DAWN® AC
ANTICOAGULATION SOFTWARE

Proceedings of the 8th North American DAWN AC User Group Meeting

21st November 2014

"Make life easier and safer in your anticoagulation service"

4S DAWN CLINICAL SOFTWARE

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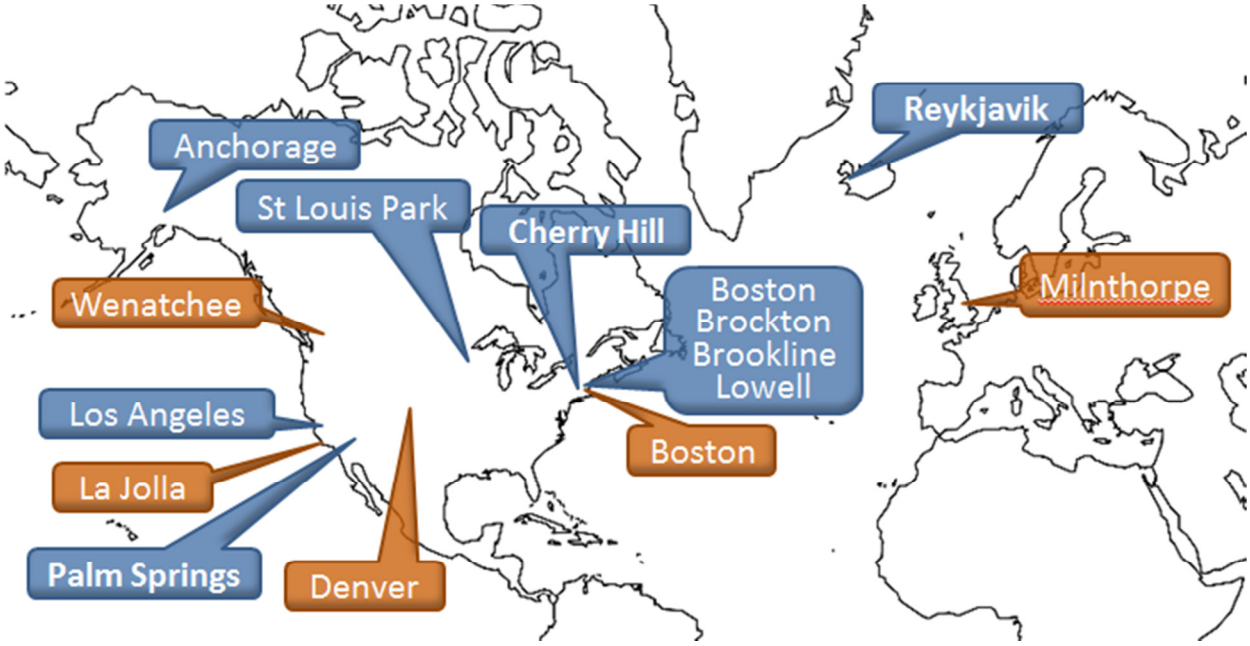
Welcome & Introduction

Lynn Oertel, Clinical Nurse Specialist, Anticoagulant Management Service (AMS), Massachusetts General Hospital, Boston
Syd Stewart, Managing Director, 4S DAWN Clinical Software, UK

Syd opened the 8th North American DAWN AC User Group by welcoming all the delegates to the meeting and introducing the Chairperson, Lynn Oertel, Clinical Nurse Specialist, Anticoagulant Management Service (AMS), Massachusetts General Hospital, Boston. Lynn presented a map showing the surprisingly large spread of delegate location:



A packed and varied programme of talks had been lined up and a summary of each talk follows.

"Is there something in the ether?...."
Lynn Oertel, Massachusetts General Hospital, Boston

