ANTICOAGULATION THERAPY MANAGEMENT SOFTWARE

DAWN AC

PROCEEDINGS OF THE 20th USER GROUP MEETING

8th/9th October 2012

BETTER CARE FOR LESS EFFORT
FROM THE COMPANY THAT REALLY CARES

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Chairman's Summary, Dr Eric Watts, Consultant Haematologist (retired), Basildon and Thurrock Hospitals, Basildon

This year's DAWN AC User Group saw an eclectic mix of presentations including NICE guidance on VTE management with an illustration of how DAWN AC can help to capture the clinical features and an overview of how patient self-testing can be incorporated into a dosing protocol through a text messaging service. There were also presentations on the GRASP AF tool; however the introduction of the new anticoagulants and their impact dominated the user group's presentations and discussions.

When and why should we adjust the dose calculated by DAWN are recurring questions and a debate by delegates covered the subject of how much we should intervene. DAWN works to a specified program which has been shown to be more effective than manual dosing, particularly for the maintenance phase, however there are good reasons for occasionally adjusting the dose, particularly in the light of changing clinical circumstances.

Coded comments for dose changes allows a review of why doses changed – most often because a patient needed a manual dose for a good reason – other reasons were because the DAWN AC dose change was considered to be too great although this occurred particularly with less experienced operators.

Additional DAWN software modules can assist with this issue, particularly Tableau. Tableau will enable us to interrogate the data, profiling the individual dosers and measuring the effectiveness of their interventions by TTR with the potential to see whose interventions were the most successful. This would enable the question to be asked of the successful dosers, 'why did you think that needed changing?' which could perhaps lead to further development of the DAWN AC system in addressing the trends identified.

A discussion on the meaning of NICE approval surrounding the new oral anticoagulants also sparked debate. NICE have stated that Dabigatran and Rivoroxaban are options and that changing from Warfarin should only be done after 'an informed decision, considered in the light of the patients level of INR control'. This means that doctors are not obliged to prescribe new oral anticoagulants if patients ask for it and currently cost seems to be an issue. However writing in Pulse, Sir Michael Rawlins, Head of NICE, specifically commented 'There is no obligation on a doctor to prescribe it (a medicine approved by NICE) but if they consider it to be in the patient's best interest the NHS must provide it'.

Introduction by Syd Stewart, Managing Director, 4S DAWN Clinical Software

Syd opened the DAWN AC User Group by welcoming everyone to the meeting and introducing Dr Eric Watts as the Chairman. Having held the position for 8 years Dr Watts will be stepping down after this year's event. An excellent and varied programme of talks had been lined up over the two days and a summary of each presentation follows:

Dr Jane Strong, Consultant Haematologist and DVT Clinical Lead, University Hospitals of Leicester, and Alistair Stewart, 4S DAWN Clinical Software covered the national guidance and protocols for DVT patient pathways, how these can be streamlined to monitor patients effectively and how the DAWN programme can assist in logging and auditing patient information and outcomes.

Catherine Reilly, Clinical Nurse Manager, St. James's Hospital Dublin explained how the AC service set up a self-testing group of patients. Describing how the service chose the patients eligible for self-testing and the training that was involved, the process of self-testing, reporting INR results and dosing was outlined, including the use of text messaging as a key part of the process. The use of text messaging has proved beneficial for patients, providing flexibility for INR testing, and results so far show that time in range figures for self-testers are currently higher than those for in-clinic patients.

Michelle Kennedy, Practice Development Nurse, Westbourne NHS Centre outlined the reasons behind an audit on dose and interval overrides. Manual changes to dose and next test dates were happening regularly within the DAWN AC system and this required investigation. This sparked a debate as to whether healthcare professionals should change the next test date and dose requirement recommendations provided by DAWN AC without evidence-based reasons.

Brenda Nicol, 4S DAWN Clinical Software presented the new Dabigatran module which is now available for use within DAWN AC. The Dabigatran module allows users to track patient initiation and

follow-up using questionnaires and includes checks to ensure that the patients are on the correct drug and dose.

4S DAWN Staff also introduced a number of other modules that are designed to work with the DAWN AC software and complement clinic activities. These included a new induction module, a module for managing MPD patients, the introduction of front screen tallies to highlight key areas of the software records that need attention, and Tableau, a business intelligence tool for data analysis and visualisation.

Libby Bak, Operations Supervisor, Brigham and Women's Hospital, Boston gave an overview of how their clinic is managed using the DAWN AC system including the processes for entering referrals into the system, receiving INR results and how they process them. Libby also explained how the patient's current dosing information and recent history is exported and displayed on the hospital's electronic medical record for other healthcare professionals to view.

Vanessa Brown, National Improvement Lead and Ian Robson, Senior Analyst, NHS Improvement discussed the role of NHS Improvement; and the introduction and subsequent utilisation of the GRASP AF tool within GP practices for the purposes of auditing.

Julie Salisbury, Anticoagulation Practitioner, Leighton Hospital outlined how their AC service is currently set up and the challenges faced. The core competencies required for delivering a quality AC service were covered, those being staff, patients, resources, technology and benchmarking. The deciding factors on whether to move patients to the new oral anticoagulants were also discussed.

Sean O'Brien, Anticoagulation Specialist BMS, Blackpool Teaching Hospitals talked about the introduction of the GRASP AF tool by Blackpool PCT and how this has impacted their anticoagulation service. They found that their patient numbers have increased and continue to do so. Sean concluded with some key points to consider if patient numbers increase substantially as a result of the uptake of the GRASP AF tool.

Dr Matt Fay, GP, Westcliffe Medical Practice and National Clinical Lead for Atrial Fibrillation, NHS Improvement gave an overview of how the detection of AF could increase if all patients over a certain age are screened during routine check-ups and discussed a number of trials that have shown anticoagulants are far superior to aspirin for treating AF patients.

