DAWN® AC

ANTICOAGULATION SOFTWARE

Proceedings of the 11th Annual North American DAWN AC User Group Meeting

30th September 2017

"I love the ability to collaborate with other DAWN users and to inspire those who are not yet using DAWN"

Massachusetts General Hospital

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Welcome and Opening Remarks

Jean M Connors MD, Co-Medical Director, Brigham & Women's Hospital Anticoagulation Management Service

Dr Connors opened by welcoming all the delegates to Brigham & Women's Hospital for the DAWN AC User Group 2017 and outlined the historic difficulties with warfarin management.

"Whilst DAWN AC makes the process of warfarin management much easier and simpler it is still a labour-intensive, time consuming process including getting the patient to test, receiving the result, looking at why the patient may be out of range when there appears to be no obvious reason for it, deciding on the dose, deciding when to next test and to then repeat the process over and over for many hundreds of patients.

The DOACs were designed to be the reverse of warfarin, a simple and one size fits all dosing scheme with patients of any age and almost any weight having the same dose with the same effects without the onerous burden of testing INR levels and monitoring.

When the DOACs were first introduced, certainly in Boston, it was more the niche cardiologists and haematologists that prescribed them to very select groups of patients but over the last few years their use is exploding throughout healthcare settings and DOACs are now being prescribed by the emergency room, the inpatient wards, and other doctors from across a range of specialities.

Because of this increased use, it is becoming apparent that DOACs are not as simple as they were purported to be.

You are unable to simply write a prescription and send the patient away. In fact, there are several nuances that need to be considered when prescribing DOACs to patients.

Anticoagulation Management Services (AMS) who have been managing warfarin patients for many years are poised to aid clinicians to ensure safe and efficient management of DOAC patients.

AMS staff can be involved in the process from start to finish, from the point of selecting the appropriate DOAC and dose for the patient, to providing education about the drugs and follow-up, particularly during times of transition. They are also in an ideal position to ensure patient adherence with the DOACs due to their prior experience with warfarin patients".

Referring to the agenda, Dr Connors noted that the morning sessions were a great example of delegates sharing their experiences of implementing DOACs in their clinics from a variety of different angles including workflows, staff education, patient management and transitions.

Introducing DOACs to your anticoagulation service

Lynn Oertel, Nursing Practice Specialist, Massachusetts General Hospital, Boston, MA

Lynn's presentation focussed on the introduction of DOACs into their traditional warfarin monitoring service and the journey the AMS went through as part of this transition.

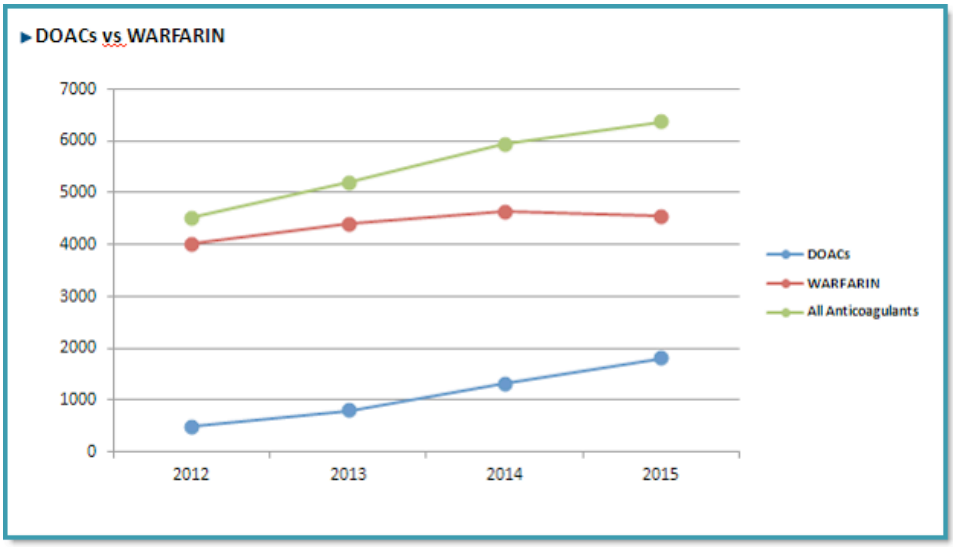
It was recognised at the beginning that there were lots of challenges:

- **Stakeholders:** consensus and agreements among stakeholders to expand the scope of a traditional warfarin clinic to include DOACs. Who would fund any extra resources to manage and educate patients on DOACs and how would the value to patients be demonstrated?
- **Technical:** in relation to the DAWN DOAC modules and the hospital systems.
- **Staff:** hesitancy from staff who were already very busy with the management of a large cohort of warfarin patients whilst also adjusting to new workflows brought by the implementation of the EPIC system within the hospital.
- **Training:** addressing knowledge gaps that would require further education and training to manage DOAC

patients.

- **Benchmark:** little quality examples from across the country of 'how to do it'. Should it be a separate DOAC clinic? Should it be integrated into one single thrombo-hemostasis service?

An analysis of trends from patients who received primary care at Massachusetts General Hospital (MGH) was completed and this highlighted the decrease in warfarin patients and an increase in DOAC patients which overall saw an increase in all anticoagulated patient numbers.



As a result of the analysis and the clear indication of the need to introduce DOACs to the AMS, the first step was for MGH to put together a comprehensive clinical staff education curriculum including classes, online training and reading assignments to enable staff to effectively manage DOAC patients.

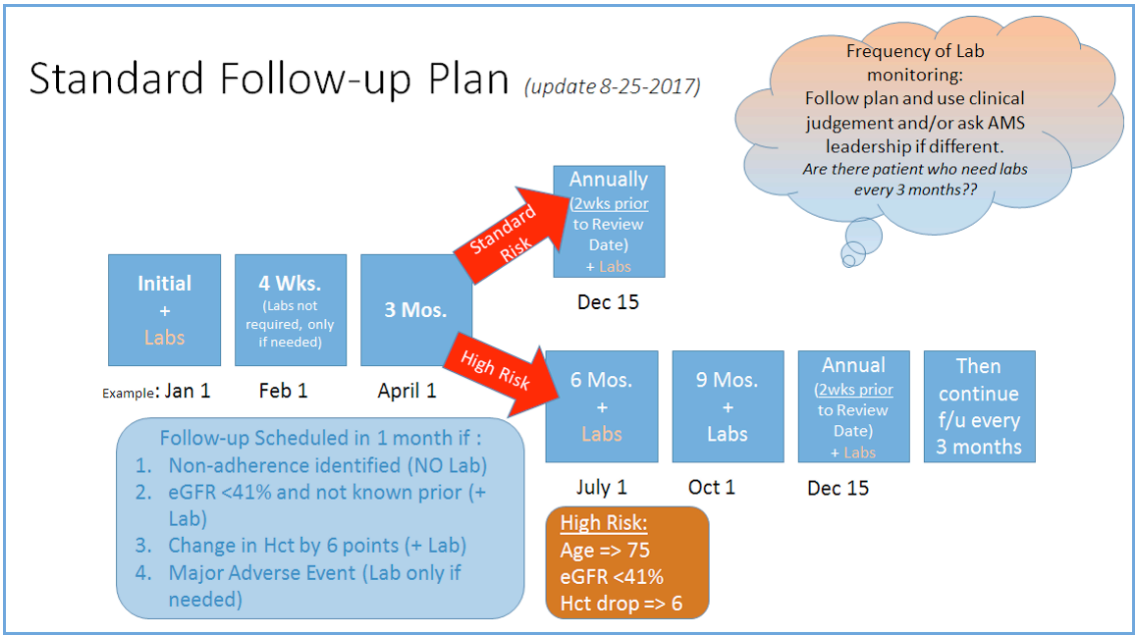
Measurable outcomes for staff education were a key requirement and a pre- and post-assessment test was taken by all staff who took part in the training. AMS staff were required to achieve 100% on the post-assessment test.

The AMS also faced the question of how to get referrals into the clinic. As a registered nurse (RN) staffed clinic, the AMS wanted to make the referral as smart as possible and a form was developed that presented cascading options for the referring physician according to:

- Indication
- Drug/dose option
- Transitioning, if applicable
- Off label use statement

The drug and dose options on the form are presented based on the indication selected. New indications approved by the FDA since developing the referral form present the challenge of keeping it up to date within the hospital system.

Historically, the AMS has always had a very standardised, systematic approach to managing thousands of patients on warfarin and so a plan was drawn up to approach the management of DOAC patients in the same organised way.



The AMS wanted the DOAC patients to establish a relationship with their primary nurse, hence the patient touchpoints early on as indicated above, are frequent.

With the DAWN AC DOAC modules installed, the AMS uses the associated DOAC list view to manage their DOAC patient population. The date filter enables the AMS staff to see a list of patients whose follow ups are due that day.

Televox, an automated call system, was already used by the AMS for communication with warfarin patients and the DOAC patients also now receive a call from the Televox system two days prior to their scheduled follow up to confirm their availability. The DOAC list view in DAWN AC shows patients who have confirmed that they will be available for their follow-up phone call as scheduled.