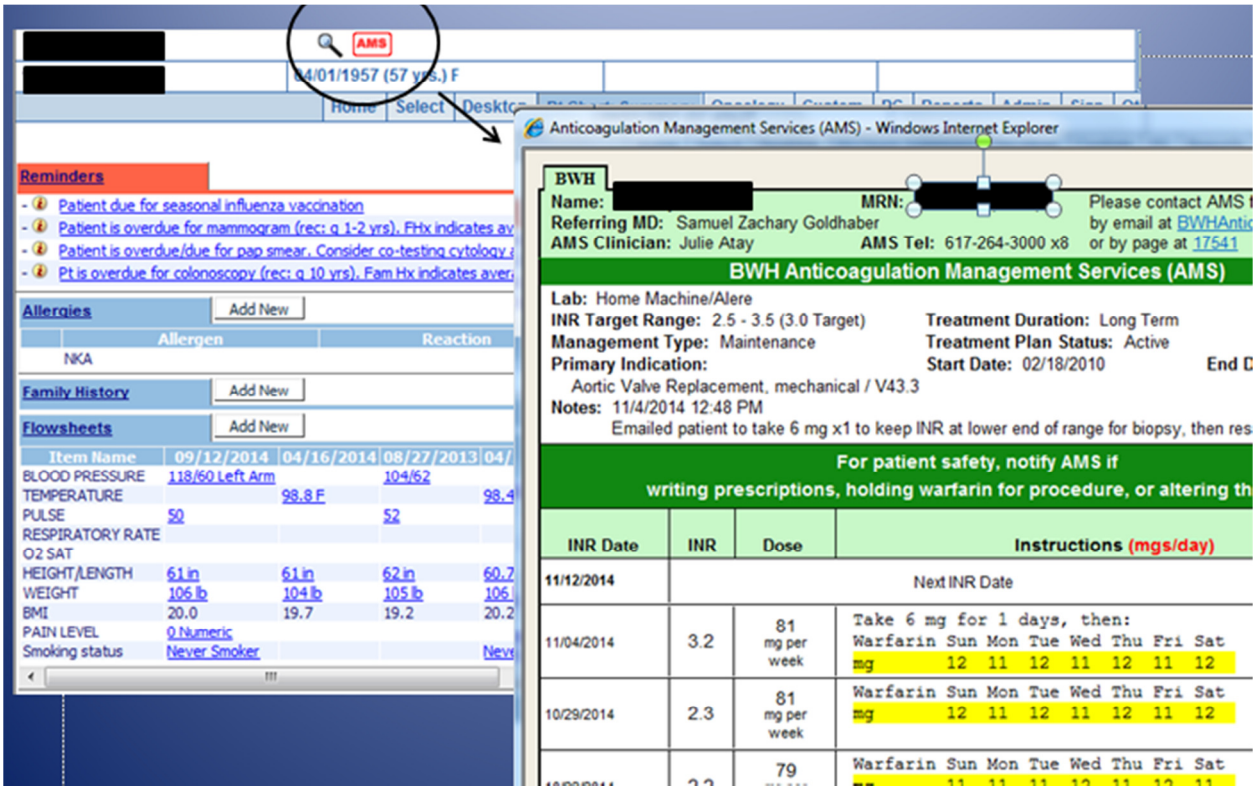
The first few sessions of the conference were located within Massachusetts General Hospital's Ether Dome and Lynn summarised for us both the long medical history of the hospital and the seminal significance of the Ether Dome:

Massachusetts General Hospital was founded in 1811 and is the 3rd oldest general hospital in the US. Annually, it has 1.7 million outpatient visits and 48,961 patient admissions with an average length of stay of 60 days. The Ether Dome is a surgical operating amphitheater that served as the hospital's operating room for 45 years. It was the site of the first public demonstration of the use of inhaled ether as a surgical anesthetic on 16 October 1846. It now serves as a lecture theater and museum.

Improvements in Patient Safety and Data Flow with DAWN AC Interfaces
Julie Atay, Anticoagulation Services Manager, Brigham and Women's Hospital, Boston

Brigham's patients are located all over the USA and rarely visit the clinic in person; and so it is particularly important that the clinic has up to date information about them. Brigham has a number of interfaces (interconnective data exchanges) between DAWN AC and other systems that have improved the topicality and transparency of this information but also considerably enhanced patient safety. These include:

AMS Icon – this is a symbol within the patient's overall medical record showing that this patient is currently on Warfarin and is being managed by one of the Partners' Anticoagulation Management Services:



Clicking on this symbol reveals a summary of the patient's anticoagulation dosing history and related details. It is a great way of ensuring communication between physicians and it is believed that this alone has prevented many safety errors. An email notifies staff if a patient is registered at two of the Partners' Anticoagulation Management Services simultaneously in order that this can be resolved.

Laboratory Interface – this transmits INRs to DAWN AC. It reduces transcription errors and saves time. A monitor within DAWN AC alerts users to discrepancies in results such as existing results for the same day and results for which later results already exist.

Demographics Interface – the users are able to initiate a request from within DAWN AC which retrieves the latest demographic data such as address/phone number for the patient from the master Electronic Medical Record (EMR).

Medication Interface – Every night DAWN AC receives a list of all the medications that each anticoagulant patient is known to be on and highlights any differences which then flags new medications to the users. It is believed that this interface has the largest safety benefit as well as saving time. Although patients and physicians are educated into passing on such information, it is known that this does not always happen.

Brigham have further interface plans including sending automated reminder calls to reduce the incidence of DNAs and incorporating more labs into the laboratory interface.

In summary, DAWN AC allows for documentation and workflow that is specific to anticoagulation and the addition of interfaces allow this specific anticoagulation data to be integrated with the EMR. These interfaces enhance the safety of the anticoagulation service through transparency of information.

Promoting Patient Safety During Transitions Of Care: Known Or Unknown

Diane DeTour, Nurse, Anticoagulation Management Service (AMS), Massachusetts General Hospital, Boston

The Joint Commission defines 'transition of care' as "*the movement of patients between various health care settings.*" This transition carries a risk of poor outcomes due to medication errors and errors of communication among health care providers, patients and family care givers. It also has a downstream effect on providers.

DAWN AC provides the Mass. General Anticoagulation Management Service (AMS) with a number of places where transitions can be identified and hence managed. Diane focussed on two of these, ADT Interface and the Hold Monitor:

ADT (Admissions, Discharges & Transfers) Interface

The ADT Interface sends information to DAWN AC regarding hospital admissions and discharges; and outpatient surgery/procedures.

For patients admitted to MGH, the AMS staff generate a hospital admission letter which becomes a 'note' in the patient's hospital EMR. This note indicates AMS staff are available to assist for discharge planning and reminds hospital staff that they should refer to the patient's AMS icon which contains important patient-specific warfarin management information and easy email or paging contact links to AMS.

For patients undergoing a procedure or emergency outpatient admission, the AMS staff monitor the status and, if admitted, create a note to the EMR.

For patients admitted to outside hospitals, the AMS staff use the reminder facility to periodically check the patient status.

