# DAWN®AC

## ANTICOAGULATION SOFTWARE

**Proceedings
of the
7th North American
DAWN AC User Group
Meeting**

**1st November 2013**

*"Make life easier and safer
in your anticoagulation
service through better
information presentation"*

## 4S DAWN

### CLINICAL SOFTWARE

# Contents

**Introduction by Dr Darlene Elias, Scripps Clinic & Scripps Green Hospital and Syd Stewart, Managing Director, 4S DAWN Clinical Software**

Dr Elias and Syd opened the 7th North American DAWN AC User Group by welcoming all of the delegates to the meeting.

**Integrating DAWN AC with EPIC Electronic Medical Record**

**Peter Chen, Information Technology Engineer, Anticoagulation Management Service, UCLA Healthcare**

UCLA's electronic health record (EHR) is Care Connect from EPIC, which provides a complete electronic health record and practice management system.

EPIC integrates the functions of approximately 65 software applications into a single system (Care Connect) that is accessible across the health system and is used by an estimated 18,000 faculty and staff members.

Prior to the integration project, UCLA Anticoagulation Management Service (AMS) ran parallel systems: EHR; DAWN AC; and paper-based systems (paper enrolment, scanning dosing reports etc.) and this prompted the integration of the two systems.

Preparing for the integration project involved collaboration between 4S DAWN, UCLA IT, DOM IT, UCLA Laboratory and Care Connect, where the functionality of EPIC and DAWN AC were considered, project steps were agreed and information flow and requirements were defined.

Within Care Connect, patient information for various encounters is listed in the Chart Review Notes in the patient record and this is where the relevant anticoagulation information from DAWN AC is shown. Selecting the relevant link in the list opens up the screen to show the relevant information.



An admissions and discharge interface (ADT) was also required to send ADT information from EPIC to DAWN AC. An 'FYI Flag – Anticoagulated by AMS' was introduced as a solution to ensure all the relevant information was filtered and sent to DAWN AC without it becoming cluttered with information from every patient at UCLA.

Integrating DAWN AC and EPIC has automated a lot of tasks and functions but there is still a small requirement to use DAWN AC and EPIC in parallel, bringing Pros and Cons:

| Pros | Cons |
|---|---|
| • Using DAWN AC to dose patients and now the dosing report is viewable by all users on Care Connect<br>• Hospital admissions automatically suspend treatment in DAWN AC and alert AMS staff<br>• Electronic enrolment<br>• FYI Flag | • Some instances of double documentation (INR results)<br>• Parallel charting is required – generally starting in DAWN then finishing charges and charting in EPIC<br>• Waves of Go-Live |

## Pharmacist Managed NOACs and DAWN AC for AF and VTE
**Dr Darlene Elias, Director, Anticoagulation Services, Scripps Clinic and Scripps Green Hospital**

The role of pharmacists as anticoagulation specialists has increased with many now operating in inpatient roles; transition of care units; outpatient roles in retail pharmacy; and dedicated anticoagulation services. Scripps has dedicated itself to a pharmacist run program.

A change in 'anti-thrombosis management' is evident, however in addition to the many positives of this new treatment such as the simplification of treatment and fewer drug to drug interactions (DDI's), there are also many unknowns and worries surrounding compliance, bleeding management and transitions on and off the drugs.

At Scripps there are quality initiatives in place that promote the safe and effective use of anticoagulation medications such as Warfarin including tracking TTR, bleeding complications and working to improve the practice and management of Warfarin. The key question is how will these new agents fit into our practice and how will we address their safety and efficacy?

Scripps traditional anticoagulation service provided organized, systematic management of warfarin and low molecular weight heparin 'bridging' on an outpatient basis but these traditional programs will have to evolve and adapt with the use of NOACs.

NOACs management has been included in the Scripps anticoagulation service which builds on the comprehensive antithrombotic service for Scripps patients and strengthens the inpatient to outpatient transition of care.

Some of the specific duties of the pharmacists include:
- Drug dose adjustment
- Follow-up renal function
- Side effects and transitions on and off therapy
- Follow-up of bleeding complications
- Follow-up of adverse drug reactions
- Track drug discontinuation and transition back to warfarin

Scripps implemented the Dabigatran module into their DAWN AC system to facilitate the safe prescribing of the NOAC and to ensure seamless transition for the patient.