Anecdotally, AMS clinicians hear about the absence of appropriate patient education, less than ideal monitoring of key lab values, and more. High quality patient education materials were developed, including written instructions pertaining to each DOAC in English and Spanish as well as a comprehensive drug-specific slide show. If patients were already enrolled in the AMS, the education is conducted via phone call after written materials and a copy of the slide show are mailed. The expectation remains that if the patient is new to the AMS, they will attend a 30-minute comprehensive educational session with their primary nurse. Additionally, the AMS patient agreement was adapted to incorporate the DOACs.

A detailed reference guide was produced for each of dabigatran, rivaroxaban, apixaban and edoxaban. Additionally, a potential drug-drug interaction reference list was developed that summarizes information from the product insert and two online drug reference programs. This has been found to be particularly valuable to the nurses within the AMS.

Changes have been made to the DOAC initiation questionnaire (QNR) by 4S DAWN to be more useful and supportive of MGH AMS workflows and to the DOACs themselves.

For the DOAC follow up questionnaires, the AMS decided a broader assessment of the patient was needed, including:

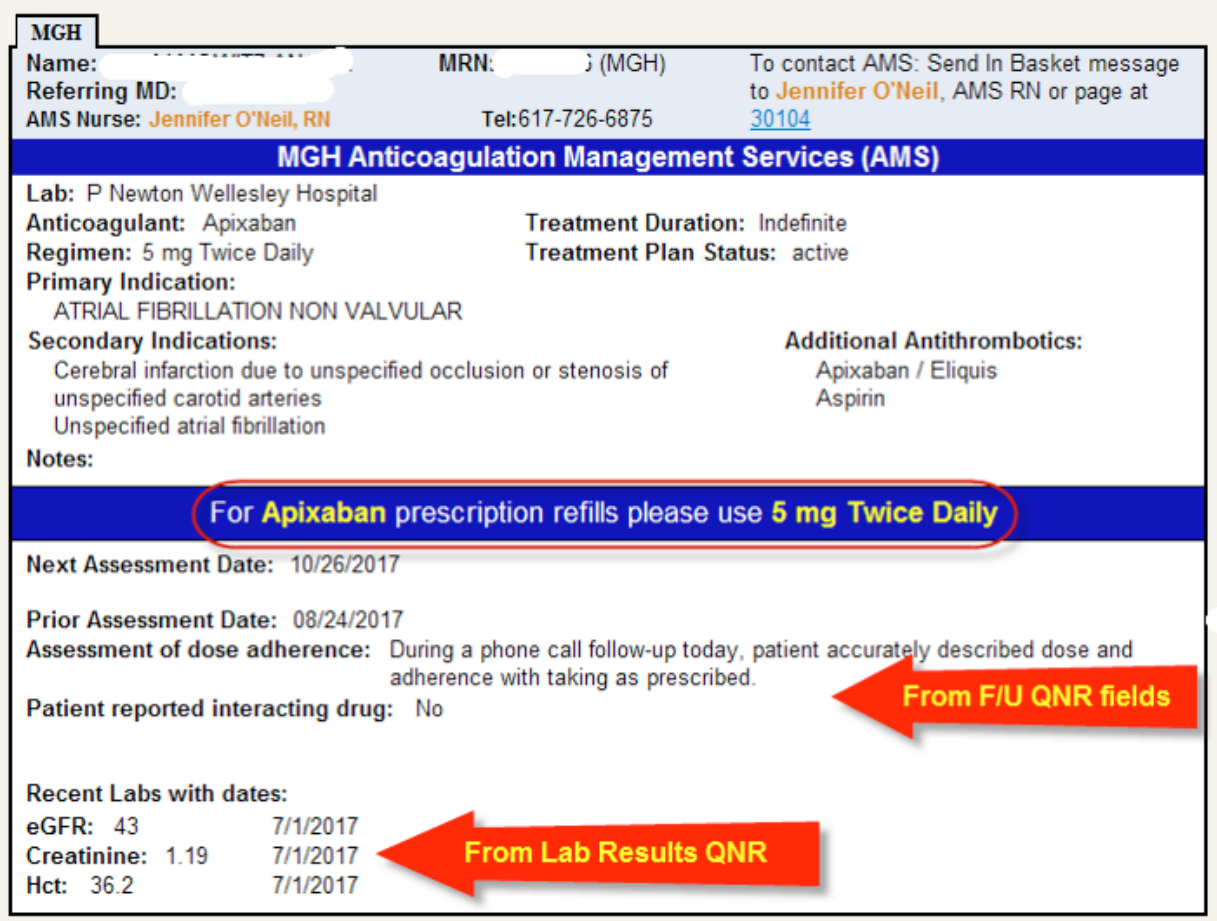
- Adherence
- Medication changes
- Hospital/Emergency Department visit
- Interruption of DOAC therapy
- Was the patient seen by a physician for another reason?

- Side effects
- Verify any change in dose
- Check refills – initial prescription, how many refills
- Issues with procurement/financial concerns

Drug, dose, adherence, interacting medications and labs, including eGFR, creatinine and Hct are recorded in DAWN AC and displayed in the EPIC patient record via an AMS icon along with the patient's next follow up date.

The AMS icon was already established for warfarin patients and enables any healthcare professional from across the healthcare system looking at the patient record in EPIC, to open a dialogue box that shows the details of the patient's anticoagulation. The AMS icon has now been adapted to include DOAC patients.

The information in this dialogue box is pushed from the DAWN AC system:



A pilot evaluation is being conducted to demonstrate the value to the organisation of incorporating the DOACs into the AMS (started in June, currently 30 patients) and this will include adherence, change in labs necessitating dose change or stopping use, identification of drug interactions requiring change in therapy, adverse events, optimal management of transitions/interruptions in care and patient experience.

Experiences encountered while managing DOACs at Desert Oasis Healthcare

Robert Mao, PharmD, Anticoagulation Management Service, Desert Oasis Healthcare, Palm Springs, CA

Desert Oasis Healthcare (DOHC) operates as an integrated managed healthcare organisation and is the largest independent practice associate including one of the first full service medical facilities in the Coachella Valley and the High Desert.

The pharmacists in Population Health and Prescription Management (PHARxM) operate ambulatory care clinics under established collaborative practice agreements with physicians and the following areas are managed under PHARxM:

Pharmacist Managed Clinic	Enrollment
Diabetes	825
CAD	296
HepC	59
Anticoagulation	3,300
COPD	519
Refill Program	16,730

The anticoagulation clinic manages 3,300 patients in Central and Southern California with 4 FTE pharmacists and 4 FTE technicians. The clinic is telephone based from start to finish with patient labs done at Quest/Labcorp.

DOACs have been monitored by the anticoagulation clinic since early 2015 and whilst other providers determine the stop/start of anticoagulation and the hold duration for procedures, the clinic can consult and provide suggestions/advice.

Clinic Workflow

1. DOAC patient encountered
2. Pharmacist reviews patient record
3. Enrolment call by highly trained pharmacy technician
4. Follow up phone call done by technician at initiation, 2 weeks, 3-6 months
    a. Pharmacist reviews call
5. As needed:
    a. Review any hospital records, urgent care records, ER records or Senior Nursing Facility visits
    b. Remind physician to re-evaluate DVT/PE duration of therapy

Follow Up Phone Call

1. Confirm which DOAC the patient is taking
2. What dose is the patient taking? Are they taking it as prescribed? Missed doses?
3. Any bleeding/bruising or (if Pradaxa) upset stomach?
4. Any cost issues/further refills?
5. Any changes in medications or health/illness?
6. Does patient have congestive heart failure? If yes:
    a. Shortness of breath?
    b. Unusual swelling?
    c. Weight gain?
    d. Changes to diet?
    e. Task back to PharmD to assess
7. Any planned procedures?
8. Check Nextgen (EHR) to see if labs within the last 3 months – update in permanent box in DAWN
9. Patient to have labs at 2 weeks and then every 6 months
10. If no labs, ask patient to go to lab (put date in permanent box in DAWN) and send lab order
11. Remind patient to call us with any bruising/bleeding, change in medication or health
12. Fill out questionnaire with new lab date
13. Task PharmD to review

Here are some problems and solutions

Problem 1 – Reducing patient numbers	Solution 1
Warfarin patient numbers are reducing and whilst DOAC referrals are increasing, it is at a disproportionate rate leading to not enough DOAC patients to replace the warfarin patients that have been lost	• Warfarin: enrolment by hospital/provider • DOAC: blanket enrolment and anyone using DOACs, no referral needed • Allows for gradual enrolment vs overnight • DOACs represent 15% of patient numbers and are rising • Now, total anticoagulation patient numbers are comparable to previous year's numbers because of this DOAC enrolment process • Haven't yet captured all patients using DOACs
Problem 2 – Demonstrating value	**Solution 2**
Physician *"Why are you drawing labs on my DOAC patients?* **Patient** *"My doctor manages me while I am taking Savaysa, why do I need you?"*	• Educating physicians that while DOACs don't need the regular monitoring of warfarin, they are still a high-risk medication and therefore do need a degree of monitoring to ensure proper use, proper dose, uninterrupted access **Compliance:** Self-reported by patient, pharmacy utilization database **Appropriate:** Proper indication, dose adjustment based on labs, concomitant medications etc. **Access:** Cost. Is it affordable? Lowest Tier? Prior authorization **Side Effects:** Bleeding, bruising, TIA, stroke, DVT, PE, MI • Demonstrate value to the patient by highlighting: ○ Free service ○ Minimal phone calls ○ Clinic monitors the labs and informs patient's primary care physician ○ Clinic explores other options if cost is a problem ○ Samples of DOACs?
Problem 3 – Interfacing labs	**Solution 3**
Patient *"I did the CBC and CMP you told me to do last week, what are my results?"* Patient will go to the lab, unscheduled and the anticoagulation clinic would not know	• Warfarin: *"go to the lab on Sept 15th"* • DOAC: *"go to the lab sometime this week"* • Labs are flagged daily in the EHR (NextGen) based on ordering provider • Manually input into DAWN AC • Use 'Questionnaire' in DAWN AC for phone call and labs • Use 'Reminders' tab in DAWN AC for prior authorization expiration, follow up after IC/hospital etc.

