therefore it is more appropriate to compare quality of control with other UK studies. The TIR results of the study are comparable to the UK literature; Poller *et al.* (1998) showed in a randomised study of CDSS

that a TIR of 63.3% was achievable, Fitzmaurice *et al.* (2000) demonstrated that a nurse led community based anticoagulation service achieved a time in range of 69% with the aid of CDSS and NPT.

Whilst alternative ways of measuring anticoagulation control may be useful in exploring different aspects of the quality of service provision, a consensus should be reached on an approach and standards to be used in studies to facilitate meaningful comparison.

Healthy survivors

TIR results were higher for patients participating at the end of the trial than those at trial commencement. This may be because practitioners became accustomed to the domiciliary services and were subsequently better able to tailor the dose to the patients, however it is more likely to be due to the large number of patients (41) leaving the trial due to death and complications of therapy. Table 5.32, shows that as the number of patients decreased at various stages of the trial, the mean baseline TIR increased.

Table 5.32: Baseline Time in Range readings for patients at different stages of the study

Trial stage	Baseline Time in Range reading*		
	Baseline n = 101	Crossover n = 81	End of trial n = 60
	60.9%	61.3%	65.6%

*Three patients at baseline were new patients, therefore baseline TIR was not available

The results suggest that the patients that left the trial were less well controlled with respect to their anticoagulation therapy. This is a recognised problem of sample attrition resulting in the 'healthy survivor effect' (Bowling 2002); the end sample consists of the healthiest members of the original sample and can bias the results. This issue was addressed by comparing the baseline anticoagulation control of patients who had reached crossover and the end of trial only; that is, the time in range readings of patients that had been lost during the course of the study were not included in subsequent analysis to avoid over inflation of the effects of the domiciliary services on anticoagulation control.

The effect of the presence of risk factors and co-morbidities on anticoagulation control

Risk factors and co-morbidities common with the older population pose difficulty in the effective management of anticoagulation therapy where prevention of adverse events through the maintenance of therapeutic INR is of paramount importance to clinicians (Perrero *et al.* 2004).

Almost a quarter (22%) of the patients participating at the end of the trial had risk factors for complications with warfarin. The presence of risk factors had a substantial impact on anticoagulation control, with an 11% difference in the time in range (58.45 with risk factors to without risk factors 69.4%). This data add weight to the need for tailored services for this high-risk group.

5.7.4.2 Time series analysis

The time series method gave a better overview of the changes in anticoagulation control over time than simply producing averages as in the TIR and proportion of tests in range methods.

The results of the time series analysis suggested that the pharmacist (investigator) was more cautious than the BLT practitioners with regards to changing doses and appeared to opt for smaller dose increments than clinic practitioners. In model 1, practitioners making dosing decisions had over twenty years experience between them and had previously been responsible for dosing these patients when they attended clinics via hospital transport. The pharmacist providing service model 2 was trained as an anticoagulation practitioner specifically for the service, and was relatively inexperienced. It has been shown that when doing a newly learnt task for instance prescribing, individuals require experience to feel confident and maintain their competence (Timbs 2003), it is therefore more likely that those with little experience are likely to be more cautious with regards to performing that task. It would have been useful to see how the pattern of acceptance and rejection of the CDSS dosing suggestions differed between the BLT anticoagulation practitioners and the pharmacist providing the model 2 service to determine how much of an influence CDSS had on both models, however this was not investigated during the trial and such data would not be retrievable retrospectively.

Although the difference in anticoagulation control between the domiciliary services and the hospital service was not significant, the time series plots suggest that domiciliary service models provided more stable control of patients' INRs with less peaks and troughs in INR than the hospital service. This is important in terms of service provision as non-therapeutic INRs contribute significantly to the occurrence of adverse events (Cannegieter *et al.* 1995). In this way the pattern of INR control achieved by the domiciliary services is preferable to that observed during the hospital services.

This study adopted a rarely used approach to investigating and comparing anticoagulation control across different service models. No literature was identified as using time series modelling as a

method for assessing anticoagulation control in this way, therefore comparison was not possible. The main limitation of this method is that it is unable to take into account factors other than the service models such as interacting drugs that may also have had an impact on anticoagulation control.

5.7.4.3 Safety

The number of adverse events that occurred in the trial were comparable to the hospital service and available literature (Fitzmaurice *et al.* 1996a; Ansell *et al.* 1995), suggesting that the domiciliary models achieved appropriate standards of safety. Throughout the trial there were three minor bleeds, two major bleeds and one thrombotic event. Lee and Schommer (1996) reported one thrombotic and two haemorrhagic events in 31 cases receiving a pharmacist managed anticoagulation service over a seven month period. Fitzmaurice *et al.* (2002) reported one haemorrhagic event in 23 patients self-managing their anticoagulation therapy over a six month period. No specified limits were identified however published data showed that the results were acceptable, particularly giving the complexity of anticoagulation management in this patient group.

The adverse event rates were intended to aid direct comparison with the available literature. Fitzmaurice *et al.* (2005) reported an annualised rate of serious adverse (haemorrhagic) events of 1.8 per 100 years. Whilst the current study results are comparable (haemorrhage 2.59 per 100 years), it is of note that the patients were much younger than BLT mobility-impaired patients (65 years versus 79.5 years); older patients are known to be at increased risk of adverse events (Perrero *et al.* 2004). Kagansky *et al.* (2004) explored the incidence of bleeding in older patients on anticoagulation therapy. Authors showed that 323 older patients (> 80 years) had a major bleed rate of 2.4 per 1000 patient months (equivalent to 2.88 per 100 years) which is comparable to the current study. Authors concluded that this was a low rate of events in this patient group, suggesting that the rate of adverse events during the domiciliary services was acceptable. In Ansell and Hughes (1996) editorial review on the rates of adverse events in controlled trials a serious haemorrhage adverse event rate of 2.8 per 100 years and a rate of 2.4 per 100 years for thrombotic events in coordinated anticoagulation care including anticoagulation clinics and patient self-management was reported. Whilst the paper was never intended to be a robust review, it does provide an indication into the rates in other studies.

Whilst the event rate should facilitate comparison, its usefulness is limited due to the variety of different approaches used in the literature. Some papers have reported combined annualised

event rates for both minor and major events, whilst others have focused on major events only, in addition, there is disparity in the definition of what constitutes a major haemorrhage in the literature. Lastly, trials with similar patient populations; over 75 years old and multiple co-morbidities are scarce, so usefulness of comparison is limited. However, comparison with baseline readings confirmed that quality of care achieved by the domiciliary services in terms of safety was comparable to that produced by the BLT anticoagulation clinic.

5.7.4.4 Pharmacist interventions made during the trial

In addition to short verbal medication counselling, the pharmacist (investigator) made 16 interventions during the course of the trial, compared to one by the phlebotomist. Thirteen of the pharmacist's 16 interventions were classified as having a significant positive impact on the health of the patient, indicating that there was a clinical advantage to having a pharmacist performing the domiciliary visits. Literature on the clinical role of pharmacists in the management of medicines in the elderly and the financial impact of their interventions is emerging, demonstrating that they undertake a significant number of interventions and produce significant cost savings (Chiquette *et al.* 1998; Petty *et al.* 2002; Zermansky *et al.* 2001). Whilst patients did not elicit any preference between visits by the phlebotomist or the pharmacist the additional benefits of a pharmacist are evidenced by the ad hoc interventions made during the trial. Although the pharmacist's interventions were not quantified it is apparent that a number of important interventions were made that would not have been possible within the outpatient setting primarily due to lack of information.

Full quantification of the interventions requires economic analysis and assumptions to be made about the results of no intervention, and calculation of the expected savings from factors such as a reduction in: hospital admissions, length of hospital stays, medical procedures and drugs. This was outside the scope of the current study and is a limitation to the usefulness of this data at present. The financial implications of model 2 will be explored in the future as part of a full economic analysis of all three anticoagulation services.

With the range of opportunities such as the pharmacy and GP contracts (Pharmaceutical Services Negotiating Committee 2004; DoH 2004b), practice based commissioning (Department of Health 2004d) and now independent prescribing rights (Department of Health 2006b), it is clear that pharmacists play a pivotal role in the Government's vision of the modern NHS. However, the success of the developing role of pharmacy is partly dependent on funding. The new NHS promotes competition with multiprovider opportunities (Practice based commissioning;

Department of Health 2004d); pharmacists need to be proactive in selling themselves, raising their profile and building and maintaining good multidisciplinary working relationships so that they can effectively use their skills and be at the forefront of health service innovations. Service funding issues are further discussed in Chapter 6 (section 6.7).

5.7.5 Limitations of methodology

This section briefly summarises the limitations of the study together with some discussion.

Small sample size

The small sample size of the study means that the power of the study to detect true differences is reduced. Further, results may only be relevant to the population studied; definitive conclusions cannot be drawn from the findings. However, as previously eluded to the study was limited to one site (BLT) and was not intended to be generalisable. Larger scale studies would be needed to find out whether the modes of domiciliary service evaluated in the study would be applicable elsewhere.

Satisfaction survey

The majority of patients did not complete the qualitative sections of the satisfaction questionnaires administered at crossover and end of trial stages of the study. In-depth interviews would have been useful to gain a fuller insight into patients' perceptions towards anticoagulation services. Such interviews may have been useful in assessing whether patients' perceived the pharmacist undertaking domiciliary visits to be of additional value to the phlebotomist visits. Employing a second investigator to conduct such interviews was not a feasible option with the available resources. If the main investigator conducted the interviews they would have been subject to a high degree of bias as the investigator had been the service provider.

Biases

The high attrition rate resulted in the end sample comprising a fairly stable population with respect to their anticoagulation control. It is possible that improved anticoagulation stability could result in increased satisfaction scores. Having a final sample of stable patients may have resulted in over inflation of the difference in satisfaction between the domiciliary services and the hospital-based service.

It is possible that the satisfaction study was subject to the Hawthorne effect (influencing their responses), as patients were aware they were being studied.

It is plausible that evaluation of interventions may have been biased, as the evaluating pharmacist had been responsible for the investigating pharmacist's training for the provision of service model 2 or as a result of assessing a fellow pharmacist's impact on patients' well-being. It is not possible to quantify the degree of subjectivity (or objectivity) of the pharmacist's evaluation. Additional evaluation of interventions by relevant health care professionals (for example consultant haematologists or anticoagulation nurse practitioners) not working within BLT anticoagulation clinics would have been a useful tool for validating the pharmacist's original evaluation.

Limited comparison due to a range of approaches

Issues around lack of uniformity in approach of measuring the quality of anticoagulation control and safety have been outlined earlier (5.7.4.1; 5.7.4.3).

5.7.6 Section summary

The anticoagulation team wanted to develop anticoagulation services for their mobility-impaired patient group that improved patient satisfaction with services. Further, they did not want developed services to compromise the quality standards they had achieved in terms of anticoagulation control and safety. Whilst the study achieved these objectives, issues arose around the degree of funding for the long-term implementation of the domiciliary services.

This chapter described the implementation and evaluation of two evidence-based domiciliary anticoagulation service models and gave insights to some of the practical issues in service provision and the challenges to implementation. The next chapter discusses the findings of the study and further explores the challenges of conducting and implementing research in practice.

Chapter 6

THESIS DISCUSSION AND CONCLUSIONS

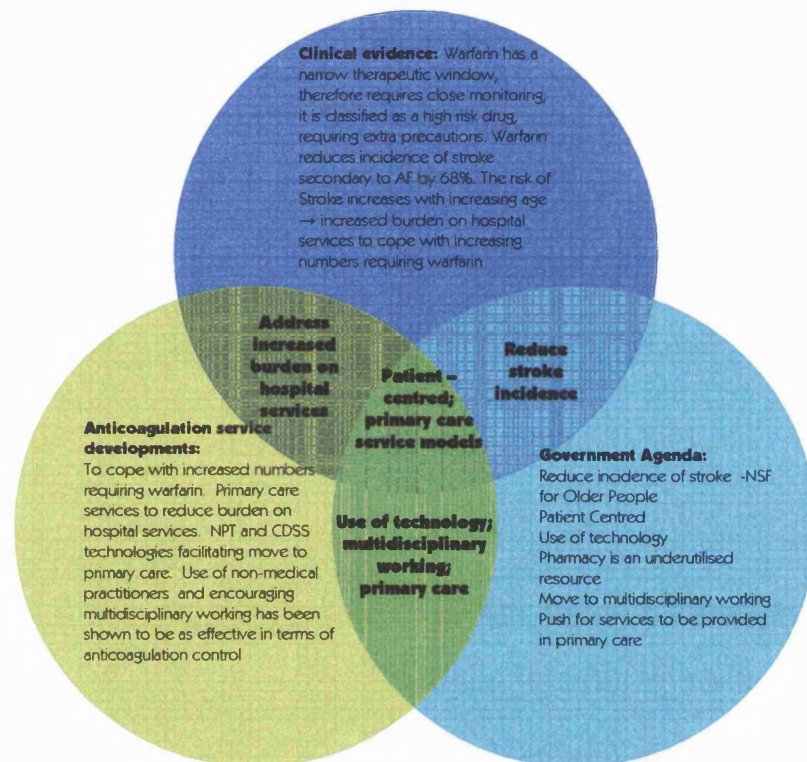
6.1 Preface

This thesis has described the development and evaluation of new ways to deliver care to patients prescribed oral anticoagulation therapy. In doing so, the thesis has outlined a pragmatic approach to research in practice, providing insights into some of the concerns of service users and providers with current anticoagulation service provision, whilst allowing for redesign of services across the healthcare interface. Furthermore, the findings provided insights into the challenges faced in conducting health services research in the real world and the gaps between theory and reality. With respect to the impact of the intervention on the predefined outcomes, the new services were a success. However, there were a number of barriers to the successful long-term implementation of the preferred model, which are discussed in this chapter. The chapter provides a brief overview of the thesis and main findings followed by a discussion around the study design and aspects of providing service model 2. In addition, the challenges of conducting and integrating research in practice are also highlighted. The chapter finishes with the study conclusions.

6.2 Study overview

In the introduction of the thesis Figure 6.1 illustrated the overlaps between the clinical evidence for the benefits of warfarin in stroke prevention; the Government's NHS modernisation and stroke reduction agendas; and the literature on anticoagulation service developments. The developmental phase of the study sought to address these areas of overlap through evaluation of the anticoagulation service development literature and capturing the feedback of service users and providers as a mechanism to design two alternative services.

Figure 6.1: Diagrammatic representation of the introduction chapter and key themes



Mobility-impaired patients using anticoagulation services often have co-morbidities; are older; and are at increased risk of thrombosis. These issues can make the task of maintaining their INRs in therapeutic range challenging. Both the implementation and evaluation of the domiciliary anticoagulation services for the mobility-impaired patients are described in the intervention phase. The findings show that there was a significant increase in patient satisfaction with the domiciliary services compared to the hospital model, as well as comparable standards of anticoagulation control and safety to those achieved in the hospital setting. The pharmacist providing model 2

made a number of interventions (judged to be significant) in the study, indicating added value in having a pharmacist perform the domiciliary service over a phlebotomist.

6.3 Multimethod approach to service evaluation

A multimethod approach was taken to developing and evaluating anticoagulation services in terms of patient satisfaction, anticoagulation control and safety. The use of multiple methods allowed substantiation and elaboration of findings to fully investigate the outcomes of interest. Key aspects contributing to patient satisfaction were revealed using a combination of quantitative and qualitative measures. Anticoagulation control was assessed using two popular methods: Time in range and Proportion of tests in range as well as time series analysis to provide more detail of the impact of the intervention on patients' anticoagulation control. The safety of the trial was determined by calculating the actual incidence of haemorrhagic and thrombotic events and the annualised rate. Such evaluation design draws on the MRC framework for evaluation of complex interventions as well as current Government policy in the context of stroke reduction targets, modernisation of the NHS and the role of the pharmacy profession. The study is an example of how relationship building and multidisciplinary working within and across sectors with clinicians, policy makers and budget holders, can lead to the safe and effective implementation of patient-centred services.

6.3.1 Challenges encountered with measuring patient satisfaction

As outlined in section 4.2.3.2, Hudak and Wright (2000) propose that the two major aspects of patient satisfaction measurement are content (areas of measurement) and method (how the instrument is administered). The possible effects of a number of different modes of administration on the patient satisfaction survey results have been previously explored (section 4.2.3.2). Cohen *et al.* (1996) showed that different satisfaction survey methods resulted in substantially different results. However, it remains unclear whether (and how) results of the present study would have differed with different modes of questionnaire administration and indeed, whilst this would have been useful insight, it was not the focus of the study. There are a variety of methods for measuring patient satisfaction, each with their advantages and disadvantages. Reasons for the suitability of postal administration during the intervention phase are outlined in Chapter 5 (section 5.7.3.1). During the developmental phase clinic administration was the most favourable option in terms of time, simplicity and cost, however a combination of methods such as group or one-to-one interviews and sending surveys via post might have provided greater coverage and more in-depth data.