A comprehensive pharmacist managed anticoagulation service is now in place at Scripps:
- NOACs have been incorporated into the scope of practice: Pradaxa, Xarelto, Eliquis
- Development of expertise in the full range of antithrombotic agents

- Peri-procedural management
- Transition between agents
- Drug-drug interactions
- Compliance management
- Monitoring of special patient populations
- Knowledge of potential risk factors for thrombotic and hemorrhagic complications
- Knowledge of intervention to avoid or minimize complications and maximize efficacy of therapy
- Patient education regarding disease state
- Patient education reading signs and symptoms of bleeding
- Anticoagulation protocols
- Physician and nurse education
- Research and QA

With pharmacist managed NOACs at Scripps, value will be delivered to the patient, to physicians and to the health care system.

## Using the Variability of INRs to Indicate the Risk of an Event in DAWN AC – Variance Growth Rate (VGR)
**Syd Stewart, 4S DAWN Clinical Software**

It is widely agreed that neither the INR alone nor the %TTR are dependable predictors of clinical events in patients receiving oral anticoagulation.

A new study, *'The clinical evaluation of International Normalised Ratio variability and control in conventional oral anticoagulant administration by use of the variance growth rate'* published by Poller, L., Ibrahim, S. and Jespersen, J. in the Journal of Thrombosis and Haemostasis looked at the possible value of an additional calculation (the variance growth rate (VGR)) as an addition to %TTR in predicting clinical events.

This study took data from a previous prospective multicentre randomised trial comparing DAWN AC computer aided treatment with experienced medical staff (*Poller L, et al. Multicentre randomised study of computerised anticoagulant dosage. Lancet. 1998, 352: 1505-09).* 661 control patients were matched to 158 event cases (bleeding, thromboembolism or death). The VGR and %TTR were measured over three time periods, overall follow-up; 6 months; and 3 months before an event.

The VGR measurements look at the variability between the patient's INR values to determine how 'stable' they are.

Three methods for calculating the VGR were assessed within the study.

Method A measures the degree to which a patient's INR differs from their target INR over a prolonged period, whilst Method B1 measures the degree to which a patient's current INR differs from the previous one. Method B2 is a similar measure to Method B1 but with some minor differences to the denominator value, however, neither Method B1 nor B2 take into account how close the patient is to their target INR.

The following figures graphically illustrate the three methods.

Patient 1
Method A = 0.01
Method B1 = 0.01
Method B2 = 0.01

Patient 2
Method A = 1.04
Method B1 = 4.06
Method B2 = 4.64

Patient 3
Method A = 3.23
Method B1 = 0.03
Method B2 = 0.03
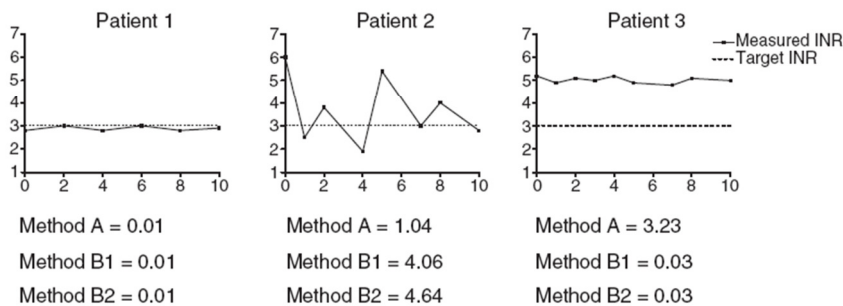
Key Findings:

- %TTR is a reasonable predictor of clinical events only when calculated over the last three or six months of treatment
- %TTR showed no correlation with bleeding events when calculated over any period of treatment
- %TTR may be a predictor of thrombotic events when calculated over the last six months of treatment
- The Variance Growth Rate (VGR-A) showed a very strong correlation with clinical events when calculated over the last three or six months of treatment
- The Variance Growth Rate (VGR-A) showed a good correlation with bleeding events when calculated over the last three or six months of treatment
- The Variance Growth Rate (VGR-B1) showed a very strong correlation of bleeding events when calculated over the last three months of treatment
- The Variance Growth Rate (VGR-A) *may be* a reasonable predictor of thrombotic events when calculated over the last three months of treatment

It should be noted that there were very few thrombotic events, which made the prediction of events difficult to measure.

In conclusion, the study determined that INR monitoring with a measure such as the VGR and %TTR, three to six months before the current INR, may offer additional safety by detecting and isolating patients who may be at increased risk of possible adverse episodes.

It should be noted that a large prospective trial is needed to confirm the findings above.