Problem 4 – Cost issues	Solution 4

Patient
"The doctor at the hospital says I need to be on Pradaxa but it's too expensive"
 	
"I'm in the donut hole, I can't afford Xarelto anymore"
	• Why is it expensive?
	  ○ Prior authorization needed?
	  ○ Improper dosing?
	  ○ Not covered by plan?
	• Compare against drug plan formularies. Is it the lowest Tier DOAC? Tier reduction?
	• Free month supply for everyone
	• If commercial insurance, monthly co-pay card
	• Low income subsidy
	• Manufacturer patient assistance program
	• Samples – Align with drug representatives. Provide samples for how long?
	• Switch to warfarin

Problem 5 – Difficult cases	**Solution 5**
• Afib patient on Eliquis for a new DVT. 90 years old, weight = 50kg. Plan to start at 10mg PO q12hr x1 week, then 5mg PO q12hr. At what point do you lower to 2.5mg PO q12hr? What if patient has a bleed 3 days into therapy? Or 3 weeks into therapy? • Dialysis patient refusing to be on warfarin. Labile INRs with INR >10 drawn at dialysis. Off label Xarelto, Eliquis?	• Your license, your liability • Doing nothing can be seen as negligence • Patient safety at stake • Who do you call? Cardiology or PCP • Desert Oasis are aligned with an outpatient cardiology clinic • Dr Perlowski and three cardiology trained NPs available Monday to Friday • On call physicians available out of hours • Alternatives: Urgent Care Physician

Future Endeavours

- Peri-procedural management of anticoagulation, without physician buy-in. Still seeing DOAC hold times of 5-7 days
- Ability to address starting/stopping aspirin
- Further streamline DOAC process so that its suits our workflow better
- CA law SB 493 – pharmacist provider status, order and interpret labs
  - Ability to order and make clinical decisions based on Ultrasounds, CT exams
  - Ordering and interpreting hypercoagulable workup

Incorporating DAWN DOAC modules into our practice

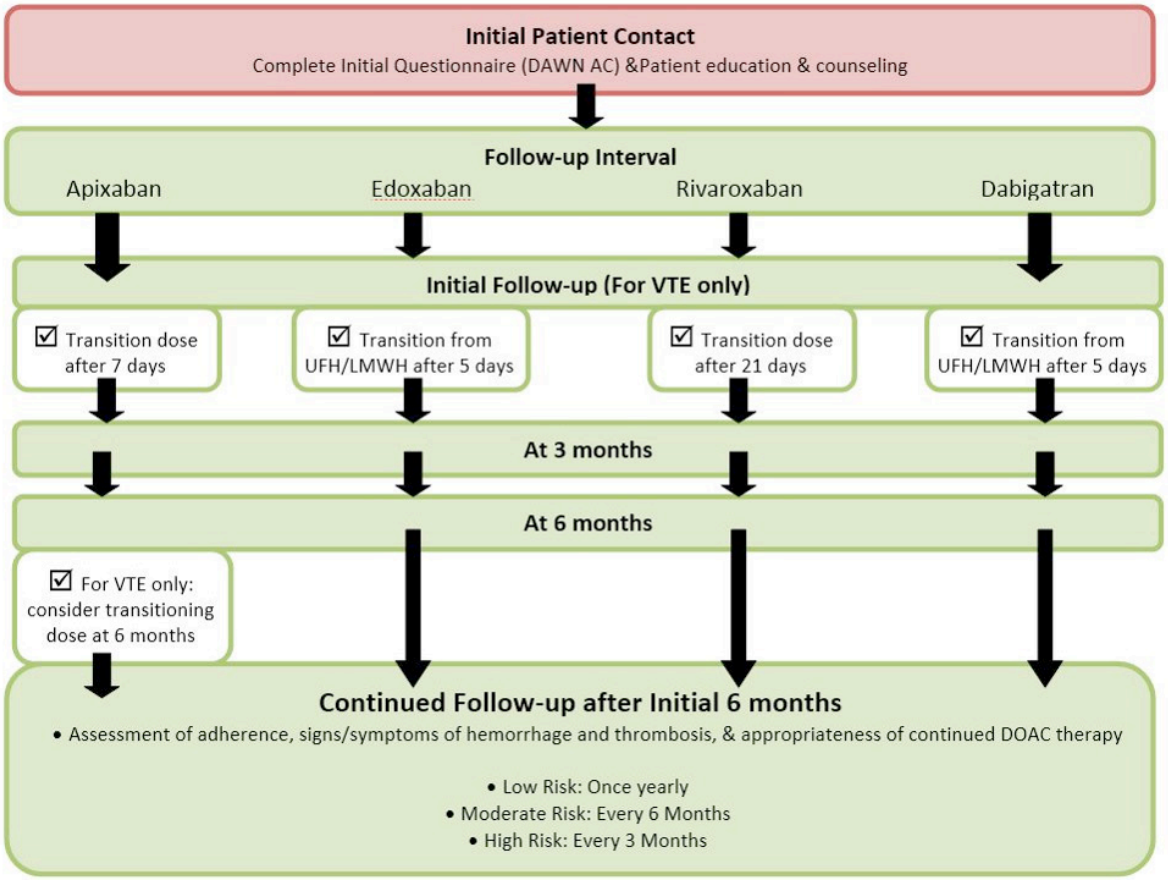
Peter Collins, PharmD, Advanced Practice Clinical Pharmacist, Anticoagulation Management Service, Brigham & Women's Hospital (BWH), Boston, MA

BWH and the team at 4S DAWN have worked together extensively over the last few months in preparation for the launch of the BWH Anticoagulation Management Service's DOAC clinic in June 2017.

Changes to the DAWN DOAC modules were required in order to better fit the AMS workflow and serve the patient population more effectively.

- Questionnaire format – candidate and follow up
- Supported diagnosis
  - Pulmonary Embolism (Provoked, Non-Provoked, Recurrent)
  - Deep Vein Thrombosis (Provoked, Non-Provoked, Recurrent)
  - Non-Valvular Atrial Fibrillation (NVAF)
  - Orthopedic Surgery VTE Prophylaxis
    - Total Hip Replacement
    - Total Knee Replacement

- Supported DOAC Agents
    - Rivaroxaban
    - Dabigatran
    - Apixaban
    - Edoxaban



Candidate Questionnaire

- Documents patient characteristics (age, gender, etc.) and indication for anticoagulation therapy
- Aids with transition from previous anticoagulant (if applicable)
- Assesses:
    - Renal function
    - Drug-Drug interactions
    - Contraindications to DOAC therapy
- Provides dosing regimens with additional advice

Follow Up Questionnaire

- Aids with documentation of induction dose to maintenance dose transition (VTE indications only)
- Assesses:
    - Adherence/compliance
    - Adverse events
    - Renal function
    - Drug-Drug interactions
    - Contraindications to DOAC therapy
- Provides dosing regimens with additional advice

Initial changes made prior to DOAC clinical launch

- Updating dosing regimens for DOAC agents
    - Inconsistencies existed between preloaded European dosing regimens and regimens used in the United States

- Examples include:
  - Dabigatran 110mg twice daily for atrial fibrillation (not approved in the United States)
  - Apixaban use in patients with creatinine clearance <30mL/min
  - Rivaroxaban 10mg daily for VTE prevention (based on EINSTEIN-CHOICE data)
- Integration between DAWN AC and EPIC
  - Information from DAWN AC is exported into EPIC via the AMS icon
  - DOAC AMS icon includes:
    - Patient information
      - Name, MRN
      - Referring physician
      - AMS Clinician and contact information
    - Clinical information
      - DOAC agent and regimen
      - Indication for anticoagulation
      - Treatment duration and start date
      - Laboratory values
      - Last note entered in DOAC questionnaire


BWH

Name: PHSCDSTEST,BPAWPIOCJ **MRN:** 97209183 (BWH) Please contact BWH AMS for further information by EPIC In-basket (BWH Anti Coag Clinic FD Pool) or by page at 17541

Referring MD: Steven Greenberg

AMS Clinician: Bridget Chisholm **AMS Tel:** 617-264-3000 x6

BWH Anticoagulation Management Services (AMS)

Lab:

Anticoagulant: Apixaban **Treatment Duration:** Long Term

Regimen: 5 mg Twice Daily **Treatment Plan Status:** active

Primary Indication: **Start Date:** 05/26/2017 **End Date:**

ATRIAL FIBRILLATION NON VALVULAR

Notes: So many comments about warfarin to apixaban. KWS Testing

Last AMS Follow-Up Date: 05/26/2017

Creatinine: 1.9 5/16/2017

Hct: 32.0 5/16/2017

Plt: 152 5/7/2017

For Apixaban prescription refills please use 5 mg Twice Daily

Please notify BWH AMS for medication changes, planned procedures, alterations in anticoagulation therapy or refills required

