



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive



STROKE

Warfarin Clinic Survey

National Stroke Programme

HSE Clinical Strategy and Programmes Directorate

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Context

The national clinical care programme for Stroke began in 2010 under the Clinical Strategy and Programmes Directorate (CSPD). As part of this programme the Atrial Fibrillation Working Group (AFWG) was convened. The aim of this group is to advise on guidelines and protocols to improve the care of Atrial Fibrillation (AF) patients in Ireland with emphasis on stroke prevention.

The objectives of this group are consistent with the Stroke Project Plan and relevant clinical care programmes project plans:

1. To advise on strategies regarding implementing AF recommendations in the Department of Health & Children policy 'Changing Cardiovascular Health, National Cardiovascular Health Policy 2010-2019'¹
2. To address the current knowledge gap with regard to epidemiology, anticoagulant therapy and current services.
3. To recommend standards on current best practice in line with HSE Policy/Procedure/Protocol/Guideline development process
4. To recommend a model of shared care for hospital and primary care services caring for patients with AF.
5. To research and recommend best practice regarding early detection of AF.
6. To review current Information and Communication Technology (ICT) solutions in use by anticoagulation services with a view to recommending one ICT solution.
7. To facilitate the development of educational materials for patients and families (in different media) in collaboration with voluntary agencies.

It was agreed that in order to fulfil objectives 2, 3, 4 and 6 of the AFWG a survey of warfarin services in the Republic of Ireland was necessary.

Specific Objectives

As a component part of an overall gap analysis regarding atrial fibrillation and anticoagulation services, the aim of this survey is to identify and map the provision of current anticoagulation services in hospital and primary care settings to facilitate future planning of services.

Background

Atrial Fibrillation is a common cardiac arrhythmia, occurring in 1-2% of the general population. The prevalence increases with age from less than 0.5% at 40-50 years, to 5-15% at 80 years^{2,3}. The United Nations Population Division and World Health Organisation estimate that the world proportion of people aged 65 or older will increase from 7.3% in 2005 to 16.2% in 2050. In Ireland, substantial increases are predicted, with increases in the over 80's by two-thirds by 2021. In population studies, AF has been found to be associated with a 5-fold increased risk of stroke, independent of other vascular risk factors. Many studies have indicated that 20-30% of all strokes are attributable to AF, both in Ireland and internationally⁴.

The risk of stroke associated with AF is reduced by up to 67% by anticoagulant prophylaxis, usually with warfarin⁵. Warfarin is used as an anticoagulant to treat such conditions as irregular heart beats (atrial fibrillation), DVT (deep vein thrombosis) and lung clots (pulmonary embolism). However, despite evidence of substantial benefit, under utilisation of anticoagulation remains very common^{6,7,8}. Warfarin is taken on a daily basis and is associated with risk of haemorrhage and the decision to begin warfarin treatment in patients with AF is often difficult, particularly for older patients who may be frail or have complex histories. No standardised approach exists for the selection of appropriate patients for warfarin therapy and consequently, physician-related and patient-related factors frequently influence the decision to prescribe⁹. Some studies have found that non-specialist hospital and community physicians may over-estimate bleeding risk and under estimate stroke risk, especially in older patients in whom there is a concern about falls. Other data suggest that some patients may incompletely understand the benefits of anticoagulation therapy. This may be improved by education, using pictorial aids and decision aids^{10,11}. Alternatively some patients may make an informed decision to decline therapy, deterred by the inconvenience of travelling for blood tests for warfarin monitoring, the need to avoid alcohol, or other reasons. Due to a narrow therapeutic range of warfarin, anticoagulation monitoring is essential and is delivered in a hospital clinic, primary care, or home based setting. This monitoring is performed utilising a blood test called an International Normalised Ratio (INR) which is performed regularly and this gives a number which is used to monitor such patients in order that their blood is not too thick or too thin.

Atrial Fibrillation in Ireland

Several Irish studies have identified the growing public health problem of atrial fibrillation. The North Dublin Population Stroke Study (NDPSS) identified atrial fibrillation in 31% of all incident stroke patients of which 46% were newly diagnosed¹². Of those with pre-existing atrial fibrillation, 28% were on oral anticoagulants, 55% were on anti-platelet therapy and 17% were on no treatment. In addition, the Irish National Audit on Stroke Care reported that 22% of 2,173 patients were known to have atrial fibrillation of whom 26% were on warfarin, 57% were on anti-platelet therapy and 22% were on neither¹³. These studies reiterate previous findings in both hospital and community-based studies in Ireland^{14,15}. The problem of under-detection and under treatment of atrial fibrillation has been addressed in the Department of Health and Children policy 'Changing Cardiovascular Health, National Cardiovascular Health Policy 2010-2019'¹⁶. Recommendation 4.7 highlights the need for effective means for early detection in people aged 65 years and older in addition to clinical leadership of integrated anticoagulation services. It states the following:

- A screening programme for atrial fibrillation should be established with formal evaluation to ensure an effective means of implementation for people aged 65 or older
- Clinical leadership of integrated anticoagulation services must be established within service networks so that GPs and hospital staff achieve and assure optimal care for all.
- Structured anticoagulation services will be developed between primary care services and hospital anticoagulation clinics

Despite the well recognised association between atrial fibrillation and ischaemic stroke, and the benefits of anticoagulation therapy, a large proportion of patients in Ireland with atrial fibrillation remain undetected and under treated.

In 2010, approximately 57,000 people in Ireland were prescribed warfarin¹⁷. Literature would suggest that indications for warfarin therapy are predominately for atrial fibrillation (64%), venous thrombosis (19%) and heart valve dysfunction (13%)¹⁸. Anecdotal Irish figures would suggest that indications for warfarin therapy are somewhat consistent with international trends; atrial fibrillation (55%), venous thrombosis (23%) and heart valve dysfunction (23%).

At present, it is estimated that from 40-83% of GPs are providing warfarin services in their practices in primary care¹⁹, however, it is difficult to establish at this stage the exact figure as no national census of this information has been undertaken. Anecdotally, it appears that the GP provision of warfarin services

appears limited in urban areas where patients are referred into the acute hospitals to be managed while in more rural areas GP's appear to be providing a warfarin service but there are no concrete data to support this.

As noted earlier, warfarin monitoring can be performed in a dedicated hospital clinic or in Primary Care.

There are two ways that an INR test can be performed:

1. Finger prick test in the GP surgery using a small machine called a coagulometer.
 - This provides the INR result in two minutes
2. Blood sample sent to a laboratory (the blood sample can be either taken in Primary Care or at the Hospital clinic)

The result is then communicated in the following ways:

- phoned through to the GP
- phoned to the hospital clinic
- communicated through a computerised lab system

The decision on the dose of the warfarin to be taken is then based on the INR result.

Methods

A list of warfarin clinics providing returns to the HSE Business Intelligence Unit was obtained which identified 20 hospitals that were providing a warfarin service. However, anecdotal evidence suggested that other hospitals were also providing a warfarin service. A telephone survey of all acute and non-acute hospitals was carried out to ask if there was a warfarin clinic in their hospital. A database of the names and email addresses of the Clinical Directors and the Clinical Lead responsible for the warfarin clinics in identified hospitals was created. An internet based survey was carried out using Zoomerang software where the survey was emailed to the Clinical Leads of the warfarin service and the hospital Clinical Directors were also made aware of the survey. The survey was completed and submitted online. In many instances the completion of the survey was delegated to staff members of the warfarin clinic and it is assumed that rough estimations were used when estimating clinic activity. During the data analysis phase, emails were circulated to all respondents to confirm that they were satisfied that the responses provided to the workload element of the survey were an accurate reflection of the level of activity at their warfarin clinic.

Data Analysis

Data were analysed using Predictive Analytics Software (PASW v18) and Microsoft Excel where appropriate. As this is a descriptive piece of work, basic descriptive statistics shall be used such as frequencies with means, medians etc where appropriate. At this stage there does not seem to be any requirement for any statistical tests to be employed.

Free text comments shall be analysed qualitatively using a general inductive approach where minor themes are identified and then grouped into major themes for comment and discussion where relevant.

It was noted during the analysis that a number of centres did not have a database specific to their warfarin clinics. Therefore, some caution needs to be exercised when interpreting the results.

Results

1. General Demographic Details

The survey was distributed to 33 hospitals and returns were received from 31 which is a response rate of 94%. Two hospitals indicated in their response that they do not provide a standard warfarin clinic in that they provided either a phlebotomy service only with the results sent back to the GP for management, or they stabilised patients in their Medical Assessment Unit (MAU) before discharging the patient back to the care of the GP. Therefore, the responses from these two hospitals were removed from the database, thus leaving 29 hospital responses for analysis.

