

Manuscript Details

Manuscript number	RSAP_2018_428_R1
Title	The Comparison of Service Models of Warfarin Monitoring in Calderdale and Huddersfield Foundation Trust Hospitals in West Yorkshire, UK
Article type	Research Paper

Abstract

Background: Warfarin-related knowledge and patient satisfaction with warfarin monitoring services are generally high with respect to anticoagulation-related care received. Providing a cost-effective warfarin monitoring service while improving warfarin-related knowledge, patient safety and satisfaction can be challenging. Objectives: To compare 'post and dose' service offered by the Calderdale Royal Hospital (CRH) and 'face-to-face' service offered by Huddersfield Royal Infirmary (HRI) in terms of costs of service delivery, patient satisfaction, warfarin-related knowledge and safety indicators. Methods: A cross-sectional sample of 160 patients on long-term warfarin therapy from anticoagulation (outpatient) clinics at CRH and HRI using interviewer-administered data collection form. International Normalized Ratio (INR), Time in Therapeutic Range (TTR) and Variance Growth Rate (VGR) values of last 12 months and the data on costs of service delivery, knowledge and satisfaction were collected. Results: Patients monitored at HRI had higher mean VGR value (0.35 ± 0.62 vs. 0.17 ± 0.17 , $p=0.092$) and slightly lower mean TTR (68.70 ± 19.43 vs. 69.63 ± 17.71 , $p=0.756$) compared with CRH patients. Patients monitored in 'post and dose' were estimated at a price of £11.06 per patient per visit and each patient in face-to-face service only cost £9.70 per visit. Patients monitored at HRI had marginally higher overall knowledge score (65.22 ± 23.29 vs. 60.31 ± 20.93 , $p=0.165$) and overall satisfaction score (15.59 ± 3.16 vs. 15.05 ± 3.10 , $p=0.279$) compared with CRH patients. A positive and significant correlation was found between patients' knowledge and patient satisfaction ($r=+0.327$, $p=0.001$). Conclusion: Although, HRI provided monitoring service at a slightly lower cost than CRH, patients monitored at CRH had better anticoagulation control and favourable indicators. Warfarin-related knowledge needs to be improved to achieve further improvement in quality of warfarin use.

Keywords	Costs, knowledge, monitoring service, safety indicators, satisfaction, warfarin
Taxonomy	Medication Therapy Management Service, Cardiovascular System
Manuscript category	Research Paper
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Data will be made available on request

Date: October 20, 2018

The Editor-in-Chief
Research in Social and Administrative Pharmacy (RSAP)

Dear Editor,

We are pleased to submit our revised manuscript entitled: "*The Comparison of Service Models of Warfarin Monitoring in Calderdale and Huddersfield Foundation Trust Hospitals in West Yorkshire, UK*", for consideration as an original article.

We believe the findings of our study will be of great interest to researchers in hospital pharmacy in general, and to researchers working on health services in particular. As a premier international journal devoted to the rapid dissemination of significant findings about hospital pharmacy, RSAP represents the perfect platform for us to share these findings with the international research community.

We confirm that this manuscript, and parts of it, has not been published elsewhere and is not under consideration by another journal. All authors significantly contributed to the review paper. All authors read and approved the final manuscript and agree with the submission to RSAP. The authors have no conflicts of interest.

We look forward to a favourable reply at your earliest convenience.

Yours Sincerely,

Dr Syed Shahzad Hasan (On behalf of the Research Team)

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Dear Editor,

Thank you for sending our manuscript for review and for providing constructive feedback on our work. We have tried our level best to address all issues/questions raised by the reviewers. All changes in the text (manuscript) are highlighted in Yellow. Below are our responses to comments from reviewers.

Title of Project: The Comparison of Service Models of Warfarin Monitoring in Calderdale and Huddersfield Foundation Trust Hospitals in West Yorkshire, UK	
Comments from Reviewer 1	Response of Reviewer
Line 16: remove the word 'safety'	Removed
Line 30: specify these are outpatient settings	Added that these are outpatient settings
Lines 47 – 51: Maybe useful to add; by how much is the self-testing cost effective	Added the values
Line 134: replace 'and patients with' with 'for'	Replaced
Line 142: It is not clear from here onwards whether CRH, test INR, by finger picking or a venous sample is taken. The presence of phlebotomist suggests venous sample, whereas table 6 suggests finger-pick.	Both services use finger-pick method for INR measurement. At CRH, phlebotomist measure patients' INR, and at HRI it is done by nurse. We have added this information in the methods
Line 149: There is only a mention of letter posted, please clarify if this process involves the use of the yellow book (CRH). Later in the paper there is a suggestion that it is used.	The letter posted to patients attending clinics at CRH contain INR reading, dose and the date of next appointment. They are instructed to paste the letter in their yellow book. We have added this information.
Line 158: specify the anticoagulation book is the yellow warfarin book.	We have added the information that anticoagulation book is the yellow warfarin book.
Line 205: similar comment to above in line 142; asking patients if they use a yellow book, section 2.2 does not mention the use of a yellow book at CRH.	We have added the information that patients attending CRH also use yellow book in section 2.2
Line 226: Are these clinics nurse or pharmacy led – please clarify here. The answer to the questions was answered once reviewing table 6 later. This will be useful to know as introduction mentions pharmacy-led clinics.	We have added the information in section 2.2. Both services involve multidisciplinary team with pharmacist in a lead role.
Line 256: specify DAWN is an electronic anticoagulation software here rather than in line 261.	Corrected
Line 271-272: explain this statement, INR out of target is considered out of range, do you mean	We have defined as suprathreshold INR (>5) to make it clear.