- Add 'Labs' questionnaire
  - Easily allows for documentation within DAWN of DOAC-related laboratory values
  - Must be manually entered (no EPIC interface at this time)
  - Laboratory values are exported to AMS icon in EPIC
- Update clinical references
  - DOAC questionnaires contain links to clinical references throughout
  - European guidelines were replaced with institutional drug administration guidelines and US package inserts
  - Hyperlinks can be easily edited by end users via the DrugCoURL function in DAWN AC system menu

Post-DOAC clinic launch changes

- Increase documentation functionality
  - Focused on documentation surrounding patient interactions and hospital admissions
  - 'Notes' questionnaire was created with templates for both types of encounters
- Patients with diagnoses outside of preloaded indication list
  - Refers to DOAC patients that do not fall under the preloaded diagnoses
  - Example: history of CVA without documented atrial fibrillation
  - Temporary solution:
    - Atrial fibrillation (NVAF) is selected as diagnosis but true reason for anticoagulation therapy is noted in patients profile
- Hard stop contraindications
  - Patient specific clinical decisions may lead to using regimens that are technically contraindicated
  - Workarounds are required to allow the DAWN AC system to process and complete questionnaires

- Example - Apixaban use in patients with renal dysfunction
    - Solution: leave creatinine clearance blank and document in the notes section that patient is on dialysis
- Example - DOAC use in patients with bioprosthetic heart valves
    - Solution: Document in the notes section that patient has heart valve but do not select 'Prosthetic Heart Valve' under 'Contraindication'

Planned future updates

- Consolidation of candidate questionnaires
    - One common initiation questionnaire that can be used to enroll patients on all DOAC agents will lead to increased ease of use
    - Follow up questionnaires stratified by DOAC agent will remain at first
        - Similarities between Follow up questionnaires may eventually lead to consolidation as well
- Addition of newly approved DOAC agents
    - Betrixaban (Bevyxxa) was approved by the FDA in June 2017 for VTE prevention after hospitalization for acute medical illness
        - 160mg as a single dose on Day 1, followed by 80mg once daily for 35-42 days
    - BWH likely to see use due to involvement with clinical trial (APEX) leading to approval
    - Candidate/Follow up questionnaires will be created that document and assess patient characteristics as done with the other DOAC agents
- Advanced adherence/compliance metrics
    - Goal is to provide quantitative data that can be used for future collection and analysis
    - Possible options include the Modified Morisky Scale (MMS)
        - Six question, binary assessment that provides feedback on patient's knowledge and adherence related motivation
    - Compliance determined by timing of prescription refills

Conclusions

- DAWN AC DOAC modules provide a comprehensive system that allows for standardized follow up and DOAC therapy related documentation. Although system menus allow for some degree of customization, there is limited flexibility for managing patients with non-supported indications and severe renal dysfunction
- Changes to DOAC clinic workflow will be impacted by future changes in patient population size, patient characteristics, expanding DOAC indications, and more
- Robust reporting features of DAWN AC will continue to be useful going forward to quantitatively evaluate the value of the AMS and quality of provided care
    - Combining data from multiple AMS groups may allow for even larger data analysis

DOAC transitions: a piece of cake?.....Not all that easy!

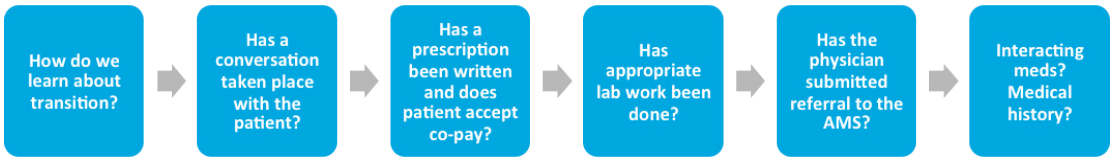
Diane DeTour, RN, Anticoagulation Management Service, Massachusetts General Hospital, Boston, MA

The future of warfarin services has been debated for many years and there is still ongoing discussion and debate around this subject, particularly in respect to DOACs, with continued learning curves for many healthcare professionals.

With the DOACs, there is no longer a requirement for laboratory testing, no dietary restrictions and fewer interactions with other medications.

Transitioning patients is difficult and the AMS has experienced many different scenarios, from patients whose physicians have transitioned them with no education and patients who actively want to have a conversation about stopping warfarin due to the inconvenience of monitoring, through to patients who prefer to stay on warfarin due to the comfort of knowing they are being monitored and having their INR checked on a regular basis and patients who are uncomfortable with the lack of reversal agents for the DOACs.

A number of things need to be considered when transitioning patients:



Correct referral and prescription to be checked?

An example of a patient referred to the AMS on Rivaroxaban

- 72 year old female with AF (CHA2DS2-VASc = 5)
- On warfarin since 2012, TTR = 50%
- eGFR = 49, Cr =1.10, CrCl = 34.9, Hct = 40.1
- Medication: dronedarone (P-gp inhibitor)
- Initial referral submitted with rivaroxaban 20mg daily (with food)
- Reviewed patient history and identified need for dose adjustment based on CrCl.
- Requested prescription be written for 15mg daily along with corrected referral
- 8/16/17 – started rivaroxaban
- 8/18/17 – developed nausea, dizziness, muscle pain to the point that patient was in bed all day.
- Stopped rivaroxaban and now back on warfarin

Can your patient afford this new drug?

Affordability is a game changer and so an important thing to do up front is to determine whether the patient can afford to be transitioned onto a DOAC.

Practice varies:

- One MD called in prescription for 3 DOACs to try to determine which co-pay would be less expensive
- Some clinicians call pharmacist and ask to process prescription to determine co-pay

How high is too high?

Some patients need to determine what their limits are in terms of what they can afford and two examples of AMS patients are shown below:

• 83 year old female with AF (CHA_2DS_2-VASc = 6) • 6/2017 started warfarin; TTR = 33% • Visited the emergency room with bleeding from one of her ears and an INR of 6.9 • eGFR = 43, Cr = 1.19, Hct = 36.2 • 7/25/17 started apixaban 5 mg bid • Willing to pay $500 annual deductible	• 71 year old female with peripheral arterial disease • 5/2014 started warfarin; TTR = 56% • 3/2017 – new right brachial DVT • Range changed to 2.5-3.5 • Prescription for rivaroxaban • Co-pay over $350 per month • Declined to switch to DOAC and now back on warfarin

Financial aid cards

Another way to address the affordability question is to let the patient know via the financial aid cards. These cards change constantly so it is difficult for the AMS staff to keep up with.

Rivaroxaban	Apixaban	Dabigatran
• Medicare, Medicaid or no insurance – free 30 day trial • Commercial insurance - $0 co-pay every month (max $3,400 per calendar year) • If savings card not accepted or use mail order pharmacy – complete rebate form	• Medicare and commercial – free 30 day trial • Commercial insurance - $10 per month x 30 days, up to 24 months (max benefit $3)	• One time voucher for free 30 day supply for Partners patients • Commercial, VA starting 2017: covered by Silverscript Medicare Part D Plan

Communication among all team members of the healthcare team

The AMS has found that communication across all members of the healthcare team when transitioning patients is very important in order to determine whether patients are good candidates or not.

Example case:

- 59 year old male with AF (CHA2DS2-VASc = 3), seizure disorder
- 7/19/17 started warfarin
- Has taken carbamazepine for many years (P-gp inducer, CYP3A4 inducer)
- Discussion about whether the patient is a candidate for DOAC
- MGH pharmacy advised that ALL DOACs are contraindicated in setting of carbamazepine
- Product insert indicates AVOID only for rivaroxaban and apixaban
- Hematology did not have strong feeling to avoid drug but promoted idea of a consistent approach across the institution to come to a decision about patients
- After discussions amongst team members, the patient was kept on warfarin

Documentation of Off-Label use

The AMS are also receiving referrals for some off-label usage of the medications and so they have developed language within the referral that they ask the physician to sign off on.