For patients alerted as discharged, the AMS staff:

- review the discharge instructions/labs/hospital course
- make an assessment phone call to the patient within 24 hours
- reconcile the medications
- update events, procedures & risk class
- assess the need for manual/bridging therapy
- use the DAWN AC Coded Comment feature for consistent note taking
- copy the Quick Note to the EMR

The usefulness of the Hold Monitor in identifying transitions

The DAWN AC Hold Monitor typically contains unknown/unexpected interface messages. AMS focus on 2 types of messages:

1 – failed messages e.g. an email being sent to an invalid email address. This could involve both patient and physician email address and requires manual resolution.

2 – warnings such as the patient's treatment plan is not active. This may be because treatment plan status prevents new information from being electronically added to the Dawn record. Some examples include:

If an INR arrives for a patient who is marked as:

- 'suspended' due to extended travel, this is a hint that the patient may have now returned and therefore requires follow up.
- 'deceased', this needs resolving as it may be that the patient was inadvertently marked as deceased or death was unknown to AMS.
- 'new', this requires resolving as it may be that the patient has been referred but not yet seen for their educational session in AMS and warfarin is managed by their referring physician. If the INR is high, AMS reminds the referring physician that they need to manage the patient.

The AMS has analysed the workload impact of both the ADT messages and the Hold Monitor messages as they have a significant impact on workload but it is believed this time is well-spent due to the risks associated with care transitions.

The speaker reminded us of some significant warfarin headlines:

- Warfarin is at the top of the list for older Americans admitted to emergency rooms
- Estimated 21,010 warfarin-related hospitalizations
- In the US, 54% of adverse drug events for hospitalized older adults are attributable to drugs that require regular monitoring

21st Century Benchmarking

Jenny Wood, 4S DAWN Clinical Software, UK

What is benchmarking and its objectives?

"A measurement of the key metrics of an organization and its comparison with standard measurements or similar measurements of its peers"

The objectives of benchmarking are to:

(1) Determine what and where improvements are called for
(2) Analyze how other organizations achieve their high performance levels
(3) Use this information to improve performance

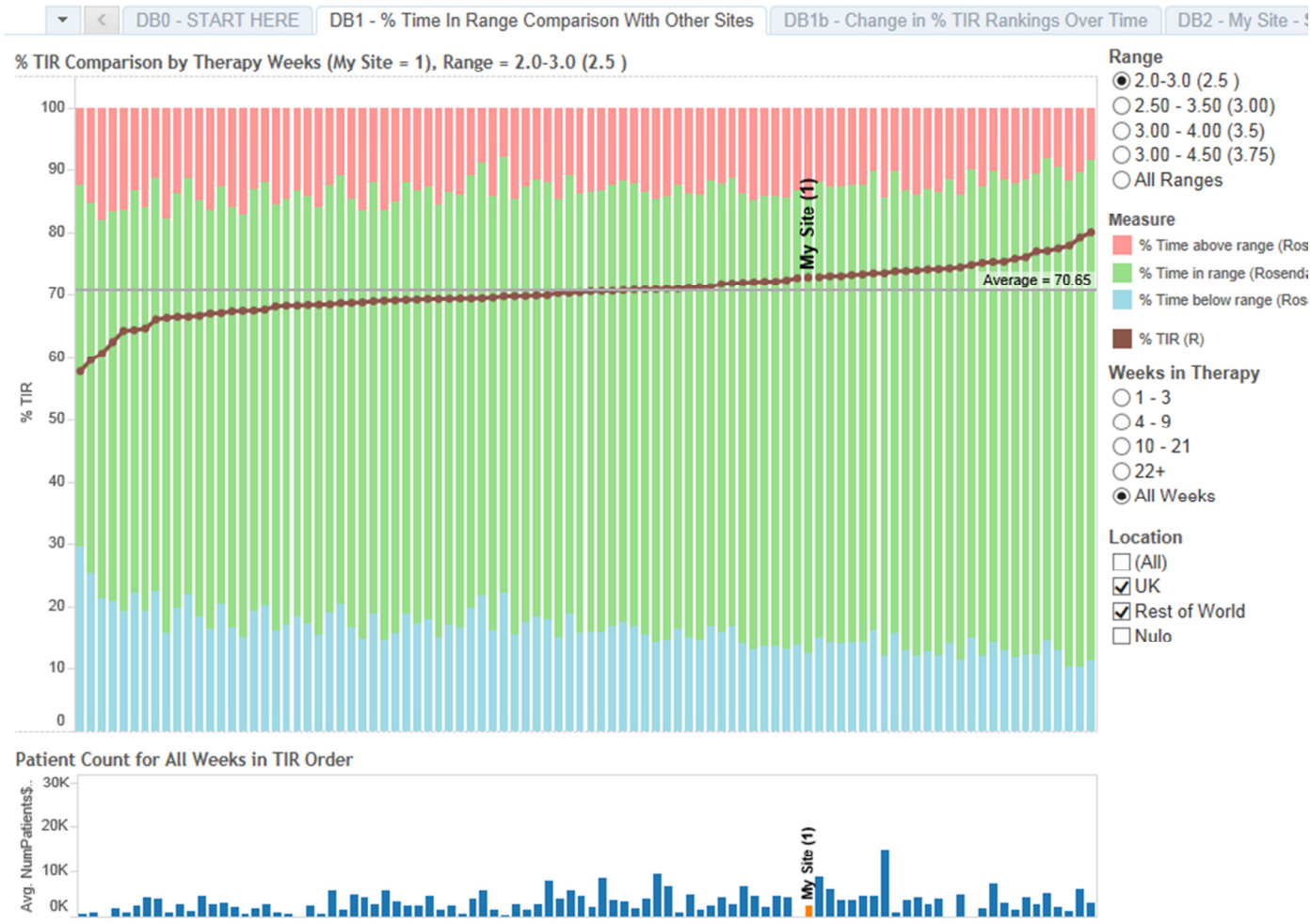
An overview of the DAWN AC Benchmarking service was then given:

- 16 years old, approx. 94 anticoagulation services
- Anticoagulation services send anonymised data to 4S DAWN
- Compare your service against:
    - your previous results
    - other AC services
    - using different measures e.g. %Time In Range, INRS >5, % manual interventions

Jenny then discussed how the benchmarking service is changing. Historically, printed and bound benchmarking reports were distributed to all sites that took part in the benchmarking twice yearly. In the future, in order to make accessing/ distributing the benchmarking reports easier and quicker, and to provide flexibility in viewing & manipulating the data, the reports will be electronic.

This will also give a better technological platform on which to further improve what is captured, analyzed & reported on. For example, various participating services have requested INRs >8, viewing two related sites together etc. It is also hoped that the more dynamic nature of the new method will better enable sites to identify strengths/weaknesses & changes; and provide better insights for future planning.

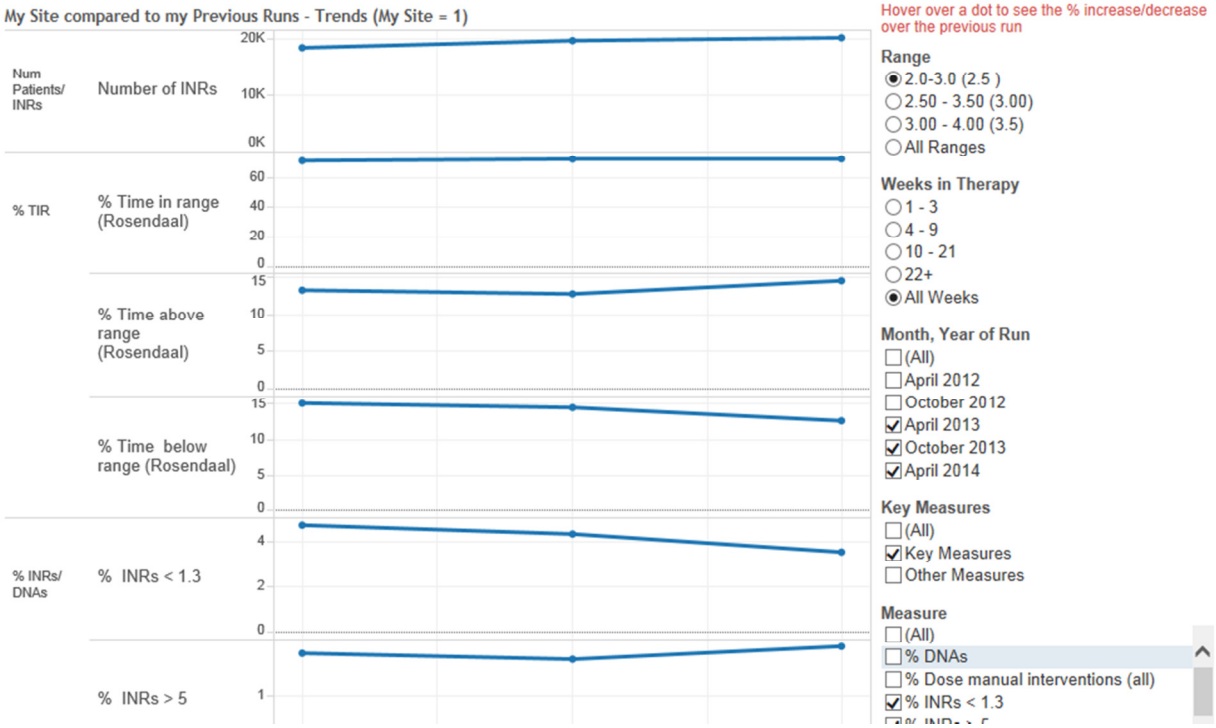
Jenny then demonstrated how the new reports are going to be accessed and how they will look. The participating service would be provided with a website link which it would click on, then key in their site number (known only to them). It would then be presented with a set of on-line graphs/ tables, for example, for Time In Range Comparison:



These are very similar to the ones within the existing paper reports but have ‘filters’ on the right hand side so that the user can dynamically / interactively refine the data they wish to see. There are also some extra reports that are not available within the paper version.

These include:

- viewing Time In Range comparisons for two different Benchmarking runs simultaneously so progress can be compared
- selecting particular measures to graph so trends/differences are more visible, for example:



The views can be saved as PDFs for printing and/or distribution, either individually or a whole set with a particular selection of filters such as for Target Range 2 – 3. Individual screens can also be exported to images which are useful for inclusion in presentations, business cases etc.