significantly supra-therapeutic?	
Line 555: Not clear if CRH do a finger-pick test from methodology	We have added the information in section 2.2 (methods)
Table 6, line 328: is postage used at HRI? – not motioned in methodology	No, it is not used for dosing or INR reading like CRH.
Comments from Reviewer 2	
An interviewer-administered data collection tool was used..... “Who were the interviewer..?”	Four authors of this paper interviewed the patients using a data collection tool. We have added this information
I will suggest to elaborate and covers all possible gap like; a) They were member of the research group OR not; b) If not then they were understand the theme of the research and interviewed accordingly; c) Interviewer, consent, conflict and interest, if he/she is not a research team member	Yes, interviewers were the member of our research group and were involved in the project from the beginning to the end.
Tool validity needs to describe in detail	We have described the reliability and validity of the questionnaires included in the data collection tool. The validity has also been described in previous study as mentioned in the methods.
Conclusion should be more specified and should be based on study findings	Our conclusion is written in view of our objectives, but we still revised it to address your comment.

- | | |
|-------------------------------------|-----------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | I declare that we have made the suggested changes as recommended. |
| <input type="checkbox"/> | I confirm that no amendment is required to be made to the manuscript. |



Date: 20-10-2018

Name of Corresponding author: Dr XXX

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The Comparison of Service Models of Warfarin Monitoring in Calderdale and Huddersfield Foundation Trust Hospitals in West Yorkshire, UK

ABSTRACT

Background: Warfarin-related knowledge and patient satisfaction with warfarin monitoring services are generally high with respect to anticoagulation-related care received. Providing a cost-effective warfarin monitoring service while improving warfarin-related knowledge, patient safety and satisfaction can be challenging.

Objectives: To compare 'post and dose' service offered by the Calderdale Royal Hospital (CRH) and 'face-to-face' service offered by Huddersfield Royal Infirmary (HRI) in terms of costs of service delivery, patient satisfaction, warfarin-related knowledge and safety indicators.

Methods: A cross-sectional sample of 160 patients on long-term warfarin therapy from anticoagulation (outpatient) clinics at CRH and HRI using interviewer-administered data collection form. International Normalized Ratio (INR), Time in Therapeutic Range (TTR) and Variance Growth Rate (VGR) values of last 12 months and the data on costs of service delivery, knowledge and satisfaction were collected.

Results: Patients monitored at HRI had higher mean VGR value (0.35 ± 0.62 vs. 0.17 ± 0.17 , $p=0.092$) and slightly lower mean TTR (68.70 ± 19.43 vs. 69.63 ± 17.71 , $p=0.756$) compared with CRH patients. Patients monitored in 'post and dose' were estimated at a price of £11.06 per patient per visit and each patient in face-to-face service only cost £9.70 per visit. Patients monitored at HRI had marginally higher overall knowledge score (65.22 ± 23.29 vs. 60.31 ± 20.93 , $p=0.165$) and overall satisfaction score (15.59 ± 3.16 vs. 15.05 ± 3.10 , $p=0.279$) compared with CRH patients. A positive and significant correlation was found between patients' knowledge and patient satisfaction ($r=+0.327$, $p=0.001$).

Conclusion: Although, HRI provided monitoring service at a slightly lower cost than CRH, patients monitored at CRH had better anticoagulation control and favourable indicators. Warfarin-related knowledge needs to be improved to achieve further improvement in quality of warfarin use.

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The Comparison of Service Models of Warfarin Monitoring in Calderdale and Huddersfield Foundation Trust Hospitals in West Yorkshire, UK

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The Comparison of Service Models of Warfarin Monitoring in Calderdale and Huddersfield Foundation Trust Hospitals in West Yorkshire, UK

1. Introduction

Warfarin is the most commonly prescribed oral anticoagulant in the UK.¹ It is estimated that there are between 500,000 and 1 million people in the UK currently on oral anticoagulant therapy.² Vitamin K antagonists such as warfarin are the first line of treatment in several thrombotic diseases.^{3,4} Patient safety can be enhanced by specialised anti-coagulation clinics that optimise warfarin effectiveness and minimise the safety risks. Several studies showed that patients who are regularly monitored at anticoagulation clinics are more aware of interactions.⁵⁻⁷ Hasan et al., (2011) concluded that patients in pharmacist-managed anticoagulation clinics had better INR control in comparison to patients from physician therapy adherence clinics.⁶ A meta-analysis also found that pharmacist-led clinics had improved clinical outcomes for patients; especially surrounding the reduced risk of bleeding complications.⁷

Cost is an important factor when comparing warfarin monitoring services. An English study (2014) looking at the cost of monitoring elderly patients taking warfarin over 3 care settings; in hospital, in general practice and in a domiciliary setting concluded that patients who had domiciliary monitoring had a lower TTR (68%) compared to those in hospital and general practice, therefore costed the NHS more at a price of £222 per patient per annum (including cost of medication).⁸ Patients monitored in hospital were costed at a price of £128 per patient per annum and each patient in General Practice only cost £126 per annum per year. A systematic review (2010) of 29 studies found that staff time (19 studies; 66%) and measurement of INR (16 studies; 55%) were the most common costs associated with monitoring.⁹ With new models of monitoring continuously evolving to help cut costs, there are ideas surrounding patients being able to use self-testing techniques to monitor their INR.