Content: Validated tool versus non-validated tool

The approach to measuring patient satisfaction applied in the present study, i.e. combining a validated satisfaction scale with service-specific original items, allowed brief self-administration of the tool whilst producing a robust measure of patients' global satisfaction as well as identification of specific areas of service delivery that could be focussed on for service developments. The longitudinal measurement of patient satisfaction also used in this study was useful in demonstrating that patients were more satisfied with the domiciliary services primarily due to increased access and convenience (no reliance on transport). Whilst authors have relayed these findings as suppositions of the benefits of domiciliary services (Hall and Radley 1994) for the mobility-impaired, this study has provided evidence to support these assumptions.

The usefulness of the specific non-validated items leaves the investigator asking the question, how valid is valid? Whilst the validated scale was useful for allowing comparison of global patient satisfaction, it was of limited use in directing service developments. It was the specific items that actually pin-pointed areas in need of service development. Further, multiple linear regression demonstrated that the specific items had a large effect on the variance of patient satisfaction as measured by the validated CSQ-8 scale. The findings suggest that validated tools are not the only "valid" instruments for measurement of satisfaction.

The issue is not just about the use of or choice between validated or non-validated scales; but rather it is about the appropriate combination of a generic validated scale with a service specific non-validated battery of items. This combination can provide complementary data; with generic scales (such as the CSQ-8) enabling the comparison of diverse groups and multidimensional service specific items allowing an understanding of the service-specific context of differences in satisfaction (Asadi-Lari *et al.* 2004; Hudak and Wright 2000). Whilst it is accepted that the use of non-validated scales is less reliable as a measure of satisfaction, the results of the study suggest that the findings of non-validated measures should not be disregarded as unimportant and perhaps more work is needed to validate these as yet non-validated scales. Further, with the volume of literature available on anticoagulation service developments, it appears developing a suitable service specific valid satisfaction scale should be a priority for researchers to allow meaningful comparison and evaluation of redesigned services.

6.4 Selecting models for long-term implementation

Following the evaluation trial, the anticoagulation team preferred domiciliary service model 2. Reasons cited for this preference included, the ability of the pharmacist to manage a range of issues across a number of sectors, reduced workload for the team and the provision of a whole package of care to the patients. However, due to the lack of evidence of improvement in measured outcomes with provision of service model 2 over service model 1 and, as potential cost savings produced by pharmacists would not materialise as cash flow for the pathology department, funding for service model 2 was not made available. The evidence in favour of the pharmacist-led service over the phlebotomist service in terms of the benefit of the interventions conducted could be described as anecdotal. At the outset of the intervention phase, it was clear that service model 2 would be considerably more costly than service model 1, therefore arguably, the study design should have had an increased focus on attempting to decipher whether there were benefits to patients and healthcare providers in the delivery of service model 2 and if benefits were (perceived to be) worth the additional cost. Such work may have involved increasing the level of detail recorded for interventions made; reaching consensus amongst anticoagulation practitioners on the implications and significance of the interventions and adequately costing the benefits of the interventions to see to what extent they might offset the cost of the service. Given the numerous competing priorities and lack of sufficient supportive data, the level of insight into service model 2 offered by the study was inadequate to make a case for funding this costly service. After a thorough review of the evidence from the current study, the anticoagulation team selected a model that was a compromise between the two domiciliary models for long term implementation. The alternative model involved the phlebotomist visiting all domiciliary patients as in model 1, utilising capillary sampling and an NPT device as in model 2.

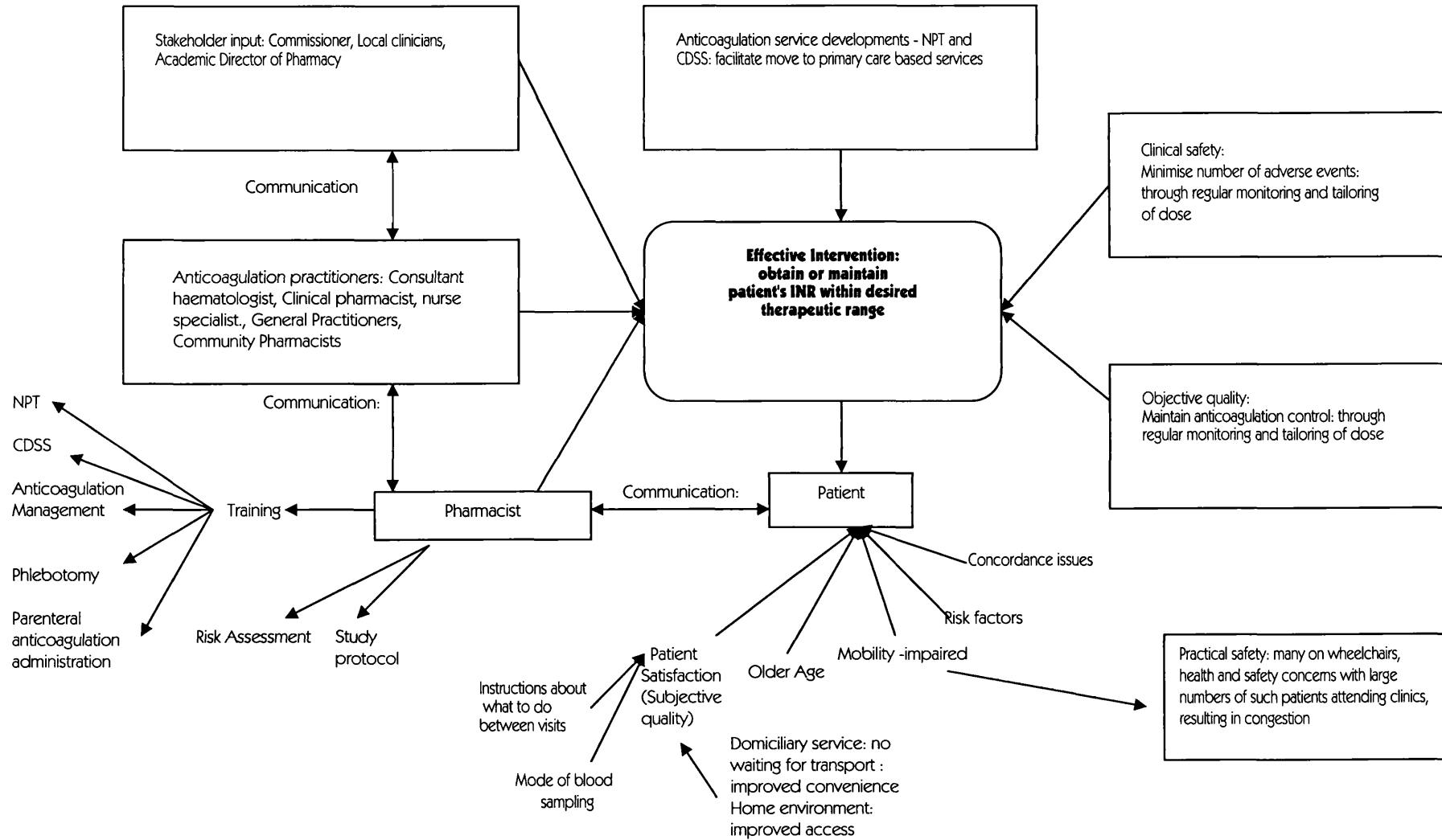
6.5 Aspects of providing model 2

This study outlined the development and evaluation of a complex pharmaceutical intervention. Figure 6.2 goes some way to illustrate the complexity of service model 2.

In addition to building and maintaining relationships with the anticoagulation team, the pharmacist had to build relationships with patients, patients' GPs and community pharmacists to aid the process of seamless pharmaceutical care across and within the health sectors. This interface role gave the pharmacist the advantage of being able to easily contact hospital consultants to verify changes to medication and anticipate affects of factors such as diet and surgery on anticoagulation

control sooner than in the outpatient setting and also communicate medication-taking difficulties patients might be having to the relevant healthcare professionals.

Figure 6.2: Diagrammatic representation of service model 2



The role of pharmacists in medication review, proposal of clinically relevant interventions and provision of pharmaceutical care plans with definite outcomes is increasingly recognised as valuable in the literature (Alldred *et al.* 2003; Zermansky *et al.* 2001; Burns and Still 2003). Alldred *et al.* (2003) demonstrated that clinical medication review by a pharmacist for older people in care homes resulted in an average of 2.75 interventions per resident. Further, 85% of the pharmacist's interventions were accepted by GPs and of those 76% were actually implemented. Zermansky *et al.* (2001) explored the impact of a pharmacist conducting medication reviews of older patients receiving repeat medication in general practice in a 12 month randomised controlled trial. The pharmacist made recommendations for 21% of patients on repeat medication (603 / 2927). Whilst there was no difference in the number of outpatient appointments and hospital visits between the groups, economic analysis showed that there was a cost saving of £61.75 per patient per year in the intervention group compared to the control group. Authors concluded that the pharmacist's visits provided important therapeutic benefits associated with cost neutral implications.

The elderly are known to be a vulnerable group in terms of medicines management. A domiciliary service with pharmacist involvement, seems a sensible approach to helping this group to effectively manage their medicines. Further, pharmacists can play a role in achieving the aims and targets set out in the NSF for Older People by providing domiciliary services for those patients experiencing difficulty accessing general practice and pharmacy services (Livingston 2003).

In 1988, a working party of the Royal Pharmaceutical Society of Great Britain suggested that domiciliary pharmaceutical services be provided to all patients who did not have direct access to pharmaceutical services (Bhattacharya *et al.* 2003). Almost 20 years later and with an increased awareness of the role of pharmacists and of the need to improve access to services through provision of domiciliary services when appropriate, Bhattacharya *et al.* (2003) found that central funding for such services is not widely available. Instead, where pharmacists do provide domiciliary services, funding is through local initiatives (Bhattacharya *et al.* 2003). Whilst, some studies were identified that explored pharmacists providing domiciliary services, data was not found on sources of funding and long-term implementation plans (Harris and Anderson 2003; Foulsham and Goodyer 2005); this is not to assume that in all cases these factors have not been considered.

It appears that there needs to be an increased awareness of the streams of funding and local priorities within PCTs to ensure that such services have an opportunity to bid for allocation of adequate resources. In recent years, PCTs have changed their budgeting and planning process.

Now instead of numerous individual targets, they produce a local delivery plan (LDP) which outlines how resources will be used and how value for money will be achieved over a three year period (Parsons and Craig 2003). The Department of Health has produced guidance on the priorities that all LDPs should address, priority areas include access; and improving care for older people (2002b); such areas are directly relevant to this study. These areas receive monies to achieve targets within them. It appears more work needs to be done on successfully securing sufficient funds for long term implementation of domiciliary pharmaceutical services.

Provision of a primary care anticoagulation service is listed as an enhanced service on both the pharmacy and GMS contracts (Pharmaceutical Services Negotiating Committee 2004; DoH 2004b). Within the GMS contract there is a mechanism for commissioning these services from primary care, this gives an indication of the cost of various options available (Table 6.1) to GPs. Whilst services involving pharmacists may be the most expensive, as Coleman *et al.* (2003; page 823) so aptly puts it: "Pharmacists' knowledge of drug interactions, influence of disease, pharmacokinetics and drug counselling skills makes them well suited to the role of anticoagulation practitioner." Adequate funding for intermediate to high level services (Levels 3 - 4) may only be available were the role of pharmacists (medicines management; cost savings) is fully recognised.

Table 6.1: Models of anticoagulation service and benchmark fees under enhanced service in GMS contract

Models (Levels) of practice based anticoagulation services		Benchmark fee payable to practices
Level 1	Laboratory outreach sampling test and dose	£6 -10
Level 2	Health authority trust or other externally funded phlebotomist or pharmacist etc, practice sample, laboratory test, practice dosing	£75 – 100
Level 3	Practice funded phlebotomist or pharmacist etc, practice sample, laboratory test practice dosing	£80 – 110
Level 4	Practice funded phlebotomist or pharmacist etc, practice sample, test, dosing	£85 – 120

6.6 Some challenges with conducting research in practice

As outlined in the introduction of the thesis the Government has introduced a raft of policy documents and professional contracts in efforts to modernise the NHS. However, if practice is not effectively changed by policy, there is a danger that these documents will be regarded as Government spin. Whilst overburdened with Government policies and targets (BBC talking point 2001), there is anecdotal evidence that NHS employees largely feel the 'modern NHS' concepts (such as a move to primary care provision of services) are admirable. However, the resources required for effective and sustained implementation of these changes are frequently underestimated (Callaghan 2006) and there is little emphasis on the monitoring and reporting on the impact of these

changes (McDonnell *et al.* 2006). This appears to have resulted in the NHS going round in circles introducing “innovative” ways of working which are not dissimilar to previously phased-out initiatives, e.g. practice based commissioning versus fund-holding GPs (Walshe 2003). This section explores the challenges presented in performing and integrating research in practice and questions whether Government Policy is reality or rhetoric.

Patients should be involved in service redesign (Commissioning a Patient- led NHS)

A patient-centred approach to service development was one of the key aspects of the present study. However, exclusion of non-English speaking patients during the developmental phase made it difficult to draw definitive conclusions about the perceptions of all patients regarding the quality of anticoagulation services. Loss of this group may have resulted in an over-inflated satisfaction score at the developmental phase (see also section 4.7.1.5). More resources are needed to ensure that in areas where there is high ethnic diversity service quality (satisfaction) measurements are available to all; only then will service redesign be truly patient-centred.

Where possible services should be provided in patients’ homes (NSF for Older People 2001).

The Government advocates domiciliary services, such as those evaluated in the trial. However, practical problems experienced by the staff performing the services during the trial do not evidence implementation in practice of this notion. For example, the staff performing the services struggled to obtain any form of permit to enable them to park their vehicles in restricted areas during domiciliary visits. The use of patients’ visitors’ permits that the issue frequently resulted in, was inappropriate for the provision of a much needed health service to a vulnerable group of patients. It appears that locally, phlebotomists and pharmacists are not currently supported in providing services at home through permits in the same way as district nurses and doctors are (brief review of council parking permit schemes). This restriction works against the push for domiciliary pharmaceutical services for the elderly.

The concept of evidence-based health care (Department of Health 2001e)

Evidence based health care has become a major driver in the modern NHS, having important implications on education, policy making and research (Cox 2004). One of the key challenges in conducting the research in the present study with such a frail and elderly population was the high attrition rate. This presents a problem in reporting as the small sample size limits the usefulness of the data (Smith 2005). This challenge may go part way to explaining why studies in this patient group are scarce. The current evidence base puts the spotlight on a move to different “professional” primary care sites (such as community pharmacies and general practices), self-management and increased flexibility for working patients, but provides minimal insight into the needs of the mobility-impaired (Chapter 1; literature review 1.4). A continued lack of focus on this group could potentially lead to greater differentials in access and levels of health care if further work is not done to focus on those identified as most in need of service developments.

Stakeholder input / Multidisciplinary working (Pharmaceutical Services Negotiating Committee 2004; DoH 2004b)

As outlined in the introduction chapter of this thesis, not only does the Government advocate increased input from patients around the delivery of health services they receive in the modern NHS (Our Health, Our Care, Our Say; Department of Health 2006a) but it also encourages a multidisciplinary approach with a focus on quality rather than quantity of service provision (Carter *et al.* 2003; GMS contract, DoH 2004b, Pharmacy contract – Pharmaceutical Services Negotiating Committee 2004). Authors suggest the key to successful service developments is through relationship and network building; forming key links with the influential and decision makers (including budget holders) to seek important endorsements for services (Parsons and Craig 2003; Sheehan *et al.* 2000; Radley *et al.* 2000). It was with these principles in mind that healthcare professionals’ and stakeholders’ perceptions of current and future anticoagulation service delivery were explored in this study. The aim was to gain a true insight into stakeholders’ perceptions and in this way push forward appropriate service developments. Having inputted into the process, it was believed stakeholders would support the long term implementation of service developments.

Unfortunately, the response rates to the stakeholder meetings were poor. Reasons for this are unclear and the reviewed literature does not shed light. As a consequence, the data derived from the group discussions might be subject to response bias, not providing a sound reflection of the views of all local clinicians. Stakeholder ownership is the key to successful service developments, however

without motivated clinicians and a lack of incentives and adequate remuneration, implementing service developments can be an uphill struggle.

6.7 Implementing research in practice

From the inception of the study the aim was to implement one of the services that had been evaluated in practice. The research was conducted in a real life situation and involved input from local stakeholders and the target population. This section briefly summarises barriers identified to implementing research in practice. Whilst they appear different they all centre around a lack of resources limiting service development and capacity.

Limited resources and competing priorities

Limited funding and competing priorities were the barriers to implementing model 2. Indeed, the domiciliary anticoagulation service was competing with a proposed anticoagulation outpatient NPT service. Whilst the commissioners were supportive of domiciliary service developments, new monies allocated to the anticoagulation service were inadequate to undertake the preferred model 2. At this time commissioners stated that there were infinite demands on finite resources and decisions had to be made on what to prioritise. The momentum of anticoagulation service development at BLT may have had an impact; funding was provided for the phased implementation of NPT in the BLT anticoagulation clinics. If the anticoagulation team's efforts had been fully focussed on the domiciliary service adequate funding may have been offered for service model 2.

Lack of time

Within the NHS, there are anecdotal reports of staff being too busy to attend educational sessions and participate in all training opportunities. It is possible that this lack of training tends to yield misconceptions around aspects of healthcare such as the risks of anticoagulation therapy. More needs to be done to free up primary care clinicians time (for instance move of services from GP to community pharmacy setting; checking technicians in dispensaries) and get them on board with service developments. Bateson (2004) reported that time and resources were repeatedly cited as barriers by pharmacists to undertaking (and therefore implementing) research in practice, which suggests that these are legitimate concerns.