Dr Rhona Maclean, Consultant Haematologist, Sheffield Teaching Hospitals presented on their experience of starting patients on the new oral anticoagulants and the criteria used for moving patients to the new drugs. As yet, only 8 patients have made the switch and this is due to a number of factors including increased cost and the implications of moving patients to a new and unfamiliar drug. Rhona concluded by discussing the best pathway in future for anticoagulation patients.

Syd Stewart, 4S DAWN Clinical Software discussed whether the time within therapeutic range is actually the best indicator of a patient event and gave an overview of variance growth rate (VGR) which looks at the variability of INR results over time in order to better predict the likelihood of an event.

Dr Eric Watts, Consultant Haematologist (retired) looked at information from the most recent new oral anticoagulant studies and explained that while the new drugs are approved for treating patients, much is still unknown and emerging side effects and an increasing number of interacting medications means that further knowledge is needed.

VTE National Guidance and New Protocols

Dr Jane Strong, Consultant Haematologist, Leicester Royal Infirmary

Following the previous DAWN AC User Group and a presentation on VTE Pathways, Dr Strong talked of a 'light bulb' moment with regards to VTE governance and the potential to get a VTE clinical pathway established within the DAWN system and approved by the Trust. The aim was to improve care, prevent lost records, and to take advantage of other key benefits gained from establishing, formalising and digitising a key patient pathway.

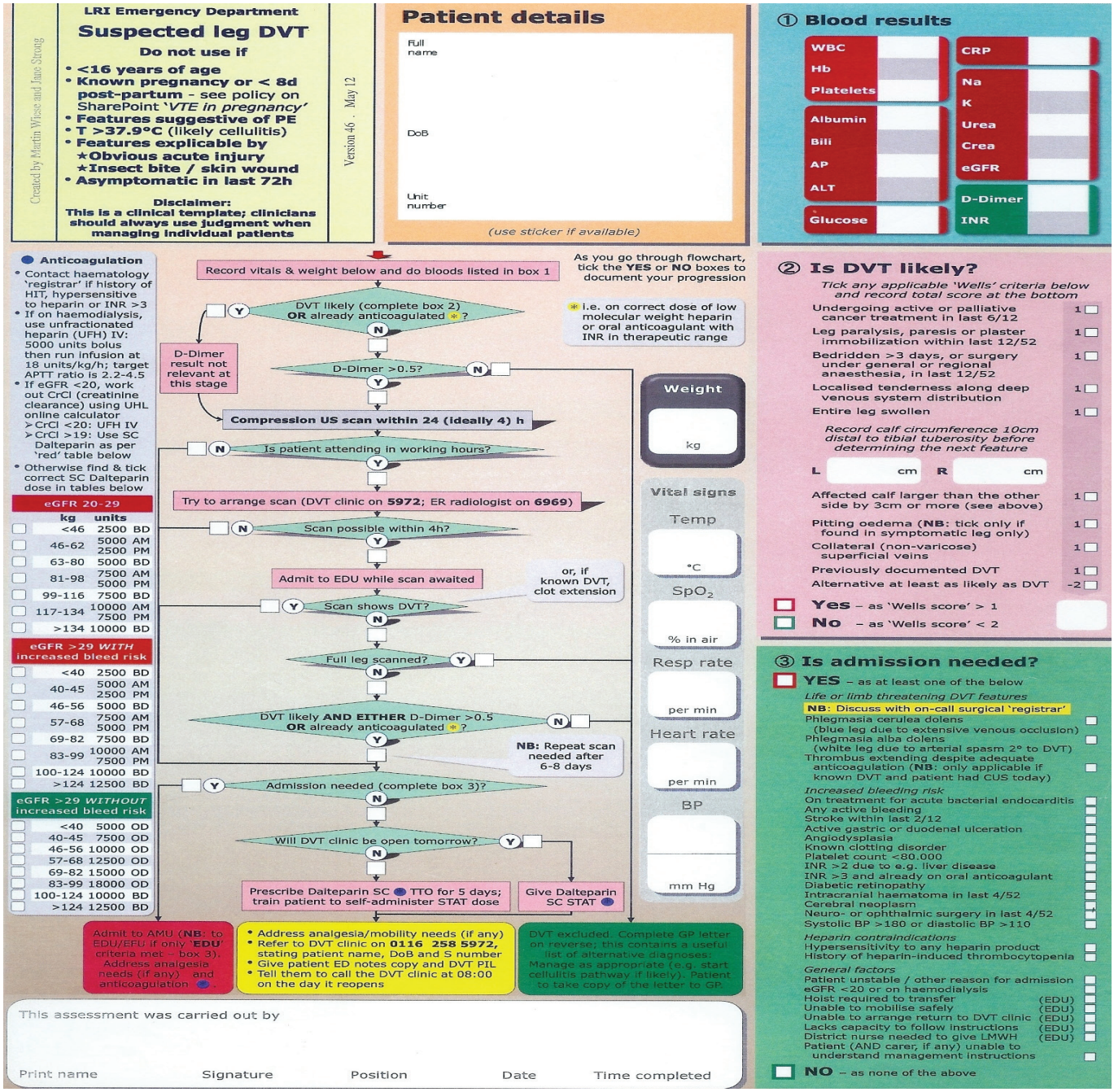
Communications from the Department of Health have moved the emphasis from 'stopping the clots' to 'spotting the clots' and the NICE clinical guidelines issued in June 2012 for Venous Thromboembolic diseases give exacting standards. Covering the entire pathway, these guidelines present challenges to many providers. One of the biggest challenges is the requirement to carry out scans within 4-24hrs and meeting this timescale can be extremely difficult. If the

timescale for patients receiving a scan is longer than 4 hours, patients are anticoagulated on a presumptive basis to ensure some form of treatment while diagnosis is confirmed. However, only 20% actually have DVT so although it makes sense for the patient to have a quick scan, this is not always practical.