A Thailand based study comparing the cost-effectiveness of patient-self testing, anticoagulation clinic and usual care found that incremental cost-effectiveness ratios with self-testing was 128,697 (3625 USD) and 130,493 THB (3676 USD) per QALY gained compared with usual care and anticoagulation clinic, respectively. They concluded that patient-self testing is highly cost-effective compared with usual care and less cost-effective against anticoagulation clinic.¹⁰

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63 Patient satisfaction is an essential factor of warfarin monitoring. It consists of a range of
64 factors such as the arrangement of visits and satisfaction associated with staff. A study carried
65 out by Carris et al., (2016) found that follow-up burden was reduced, and patient satisfaction
66 improved with the addition of extended-interval monitoring.¹¹ Similarly, improved patient
67 satisfaction can also correlate with optimum anticoagulant control. A study by Kagansky et
68 al., (2004) found that patients whose INR was in therapeutic range had a higher level of
69 service satisfaction and were more satisfied with their anticoagulant education.¹²
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76 Service monitoring is thought to cost the National Health Service (NHS) a great deal of money
77 each year. Developments of new methods of monitoring are continually arising to help cut
78 costs, and to allow patients to access services closer to home. It is apparent that there is a
79 range of standard variables associated with warfarin monitoring services. This present study
80 aims to compare two warfarin service models provided by two hospitals in the Calderdale and
81 Huddersfield Foundation Trust (CHFT) in the West Yorkshire, United Kingdom. Our specific
82 aims were to estimate the cost of both service models, patient satisfaction, warfarin-related
83 knowledge and safety indicators.
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2. Methods

2.1. Study design and participants

This cross-sectional study was conducted amongst patients aged 18 and over who attended the Calderdale and Huddersfield Foundation Trust (CHFT) hospital (outpatient) clinics between January 2018 and February 2018 in the West Yorkshire, United Kingdom. All participants were required to give their written or verbal consent to partake. Participants would need to be able to articulate, prescribed warfarin for longer than 6 months for any indication.

2.2. Monitoring services at HRI and CRH

Calderdale Royal Hospital (CRH) and Huddersfield Royal Infirmary (HRI) operate different services as they belong to different Clinical Commissioning Groups. CRH offers a 'post and dose' service. This consists of patient's having their INR measured by a phlebotomist. The results are then sent to the patient via the anticoagulation department based at HRI in which the nurses adjust the dose of warfarin accordingly. Patients are contacted by telephone by the anticoagulation nurses with any dose adjustments and receive a dosing instruction letter in the post. The letter also contains INR reading and date of next appointment. Patients are instructed to paste the letter in their yellow warfarin book. The service is a walk-in service so that patients can attend at any time during their allocated appointment day.

In contrast, HRI hosts a face to face clinic. This consists of the patient attending the hospital's anticoagulant clinic. An anticoagulation nurse carries out a finger-prick test and instantly provides the INR value. Dose adjustments are completed during the appointment and the dosing instructions are written in the patient's anticoagulant book (yellow warfarin book) immediately. Patients must adhere to their allocated time slot. Both services use finger-pick method for INR measurement and is performed by a phlebotomist (at CRH) and a nurse (at HRI). The monitoring services at CRH and HRI are run by multidisciplinary team (e.g. pharmacist, nurse).

2.3. Data collection form

An interviewer-administered data collection tool was used to gather patients' demographic, prescribed medication, INR values over the last 12 months and information regarding the number of telephone calls, letters and clinic visits, indication and duration of warfarin

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183 treatment. Four researchers (Ahmed N, Royle-Pryor A, Ahmed R and Brkic A) performed the
184 interviews. Patients were also asked about hospital admissions in the previous year and
185 whether the admission was related to warfarin. In addition to this, they were asked about
186 whether they had experienced any side effects while on warfarin. Finally, whether they take
187 their medication with supervision or support. The data collection form is divided into
188 following sections, evaluating certain aspects of the study aims.
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194 **2.4. Warfarin-related knowledge**

195 Patients knowledge of warfarin treatment was assessed using 8-item questionnaire.⁶ The
196 questionnaire included asking the patient if they were aware of interactions with warfarin
197 and other medication, food or alcohol. They were also asked whether they thought the
198 addition of a new medicine or a change of dose of current medicines would influence their
199 INR.⁶ All 8 items were provided with options of 'yes', 'no' and 'don't know'. The questionnaire
200 was found to be reliable (Cronbach alpha = 0.70). To identify the overall knowledge and
201 satisfaction score, each answer was scored to achieve an overall percentage. A score of 1 was
202 given for each correct answer. The percentage was calculated by dividing the number of
203 correct answers by the total items.⁶
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212 **2.5. Patient satisfaction**

213 A 12-item questionnaire was used to identify patients' satisfaction of the warfarin service.
214 Patients were asked if they had a yellow warfarin book and if they were aware of when their
215 next blood test was. They were also asked if they had received clear counselling on the use of
216 warfarin, what to do in case of a missed dose and if they were aware of what to do in an
217 emergency., Patient satisfaction was tested by asking patients to rate the care given by staff
218 involved in the service, and a satisfaction rating for the service as a whole. These questions
219 were developed by the anticoagulation monitoring service to assess satisfaction. The
220 questionnaire was found to be reliable (Cronbach alpha = 0.74). The overall satisfaction score
221 was achieved by scoring all participants in agreement as 1 or 2, and those that disagreed were
222 given a value of 0, producing a possible range of 0 (not satisfied at all) to 21 (fully satisfied).
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232 **2.6. Costs of monitoring services**