As a result of the findings of the study, the 4S DAWN team have been developing the VGR calculation within DAWN AC as illustrated below:

This will be available to customers in the near future and is offered as an option, with users having the choice as to whether the VGR is displayed on the patient records.

## Project VTE – Using DAWN AC to Improve Safety and Billing
**Katie McCool, PharmD, Clinical Pharmacy Anticoagulation and Anemia Service (CPAAS), Kaiser Permanente**

Project VTE was prompted by new ICD-9 codes being introduced for chronic DVT or Chronic PE and the aim of improving reimbursements for the CPAAS. This required updating of patient codes.

Patient records went back to 1996 when the CPAAS was established. Coding for recurrent/chronic DVT was previously not an issue as only acute DVT/PE indications and codes were in use, therefore there was very little information in DAWN AC for what was required, resulting in new codes needing to be added to patient records.

A further challenge was incomplete referrals. More than 8,000 patients were currently enrolled and it was historically unknown how good the service was at maintaining records and discharging patients when appropriate. Most referral to CPAAS don't include an anticipated length of therapy.

Initially CPAAS had to determine how big the project was going to be. The first step was to report on the DAWN data, looking at anticoagulation patients by diagnosis – specifically, 'DVT' or 'History of VTE'. The DAWN reports highlighted the large scale of the project due to the enormous number of patients to go through.

The next issue was obtaining staff engagement for the additional workload that need taking on and this was done through:
- Tying the results to annual goals
- Splitting the project into two parts – clinical pharmacy and specialist work

CPAAS then had to determine on the best route forward and decided that the highest impact patients, based on age and healthcare plan would be selected initially – those being over 65 and on the Medicare Advantage Plan. The report from DAWN allowed patients to easily be sorted by D.O.B. and then filtered by healthcare plan.

Communication with physicians was the next vital step to ensure they were aware of what was required from them in terms of entering the correct ICD-9 code. The codes are divided into categories which influence reimbursement so it is important that these codes are accurate and up-to-date.

All information regarding VTE events is logged in DAWN AC along with dates. This helps with planning procedures and improved documentation. In addition, two new diagnosis codes were added to DAWN AC to help clarify treatment plans.

A consistent process was required to ensure all patients were evaluated and to verify the appropriate length of treatment.

Final documentation in Health Connect (Kaiser's EHR system) and DAWN AC completed the process.

## Software Guidance on VTE Diagnosis and Treatment
**George Kitching, Lead Developer, 4S DAWN Clinical Software**

A demonstration of the new DVT Diagnosis Assessment module was given by George Kitching who took delegates through the DVT pathway and outlined how it can be configured specifically to fit customer's workflows. Within this

module, important steps in the patient care pathway are documented electronically enabling protocol-driven patient care and follow up.

The module is designed to lead healthcare professionals through established protocols, in the form of visual flowcharts. Different paths can be selected depending on the outcome of patient assessments.
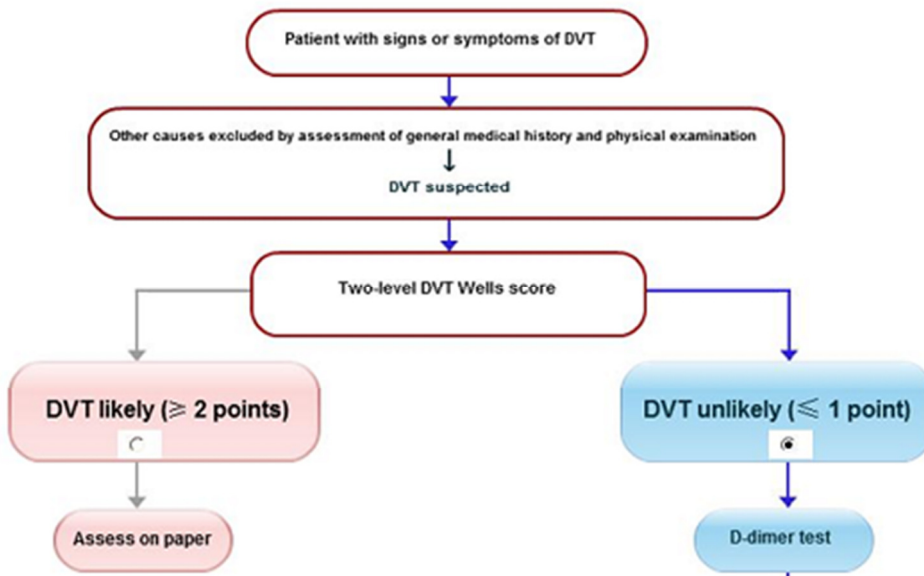


The completion of questionnaires form a major part of the DVT assessment process within DAWN AC. This facility enables the collection of important information used in the assessment such as the patient's Wells Score and the documentation of Risk Factors. Being able to quickly ascertain the current status of a patient and then being able to see what the next step should be is very important.