Other aspects bringing possible further changes to the VTE pathway come in the form of NICE technology assessments such as that for Rivaroxaban, which could effectively replace Low Molecular Weight Heparin (LMWH) and Warfarin. This could potentially revolutionise how DVT treatment is administered after guidelines stated it is as effective as the standard of care we now have with Warfarin and LMWH.

The New Oral Anticoagulants therefore, will provide challenges from an organisation perspective and will require work on how pathways are implemented and funded. However until this is developed further, the NICE guidelines for the DVT patient pathway provided the catalyst for the changes that are being implemented at Leicester.

A flowchart for the desired DVT patient pathway was produced for A&E for new staff to follow. This is also to be used within the DVT service and other relevant areas so that they use a standard approach. Dr Strong is currently working with 4S DAWN to produce this pathway within DAWN and so benefit from the functionality of the system in ensuring that the pathway is documented, monitored and audited.



DVT Diagnoses and Assessment

Alistair Stewart, 4S DAWN Clinical Software

Alistair followed Dr Strong's presentation with an overview of the mechanics of implementing the DVT patient pathway flowchart in the DAWN system. This covered 4 key areas of functionality:

- Disease areas
- Therapy templates
- Questionnaires
- Interventions

The new DVT Diagnosis and Assessment module gives the ability to keep DVT patients separate to the AC patients. A subtly different screen to the AC maintenance module provides a diagnosis field that is DVT specific whilst the Therapy Template function enables the user to set up the various phases of treatment that we saw on Dr Strong's flowchart. Questionnaires were implemented for areas of the system that were more complex such as a pre-cursory questionnaire for patient suitability and a Well's score questionnaire.

This module leverages the existing functionality of the DAWN system, bringing a range of benefits including enhanced communication, reporting metrics and management statistics and auditing. All DVT Assessment information is recorded and will sit permanently on a patient record making the transfer from assessment to anticoagulation maintenance a seamless process.

Patient Self Testers and Texting

Catherine Reilly, Clinical Nurse Manager, St James's Hospital, Dublin

St James's Hospital houses the National Centre for Hereditary Coagulation Disorders (NCHCD) which has responsibility for 1500 patients who attend the anticoagulation clinic. In 2003, plans to improve the anticoagulation service involved the presentation of a business case to the Health Service Executive with the aim to introduce patient self-testing. The proposal included a web based dosing system (DAWN AC V7) with remote access by GP's, the purchase of 300 CoaguChek XS devices and a third party software application for text messaging (Valentia Technologies).

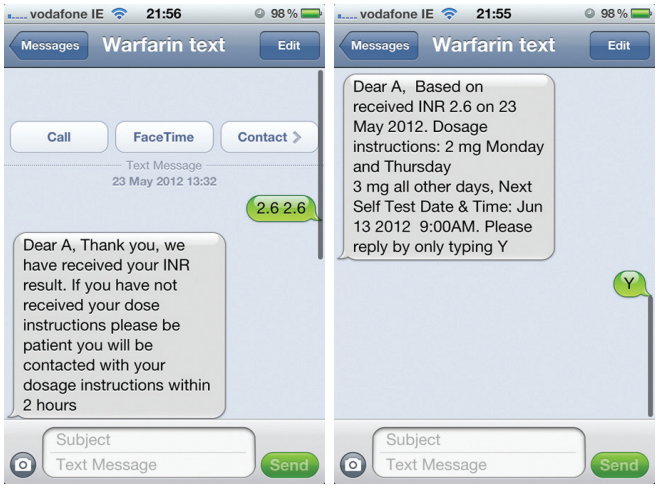
The business case was successful and resulted in funding been granted from the Health Service Executive Innovation Fund. The first stage of the Self-Testing element of the project was to determine how to select patients for self-testing and the following acceptance criteria was agreed:

- Patients on Warfarin long term
- Patients who have sufficient manual dexterity, eyesight and cognitive skills for daily tasks
- Individuals who are motivated to be involved with their own care or primary carers who will take the responsibility
- Patients who have been compliant in attending the anticoagulation service and taking their medication

A training programme was developed that involved visual and verbal device demonstrations, competency tests, a supporting DVD from Roche on monitoring INR levels accurately, and a signed contract of compliance. The training also provided the opportunity to re-educate the patients and this was carried out with the following learning objectives:

- The indication for Warfarin
- Warfarin therapy monitoring
- Side effects of Warfarin therapy
- The importance of reporting any adverse incident
- Potential for drug interactions with Warfarin and reporting any medication changes
- Keeping a record of any INR results and doses
- Operating the CoaguChek XS and finger stick testing
- Quality Control

All patients were reviewed after 3 months and then subsequently at 6 monthly intervals. Monthly audits using the DAWN system showed that self-testers had a higher percentage time in range than those who attended the clinic.



Because of the success of the self-testing, the volume of phone calls from patients reporting their INR results proved to be a problem for staff. In response to this new challenge, the anticoagulation service worked with Valentia Technologies to design and develop a web based Warfarin Management Service (WMS) which was designed to accept the self-test patient INR result in the form of a text message and transmit it automatically into the DAWN system where it appears in exactly the same way as an INR result transmitted from the laboratory. Once the patient has submitted their INR results, they receive their dosage instructions back in the form of a text message and are asked to confirm receipt, again via text. Prior to launch, the system was validated with respect to accuracy, functionality, reliability and ease of use. So far results have been extremely positive.

Coded Comments: Reasons for Adjusting Dose

Michelle Kennedy, Practice Development Nurse, CHCP (CIC), Westbourne NHS Centre, Hull

Hull Anticoagulation Service is a nurse led service which manages 3500+ patients. The service runs 365 days per year carrying out city wide clinics and home visits.

The service uses DAWN V7 and as part of a review into clinical practice it was noted that while DAWN allows the user to use clinical judgement to adjust the suggested dose and/or follow-up interval if deemed necessary, a proportionately large number of nurses appeared to be doing so. This prompted the question 'What constitutes a valid reason to adjust the dose/follow-up interval offered by DAWN?'

