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War on warfarin: Integrating DOACS into your anticoagulation service

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Brigham and Women's Anticoagulation Management Service (AMS) are in the process of building a direct oral anticoagulant (DOAC) clinic and integrating it into their traditional anticoagulation management services. David's presentation aimed to look at the importance of an AMS in managing warfarin; national trends in anticoagulation; the role of an AMS in managing DOACs; and the approaches to integrating a DOAC clinic into an AMS.

Advantages and Importance of Anticoagulation Management Services

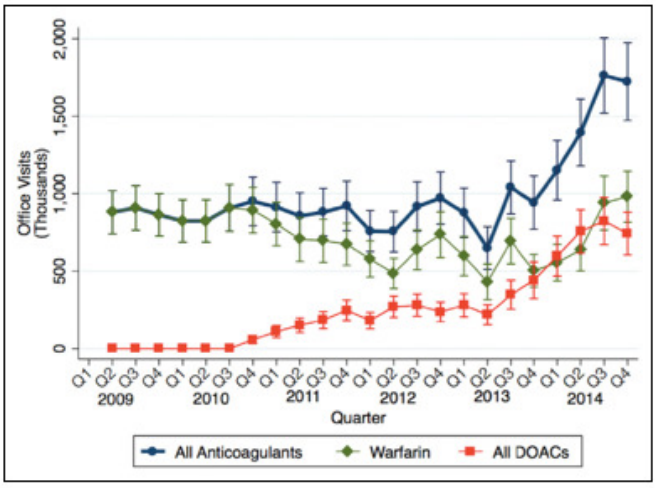
- Dedicated sites of service for anticoagulation
  Having dedicated anticoagulation staff ensures quality results for the patient population
- Consistent provider-patient interactions
  Frequent interactions allow for continued education and assessment of the patient
- Systematic follow-up
  Reliable follow up of patients who don't attend their scheduled INR
- Quality assurance measures
  Assesses anticoagulation management performance by tracking patient census, time in therapeutic range (TTR), critical INRs, events etc.

Time in Therapeutic Range (TTR) is lower for patients who visit their physicians for anticoagulant care with an average TTR of 57% which is considered poor control in most disease states. Generally, TTR for anticoagulation management services is around 66% which is considered good quality control.

National Trends in Anticoagulation

In 2015, important changes were seen in the utilization of oral anticoagulants, particularly with the newer direct oral anticoagulants, dabigatran, rivaroxaban, apixaban and edoxaban. Dispensed prescriptions for direct oral anticoagulants rose 73.6% from early 2014 through to the end of 2015, while Warfarin use decreased by 10.9% during the same time period.

By the fourth quarter of 2015, the four direct oral anticoagulants had captured 34% of the market, leaving 66% to warfarin.



Quarterly visits for atrial fibrillation by anticoagulant type

- A-fib visits with AC use increased from 51.9% to 66.9% between 2009 and 2014
- DOAC usage rose 73.6% from early 2014 through 2015
- Warfarin use decreased by 10.9% from early 2014 through 2015

The AMS at Brigham & Women's Hospital is seeing the same trend along a similar timescale. Since 2009, the service has been growing exponentially, yet from 2014 there has been a decline in patient numbers from over 3500 to around 3100 patients in the most recent quarter of 2016. This is due to a large percentage of anticoagulated patients being atrial fibrillation or VTE patients which are the main indications for DOACs.

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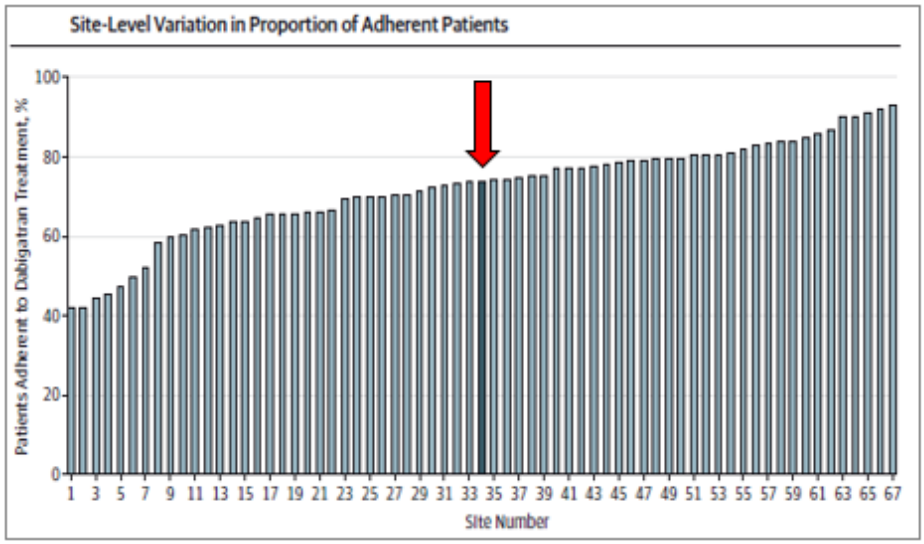
With a strong trend towards increased DOAC usage the industry is seeing a lot of adverse events reported to the FDA. In 2011, dabigatran and warfarin had the first and second most FDA direct adverse event reports proving that inhibiting clotting still ranks as the highest risk chronic therapy regardless of whether you are administering VKA or non-VKA medications.