One of the most time consuming and potentially error prone steps in the assessment process is reporting the assessment outcome to the patient's GP or the referring clinician. By utilising DAWN's in-built messaging system to email, fax, or mail this step can be executed in a single click.

Questionnaires ensure all the required information is collected from the patient and no steps in the process are overlooked. Summary information is displayed on the surface of the patient record giving visibility of the information collected using a questionnaire.

The DVT Diagnosis Assessment module was developed with one of 4S DAWN's key UK customers, University Hospitals of Leicester NHS Trust and has revolutionised their DVT clinic with the following results and benefits.

As only 20% of patients scanned actually have a DVT, the DAWN DVT module enabled the clinic at Leicester to reduce their workload by 80% as they were clearly able to determine at each stage, whether the patient needed to be progressed through the defined DVT workflow or discharged from the clinic.

Leicester DVT clinic also outlined further benefits from the introduction of the DVT module:

- Information electronically stored therefore easy to access for future episodes
- Provides an audit trail
- Saves time and resources as only collecting relevant information

- Fluent, methodical way of working
- Simplified algorithms easy to use
- Message box to highlight information for other users
- Ability to add messages for letters to GPs, e.g. abnormal blood results
- No more writing endless discharge and blood results letters
- Easy referral to the anticoagulation clinic
- As 80% of patients scanned are negative and now discharged, this allows the DVT clinic team to spend more time with those patients who require treatment

For further information on the new DVT Diagnosis Assessment module, please contact the 4S DAWN team on sales@4s-dawn.com.

## Anticoagulation Care for Alaska Native Customer-Owners within the Nuka Model of Care
**Brian Schilling, PharmD, Anticoagulation Clinic Coordinator, Alaska Native Medical Center**

The Alaska Native Medical Center (ANMC) is tribally owned and jointly operated by the AK Native Tribal Health Consortium (15 tribes) and Southcentral Foundation. Covering Anchorage and surrounding villages, the ANMC has 63,000 customer-owners (this is the name given to patients in the South Central Foundation) and covers an area of 107,413 square miles, roughly equivalent to the state of Colorado.

ANMC operates a telepharmacy with medication vending machines in village clinics remotely controlled by an Anchorage pharmacist. In 2006, the ANMC telepharmacy received an Award for Excellence in medication-use safety from the American Society of Health System Pharmacists.

In 1999, the ANMC Anticoagulation Clinic was a pharmacist managed service that saw patients face-to-face. DAWN AC was introduced in 2006 with transitioned labs to support the clinic.

In late 2012 an integrated care model was introduced to better align with the Nuka system of care. Anticoagulation was divided between 5 integrated pharmacists with three based at Anchorage Primary Care Center, one at Valley Native Primary Care Center and one at a rural pharmacy.

| Anticoagulation Clinic - 1999 | Anticoagulation Clinic - 2012 |
|---|---|
| - Point of Care<br>  o Face to face exclusively<br>  o Telephonic – none<br>  o Pharmacist managed<br>- Software management since 2006<br>  o Customer-owners per FTE<br>    ▪ 175 in 2007<br>    ▪ 321 in 2011<br>- Transitioned laboratories to support clinic | - Integrated care model<br>- Better aligned with Nuka System of Care<br>- Anticoagulation divided between 5 integrated pharmacists<br>  o Anchorage PCC – 3<br>  o Valley Native Primary Care – 1<br>  o Rural Pharmacy – 1<br>- Outcomes similar to prior care<br>- Target specific oral anticoagulants – all 3 on formulary |

Patient outcomes after the introduction of DAWN AC software showed that whilst time in therapeutic range dropped, the bleed rate also dropped, by 64%. In addition, the length of appointments dropped 25% from 20 to 15 minutes.