Location of Warfarin Clinics

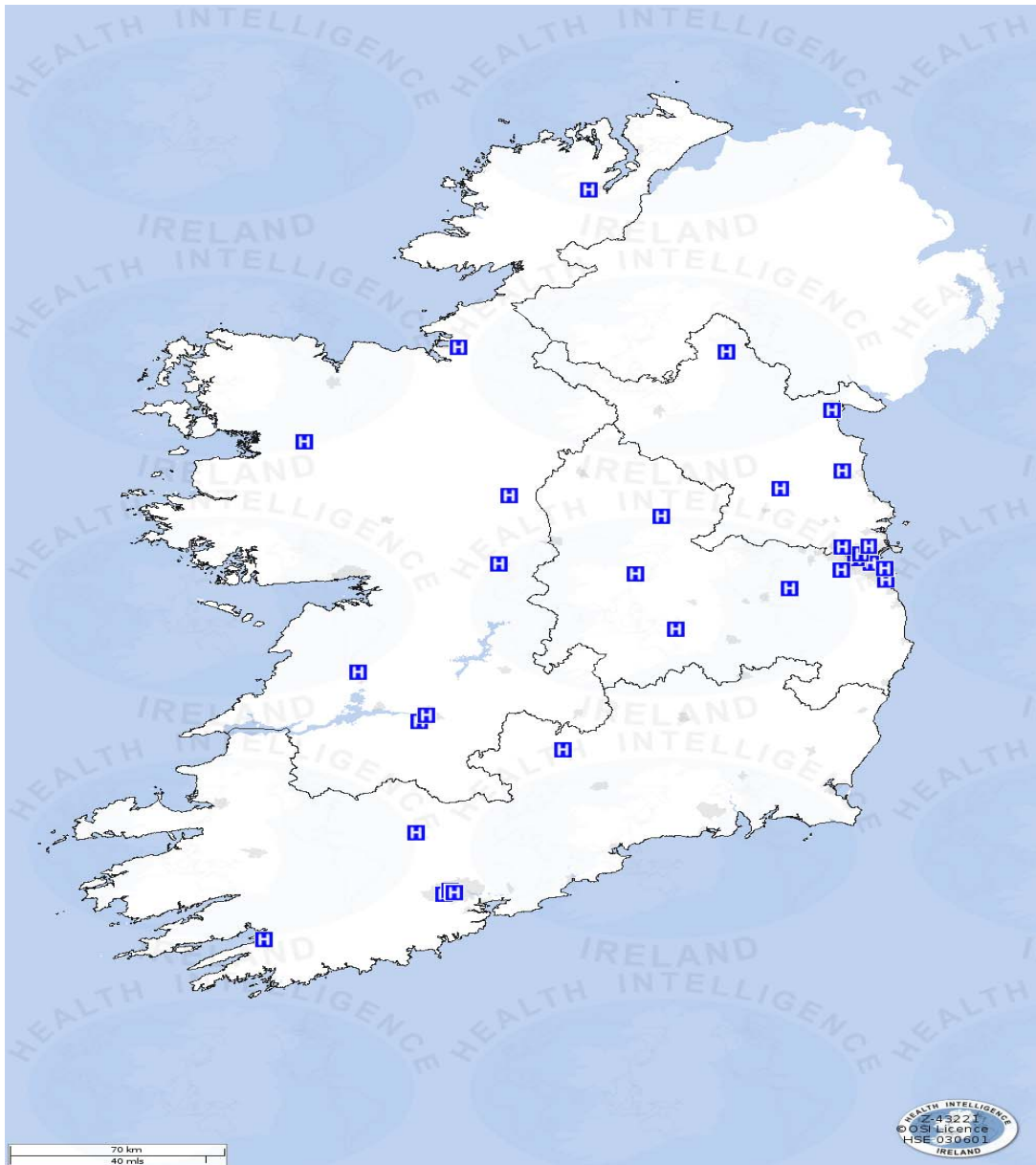
Warfarin clinics are located in hospitals throughout the country. There were two hospitals that did not provide a response to the survey but as they have a warfarin clinic they are included in Table 1 and Figure 1 which outlines the distribution of warfarin clinics by HSE area, though the level of service at these two hospitals is unknown.

Table 1: Warfarin clinic by HSE Area

HSE Area	Frequency	%
Dublin Mid-Leinster	9	29.0
West	8	25.8
South	7 (1)	22.6
Dublin North East	7 (1)	22.6
Total	31	100

Note: numbers in parenthesis refer to the two hospitals that did not provide a response to the survey

Figure 1: Location of Hospital Warfarin Clinics



2. Warfarin Services Within Hospitals

Respondents were asked which department was responsible for the provision of warfarin services in their hospital. The options provided on the survey were haematology, cardiology, care of elderly and other and the breakdown is shown in Table 2.

Table 2: Which Department is responsible for the warfarin service?

Department	Frequency	%
Haematology	12	41.4
Cardiology	3	10.3
Care of Elderly	1	3.4
Other	13	44.8
Total	29	100

If 'Other' was selected, respondents were asked to specify and 46.2% (n=6) recorded General Medicine, 23.1% (n=3) noted Outpatients Department (OPD), 15.4% (n=2) noted Pharmacy/Laboratory and there were two additional responses:

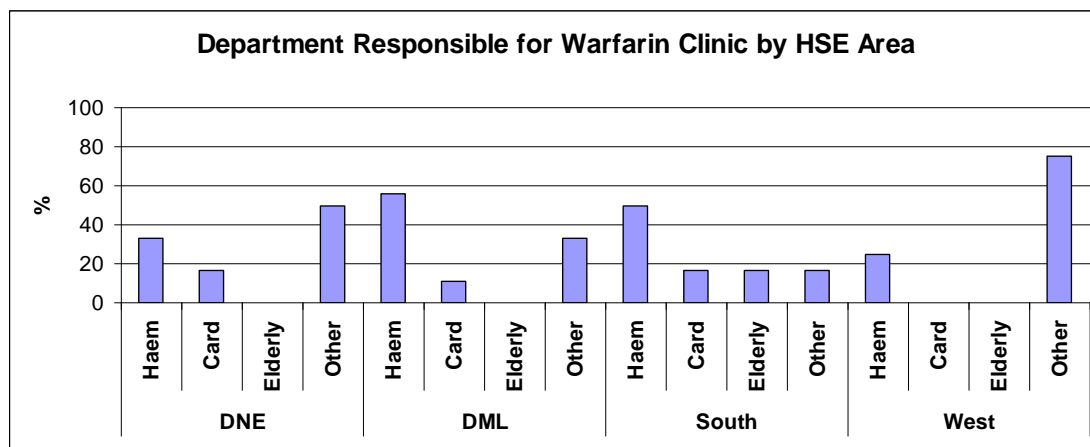
- "All of the above/medical services"
- "Nurse managed service, accessed by all hospital consultants who are responsible for the patient's medical/surgical care. Their responsibilities include prescribing OAC, referring patients for on going monitoring and reviewing their patients, if they have difficulty in achieving therapeutic range. A Consultant Haematologist provides clinical supervision of the service and development of the service in line with best practice. Also available for clinical consultation"

Analysis was performed by HSE area to see if there were any geographical variations on the department responsible for the provision of the warfarin clinic – see Table 3, Figure 2. Warfarin clinics in HSE Dublin Mid Leinster and HSE South were primarily the responsibility of either the haematology or cardiology departments. In HSE Dublin North East and HSE West the responsibility lay in other areas such as General Medicine or Pharmacy.

Table 3: Department Responsible for Warfarin Clinic by HSE Area

HSE Area	Department	Frequency	%
Dublin North East (n=6)	Haematology	2	33.3
	Cardiology	1	16.7
	Care of Elderly	0	0
	Other	3	50
Dublin Mid Leinster (n=9)	Haematology	5	55.6
	Cardiology	1	11.1
	Care of Elderly	0	0
	Other	3	33.3
South (n=6)	Haematology	3	50
	Cardiology	1	16.7
	Care of Elderly	1	16.7
	Other	1	16.7
West (n=8)	Haematology	2	25
	Cardiology	0	0
	Care of Elderly	0	0
	Other	6	75

Figure 2: Department Responsible for Warfarin Clinic by HSE Area



How many days per week does your hospital provide a warfarin clinic?

The frequency distribution for the 29 hospitals is noted in table 4 and Figures 3 and 4 which shows that one in five hospitals (20.7%) indicated that they had a clinic on a half day per week with 17.2% reporting that they had a warfarin clinic five days per week with all others somewhere in between. Note that a full day is defined as two clinic sessions, morning and afternoon. The hospitals that had a warfarin clinic every day were, as expected, some of the larger hospitals –

Beaumont, St Vincent's, Mater and St James's although Midland Regional Hospital Portlaoise reported that they were amongst this group. AMNCH and Cork University Hospital reported that their warfarin clinics were held 4.5 days per week

Table 4: Number of days per week for Warfarin clinic

	0.5	1	1.5	2	2.5	3	3.5	4	4.5	5
%	20.7	10.3	6.9	13.8	6.9	6.9	6.9	3.4	6.9	17.2

Figure 3: Number of days per week for Warfarin clinic

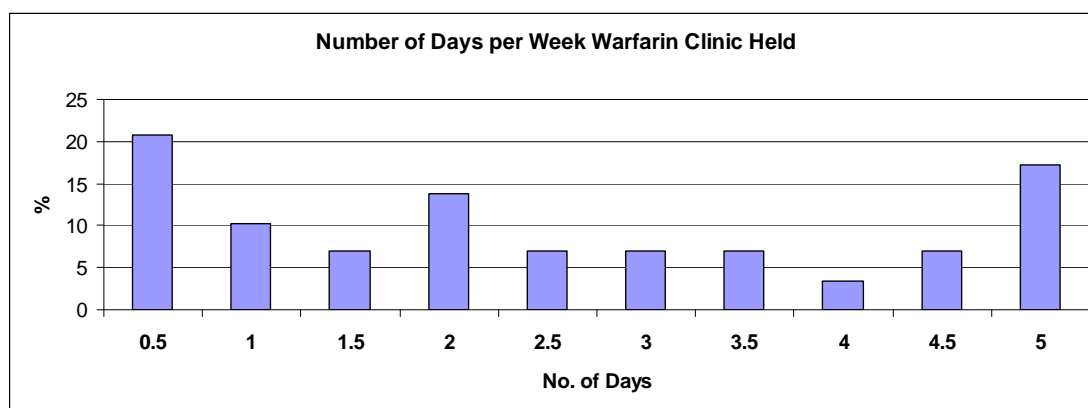
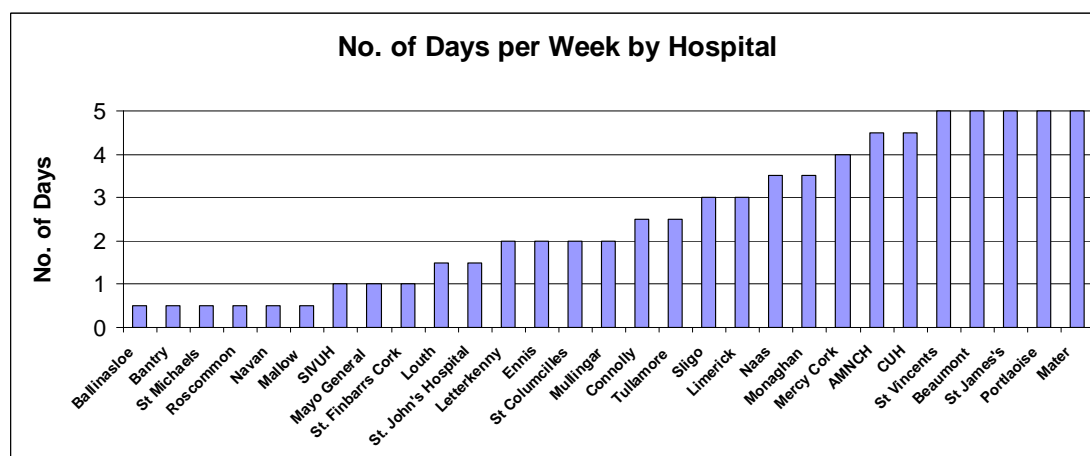


Figure 4: Number of days/week for Warfarin Clinic by Hospital



There were a number of comments recorded to provide further clarity around the number of clinics that were held:

- "20 hours per week" – **Monaghan (3.5 days)**
- "8-9.30am" – **Connolly (2.5 days)**
- "Main warfarin clinic is on Wednesday, other days for new, non-therapeutic patients and discharges from Hospital etc" – **Naas (3.5 days)**
- "Morning clinic 5 days per week for patient attendance for bloods but full time service provided with nursing staff dosing, reviewing and education patients in the afternoons" – **St James's (5 days)**

- "4 clinics a week" – **Mullingar (2 days)**
- "Phlebotomy open 08:00-11:00 and Nursing admin 08:00-16:30" - **St Vincent's (5 days)**
- "Flexibility for 5 days" – **Letterkenny (2 days)**
- "Other days as necessary for individual patients - **Portiuncula, Ballinasloe (0.5 days)**

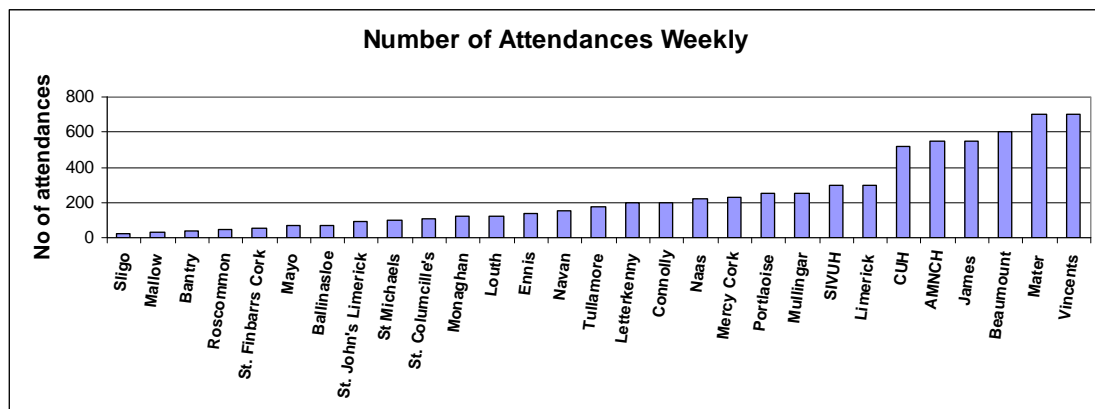
Workload of Warfarin Clinic

Respondents were asked to provide details of the number of patients that attended their warfarin clinic per week on average and also how many new patients were registered in 2010. A separate request was issued via email to the contact names provided asking for the total number of patients registered with their warfarin clinic at the end of 2010.

The survey did not ask how the data were collected but did ask which hospitals had Computer Assisted Dosing (CAD) systems and it is recognised that these systems are ideal for collecting data on warfarin patients and would indicate that data from hospitals with these systems may be more reliable. The topic of CAD is addressed later in this report but for the tables in this section the hospitals that have CAD systems are noted with an '*'.

Regarding the number of patients that attended each clinic per week, this obviously varied depending on the size of the hospital and the number of clinics they reported that they held each week. As expected, the larger urban hospitals reported the greatest patient throughput – St Vincent's (700), Mater (700) Beaumont (600), St James's (550), CUH (520) and Limerick (300). Figure 5 outlines this in more detail.

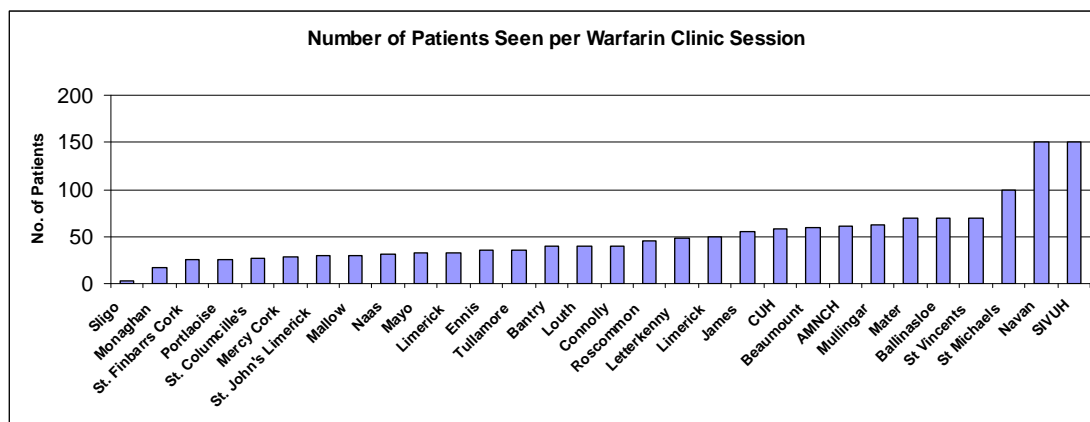
Figure 5: Number of attendances to warfarin clinics per week



Analysing this weekly workload by the reported number of weekly warfarin clinic sessions held by each hospital, throws up some interesting figures with the clinic

throughput in St Michaels, Navan and South Infirmery Cork greater than that seen in the bigger urban hospitals – Figure 6. Note that a clinic session = 0.5 day – morning or afternoon.

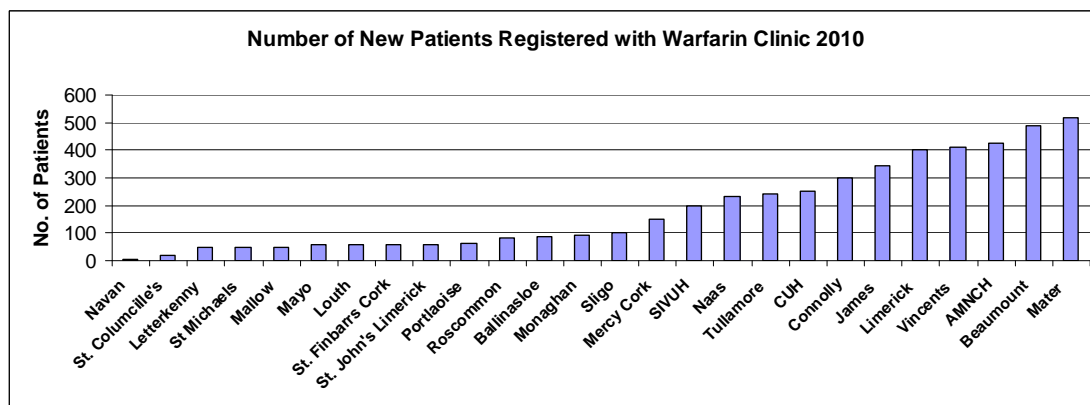
Figure 6: Number of patients seen per warfarin session



New patients registered in 2010

Respondents were asked to indicate the number of new patients (to the nearest estimate) that were registered with their service in 2010 – Figure 7. Twenty six hospitals responded and the number of new patients ranged from 3 in Navan to 520 in the Mater with 54% of hospitals reporting that they registered 100 new patients or less in 2010.

Figure 7: Number of new patients registered with warfarin clinic in 2010



Summary of workload

Table 5 and the accompanying map below outlines the number of new patients registered in 2010, the number of patients that each hospital reported that they saw on average each week, the total number of actual patients registered with the warfarin clinics at the end of 2010 and a calculation showing the average number of visits per patient per year. There were three hospitals that were unable to provide data for the number of new patients registered in 2010 and these are noted by 'N/R' in the table.

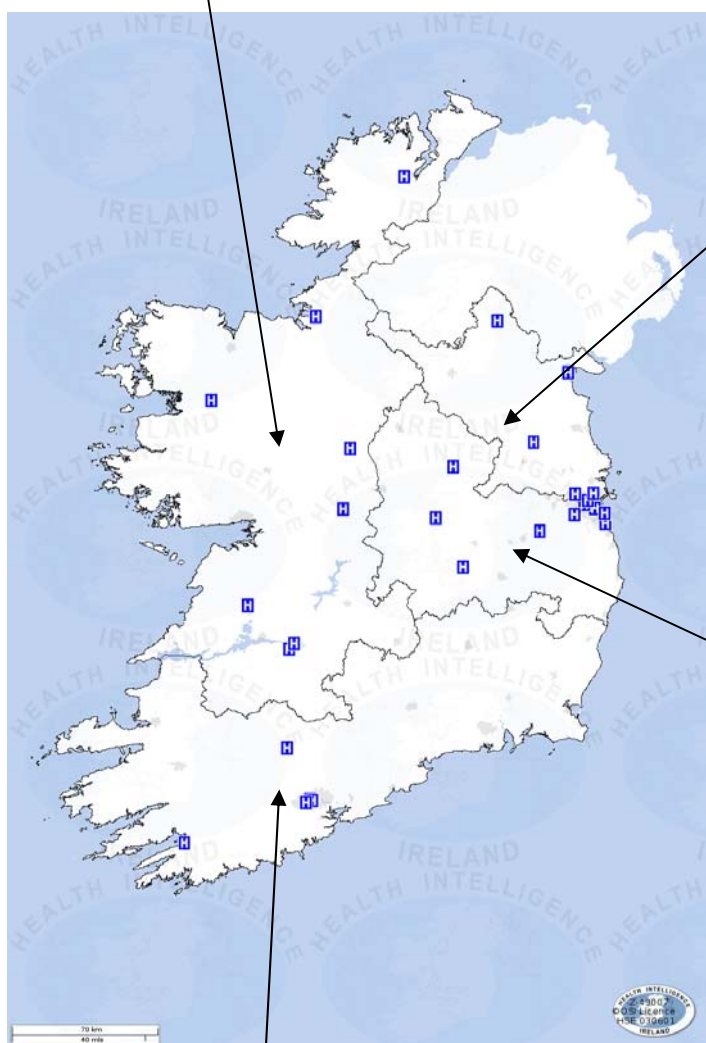
Table 5: Summary of workload 2010

Hospital	New Patients Registered 2010	No of Patients Seen Per Week	No of Patients Registered 2010	No of visits/patient/year†
Dublin North East				
Navan	3	150		
Louth	60	120		
Monaghan	90	120		
Connolly	300	200	780	13.3
Beaumont*	490	600	2826	11.0
Mater*	520	700	1901	19.1
Dublin Mid Leinster				
St Michael's*	50	100		
St. Vincent's*	410	700	1600	22.8
St Columcille's	20	110		
AMNCH*	425	550	1966	14.6
St James's*	343	550	1573	18.2
Mullingar	N/R	250	600	21.7
Portlaoise	65	250	584	22.3
Tullamore	240	175	674	13.5
Naas	230	220	680	16.8
South				
South Infirmary	200	300	4069	3.8
CUH*	250	520	1100	24.6
Bantry	N/R	40	120	17.3
Mercy Cork*	150	230		
St Finbarr's	60	50	80	32.5
Mallow	50	30		
West				
Letterkenny*	50	195	640	15.8
Mayo	56	65		
Sligo	100	20		
Portiuncula*	88	70	302	12.1
Roscommon	83	45		
Limerick*	400	300	395	39.5
St John's Limerick*	60	90	300	15.6
Ennis	N/R	140		
Total	4793	6890	20190	14.8**