233 The estimated costs of the service monitoring per year was assessed by examining the two
234 clinics that were operated at each base hospital. It did not take into account any satellite
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clinics. The costs included professional fees (cost of anticoagulation team, e.g. nurses), the cost of consumables and the administrative costs. Although indirect costs to the patient is equally important, the present study was restricted to explore the direct costs of the monitoring service to the hospital trust including the two most common costs associated with monitoring: staff time and measurement of INR.⁹

2.7. Anticoagulation control and safety indicators

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The Time in Therapeutic Range (TTR) is an important indicator as it specifies the duration of time a patient's INR values lie within their target range. It is vital in assessing the control and intensity of warfarin therapy. However, it fails to measure the variance in INR readings. Thus, the Variance Growth Rate (VGR) is also required. The VGR value is an essential safety marker as it incorporates the variability and control while highlighting the risk of clinical events such as bleeding.¹³

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Using the patients DAWN (an electronic anticoagulation software) records, the patients INR measurements over the last 12 months, target range, TTR and VGR values were collected. TTR was categorised as excellent (TTR > 80%), good (TTR, 80–69%), average (TTR, 69–57%), below average (TTR, 57–39%) and poor (TTR < 39%).¹³ As per the DAWN records, the VGR when calculated over the previous 3 or 6 months, shows a strong correlation between bleeding events. To calculate the VGR, multiple methods can be used (e.g. the Fihn or the Cannegieter method).¹⁴ Regardless of VGR method, a higher VGR value indicate unstable anticoagulation and a lower VGR (close to 0) value indicates stable anticoagulation.¹³

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An INR value of > 5 on two or more occasions in the past one year was considered as out of range (supratherapeutic INR). In addition to this, patients were asked for consent to access their Summary Care Records (SCRs) to provide a list of current prescribed medication, number of visits to the anticoagulation clinic, the number of INR tests performed, the number of postage from the anticoagulation clinic and the number of telephone calls from the anticoagulation clinic.

2.8. Sample size and sampling procedure

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Using a software (Raosoft, Inc.), a required sample size of 149 was demonstrated (power 80%, distribution of response 50%, with 95% confidence interval). A total of 160 patients on

301 warfarin therapy aged 18 years and above participated in this study.¹⁵ Interviews were done
302 immediately after their clinical encounter with the anticoagulation staff. Convenience
303 sampling was used as the sampling method in this study. Patients were taken into a
304 consultation room to carry out the interview. The study information sheets were shown or
305 given (upon request), and consent (verbal and written) was obtained from each participant
306 before participation in this study.
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313 **2.9. Ethics approval and confidentiality**

314 The ethics approval was obtained from the School of Applied Sciences Research and Ethics
315 Committee (Project ID: SAS-REIC-18-1001-1). The study data had a separate code
316 corresponding to the patients' details. This was only accessible to the PI and stored in a
317 password-protected file.
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324 **2.10. Statistical analysis**

325 The data were analysed using SPSS (version 22) with 0.05 as the level of significance.
326 Descriptive statistics were used to present percentages, frequencies, mean, median and
327 standard deviation. Chi-Squared test was used to compare the characteristics of participants
328 sociodemographic data. Where applicable, the p-value has been computed using the Chi-
329 squared test to distinguish whether the characteristics are statistically significant or not.
330 Independent t-test was applied to compare the sites for mean INR, TTR and VGR values.
331 Spearman correlation was used to assess the relationship between study variables (e.g.
332 knowledge and satisfaction scores).
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3. Results

3.1. Socio-demographic variables of study participants

Table 1 shows that the average age of participants across two study sites was 70.61 ± 14.39 . A large proportion of participants were between the age of 64-74 (26.3% of patients across both sites). Approximately, 74% of patients were above the age of 63. However, more participants between the ages of 18-63 were from HRI (28.7%) as opposed to CRH (22.5%).

More than two-thirds (83.1%) of patients were on warfarin therapy for longer than 24 months. Approximately 42% of patients from CRH and 41% from HRI. Only 3.8% of patients were on warfarin therapy for 6-12 months. Furthermore, the results show that half of the participants (50.6%) had an indication atrial fibrillation. Whereas an indication of DVT was the least common; which consisted of 10% of sample group.

3.2. Patients experience with warfarin treatment

Table 2 displays that overall a quarter of the sample group was admitted to hospital in the last year; with 1.9% of patients being admitted to hospital on a warfarin-related incident. About 89% of the patients stated that they take their medication themselves. Approximately 10% of patients from HRI and 16% from CRH, experienced side effects related to warfarin.

3.3. Patients knowledge of warfarin

Overall, the average percentage of correct answers over both sites was $62.74\% \pm 22.19$ (**Table 3**). Comparing the overall average of correctly answered questions between both locations, HRI had an average of $65.22\% \pm 23.39$, whereas CRH had an average of $60.31 \pm 20.93\%$. A total of 102 patients answered correctly that warfarin affects the blood, whereas, 125 of the patients across both sites did not think warfarin thickens the blood. A positive and statistically significant correlation was found between patients' knowledge and patients' satisfaction ($r=+0.327$, $p=0.001$).