Table 2. Outcomes before and after implementation of anticoagulation software. Data reported as the occurrence of the outcome and the incidence per patient-treatment-year noted in parentheses.

| Study Outcome | PRE | POST | p-value |
|---|---|---|---|
| % of Days within Therapeutic INR | 64% | 61.6% | <0.01 |
| Hemorrhagic OPD Visits | 12 (0.56) | 5 (0.2) | 0.05 |
| Hemorrhagic Events | 16 (0.75) | 11 (0.45) | 0.25 |
| Hemorrhagic ER Visits | 8 (0.37) | 9 (0.37) | 1.00 |
| Total Visits (ER and OPD) | 20 (0.93) | 14 (0.57) | 0.17 |
| Thrombotic Events | 0 | 0 | ** |
| Inpatient Admissions | 1 (0.05) | 1 (0.04) | ** |
| Number of Days Admitted | 4 (0.19) | 6 (0.25) | ** |

**Not tested due to sample size limitations.

Evidence was presented that indicated that VTE incidents within the American Indian and Alaska Native population are significantly lower compared to the Caucasian population. Also the Alaskan Native population have a lower average Warfarin dose than Caucasians (4.34mg versus 5.19mg).

## NOACs for the Treatment of VTE
**Dr Darlene Elias, Director, Anticoagulation Services, Scripps Clinic and Scripps Green Hospital**

A number of trials were looked at in relation to the treatment of VTE with NOACs, including Edoxaban, Rivaroxaban, Apixaban and Dabigatran in comparison to Warfarin.

| Trial | NOAC | Inferiority to Warfarin | Bleeding Rates Compared to Warfarin | No. of Patients |
|---|---|---|---|---|
| The Hokusai-VTE Investigators | Edoxaban | Noninferior | Significantly less with Edoxaban | Over 8200 |

Kaplan‑Meier Cumulative Event Rates for the Primary Efficacy Outcome.

Kaplan‑Meier curves are shown for the first occurrence of the primary efficacy outcome of adjudicated symptomatic recurrent venous thromboembolism (VTE) – a composite of deep-vein thrombosis or nonfatal or fatal pulmonary embolism – in the overall study period. The inset shows the same data on an enlarged y axis.
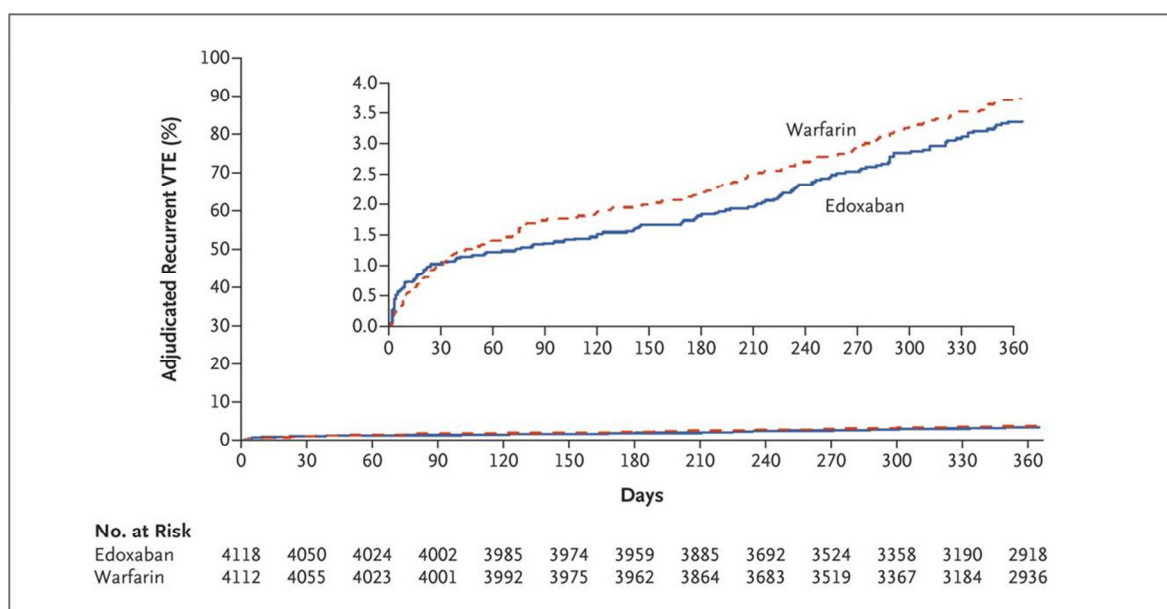
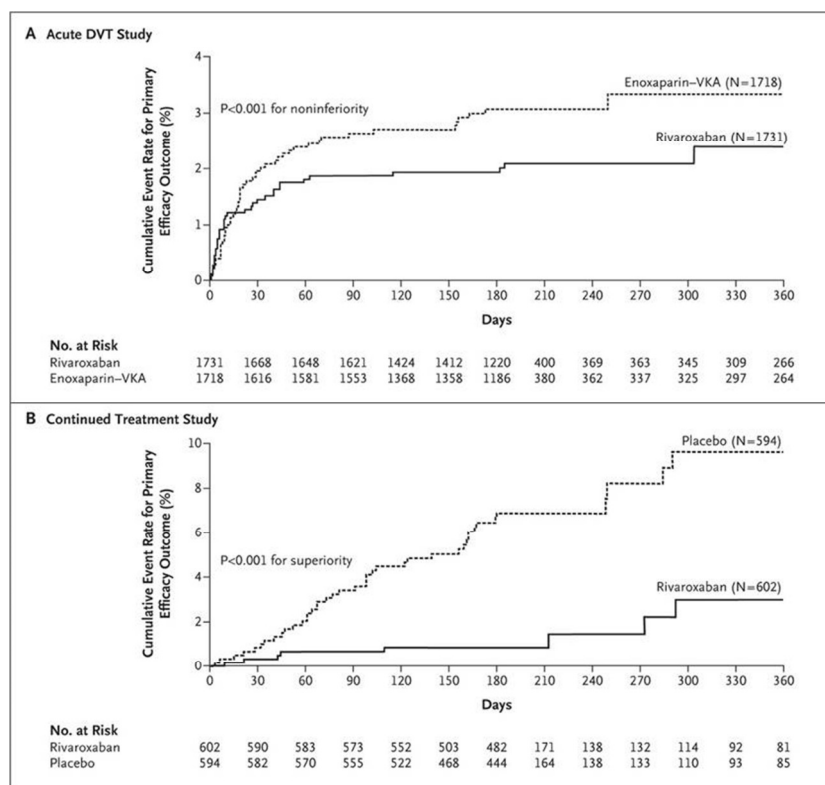| Trial | NOAC | Inferiority to Warfarin | Bleeding Rates Compared to Warfarin | No. of Patients |
|---|---|---|---|---|
| The EINSTEIN Investigators | Rivaroxaban | Noninferior | Similar with Rivaroxaban | 1196 |