History repeats itself

Now that the domiciliary service has been rolled out at Barts and The London NHS Trust, again demand has outstripped capacity and new mobility-impaired patients are now placed on a waiting list, only receiving domiciliary services when one patient has left the service (through discontinuation of therapy, death etc.; Ortiz 2006: personal communication). More funding is needed for the full potential of the service to be realised. Recent media coverage suggests issues with funding appear to be present throughout the NHS.

Too much change?

It has been proposed that the ambitious modernisation policy of the NHS is in fact a barrier to effective change (Walshe 2003). There is recognition that NHS' financial systems have been failing as a result of the scale of targets "thrown at" NHS organisations, which haven't been well costed (Callaghan 2006). Numerous NHS reforms (18 between 1980 and 2003; Walshe 2003), over the last two decades, have required substantial resource and the perpetual influx of reforms results in the "theoretical benefits" of each set of changes not materialising in practice (Walshe 2003). Walshe comments (2003), that due to a culture of reform, the NHS has become change resistant, making it harder to introduce innovative services for patients and promoting a short-term perspective on service developments by managers.

Within the context of the study, it is hoped that subsequent to a full economic evaluation of the domiciliary and hospital services, model selection will be reviewed and if appropriate more resources will be allocated. A limitation of the current study is that it was not designed to quantify interventions or capture data around other patient specific aspects than those measured, that may have differentiated the domiciliary services from each other. Further, comparison between service models 1 and 2 with respect to interventions conducted is inherently biased. Supporting appropriate use of medicines and promoting health through interventions is recognised as part of a pharmacist's role. Historically, conducting such interventions has not fallen within the remit of the phlebotomist's role. These limitations may present challenges in conducting a robust and balanced economic evaluation of the services.

Evidence based practice

The drive for evidence-based practice calls for the integration of professional judgement with the best available clinical evidence on health care (Haynes and Haines 1998). This evidence needs to be clinically relevant, patient-centred and should evaluate the effectiveness and the safety of services (Dawes *et al.* 2005). It is not enough to simply disseminate findings of research and hope for wide spread uptake. It is apparent that the instrumental use of research in practice is disappointingly rare (Weiss 1980). Clearly, more work needs to be done to successfully integrate research into practice and guard against the implementation of poorly evaluated services, such as acute pain teams and NHS Direct, which have resulted in lack of clarity over funding and doubts over cost benefits (McDonnell *et al.* 2006).

6.8 Studying anticoagulation services in primary care

As previously mentioned in this chapter, the MRC framework for evaluation of complex health interventions (2000) was used as a broad foundation for the study. The developmental phase of the study covered the preclinical and phase I stages of the framework; exploring the literature aided in development of a theoretical basis for the study. Obtaining the perceptions of service users and providers gave a focus and direction for the service developments along with the key aspects of the intervention, such as domiciliary visits, to increase access for the mobility – impaired. The randomised crossover study was parallel with the MRC's phase II exploratory trial, testing the hypotheses formed as a result of the developmental work. The next phase of the MRC framework is a randomised controlled trial. This would be a reasonable option for a larger sample size, ensuring appropriate statistical power. The current study did not aim to be generalisable to a large population and thus this stage did not form part of the study. Whilst a randomised controlled trial was not undertaken, the findings of the research and experience over the trial year, were useful in establishing the service and ensuring systems were in place for long-term implementation of domiciliary anticoagulation services in the Tower Hamlets locality.

6.9 Summary

The traditional anticoagulation service model (and potentially the inaccurate risk benefit ratios derived by GPs (Gross *et al.* 2003; Chapter 1 section 1 4.2.3; Chapter 4 sections 4.3 and 4.4) has resulted in mobility-impaired patients in need of antithrombotic therapy being marginalized with respect to receipt of oral anticoagulation. The positive outcomes with respect to anticoagulation control and safety observed in this study might encourage local GPs to initiate warfarin therapy in this high risk vulnerable group of patients. However, whether it will have an effect on GPs' willingness to be

directly involved in anticoagulation service provision remains to be seen. A reduction in marginalization should increase the numbers of patients receiving warfarin and would increase the likelihood of meeting local stroke reduction targets. However, increased funding is needed to ensure that all mobility-impaired patients wanting domiciliary service provision can be offered it. The redesign of the BLT anticoagulation services has taken a high risk, high maintenance group away from the hospital setting and provided a primary care alternative, addressing some of the issues of increasing burden on the BLT anticoagulation practitioners. The support of the service development by the entire BLT anticoagulation team and by relevant stakeholders, made the domiciliary services an example of a multidisciplinary approach to service delivery. The use of NPT (model 2) and the emphasis on patient satisfaction, is in line with the Government's call for the use of available technology and a patient-centred approach to service development (Spoonful of sugar; Audit Commission 2001; Our Health, Our Care, Our Say; Department of Health 2006a). Further, the domiciliary service trial adds to the evidence base on anticoagulation service developments. Clinical governance is at the forefront of the NHS' efforts to continuously modernise and improve provision of healthcare. The three main aspects that clinical governance seeks to address are the management of quality, risk and finance. This study has focussed on the first two factors. The next stage of the service development will involve a full economic evaluation of the services, including the impact of the pharmacist's interventions.

Section 1.3 of this thesis provides an overview of the Government's agenda and outlines areas where pharmacists have a role. Despite the current challenges within the modernisation of the NHS, there are also opportunities. The Government recognises that for some time pharmacists have been an underutilised resource and that they have a key role to play in achieving targets and supporting effective medicines management in older patients (Pharmacy in the Future; Department of Health 2000b; Medicines and Older People; 2003). It also recognises that a lack of time and resources may be a barrier to pharmacists providing key services and advocates the development of skill mix within pharmacy (National Institute for Clinical Excellence 2005). The current climate of modernisation within the NHS, should be an opportunity for the pharmacy profession to change its focus from supply of medicines to provision of advice and services ((National Institute for Clinical Excellence 2005). However, whilst there are number of papers and initiatives outlining the opportunities for the pharmacy profession to develop, few appropriately tackle the apparently thorny issue of funding.

With respect to domiciliary anticoagulation services, pharmacists are well-placed to provide such a service (Hall and Radley 1994; Coleman *et al.* 2004) and would appear to be willing to provide other

services such as medication review during domiciliary visits to ensure economic viability (Pharmacy Forum; Developmental Phase).

Whilst the findings of the study were largely positive with respect to the predefined outcomes measured, the issue of funding such service developments remains to be clarified.

The outcome of the study begs the following questions:

- Is it possible for the full potential of the Government's NHS modernisation agenda to be realised under the current climate of cost savings within the NHS?
- If the Pharmacy profession is an under-utilised resource (Department of Health 2000b), why are resources for pharmacist remuneration scarce?

These questions are outside the scope of the study, but give an idea of the gap between what policy advocates and what current practice allows. The media reports that the NHS is currently facing a cash flow crisis, many Trusts have overspent on their budgets and are being forced to halt service developments and freeze vacant posts in an attempt to save money. Indeed, some NHS employees are being faced with redundancy. Whilst this current climate does not fit in with the Government's modernisation agenda, the forced and fast momentum of change within the NHS appears to have been the cause of much of the problems. The disparity between the rhetoric and reality is all too apparent on the ground; with what seems like a continuous stream of targets from the Government with little extra resource to fund innovative service redesign. NHS managers are left in a quandary: maintain the status quo or continue to invest in research and service redesign, which might prove unsustainable in subsequent budget years.

With the move to practice-based commissioning, practices now have more power to tailor services through directing funds as they see fit to the needs of their practice population, whether this will be a useful tool in encouraging multidisciplinary working and innovative service use remains to be seen.

Whilst the Government encourages innovation in service delivery it appears to have underestimated the resources required to actually evoke lasting positive changes to the delivery of health services.

6.10 Study Conclusions

The initial call for this study was brought about by concerns of the anticoagulation team at BLT that felt services were no longer adequate for their patient population. Staff were eager to push forward service developments but wanted to do so in a systematic way, ensuring that there was service user and provider input. Further, it was understood that service developments had been taking place elsewhere and reviewing the research literature would provide a foundation for local service redesign. The study utilised an evidence-based approach in the development and evaluation of a complex health intervention in a local setting.

The thesis attempted to answer some key questions. The key questions were:

- i. Are patients satisfied with the current anticoagulation service?
- ii. Which patient groups could be prioritised for service developments?
- iii. How should BLT anticoagulation services be developed?
- iv. How do service developments affect patient satisfaction?
- v. Are anticoagulation service developments suitable in terms of anticoagulation control and patients' safety?

Despite the previously outlined limitations, the study answered these questions; BLT anticoagulation patients were largely satisfied with the service they were receiving. However there was room for improvement with regards to the waiting times, the mode of blood sampling and the transport service for the mobility-impaired. Multidisciplinary discussions alongside patient satisfaction data revealed that mobility-impaired patients should be prioritised for service developments. The research perspective underpinning the study directed the design of the intervention, ensuring that not only was the development relevant to the local service users and providers and in line with the Government's agenda but also that the research contributed to the available literature on anticoagulation service developments. This evidence-based approach to service developments resulted in an increase in patient satisfaction without compromising patients' anticoagulation control and safety.

The following hypotheses were posed at the start of the study:

- I. An evidence-based approach can be integrated with a pragmatic approach to ensure local anticoagulation service developments are relevant, can be implemented and are sustainable.
- II. Service development, incorporating service user and provider feedback and the current evidence base from literature will increase patient satisfaction with anticoagulation services when compared to the traditional anticoagulation service model.
- III. The approach to service developments will ensure that anticoagulation control and safety of the developed domiciliary services for BLT mobility-impaired patients will be comparable to that achieved with the traditional service model.

The first hypothesis was not fully confirmed; whilst the approach taken should have resulted in the implementation of sustainable services a lack of funds resulted in a hybrid of the evaluated services being implemented instead. The latter two hypotheses were confirmed despite study limitations.

As discussed, throughout the study a balance between theory and practicalities was struck to give rise to a pragmatic approach to service development. The research project highlighted the complexity of carrying out research alongside practice. In addition, it gave some insight into the potential barriers of applying research into service developments and pharmacy practice.

In clinical practice, service developments often take place over a protracted period of time (Baird 2001) with discussions and feedback sessions between stakeholders. A main driver for service development is patient need, the main limiting factor / barrier is available resources. Whilst service development has been conducted in an ad hoc manner (Baird 2001) this study utilised a research perspective to provide both relevance and rigour.

The results from the study suggest that the domiciliary anticoagulation services were the preferred mode of service delivery by both the patients receiving them and the BLT anticoagulation practitioners and that the evidence-based domiciliary anticoagulation service models were suitable alternatives to the traditional anticoagulation service model. Future work should explore the financial implications of each model and larger studies are needed to determine whether the alternative services might be useful elsewhere.

In conclusion, challenges exist with the broad concepts of undertaking research in practice and implementing research evidence in both the practice and policy settings (the macro level), there are

challenges with appropriate (and pragmatic) study design and measurement (the micro level), as well as evaluating the unknown (or at least not fully known) and therefore, the gap between expected and actual. These are the foundations for training and educating practitioners to undertake research and change their practice (and that of others) based on what they find, rather than anecdote. Such challenges are to be faced not avoided if health service development is to be truly evidence-based and patient-centred.

References

Acomb, C. (2001) The role of the pharmacist in the home treatment of deep vein thrombosis. *Pharmacy in Practice* 250-253.

Adams, P. (1998) Drug interactions that matter: Warfarin. *Pharmaceutical Journal*. **261** 704-707.

Akhtar, W, Reeves, WC, Movahed, A (1998) Indications for anticoagulation in atrial fibrillation. *American Family Physician* **58** 130-135.

Aldred, D.P., Zermansky, A.G., Petty, D.R., Raynor, D.K., Thornton, S., Bowie, P. (2003) Clinical medication review by a pharmacist for older people in care homes: preliminary report. *International Journal of Pharmacy Practice* **11** R90.

Alonso, R. R., Puche Lopez, N., de la Fuente Arriaran, M. D., Garcia Monterrubio, L. (1995) Therapeutic quality control of follow-up of oral anticoagulation in primary care: 4-year experience. *Aten Primaria*. **15** 555-560.

Altman, D. G. (1991) Practical statistics for medical research. Chapman and Hall, London.

Amos, R. (2006) A potential disadvantage of developing primary care anticoagulation services could be a loss of the clinical expertise of anticoagulation specialists such as consultant haematologists. (Personal communication 2006).

Amruso, N. A. (2004) Ability of clinical pharmacists in a community pharmacy setting to manage anticoagulation therapy. *Journal of the American Pharmacists Association*. **44 (4)** 467 - 471.

Anderson, R. (1987) The unremitting burden on carers. *British Medical Journal (Clinical Research Ed)* **294(6564)** 73-74

Anderson, D. R., Harrison, L., Hirsh, J. (1993) Evaluation of a portable prothrombin time monitor for home use by patients who require long-term oral anticoagulant therapy. *Archives of Internal Medicine*. **153(12)** 1441-1447.

Ansell, J., Tiarks, C., Hirsh, J., McGehee, W., Adler, D. S., Weibert, R. T. (1991) Measurement of the activated partial thromboplastin time from a capillary (fingerstick) sample of whole blood. *American Journal of Clinical Pathology*. **95** 222-227.

Ansell, J. E., Patel, N., Ostrovsky, D., Nozzolillo, E., Peterson, A. M., Fish, L. (1995) Long-term patient self-management of oral anticoagulation. *Archives of Internal Medicine*. **155** (20) 2185-2189.

Ansell, J. E., Hughes, R. (1996) Evolving models of warfarin management: anticoagulation clinics, patient self-monitoring, and patient self-management. *American Heart Journal* **132** 1095-1100.

Ansell, J. E. (1999) Empowering patients to monitor and manage oral anticoagulation therapy. *The Journal of the American Medical Association*. **281** (2) 182-183.

Ansell, J., Hirsh, J., Dalen, J., Bussey, H., Anderson, D., Poller, L., Jacobson, A., Deykin, D., Matchar, D. (2001) Managing oral anticoagulant therapy. *Chest*. **119** (suppl.1) s22-38.

Asadi-Lari, M., Tamburini, M., Gray, D. (2004) Patients' needs, satisfaction, and health related quality of life: towards a comprehensive model. *Health and Quality of Life Outcomes* **2** 1-15.

Attkisson, C. C., Zwick, R. (1982) The client satisfaction questionnaire. Psychometric properties and correlations with service utilization and psychotherapy outcome. *Evaluation and Programme Planning*. **5**(3) 233-237.

Attkisson, C. C., Greenfield, T. K. (1994) Client Satisfaction Questionnaire - 8 and Service Satisfaction Scale - 30, in *The use of Psychological Testing for Treatment Planning and Outcome Assessment*, M. E. Maruish, ed., Lawrence Erlbaum Associates.

Attkisson, C. C., Greenfield, T. K. (1995) The Client Satisfaction Questionnaire (CSQ) Scales: A history of scale development and a guide for users. (Unpublished Report) Department of Psychiatry, University of California at San Francisco. 1-15.

Attkisson, C. C., Greenfield, T. K. (2000) The Client Satisfaction Questionnaire - 8 and the Service Satisfaction Scale - 30, in *Psychological testing: Treatment planning and outcome assessments*. 2nd Edition. M. Maurish, ed., Hillsdale, N.J: Lawrence Erlbaum Associates.

Attkisson, C. C., Greenfield, T. K. (2004) The UCSF Client Satisfaction Scales: I. The Client Satisfaction Questionnaire-8. *The use of psychological testing for treatment planning and outcomes assessments*. Volume 3 799 - 811. 3rd Edition. M. Maurish, ed., Mahwah, N.J: Lawrence Erlbaum Associates.

Audit Commission. (2001) A spoonful of sugar — medicines management in NHS hospitals. London: Audit Commission.

BAATAF Investigators. (1990) The effect of low-dose warfarin on the risk of stroke in patients with non-rheumatic atrial fibrillation. *New England Journal Medicine*. **323** 1505-1511.

Baglin, T.P., Keeling, D.M., Watsons, H.G. for the British Committee for Standards in Haematology. (2006) Guidelines on oral anticoagulation (warfarin): third edition – 2005 update. *British Journal of Haematology*. **132** 277-285.

Baird, A. (2001) Anticoagulation in general practice. *Practice Nursing*. **10 (18)** 21 - 26.

Baker, R. (1997) Pragmatic model of patient satisfaction in general practice: progress towards a theory. *Quality in Health Care*. **6** 201-204.

Barts and The London Trust: General Risk Assessment Form. (1997).

Barts and The London Trust: Anticoagulation Team. (1998) *Training Programme for anticoagulation practitioners*. Barts and The London Trust.

Barts and The London Trust. (1999) Occupational Therapy Service: Safety on Community Visits Policy. St. Bartholomew's Hospital internal publication. *Barts and The London Trust*.

Barts and The London Trust. (2000) Phlebotomy Handbook. *Barts and The London Trust*.