† Based on 52 weeks

** Calculated on those hospitals that returned full set of data

Hospital	No of New Patients Registered 2010
Letterkenny	50
Mayo	56
St John's	60
Roscommon	83
Portiuncula	88
Sligo	100
Limerick	400
Ennis	N/R



Hospital	No of New Patients Registered 2010
Navan	3
Louth	60
Monaghan	90
Connolly	300
Beaumont	490
Mater	520

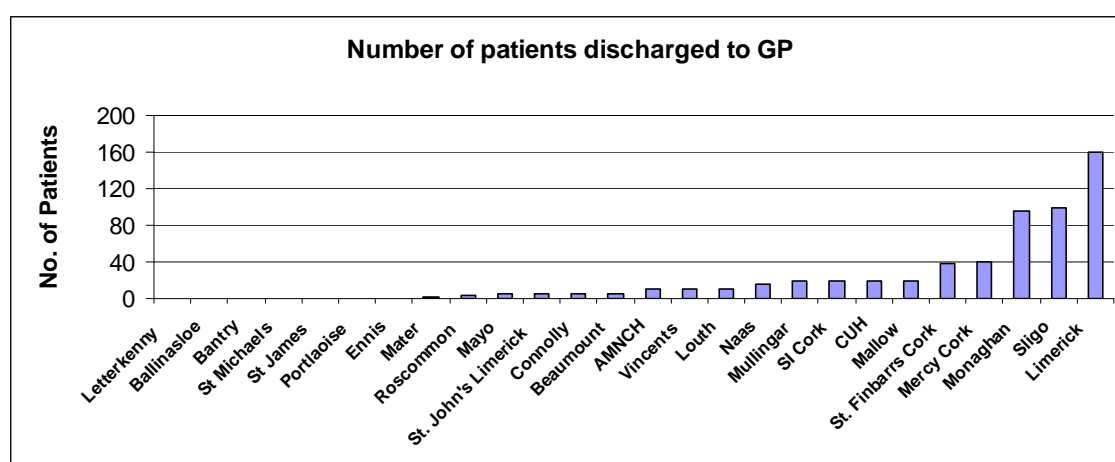
Hospital	No of New Patients Registered 2010
St Columcille's	20
St Michael's	50
Portlaoise	65
Naas	230
Tullamore	240
St James's	343
St Vincent's	410
AMNCH	425
Mullingar	N/R

Hospital	No of New Patients Registered 2010
Mallow	50
St Finbarr's	60
Mercy	150
South Infirmary	200
CUH	250
Bantry	N/R

Patients discharged to their GP

Hospitals were asked how many patients in 2010 were discharged from the warfarin clinic back to the care of their GP and 26 hospitals provided data. The distribution by hospital is shown in Figure 8. Of interest is the fact that in seven hospitals (26.9%), no patients were discharged back to their GP and in a further six hospitals (23.1%), less than ten patients were discharged. Of particular interest is that one of the biggest services in the country with on average 700 patients seen per week only discharged two patients from their warfarin clinic while another with 550 per week did not discharge any patients.

Figure 8: Number of patients discharged to GP



Appointments

Respondents were asked to identify what appointment system that they used for the warfarin clinic. There were a number of multiple responses to this question with one hospital reporting that patients can walk in without an appointment and also by appointment within a time range. Therefore n=30 for this analysis and the majority (66.7%) reporting that patients are invited by appointment within a time range – see Table 6. One hospital noted that while they try to implement an appointment time policy, some patients arrive at different times or just walk in.

Table 6: Appointment system in use for warfarin clinic

	Frequency	%
Walk-in without appointment	2	6.7
By appointment with a specific time	8	26.7
By appointment with time range	20	66.7
Other	0	0
Total	30	100

Table 7: Appointment type by hospital

	Hospital
Walk-in without appointment	Letterkenny
	Ennis
By appointment with a specific time	AMNCH
	Mallow
	Mullingar
	Ballinasloe
	Roscommon
	St Columcilles
	St James
By appointment with time range	Mater
	Bantry
	Beaumont
	Connolly
	CUH
	Letterkenny
	Louth
	Mayo
	Mercy
	Limerick
	Portlaoise
	Tullamore
	Monaghan
	Naas
	Navan
	Sligo
	SIVUH
	St Finbarr's
St Johns Limerick	
St Michaels	
St Vincent's	

Waiting time from referral to clinic attendance

All 29 hospitals provided responses to this question with 28 providing an actual answer – see Table 8. One hospital – did not indicate a referral time but provided two comments:

- “Following stabilisation by referring doctor” – **St Vincent's**

Analysing the remaining responses showed that three quarters of patients are waiting less than one week to attend their local warfarin clinic – one hospital commented “immediate, dictated by clinical status”. A further 18% reported that their patients were waiting less than two weeks.

Table 8: Waiting time from referral to clinic attendance

	Frequency	%
Less than 1 week	21	75
7 – 14 days	5	17.9
15 – 28 days	2	7.1
Greater than 4 weeks	0	0
Total	28	100

Who refers patients to the clinic?

The respondents were asked to indicate who referred patients to the warfarin clinic and multiple responses were allowed for this question. The analysis is shown in Table 9 and shows that in all 29 hospitals a Consultant refers patients while in 21 hospitals an NCHD may refer. Sixteen hospitals indicated that a GP may refer with only two hospitals noting that a nurse can refer.

Table 9: Who refers patient to the warfarin clinic

	Frequency	%
Consultant (n=29)	29	100
NCHD (n=29)	21	72.4
Nurse (n=29)	2	6.9
GP (n=29)	16	55.2
Pharmacist (n=29)	0	0

There were a number of comments (n=5) indicating that other hospitals may also refer patients to the warfarin clinic and St James's indicated that nurses from the "Specialist Coag Centre NCHCD" may also refer.

Who determines the required INR range for the new patient?

There were responses from all 29 hospitals to this question with 93% (n=27) indicating that it was the referring physician and 7% (n=2) indicating that it was the warfarin clinic.

Who determines the warfarin dosing schedule on the patient's first visit?

The respondents were asked to indicate who determines the warfarin dosing schedule on the patient's first visit and multiple responses were allowed for this question. The analysis is shown in Table 10 and shows that across the country there is a variation in who determines the dosing schedule. Further analysis of the data demonstrates that warfarin dosing is determined by consultant only in 17.2% of hospitals (n=5), in 37.9% of hospitals (n=11) it is determined by NCHD only and in

20.7% of hospitals (n=6) it is determined solely by nursing staff. The pharmacist has sole responsibility for the warfarin dosing schedule in 6.9% of hospitals (n=2) and in the remaining five hospitals it is a combination of staff.

Table 10: Who determines warfarin dosing schedule at first visit

	Frequency	%
Consultant (n=29)	10	34.5
NCHD (n=29)	15	51.7
Nurse (n=29)	9	31.0
Pharmacist (n=29)	3	10.3

What guidelines do you use in the warfarin service?

Respondents were asked to indicate the guidelines, if any, that they used in the running of their warfarin service. The results are shown in Table 11 with the vast majority (86.2%) reporting that they used the British Society for Haematology 'Guidelines on oral anticoagulation' with four of these hospitals indicating that they used both the British Society for Haematology and the ACCP guidelines while one hospital reporting that they used the British Society for Haematology and Ansell J.E., et al 'Consensus guidelines for co-ordinated outpatient oral anticoagulation therapy management'. Four hospitals indicated that they didn't use any of these and three commented:

- "BNF39 March 2000, Fennerty"
- "Local Guidelines"
- "On INR result"

Table 11: Guidelines used in warfarin clinics

	Frequency	%
British Society for Haematology 'Guidelines on oral anticoagulation' (n=29)	25	86.2
Ansell J.E., et al 'Consensus guidelines for co-ordinated outpatient oral anticoagulation therapy management' (n=29)	1	3.4
ACCP Guidelines (n=29)	4	13.8
Other	3	10.3

For patients within the therapeutic INR range, who recommends the warfarin dose?

This was a multiple answer question and results are shown in Table 12. Twenty eight hospitals provided an accurate answer with one hospital providing an answer of 'Other'. No hospital was Consultant only with regard to determining the dosing schedule for patients within therapeutic INR while ten hospitals indicated that it was NCHD only that did this. Another eight hospitals indicated that the nurse solely recommended the dosing for patients within therapeutic INR range, while a pharmacist was solely responsible in a further two hospitals. The remaining eight hospitals indicated that it was a combination of staff – 3 Consultant/NCHD, 2 Consultant/NCHD/Nurse, 2 NCHD/Nurse and 1 Nurse/Pharmacist. The hospital that recorded 'Other' commented:

- "Computerised/Nurse"

Table 12: Who recommends warfarin dose for patients within therapeutic INR range

	Frequency	%
Consultant (n=29)	5	17.2
NCHD (n=29)	17	58.6
Nurse (n=29)	13	44.8
Pharmacist (n=29)	3	10.3
Other	1	3.4

How often are patients who are well controlled within the therapeutic INR range recalled for INR testing by the warfarin clinic?

Over half of all patients that are well controlled within therapeutic INR range are recalled within 6 weeks with another 28% recalled within 6-8 weeks. There were no patients waiting more than 12 weeks for recall.

Table 13: How often are well controlled patients recalled for INR Testing?

	Frequency	%
Less than 4 weeks	1	3.4
4 – 6 weeks	15	51.7
6 – 8 weeks	8	27.6
8 – 12 weeks	5	17.2
Greater than 12 weeks	0	0

For patients outside the therapeutic INR range who recommends the warfarin dose?