Kaplan‑Meier Cumulative Event Rates for the Primary Efficacy Outcome in the Two Studies.

VKA denotes vitamin K antagonist.

| Trial | NOAC | Inferiority to Warfarin | Bleeding Rates Compared to Warfarin | No. of Patients |
|---|---|---|---|---|
| Angelli, G., et al | Apixaban | Noninferior | Less with Apixaban | 5395 (acute) 2482 (extended) |
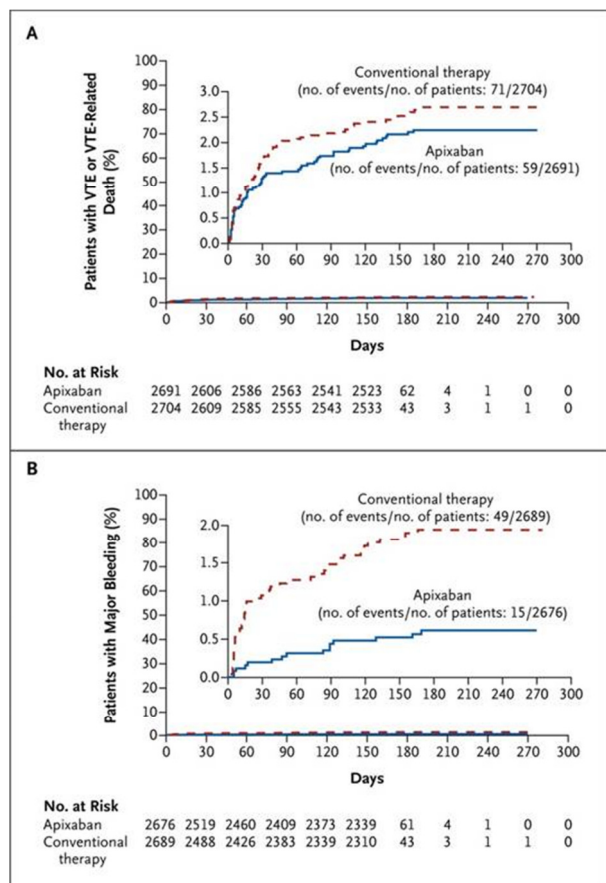


Kaplan‑Meier Cumulative Event Rates.