3.4. Patient satisfaction

Table 4 displays that half (56.6%) of the participants felt that they received explicit counselling. Almost 97.5% of patients across both sites, rated the care provided by staff at both locations as excellent. The warfarin service as a whole was ranked as excellent from a total of 158 (98.7%) patients. The overall satisfaction score for patients from HRI was 15.59

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423 versus 15.05 from CRH. More than two-thirds of patients from HRI (91%) were told of the
424 importance of blood monitoring, compared to 69% from HRI.
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427 **3.5. Safety indicators**

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429 Patients monitored at HRI had higher mean VGR value (0.35 ± 0.62 vs. 0.17 ± 0.17 , $p=0.092$)
430 and slightly lower mean TTR (68.70 ± 19.43 vs. 69.63 ± 17.71 , $p=0.756$) compared with CRH
431 patients. The average number of INR values above 5 (11.3%) for both places, with patients
432 from HRI had slightly higher number than CRH (12.5 vs 10.0%, $p=0.617$). However, more
433 patients from HRI (26.2%) achieved a TTR above 82% compared to 21.2% from CRH (**Table 5**).
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435 On average, ten patients across both sites had a poor TTR value (<39%). Despite this, patients
436 in this category had an average knowledge score of $67.5\% \pm 19.7\%$. Also, patients with a poor
437 TTR had an overall satisfaction score of $15.4\% \pm 3.8$. Patients with INR readings above 5,
438 generally scored a higher knowledge percentage (64.6% vs 62.5%) compared to patients with
439 INR values below 5.
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447 **3.6. Cost of service delivery**

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449 The service at HRI operates six clinics per week. Whereas, the clinic based at CRH delivers five
450 clinics per week (**Table 6**). Although HRI provides more clinics, on average, they monitor
451 nearly half the number of patients as opposed to CRH. From the data obtained, HRI monitored
452 an average of 628 patients per month, while CRH monitored 1040 patients. The estimated
453 costs (per patient per visit) at CRH, was approximately £11.06, whereas the cost of dosing a
454 patient at HRI was an estimate of £9.70.
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460 Although the cost of these items was identical across both sites; CRH monitors more patients
461 on average; thus, the cost of consumables will be considerably higher in comparison to HRI.
462 However, this aspect of cost analysis is insignificant when comparing both service models
463 within the CHFT. Furthermore, the significant difference between services was the cost of
464 professionals. CRH has more members of staff involved in the service, for example
465 phlebotomist.
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4. Discussion

The study examined the comparison between two warfarin monitoring services while assessing safety indicators, warfarin-related knowledge, patient satisfaction and the costs associated with running both services. Atrial fibrillation (AF) was the most common indication for warfarin therapy amongst patients in this study. The prevalence of AF increases with age and more men are likely to develop the condition.^{16,17} In 2016, it was reported that 983,254 people across England had atrial fibrillation.¹⁸ Similarly, research conducted in 2014 by NICE found that 34% of patients with atrial fibrillation were undergoing warfarin therapy.

It is vital to consider patient safety when comparing a face-to-face clinic and a 'post and dose' service. Throughout the data collection process, several safety concerns were identified. Warfarin patients are required to carry a yellow anticoagulant therapy book and alert card. The book contains various details, including emergency contact details, information regarding the patients' warfarin therapy, previous and current INR readings and warfarin doses.¹⁹ It was identified that 4 in 5 patients of our study carried a yellow warfarin book. More patients from HRI had a yellow warfarin booklet which may reflect on the type of service offered.

The VGR value is found to be an essential safety marker as it gives the strongest association with clinical events such as bleeding.¹³ The VGR values provided an insight into the relationships between patient safety and warfarin-related knowledge and satisfaction. In this study, patients with a poor VGR had a better knowledge score compared to any other category. Thus suggesting that warfarin-related knowledge may not be a significant predictor of changes in VGR. The patients monitored at CRH and HRI clinics was not significantly different in terms of hospital admissions or adverse effects. Similarly, another found that there was no significant difference in the number of warfarin-related hospital admissions and the type of monitoring service offered.²⁰ This reinforces the importance of considering patient-related factors when discussing hospital admissions. On the other hand, a study conducted by Rudd & Dier (2010), found that pharmacist-managed anticoagulant services significantly improved patient safety by reducing the number of anticoagulation-related events.²¹

In this study, HRI had a slightly higher overall satisfaction score. Patient satisfaction is an important variable when discussing warfarin treatment. It can ultimately affect the quality of