DAWN AC Product Update

Alistair Stewart & Heather Stevenson, 4S DAWN Clinical Software, UK

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, providing a range of tools and functionality. These include:

- **Load Balanced Application Pools** have been introduced behind the scenes to significantly improve system performance.
- The new **Patient View Button** enables a printable summary message to be produced for the patient that contains details of their treatment plan, recent history and additional clinical information.
- For safety reasons, **Password Protection** has now been added to the General Lookup Category; Target Range; and Regimes within the system settings of DAWN AC.
- A **Rivaroxaban** (Xarelto) Module has been introduced to enable management of Rivaroxaban using DAWN AC including the switching of patients between Rivaroxaban and warfarin.
- The **Login** screen now includes access to DAWN AC help and better assistance on setting the password.
- The **Dosing Instructions** table on the main patient screen can now show the daily tablets in fractions whilst the Total mg line at the bottom of the table is in decimals.
- The **6 month %TIR and 3 month Variance Growth Rate (VGR)** can now be calculated and displayed as traffic light indicators of the risk of a patient having a bleeding or thrombotic event. This functionality is disabled by default but can be turned on by changing a System Setting.

Apixaban management and Point of Care Device Data Integration are in the pipeline for future release. The following are being considered: Texting/SMS, E-mail PDF documents, Referral by e-mail, Screen sizing/Browser compatability, Web Questionnaire for patients.

Also over the past year, the support process has been improved and streamlined. It was explained why some support requests cannot be satisfied immediately due to having safety implications that require thorough testing.

A reminder about the **DAWN AC Reports Webpage** was issued. This contains a large number of reports that the support team have created for customers over the years. The webpage contains the name and a description of each report as well as a document that can be downloaded which contains instructions for setting up the reports. You can find it here: http://www.4s-dawn.com/dawn-ac-reports/

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, UK

It is widely agreed that neither the INR alone nor the %TTR are dependable predictors of clinical events in patients receiving oral anticoagulation. For example, in one study with DAWN AC, computer aided dosing gave better INR control, but there was no significant difference in event rates *(Professor Poller et al Thromb Haemost 2009; 101: 487–494).*

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.

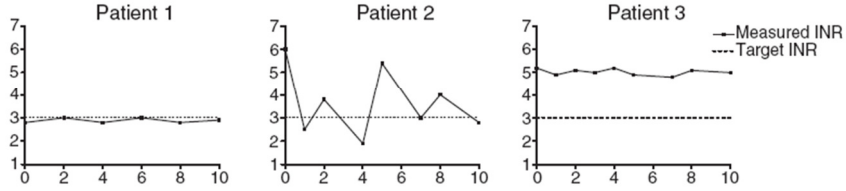
The VGR measurement looks at the variability between a patient's INR values, to determine how 'stable' they are.

This study took data from a previous prospective multicentre randomised trial comparing DAWN AC computer aided treatment with experienced medical staff *(Professor Poller et al Thromb Haemost 2009; 101: 487–494).* (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.)

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.



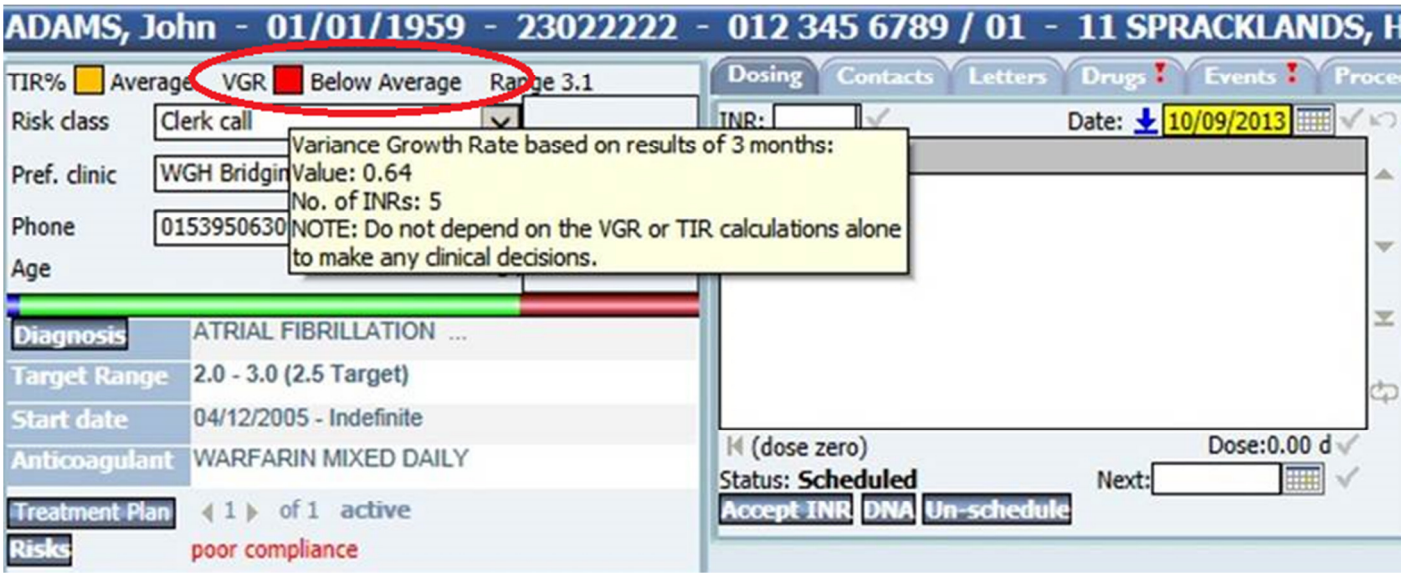
The key findings of the new study were:

- %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

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 developed the VGR calculation within DAWN AC as illustrated below:



This is available to customers now and is offered as an option, with users having the choice as to whether or not the VGR is displayed on the patient records.