Barts and the London Trust. (2001) Safe working procedure for lone workers within the peritoneal dialysis department. St. Bartholomew's Hospital internal publication. *Barts and The London Trust*.

Barts and The London Trust. (2003a) Patient Group Direction for the Supply, Administration and Dosing of Anticoagulants by the Authorised Pharmacists and Nurse Practitioners working in the Anticoagulation Clinic. *Barts and The London Trust*.

Barts and The London Trust. (2003b) Standard Operating Procedure for the use of the CoaguChek S NPT device in the BLT anticoagulation clinic. *Barts and The London Trust*.

Barts and The London Trust: Anticoagulation Team. (2003c) *Anticoagulation Clinic Training Manual For C/D Clinical Pharmacist*.

Barts and The London Trust. (2005) Barts and The London Trust. <http://www.bartsandthelondon.org.uk/aboutus/introducing.asp>

Bateson, C. (2004) Evaluating the effectiveness of a pharmaceutical intervention at the hospital discharge interface: An evidence based approach. London: The School of Pharmacy *PhD Thesis*.

Bauer, M., Bohrer, H., Aichele, G. Bach, A. Martin, E. (2001) Measuring patient satisfaction with anaesthesia: perioperative questionnaire versus standardised face-to-face interview. *Acta Anaesthesiologica Scandinavica*. **45** (1) 65 - 72

BBC Talking point. (2001) NHS: Should government targets be scrapped? news.bbc.co.uk/1/hi/talking_point/1719093.stm

Bellelli, G., Barbisoni, , Gusmeri, A., Sabatini, T., Rozzini, R., Trabucchi, M. (1999) Underuse of anticoagulation in older patients with chronic atrial fibrillation: malpractice or accuracy? *Journal of the American Geriatrics Society*. **47** 1034-1035.

Bellingham, C. (2001) Point-of-care testing in the community: a new role for pharmacists. *Pharmaceutical Journal* **267** 256-257.

Bernado, A. (1995) Experience with patient self-management of oral anticoagulation. *Journal of Thrombosis and Thrombolysis* **2** 321-325.

Beyth, R.J., Quinn, L., Landefeld, S. (2000) A multicomponent intervention to prevent major bleeding complication in older patients receiving warfarin. *Annals of Internal Medicine*. **133** 687-695.

Bhattacharya, D., Wright, D.J., Purvis, J.R. (2003) Pharmacist domiciliary visiting: Review of English services. *International Journal of Pharmacy Practice*. **11** R8.

Black, N. (1994) Why we need qualitative research. *Journal of Epidemiology and Community Health*. **48(5)** 425-426.

Bland JM, Altman DG. (1987). Statistical methods for assessing agreement between measurement. *Biochimica Clinica*, **11** 399-404.

Blann, A. D., Landray, M. J., Lip, G. Y. (2002) ABC of antithrombotic therapy: An overview of antithrombotic therapy. *British Medical Journal*. **325(7367)** 762-765.

Blann, A. D., Fitzmaurice, D. A. Lip, G. Y. (2003) Anticoagulation in hospitals and general practice. *British Medical Journal*. **326** 153-156.

Boehringer Mannheim Diagnostic. (1995) aPTT policies and procedures from CoaguChek Plus Policy and Procedure Manual.

Bowling, A. (2002) *Research Methods in Health*. Buckingham: Open University Press.

Breckenridge, A. M. (1977) Interindividual differences in the response to oral anticoagulants. *Drugs* **14(5)** 367-375.

Brennan, P.F. (1995) Patient satisfaction and normative decision theory. *Journal of the American Medical Informatics Association*. **2** (4) 250 – 259.

British Committee for standards in Haematology. Haemostasis and Thrombosis Task Force (1998) Guidelines on oral anticoagulation: third edition. *British Journal of Haematology*. **101** 374-387.

British Heart Foundation (2006) Medicines and Supplements: Warfarin.

<http://www.bhf.org.uk/questions/index.asp?secondlevel=1172&thirdlevel=1392#6475>

British Medical Association and Royal Pharmaceutical Society of Great Britain (1988) *British National Formulary*, 16th Edn. London: BMA and RPSGB.

Bryman, A., Cramer, D. (1997) *Quantitative data analysis with SPSS for Windows a guide for social scientists*. London: Routledge.

Burns N., Still E. (2003) Pharmaceutical care—a model for elderly patients. *Hospital Pharmacist*. **10** 266–268.

Callaghan, D., (2006) Who really made the NHS sick? *Accountancy Age*.
<http://www.accountancyage.com/accountancyage/analysis/2155676/really-made-nhs-sick>

Calman, KC. (1993), *Hospital Doctors: Training for the future. The report of the working group on specialist medical training*. HMSO, London.

Cannegieter, S.C., Rosendaal, F.R., Wintzen, A.R., van der Meer, F.J.M., Vandenbroucke, J.P., Briet, E. (1995) Optimal oral anticoagulant therapy in patients with mechanical heart valves. *New England Journal of Medicine*. **333** 11-17.

Carley, S. D., Mackway-Jones, K., Donnan, S. (1999) Delphi study into planning for care of children in major incidents. *Archives of disease in childhood*. **80** 406 - 409.

Carrasquillo, O., Orav, E.J., Brennan, T.A., Burstin, H.R. (1999) Impact of language barriers on patient satisfaction in an emergency department. *General Internal Medicine*. **14**(2) 82 – 87.

Carter, S., Garside, P., Black, A. (2003) Multidisciplinary team working, clinical networks, and chambers; opportunities to work differently in the NHS. *Quality, Safety and Health Care*. **12** suppl 1 25 - 28.

Casey, M., Hanley, K. (2001) A measurement of the efficacy of anticoagulation monitoring in a general practice based setting. *Irish Medical Journal*. **94**(8) 245-246.

Chatfield, C. (2005) Time-series forecasting. *Significance* **2** 131-133.

Chaudry, R., Scheitel, SM., Stroebe, R.J., Santrach, P.J., Dupras, DM., Tangalos, EG. (2004) Patient satisfaction with point-of-care international normalized ratio testing and counselling in a community internal medicine practice. *Managed Care Interface* **17(3)** 44-46.

Chiquette, E., Amato, M. G., Bussey, H. I. (1998) Comparison of an anticoagulation clinic with usual medical care: anticoagulation control, patient outcomes, and healthcare costs. *Archives of Internal Medicine*. **158(15)** 1641-1647.

CHtPCT (2005) *City and Hackney Health Improvement and Modernisation Programme: 2005 - 2008*.
www.chpct.nhs.uk

Cohen, I. A. (1985) Evaluation of a pharmacist managed anticoagulation clinic. *Journal of Clinical and Hospital Pharmacy*. **10** (2) 167-175.

Cohen, G., Forbes, J., Garraway, M. (1996) Can different patient satisfaction survey methods yield consistent results? Comparison of three surveys. *British Medical Journal*. **313(7061)** 841-844.

Coleman, B., Patterson, D., Long, M. (2003) Setting quality standards for a community pharmacist-led anticoagulant clinic. *Pharmaceutical Journal*. **270** 308-311.

Coleman, 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*. **273** 822-824.

Connolly, S. J., Laupacis, A., Gent, M., Roberts, R. S., Cairns, J. A., Joyner, C. (1991) Canadian Atrial Fibrillation Anticoagulation (CAFA) Study. *Journal of The American College of Cardiology*. **18** 349-355.

Connor, C. A., Wright, C. C., Fegan, C. D. (2002) The safety and effectiveness of a nurse-led anticoagulant service. *Journal of Advanced Nursing*. **38 (4)** 407-415.

Conte, R.R., Kehoe, W.A., Nielson, N., Lodhia, H. (1986) Nine-year experience with a pharmacist-managed anticoagulation clinic. *American Journal of Hospital Pharmacy*. **43** 2460-2463.

Cox, C. (2004) Evidence-Based Medicine. *University of Hertfordshire*.
www.herts.ac.uk/lis/subjects/health/ebm.htm

Cromheecke, M., Levi, M., Colly, L, Mol, B., Prins, M., Hutten, B., Mak, R., Keyzers, K., Buller, HR. (2000) Oral anticoagulation self-management and management by a specialist anticoagulation clinic: a randomised cross-over comparison. *Lancet*. **356** 97-102.

Crow R., Gage H., Hampson S., Hart J., Kimber A., Storey L., Thomas, H. (2002) The measurement of satisfaction with healthcare: implications for practice from a systematic review of the literature. *Health Technology Assessment*. **6** (32).

Darley, M., Siller, C., Anderson, D. (2004) Domiciliary phlebotomy for elderly people with mental illness. *Psychiatric Bulletin* **28** 120 - 122.

Dawes, M., Summerskill, W., Glasziou, P., Cartabellotta, A., Martin, J., Hopayian, K., Porzolt, F., Burls, A., Osborne, J. (2005) Second International Conference of Evidence-Based Health Care Teachers and Developers. Sicily statement on evidence-based practice. *BMC Medical Education* **5**(1) 1

Delaney, B. C., Hyde, C. J., McManus, R. J., Wilson, S., Fitzmaurice, D. A., Jowett, S., Tobias, R., Thorpe, G. H., Hobbs, F. D. (1999) Systematic review of near patient test evaluations in primary care. *British Medical Journal*. **319**(7213) 824-827.

De Miguel, D., Burgaleta, C., Reyes, E., Pascual, T. (2003) Capillary whole blood testing by a new portable monitor. Comparison with standard determination of the international normalised ratio. *American Journal of Clinical Pathology*. **120** (1) 28-33.

Department of Health (1997) *The New NHS: modern, dependable*. London: Stationary office. (Cm 3807).

Department of Health (1998) *A first class service: Quality in the New NHS*. London: Department of Health.

Department of Health (1999) *Saving lives: Our Healthier Nation*. London: The stationary office. (Cm 4386).

Department of Health (2000a) *An organisation with a Memory*. London: The Stationary office.

Department of Health. (2000b) *Pharmacy in the Future: implementing the NHS Plan - a programme for pharmacy in the National Health Service*. London: The Stationary Office.

Department of Health (2000c) *The NHS plan : a plan for investment : a plan for reform*. London: Stationery office. (Cm 4818 - 1).

Department of Health (2001a) *National Service Framework For Older People Standard five: Stroke*. London: The Stationery office.

Department of Health (2001b) *The expert patient: a new approach to chronic disease management for the 21st century*. London: The Stationery office.

Department of Health (2001c) *Involving Patients and the Public in Healthcare: A Discussion Document*. London: The Stationery office.

Department of Health (2001d) *Teaching PCTS: 2001*. London: Department of Health.

Department of Health (2001e) *Evidence into practice: Standing Medical Advisory Committee advice*. London: Standing Medical Advisory Committee.

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4120727&chk=NuPyio

Department of Health (2002a) *A Guide to NHS Foundation Trusts*. London: Department of Health.

Department of Health (2002b) *Improvement, expansion and reform - the next 3 years: priorities and planning framework 2003-2006*. London: Department of Health.

Department of Health (2003) *Medicines and Older People: Implementing medicines-related aspects of the NSF for Older People*. London: Department of Health.

Department of Health (2004a) *Building a safer NHS for patients: Improving medication safety. A report by the Chief Pharmaceutical Officer*. London: Department of Health. URL: <http://www.dh.gov.uk/PublicationsAndStatistics>.

Department of Health (2004b) National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2004. London: The Stationery office.

Department of Health (2004c) *NHS Improvement Plan: Putting People at the Heart of Public Services*. London: The Stationery office. Cm 6268

Department of Health (2004d) *Practice based commissioning: Engaging practices in commissioning*. London: Department of Health. [wwwdocument. url: http://www.dh.gov.uk/assetRoot/04/09/03/59/04090359.pdf](http://www.document.url:04/09/03/59/04090359.pdf)

Department of Health (2005a) *Commissioning a Patient-led NHS*. London: Department of Health

Department of Health (2005b) *Supporting People with Long Term Conditions. An NHS and Social Care Model to support local innovation and integration*. London: The stationery office.

Department of Health (2006a) *Our Health, Our Care, Our Say: A New Direction for Community Services*. London: The Stationery office. (Cm 6737).

Department of Health (2006b) Improving patients' access to medicines: A guide to implementing nurse and pharmacist independent prescribing within the NHS in England. London: The Department of Health.

Department of the Environment, Transport and the Regions. (200) Indices of deprivation. London: Department of the Environment, Transport and the Regions. www.urban.odpm.gov.uk/research/summaries/03100/pdf/rrs03100.pdf

De Souza, A. (2005) The New Pharmacy Contract: Community Pharmacy Development. *City and Hackney Teaching Primary Care Trust*.

Eccles, M., Mason, J. (2001) How to develop cost-conscious guidelines, *Health Technology Assessment*. **5** 16.

England, E. (2005) How interrupted time series analysis can evaluate guideline implementation, *Pharmaceutical Journal*. **275** 344-347.

Engova, D., Duggan, C., Shearer, M., Arain, S., Harrington, D., McElwain, S., Cotter, F., Madhani, M., MacCallum, P. (2002) Influence of Cytochrome P450 CYP2C9 Polymorphisms on S- and R-Enantiomers of Warfarin. *British Journal of Haematology*. **117** (suppl. 1) 94-100.

Ezekowitz, M. D., Bridgers, S. L., James, K. E. (1992) Warfarin in the prevention of stroke associated with non-rheumatic atrial fibrillation. *New England Journal of Medicine* **327** 1406-1412.

Fitzmaurice, D. A., Hobbs, F. D., Murray, J. A. (1996a) Monitoring oral anticoagulation in primary care. *British Medical Journal*. **312**(**7044**) 1431-1432.

Fitzmaurice, D. A., Hobbs, F. D., Murray, E. T., Bradley, C. , Holder, R. (1996b), Evaluation of computerized decision support for oral anticoagulation management based in primary care. *British Journal of General Practice*. **46**(**410**) 533-535.

Fitzmaurice, D. A., Hobbs, F. D., Murray, E. T. (1998) Primary care anticoagulant clinic management using computerized decision support and near patient International Normalised Ratio (INR) testing: routine data from a practice nurse-led clinic. *Family Practice*. **15**(**2**) 144-146.

Fitzmaurice, D. A., Hobbs, F. D., Murray, E. T., Holder, R. L., Allan, T. F., Rose, E. (2000) Oral anticoagulation management in primary care with the use of computerized decision support and near-patient testing: a randomized, controlled trial. *Archives of Internal Medicine*. **160**(**15**) 2343-2348.

Fitzmaurice, D. A., Machin, S. J. (2001) Recommendations for patients undertaking self management of oral anticoagulation. *British Medical Journal*. **323** (**7319**) 985-989.

Fitzmaurice, D. A., Murray, E. T., Gee, K. M., Allan, T. F. (2001) Does the Birmingham model of oral anticoagulation management in primary care work outside trial conditions? *British Journal of General Practice*. **51(471)** 828-829.

Fitzmaurice, D. A., Murray, E. T., Gee, K. M., Allan, T. F., Hobbs, F. D. (2002) A randomised controlled trial of patient self management of oral anticoagulation treatment compared with primary care management. *Journal of Clinical Pathology*. **55(11)** 845 - 849.

Fitzmaurice, D. A., Kesteven, G.K. (2003) How to evaluate the performance of oral anticoagulation clinics. *British Journal of Cardiology*. **10** 370-372.

Fitzmaurice, D. A., Kesteven, G. K., Murray, E. T., McManus, R. J. M. (2003) A systematic review of outcome measures reported for the therapeutic effectiveness of oral anticoagulation. *Journal of Clinical Pathology*. **56** 48-51.

Fitzmaurice, D.A., Murray, E.T., McCahon, D., Holder, R., Raftery, J.P., Hussain, S., Sandhar, H., Hobbs, F.D.R. (2005) Self management of oral anticoagulation: randomised trial. *British Medical Journal*. **331(7524)** 1057. Electronic publication, url: <http://www.bmj.com/cgi/rapidpdf/bmj.38618.580903.AEv1>

Foulsham, R.M., Goodyer, L.I. (2005) The Development and delivery of pharmaceutical domiciliary services to housebound patients. 11th Health Services Research and Pharmacy Practice Conference. London: Royal Pharmaceutical Society; 2005.

Froom, P., Miron, E., Barak, M., (2003) Oral anticoagulants in the elderly. *British Journal of Haematology*. **120** 526 - 528.

Garabedian-Ruffalo, S.M., Gray, D.R., Sax, M.J., Ruffalo, R. (1985) Retrospective evaluation of a pharmacist-managed warfarin anticoagulation clinic. *American Journal of Hospital Pharmacy*. **42** 304 - 308.

Gardiner, C. (2003) MHRA; Department of Health Evaluation Centre: CoaguChek S is appropriate for use in a domiciliary anticoagulation service. Personal Communication

Garson, G.D. (1998) Multiple Regression. www2.chass.ncsu.edu/garson/PA765/regress.htm

Gaston, L., Sabourin, S. (1992) Client satisfaction and social desirability in psychotherapy. *Evaluation and Program Planning*. **15** 227-231.

Gordon, G., Morse, E. V. (1975) Evaluation Research. *Annual review of sociology*. **1** 339 - 361.

Government Actuary (1999) *National Insurance Fund Long Term Financial Estimates*, The Stationery Office, Cm 4406.