After a literature search that produced substantial evidence to demonstrate the safety and effectiveness of computer assisted dosing, an audit was carried out with the help of 4S DAWN to dig deeper into the figures in order to understand from clinicians why they were making the decisions to adjust doses and follow-up intervals; and whether those decisions could be grouped into categories.

A look at the figures within DAWN showed that out of a total of 5215 contacts, at least 1649 dose/follow-up suggestions had been adjusted and at 32% this was judged to be a high figure. Further investigation revealed that 82% of the adjustments were made due to patients being left in a manual dosing mode, meaning DAWN was unable to recommend a dose/follow-up interval suggestion, leading to staff having to use clinical judgement. However, the number of remaining dose change reasons (below) still led to the concern that staff were routinely adjusting doses and it was highlighted that whilst some were new staff and so perhaps lacked confidence in computer aided dosing, many were experienced staff.

Reasons identified for adjusting dose:

- Dose deemed to be increased too aggressively = 30 (2%)
- Dose deemed to be decreased too aggressively = 55 (3%)
- Follow-up deemed too short = 98 (6%)
- Follow-up deemed too long = 79 (5%)
- Dawn does not suggest miss a dose when miss a dose is required = 18 (1%)

As a result of the review and audit a number of issues were identified. First, the major reason why dose and follow-up suggestions were not being offered by DAWN was identified as patients who had been changed to manual dosing due to large dose changes, indication instability and not being manually changed back to maintenance. This will be addressed with the aim of reducing the number of 'no suggestions'. Second, of the suggested dose/follow-ups provided by DAWN and adjusted by clinicians only 1% were based on evidenced reasons, whilst 17% required further investigation into what staff were basing the adjustment decisions on.

There are conflicting views within the service based on dosing via clinical judgement or computer aided from the DAWN system and future plans for further investigation and re-audit are to be put in place to resolve this.

Product Update – New Oral Anticoagulant Module

Brenda Nicol, 4S DAWN Clinical Software

The new Dabigatran module was introduced by 4S DAWN to enable anticoagulation clinics to manage Dabigatran using DAWN AC. An overview of the module was given to show the functionality, including initiation and follow up stages along with the workflow that has been configured according to the guidelines set out by Boehringer Ingelheim.

A show of hands revealed that only three members of the delegation were currently prescribing Dabigatran

and further discussion identified a number of factors why there hadn't been a higher uptake, mainly cost, uncertainty due to its newness to the market and patient choice.

Libby Bak from Brigham and Women's Hospital in Boston, USA commented that they have been using Dabigatran for around 12 months and currently have a return rate of 1 in 3 patients who revert back to Warfarin due to complications. Some delegates commented that there is an issue of affordability where some Trusts were not prepared to pay for Dabigatran, while other Trusts were pushing for its introduction.

Syd Stewart informed delegates about the funding available from Boehringer Ingelheim which will cover the cost of the new Dabigatran module for existing DAWN AC users to enable them to track and measure the introduction of the new drug.

Introductory Sessions: Induction, MPD, Front Screen Tallies and Tableau

Brenda Nicol, Louise Pearson, Jenny Wood, 4S DAWN Clinical Software

A number of 4S DAWN staff presented various modules and features that are available to DAWN AC users in order to enhance their service and productivity. A new product catalogue showcasing the modules available was distributed to delegates whilst a selection of these were discussed in this last session of the day.

- **Induction Module:** The induction module sits within DAWN AC to monitor anticoagulation induction patients. Features include preloaded configurable algorithms, protocols, stability checks and induction to maintenance transfer which facilitate a smooth transfer process whilst enabling key induction data to be reported and analysed and NPSA standards met.

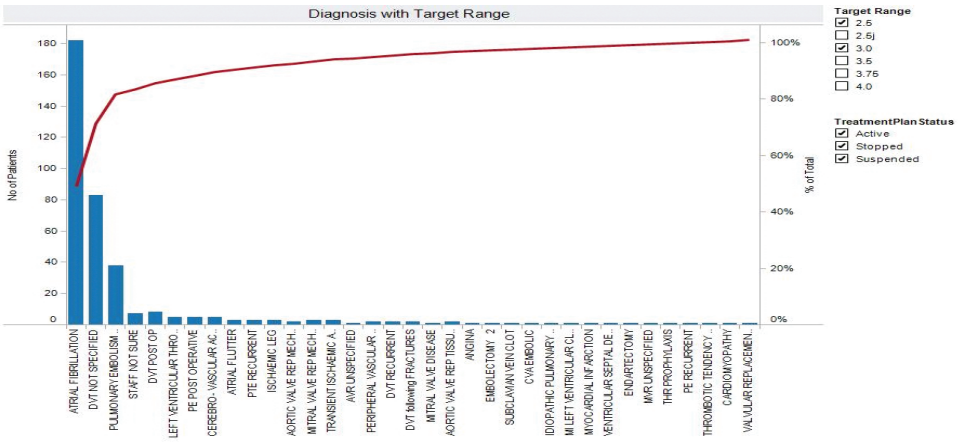
- **MPD Module:** A new module that helps manage long term therapy of patients with Myeloproliferative Disease (MPD), Haemochromatosis and Monoclonal Gammopathy of Unknown Significance (MGUS). The MPD module detects trends or deviations in results and flags them to the user, enhances communication, audits patient records and reduces waiting list times by devolving care to pharmacy/nurse led clinics.

- **Front Screen Tallies:** Designed to highlight areas of the system that need attention such as setup problems or patient(s) with unusual action logged against their record. Available patient license numbers and interfaces are also displayed. The front screen tallies are currently being finalised and feedback was requested from delegates.

- **Tableau:** A powerful data visualisation tool, Tableau is able to drill down into the DAWN database and examine the data, providing an attractive and easy to read presentation of the data. The benefits of the system were discussed alongside a demonstration of the software and its ease of use.