Some final thoughts were shared with the audience:

- What meaningful actions to reduce the variability of patients' INRs could you take?
- A large prospective trial is needed to confirm the conclusions above?
- Novel Oral Anticoagulants – no method of predicting events yet?
- Need volunteer DAWN AC users to try out/give feedback on new VGR/%TTR features

Integrated Peri-Procedure Anticoagulation

Lisa Vaughn, Clinical Manager, Anticoagulation Service, Confluence Health, Wenatchee

Motivated by a few adverse outcomes, the *Confluence Health* (CH) Anticoagulation Service wished to develop an integrated Peri-Procedure Program. They were mindful, though, of the Machiavellian quote along the lines of:

> *`..there is nothing more difficult to carry out, nor more dangerous to conduct, nor more doubtful in its success, than an attempt to introduce innovations. For the leader in the introduction of changes will have for his enemies all those who are well off under the existing order of things, and only lukewarm supporters in those who might be better off under the new.''*

There were so many groups/stakeholders (such as two EMRs and many geographically spread-out anticoagulation clinics) to involve and gain the agreement from that it sometimes felt like herding cats.

The initiative had 3 main goals:

- Standardize care by development of evidence based CH Clinical Guidelines for peri-procedure management
- Develop communication pathways between Anticoagulation Clinic (ACC), physicians, pharmacists, hospitals, caregivers and multiple EMRs
- Create standard work plans for developing, documenting and communicating a peri-procedure anticoagulation management plan

The initiative bore in mind the following '*Keys to Successful Management*':

- Advance planning to allow time to develop and communicate a plan
- Communication is key to development of a plan that will be patient specific, minimize risks and have buy-in by all involved.
- Include patient in decision making
- Assess risk of thromboembolism if anticoagulation is temporarily discontinued
- Assess risk of procedural bleeding if anticoagulation is continued
- Timing of re-initiation of anticoagulation is important to prevent post procedural bleeding
- Communication post procedure: Did anything occur during the procedure that alters the post procedure plan?

As regards communication, Lisa found that verbal discussion with ACC providers, surgeon and primary care physician or cardiologist was more effective than email when discussing patients with complex comorbidity and risk factors.

The Peri-Procedure Program starts when the surgeon sends an order to ACC detailing:

- Procedure, date, where being done
- Antiplatelet therapy
- INR goal for procedure
- Post procedure bleeding risk
- Recommendation re: when to resume anticoagulant
- Plan to admit or outpatient?

Standard Order Templates were created for Physiatry, GI, Ophthalmology, Invasive Radiology, Cardiology.

DAWN AC has a facility for adding procedures. This facility is utilised to record the upcoming procedures and highlight/communicate the need for a plan.

DAWN AC also has a facility for recording Risk Classes. The facility identifies thromboembolic risk. In addition to procedure-specific bleeding risk, other bleeding risks are detailed in the RISKs facility and the Drugs tab.

A Procedure Plan is created consisting of:

1. Plan for antiplatelet management
2. ACC treatment plan
3. Procedure summary
4. Bridging plan
5. Pre-procedure management
6. Post-procedure management
7. Review by surgeon, cardiologist, Primary Care Physician (PCP), ACC Medical Director
8. All plans sent to *Ambulatory Surgery Center* (ASC) or hospital pre-op nurse 24 hours pre operation
9. If the plan is not present in the chart, the surgery is cancelled

24 hours after the procedure, phone calls are made to patients to confirm the post procedure plan and assess for symptoms of bleeding.

As the majority of Thromboembolic (TE) and bleeding events occur during the initial 2 weeks post procedure, post-procedure follow-up soon after the procedure date allows for early detection and treatment of complications. Staff monitor the DAWN AC List View *Work List - Not Scheduled* to identify patients who need post procedure appointments scheduled.

Staff also monitor the list view *All Patients* for patients with suspended Treatment Plans who need to be tracked for follow up.

In the best case scenario, plans are made & followed and there are no bleeding or TE events. In real life, however, there are ongoing challenges to mistake-proof and simplify the workflows. Thus CH are continuously working on improving it.

The Use of Telephone Reminder Calls Improves Compliance with INR Testing

Irina Seliverstov, Nurse, Anticoagulation Management Service (AMS), Massachusetts General Hospital, Boston

Until 2011, Mass General AMS sent Non-Attendance (Did Not Attend (DNA)) reminders by post. The DNA first and second reminders for missed appointments were a large portion of the daily outgoing AMS mail. In 2011, an automated telephone message system (using Televox – a third party tool) was implemented for missed first and second INR tests. The vast majority of patients received DNA 1 and 2 notices by phone call. (Third, fourth & discharge letters continued to be mailed.)

The AMS DNA procedure is as follows:

- Triggered if no INR is received two business days after a scheduled INR date
- DAWN AC bulk reschedules next INR date one week from previous date (two weeks if notice mailed)
- Daily Televox report managed by Office Manager
- Reminders created on patient record for nurse to follow-up:
    - Investigate if INR is available
    - Call patient
    - Inform physician and request support, danger of potential discharge
    - Documents status in DAWN AC and hospital record

- Nurse makes final decision for discharge

DAWN AC generates electronic messages for patients who have a first or second missed appointment. The messages are used by Televox each day at 6pm to call the patient and leave a non-personalised (for HIPAA compliance reasons) message in their preferred language. Televox then returns a report to the AMS clinic of calls that require follow-up, e.g. if the phone number was invalid.