Statement in DOAC referral to acknowledge off label use: ***"I have reviewed the patient's medical record and I am aware that the use of this drug is off label for this indication. However, the benefits outweigh the risks in this case"***

Example case:

- 73 year old female with AF, rheumatic heart disease
- 6/6/17 mitral valve replacement (bioprosthetic) for rheumatic mitral stenosis, bilateral maze and LAA excision
- On warfarin x 1 month then transitioned to rivaroxaban 20mg daily
- eGFR = 49, Cr = 1.1, Hct = 31.2
- Conversation with cardiologist:
    - There is nothing fundamentally different about AF that occurs in patients with MVR or MS. Drug manufacturers were worried that physicians would treat their patients with mechanical valves with a DOAC
    - More recent studies (edoxaban) do not have exclusion criteria
    - Recent JACC data show same benefits for patients with or without valvular disease

Misconceptions

There are also sometimes misconceptions that need rectifying:

- 72 year old female with AF (CHA2DS2-VASc = 4)
- On warfarin since 2010; TTR 89%
- 6/9/17 – started rivaroxaban and prefers to take in 'am' with other medications
- Office nurse thought that it should have been taken with evening meal and as a result developed a complicated plan to take rivaroxaban two hours later each day until taking with 'evening meal'
- Key is to take 'with food' and at the same time each day
- So there is still some ongoing education required

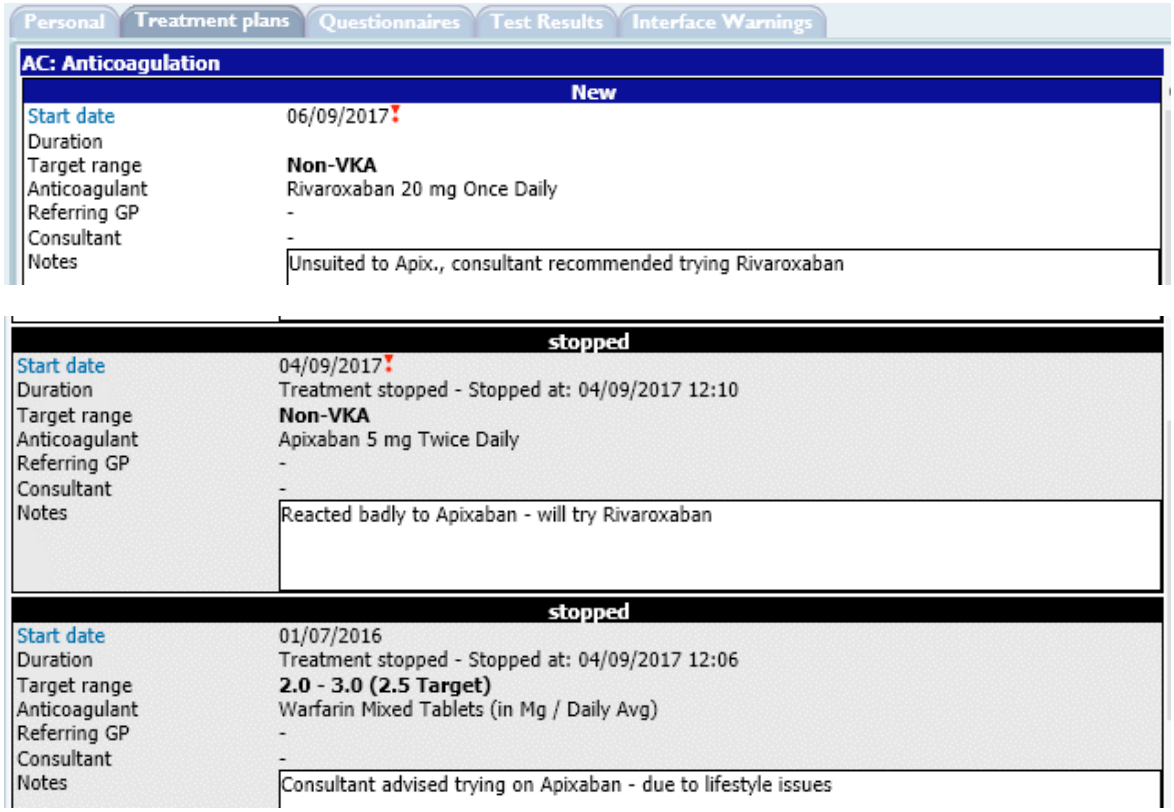
There are a lot of moving pieces when transitioning patients among anticoagulants. As prescribing becomes even more common and we get better at making sure all the pieces are in place…… we will be able to have our cake and eat it too!

DAWN AC DOAC modules – updates & improvements to latest version

Jenny Wood, 4S DAWN Clinical Software

Overview

The DAWN AC DOAC modules use treatment plans similar to warfarin and so retain an integrated warfarin and non-VKA patient anticoagulant history for easy viewing and transitioning:



For each DOAC (Dabigatran, Rivaroxaban, Edoxaban and Apixaban) there are questionnaires for initiation and follow up which provide checks for contraindications, interactions and risks etc. with on-screen help to follow the recommended prescribing guidelines.

The initiation questionnaires can be used for initiating a patient onto a new drug or initiating the patient into your anticoagulation service even if they are already taking that DOAC.

DOAC questionnaires can be scheduled for future dates so you can keep track of patients due for a follow up, dose change or renal function check etc. using the non-VKA list view for easy management of DOAC patients.

Recent updates to the DOAC modules

1. Addition of US measurement for Serum Creatinine (mg/dL)	
2. Addition of a key information summary	
3. Ability to hide the 'Suggested Dose'	

Other recent DAWN AC DOAC module changes include:

- Apixaban & multiple contraindicated drugs or other contraindications
    - A safety update has been made which will require an upgrade of the DAWN AC DOAC modules at customer sites

- Coded comments
    - Can now be used in every notes field

- Reporting events to an external party – hyperlink address now configurable
    - Choose what to display in the follow up questionnaire and which website to link to

- A configurable option to replace CHADS2 with CHA2DS-2VASc for rivaroxaban and edoxaban
    - CHADS2 is the default and can be changed in system settings

- Renal limit for contraindication in dabigatran now configurable from 30mL/min default
    - Can now be changed to 15mL/min. If this limit is breached, the questionnaire will be rendered as contraindicated.

Future Plans

The next 18 months will see the development of a combined DOAC module which has one initiation questionnaire and one follow up questionnaire for use with any DOAC rather than an initiation and follow up questionnaire per DOAC.

The aim of this generic module will be to prevent multiple questionnaires being completed for different DOACs, ensure consistency between the questionnaires; and to make it easier and faster to provide future development improvements and also to add new drugs e.g. betrixaban.

Developing a model to evaluate risk and workload with DOAC patients

Walter Moulaison Jnr, MSN MBS, RN, Co-Director, Anticoagulation Management Service, Massachusetts General Hospital (MGH), Boston, MA

Measuring risk and workload amongst warfarin patients is something that MGH have been doing since implementing the DAWN AC system in 2007 and use the information to benchmark with themselves to help obtain the resources needed to manage their patients. This enables the AMS to organize their service in order to manage their patients in the best possible way.

The value of a well organized AMS clinic is well understood for monitoring warfarin patients and ensuring quality of care.

We also need to be aware of why this measuring of risk and workload needs to be done for DOAC patients and why it is important.

Evolution of the AMS: The Medication Safety Clinic

The AMS was originally developed to provide safe and efficient care for warfarin-treated patients requiring laboratory monitoring and dose adjustment by expert providers.

- Need for expanded role
    - Assistance with selection of most appropriate anticoagulant and dose
    - Minimize risk of serious bleeding complications
    - Peri-procedural management
    - Encourage on-going medication adherence

Why is measuring work important?

It is important to demonstrate the worth of AMS' in terms of adding value for improving patient care quality and safety but it is also important to be able to demonstrate the cost of the service and that the service itself if using adequate resources in order to manage the patient population.

Barriers	Drivers
• Greatest challenge is financing • Studies of cost-effectiveness for DOACs do not include costs of clinic support • Greatest need for support is up front; requires a change in culture, early consult for assistance is a change in practice for most providers	• Changing payment landscape • Focus on holistic strategies to improve care and reduce expenses • Responsibility for costs of care not just fee-for-service costs • Strategies to reduce adverse drug events financially beneficial

Primary functions of AMS

- Provide a safety net for patients taking anticoagulant drugs with critical safety profiles
- Act as an informational resource and decision support service
- Assure appropriate drug selection and dosing given renal or liver impairment and concurrent medication use; ongoing monitoring is often overlooked
- Spend quality, focussed time with patients to answer questions or concerns; ongoing relationships will likely improve DOAC adherence
- Reduce harm from bleeding: inappropriate dosing; peri-procedural periods
- Rapidly incorporate and implement new clinical evidence – certainly as DOAC management is still new and there is a range of healthcare professionals managing them without collecting much evidence

Top priority for patient-centred care

- Serving a broader need - looking to the future of possible nurse and pharmacist combined led clinics
- Reduce costly emergency visits and hospital admissions
- Improve patient satisfaction
- Central role in standardized peri-procedural bridging and reductions in the use of frequently overused heparins
- Potential for longitudinal medication monitoring in patients taking other cardiovascular medications

Robust data is lacking

There is a lack of robust data in many areas.

Assessing patient outcomes, clinic function and the cost of running the clinic is important along with demonstrating that costs are being avoided through decreased hospital admissions and preventing patients from accessing the health system for other reasons that could be avoided.

Budgeting; not simply a plan for doing what we've always done

The goal of budgeting is to constantly get better at what we do and this can be achieved through benchmarking, not only internally but with other AMS' in order to find and learn best practice.

We also need to look at productivity in order to cut fat rather than lean and to guard against the motivation to sacrifice the mission of quality patient care. Whilst it is clear to AMS' that they are providing a quality service and ensuring patient care, this is not so obvious to those in charge of finances.

Therefore, carrying out cost benefit/cost effectiveness analysis and changing processes in order to work smarter not harder is also important.

Goals

The goals of MGH AMS' workload measurement system are:

- To measure the relative amounts of resources consumed in providing specific services for patients – for both warfarin and DOAC patients
- To consider RN time and care intensity in the measurement
- To provide an analytical method for measuring productivity
- To use historical data for deriving meaningful benchmarks
- To remove subjectivity – ensure quantitative data is available to present
- To bring credibility to requests for equipment and staffing

Leveraging the warfarin Risk Class Assessment Relative Value Units (RCA RVU) model for DOAC patients

Weighted Risk Class Assessment	Relative Value Units

• Grouping patients on basis of common clinical characteristics and level of resource use
• Requirement for nursing care
  ○ *Critical indicators predict intensity of care needs*
• Quantification of nursing care resources
  ○ *Direct observation and time studies*
• Method for calculating staffing for required nursing hours
  ○ *RVU model*
	• Analytical method for measuring productivity
	  ○ *Removes subjectivity*
	  ○ *Adjusts for variations among patients*
	  ○ *Captures major work drivers*
	  ○ *Informs understanding of patient needs and changes in the population*

Measuring workload (warfarin patients)

The numbers below are pulled directly from the DAWN system and represent monthly figures of Authorizations, Time in minutes for dealing with patients and then converting this to Relative Value Units.