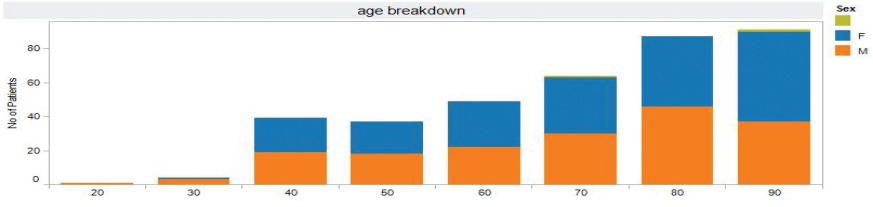
Treatment Plan Status

TreatmentPl..	Target Range	No of Patients	%
Active	2.5	201	54.0%
	3.0	4	1.1%
Stopped	2.5	160	43.0%
Suspended	2.5	10	2.7%
	3.0	1	0.3%
Grand Total		372	100.0%



Dosing Regimes

Dosing Regimen	No of Patients	%
Warfarin 1 Mg Daily Dose	3	0.8%
Warfarin 3 Mg Daily Dose	3	0.8%
Warfarin 3 Mg Weekly Dose	1	0.3%
Warfarin 5 Mg Daily Dose	1	0.3%
Warfarin 5 Mg Weekly Dose	2	0.5%
Warfarin By Tablet Colours	64	17.2%
Warfarin Mixed Tablets Daily	2	0.5%
Warfarin Mixed Tablets Weekly	297	79.8%
Grand Total	372	100.0%



Brigham and Women's Hospital Anticoagulation Management Service & DAWN AC: A Continual Process Improvement Process

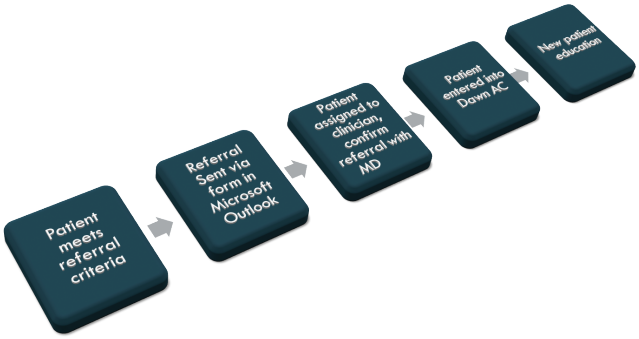
Libby Bak, Operations Supervisor, Brigham and Women's Hospital, Boston, USA

Partners HealthCare was founded in 1994 by Brigham and Women's Hospital and Massachusetts General Hospital and is now the largest integrated healthcare delivery network in New England. Partners HealthCare includes community and speciality hospitals, a managed care organisation, a physician network and other health-related entities.

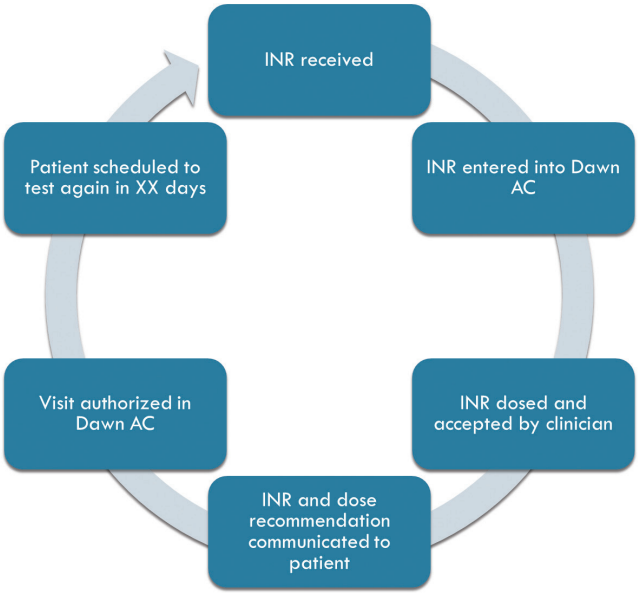
The Anticoagulation Management Service (AMS) at Brigham and Women's Hospital is overseen by the Department of Pharmacy. Originally a practice based model, the hospital switched to a pharmacy driven primary care model in 2009, where each pharmacist manages their own panel of patients. The AMS currently serves 3500 active patients and has a staff of 17.

Partners HealthCare produced a list of endorsement criteria which included 18 items decided on by the Patient Safety Team for High Performance Medicine to ensure system wide quality of care for Anticoagulation Services across Partners HealthCare. By March 2012 every Anticoagulation clinic within Partners HealthCare had to meet these criteria. The move to DAWN AC V7 was to increase patient safety and staff efficiency whilst facilitating meeting the endorsement criteria goals.

New Patient Referral Process – *Streamlining the referral and education process*



Dosing Patients – *Streamlining dosing and communication process*



Safety and Performance through DAWN AC - *Using reports to measure performance*

- *Intervention Tracking:* Coded comments were developed to track different interventions used by each clinician. Whilst intervention monitoring had always been done in the pharmacy department, it was new to the AMS. New reports of interventions by clinician show where most of the time is spent and therefore the value of the AMS.

- *Therapeutic Time in Range:* The AMS at Brigham and Women's Hospital do not take out induction or bridging INRs from their therapeutic time in range reports. The report is run for the AMS as a whole before being run for each individual clinician.

- *Tracking Critical INRs and Events:* An events report is generated through the events added to a patient's profile and the graph is used to compare event rates from 6 months ago to the current 6 months for indefinite treatment plans.

- *Safety and Reducing Human Error:* There are several places within DAWN AC that are checked to account for human error including scheduling, transcription and treatment plan status.

What is next for Brigham and Women's AMS and DAWN AC?