Gray, DR., Garabedian-Ruffalo, SM., Chretien, SD. (1985) Cost-justification of a clinical pharmacist-managed anticoagulation clinic. *Drug intelligence and clinical Pharmacy*. **19** 575-580.

Green, S., Goodwin, H., Moss, J. (1996) Problems in General Practice. Medication Errors. Manchester: Medical Defence Union.

Greene, J. C., Caracelli, V. J., Graham, W. F. (1989) Toward a conceptual framework for mixed-method evaluation designs. *Educational Evaluation and Policy Analysis*. **11 (3)** 255-274.

Greenfield, T. K. Attkisson, C. C. (1989) Progress toward a multifactorial Service Satisfaction Scale for evaluating primary care and mental health services. *Evaluation and Program Planning*. **12** 271-278.

Greenhalgh, T., Taylor, R. (1997) *How to read a paper*. Papers that go beyond numbers (qualitative research). *British Medical Journal*. **315** 740 - 743.

Gross, C., Vogel, E.W., Dhondi, A.J. (2003) Factors influencing physicians' reported use of anticoagulation therapy in non-valvular atrial fibrillation: A cross-sectional survey. *Clinical Therapeutics*. **25** 1750-1764.

Guadagnino, C. (2003) Role of Patient Satisfaction. *Physician's News Digest*. www.physiciansnews.com/cover/1203.html

Guldvog, B. (1999) Can patient satisfaction improve health among patients with angina pectoris? *International Journal of Quality Health Care*. **11** 233-240.

Hall, J., Radley, A. S. (1994) A role for community pharmacists in the control of anticoagulant therapy. *Pharmaceutical Journal*. **252** 230-232.

Hall, J., Radley, A. S. (1995) Community and hospital pharmacist co-operation in an outreach anticoagulant clinic. *Pharmaceutical Journal*. **225 (suppl)** R24.

Harris D., Anderson C. (2003) Interventions by community pharmacists for older people with mental health problems: are they appropriate? [abstract]. *International Journal of Pharmacy Practice*. **11** R56.

Hart, R.G., Benavente, O., McBride, R., Pearce, L.A. (1999) Antithrombotic therapy to prevent stroke in patients with atrial fibrillation: a meta-analysis. *Annals of Internal Medicine* **131** 492-501.

Hasenkam, J. M., Knudsen, L., Kimose, H. H., Gronnesby, H., Attermann, J., Andersen, N. T., Pilegaard, H. K. (1997) Practicability of patient self-testing of oral anticoagulant therapy by the international normalised ratio (INR) using a portable whole blood monitor. A pilot investigation. *Thrombosis Research*. **85(1)** 77-82.

Haynes, B., Haines, A. (1998) Barriers and bridges to evidence based clinical practice. *British Medical Journal*. **317** 273 -276.

Health and Safety Executive. (1997) Successful Health and Safety Management. HSG65. London: HSE books.

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)** 34-36.

Hepler, C.D., Stand, L.M. (1990) Opportunities and responsibilities in pharmaceutical care. *American Journal of Hospital Pharmacy*. **47** 533-543.

Hermansen, C. J., Walbrandt Pigarelli, D., Sorkness, C. A., Wiederholt, J. B. (2000) The patient perspective of pharmacy clerkship students roles in pharmacist-patient relationship development and the delivery of care. *American Journal of Pharmacy Education*. **64** 413-419.

Hirsh, J., Fuster, V., Ansell, J., Halperin, J.L. (2003) American Heart Association/American College of Cardiology Foundation guide to warfarin therapy. *Circulation*. **107(12)** 1692-711.

Hobbs, R. (1996) Near patient testing in primary care. *British Medical Journal*. **312(7026)** 263-264.

Hobbs, F. D., Delaney, B. C., Fitzmaurice, D. A., Wilson, S., Hyde, C. J., Thorpe, G. H., Earl-Slater, A. S., Jowett, S., Tobias, R. S. (1997) A review of near patient testing in primary care. *Health Technology Assessment*. **1(5)**.

Holden, J., Holden, K. (2000) Comparative effectiveness of general practitioner versus pharmacist dosing of patients requiring anticoagulation in the community. *Journal of Clinical Pharmacy and Therapeutics*. **25** 49-54.

Holden, K., Holden, J. (2001) A comparative study of pharmacist and GP management of anticoagulant therapy following deviation from the target international normalised ratio. *International Journal of Pharmacy Practice*. **9** (suppl) R24.

Holm, T., Deutch, S., Lassen, J. F., Jastrup, B., Husted, S. E., Heickendorff, L. (2002) Prospective evaluation of the quality of oral anticoagulation management in an outpatient clinic and in general practices. *Thrombosis Research*. **105 (2)** 103-108.

Homerton (2005) *Annual Report - Homerton Hospital 2004 - 2005*.

Homerton (2006) Aims, targets and achievements.
<http://www.homerton.nhs.uk/about/11579694232796.html>

Horskotte, D., Piper, C., Wiemer, H. D., Schulte, H. (1996) Improvement of prognosis by home prothrombin estimation in patients with life-long anticoagulant therapy. *European Heart Journal* **17(Suppl)** s230. Abstract

Horton, J. D., Bushwick, B. M. (1999) Warfarin therapy: evolving strategies in anticoagulation. *American Family Physician*. **59(3)** 635-646.

Hudak, P.L., Wright, J.G. (2000) The characteristics of patient satisfaction measures. *Spine* **25** 3167–3177

Hunt, D. L., Haynes, R. B., Hanna, S. E., Smith, K. (1998) Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systematic review. *Journal of the American Medical Association*. **280(15)** 1339-1346.

Hylek, E. M., Skates, S. J., Sheehan, M. A. (1996) An analysis of the lowest effective intensity of prophylactic anticoagulation for patients with nonrheumatic atrial fibrillation. *New England Journal of Medicine*. **335** 540-546.

Jacobs, E. (2001) NACB evidence-based practice for POCT. Clinical Laboratory Evaluation Program. www.nacb.org/Impg/am04/Introduction_Group_Jacobs.pdf

Jones, J., Hunter, D. (1995) Qualitative Research: Consensus methods for medical and health services research. *British Medical Journal*. **311** 376-380

Jones, C. (2003) The evidence base for community pharmacy service development. *Pharmaceutical Journal*. **271** 300 - 302.

Kaatz, S. S., White, R. H., Hill, J., Mascha, E., Humphries, J. E., Becker, D. M. (1995), Accuracy of laboratory and portable monitor international normalised ratio determinations. Comparison with a criterion standard, *Archives of Internal Medicine*. **155(17)** 1861-1867.

Kagansky, N., Knobler, H., Rimon, E., Ozer, Z., Levy, S. (2004) Safety of anticoagulation therapy in well-informed older patients. *Archives of Internal Medicine*. **164** (18) 2044 - 2050.

Kalra, L., Yu, G., Perez, I., Lakhani, A., Donaldson, N. (2000) Prospective cohort study to determine if trial efficacy of anticoagulation for stroke prevention in atrial fibrillation translates into clinical effectiveness. *British Medical Journal*. **320** 1236-1239.

Keech, A.C., Gebiski, V. (2002) Managing the resource demands of a large sample size in clinical trials: can you succeed with fewer subjects? *The Medical Journal of Australia*. **177** (8) 445-447.

Khan, A., Rutter, M. (2002) The provision of anticoagulant services by primary care groups and trusts: has community pharmacy a role to play? *International Journal Pharmacy Practice* **10** (suppl) R50.

Kinnear, R., Gray, C. (2004) Regression, in *SPSS 12 made simple*, First edition, Psychology Press. 324-352.

Knowlton, CH., Thomas, OV., Willimason, A., Gammaitoni, AR., Kirchain, WR., Buttaro, M., Zarus, SA. (1999) Establishing community pharmacy-based anticoagulation education and monitoring programs. *Journal of American Pharmacists Association*. **39**(3) 368-374.

Kortke, H., Minami, K., Breymann, T., Seifert, D., Baraktaris, A., Wagner, O., Kleikamp, G., el-Banayosy, A., Mirow, N., Korfer, R. (2001) [INR self-management after mechanical heart valve replacement: ESCAT (Early Self-Controlled Anticoagulation Trial)]. *Z.Kardiol*. **90** Suppl 6 118-124.

Krass, I., Bajorek, B.V., Ogle, S.J., Duguid, M.J., Shenfield, G.M., (2002) Consumers' and healthcare professionals' perspectives on the use of antithrombotic therapy in elderly patients with atrial fibrillation. *National Medicines Symposium: Linking people, actions and policy for Quality Use of Medicines*. Abstract **6** 26.

Larsen, D. L., Attkisson, C. C., Hargreaves, W. A., Nguyen, T. D. (1979) Assessment of client/patient satisfaction: development of a general scale. *Evaluation and Program Planning*. **2** (3) 197-207.

Larson, L. N., Rovers, J. P., MacKeigan, L.D. (2002) Patient satisfaction with pharmaceutical care. *Journal of the American Pharmaceutical Association*. **42** (1) 44 - 50.

Lawler, E. E. (1973) *Motivation in work organizations*. California: Brooks/Cole Publishing Co.

Lee, Y., Schommer, JC. (1996) Effect of a pharmacist-managed anticoagulation clinic on warfarin-related hospital readmissions. *American Journal of Health-System Pharmacy*. **53** 1580-1583.

LeVois, M., Nguyen, T. D., Attkisson, C. C. (1981) Artifact in client satisfaction assessment: experience in community mental health settings. *Evaluation and Programme Planning*. **4**(2) 139-150.

Linder-Pelz, S. (1982) Toward a theory of patient satisfaction. *Social Science and Medicine*. **16** 577-582.

Lip, G. Y., Kamath, S., Hart, R. G. (2002) ABC of antithrombotic therapy: Antithrombotic therapy for cerebrovascular disorders. *British Medical Journal*. **325 (7373)** 1161-1163.

Lipkin, M., Schwartz, M.D. (2000) I can't get no patient or practitioner satisfaction. *Journal of General Internal Medicine*. **15(2)** 140 – 141

Lipman, T., Murtagh, M.J., Thomson, R. (2004) How research conscious GPs make decisions about anticoagulation in patients with atrial fibrillation: a qualitative study. *Family Practice*. **21** (3) 290 - 298.

Livingston, S. (2003) Stroke. *Pharmaceutical Journal*. **271** (7256) 19-21.

Lizotte, A., Quessy, I., Vanier, M., Caron, S., Darveau, M., Dube, A., Gilbert, E., Blais, N., Lalonde, L. (2002) Reliability, Validity and Ease of use of a portable point-of care coagulation device in a pharmacist-managed anticoagulation clinic. *Journal Thrombosis and Thrombolysis*. **14(3)** 247-254.

MacCallum, K. P. (2004) The reason for patients' sporadic INRs is sometimes clear, whilst at other times, there has been no apparent factors that can be attributed to observed peaks and troughs in INR. (Personal Communication).

Macgregor, S. H., Hamley, J. G., Dunbar, J. A., Dodd, T. R., Cromarty, J. A. (1996) Evaluation of a primary care anticoagulant clinic managed by a pharmacist. *British Medical Journal* **312** 560.

Macgregor, S. (1999a) A general practitioner perspective. *Primary Care Pharmacy*. **1** (1) 18-19.

Macgregor, S. (1999b) Looking at anticoagulation services, *Primary Care Pharmacy*. **1** (1).www.pharmj.com/PrimaryCarePharmacy/199911/articles/anticoagulation.html

Majeed, A., Moser, K., Carroll, K. (2001) Trends in the prevalence and management of atrial fibrillation in general practice in England and Wales, 1994 - 1998: analysis of data from the general practice research database. *Heart*. **86** (3) 284-288.

Management of health and safety at work. (1999) *Management of Health and Safety at Work Regulations. Approved Code of Practice and guidance* (Second edition) Suffolk: HSE Books 2000.

Mannotti, C., Moia, M., Palareti, G., Ria, L., and Dettori, A. G. (2001) Effect of computer-aided management on the quality of treatment in anticoagulated patients: a prospective, randomized, multicenter trial of APROAT (Automated PProgram for Oral Anticoagulant Treatment). *Haematologica*. **86** 1060-1070.

Mason, P. (2004) Near-patient testing in the pharmacy. *Pharmaceutical Journal*. **272** 708-710.

McCahon, D., Fitzmaurice, D. A., Murray, E. T., Fuller, C. J., Allan, R., Raftery, J. (2003) SMART: Self-Management of Anticoagulation, a Randomised Trial. *Family Practice*. **4** 11.

McCormick, D., Gurtwitz, J.H., Goldberg, R.J., Becker, R., Tate, J.P., Elwell, A., Radford, M.J. (2001) Prevalence and Quality of Warfarin Use for Patients With Atrial Fibrillation in the Long-term Care Setting. *Archives Internal Medicine*. **161** 2458-2463

McCurdy, S. A., White, R. H. (1992) Accuracy and precision of a portable anticoagulation monitor in a clinical setting. *Archives of Internal Medicine*. **152** 589-592.

McCurdy, M. (1993) Oral anticoagulation monitoring in a community pharmacy. *American Pharmacists*. NS33 **10** 61-70.

McDonnell, A., Wilson, R., Goodacre, S. (2006) Evaluating and implementing new services. *British Medical Journal*. **332** 109 -112.

Medical Devices Agency. (2001) Roche CoaguChek S coagulometer: Evaluation Report MDA 01026.

Medical Devices Agency. (2002) Management and Use of IVD Point of Care Test Devices. Bulletin MDA DB(2002)(03).

Mediplus analysis of oral anticoagulant therapy (OAT). London: IMS Health, 1999. (Study number MP990207.)

Medicines and Healthcare products Regulatory Agency. (2004) Patient self-testing using the Roche CoaguChek S: Evaluation Report MHRA 04002. Medicines and Healthcare products Regulatory Agency.

Monette, J., Gurwitz, J., Rochon. (1997) Physician attitudes concerning warfarin for stroke prevention in atrial fibrillation: Results of a survey of long term care practitioners. *Journal of the American Geriatrics Society*. **45(9)**1060-5.

MRC (2000) *Medical Research Council. A framework for the development and evaluation of randomised controlled trials for complex interventions to improve health*. London: MRC.

Murray, E., Fitzmaurice, D. (1996) Oral anticoagulation therapy. *Practice Nursing*. **7(7)** 29-32.

Murray, E. T., Fitzmaurice, D. A., Allan, T. F., Hobbs, F. D. (1999) A primary care evaluation of three near patient coagulometers. *Journal of Clinical Pathology*. **52(11)** 842-845.

Murray, E. T., Greaves, M. (2003) INRs and point of care testing. *British Medical Journal*. **327** 5-6.

Murray, E. T., Fitzmaurice, D. A., McCahon, D. (2004) Point of care testing for INR monitoring: where are we now? *British Journal of Haematology*. **127(4)** 373-378.

National Assembly for Wales (2001) Tackling CHD in Wales: Implementing Through Evidence. National Assembly for Wales.

National Institute for Health and Clinical Excellence (2005) Research to explore training programmes in smoking cessation for pharmacists and pharmacy assistants. ISBN: 1846290228.

National Patient Safety Agency (2006) Risk assessment of anticoagulant therapy. London: NPSA

Nguyen, T. D., Attkisson, C. C., Stegner, B. L. (1983) Assessment of patient satisfaction: development and refinement of a service evaluation questionnaire. *Evaluation and Programme Planning*. **6** (3-4) 299-313.

Norris, P., Roswell, B. (2003) Interactional issues in the provision of counselling to pharmacy customers. *International Journal of Pharmacy Practice*. **11**(8) 135-142.

Oertel, L.B. (1999) Monitoring warfarin therapy. How the INR keeps your patient safe. *Nursing*. **29** (11) 41 - 44

Office of the Deputy Prime Minister (2004) *The English Indices of Deprivation 2004: Summary (revised)*. London: The Stationery Office.

Office for National Statistics (2001) Census: Standard Area Statistics (England and Wales 2001) [computer file]. www.statistics.gov.uk/census.

Oldridge, N., Gottlieb, M., Guyatt, G., Jones, N., Streiner, D., Feeny, D. (1998) Predictors of health-related quality of life with cardiac rehabilitation after acute myocardial infarction. *Journal of Cardiopulmonary Rehabilitation*. **18** 95-103.

O'Malley, K., Stevenson, I. H., Ward, C. A., Wood, A. J., Crooks, J. (1977) Determinants of anticoagulant control in patients receiving warfarin. *British Journal of Clinical Pharmacology*. **4** (3) 309-314.

Oppenkowski, T. , Murray, E. T., Sandhar, H. S., Fitzmaurice, D. A. (2003) External quality assessment for warfarin dosing using computerised decision support software. *Journal of Clinical Pathology*. **56** 605-607.

O'Reilly, R. A., Aggeler, M. (1970) Determinants of the response to oral anticoagulant drugs in man. *Pharmacology Review*. **22** (1) 35-96.

Ortiz, K. (2006) Demand for the domiciliary anticoagulation service has outstripped capacity. (Personal Communication).

Owens, D. J., Batchelor, C. (1996) Patient satisfaction and the elderly. *Social Science and Medicine*. **42(11)** 1483-1491.

Oxford University Press (2001) *Concise Oxford Dictionary on CD-ROM version 1.1*, Tenth Edition edn, Oxford University Press, Oxford.