This was a multiple answer question and results are shown in Table 14. Twenty eight provided an accurate answer with one hospital providing an answer of 'Other'. Two hospitals were Consultant only with regard to determining the dosing schedule for patients outside therapeutic INR, a further eleven hospitals indicated that it was NCHD only that did this. Another four hospitals indicated that the nurse solely recommended the dosing for these patients although a comment "occasionally consultant haematologist, registrar haematology" was recorded, while a pharmacist was solely responsible in a further two hospitals. The remaining nine hospitals indicated that it was a combination of staff – 3 Consultant/NCHD, 2 Consultant/NCHD/Nurse, 1 Consultant/Nurse and 3 NCHD/Nurse. The one hospital that recorded 'Other' commented:

- "Nurse up to INR of 5 and Haem registrar above 5"

Table 14: Who recommends warfarin dose for patients outside therapeutic INR range

	Frequency	%
Consultant (n=29)	8	27.6
NCHD (n=29)	19	65.5
Nurse (n=29)	10	34.5
Pharmacist (n=29)	2	6.9
Other (n=29)	1	3.4

How do you inform the patient of the latest INR result?

All 29 hospitals provided an answer to this question which allowed for multiple responses. The results are shown in Table 15. Telephone call was the most common method of informing the patient followed by directly or during a clinic visit. There were multiple responses allowed for this question but six hospitals only told patients by telephone, three hospitals indicated that they only told patients directly; with a further two reporting that they just wrote letters. The remaining 18 hospitals reported a combination of methods – nine hospitals directly or by telephone, five hospitals by telephone call or by letter, two hospitals reported a combination of directly or telephone call or letter and one hospital directly or by letter. One hospital reported 'Other' and commented "written in yellow book which is posted. If there is a change in patient dose, patient is phoned". It was interesting to note that no hospital used technology such as texting or emailing patients their results.

Table 15: How are patients informed of latest INR RESULT?

	Frequency	%
Directly or during clinic visit (n=29)	15	51.7
Telephone Call (n=29)	22	75.9
Text (n=29)	0	0
Letter (n=29)	10	34.5
Email (n=29)	0	0
Other (n=29)	1	3.2

There were seven additional comments recorded even though the respondent had indicated how patients were informed:

- "Sending out yellow book" – **Directly, telephone call or letter**
- "Some patients have their books posted out, these patients are also contacted IF their warfarin dose has changed" – **Directly or letter**
- "Some patients collect books at main reception on the day" – **Directly**
- "Yellow warfarin book posted on day of clinic" – **Telephone call**
- "We phone new patients, patients with high or low results will be phoned otherwise books are posted out same day of test" – **Telephone call**
- "Phone call to stops/LMWH etc" – **Letter**
- "Telephone if out of range" – **Letter**

Do you provide a telephone advice service between appointments?

There were 28 responses to this question although the hospital that did not provide an answer commented 'No' so they shall be included amongst the 'No' response, i.e. n=29. The vast majority, 96.6% indicated that they provided a telephone advice service between appointments and of those that provide a service 84% reported that it was the nurse that carried out the service, followed by Consultant/Doctor (8%) and Pharmacist (8%). A combination of nurse and pharmacists carried out the service in one hospital with one miscellaneous comment.

How do you provide patient education on the use of warfarin?

There were responses from all 29 hospitals and this again was a multiple response question and results are shown in Table 16 and 93.1% of hospitals provided either face to face education sessions and/or leaflets/booklets/ printed media. Twenty five hospitals reported that they provided both forms of education with two indicating that the only used face to face education sessions and the remaining two stating they only used leaflets/booklets/printed media.

Table 16: How do you provide patient education on the use of warfarin?

	Frequency	%
Face to face education session (n=29)	27	93.1
Leaflets/booklets/printed media (n=29)	27	93.1
Internet based information	0	0
None provided	0	0
Other	0	0

If face to face education sessions are available to patients, who carries this out?

Twenty seven hospitals indicated that face to face education sessions are available to patients and the staff members that carry this out are reported in Table 17. This was a multiple answer question also. There were no hospitals where it was only the consultant who provided this education. Twelve hospitals reported that it was the nurse on their own who carried out the face to face education sessions with a further two hospitals indicating that it was the pharmacist only. One other hospital indicating that it was solely the responsibility of an NCHD. The remaining 12 hospitals indicated that it was a combination of professionals who provided this education – one reported all four staff types were involved with another indicated that Consultant/NCHD and Nurse provided the education. One hospital stated Consultant and Nurse while six hospitals reported NCHD and Nurse and three hospitals recording nurse and pharmacist.

Table 17: Who carries out face to face education sessions?

	Frequency	%
Consultant (n=27)	3	11.1
NCHD (n=27)	9	33.3
Nurse (n=27)	24	88.9
Pharmacist (n=27)	6	22.2
Other (n=27)	0	0

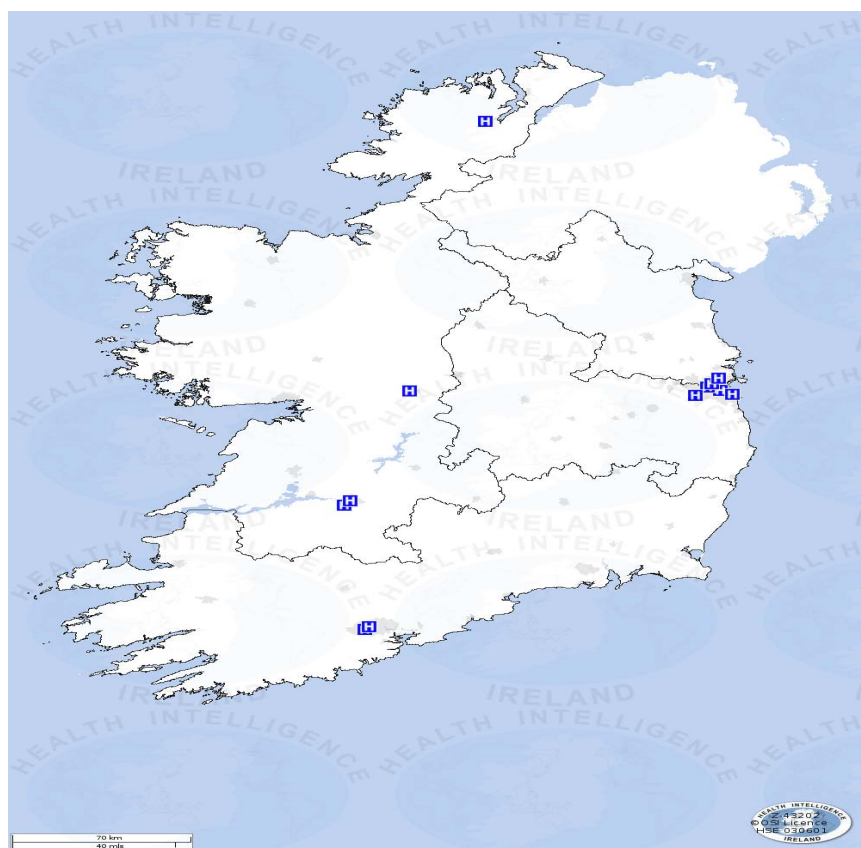
Does the warfarin clinic use computer assisted dosing?

The British Committee for Standards in Haematology (BCSH) Guidelines on Oral Anticoagulation with Warfarin – fourth edition (2011) recommend that for patients on warfarin, computer assisted dosing is superior to manual dosing²⁰. Twelve hospitals (38.7%) indicated that they used computer assisted dosing in their warfarin clinics with five (41.7%) using DAWN, four (30.8%) using RAID, two using Apex iSoft/iLab and the remaining hospital using BAP-PC. The twelve hospitals that use computer assisted dosing are noted in Table 18.

Table 18: Hospitals that use computer assisted dosing

Warfarin Computer Dosing System	Hospital
DAWN	AMNCH
	Mercy Cork
	St James's
	Beaumont
	Mater
RAID	St Vincent's
	St Michael's
	Portiuncula, Ballinasloe
	Letterkenny
Apex iSoft/iLab	CUH
	Limerick Regional
BAP-PC	St John's Limerick

Figure 9: Map of Hospitals that use Computer Assisted Dosing



Does the warfarin clinic use an INR Point of Care Test (POCT) device?

Twenty seven hospitals provided an answer to this question and six of these (21.4%) reported that they used an INR POCT device with five hospitals indicating they used Coagucheck while the other hospital did not record what they used. Point of care testing involves the use of a test in the immediate vicinity to a patient to provide a rapid result outside the conventional laboratory environment. The hospitals that use an INR POCT are noted in Table 19.

Table 19: Hospitals that use INR POCT device

INR POCT Device	Hospital
Coagucheck	AMNCH
	St Vincent's
	St James's
	St Finbarr's Cork
	Connolly

There were two hospitals that recorded that they did not have an INR POCT device but provided comments that are related to patient self testing:

- "2 patients are on Coagucheck both with support from the clinic"
- "We are in the process of rolling out a pilot POC self testing programme within the next couple of months"

How do you validate the INR POCT device?

The British Committee for Standards in Haematology (BCSH) published Guidelines for Point of Care Testing: Haematology in 2008²¹. Contained in these guidelines is the recommendation that an accredited external quality assessment programme and internal quality control system must be established. For the six hospitals that reported that they had an INR POCT device, one reported that it used an external process only, two reported that they used an internal process only while three hospitals reported that they used both internal and external processes.

Hospitals were then asked to describe their internal validation systems for their INR POCT devices.

For the two hospitals that indicated that they used an internal validation process only one commented:

- "Internal process based on the recommendations for maintenance of POC anticoagulation clinic CUH. Weekly POC Quality Control System test. 2 patients POC check and laboratory blood INR results should be cross checked of each other"
- "Not applicable"

For the three hospitals that reported that they used both an external and internal validation process, three commented:

- "Weekly controls using a control fluid. Internal quality control in device"
- "Done every morning in phlebotomy"
- "IQC conducted with manufacturer provided IQC materials"

How often are the INR POCT devices validated?

The BCSH guidelines on POCT recommend that internal quality control should be performed at regular intervals, the frequency of which will be influenced by the nature of the device, pattern of testing and number of tests performed. Five of the six hospitals that reported that they had INR POCT provided a response to this question. The time frame for validation varied between each hospital even though they indicated they had the same device although three did report external quality assurance every quarter.

Coagucheck:

- "Weekly. 3 monthly EQA"
- "NEQAS 4 times a year"
- "Daily internally and every 3 months externally"
- "Twice weekly"
- "Weekly"

Does your clinic have a patient self-testing service?