Kaplan‑Meier curves are shown for the first event of recurrent venous thromboembolism (VTE) or VTE-related death (Panel A) and for the first episode of major bleeding (Panel B).

In each panel, the inset shows the same data on an enlarged y axis.

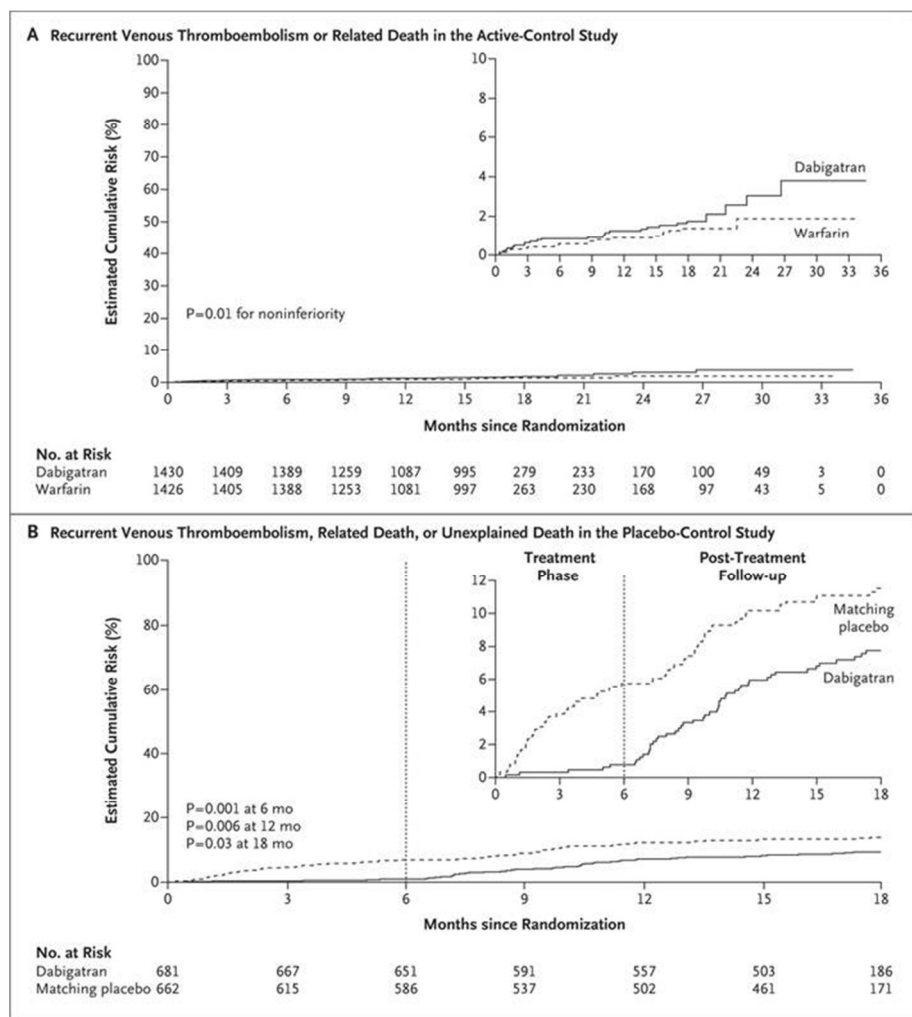| Trial | NOAC | Inferiority to Warfarin | Bleeding Rates Compared to Warfarin | No. of Patients |
|---|---|---|---|---|
| Schulman, S., et al | Dabigatran | Noninferior | Less with Dabigatran | 2866 (acute) 1353 (extended) |



Cumulative Risk of Recurrent Venous Thromboembolism or Related Death (or Unexplained Death in the Placebo-Control Study).

Panel A shows data from the active-control study, and Panel B shows data from the placebo-control study.

Specific elements of each trial were looked at in more detail including Patient Characteristics; Treatment; Therapeutic Time in Range (TTR); and Major Bleeding.

Within a few years, physicians will likely have the choice of at least four novel oral anticoagulant agents to use instead of warfarin to treat VTE.

## DAWN AC Messaging: Communication is Everything
**Russell Peris, Support Staff Manager, Medication Management Services, Desert Oasis Healthcare**

Desert Oasis Healthcare is an Integrated Managed Healthcare Organisation and a pioneer Accountable Care Organisation. Clinics for Anticoagulation, Diabetes, Hepatitis C and Coronary Artery Disease are managed by pharmacists under established collaborative practice agreements.