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543 life of patients. Murray et al., (2005) conducted a study with 28 participants on long-term
544 warfarin therapy and found that warfarin therapy reduced the quality of life of patients, with
545 28% of patients reported that warfarin treatment had a negative impact on their work.²² This
546 highlights the effect of poor satisfaction with warfarin treatment and the warfarin service.
547 They also found that patients attending anticoagulation clinics as opposed to primary care
548 surgeries felt that attending the clinics were an inconvenience due to the location. Similarly,
549 appointments at CRH were less time consuming as patients were just required to undergo a
550 finger-prick test. Whereas, patients at HRI had less flexibility when attending the clinic as they
551 were required to attend at a specific time. Nevertheless, patients were given dose
552 adjustments immediately.
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561 As warfarin has a narrow therapeutic index, close monitoring is essential.²³ Thus, it is critical
562 patients can contact the anticoagulation team with any queries. It is important to note that
563 patients with poor INR control may benefit from speaking to a specialist healthcare
564 professional face-to-face. However, patients from CRH do not have this opportunity; thus
565 they have to rely on telephone consultations. Research shows that face-to-face contact has
566 more impact on counselling as opposed to telephone consultations. For example, Hewitt et
567 al., (2010) conducted a study at eight GP surgeries in Scotland and found that telephone
568 consultations were shorter and included less discussion of problems as opposed to face-to-
569 face consultations.²⁴ This is consistent with the present study as patients from HRI displayed
570 better anticoagulant control. Moreover, the literature has suggested that patients feel more
571 comfortable with face-to-face interaction in comparison to telephone consultations. Bungard
572 et al., (2013) assessed the patient satisfaction amongst multidisciplinary anticoagulation
573 clinics and found that patients preferred the care they received from a face-to-face
574 anticoagulant clinic as opposed to visiting their GP.²⁵
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586 Warfarin-related knowledge is an essential indicator of the comparison between two services.
587 However, in our study, only half of the participants across both sites felt that they received
588 counselling on the use of warfarin. As mentioned, the advice is a necessity in all cases where
589 medication is involved mainly in patients taking 'high-risk' medicines such as warfarin.²⁶ Thus,
590 the target for all patients is to ensure that clear counselling is provided and reinforced during
591 their initial therapy and throughout their warfarin journey. The NHS offers checklists for
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603 hospital staff to complete when counselling patients on warfarin.²⁷ The importance of
604 counselling can be found in a study conducted by Collins in 2014 where patients warfarin-
605 related knowledge improved from an average of 65% to 82% after patients received verbal
606 counselling.²⁸ Another study by Lakshmi (2013) found that patients knowledge improved
607 significantly upon the introduction of counselling.²⁹
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613 The cost of running the warfarin monitoring service at CRH was higher in this study (£11.06
614 per patient per visit) compared to £9.70 per patient, per visit at HRI. Despite HRI providing
615 more clinics, fewer patients attended the clinic compared to CRH. On average, CRH monitors
616 52 patients per day, whereas HRI monitors an average of 27 patients per day. The clinic
617 opening times may be responsible for this. CRH clinics operate for 140 hours per month, while
618 HRI operated for 78 hours per month. When discussing the number of patients per day, it is
619 crucial to consider the time spent when dosing these patients.
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626 Furthermore, when analysing the cost data from CRH, it is vital to consider the cost of
627 telephone calls and postage. A 'post and dose' service requires the clinic to send dose
628 adjustments via the post. Thus, postage is an essential aspect of the service which can
629 significantly impact the total cost of running a clinic. Finally, the cost of consumables affected
630 the total cost of the services. Although the cost of consumables was identical across both
631 sites, costs vary depending on the number of items and patients monitored in both clinics.
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638 When interpreting the data presented in this study, it is essential to consider the limitations
639 associated with this study such as sample size, cross-sectional study design and non-
640 probability sampling. The present study aimed to estimate the costs of service delivery in two
641 hospitals which constituted only a part of the the overall service provision. On the other hand,
642 indirect costs are also a vital factor to consider. Indirect costs can significantly affect patient
643 satisfaction and safety. For example, increased waiting time and longer follow-up
644 consultations can reduce patient satisfaction. Furthermore, the cost of treating adverse
645 events can play a crucial role in the comparison between different service models.
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663 **5. Conclusion**
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665 This study has successfully highlighted the similarities and differences between a face-to-face
666 clinic and a post and dose service while assessing warfarin-related knowledge, safety
667 indicators, patient satisfaction and cost of service delivery. Patients from HRI had a marginally
668 higher knowledge score and satisfaction rating compared with patients from CRH. **Although,**
669 **HRI provided monitoring service at a slightly lower cost than CRH, patients monitored at CRH**
670 **had better anticoagulation control and favourable safety indicators.** A cost-effective warfarin
671 monitoring service is essential to improve patient satisfaction, warfarin-related knowledge
672 and patient safety. Overall, the data within this study shows the importance of incorporating
673 all four characteristics to provide the best possible care for warfarin patients attending a
674 warfarin monitoring service.
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683 **Conflict of interest**
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685 None to declare.
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688 **Acknowledgments**
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690 We thank the University of Huddersfield and the management of warfarin monitoring services
691 at CHFT, West Yorkshire for the support during this study and extend our appreciation to all
692 participants who took part in the study.
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Table 1: Socio-demographic data and warfarin-related factors, by CRH and HRI (n=160)

Variable	Total n (%)	CRH n (%)	HRI n (%)	p-value
Mean age (SD)	70.61 (14.39)	71.69 (14.43)	69.53 (14.36)	0.344
Age Groups				
18-63	41 (25.6)	18 (22.5)	23 (28.7)	0.788
64-74	42(26.3)	21 (26.3)	21 (26.3)	
75-80	39 (24.4)	20 (25)	19 (23.8)	
>80	38 (23.7)	21 (26.3)	17 (21.2)	
Sex				
Male	91 (56.9)	47 (58.8)	44 (55.0)	0.632
Female	69 (43.1)	33 (41.2)	36 (45.0)	
Warfarin indication				
AF	81 (50.6)	40 (50.0)	41 (51.2)	0.894
PE	19 (11.9)	8 (10.0)	11 (13.8)	
DVT	16 (10)	8 (10.0)	8 (10.0)	
Mechanical heart valve	26 (16.2)	15 (18.7)	11 (13.8)	
Other	18 (11.2)	9 (11.2)	9 (11.2)	
Duration of warfarin (months)				
6-12	6 (3.8)	4 (5.0)	2 (2.5)	0.773
13-18	12 (7.5)	5 (6.2)	7(8.8)	
19-24	9 (5.6)	4 (5.0)	5 (6.2)	
>24	133 (83.1)	67 (83.8)	66 (82.5)	

Note: p-value calculated using Chi-Square test of proportionality. SD; standard deviation, N; Number of participants, HRI; Huddersfield Royal Infirmary, CRH; Calderdale Royal Hospital, AF; Atrial Fibrillation, PE; Pulmonary Embolism, DVT; Deep Vein Thrombosis, Other; for example, cerebral embolism, femoral popliteal bypass surgery.