Parekh, R., Ghee, C. (1987) Evaluation of a pharmacist controlled anticoagulation clinic. *British Journal of Pharmacy Practice*. **9** 370-381.

Parsons, B., Craig, G. (2003) National health service funding for community pharmacy service development in England. *Pharm J* **271** 323 -325.

Pascoe, G. C. (1983) Patient satisfaction in primary healthcare, *Evaluation and Programme Planning*. **6** 185-210.

Pascoe, G. C., Attkisson, C. C. 1983, The evaluation ranking scale: a new methodology for assessing satisfaction. *Evaluation and Programme Planning*. **6(3-4)** 335-347.

Pegg, M., Bourne, J., Mackay, A. D., Lawton, W. A., Cole, R. B. (1985) The role of the pharmacist in the anticoagulant clinic. *Journal of Royal College of Physicians*. **19** 39-44.

Pell, J., McIver, B., Stuart, Malone, D. N., Alcock, J. (1993) Comparison of anticoagulant control among patients attending general practice and a hospital anticoagulant clinic. *The British Journal of General Practice*. **43(369)** 152-154.

Pellegrini, A., Colombo, T., Quaini, E., Russo, C., Vitali, E., Donatelli, F. (1991) Mitral valve replacement with the SORIN valve. Long-term follow-up of 1,161 patients. *Texas Heart Institute Journal*. **18(1)** 16-23.

Perrero, Willoughby, D., Eggert, J., Counts, S. (2004) Warfarin therapy in older adults: Managing treatment in the primary care setting. *Journal of Gerontological Nursing*. **30 (7)** 44-54.

Petty, D., Zernansky, A. G., Raynor, D. K., Lowe, C. J., Freemantle, N., Vail, A. (2002) Clinical medication review by a pharmacist of elderly patients on repeat medications in general practice — pharmacist interventions and review outcomes. *International Journal of Pharmacy Practice*. **3** 39-46.

Poller, L., Shiach, C. R., MacCallum, K., Johansen, A. M., Munster, A. M., Magalhaes, A., Jespersen, J. (1998) Multicentre randomised study of computerised anticoagulant dosage. European Concerted Action on Anticoagulation. *Lancet*. **352 (9139)** 1505-1509.

Poller, L., Keown, M., Chauhan, N., van den Besselaar, A. M., Tripodi, A., Shiach, C., Jespersen, J. (2003) Reliability of international normalised ratios from two point of care test systems: comparison with conventional methods. *British Medical Journal*. **327(7405)** 30.

Pharmaceutical Services Negotiating Committee: PSNC. (2004) The new contract for community pharmacy.

Radley, A. S., Hall, J. (1994) The establishment and evaluation of a pharmacist developed anticoagulant clinic. *Pharmaceutical Journal*. **252** 91-92.

Radley, A. S., Hall, J., Farrow, M., Carey, J. (1995) Evaluation of anticoagulant control in a pharmacist operated anticoagulant clinic. *Journal of Clinical Pathology*. **48** 545-547.

Radley, A. S., Dixon, N., Hall, J. (2000) Primary care group anticoagulant clinics. *Primary Care Pharmacist* **1(3)** 70-72.

Rashid, S. T., Thursz, M. R., Razvi, N. A., Voller, R., Orchard, T., Rashid, S. T., Shlebak, A. A. (2005) Venous thromboprophylaxis in UK medical inpatients *Journal of The Royal Society of Medicine*. **98** 507-512.

Reinders, T., Steinke, W. E. (1979) Pharmacist management of anticoagulant therapy in ambulant patients. *American Journal of Hospital Pharmacy*. **36** 645-648.

Roberts, C., Torgerson, D. (1998) Randomisation methods in controlled trials, *British Medical Journal*. **3177(168)** 1301.

Roche Diagnostics Glossary (2004) <http://www.roche-diagnostics.com/servicebox/glossary/glossary.php?char=R>

Rodgers, H., Sudlow, M., Dobson, R., Kenny, R. A., Thomson, R. G. (1997) Warfarin anticoagulation in primary care: a regional survey of present practice and clinicians' views. *British Journal of General Practice*. **47 (418)** 309-310.

Rose, E. (1996) Audit of anticoagulant therapy. *Journal of Clinical Pathology*. **45** 5-9.

Rosendaal, F. R., Cannegieter, S. C., van der Meer, F. J., Briet, E. (1993) A method to determine the optimal intensity of oral anticoagulant therapy. *Thrombosis and Haemostasis*. **69 (3)** 236-239.

Rothwell, M. (2001) The high cost of not funding stroke research: a comparison with heart disease and cancer. *Lancet*. **357** 1612-1616.

Royal Cornwall Hospital (2000) Framework for INR testing in Primary Care in Cornwall. *Royal Cornwall Hospital*.

Rozzini, R., Sabatini, T., Trabucchi, M. (1999) Risk assessment and anticoagulation in atrial fibrillation in the elderly: malpractice or accuracy? *Stroke*. **30** 2239-2240.

Rozzini, R., Sabatini, T., Bellelli, G., Trabucchi, M. (2001) Anticoagulation in elderly patient with chronic atrial fibrillation: the need for geriatric assessment. *Age Ageing*.

Ryan, J., Gilbert, M., Rose, E. (1989) Computer control of anticoagulant dose for therapeutic management. *British Medical Journal*. **299 (6709)** 1207-1209.

Quantitative Methods. Salford University. (2005) Internet Communication.

Saal, D., Nuebling, M., Husemann, Y., Heidegger, T. (2005) Effect of timing on the response to postal questionnaires concerning satisfaction with anaesthesia care. *British Journal of Anaesthesia* **94 (2)** 206-10

Salisbury, C. (1997) Postal survey of patients' satisfaction with a general practice out of hours cooperative. *British Medical Journal*. **314** 1594.

Samsa, G. , Matchar, D. B., Goldstein, L. B., Bonito, A. J., Lux, L. J., Witter, D. M., Bian, J. (2000) Quality of anticoagulation management among patients with atrial fibrillation: results of a review of medical records from 2 communities. *Archives of Internal Medicine*. **160 (7)** 967-973.

Sandelowski, M. (2000) Combining qualitative and quantitative sampling, data collection, and analysis techniques in mixed-method studies. *Research in Nursing and Health*. **23 (3)** 246-255.

Sawicki, T. (1999) A Structured Teaching and Self-management Program for Patients Receiving Oral Anticoagulation . A randomized controlled trial. *The Journal of the American Medical Association*. **28** 145-150.

Saxena, R., Koudstaal, P.J. (2000) Anticoagulants Versus Antiplatelet Therapy for Preventing Stroke in Patients With Nonrheumatic Atrial Fibrillation and a History of Stroke or Transient Ischemic Attack. *Cochrane Database Systematic Review*. (2) CD000187.

Scherer, S., LaPier, T. K. (2001) Evidence-based practice: When numbers are not enough part I: Understanding qualitative research methods. *Cardiopulmonary Physical Therapy*. **12 (4)** 123-125.

Schommer, J.C., Kucukarslan, S.N. (1997) Measuring patient satisfaction with pharmaceutical services. *American Journal of Health System Pharmacy*. **54(23)** 2721 - 2732.

Shakespeare, J. (1994) Anticoagulation in patients with atrial fibrillation GPs struggle to meet demand: Letter. *British Medical Journal*. **308** 415.

Sheehan, O., Stinson, J. C., Feely, J. (2000) Establishing a primary care based anticoagulation clinic. *Irish Medical Journal*. **93 (2)** 45-48.

Shiach, C. R., Campbell, B., Poller, L., Keown, M., Chauhan, N. (2002) Reliability of point-of-care prothrombin time testing in a community clinic: a randomized crossover comparison with hospital laboratory testing. *British Journal Haematology*. **119 (2)** 370-24.

Sickles, J., Elston-Lafata, J., Ansell, J. (1999) Point-of-care testing in Oral Anticoagulation monitoring: implications for patient management. *Disease Management and Health Outcomes*. **6** (11) 291-301.

Smith, F. (2005) *Research Methods in Pharmacy Practice*. 2nd Edition. Pharmaceutical Press.

Southport and Formby Primary Care Trust. (2000) Lone Workers Policy. *Southport and Formby Primary Care Trust*.

SPAF Investigators. (1996) Adjusted-dose warfarin versus low-intensity, fixed-dose warfarin plus aspirin for high-risk patients with atrial fibrillation: Stroke Prevention in Atrial Fibrillation III randomized clinical trial. *Lancet* **348** 633-638.

SPSS for Windows. Statistical Package for the Social Sciences. (2001) Chicago: SPSS Inc. 11-1.

SPSS Inc. (1993) *SPSS for Windows: Trends. Release 6.0*.

Stevens, C. (2003) Talking with S. Wayne Kay: Quidel Cor's CEO shares his views - Expert Opinion - Interview. Medical Laboratory Observer ..
(Magazine Article)

Stevens, M., Reininga, I.H.F., Boss, N.A.D., van Horn, J.R. (2006) Patient satisfaction at and after discharge. Effect of a time lag. *Patient Education and Counseling* **60** 241-245

Stewart, S., Hart, C. L., Hole, D. J., McMurray, J. J. (2001) Population prevalence, incidence, and predictors of atrial fibrillation in the Renfrew/Paisley study. *Heart* **86** (5) 516-521.

Sudlow, M., Thomson, R., Thwaites, R., Rodgers, H., Kenny, R. A. *Lancet*. (1998) Prevalence of atrial fibrillation and eligibility for anticoagulants in the community. **352** 1167-1171.

Tasso, K., Behar-Horenstein, L. S., Aumiller, A., Gamble, K., Grimaudo, N., Guin, P., Mandell, T., Ramey, B. (2002) Assessing patient satisfaction and quality of care through observation and interview. *Hospital Topics*. Summer. **80**(3) 4 - 10.

Taylor, F. C., Gray, A., Cohen, H., Gaminara, L., Ramsay, M., and Miller, D. (1997) Costs and effectiveness of a nurse specialist anticoagulant service. *Journal of Clinical Pathology*. **50 (10)** 823-828.

The Department of Primary Care and General Practice (2002a) Primary Care Oral Anticoagulation Services for the 21st Century. *The University of Birmingham*.

The Department of Primary Care & General Practice (2002b) *Clinical guidelines for implementing patient self-testing and self-management of oral anticoagulation in primary care*. *The University of Birmingham*

Thompson, D.R., Meadows, K.A., Lewin, R.J. (1998) Measuring quality of life in patients with coronary heart disease. *European Heart Journal* **19** 693-695

Tower Hamlets Primary Care Trust. (1999) Code of Safe Practice: Helpful advice for staff working alone in the community. *Tower Hamlets Primary Care Trust*.

Tower Hamlets Primary Care Trust. (2002) Musculoskeletal team: Home Assessment Policy, Standards for Practice. *Tower Hamlets Primary Care Trust*.

Tower Hamlets Primary Care Trust. (2005) *Tower Hamlets Public Health Report*. <http://www.publichealth.thpct.nhs.uk/PublicHealthReport/index.aspx?pid=-2>

Timbs, O. (2003) What pharmacist prescribers can learn from those who have gone before. *Prescribing and Medicines Management*. **5** 5.

Tripodi, A., Arbini, A. A., Chantarangkul, V., Bettega, D., Mannucci, M. (1993) Are capillary whole blood coagulation monitors suitable for the control of oral anticoagulant treatment by the international normalised ratio? *Thrombosis and Haemostasis*. **70(6)** 921-924.

Tripodi, A., Chantarangkul, V., Mannucci, M. (2001) Near-patient testing devices to monitor oral anticoagulant therapy. *British Journal of Haematology*. **113 (4)** 847-852.

Tripodi, A., Breukink-Engbers, MD., van den Besselaar, A. M. H. (2003) Oral anticoagulant monitoring by laboratory or near-patient testing: what a clinician should be aware of. *Seminars in Vascular Medicine*. **3 (3)** 243-254.

Upton, D. R., Cousins, D. H. (1998) Medication Errors: Risk assess your dispensing, *Pharmacy in Practice*. **8** 253-256.

Vadher, B., Patterson, D. L., Leaning, M. (1997a) Evaluation of a decision support system for initiation and control of oral anticoagulation in a randomised trial. *British Medical Journal*. **314 (7089)** 1252-1256.

Vadher, B. D., Patterson, D. L., Leaning, M. (1997b) Comparison of oral anticoagulant control by a nurse-practitioner using a computer decision-support system with that by clinicians. *Clinical Laboratory Haematology*. **19 (3)** 203-207.

Van Heugten, C., Visser-Meily, A., Post, M., Linderman, E. (2006) Care for carers of stroke patients: Evidence-based clinical practice guidelines. *Journal of Rehabilitation Medicine* **38** 153-158(6).

VITAE Study Shows That Fatal Blood Clots Due to Venous Thrombosis Claim Over 500,000 Lives in the EU Each Year. (2005) <http://www.pnnewswire.co.uk/cgi/news/release?id=153801>

Walling, A. D. (2000) Aspirin vs. Coumadin for Atrial Fibrillation. *American Family Physician*. **61 (7)**.

Walshe, K. (2003) Foundation hospitals: a new direction for NHS reform? *Journal of Royal Society of Medicine*. **96** 106 - 110.

Ward S.E., Gordon D.B. (1996) Patient Satisfaction and Pain Severity as Outcomes in Pain Management: A Longitudinal View of One Setting's Experience. *Journal of Pain and Symptom Management* **11 (4)** 242 - 251.

Waring, B. (2005) Near Patient Testing. Sharing experiences: Letter. *Pharmaceutical Journal*. **274** 55.

Warner (2005) Warner puts convenience, access and choice at the heart of modern diagnostics. Department of Health website. Published: Friday 9 September 2005 Reference number: 2005/0316

www.dh.gov.uk/PublicationsAndStatistics/PressReleases/PressReleasesNotices/fs/en?CONTENT_ID=4118780andchk=wSUs6%2B

Weiss, C. (1998) Have we learned anything new about the use of evaluation? *American Journal of Evaluation*. **19**(1) 21–33.

Wheeldon NM. (1995) Atrial fibrillation and anticoagulant therapy. *European Heart Journal* **16** 302-312

White, R. H., McCurdy, S. A., von, M. H., Woodruff, D. E., Jr., Leftgoff, L. (1989) Home prothrombin time monitoring after the initiation of warfarin therapy. A randomized, prospective study. *Annals of Internal Medicine*. **111**(9) 730-737.

White, R. H., Mungall, D. (1991) Outpatient management of warfarin therapy: comparison of computer-predicted dosage adjustment to skilled professional care. *Therapeutic Drug Monitoring*. **13**(1) 46-50.

Whittington Hospital (2003) Whittington Hospital anticoagulation monitoring and stroke prevention service: Standard Operating Procedure. Community Pharmacy Pilot Version 3.0.

Williams, B. (1994) Patient satisfaction: a valid concept? *Social Science and Medicine*. **38** 509.

Williams, K. E., Gardiner, C., Mackie, I. J., Machin, S. J., Cohen, H. (2003) Preliminary data from the Medical Devices Agency (MDA) study of the CoaguCheck S in a patient self-testing environment. *British Journal of Haematology*. 121[(Suppl. 1)], 7. Abstract

Wilson, P.M. (2002) The expert patient: issues and implications for community nurses. *British Journal of Community Nursing*. **7** (10) 514-519.

Wilson, S. J., Wells, S., Kovacs, M. J., Lewis, G. M., Martin, J., Burton, E., Anderson, D. R. (2003) Comparing the quality of oral anticoagulant management by anticoagulation clinics and by family physicians: a randomized controlled trial, *CMAJ*. **169** (4) 293-298.

Wilt, V. M. (1995) Outcome analysis of a pharmacist managed anticoagulation service. *Pharmacotherapy* **15** 732-739.

Winter, M., Kneeling, D., Sharpen, F., Cohen, H., Vallance. (2003) *Procedures for the outpatient management of deep venous thrombosis*. On behalf of the Haemostasis and Thrombosis Task Force of the British Committee for Standards in Haematology.

Wolfer, J. (1993) Aspects of reality and ways of knowing in nursing: in search of an integrating paradigm. *Image: The Journal of Nursing Scholarship*. **25 (2)** 141-146.

York, M., Agarwal, A., Ezekowitz, M. (2003) Physicians' attitudes and the use of oral anticoagulants: surveying the present and envisioning the future. *Journal of Thrombosis and Thrombolysis*. **16 (1-2)** 33.

Zermansky, A. G., Petty, D. R., Raynor, D. K., Freemantle, N., Vail, A., Lowe, C. J. (2001) Randomised controlled trial of clinical medication review by a pharmacist of elderly patients receiving repeat prescriptions in general practice. *British Medical Journal*. **323 (7325)** 1340-1343.

Zimmerman, C. R. (2000) The role of point-of-care anticoagulation monitoring in arterial and venous thromboembolic disorders. *Journal of Thrombosis and Thrombolysis*. **9 (3)** 187-198.

APPENDICES

Appendix one : CSQ – 8 questionnaire

CSQ-8 CLIENT SATISFACTION QUESTIONNAIRE

Please help us to improve our programme by answering some questions about the service you have received. We are interested in your honest opinions, whether they are positive or negative. *Please answer all of the questions.* We also welcome your comments and suggestions. Thank you very much, we really appreciate your help.