The anticoagulation clinic started in 2005 with six employees and 450 anticoagulation patients. DAWN AC Version 7 was implemented and email was the primary departmental communication tool, particularly for allocating/informing other healthcare professionals (HCP) of tasks that required completion. By 2013 the clinic had grown to 27 employees and 3800 anticoagulation patients.

By this stage, using email as the primary communications tool had become problematic for three main reasons; the volume of email being received (500 per day) meant that staff were struggling to work through them; the inefficiencies caused by the potential duplication of effort; and server space limitations, with so many incoming emails, inboxes were often reaching capacity.

In order to address this growing problem and promote effective healthcare team communication, the anticoagulation clinic utilised the DAWN Message Center, an application within DAWN AC that facilitates improved communication.

Using the DAWN Message Center brought a number of benefits including:
- Removing the need to use email
- Grouping messages by type/category as many messages are repetitive
- Message is removed from the list once it has been accepted and so avoids repetitive work
- An electronic tag indicates when and by whom the task was done

**Using DAWN Message Center**
The most recent quick note is included in the message which is then categorised (using a customised list of categories) by type of message and the HCP i.e. support, pharmacist, supervisor.

Within list view, message categories can be searched on, including by date and time and these lists are accessible by all staff. This process allows for accountability as staff sign off on the task once it has been completed. The audit history within DAWN AC keeps a record of when the task was completed and who by. Once the task has been marked as completed it is removed from the list view.

As a result of changing the process to incorporate the use of the DAWN Message Center for sending tasks and messages to other HCPs the volume of email has been significantly reduced and mailboxes are now longer reaching capacity. Efficiency has improved due to the removal of task duplication and this has led to a much happier staff. Finally, as messages are sent through DAWN, there is an electronic record which facilitates accountability and enables the clinic to educate on an individual basis.

## DAWN AC at Sharp Community Medical Group: An Independent Practice Association
**Michele Bautista-Meredith, Lead Pharmacist, Medication Therapy Management & Outpatient Anticoagulation Programs, Sharp Community Medical Group**

Sharp Community Medical Group (SCMG) is an Independent Practice Association (IPA). An IPA is a multi-specialty organisation comprised of physicians in private practice responsible for the financial and clinical management of a population of patients, through contractual agreements with health plans. There is no common electronic health record that all physicians in SCMG use and laboratories are contracted throughout the county.

The SCMG anticoagulation program has 720 patients and is primarily telephone based with voluntary monthly patient education classes.

In 2013 a number of changes were implemented that included a work from home initiative, and the transition to a Medication Therapy Management Program for pharmacists which resulted in changes in staff. The staffing of the service now includes one ancillary staff, three full-time registered nurses, pharmacists and pharmacy interns.

DAWN AC is used by the anticoagulation program for new enrolments, follow-ups and reminders, and reviews. This has facilitated efficiency gains in a number of areas:
- individualized clinics

- patients to be enrolled
- scanning of documents
- sending letters to patients
- better communication

Quality was also impacted with new enrollments being standardised and productivity reports on each user to include TTR, Critical INRs and Event Rates to see where service improvements could be made.

## DAWN AC Product Update
**George Kitching, Lead Developer, 4S DAWN Clinical Software**

A number of developments have been made within the DAWN AC product over the last twelve months both from a safety perspective and to improve workflows and the usability of the software for the user, providing a range of tools and functionality.

- The **Quick Notes** section on the main patient screen has had the date and time reformatted to a bold, black font. This is now much easier to read than the previous white text.
- **System Generated Passwords** have been made easier for users to remember, consisting now of just 6 characters and containing numbers from 2-9 and lower case letters (other than g, i, j, l, o, p and q) which some users found difficult to read.
- If you cancel out of the diary screen without scheduling the patient's appointment, a **Cancel Diary Screen Warning** box now appears to inform users that messages such as letters, faxes, email etc. will not be generated automatically until the appointment is scheduled into the diary.
- A new local drug code can now be entered for each drug in DAWN. The **Drug Code Field** is intended to hold the code from your own hospital computer systems and is used by the optional medications interface that can automatically add the details of which drugs a patient is taking.
- A **Post Clinic Checklist** view has been added to list views within DAWN AC to provide a final checklist that can be used at the end of each clinic to ensure there are no patient actions outstanding. This can be sorted by dose or by interval.
- The support team have created many custom reports for customers over the years and these have been added to a **Reports Webpage** so that customers have easy access to the range of reports available to them.