Twenty eight hospitals provided an answer to this question with eight (28.6%) indicating that they had a patient self-testing service. Letterkenny indicated in a previous comment that they had 2 patients in Coagucheck with support from the warfarin clinic so they have been included here even though they indicated here that they did not have a patient self-testing service. In addition, Naas commented that they were in the process of rolling out a pilot POC self testing programme but they have not been included here. The eight hospitals were:

- AMNCH
- Connolly
- St James's
- Navan
- Monaghan
- Cork University
- Limerick Regional
- Letterkenny

If there is a patient self-testing service, how is the necessary follow up with patients carried out?

Four of the eight hospitals (50%) reported that the follow up was carried out by clinic appointment only with a further three hospitals (37.5%) reporting that it was done by telephone only. One hospital indicated that it carried out follow up by clinic appointment and by using a web based service.

One of the hospitals that provided follow up by clinic appointment recorded a general comment for this question

- "Approx 10 of our patients self test as well as attending approx 12 weeks interval for venous sample"

How often is the warfarin service audited?

The BCSH Guidelines on oral anticoagulation with warfarin – third edition 2005 update, notes the standards regarding clinical audit that were outlined in the third edition^{22,23}. However, the more recent 4th edition does not mention clinical audit.

There appeared to be no formal audit process across the hospitals and without Computer Assisted Dosing systems it may be difficult to perform robust clinical audit. The response to this question is noted in Table 20 and figures in brackets note the number of hospitals who perform audit that have Computer Assisted Dosing.

Table 20: How often is the warfarin service audited?

	Frequency	%
Quarterly (n=29)	2 (2)	6.9
6 Monthly (n=29)	5 (3)	17.2
Annually (n=29)	6 (2)	20.7
Every 2 years (n=29)	5 (2)	17.2
Never (n=29)	4 (0)	13.8
Other (n=29)	7 (2)	24.1

Seven respondents did not utilise any of the suggested options and were categorised as 'Other'. Three of these noted that audits were performed:

- "Monthly"
- "Audit patient's attendance monthly"
- "DNA audit is once weekly with an in-depth audit quarterly"

The other hospitals recorded that they had nothing definite in place regarding audit:

- "Irregularly"
- "No formal audit but TTR calculated once or twice a year"
- "Audited 2006 research nurse"

Which of the following areas are audited?

Hospitals were asked to identify which areas of their warfarin service were audited and responses are shown in Table 21. All 29 hospitals provided answers to this question and there were multiple answers allowed. These options were taken from the third edition of the BCSH guidelines.

Table 21: Which areas are audited?

	Frequency	%
Review of medical records for information that the patient is currently on warfarin and for the use of dosage schedules	11	37.9
Provision of warfarin cards for patients on hospital discharge	7	24.1
Patient information: awareness of needs for warfarin and possible side effects of treatment	10	34.5
Follow up arrangements for patients failing to attend appointments	13	44.8
Achievement of target INR: 50% of INR's within 0.5 INR units and 80% within 0.75 INR units of target	15	51.7
Other	9	29

Six hospitals did not provide an answer any of these and two of these hospitals provided comments:

- "All as part of Haematology accreditation"
- "None of these are audited at present"

There were a further five comments provided by hospitals that indicated that they audit one or more of the areas highlighted:

- "Annual Patient satisfaction survey conducted"
- "We now audit the new targets as per the BSHC guidelines 2008 update"
- "Self testers audited 3 monthly"
- "overall care of patients attending"
- "All medical notes are reviewed on referral and each patient gets a warfarin card on discharge."

What warfarin services do General Practitioners provide in your area?

Table 22 below and Figure10 outlines the response of the hospitals regarding the level of warfarin services provided by GPs in their area and it is clear that there is no consistency throughout the country on the level of warfarin service provided in primary care.

Table 22: Warfarin service provided by GPs

	Frequency	%
GPs refer to the clinic without testing (n=29)	11	37.9
GPs provide INR point of care testing service (n=29)	7	24.1
GP care with laboratory analysis of INR (n=29)	12	41.3
Do not know what services GPs are providing (n=29)	7	24.1
Other (n=29)	5	17.2

Again this was a multi response questions with seven hospitals reporting that they did not know what service the GPs were providing in their area. Five hospitals reported that 'GPs refer to the clinic without testing' only and there were three comments provided to support this:

- "GPs in the area patients to the clinic via a consultant referral as they do not provide INR testing"
- "I'm aware of one or two GPs providing INR monitoring (blood test and dosing), in area most refer to hospital clinic"
- "Most GP's in the area monitor their own patients and currently 1 GP in this area looks after his own patients"

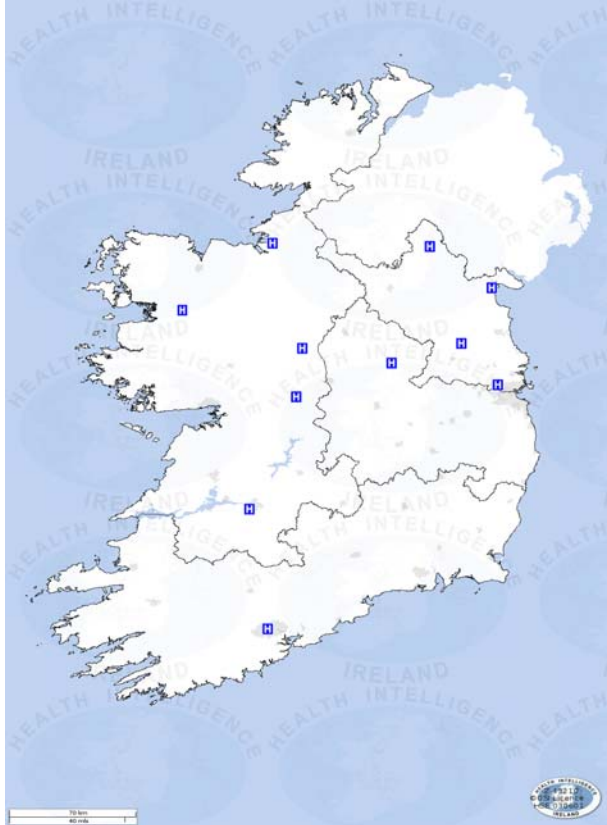
Three hospitals indicated that the service provided by GPs in there area was 'GP care with laboratory analysis of INR' only.

Four hospitals indicated that in their area the service provided by the GPs fell under both categories of 'GP's provide INR point of care testing' and 'GP care with laboratory analysis of INR' and a further three hospitals reported that these two categories and 'GP refer to the clinic without testing' were applicable.

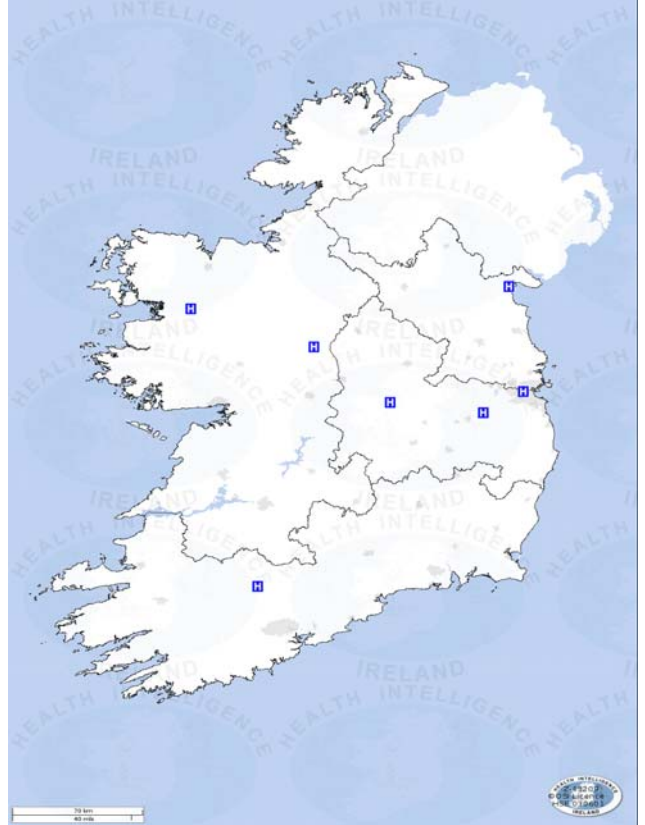
Three hospitals reported that in their areas the 'GPs refer to clinic without testing' and 'GP care with laboratory analysis'

Figure 10: Maps of GP Warfarin Services According to Hospitals

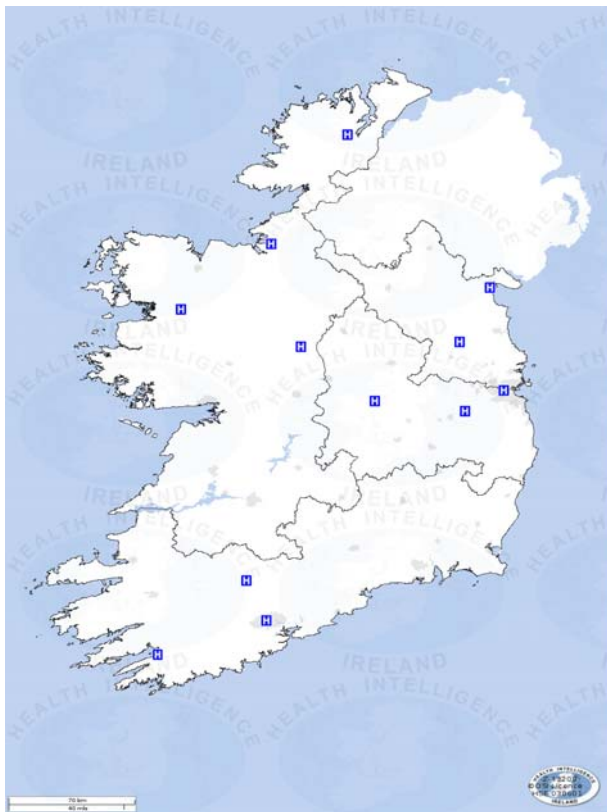
Hospitals GPs refer to without testing



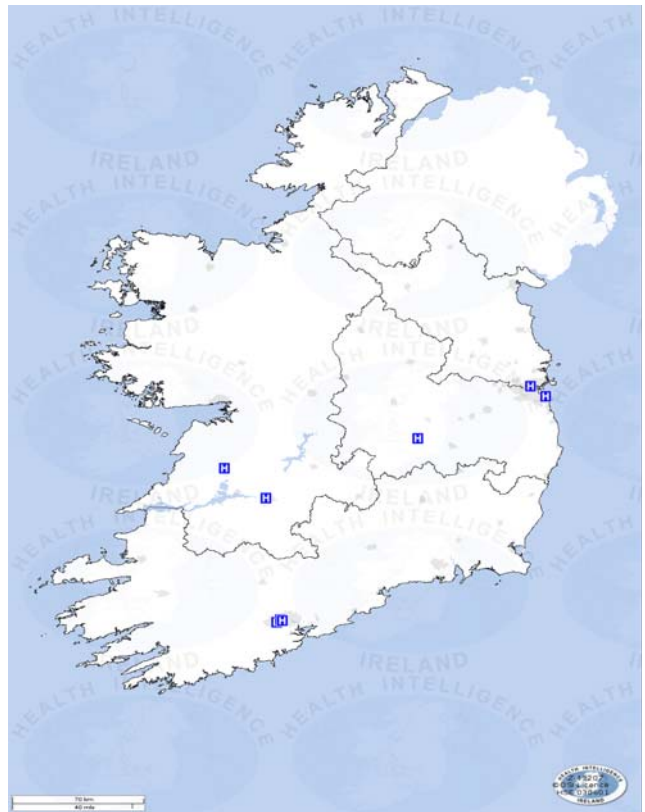
GP Provides Point of Care Testing



GP Care Lab Analysis of INR



Don't Know what GP Provides



Five hospitals selected other and provided comments which indicated that the GP's generally in their area did not provide warfarin services and if they did it was limited and practice nurse dependent:

- "GPs in area generally do not provide warfarin services"
- "Extremely limited"
- "Very, very occasionally they will draw blood"
- "The GPs in the Cork Area vary but it seems the ones who have practice nurses do the INR - and again it varies some send to the lab and others use POC"
- "Some GPS do warfarin clinics in their surgery others don't"

Discussion

In 2010, approximately 57,000 patients in Ireland were prescribed warfarin through the reimbursement system. This figure corresponds to approximately 1.3% of the population. Warfarin is a blood thinning drug that is used to prevent blood clots which can lead to stroke, pulmonary embolism and deep vein thrombosis. It is used to prevent stroke in patients with atrial fibrillation (AF). Warfarin treatment has been shown to reduce the risk of embolic stroke by two-thirds in these patients . Approximately 55% of warfarin prescriptions in Ireland are for patients with atrial fibrillation. This is somewhat lower than the 64% recently reported in a study from Sweden. Treatment with warfarin however, has a number of limitations. It can interact with many common medications and its activity needs to be monitored relatively frequently. Monitoring is achieved by the blood INR test to ensure an adequate and safe dose of warfarin is taken. Currently, there are varying models of care for patients who are prescribed warfarin. As part of the National Clinical Care Programme for Stroke, an Atrial Fibrillation Working Group (AFWG) was convened to advise on guidelines and protocols to improve care of AF patients in Ireland with an emphasis on stroke prevention. In order to address a number of objectives of the Stroke Programme, it was decided that a survey of all hospital based warfarin services in the country was necessary. This survey examines the current service provision of anticoagulation services in Ireland. Responses were received from 94% of hospitals surveyed with two of these hospitals indicating that they did not provide a standard warfarin clinic.

Geographic Inequity

This survey very clearly demonstrates that hospital based warfarin clinics are inconsistently distributed throughout the county and geographical inequities exist for patients regarding access to quality hospital based warfarin services. Most notably the south-east area, incorporating counties Carlow, Kilkenny, Wexford, Waterford and South Tipperary, has no hospital based warfarin service. Similar gaps are evident in Kerry, Galway and Cavan. It is assumed that GP's are providing a service in these areas but they are receiving no clinical support from their hospital centres except for laboratory analysis of samples in some cases. This gives rise to an unsupported service in primary care with no clinical governance and no integrated care pathway for more complicated patient types.

Clinical Governance and Audit

There is a lack of consistency across the country regarding the governance of the hospital based warfarin clinics. Warfarin clinics are the responsibility of Haematology or General Medicine departments in the main. Ten per cent of warfarin clinics are the responsibility of Cardiology departments whilst 96% of patients have vascular indications such as arrhythmia, valve replacements and arterial thromboembolisms. The skills and expertise of a Haematologist in dealing with difficulties in anticoagulation management or in managing quality systems in the laboratory relating to anticoagulation monitoring are particularly relevant. Consultant Haematologists are in a position to provide clinical governance for warfarin clinics through implementing a national standardised model of care including a standard integrated care pathway with primary care. This would provide a supported system for GP's providing a warfarin service. National standard Quality and Risk structures are necessary to ensure that the service provided is quality assured through regular audit and evaluation.

Despite the lack of consistency in clinical governance for warfarin clinics across the country, the vast majority of hospitals reported that they use some form of evidence based guidance in running their warfarin service. The British Society for Haematology Guidelines on Oral Anticoagulation are the recommended guidelines and 86% of hospitals reported using these guidelines. There were three hospitals that indicated that they used other non evidence based guidelines such as locally developed, guidelines based on the Fennerty algorithm or simply based on the INR result.

In a recently published Swedish study on anticoagulation control, the mean number of visits per patient per year was 13.6 on a sample of 18,391 patients. In this survey, the average number of visits per patient per year ranged from 3.8 visits per patients to 39.5 visits per patient – median was 17.1 visits per patient per year. This raises concerns over patient safety with one hospital only seeing patients once every 13 weeks while others seeing patients every 1.3 weeks. However, it is important to be cognisant of the possibility of poor data quality in the absence of databases in some centres. Hospitals also indicated the number of clinics they provided per week. This allowed a calculation of the number of patients seen per warfarin clinic. This indicated that a number of the smaller hospitals were seeing a relatively large number of patients per clinic. Once again this raises concerns over patient safety. Large numbers of patients seen in a relatively short time period may give rise to error and increased risk of error.

No formal clinical audit process was evident across the hospitals that responded to the survey. Without Computer Assisted Dosing systems it may be somewhat difficult to perform robust clinical audit. Centres that have Computer Assisted Dosing conducted clinical audits, albeit at different intervals and were auditing different topics. Just over half of hospitals reported that they audit the achievement of target INR with just over a third auditing the level of patient awareness of warfarin and possible side effects. Standards regarding clinical audit are outlined in the BCSH guidelines (3rd edition update 2005). The BCSH guidelines (3rd edition update 2005) emphasised the need for audit of non-laboratory based outcome data. The following areas of practice require regular review; compliance with dosing, drug interactions, review of duration of therapy and risk:benefit analysis. Anticoagulant treatment is recognised as a significant risk with large numbers of patients exposed to both potential harm and failure of adequate treatment. In the UK, anticoagulants such as warfarin are included in the Patient Safety First 'Guide for reducing harm from high risk medications' which defines high risk medications as those most likely to cause significant harm to the patient even when used as intended. Other examples include injectable sedatives, opiates and insulin²⁴. In Ireland, the HSE does not have a centrally held register for high risk medications although individual hospitals possess medication risk management policies which usually include lists of high-risk or high-alert medication. Where these are in place, warfarin would typically be on that list. Effective clinical audit of warfarin services and implementation of recommendations of these audits should be overseen by hospital clinical governance committees. This would ensure that warfarin is being prescribed and monitored in the safest way possible so as to reduce the potential risk to the patient. It was very evident throughout this survey that the data provided regarding the warfarin clinics was quite unreliable from a large number of hospitals where best estimates were provided. There is no consistent method of data collection across the country or any consistent database/ICT system in place. As a result credible audit is currently impossible at a national level.

Computer Assisted Dosing

Computer Assisted Dosing is available in 12 of the hospitals surveyed and even in these 12 hospitals there were four different systems used. Computer Assisted Dosing systems are recognised by the British Society of Haematology (BSH) as being safe and effective with regard to the overall percentage time for which patients are in their target INR range and also are recognised as having adequate data collection and audit capabilities. Computer Assisted Dosing software is expensive. There is, depending in the system used, an initial purchase cost followed by annual licensing and maintenance costs. However, this cost may well be offset by the standardisation of safe prescribing that they provide, the ability to collect

reliable data and, in time, the reduction in Consultant or higher grade staff involvement which can reduce the labour cost to the warfarin clinic. The BSH also comment in their latest guidance that Computer Assisted Dosing has been shown to significantly reduce the risk of bleeding and thrombo-embolic events and overall is a more cost effective option to manual dosing. Computer Assisted Dosing should be a minimum requirement for hospital based warfarin clinics.

Point of Care Testing and Patient Self Testing

Six hospitals reported using a point of care testing device (POCT), Coagucheck, in their clinics. POCT involves the performance of a test in the immediate vicinity to a patient to provide a rapid result outside the conventional laboratory environment. The capacity to provide a rapid test result which can be acted upon directly permits increased clinical effectiveness and improved outcome for the patient. However, this is only true if the result delivered is accurate and reliable. The Faculty of Pathology (RCPI), the Association of Clinical Biochemists in Ireland, the Academy of Medical Laboratory Scientists and the Irish Medicines Board published guidelines on the safe and effective management and use of POCT²⁵. Also, the BSH Guidelines on POCT also provide recommendations on POCT and are broadly similar to the Irish guidelines. The Irish guidelines document 15 key recommendations which are necessary for the implementation and management of safe and effective POCT. Quality assurance is key to assuring the accuracy and reliability of a POCT service and quality control starts with adequate clinical governance, best delivered by the establishment of a multidisciplinary POCT Steering Group which would be accountable for the delivery of all POCT services. Quality assurance is an integral part of any POCT service and should be overseen by POCT Operational Teams appointed by the POCT steering group. Internal quality control is a means of determining that the POCT device is technically performing correctly at a specific time and that the patients result is reliable before it is returned to the clinician. External quality assessment is a means of determining how a POCT device is performing in comparison to similar devices at different sites and is usually provided by way of an external quality assurance scheme such as the Irish External Quality Assurance or the UK External Quality Assurance (UK-NEQAS). The survey showed that there appeared to be inconsistent validation of these POCT devices with one hospital reporting that it used an external process only; two reported utilising an internal process only while the remaining three reported the use of both internal and external processes. The time frame for validation varied between each hospital even though they indicated that they all had the same device. Three hospitals reported that external quality assurance occurred every quarter.

Eight hospitals reported that they had a patient self-testing service with follow up carried out by clinic appointment or by telephone. The numbers or type of patients

involved was not recorded but it would be presumed that these were quite stable patients and numbers were relatively small. Patients self testing is limited to some extent by patient capacity and capability to self-test and also computer literacy if they are submitting results into an internet based system. There are some costs to patient self-testing, notably the cost of the test strips and this could be an issue for some patients. A study carried out in UCC in 2008 looking at patient self testing and an internet based system to allow patients to manage their warfarin remotely was very successful with patients reporting a higher percentage of their blood tests within the desired range, 98% of patients preferring this method to clinic attendance and the number of patients attending acute care was reduced showing the potential benefits to patient self testing²⁶. Self-testing as an option is a model of care that such be explored in greater detail in the development of a standard model of care for warfarin.