Authorizations	Bridging	Induction	Maintenance
Controlled (0-25)	68	5	4962
Low Watch (26-50)	28	103	1316
High Watch (51-75)	16	107	655
Complex Care (>75)	31	114	497

Times	Bridging	Induction	Maintenance
Controlled (0-25)	10	15	5
Low Watch (26-50)	15	20	8
High Watch (51-75)	20	25	12
Complex Care (>75)	25	30	15

RVU			
Controlled (0-25)	680	75	24810
Low Watch (26-50)	420	2060	10528
High Watch (51-75)	320	2675	7860
Complex Care (>75)	775	3420	7455

Dosing Work Units	61078	
Teaching Work Units	1018	
Total Work Units	80	* Converted to hours
	1098	

Measuring productivity (calculating relative value units)

Paid direct care FTEs taken from payroll reports is compared with budget targets

$$\frac{\text{RVUs}}{\text{Month Hours}} = \text{Direct FTES} \qquad \frac{1098}{176.6} = 6.22$$

$$\frac{\text{Worked FTES} * \text{Month Hours}}{\text{RVU}} = \text{Avg. Hrs./RVU} \qquad \frac{8.2 * 176.6}{1098} = 1.32$$

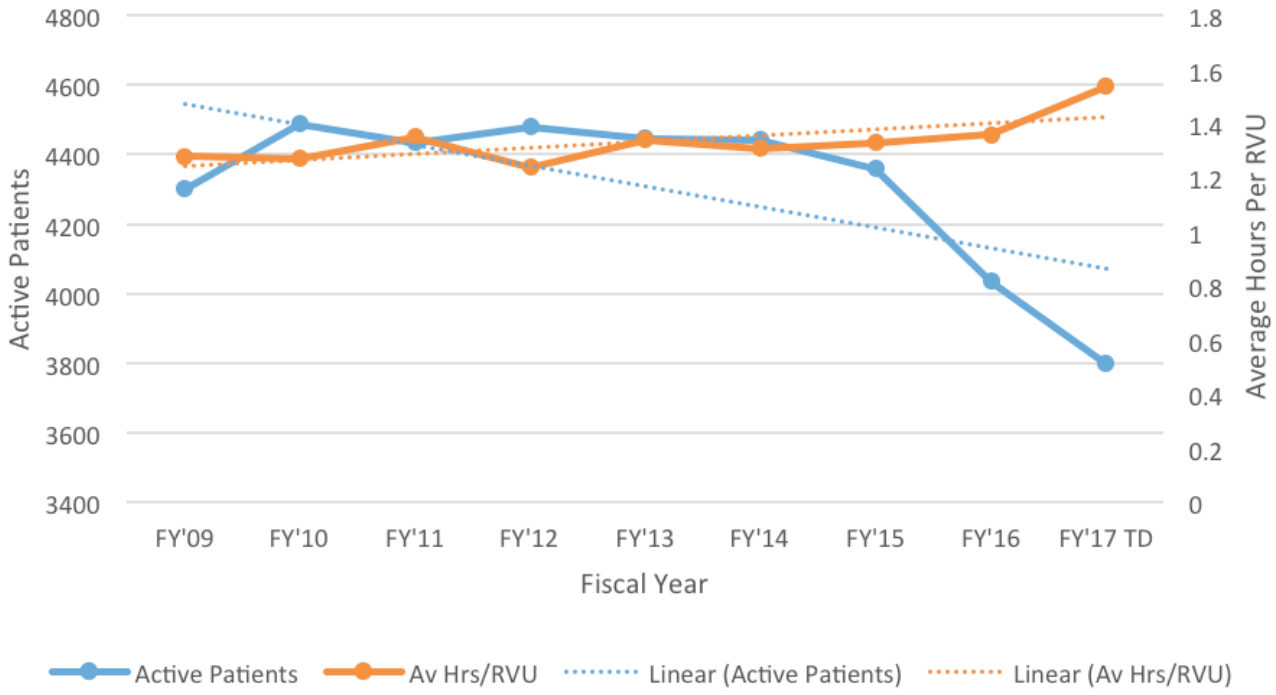
The equation above highlights that it took 1.32 people to do 1 hour of work. It took several years to build the history but this is a model similar to what is being used in patient care services by the department of nursing, measuring workload against an acuity system and the budgets are aligned that way.

This approach helps the AMS when talking to those in charge of budgets as they are able to talk to them in terms they can relate to and take an approach that they value in terms of hard evidence rather than subjective.

This is the reason that the AMS developed a measuring system that is similar to those used elsewhere in the hospital and it has provided the service with a powerful voice to enable them to grow.

Active warfarin patients versus average hours per RVU

However, the graph below shows that as patient numbers have decreased, so has productivity and the number of hours per RVU has gone up.



There are other elements that impact this graph including the implementation of EPIC and the start of managing DOAC patients, both of which are not shown on the graph above but both had significant impact on workload.

However, TIR and patient compliance amongst the patient population are both high and are increasing which show quality, whilst intangible to a degree, is still high despite a fall in productivity.

The question therefore, is what measures should the AMS use to leverage the same framework for the DOAC patients?

DOAC risk

Each risk, event, procedure, age and whether they are a new patient is attached to a severity level which are allocated a number of points and this is where the value of the risks are scored in DAWN.

Elements	Severity/Warning Level

• Risks
  ○ Age =>75
  ○ Non-adherence
  ○ eGFR <41%
  ○ Hct drop =>6
	
	• DOAC risk – 27 points (p)
	• DOAC risk – 9 (p) or resolved 0
	• DOAC risk – 27 (p) or resolved 0
	• DOAC risk – 27 (p) or resolved 0

• Events
  ○ Bleeding
  ○ Thromboembolic
  ○ Incoming calls
  ○ Outgoing calls
	
	• Minor (Report No F/U) – 11 (p)
	• Moderate (Medical Attention) – 26 (p)
	• Major (Hospitalization/Transfusion) – 51 (p)
	• DOAC contact – 11 (p)

• Procedures	• Pre- and Post- Duration – variable
• Age ○ Age =>65	 • All patients – 10 (p)
• New patient score ○ 8 weeks or less	 • DOAC patients – 27 (p)

Also need to do a time study to determine how much time it takes to deal with a DOAC patient and to include any education that is required. How many initial questionnaires and follow-up questionnaires are being completed and comparing these against the risk class will also provide the data required to measure risks and workflow.

There is still more work to do to develop the reports and queries regarding the DOAC patients to enable accurate measuring to take place and there are many more DOAC patients yet to come on board with the AMS which will also provide more raw data.

Inpatient Anticoagulation Management Services to improve transitions of care

Andrea Resseguie, PharmD, Advanced Practice Clinical Specialist, Anticoagulation Management Service, Brigham & Women's Hospital (BWH), Boston, MA

High risk populations followed as inpatients by the AMS:

AMMO: Major Orthopedic Surgery (Total hip replacement, total knee replacement)
HAT: Ventricular Assist Device (VAD)

- Inpatient physician orders consult
- BWH department of pharmacy monitor and order warfarin every day
- AMMO – post orthopaedic surgery patients requiring warfarin
  - INR target range of 1.8-2.3
  - Duration – 3 weeks
- HAT – VAD patients requiring warfarin
  - INR target range dependant on VAD device
  - Duration – indefinite

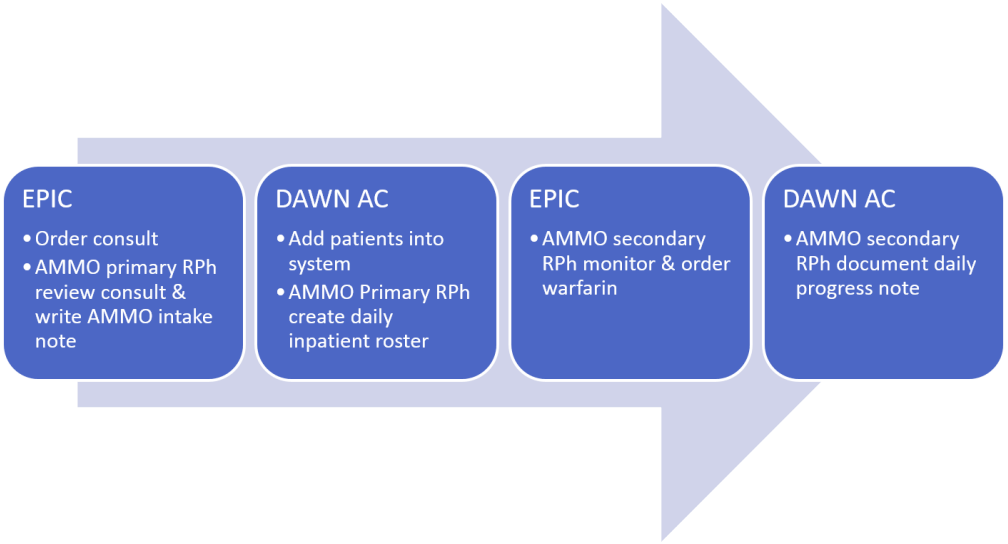
AMMO service roles and responsibilities

Pharmacy drives the service, monitoring and ordering the warfarin daily and collaborates with the Orthopedic Surgery team.