- *Partners HealthCare Lab Interface* – Expected to reduce manual entering of INRs by 40%
- *Vocantas* – Due to be piloted soon with the aim of reducing call volume
- *Medication Interface* – To help meet the safety criteria for medication changes on admissions and discharges

- *EMPI Interface* – To reduce errors in entering new patients and keep existing patient contact information up to date

How I Audit My Service

Vanessa Brown, National Improvement Lead, NHS Improvement and Ian Robson, Senior Analyst, NHS Improvement

NHS Improvement is a national service improvement organisation that has been in existence for around 10 years working with the DoH, primary and secondary care providers, networks and charities. The organisation is now moving into the new NHS Commissioning Board as part of their improvement body in order to provide a range of services, including tools for GPs to audit themselves under the changes that are taking place within the NHS.

Heart and Stroke are among the key areas of focus for NHS Improvement and the current Atrial Fibrillation (AF) programme is focussed on preventing strokes as they are the leading complication of AF. According to figures, 15% of strokes are directly attributable to AF and there are a high number of people suffering from AF who are not anticoagulated. NHS Improvement is looking at what can be done to prevent this and one of the solutions is the GRASP AF tool.

The GRASP AF tool is currently used in over 2200 primary care practices and looks for patients with AF, pulling out their medical history. The tool shows risk factors, current anticoagulant use and also predicts the number of patients likely to have a stroke.

Providing list views of patients broken down into risk, the GRASP AF tool shows which patients are not being anticoagulated enabling the GP to make a decision on each patient. For patients coded as contraindicated, some require a review which can lead to them starting anticoagulation therapy.

In one example, a 2.38% increase in anticoagulation therapy for high risk patients prevented 92 AF related strokes. At an estimated cost of £11,800 in the first 12 months of a stroke, the GRASP AF tool is an effective method for not only identifying high risk patients and reducing potential stroke numbers but also for cost savings.

Core Competencies for Delivering a Quality AC Service

Julie Salisbury, Anticoagulant Practitioner, Leighton Hospital, Crewe

Core competencies discussed were Staff, Patients, Resources, Technology, Benchmarking and New Oral Anticoagulants.

Staff

It is clear that patients prefer to see the same team but who makes the best team? Nurses? Biomedical Scientists? Pharmacists? It was agreed that a mix of them all is ideal. Staff within Leighton Hospital's Anticoagulation Service receive 4-8 weeks of full time training before taking up their post within the service and this is followed by regular on-going training. As new staff tend to be cautious and unsure of DAWN's dosing capabilities, their performance is audited regularly.

Patients

Education is key! All new patients have a thirty minute appointment during which they are told about their AC treatment plan and given information booklets. This gives the patient a chance to ask questions before they are then sent to one of twenty community clinics held in various locations. Clinics limit the number of patients seen in an hour to 16.

Resources

Availability of funding is a constant issue; however the importance of ensuring a well-resourced and therefore effective anticoagulation service is highlighted by a powerful statement used by Julie within the Leighton AC service, ***'Anticoagulation is the second most litigious area of healthcare!'***

Technology

The choice of technology used in terms of wet or dry technology depends on a number of factors including cost, level of technical expertise, time available and the location of clinics. What works for some services does not work for others. Whilst Leighton started with wet technology, the conclusion that it was no longer

working for the service led to a change in approach which saw the introduction of dry technology in the form of CoaguChek.

Benchmarking

Leighton joined the benchmarking service in 2004. Benchmarking enables AC services to compare results against other providers and highlight areas which need addressing/improvement. As a result of joining the benchmarking service and being positioned as 64 out of 74 in 2004, Leighton were able to approach the PCT for more resources in order to improve the service and currently occupy position 8 out of 102 in the latest 2012 results.

New Oral Anticoagulants

Leighton runs a very cost effective service and was concerned about the impact of the new oral anticoagulants. The service is currently looking to use the drugs for selected patients based on certain criteria such as an allergy/intolerance to Warfarin or those that are poorly controlled, where the risks of using Warfarin outweigh the benefits. There are now 3 patients on the new oral anticoagulants who were on Phenindione due to reactions with Warfarin and the progress of these patients will be monitored.

The improvements in the service were attributed to the staff's use of the DAWN AC software and the move from wet to dry technology within the clinics.

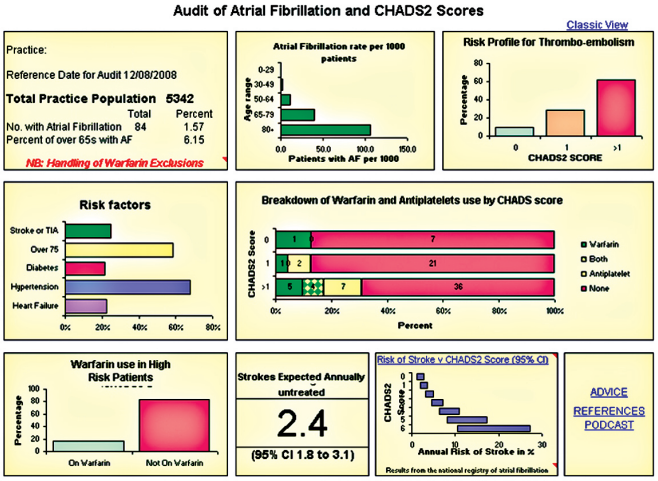
GRASP-AF: Coming to a PCT near you

Sean O'Brien, Anticoagulation Specialist BMS, Anticoagulation Dosing Advisory Service (ADAS), Blackpool Teaching Hospitals Trust

Developed by the West Yorkshire Cardiovascular Network as part of the 'AF in Primary Care' national project, the GRASP-AF tool is now available nationally through the NHS Improvement website. The tool searches GP patient records to identify high risk AF patients and produces a dashboard report breaking down their anticoagulation status.

The AF Case Finder is a piece of software that comes with the GRASP-AF tool and acts as a pre-requisite for running GRASP. Identifying patients with possible/probable AF and who are missing a diagnostic code or have an unconfirmed diagnosis, it improves the accuracy of AF registers by calculating stroke risk using CHADS2 and highlighting those with a score of 2 or more who would benefit from anticoagulation.