By default, all patients are included within the automated reminder service but individual ones can be opted out e.g. if they have no phone. Patients are informed about the automated reminders as part of their education.

An exploration of the impact of this on patient compliance and cost savings was done. It was found that Automated Telephone Reminder Calls not only improved patient compliance by preventing progression to subsequent DNAs but also had saved the AMS significant money. The patients liked the reminder calls, for example, one patient said

"…..For me, the phone messages have been far more effective. I do just about everything online and over the phone now. Most of the stuff I get in the mail these days tends to be junk so I don't pay attention to it. I usually see the date of my next test in the emails, but tend to forget about it until I get the phone call to remind me."

Pharmacist Management of Novel Oral Anticoagulants (NOACs)

Jeff Vandemark, Pharmacist, Anticoagulation Services (AS), Scripps Green Hospital, La Jolla

The role of anticoagulation specialist pharmacists at Scripps includes NOAC management. This NOAC management is done using DAWN AC modules. Most patients start outpatient NOAC initiation of treatment; and transition to and from warfarin. The AS works with Scripps inpatient physicians and pharmacists, Transition of Care Units and outpatient retail pharmacists.

There is concern over non-adherence to NOACs: Poor adherence is an important factor to consider when explaining instability of anticoagulation control and places the patient at risk of thrombotic events. For Vitamin K Antagonist (VKAs), rates of non-adherence have been reported at between 22 and 58%. (Arch Intern Med 2007). Medication adherence to NOACs has been poorly documented and may be an issue now that these drugs are used with increased frequency outside of clinical trials. The fact that NOACs do not require regular monitoring means adherence will be harder to encourage and establish. Although clinical trials had high adherence rates, the trial patients would have been subject to careful follow-up. Jeff displayed a table (from a Longitudinal Veterans Study ref. *Shore, S., et al., Am Heart J 2014; 167: 810-17*) demonstrating that adherence in a larger trial was less than in the previous smaller trials.

To manage the NOACs, pharmacists at Scripps are responsible for the following:

- Encouraging adherence
- Adjusting drug dose and follow up renal function
- Handling adverse drug reactions
- Issuing pre and post op therapy instructions
- Following-up of bleeding complications
- Tracking drug discontinuation and transition back to warfarin

The following drugs/indications are employed:

Pradaxa® (dabigatran)	Non-valvular atrial fibrillation
Xarelto® (rivaroxaban)	Non-valvular atrial fibrillation & Treatment and prevention of DVT and PE
Eliquis® (apixaban)	Non-valvular atrial fibrillation & Treatment and prevention of DVT and PE

Currently about 16% of patients transition back to warfarin within a year. For the majority, the reason is cost but some like the reassurance of regular monitoring.

How Dabigatran is managed using the DAWN AC Dabigatran module (which covers both initiation and follow-up) using a series of guided question forms and the following steps was then demonstrated:

- Complete an Initiation Questionnaire
- Stop any existing treatment plan (for other anticoagulant or dose)
- Activate a treatment plan for the chosen anticoagulant and dose
- Schedule a follow-up date for your patient

Patients are followed-up once a week for two weeks, then once a fortnight and then gradually stretched out to once a month and eventually once every 6 months.

The DAWN AC NOAC module:

- Provides a full anticoagulant history
- Ensures patients are on appropriate drug and dose
- Schedules follow-ups
- Manages missed appointments
- Generates reports
- Provides an audit log

NOACs have led to a redesign of the Scripps warfarin clinic. The following quote was considered very apposite:

> ***"Clinics that survive the introduction of novel agents will likely be those that shift from a primary focus on monitoring warfarin to management of thrombotic disease and coordination of all antithrombotic therapy in the form of multidisciplinary comprehensive antithrombosis centers."***

Edith A. Nutescu, Pharm.D, et.al., Transitioning from traditional to novel anticoagulants: the impact of oral direct thrombin inhibitors on anticoagulation management. Pharmacotherapy 2004; 24: 199S-202S.

Too Much of a Good Thing – Aspirin Discontinuation in Chronic Warfarin Users

Katie McCool, Supervisor, Clinical Pharmacy Anticoagulation and Anemia Services (CPAAS), Kaiser Permanente Colorado, Aurora

In 2004, there was no process within CPAAS for addressing concurrent aspirin use and an unknown prevalence of antiplatelet use, suspected to be predominantly aspirin. There was obviously potential for a study as there was limited data regarding true "real-world" risk vs. benefit of combination therapy and the existing consensus guidelines did not adequately address appropriateness.

Because of this, CPAAS began documenting concurrent use in DAWN AC but there was initially no proactive discontinuation of aspirin.

In addition to the drug Aspirin, a new drug type of 'No aspirin' was explicitly recorded against patients so that those patients who were *not* taking aspirin were clearly visible.

DAWN AC has a facility for patient reminders, this creates a list of tasks that need to be done for individual patients, due and overdue tasks can then be highlighted. This facility was utilized to create a set of tasks for assessing aspirin use in existing patients to ensure patients were not overlooked.