Inpatient workflow

Individual	Responsibilities
Orthopedic Surgery Resident / Responding Clinician	• Orders initial consult, warfarin dose day before surgery and warfarin dose day of surgery • Communicate changes in patients' clinical conditions • Co-sign daily warfarin orders
AMMO Primary Pharmacist	• Process the consult (viewable through 'Consult Messages') • Enters new patient demographic into DAWN AC • Write EPIC consult note • Emails daily patient roster to pharmacists
AMMO Secondary Pharmacist	• Orders warfarin dose in EPIC • Documents daily progress note into DAWN AC

Required for consult:



Referring physician (surgeon)
Primary indication for anticoagulation (Orthopedic surgery)
Type of surgery
Date of surgery
INR target range
Duration

Orthopedic surgery residents will order the first post-op dose of warfarin and an AMS consult via one of four Orthopedic Order Sets in EPIC.

Consults are reviewed for clinical appropriateness and entered into DAWN. The Primary AMMO Pharmacist will enter patient demographics into DAWN AC daily and once all new patients have been entered into DAWN for that day, the Pharmacist creates a daily roster and emails it out to the BWH Rx Pharmacist with assignments for the AMMO Secondary Pharmacists.

Once the daily roster has been sent out, the pharmacist is able to start dosing and ordering warfarin. BWH AMS will also update the emailed roster with additional information from rounds in the morning.
The patient's INR is entered and their daily progress note is documented in the DAWN AC treatment notes field

using coded comments based on the initiation dosing protocol:

.POD1 is for post-op day 1 and lists the information required. .POD is for any day after the procedure and can be customised accordingly.
The next test date is then set and the dose accepted and authorized.

The AMS pharmacist is responsible for determining disposition and maintaining outpatient care for the remaining duration of anticoagulation therapy. Upon discharge, any missing or pertinent information regarding the patient is entered onto the DAWN AC patient record.

The patient's INR is taken the day after discharge. Also, education and counselling points are reinforced.

Problems with transitions of care may lead to adverse events and higher hospital readmission rates and costs and the table below shows three barriers to successful transitions of care – communication, patient education and accountability - along with possible solutions.

Summary of AMMO transition of care

Communication	Patient Education	Accountability
• Clinicians effectively and completely communicate important information in a timely fashion among themselves and to patient/caregiver • Culture promotes successful hand-off (teamwork, respect) • Standardised procedures in conducting successful hand-off	• Resolve conflicting recommendations, confusing medication regimens, and unclear instructions • Include patient/caregiver in planning related to the transition process • Sufficient understanding of medical condition so the patient will more likely buy into the importance of following the care plan	• Having a clinical entity take responsibility to assure that the patient's health care is coordinated across various settings and among different providers • Steps are taken to ensure that sufficient knowledge and resources will be available to the patient upon discharge

- No gap in AMS coverage between inpatients and outpatients
- Standardised AMMO training
- Multidisciplinary communication, collaboration and coordination, including patient/caregiver education from admission through transition
- Clinician involvement and shared accountability during all points of transition
- Timely follow-up, support and coordination after patient leaves a care setting

- Allows for efficacy/safety monitoring
    - TTR
    - Thrombosis
    - Bleeding
- Patients that have thrombosis
    - INR range of 2.0-3.0
    - Duration of 3 months
    - Ensure follow-up with outpatient provider to assess long term anticoagulation needs

Sharing of best practices: Leveraging DAWN and a unique staffing model for a successful practice

Paul Kuo, PharmD, Manager, Anticoagulation and Anemia Management Service, Kaiser Permanente, Seattle, WA

Kaiser Permanente (KP) Washington Region was formed in 2017 after KP acquired Group Health Cooperative. It is a managed care organisation with 680,000 members, 25 full-service outpatient medical centers, 15 walk-in clinics, 5 urgent care locations and 3 ambulatory surgery centers. In addition, it has a 24/7 consulting nurse service and contracted hospital services.

The Anticoagulation and Anemia Management Service (AMS) manages patients on warfarin, LMWH, DOACs, epoetin and iron using a centralised telephone system. There are 7,000 warfarin patients, 350 DOAC patients, 100 anemia patients and 2,000 procedure plans annually.

Staff within the AMS are allocated tasks and patient sub-groups based on risk level:

Staff	DAWN AC Patient Risk Class	Tasks
Patient Care Representatives (PCR) x 3	-	Call triage, patient letters, faxes, non-attendance outbound calls
Medical Assistants (MA) x 3	-	Open patients in DAWN, email/EPIC message triage, PST program, processing referrals
Licensed Practical Nurses (LPN) x 5	• Low • Low with Drug Interactions	Low acuity, stable and in-range patients
Registered Nurses (RN) x 10	• Medium • Medium with Drug Interactions	Moderate acuity patients, INRs between 1.0 and 6.0, DOAC monitoring and education
Midlevels (ML) x 10 (1 x ARNP (Nurse Practitioner) / 9 x Pharmacists)	• High • Bridging • Enoxaparin only • Enoxaparin transition	High acuity patients, new starts, peri-procedural management, DOAC initiation and monitoring, anemia management, refills

Clinics run Monday to Friday 8.00am – 5.00pm, Saturday 8.00am – 4.00pm and one Midlevel works from home from 3.00pm – 5.00pm on a Sunday. Out of hours support is provided by consulting nurse services.

The 25 medical centres are divided into three clinics of over 2,000 patients each and providing care for all needs (warfarin, LWMH, DOAC, anemia). Each clinic consists of 2 MLs, 2 RNs and 1 LPN with additional flexible staff to cover specific duties as clinic needs fluctuate i.e. incoming calls, referrals, procedures etc.

Patients are allocated to a risk class based on their INR result and time in range. New patients start in the high risk clinic. As the new patients come into range, they are transferred to the medium clinic. For those that are consistently in range, they are allocated to the low risk clinic. If a low risk clinic patient moves out of range and with INRs between 1.0 and 6.0, they are reallocated to the medium risk clinic. Any patient outside of the 1.0-6.0 range are reallocated to the high risk clinic for management.

Using DAWN AC – communications and settings

The following direct print letters are set up in DAWN AC:

- New patient packets
- Travel letter
- Overdue letter
- Unable to reach letter
- In-range letter
- Transition of care
- Insurance termination

In addition, the following custom messages are used:

- Lab orders and AMS treatment notes are sent to the Lab Information System interface which pushes the information into the EPIC patient record – this happens automatically when a dose is accepted in the DAWN AC patient record. It is also possible to send this message manually e.g. if additional labs are required
- Faxed orders and communications are sent through the RightFax interface

Reminders are used by MAs to assign a new referral patient to the clinic for work and by MLs as a daily clinic task list for Non-INR work and as a follow up reminder system.

Other features used include:

- Non-attendance
- Procedures
- Groups: used to track patients in the self-testing program
- Drugs: to document drug interactions
- Events: track adverse (bleeding/thrombosis) events
- Review: MAs use to review continuation of care after initial specified duration of therapy on referral and if necessary contacts the physician for referral extensions
- Status: Patients suspended from service due to non-compliance

In terms of outcomes, on a daily basis there are close to 600 INRs processed. Our Time in Range for all ranges is 75% including bridging patients. The AMS' mean test interval is fairly low at 16.5 days and the service would like this to be longer.

What's next?

- DAWN AC patient self-testing module
- Expanding the use of DAWN Messaging for internal communications
- Extending the maximum testing interval to 12 weeks
- Monitoring adverse events from claims data – to validate the benchmarking TTR and quality patient care
- DAWN DOAC modules – look to incorporate into the DAWN AC system as the DOAC patient population grows.

DAWN AC product development – what's new in DAWN AC

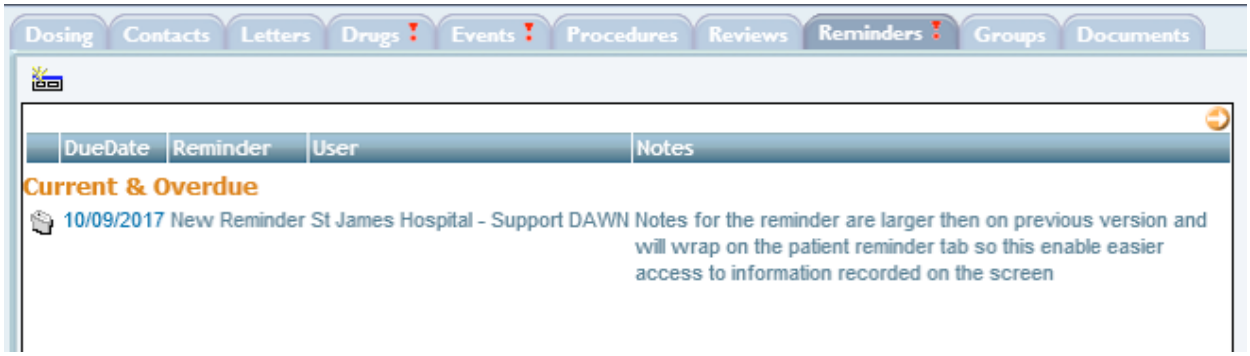
Alistair Stewart, 4S DAWN Clinical Software

Alistair covered some the product developments that had been introduced to DAWN AC over the last year.