The benefits of such a tool are supported by figures that show anticoagulation in AF patients reduces the risk of stroke by around 70% and whilst the average cost of maintaining one patient on Warfarin for one year is approx. £242, the cost per stroke due to AF is estimated to be £11,800 in the first year after the stroke occurs. However, only around half of those diagnosed with AF who would benefit from being anticoagulated are receiving Warfarin or other anticoagulants, indicating that clinics are facing potentially large growth in patient numbers.



Costing review discussions between Blackpool ADAS and the PCT highlighted the GRASP AF tool and the likelihood of an extra 600 patients requiring anticoagulation. Preparation work for this increase in patients saw new funding agreed to better suit a growing service; a re-design of clinics that included the use of outpatient departments within PFI buildings; a new service specification for all GP surgeries; a review of the VITk policy for the domiciliary service and the alignment of the referral process between Primary and Secondary care.

The vast majority of referrals to ADAS are AF and the impact has seen patient test numbers in clinics and home visit numbers increase. Despite the continuous growth in patient numbers, ADAS runs a very proficient service, both domiciliary and clinic based, with the cost per test now at around £10.

Atrial Fibrillation: New Developments and Decisions

Dr Matthew Fay, Westcliffe Medical Practice and National Clinical Lead, NHS Improvement Heart and Stroke

Dr Fay discussed the need to understand when and how much AF is significant and highlighted that a

similar risk was reported for paroxysmal, persistent and permanent AF. Pacemaker Interrogation was considered as a key approach to determine whether AF is occurring. The relationship between silent AF and stroke rates was illustrated and concluded that very little AF is needed to increase the rate of strokes.

There is currently no national screening programme for AF. The RCP Consensus Conference as reported in the British Medical Journal (March, 2012), produced a statement recommending that a national screening programme should be introduced for over 65's which would satisfy the UK National Screening Committee Criteria for a UK programme. This statement was supported by research from BMJ that highlighted the ease of screening for AF in patients aged 65 or over.

The debate over whether a national screening programme should be introduced is currently with the National Screening Committee and it is thought that the decision will be ultimately down to cost issues.

The effect of Oral Anticoagulants versus Aspirin for AF patients was then examined through the results of 7 trials involving 4052 patients in AF and randomised to full anticoagulation or aspirin (Walraven et al). It was clear from the results of the study that anticoagulants were far superior to Aspirin. However, communicating that Aspirin is ineffective for AF and preventing stroke will prove to be a difficult task with many people to convince, right the way through the health service.
A further study by BAFTA into the randomised controlled trials (RCT) of Warfarin versus Aspirin for stroke prevention in AF for patients over 75 supported the previous trials by establishing that anticoagulants were far more effective in the elderly than Aspirin for treating AF.

Dr Fay followed the Warfarin versus Aspirin discussion with the introduction of NOACs and potential problems within the elderly patient population, underlining concerns about drugs that can't be monitored and particularly those that are highly sensitive to renal function.

	Dabigatran	Rivaroxaban	Apixaban
Half life	12-14	7-11	12
Excretion	85% renal	33% renal 67% hepatic	25% renal 75% non-renal
Dose	150mg	20mg	5mg
Step Down	110mg	15mg	2.5mg

An Early Evaluation of the Impact of the North Trent Policy Regarding the Use of Non-Vitamin K Antagonists for SPAF in a Secondary Care Anticoagulation Clinic

Dr Rhona Maclean, Consultant Haematologist, Sheffield Teaching Hospitals

The Anticoagulation Clinic for North Trent is currently working with the PCT regarding the introduction of NOACs. Whilst Warfarin is effective at keeping INRs in range, it is hoped that NOACs will prove beneficial for patients for whom the use of Warfarin is unsuitable.

NORCOM Guidelines for the introduction of Non-Vitamin K Antagonists include the following:

- Patients will be prioritised on the basis of gaining the greatest benefit
- Warfarin remains the first line drug for those able to take it
- Patients only offered non-vitamin K antagonist within their licensed indications at a CHADS2 score of 2 or more
- Patients with CHADS2 score of less than 2 who are well controlled should generally be maintained on Warfarin

There are now a range of effective drugs available and it is imperative that healthcare providers keep the end goal in sight – preventing strokes – therefore patients should be treated accordingly regardless of cost issues. Warfarin is an effective anticoagulant; however poorly controlled patients or those with unstable INR should be offered the option of NOACs.

A number of drivers for change in AF anticoagulation were outlined including new data that demonstrates the benefit of anticoagulation in elderly patients with AF; new QoF targets; and new technology and drugs. Dr Maclean also presented her predictions on the impact on clinics of the NORCOM guidance, these being that most patients with AF will be offered Warfarin and that clinic numbers will continue to grow due to QoF changes and demographics. At the same time, patients who are intolerant/unstable will be reassessed and considered for a switch to NOAC.

Dr Maclean concluded the presentation by outlining a strategy for the maintenance of patients with AF along with questions about future pathways and followed with a discussion surrounding the 'ideal' pathway.

Variance Growth Rate (VGR): A Factor That May Predict Events?

Syd Stewart, 4S DAWN Clinical Software

Nineteen years ago, a calculation (Variance Growth Rate) was identified to work out the variability of a patient's PTR (INR) as part of a multi-centre study looking at risk factors that can increase event rates in anticoagulation patients. The study concluded that "…it is possible to reduce risk for complications by attending to modifiable risk factors such as intensity of treatment and PTR (INR) variability…", *(Risk Factors for Complications of Chronic Anticoagulation, Stephen D. Fihn et al, Annals of Internal Medicine, 1993)*.

The VGR measurements look at the variability between the patient's INR values to determine how 'stable' they are. As a result of the study, three formulae were produced that offered different methods for the variability measures.