DAWN AC could then generate reports detailing how many warfarin patients had concurrent aspirin use.

Study results were published in CHEST in 2007/2008 (in studies entitled *Warfarin and Antiplatelet Combination Use Among Commercially Insured Patients Enrolled in an Anticoagulation Management Service* and *Outcomes Associated with Combined Antiplatelet and Anticoagulant Therapy*). The results were:

- There was a high prevalence of antiplatelet use, predominately aspirin and >30% without apparent indication
- The combination resulted in increased hemorrhagic risk, they were 2.75 times more likely to experience bleeding and the rate was consistent with other published studies
- There was no difference noted in thromboembolism. Although overall incidence was very low which could mean there was not enough data to see any appreciable difference.

These results suggested it was time to act. This meant getting physician agreement including creating a list of indications in which combination therapy was appropriate. Then creating a system to ensure that new patients' aspirin use is addressed and all existing patients are reviewed.

For existing patients, a flowchart was developed to handle encouragement of discontinuation of aspirin for appropriate patients. A summary of any discontinuation was placed in the central Electronic Medical Record (EMR) which was therefore available to the patient's physician. An EMR summary was also registered for those patients who elected to continue with aspirin despite contrary CPAAS advice and a request was made of the Primary Care Physician (PCP) to readdress aspirin use at the next office visit.

More research is now required to examine the change in the hemorrhage rate but it is expected that there will be an improvement.

Adverse Events Intracranial Hemorrhage and Major Bleeding

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The Scripps Anticoagulation Service provides organized, systematic management of warfarin and low molecular weight heparin "bridging" on an outpatient basis and management of NOAC patients. It monitors % Time in Therapeutic Range (%TTR) and records bleeding complications on DAWN AC. %TTR is a measure of the effectiveness of therapy management. It is a surrogate marker for risk of thrombotic & bleeding complications.

3 common ways of assessing bleeding risk, HAS-BLED, Hemorr(2)hages and ATRIA were mentioned.

A bleeding event can be classed as a *major* bleed if one of the following occurs:

- Drop in hemoglobin ≥ 2 gm/gL
- Requirement for ≥ 2 u PRBC (blood transfusion)
- Critical Organ Bleeding, eg intracranial
- Contribution to cause of death

Patient bleeds are recorded as 'Events' on DAWN AC. An analysis of the percentage of events by severity per patient year can then be obtained using the DAWN AC reports facility. An extract of the report, showing both thromboembolic and bleeding events, over a particular date range, was displayed:

Anemia/post Hemorrhagic	Major	7	2920.96	0.24
Anemia/post Hemorrhagic	Minor - No Followup Required	1	2920.96	0.03
Anemia/post Hemorrhagic	Minor With Followup	2	2920.96	0.07
Arterial Thromboembolism/le	Major	1	2920.96	0.03
Conjunctival Hemorrhage	Major	1	2920.96	0.03
Cva/stroke	Major	2	2920.96	0.07
Cva/stroke	Minor With Followup	6	2920.96	0.21
Deep Vein Thrombosis/le	Major	1	2920.96	0.03
Deep Vein Thrombosis/le	Minor With Followup	1	2920.96	0.03
Epistaxis	Major	1	2920.96	0.03
Gastrointestinal Hemorrhage	Major	27	2920.96	0.92
Gastrointestinal Hemorrhage	Minor With Followup	6	2920.96	0.21
Gingival Bleeding	Major	1	2920.96	0.03
Hemarthrosis	Major	1	2920.96	0.03
Hematoma/contusion	Major	8	2920.96	0.27
Hematoma/contusion	Minor - No Followup Required	1	2920.96	0.03
Hematoma/contusion	Minor With Followup	4	2920.96	0.14
Hematuria	Major	2	2920.96	0.07

When Scripps ran this against their large patient base of about 3000 patients, they found that the percentage was notably lower than the warfarin major bleed percentages reported by the recent NOAC drug trials such as RE-LY:

	ICH	Major Bleeding	%TTR
RE-LY	0.74	3.36	64.0
RECOVER	N/A	1.80	60.0
ROCKET-AF	0.70	3.40	55.0
EINSTEIN-DVT	N/A	1.20	57.7
EINSTEIN-PE	<0.01	2.20	62.7
ARISTOTOLE	0.80	3.09	62.2
AMPLIFY	0.20	1.80	61.0

Finally, Dr Elias discussed the main risk factors for intracranial hemorrhage which were: fall prior to event, age, INR at time of event and anti-platelet (typically aspirin) use. It was noted though that research showed that, in spite of the risk factors, such patients still benefitted from anticoagulant therapy:

> *"Patients at high risks for falls with atrial fibrillation are at substantially increased risk of intracranial hemorrhage, especially traumatic intracranial hemorrhage. However, because of their high stroke rate, they appear to benefit from anticoagulant therapy if they have multiple risk factors."*
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> *Gage BF, et. al., Incidence of intracranial hemorrhage in patients with atrial fibrillation who are prone to fall., Amer J Med 2005; 118: 612-617.*

Therefore Anticoagulation Services need to minimize the bleeding complications of the Anticoagulation Therapy by:

- assessing the bleeding risk
- intervening to minimize complications and maximize efficacy of therapy
- educating patients to reading signs and symptoms of bleeding
- adopting sound Anticoagulation Protocols
- continuing to encourage research and quality analysis