CIRCLE YOUR ANSWERS

1. How would you rate the quality of service you have received?

<u>4</u>	<u>3</u>	<u>2</u>	<u>1</u>
<i>Excellent</i>	<i>Good</i>	<i>Fair</i>	<i>Poor</i>

2. Did you get the kind of service you wanted?

<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>
<i>No, definitely not</i>	<i>No, not really</i>	<i>Yes, generally</i>	<i>Yes, definitely</i>

3. To what extent has our programme met your needs?

<u>4</u>	<u>3</u>	<u>2</u>	<u>1</u>
<i>Almost all of my needs have been met</i>	<i>Most of my needs have been met</i>	<i>Only a few of my needs have been met</i>	<i>None of my needs have been met</i>

4. If a friend were in need of a similar help, would you recommend our help to him or her?

<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>
<i>No, definitely not</i>	<i>No, not really</i>	<i>Yes, generally</i>	<i>Yes, definitely</i>

5. How satisfied are you with the amount of help you have received?

<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>
<i>Quite dissatisfied</i>	<i>Indifferent or mildly dissatisfied</i>	<i>Mostly satisfied</i>	<i>Very satisfied</i>

6. Have the services you received help you to deal more effectively with your problems?

<u>4</u>	<u>3</u>	<u>2</u>	<u>1</u>
<i>Yes, they helped a great deal</i>	<i>Yes, they helped somewhat</i>	<i>No, they really didn't help</i>	<i>No, they seemed to make things worse</i>

7. In an overall, general sense, how satisfied are you with the service you have received?

<u>4</u>	<u>3</u>	<u>2</u>	<u>1</u>
<i>Very satisfied</i>	<i>Mostly satisfied</i>	<i>Indifferent or mildly dissatisfied</i>	<i>Quite dissatisfied</i>

8. If you were to seek help again, would you come back to our programme?

<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>
<i>No, definitely not</i>	<i>No, not really</i>	<i>Yes, generally</i>	<i>Yes, definitely</i>

Appendix two: Additional questionnaire items

9) What do you think about the waiting times in the anticoagulation clinic?

1 2 3 4
I always wait long *I sometimes wait long* *I rarely wait long* *I never wait long*

10) How easy or difficult is it to get to the clinic?

1 2 3 4
It is complicated *It is somewhat complicated* *It is not really complicated* *It is not complicated*

11) How do you feel about the way your blood sample is taken, i.e. from a vein on your arm?

4 3 2 1
I do not at all mind this way *I do not generally mind this way* *I quite dislike this way* *I definitely dislike this way*

12) How satisfied are you with the staff who takes blood samples?

4 3 2 1
Always satisfied *More often satisfied than dissatisfied* *More often dissatisfied than satisfied* *Always dissatisfied*

13) What do you think about the staff dealing with all other parts of the service?

4 3 2 1
Always satisfied *More often satisfied than dissatisfied* *More often dissatisfied than satisfied* *Always dissatisfied*

14) Normally, how clear is the explanation what to do between the visits, i.e. what dose to take?

1 2 3 4
Never clear *Rarely clear* *Mostly clear* *Always clear*

15) How satisfied are you with the environment where the service is provided?

4 3 2 1
Satisfied *Rather satisfied* *Rather unsatisfied* *Unsatisfied*

9) What do you think about the waiting times in the anticoagulation clinic?

1 2 3 4
I always wait long I sometimes wait long I rarely wait long I never wait long

10) How difficult or easy is it to get to the clinic?

1 2 3 4
It is complicated It is somewhat complicated It is not really complicated It is not complicated

11) How do you feel about the way your blood sample is taken, i.e. from a vein on your arm?

4 3 2 1
I do not at all mind this way I do not generally mind this way I quite dislike this way I definitely dislike this way

12) How satisfied are you with the staff who takes blood samples?

4 3 2 1
Always satisfied More often satisfied than dissatisfied More often dissatisfied than satisfied Always dissatisfied

13) What do you think about the staff dealing with all other parts of the service?

4 3 2 1
Always satisfied More often satisfied than dissatisfied More often dissatisfied than satisfied Always dissatisfied

14) Normally, how clear is the explanation what to do between the visits, i.e. what dose to take?

1 2 3 4
Never clear Rarely clear Mostly clear Always clear

15) How satisfied are you with the environment where the service is provided?

4 3 2 1
Satisfied Rather satisfied Rather unsatisfied Unsatisfied

16) If you need to contact the clinic, how easy or difficult is it to contact them over a telephone?

1 2 3 4
Always difficult to get through Sometimes difficult to get through Rarely difficult to get through Never difficult to get through

17) How long does it take before you receive your 'yellow book' back?

1 2 3 4
I always wait long I sometimes wait long I rarely wait long I never wait long

9) What do you think about the waiting times in the anticoagulation clinic?

Transport

1 2 3 4
I always wait long I sometimes wait long I rarely wait long I never wait long

10) How easy or difficult is it to get to the clinic?

1 2 3 4
It is complicated It is somewhat complicated It is not really complicated It is not complicated

11) How do you feel about the way your blood sample is taken, i.e. from a vein on your arm?

4 3 2 1
I do not at all mind this way I do not generally mind this way I quite dislike this way I definitely dislike this way

12) How satisfied are you with the staff who takes blood samples?

4 3 2 1
Always satisfied More often satisfied than dissatisfied More often dissatisfied than satisfied Always dissatisfied

13) What do you think about the staff dealing with all other parts of the service?

4 3 2 1
Always satisfied More often satisfied than dissatisfied More often dissatisfied than satisfied Always dissatisfied

14) Normally, how clear is the explanation what to do between the visits, i.e. what dose to take?

1 2 3 4
Never clear Rarely clear Mostly clear Always clear

15) How satisfied are you with the environment where the service is provided?

4 3 2 1
Satisfied Rather satisfied Rather unsatisfied Unsatisfied

16) How long does it take before the transport picks you up from home before the clinic?

1 2 3 4
I always wait long I sometimes wait long I rarely wait long I never wait long

17) How long does it take them to drop you off at home after the clinic?

1 2 3 4
I always wait long I sometimes wait long I rarely wait long I never wait long

18) Has the transport ever failed to pick you up?

4 3 2 1
Never Rarely Sometimes Often

Appendix three: Nominal group session invitation letter to general practitioners

Dear Sir/Madam,

Re: N/02/065 – Models of anticoagulation monitoring in primary and secondary care. Feasibility study.

My name is Frances Akinwunmi. I am a research pharmacist at the Academic Practice Unit, Homerton University Hospital and The School of Pharmacy, University of London. I am writing regarding the above research project. This research is being conducted in collaboration with Haematology Departments in Barts and The London, Homerton University Hospital and Newham Healthcare NHS Trusts.

With the continuously increasing number of patients anticoagulated with warfarin, the revision of services in this healthcare area has become imperative. The purpose of this project is to provide evidence for developments of anticoagulation services in East London. To provide evidence that is relevant, I am very keen to investigate general practitioners' perceptions and opinions about issues regarding anticoagulation services.

Therefore, I would like to invite you to attend and participate in a group discussion session, so we can identify the issues you feel are important for the provision of anticoagulation services in primary and secondary care in East London, and to discuss the ways to address these issues.

The group discussion session will be about an hour long. Afterwards, whilst food and refreshments are being served, a representative of Roche Diagnostics Ltd will hold a presentation on available anticoagulation Near Patient Testing (NPT) devices. If you attend the group discussion session you will not be obliged to stay for the rest of the programme. The session will be expected to start at approximately 4pm (please indicate on the reply slip if this time is inconvenient).

If you are interested in attending the session and ensuring your views and opinions are heard, please return the reply slip at the end of the letter in the freepost envelope provided. Showing an interest at this stage does not mean you are obligated to attend the session.

I hope you will be interested in this research and look forward to meeting you at the group discussion session. Should you require more information at this stage, please do not hesitate to contact me on 020 7753 5959, or via email on frances.akinwunmi@ulsop.ac.uk.

Yours faithfully,

Frances Akinwunmi, MRPharmS
Research Pharmacist

I am interested in participating in the group discussion session.

Preferred date (please tick): Wed July 9th ☐ Wed July 16th ☐ Wed July 30th ☐ Any of these dates ☐

Time convenient (tick or state): Yes ☐ Other time:.....

Name

Address

Telephone

Appendix four: Nominal group session invitation letter to community pharmacists

Dear Sir/Madam,

Re: N/02/065 – Models of anticoagulation monitoring in primary and secondary care. Feasibility study.

My name is Frances Akinwunmi. I am a research pharmacist at the Academic Practice Unit, Homerton University Hospital and The School of Pharmacy, University of London. I am writing regarding the above research project. This research is being conducted in collaboration with Haematology Departments in Barts and The London, Homerton University Hospital and Newham Healthcare NHS Trusts.

With the continuously increasing number of patients anticoagulated with warfarin, the revision of services in this healthcare area has become imperative. Due to their easy accessibility and drug-related expertise, community pharmacists have been identified as an important group that could potentially provide this service. The purpose of this project is to provide evidence for developments of anticoagulation services in East London and I am very keen to investigate community pharmacists' perceptions and opinions about issues regarding anticoagulation services.

Therefore, I would like to invite you to attend and participate in a group discussion session, so we can identify the issues you feel are important for the provision of anticoagulation services in primary and secondary care in East London, and to discuss the ways to address these issues.

The group discussion session will be about an hour long. Afterwards, whilst food and refreshments are being served, a representative of Roche Diagnostics Ltd will hold a presentation on available anticoagulation Near Patient Testing (NPT) devices. If you attend the group discussion session you will not be obliged to stay for the rest of the programme. The session will be expected to start at approximately 4pm (please indicate on the reply slip if this time is inconvenient).

If you are interested in attending the session and ensuring your views and opinions are heard, please return the reply slip at the end of the letter in the freepost envelope provided. Showing an interest at this stage does not mean you are obligated to attend the session.

I hope you will be interested in this research and look forward to meeting you at the group discussion session. Should you require more information at this stage, please do not hesitate to contact me on 020 7753 5959, or via email on frances.akinwunmi@ulsop.ac.uk.

Yours faithfully,

Frances Akinwunmi, MRPharmS
Research Pharmacist

I am interested in participating in the Nominal Group session.

Preferred date (please tick): Wed July 9th ☐ Wed July 16th ☐ Wed July 30th ☐ Any of these dates ☐

Time convenient (tick or state): Yes ☐ Other time:.....

Name

Address

Telephone

Appendix five: Nominal group model worksheet (model 1 displayed only)

Model 1

Patients	Sample site	Type of sample	Test site	Dosing site	Patient contacted by	Responsibility
Mobile	Hospital	Venous	Hospital	Hospital	Hospital	

Advantages

A).....

B)

C)

Disadvantages

A)

B)

C)

Comments:

.....

.....

Rank (Please circle one. Use each rank once only): 1 2 3 4 5

Anticoagulation monitoring in primary and secondary care. Feasibility study.
Nominal Group Session, 30th July 2003

Appendix six: Domiciliary anticoagulation services trial protocol

Barts and The London NHS Trust



September 2003

Contents

	Page No.
List of Appendices	3
1. Introduction	4
2. Aim	4
3. Objectives of the Service	4
4. Anticoagulation Practitioners	5
5. Responsibilities of the Pharmacist practitioner running the domiciliary service	5
6. Service Provision	5
7. Training requirements	6
8. Use of Technology	7
9. Patient consultation- General advice on dosing for research pharmacist	8
10. INRs within normal range	9
11. Procedure for 'out-of-range' INRs	9
12. Procedure for making follow up appointments	9
13. Venesection	9
14. Handling of blood samples	9
15. Dealing with body fluid spillages	10
16. Waste disposal	10
17. Needle-stick injury	10
18. Hepatitis immunisation	10
19. Discontinuing Treatment	10
20. Complaints	10
21. Untoward Incidents	11
22. Errors	11
23. Clinical Audit	11
24. Statutory Regulations	11
25. Holiday Period	12

List of Appendices

1. Patient Group Direction for the Supply, Administration and Dosing of anticoagulants by the Authorised Pharmacists and Nurse Practitioners working in the Anticoagulation Clinic
2. Training Package for Practitioners
3. Standard Operating Policy for CoaguChek
4. CoaguChek recording forms
5. Postal Check-list
6. Barts and The London Trust Phlebotomy Handbook
7. Policy for the Safe Handling of Body Fluid Spillages
8. The Barts and The London NHS Trust's Blood Contamination Incident Procedure

Introduction

Traditionally anticoagulation service provision for Barts and the London Trust (BLT) mobility-impaired patients has relied on utilizing the hospital transport system. The problems with this method of transporting the patients to and from the hospital are numerous; they include additional time constraints and inconvenience to the patients, and cost and organizational burden for the service provider. Nationally and locally, there is wide support for increasing the delivery of anticoagulation services in the primary care/community setting. In various parts of the UK different models of primary care service provision are in successful operation, however there is few data on comparing these different models. In order to improve the service for BLT transport patients we are evaluating two primary-care models specifically designed for the patients with mobility impairment. These models will be compared to the traditional method of service provision, the models will also be compared to each other, the purpose being to assess different service delivery in primary care and to address increasing service demand.

Aim

To explore feasibility of different models of anticoagulation service for mobility impaired patients, looking at the primary- secondary care interface in the Tower Hamlets area.

Objectives of the service

- To identify if provision of outreach anticoagulation services to house-bound patients would address problems outlined above.
- To establish a safe, high quality service for transport and mobility-impaired patients that delivers defined health benefits of anticoagulant therapy according to evidence based guidelines.
- To identify patients currently attending BLT anticoagulant clinic, who also require hospital transport.
- To maximise the benefits and minimise the risks associated with anticoagulation therapy by maximising the time spent within the target range.
- To maintain anticoagulation within a prescribed therapeutic INR range by dose adjustment of oral anticoagulants and by anticipating changes.
- To maintain patient records.
- To be involved in research & development.
- To initiate follow up with regards to monitoring therapy.
- To assess patients for possible complications of over and under anticoagulation.
- To educate patients on anticoagulation therapy.
- To maintain good communication within the anticoagulation team, other healthcare professionals and patients.
- To maintain documentation in patients anticoagulation book and the clinic record system (Dawn computer software).
- To increase the convenience and acceptability of the anticoagulation service.

Anticoagulation Practitioners

The domiciliary service will be managed by Research Pharmacist Practitioner Frances Akinwunmi under the supervision of Consultant Haematologist, Dr Peter MacCallum and Senior anticoagulation practitioners, Manisha Madhani (anticoagulation pharmacist), Tracey Harrison and Sarah Mills (Senior nurse practitioners).

Frances Akinwunmi will work under the BLT PGD (Appendix 1) which has been assessed and endorsed by the Patient Group Review Committee.

The Responsibilities of the Pharmacist practitioner running the domiciliary service (see PGD –Appendix 1 for details)

The pharmacist practitioner must :

- ◆ Understand the content of the Patient Group Direction (PGD) and agree to undertake the dosing of oral anticoagulants as an extended role of service provision.
- ◆ The pharmacist practitioner must at all times adhere to the principles and conditions of the PGD protocol.
- ◆ The pharmacist practitioner will adjust doses of oral anticoagulants according to the PGD.
- ◆ The pharmacist practitioner must recognize the need for medical opinion/advice from senior practitioners.

Service provision

Patients participating in the domiciliary service will be randomised by the process of minimization to two treatment arms, Model 1 and Model 2.

Model 1

A general phlebotomist, will carry out domiciliary visits to the patients that require transport to the hospital for anticoagulation monitoring.

- A standard sample collection will be performed, i.e. 4.5 ml of venous blood will be collected into a tube containing sodium citrate (tube with light blue lid).
- The samples will be transferred to the Barts and The London haematology laboratory along with the patient's yellow book for analysis on the same day.
- Practitioners at BLT will check the INR results on the Trust's Patient administration system (PAS), dose the patients and contact the patient by phone on the same day, if doses have been changed.
- The INR, dosage instructions and date of the next phlebotomist visit will be written in the yellow book which will be posted to the patient no later than the following day after dosing.
- The next visit date for each patient will also be written in the domiciliary anticoagulation diary, so that the phlebotomist is aware of when to revisit each patient.

Model 2

- Following competency based training (according to BLT: Anticoagulation clinic training manual for C / D clinical pharmacist), a pharmacist practitioner will perform domiciliary visits to the transport patients with one-stop anticoagulation service, i.e., will perform INR testing using the point-of-care monitor and make decisions about the dosing, with the aid of computer dosing support (Dawn software). If the pharmacist practitioner is unsure about dosing then the senior practitioners will be contacted for advice.
- Patients participating in the trial will be labelled on the Dawn system for easy identification.
- At the start of each day a list of patients that need to be seen should be downloaded on to the pharmacist's laptop. Once the pharmacist arrives at the patient's home, the laptop should be put on and the CoaguChek S device should be set up.

Documentation

- ◆ Results will be recorded on the patients yellow book together with dosing instructions.
- ◆ Results will also be recorded in a paper based record of patients' INRs- this will allow a secondary audit trail.
- ◆ When a result has been produced by the CoaguChek S device the results are entered on to the dawn dosing system. The dawn software will produce a dosing suggestion which can be accepted or overridden at the pharmacist's discretion.
- ◆ Once the clinic is over the pharmacist will return to the host computer and manually enter the results onto the host computer.