The question is: How can Anticoagulation Management Services help this problem?

A study of 67 sites representing just under 5000 patients looked at dabigatran adherence:



- 4,863 patients at 67 sites
- Adherence defined as proportion of days covered (PDC) ≥ 80%
- Median site adherence rate was 74%

The height of each bar represents the proportion of patients who had adhered to their medication regimen at that site. The dark bar represents the median proportion (74%) who were adherent, across all 67 sites. Those sites with higher than average adherence were found to provide more pharmacist-led event monitoring, patient follow up, and have more involvement from an anticoagulation clinic.

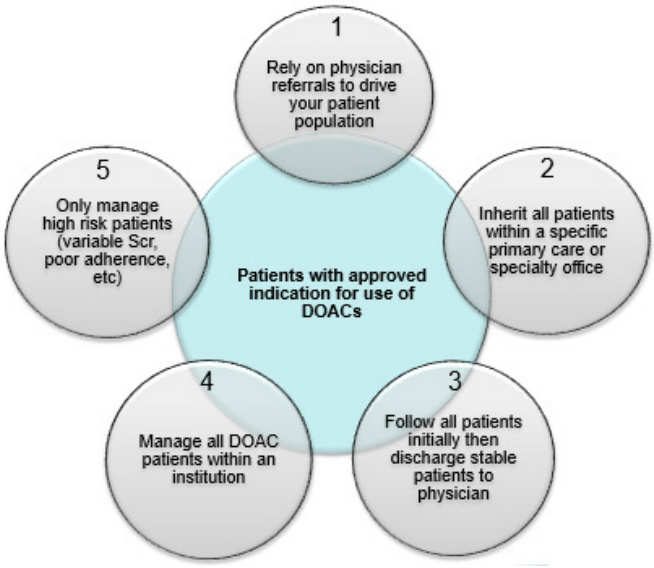
Increased adherence is key for these patients since every 10% decrease in dabigatran PDC results in a 13% increase in hazard ratio for all-cause mortality and stroke (Shore S, Carey EP, Turakhia MP, et al. Adherence to dabigatran therapy and longitudinal patient outcomes: insights from the veterans health administration. *Am Heart J. 2014; 167(6):810-817*).

What is the role of the AMS in prescribing and monitoring DOACs?

Initial	**Ongoing**
• Assess patient, medication and dose selection • Confirm initial fill of prescribed medications • Ensure proper acute treatment and transition to maintenance doses • Facilitate transition to and from other anticoagulants	• Facilitate proper labelled dose transitions • Manage periprocedural anticoagulation • Facilitate discontinuation of anticoagulants upon treatment completion • Manage minor bleeding and triage clinically relevant events
Initial and Ongoing	
• Identify drug-drug interactions • Provide patient education • Assess medication adherence • Obtain laboratory markers	

Approaches to Integrating DOAC clinics into the AMS

Firstly, consider what the target patient population is and where you will get your patients from.



Secondly, you need to understand what exactly the intervention from the AMS is going to be and when you will intervene.

What is your intervention?	When will you intervene?
• Patient chart review • Face-to-face initial or continued follow up • Telephone follow up • Telemedicine visits • Health care provider consults	• At the time of qualifying diagnosis • During the anticoagulant selection process • After prescription is given to the patient • At the time of discharge • Only within high risk patients and situations

Once the AMS has considered its target patients and what the clinic's intervention will be, the next step is understanding how you will manage the patients on DOACs.

The reason an AMS can operate at a high level of efficacy and safety are due to the policies and procedures that they institute to standardize care in anticoagulation. This same theory needs to be applied to your new DOAC clinic if you want it to be successful as well.

As such, policies and procedures are being drawn up for the following areas:

- Patient education
- Assessing adherence
- Medication management plans and routine follow up
- Converting to and from anticoagulants
- Periprocedural management of each DOAC

The AMS believes that disease management software like DAWN AC that can track patients and ensure correct follow up in a systematic way is essential for initiating a DOAC clinic, monitoring your patients, and taking quality assurance measures for patients on DOACs.

Closing the presentation, David summarised helpful tips for integrating DOACs into an AMS:

- Define a target patient population that is consistent with the needs of your institution
- Clearly define your intervention
- Develop a patient education program with the goal of providing consistent, structured education to patients
- Create guidelines for patient management to standardize care across your AMS

- Use comprehensive software such as DAWN AC DOAC modules to support your intervention and report your results
- Train and educate your staff!
- Don't over manage DOAC patients. Management should be far less burdensome for the health care provider and the patient.
- Consider surveying other DOAC clinics and conducting pilot testing in order to help you
    - Establish the target population that works best for your anticoagulation service
    - Determine if you are ready for full scale implementation
    - Make decisions on where to allocate your time and resources
    - Ensure that you are well prepared to measure the success of your program
    - Establish an evidence-based program that meets the needs of your institution