Table 2: Summary of patients' experience with warfarin therapy

Statement	Total YES	HRI YES	CRH YES	p- value
	n (%)	n (%)	n (%)	
Have you been admitted to hospital in last one year?	40 (25.0)	21 (26.2)	19 (23.7)	0.715
If yes, for how long in total? mean (range) days	3.6 (0 - 90)	2.1 (0 - 77)	10.0 (1 - 90)	
If admitted into hospital, was this because of warfarin?	3 (1.9)	2 (2.5)	1 (1.2)	0.560
If yes, how many times? mean (range) times	0.04 (0 - 1)	0.02 (0 - 1)	1.0 (1 - 1)	
Have you previously experienced any side effect (e.g. bleeding) because of anticoagulant (warfarin)?	21 (13.1)	8 (10.0)	13 (16.2)	0.242
If yes, how many times? mean (range) times	0.3 (0 - 3)	0.1 SD = 0.3	1.6 (1 - 3)	
On a daily basis, do you currently take your medicines yourself without supervision (self-administered) or support?	142 (88.7)	69 (86.2)	73 (91.2)	0.349

Note: p-value calculated using Chi-Square test of proportionality. N; Number of participants, HRI; Huddersfield Royal Infirmary, CRH; Calderdale Royal Hospital

Table 3: Participant's warfarin-related knowledge, by type of service model

Item	Total		HRI		CRH	
	Yes n (%)	No n (%)	Yes n (%)	No n (%)	Yes n (%)	No n (%)
Warfarin does affect the blood (Q1)	102 (69.9)	44 (30.1)	59 (40.4)	14 (9.6)	43 (29.4)	30 (20.5)
Warfarin thins the blood (Q2)	138 (93.9)	9 (6.1)	74 (50.3)	1 (0.7)	64 (43.5)	8 (5.4)
Warfarin thickens the blood (Q3)	14 (10.1)	125 (89.9)	8 (5.8)	63 (45.3)	6 (4.3)	62 (44.6)
Alcohol does affect warfarin treatment (Q4)	79 (57.7)	58 (42.3)	33 (24.1)	26 (19.0)	46 (33.6)	32 (23.4)
Do you know which drugs should be avoided when receiving warfarin treatment? (Q5)	80 (53.7)	69 (46.3)	35 (23.5)	41 (27.5)	45 (30.2)	28 (18.8)
Do you know which food items should be avoided when taking warfarin? (Q6)	109 (74.1)	38 (25.9)	54 (36.7)	24 (16.3)	55 (37.4)	14 (9.5)
Will starting a new medicine, or any other preparation affect your warfarin treatment? (Q7)	109 (83.2)	22 (16.8)	52 (39.7)	13 (9.9)	57 (43.5)	9 (6.9)
Will changing the dose of a medicine you are already taking affect your warfarin? (Q8)	108 (75.0)	36 (25.0)	47 (32.6)	19 (13.2)	61 (42.4)	17 (11.8)
Number of correct answers, mean (SD)	5.02 (1.78)		5.22 (1.86)		4.83 (1.67)	
Overall knowledge percentage, mean (SD)	62.74 (22.19)		65.22 (23.29)		60.31 (20.93)	

Note: P-value calculated using Chi-Square test of proportionality. N; Number of participants, HRI; Huddersfield Royal Infirmary, CRH; Calderdale Royal Hospital

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Table 4: Patient satisfaction with the warfarin monitoring service at HRI and CRH

Statement	Response in agreement	Total n=160	HRI n=80	CRH n=80
		n (%)	n (%)	n (%)
Have you got a yellow warfarin book? (4a)	Yes	136 (85.0)	79 (98.7)	57 (71.2)
Is the dose of warfarin written clearly in the yellow book? (4b)	Yes	119 (74.4)	77 (96.2)	42 (52.5)
Do you know when and where your next blood test is? (4c)	Yes	77 (48.7)	77 (96.2)	0 (0.0)
Were you given counselling on the use of warfarin? (4d)	Yes, and clear	90 (56.6)	50 (62.5)	40 (50.0)
Was the advice clear and easy to understand? (4e)	Yes	110 (69.6)	52 (65.0)	58 (72.5)
Were you told about the importance of blood monitoring, and was this clear to you? (4f)	Yes, and clear	128 (81.0)	73 (91.2)	55 (68.7)
Were you told of the actions to be taken in case of missed doses, and was this clear to you? (4g)	Yes, and clear	95 (59.4)	57 (71.2)	38 (47.5)
Have you been given details of what to do in an emergency? (4h)	Yes	82 (51.6)	51 (63.7)	31 (38.7)
Have you needed to telephone the Anticoagulation helpline in the last year? (4i)	Yes	43 (39.1)	21 (26.2)	22 (27.5)
If YES, how satisfied are you with our helpline service? (4j)	Very satisfied or satisfied	100 (62.5)	21 (26.2)	79 (98.7)
How do you rate the care given by our staff? (4k)	Excellent or Good	156 (97.5)	77 (96.2)	79 (98.7)