Activity Levels and cost of Warfarin Clinics

This survey showed that, on average, just less than 7,000 patients are being seen per week at warfarin clinics. Extrapolating this to an annual figure equates to over 358,000 outpatient visits per year. This is a significant burden on hospital outpatient services.

Sensitivity analyses have been performed using costings from two sites with quality and audit systems in place looking at cost per patient visit to the warfarin clinic. The model of care varied between sites with Model 1 being largely a nurse led service and Model 2 having more consultant and senior pharmacist time. It must be noted that in the nurse-led model (Model 1) there was greater infrastructural investment with computer assisted dosing and quality audit systems in place. Depending on the model of care, cost per patient visit varied significantly between centres. This cost difference was primarily due to labour costs. Cost per patient in Model 1 = €20.92; Cost per patient in Model 2 = €40. Using these costings, the cost of warfarin clinics in 2010 ranged between €7.4 million and €14.3 million euros per annum to the health service. In practice however, the service currently in place in many centres would not achieve the quality and safety standards of either model 1 or model 2 sites.

Provision of GP services

It was clear from the survey that the hospitals in general were unclear as to what level of warfarin service was being provided by GPs in their locality with just under a quarter indicating that they did not know what service GPs provided. The service that is provided by the GP is quite variable across the country according to the hospitals, varying from referral to clinics without blood testing, to GPs providing

care but submitting blood samples to a local laboratory, to some GPs providing POCT. A survey of GP's carried out by Byrne et al in 2009-2010 demonstrated that up to 82% of GP's surveyed were providing an anticoagulation service and 15% were relying solely on hospital clinics. Of those providing a warfarin service 28% had POCT devices and almost 80% were getting samples analysed in the local laboratory with the turnaround time for results from 6 hours to 5 days. It is reasonable to assume that the majority of the 82% of GP's providing the service are in areas where there is currently no hospital warfarin clinic service or integrated care pathway. In these areas patients must be managed by their GP although the level and quality of this service is unknown at present.

Warfarin clinics are discharging very small numbers of patients back to the GP. The survey showed that half of hospitals discharged less than ten patients to the care of their GP in 2010. Particularly interesting was that the large urban hospitals, particularly in Dublin, were not discharging patients from their clinics. This may constitute evidence of a lack of warfarin based services in primary care in these urban centres and point to the requirement for the development of primary care anticoagulation services supported by an integrated care pathway. Conversely, in areas where warfarin management is solely provided by the GP, there is an immediate need for the agreement of an integrated care pathway with the specialist centre.

New Agents

Dabigatran is an oral anticoagulant which binds directly and reversibly to thrombin to inhibit its actions, thereby interrupting the formation of blood clots. The use of dabigatran does not require routine monitoring of coagulation tests. This drug has been recently licensed in Europe and is recommended in the American and Canadian guidelines as oral anticoagulation for stroke prophylaxis in patients with non-valvular atrial fibrillation. There are a number of similar agents currently in development such as the Factor Xa inhibitors rivaroxaban and apixoban. Because of their ease of use, this family of agents have the potential to change the landscape of anti-coagulation services internationally and in Ireland and to increase the numbers of patients receiving anticoagulation therapy.

As is evident from our survey, geographical inequities exist throughout the current warfarin service and patient safety is questionable in many of the current locations providing a service. Areas exist that have no access to specialist haematology advice or support and the warfarin service is provided by general practitioners with no standardised governance structure and no integrated care pathway to a specialist centre. Of those hospital centres providing warfarin clinics, computer

assisted dosing is severely limited to the larger hospital centres. International auditable quality systems are in place in only 9 of the 29 centres providing a service in Ireland. In order to achieve a safe service for warfarin patients significant investment is warranted. This investment must be scrutinised and balanced against the cost of thrombin inhibitors. All things being equal, the new agents are more user friendly in primary care and there is an argument for their use in non-complicated patients in primary care with an indication for anticoagulation.

Despite the introduction of the new agents there will be a proportion of patients that will be more complicated and will require warfarin therapy. It is recommended that warfarin services that remain are standardised. A national standard model of care for the provision of warfarin services should be agreed. Clinical governance structures need to be implemented in all centres. All centres should have computer assisted dosing and adhere to a nurse-led cost effective model. In addition patient self-testing should be encouraged with support from the GP in conjunction with coagulation centre. This process is dependant on an integrated care pathway to allow safe, fast and efficient referral of difficulties that may arise.

Operational aspects of current services

Regarding the day to day operation of the current warfarin clinics, there was a large variability in clinic appointment structure across the hospitals. However, 75% of patients were waiting less than a week from referral to clinic attendance with 93% seen within two weeks and no patients were waiting more than four weeks which shows that the appointment system used is immaterial. Over half of all patients in therapeutic INR range are recalled between 4-6 weeks with almost 83% having a recall visit within 8 weeks and no patient was reported to be waiting for more than 12 weeks.

There is a level of inconsistency across the country regarding who determines the warfarin dosing schedule at the patients' first visit. While a consultant is involved in the decision making in 35% of hospitals (n=10) they are only exclusively involved in 17% of hospitals. Only three of these ten hospitals have Computer Assisted Dosing, as if this was in place it could be argued that there may be need for less Consultant involvement. NCHD involvement is reported at over half of hospitals with NCHDs exclusively determining dosing schedule in 38% of hospitals (n=11). Nursing staff are involved at 31% of hospitals and exclusively involved at 21% of hospitals and further investigation shows that these are primarily the bigger hospitals that have Computer Assisted Dosing systems. It is accepted that the vast majority of patients may already be on a particular dose warfarin by the time that they attend their first visit as it may have been prescribed by their GP or by a

clinician on the hospital ward. However, in hospitals without Computer Assisted Dosing, there may need to be more senior clinical involvement in determining the initial warfarin dosing schedule. While this is not necessarily a quality indicator, potentially it should be included as an element of safe standard of care.

Patient-Clinician Interaction

Patients were informed of their latest INR result by either telephone call or directly during a clinic visit or by letter. Most hospitals reported using a combination of all three. It was interesting to note that no hospital used technology such as text message or email to communicate results. As the population are predominantly elderly these methods may not be completely suitable but as the elderly are becoming more computer and technology literate these methods of communication could be examined. There may be data protection issues with sending text messages or emails where the destination may be uncertain but advances in technology may be able to circumvent these issues. The vast majority of hospitals, 97%, reported that they provided a telephone advice service for patients between their clinic appointments. This service was run predominantly by the nursing staff. In addition, patient education was provided by face-to-face education sessions and/or by administering printed media such as leaflets or information booklets and was provided by the nursing staff in the majority of hospitals. There appears to be quite a lot of time spent by nursing staff offering education and advice to patients both on the telephone and face to face and while this is an extremely important element of the service, there is scope for a reduction in this time by the provision of educational aids such as a DVD perhaps or reference to a specific website. This could subsequently be followed up with a questions and answer session.

Recommendations

Geographical Inequities

- Geographical inequities need to be addressed
- All GP's providing a warfarin service, irrespective of geographical location should have access to an integrated care pathway to allow safe fast and efficient referral of complicated patients to a specialist centre

Clinical Leadership and Clinical Governance

- Consultant Haematologists are in a position to provide clinical governance and clinical leadership for warfarin services
- A national standardised model of care including an integrated care pathway between the hospital and primary care needs to be developed
- The British Society for Haematology Guidelines on Oral Anticoagulation (4th Edition 2011) are the recommended guidelines

Clinical Audit

- Clinical Audit needs to be an integral component of warfarin services
- Standards regarding clinical audit should be consistent with the BSH guidelines (3rd edition update 2005)
- Data quality needs significant improvement to facilitate robust audit of warfarin services
- A consistent method for data collection from warfarin services needs to be addressed

Quality and Risk

- Development of a centrally held register by the HSE for 'high risk medications' and incidents which occur in relation to their administration is necessary. Warfarin should be included on this register
- National standard Quality and Risk structures are necessary to ensure that the service provided is quality assured through regular audit and evaluation
- Effective clinical audit of warfarin services and implementation of recommendations following audit should be overseen by hospital clinical governance committees
- Clear and consistent communication systems are essential for follow-up of patients (phoning results, posting books etc.). The introduction of POCT based at the point of care would reduce potential communication errors.
- Safe and effective management and use of POCT should be consistent with The Faculty of Pathology (RCPI), the Association of Clinical Biochemists in

Ireland, the Academy of Medical Laboratory Scientists and the Irish Medicines Board published guidelines²⁷.

- Quality assurance of a POCT service and quality control encompasses adequate clinical governance, best delivered by the establishment of a multidisciplinary POCT Steering Group which would be accountable for the delivery of all POCT services

Model of Care

- A national standard model of care needs to be developed to facilitate both the hospital and primary care. This should include recommendations regarding non-complicated patients where a primary care-based service with a robust clinical governance structure would be appropriate. In addition self-testing should be included as an option. Other elements for consideration in the development of the new model include the introduction of the new agents.
- The most cost effective hospital service would appear to be a nurse-led model with adequate quality, safety and governance structures
- Computer Assisted Dosing that facilitates quality improvement systems should be a minimum requirement for hospital based warfarin clinics
- Self-testing should be explored as an option in the development of a standard model of care for warfarin patients
- Warfarin clinics should discharge the majority of their patients to a developed primary care service with a robust governance structure
- The new anti-coagulation agents represent a welcome step change in oral anticoagulation management. For many patients, they have the potential to enhance overall care ensuring increased uptake of anticoagulation therapy, therefore reducing stroke risk. It is important for clinicians to be cognisant of the continuing need for patient education regarding compliance and the precautions necessary to prevent haemorrhage. Access to these new anticoagulation agents should be introduced in a timely fashion given due consideration to their cost effectiveness and national competing priorities.

ICT

- Data collection systems need to be developed urgently
- Computer Assisted Dosing should be a minimum requirement for hospital based warfarin clinics
- Computer systems may be developed to provide a three way interface between the hospital warfarin service, laboratory and the patient/General Practitioner/Practice Nurse
- It is possible to reduce nurse time in relating results by exploring ICT possibilities to relay the information safely
- Face to face education time could possibly reduced by the introduction of an educational DVD which should be standardised nationally

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