Variance growth rate Fihn (method A)	$\sigma^2 = \frac{1}{n}\sum_{i=1}^{n}\frac{(\mathrm{INR}_i - \mathrm{target}_i)^2}{\tau_i}$
Variance growth rate Cannegieter (method B1)	$\sigma^2 = \frac{1}{n}\sum_{i=1}^{n}\frac{(\mathrm{INR}_{i+1} - \mathrm{INR}_i)^2}{\tau_{i,i+1}}$
Variance growth rate Fihn (method B2)	$\sigma^2 = \frac{1}{n-1}\sum_{i=1}^{n}\frac{(\mathrm{INR}_{i+1} - \mathrm{INR}_i)^2}{\tau_i}$

*n is the number of INR measurements, τ is the time in weeks between the present and previous INR measurement.

Method A measures the degree to which a patient's INR differs from their target INR over a prolonged period, whilst Method B measures the degree to which a patient's current INR differs from the previous one. Method C is a similar measure to Method B but with some minor differences to the denominator value, however, neither Method B nor C take into account how close the patient is to their target INR.
A later study by Van Leeuwen et al (2008), published in the Journal of Thrombosis and Haemostasis also indicated that the VGR rate is linked to haemorrhagic and thrombotic complications. With VGR rates and the percentage of time spent in, above and below the range of 2.5-4.0 grouped into tertiles based on the distribution of the control group; and subsequent calculations split into time periods before both haemorrhagic and thrombotic events, results concluded that patients with high variability factors were more likely to have an event.

Further conclusions recognised that Method A, which takes into account both INR variability and the INR value in relation to the target, was the best predictor of an event, although it was also recommended that a large prospective trial is needed to confirm the conclusions. The question is – Should we add this factor to DAWN AC?

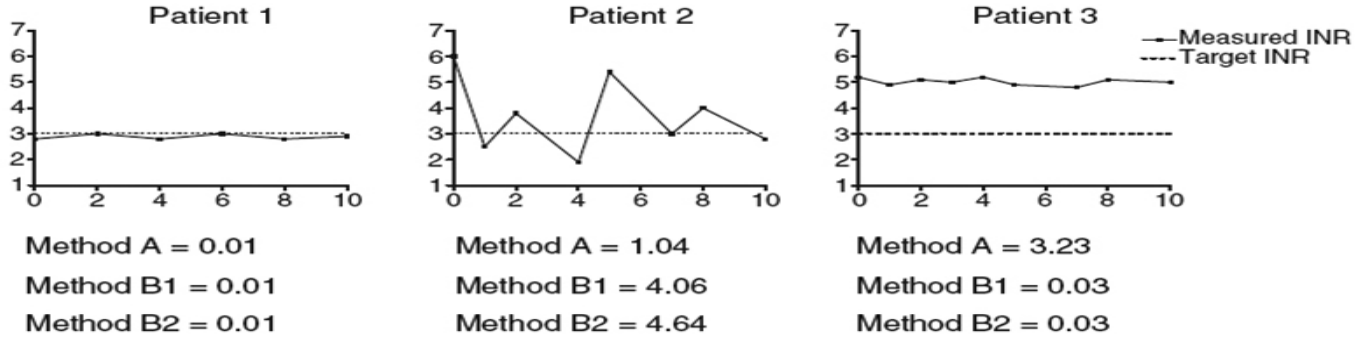
New Oral Anticoagulants

Dr Eric Watts, Consultant Haematologist (Retired), Essex Cardiac and Stroke Network

Dr Watts, Chairman of the User Group, presented on the introduction of the New Oral Anticoagulants. The 'equivalence point' at which clinically it is better to transfer a patient onto NOACs was discussed in addition to the uncertainties surrounding the new structure of the NHS and the potential conflict between a focus on reducing costs and that of improving healthcare.

A number of NOAC reviews were considered and whilst these reviews concluded that NOACs were safer or as safe as Warfarin, concerns were voiced that many healthcare providers would view this communication as an indication that any patient could be prescribed NOACs without taking into account the issue of impaired renal function.

Similarly, trials involving NOACs did not take Post Thrombotic Syndrome (PTS) into account and it was noted that, whilst NICE guidelines also recommend the use of NOACs (Dabigatran and Rivaroxaban) as



an option for the prevention of stroke, the uncertainties surrounding the new drugs and their emerging side effects should facilitate further discussion.
The Essex Cardiac and Stroke Network Board agreement that the approach to NOACs will be one of gradual implementation, recognise that these are new drugs with emerging safety concerns and, as a result, recommendations have been produced for prioritisation of groups of patients to be treated with Dabigatran. These recommendations take stroke occurrence, Warfarin medication dosage and compliance, CHADS2 score, unstable INR range and adverse reactions into account.

A policy statement for Dabigatran and Rivoroxaban has also been agreed which GPs will be encouraged to sign up to, ensuring that any decision to transfer patients from Warfarin to a NOAC is fully justified.

The emerging safety concerns of NOACs are also reflected in other organisations. Drugs.com report 295 current interacting medications, whilst Medicines.org.uk highlight that Dabigatran is a drug that they are particularly concerned about and require more information on. Further to this, case reports from New Zealand show that the transfer of a group of patients to NOACs resulted in 38 major bleeds with half proving to be fatal, mostly within patients over the age of 80 years old. This group of patients included many for whom NOACs were deemed to be an advantage. There is also no validated dose adjustment for patients who are either under or over weight.

In terms of compliance and safety, low therapeutic time in range may indicate poor compliance and so raises the question as to whether the patient should be on ANY potent anticoagulant at all. In addition, with Dabigatran having a twice daily dose, missing a dose means more rapid loss of anticoagulant effect resulting in poor compliers getting into danger sooner.

A key outcome from the information available on NOACs is to ensure that patients are fully educated on the new drugs, understanding that they are not an easy option and have a number of emerging side effects. Haematologists are still concerned that reversal of the anticoagulant effect is difficult to monitor and expert groups are still working on evidence based protocols to handle bleeding and surgery for patients on NOACs. Furthermore, the increased cost of NOACs is a major deterrent with cost estimates for a year's treatment and monitoring on Warfarin at between £220 and £480 dependant on local arrangements versus £800 for Dabigatran.

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