Training requirements

- ◆ The pharmacist practitioner will have to complete a competency training programme (Appendix 2) under the supervision of the senior pharmacist and nurse practitioners.
- ◆ Training will be via structured teaching, supervision, practice based sessions and assessments.
- ◆ The senior pharmacist practitioner will confirm by signing the agreement that the authorised pharmacist practitioner has fulfilled the training requirements and achieved an acceptable standard.
- ◆ In addition the research pharmacist practitioner will undergo training in:
- ◆ Use of the CoaguChek S device assessed by Tracey Harrison -senior nurse practitioner, this will ensure that the device is used correctly in accordance with the Standard operating policy (Appendix 3).
- ◆ Phlebotomy training; this will allow a venous sample to be taken in the case of INRs above 4.5, this is necessary as it has been shown that at higher INR values (specifically above 5), NPT devices accuracy is impaired, furthermore there is an increased risk of bleeding at INRs above 5.

Assessment of competence will ensure that the pharmacist practitioner has met the following objectives:

- ◆ To have a clear understanding of the clotting mechanism
- ◆ To have a clear understanding of the indications and contraindications and be able to describe the main side effects of warfarin therapy
- ◆ To have a clear understanding of the range of INR for each condition or disease
- ◆ To be aware of the drugs which have a significant effect on warfarin therapy and understand the mechanism of drug interaction (including on food and alcohol).
- ◆ To fully understand the Trust policy on practitioner prescribing and have knowledge of the boundaries of our own practice
- ◆ To understand the basic principles of the computer dosing system
- ◆ To clearly document results and proposed outcomes in patient yellow book
- ◆ To clearly understand and be aware of the need to seek advice from the medical team

Use of technology

Point of care

For those patients receiving one-stop treatment, the point-of –care monitor that will be used is the Roche CoaguChek S device . The CoaguChek is the most commonly used anticoagulation near patient testing (NPT) device and is the only device of its kind that has received Medicines Device Agency (MDA) approval, therefore it is deemed suitable for the purpose of conducting a domiciliary service for anticoagulant patients.

The Dawn computer dosing support software will be used in conjunction with the NPT technology. Computer assisted dosing aids interpretation of results, although it can be over-ridden if the suggestion made is not clinically indicated.

Quality Assurance

The CoaguChek S device and associated equipment/reagents will be maintained to the manufacturer's specifications and quality control and assurance procedures will be carried out as recommended.

Quality control will be performed on the coagulometer before the visits' session. If the results are out of range the hospital will be contacted to obtain a replacement machine. The recording form can be found in Appendix 4.

The CoaguChek S device will be registered with NEQAS (National External Quality Assessment Scheme) and will participate in its surveys accordingly. This scheme provides a robust external quality control system with regard to NPT devices.

Finger-prick blood taking and use of the CoaguChek S device

Ensure the CoaguChek S device is on and correctly calibrated. Insert a test card into the device, the test card needs to warm up this takes approximately 10 seconds. Once the test card is warm a light will begin to flash to indicate where the blood sample should be

placed. This light will flash for 180 seconds, giving the practitioner 3 minutes to take the sample and ensure that it is adequate before placing it on the test card. It is important to ensure that the device is not placed in areas where light will be shining on it; the device works using light reflection therefore any incidental light may produce inaccurate INR results.

Finger pricking

Massage the desired finger/thumb a few times from base to tip to encourage blood flow.

Warm the digit and cleanse using a swab

Point the selected digit downwards to assist blood flow

Holding the patient's hand and fingers firmly in one hand use a sterile lancet top pierce the skin halfway between the centre of the ball of the finger and its side.

When using the CoaguChek S device the **first** drop of blood should be used as the sample.

Use a capillary tube to collect the sample, avoid excessive squeezing as it may cause the release of tissue fluids that could contaminate the sample.

Once an adequate amount of blood (approx 25 µl/ a good sized drop) has been collected the capillary device should be placed as closely as possible on to the flashing light and the drop of blood dispensed on to it. If the sample size is adequate a result should be produced within 3 minutes

Patient consultation- General advice on dosing for research pharmacist

During the domiciliary visit carried out by the research pharmacist practitioner, the consultation with patients should be as follows:

Patients will be evaluated on the basis of both the INR and a personal interview. All patients will be questioned on:

- I Signs and symptoms of bleeding complications
- II Recent changes in diet, medication (including over the counter preparations) and alcohol intake
- III Compliance with medication review
- IV Status of medical problems necessitating anticoagulation therapy
- V Other major illness

INR results within normal range

Refer to the PGD (Appendix 1)

Procedure for "out-of-range" results

The research pharmacist practitioner will use their dosing knowledge to deal with INRs between 1.5 and 4.9 only. Where the pharmacist practitioner needs advice or support they

should contact either Dr Peter MacCallum or a senior practitioner (either Manisha Madhani, Sarah Mills or Tracey Harrison).

Low Results

Patient should be questioned to ascertain, if possible the reason for low INR e.g. any missed doses, any new medication, any changes in lifestyle. If the reason for the low INR is known then the pharmacist will dose as appropriate.

If an INR of 1.4 or less is detected referral to the afore mentioned practitioners will be required. The practitioners will be responsible for dosing in these circumstances and ensuring the patients are contacted to inform them of any dose changes or instructions.

High Results

Patients should be questioned so that if possible the reason for high INRs can be ascertained. If the reason for the high INR is known and it is less than 5 the pharmacist should dose appropriately. If an INR above 4.5 is detected a venous sample will be taken and sent to laboratory for confirmation. The above named practitioners will be informed. The practitioners will be responsible for dosing in these circumstances and ensuring the patients are contacted to inform them of any dose changes or instructions.

Procedure for making follow-up appointments

The Dawn software can be used to make follow up appointments if the pharmacist believes that the appointment interval recommended by the computer is not suitable then they can override it.

Maximum interval between appointments will be 6 weeks

During the domiciliary visit carried out by the phlebotomist, patients should be routinely asked whether they experienced any bleeding or bruising or missed any doses, or if they have started any new medicines since their last appointment. Details of bleeding, bruising etc should be entered on a patient record sheet, (i.e. the currently used postal checklist Appendix 5) which should be given to anticoagulant staff, to assist them when dosing patients.

Venesection

Refer to page 9-10 of the BLT Phlebotomy Handbook- Appendix 6

Handling of blood samples

Once a blood sample has been taken, tubes should be labelled up according to Trust guidelines (see Phlebotomy handbook – Appendix 6) and placed in plastic specimen bags.

Dealing with body fluid spillages

All spills must be dealt with promptly. Refer to the Trust Policy for the Safe handling of Body Fluid Spillages (Appendix 7)

Waste disposal

Any material used and identified as waste should be disposed of in its appropriate category:

Clinical waste (gloves, dressings, aprons etc.) in yellow clinical waste bags.

Sharps (needles, tubes etc.) in yellow sharps containers.

Household waste (newspapers, food wrappings, glass etc.) in black household waste bags.

Needle-stick injury (see also Appendix 8)

Should a needle stick injury occur:

Encourage bleeding by squeezing where skin is punctured

Wash under warm, running water (not cold or hot)

Do **not** use a scrubbing brush

Complete incident book

Go to Occupational Health, situated at St Bartholomew's hospital or Accident and Emergency Department, situated at the Royal London Hospital within one hour of the injury occurring.

Needle-stick helpline number: 020 7601 7825

For further information refer to the Phlebotomy Handbook – Appendix 6, section 9.1 and also the Policy for the Management of Inoculation and other Contamination Incidents and the Policy for the Safe Disposal of Waste

Hepatitis immunisation

Prior to service provision the pharmacist and phlebotomist should be immunized against Hepatitis if they have not been previously.

Discontinuing Treatment

Patients will be referred to senior members of the anticoagulation team for possible termination of treatment for the following reasons:

1. completion of appropriate length of treatment
2. Persistent non-compliance with anticoagulant therapy. The consultant haematologist will be asked to review such patients and decide whether or not they should be discharged.

Complaints

All complaints made against the pharmacist or phlebotomist will be forwarded to Dr. Peter MacCallum and Manisha Madhani within 48 hours. Any complaints should also be recorded in the patient's electronic record.

Untoward incidents

All untoward incidents occurring within the running of the domiciliary service will be documented in the appropriate incident forms available within the anticoagulation and pharmacy departments and brought to the attention of Dr Peter MacCallum and Manisha Madhani as soon as is practically possible.

Examples of such incidents include:

- ◆ Any incident, not related to warfarin therapy, which results in calling the emergency services.
- ◆ Any incident concerning the immediate well-being of a patient or staff
- ◆ All untoward incidents should also be recorded in the patient's electronic record.

Errors

All errors will be documented and brought to the attention of Dr Peter MacCallum and Manisha Madhani within 24 hours. All errors should also be recorded in the patient's electronic record.

The pharmacist/phlebotomist making errors will be counselled and may be required to undergo further training before providing further domiciliary services.

Clinical Audit

Audit of the service should be carried out on a regular basis and should address the following:

Clinical outcome

Completeness of documentation

Adverse events

Adverse events defined as

- ◆ INR >6.0
- ◆ Signs or symptoms of bleeding
- ◆ Signs or symptoms of thromboembolic episodes
- ◆ Patients thought to be at high risk of bleeding or thromboembolism

Audit criteria for deviations from the desired therapeutic range are:

- I. Number and percentage of INRs within 0.5 INR units of the target value;
- II. Number and percentage of INRs within 0.75 INR of the target value;
- III. Number and percentage of INRs greater than 4.5;
- IV. Number and percentage of INRs greater than 6.0;
- V. Number and percentage of INRs less than 1.5 if patients target = 2.5 or less than 2;
- VI. Average length of recall times

Statutory Regulations

The Pharmacist will comply with all relevant Acts of Parliament, Statutory Regulations and formal guidance from the Department of Health, NHS Executive and Regional Health Authority

Holiday Period

When the pharmacist practitioner is on holiday, hospital transport will be arranged for the patients so that they can be seen in the hospital for the duration of the practitioner's holiday.

Date: September 2003

Produced by: Frances Akinwunmi

Checked by: Manisha Madhani, Peter MacCallum, Sarah Mills, Tracey Harrison

Appendix seven: Checklist for community visits-general and important safety points for community visits

Checklist of general and important safety points for community visits

1. Confirm date and time of visit with patient and/or relatives/carers.
2. Ensure that appointment is documented in Anticoagulation domiciliary diary.
3. Ensure you have directions to the place you are going.
4. Take mobile phone- ensure that it is charged and switched on at all times.
5. In addition a small amount of change or a phone card should be carried for emergency phone calls if the worker is unable to access their mobile.
6. Visits should take place during daylight hours.
7. Ensure all required equipment is collected prior to the visits and that there is adequate supply of all items.
8. Home visiting staff who use personal transport must ensure that they have appropriate insurance cover.
9. Fill in drivers log for each journey i.e.: start time, finish time, starting mileage, finishing mileage.
10. Vehicles should ideally be parked in well-lit areas.
11. Before getting out of the car, thoroughly check the surroundings. If you feel uneasy, do not get out of the car. Return to the clinic and notify senior members of the team.
12. Lock any personal items in the car trunk before leaving the car.
13. Always ensure that you have the Trust ID badge with you on visits so that you can identify yourself clearly prior to entry into the patient's home.

14. As always, the identification of the patient should be confirmed even in the patient's own home e.g. name and date of birth.
15. At the end of the visit complete documentation of visit of including results dose, any patient information next appointment date and time.
16. If a patient or other person becomes verbally or physically abusive the staff member should leave the premises. The incident should be reported and documented in the appropriate form.
17. In the event of an accident or serious illness the Ambulance Service should be called and the accident report form completed.
18. In the event of minor illness/ailment the patient should be referred to their General Practitioner.
19. If the patient has pets that are protective of their owners or territorial, it is advisable to ask the owners to confine them briefly while the visit is carried out.
20. If there is going to be a change in the person visiting ensure that the patient and /or their carer/relative is notified about this before hand.
21. *Consider the needs of those who do not speak English as their first language or those who have sensory impairment or communication difficulties. Make use of translators or English speaking family members.*

Appendix eight: Patient details check

Patients name	Missed dose & when	Names of new medication/ start/duration.	Any bleeding or bruising?	Dosed & signed	Telephoned and outcome

Appendix eight: Patient details check

Patients name	Missed dose & when	Names of new medication/ start/duration.	Any bleeding or bruising?	Dosed & signed	Telephoned and outcome

Invitation to Participate in a Research Project

EVALUATION OF TWO MODELS OF DELIVERING ANTICOAGULANT CARE TO HOUSE-BOUND PATIENTS IN THE COMMUNITY

Barts and The London NHS Trust

We invite you to take part in a research study which we think may be important. The information which follows tells you about it. It is important that you understand what is in this leaflet. It says what will happen if you take part and what the risks might be. Try to make sure you know what will happen to you if you decide to take part. Whether or not you do take part is entirely your choice. Please ask any questions you want to about the research and we will try our best to answer them.

- **Why are you invited to take part in this research?**

We invited you to participate in this study because you use anticoagulation services and the hospital transport system to get to the clinic.

- **What is the goal of this research?**

By undertaking this study we aim to evaluate two novel models of anticoagulation services to patients who currently have to use hospital transport to get to the anticoagulation clinic.

- **What would participation in this research involve for you?**

If you decided to take part, there will be 3 stages to your participation in this project:

1) First, after you agreed to participate, with your permission, we will review and record your INR measurements over the last 12 months.

2) Then, for five months you would receive one of the alternative models of anticoagulation service, Model 1 or Model 2.

3) Finally, for another five months you would be provided the other model of the service, i.e. if you first received Model 1, you will receive Model 2 and vice versa. The Models are described below.

Model 1: A phlebotomist (the person that takes blood samples), will visit you at home to collect your blood sample. This sample will be taken to the hospital where INR would be tested. The anticoagulation clinic staff will then contact you with the result and will let you know what dose to take.

Model 2: A pharmacist who has training in anticoagulation treatment will visit you at home and perform INR measurement using a new device that measure INR from a drop of blood from your finger. The test takes only about 3 minutes. Therefore, the pharmacist will be able to tell you the result immediately and advice you about the dose.

As you can see, when receiving either of these models you will NOT need to come to the hospital to the anticoagulation clinic. Both the phlebotomist and the pharmacist will be directly linked to your current anticoagulation team and Dr MacCallum will make sure that you receive safe treatment.

At the end of part 2 and 3 we would ask you to complete a questionnaire investigating your views of the anticoagulation services you received. In addition, we would record your INRs to see how controlled you are over the study period over the whole period.

- **Will taking part in the research be of any benefit to you?**

During the study period you will not need to go to the anticoagulant clinic but will receive the anticoagulation service at home.

Also, importantly, through this study you will be able to experience alternative models of anticoagulation service. If we find that these models are safe and cost-effective and that you and other participants in the study are satisfied with the services, we will negotiate formal implementation of these services so that, in the future, you could receive this service on a routine basis.

- **Confidentiality**

Nobody other than the research team will have access to the data that we will collect during the study. No names will be identified during the analysis or any report from the study (unless you wish us to do so).

If you need more information about the study or have any worries
with regards to this study, please do not hesitate to contact:

Miss Frances Akinwunmi
Department of Practice and Policy
The School of Pharmacy

29/39 Brunswick Square
London
WC1N 1AX
Tel: 020 7753 5959

You don't have to join the study. You are free to decide not to be in
this study or to drop out at any time. If you decide not to be in the
study, or drop out, this will not put at risk your ordinary medical care.

WRITTEN CONSENT FORM

Evaluation of two models of delivering anticoagulant care to house-bound patients in the community

REC Number:

Name of Patient/Volunteer (Block Capitals):

Address:

- ☐ The study organisers have invited me to take part in this research.
- ☐ I understand what is in the leaflet about the research. I have a copy of the leaflet to keep.
- ☐ I have had the chance to talk and ask questions about the study.
- ☐ I know what my part will be in the study and I know how long it will take.
- ☐ I understand that I should not **actively** take part in more than 1 research study at a time.
- ☐ I know that the local East London and The City Health Authority Research Ethics Committee has seen and agreed to this study.
- ☐ I know that the researchers will review my hospital medical records and I consent to it.

- ☐ I understand that personal information is strictly confidential: I know the only people who may see information about my part in the study are the research team.
- ☐ I know that the researchers will tell my general practitioner (GP) about my part in the study.
- ☐ I freely consent to participate in the study. No-one has put pressure on me.
- ☐ I know that I can stop taking part in the study at any time.
- ☐ I know if I do not take part I will still be able to have my normal treatment.
- ☐ I know that if there are any problems, I can contact:

Frances Akinwunmi
Tel. No. 020 7753 5959

Patient's/Volunteer's: Signature

Witness's Name

Witness's Signature:

Date

The following should be signed by the Clinician/Investigator responsible for obtaining consent

As the Clinician/Investigator responsible for this research or a designated deputy, I confirm that I have explained to the patient/volunteer named above the nature and purpose of the research to be undertaken.

Clinician's Name:Clinician's Signature.....

Date:.....