Enhancements to Reminder Notes

The height and width of the notes field on the Reminders tab within the DAWN AC patient record has been enlarged so that the contents of the field are easier to read.

History Tab Default



In previous versions of DAWN AC, the Patient Tab Sheet on the bottom right of the patient screen defaulted to either the Graphs tab or the Personal tab. However, the History tab is the one that is used most and so this is now the default tab when you open the patient screen, if no preference is set in the Personal Settings section.

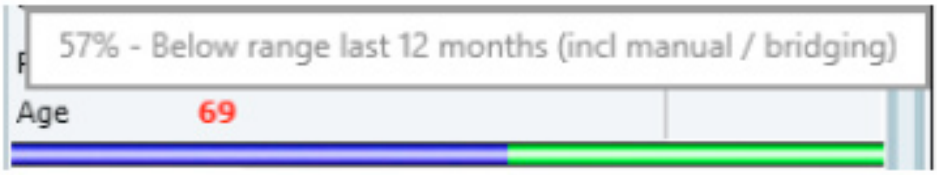
Time in Range Calculation

Historically, the time in range bar in the top left of the DAWN AC patient screen has not included INR results recorded whilst a patient was on Induction or Manual/Bridging therapy and this meant that the TIR bar was often at odds with reports that do not exclude these INRs, which can be misleading.

A new system setting now enables you to choose whether the TIR bar on the patient screen includes the Induction and Manual/Bridging INRs or not.

By hovering over the bar, a pop-up screen informs you whether these are included. See below:

Improved Letters Tab



The patient Letters tab in DAWN includes two drop down lists of letters available on the DAWN AC system. This list is in the order that letters were added to the system.

For customers who have many letters on their system, including those that are no longer used or not used often, this proved cumbersome if letters used regularly were at the bottom of the list.

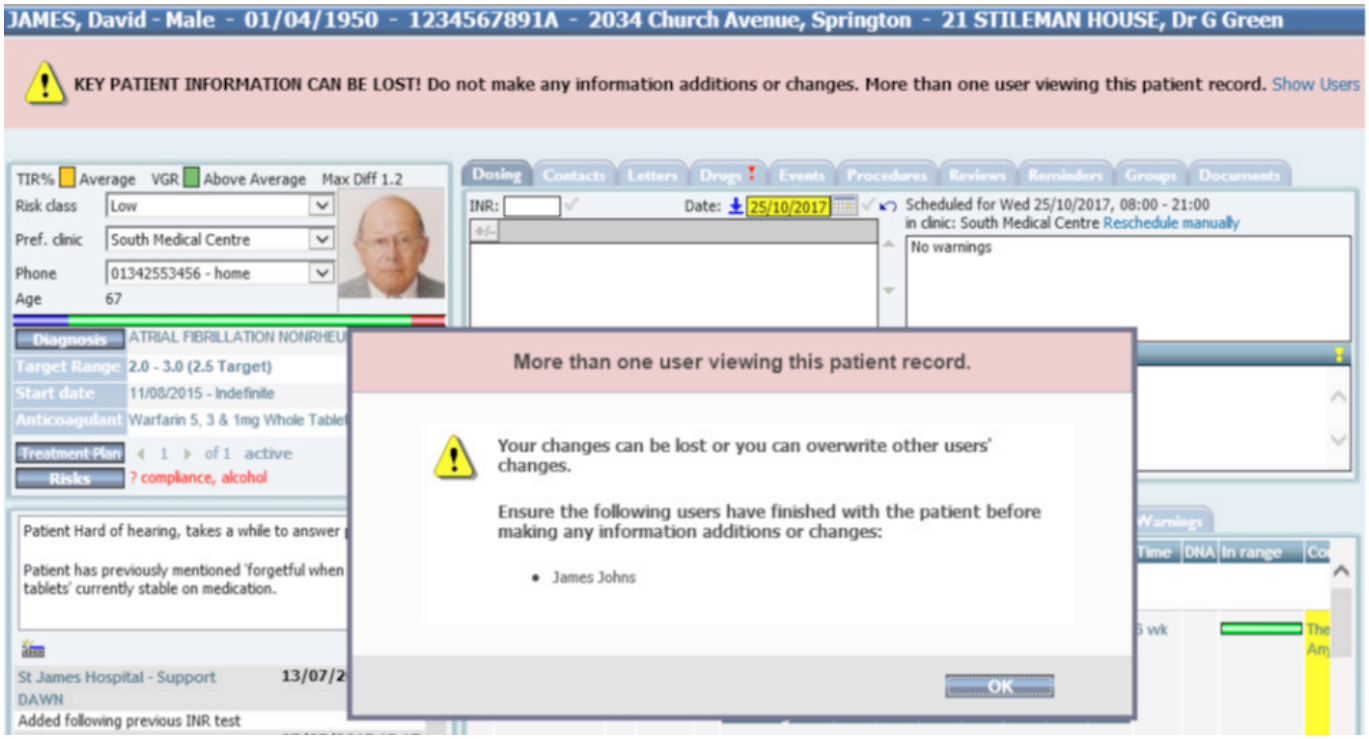
You are now able to determine the order in which letters are displayed in the list so that the most common letters are now sat at the top and easily accessible.

Concurrent User Warning

DAWN AC now displays a concurrent user warning to a user when opening a patient record that is already being viewed by another DAWN user.

A popup box is displayed showing the name of the user(s) already viewing the same record and a banner at the top of the screen has a Show Users link which will show which users are viewing the record.

Improved Emailing



Recent versions of DAWN AC have included the options to send emails with pdf attachments and to automatically trigger emails to patients and/or healthcare providers at set times.

Previously, emails could only be sent out using a mail server that did not require a secure connection however, this has been changed to include the option to enable a secure connection which allows the use of secure mail servers.

Increased List Views

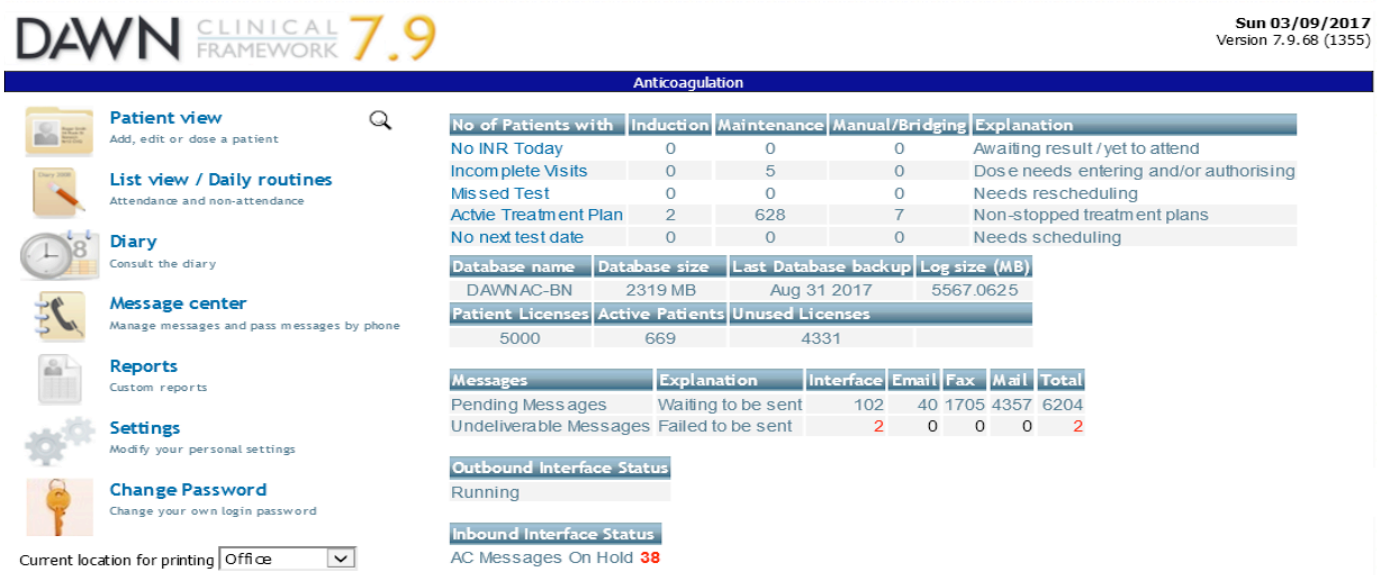
Users are now able to view up to 20 list view tabs within the list view screen where previously this was limited to 10.

New Drug Class Lookup

A new drug class lookup table allows you to define categories of drug (Beta Blocker, ACE Inhibitor, Anticoagulant, Antibiotic etc) and select the appropriate class for individual drugs. This facilitates reporting and clinical audit where tracking the use of certain drug types is important.

Improved Front Screen

The DAWN AC front screen has been reformatted to remove the picture and make the best use of space for the front screen tallies/system statistics. The page has also been widened to provide more space for this new system dashboard.



4S DAWN Clinical Software would like to thank Brigham & Women's Hospital for their support in hosting this year's DAWN AC User Group.

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