How would you rate the warfarin monitoring service as a whole? (4l)	Excellent or Good	158 (98.7)	79 (98.7)	79 (98.7)
Overall satisfaction score, mean (SD) (possible range: 0 - 21)		15.32 (3.13)	15.59 (3.16)	15.05 (3.10)

P-value calculated using Chi-Square test of proportionality. N; Number of participants, HRI; Huddersfield Royal Infirmary, CRH; Calderdale Royal Hospital

Table 5: The safety indicators, comparing the INR control of patients at HRI and CRH

Item	Total	HRI	CRH	p-value
	n=160	n=80	n=80	
Mean INR	2.60	2.56	2.65	0.170
SD/ Range	0.38/ 1.95-3.90	0.32/ 1.95-3.45	0.43/ 2.10-3.90	-
No of INR > 1 below Target (in last one year)	42 (26.2%)	20 (25.0%)	22 (27.5%)	0.719
No of INR > 1 above target (in last one year)	85 (53.1%)	43 (53.7%)	42 (52.5%)	0.874
No of INR above 4 (in last one year)	52 (32.5%)	21 (26.2%)	31 (38.7%)	0.091
No of INR above 5 (in last one year)	18 (11.3%)	10 (12.5%)	8 (10.0%)	0.617
Mean TTR	69.15	68.70	69.63	0.756
SD/ Range	18.56/ 27-100	19.43/ 29-100	17.71/ 27-100	-
Poor TTR (<39%)	10 (6.2%)	5 (6.2%)	5 (6.2%)	0.489
Below Average TTR (57-39%)	27 (16.9%)	17 (21.2%)	10 (12.5%)	
Average TTR (69-57%)	43 (26.9%)	22 (27.5%)	21 (26.2%)	
Good TTR (82-69%)	37 (23.1%)	15 (18.7%)	22 (27.5%)	
Excellent TTR (>82%)	38 (23.7%)	21 (26.2%)	17 (21.2%)	
Mean VGR (>24 months)	0.25	0.35	0.17	0.092
SD/ Range	0.43/ 0.0-2.70	0.62/ 0.0-2.70	0.17/ 0.01-0.66	-

Note: P-value calculated using Chi-Squared & Independent t-test. N; Number of participants, HRI; Huddersfield Royal Infirmary, CRH; Calderdale Royal Hospital, SD; standard deviation

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Table 6: Estimated Costs associated with warfarin monitoring services at CRH and HRI

Item	HRI	CRH
Number of clinics (average)^a	6/week	5/week
Number of patients (average)	27/day	52/day
Total time (avg min per patient)^f	7min	12min
Number of doctors (avg. per day/clinic)	NIL	NIL
Number of nurses (avg. per day/clinic)	1	1
Number of pharmacists (avg. per day/clinic)	1	1
Number of phlebotomists (avg/clinic)	NIL	1
Administrator (avg. per day/clinic)	1	1
Clerical assistant (avg. per day/clinic) ^b	1	1
	Estimated Cost	Estimated Cost
Point-of-care testing*	£3.74	£3.74
a) INR test strip (per test strip)	£2.05	£2.05
b) Consumables (gloves, tissue, plaster, medical waste wastage discharge, lancing device)	£0.30	£0.30
c) Cost of POC-INR device (based on depreciation over five years) ^c	£1.39	£1.39
Quality assurance/quality control	£3.13	£3.73
a) Quality control test (if any, e.g. QC? QA costs, Coaguchek XS control test)	£3/test	£3.60/test
b) External quality assurance programme (if any, e.g. Royal society program) ^h	£0.13/test	£0.13/test
Fee for service (if any)	NIL	NIL
Professional fees	£2.19	£3.28
a) Health Professional time (per patient per visit) ^e e.g nurse	£1.03	£1.18
b) Other staff (per patient per visit), e.g. clerical staff	£1.16	£2.10
Miscellaneous Costs	£0.64	£0.91
a) Postage from monitoring service (per patient per visit) ^g	£0.33	£0.67
b) Telephone calls (per patient per visit	£0.31	£0.24
No. of telephone calls to patients (on a typical clinic day) at 14p/min	£1.68/day	£2.24/day

Cost (per patient per visit) *	£9.70	£11.06
Cost (per patient per year) *	£116.40	£132.72
Total Cost (per clinic per day) *	£261.90	£575.12
Total Cost (per clinic per year) *	£81,712.80	£149,531.20

*= Based on low test frequency of one test or visit/ month. HRI (12x1x27) = 324 tests per year CRH (12x1x52) = 624 tests per year.

^a. CRH clinics are from 8 - 3pm Mon to Fri = 140hrs/month; HRI clinics are approx. 5 x 3.5 hours and 1 x 2 hours = 78hrs/month

^b. Approx. 5 hrs/day answering the phone for changing appointments and following up missed appointments etc. - at both services

^c. Cost = £3000; Salvage value = £500; Total depreciation = £2500

Monthly depreciation = (2500/5) ÷ 12 = £41.67; Daily depreciation = £1.39

^d. Machines are Qc'd at HRI in batches as more machines are available hence less frequently performed. Machines have been updated at CRH, and the new solutions are more expensive. All machines are Qc'd before each clinic (HRI: 4 times a week; CRH: 5 times a week).

^e. Estimated using national average salary for a Nurse: £25,820/365days

^f. CRH: 4min for blood test+ 1 for Apex transfer of result+ 7 min for ringing with dose change. Waiting time is not included.

^g. Approx. 50% of those attending clinic may need a phone call. Everyone with a dosage change receives a call. Estimated using First class post

^h. The same frequency for both sites every two months

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