The Massachusetts General Hospital (MGH) Anticoagulation Management Service (AMS) is one of the nation’s oldest and largest anticoagulation clinics. Located on the main MGH campus, the ambulatory clinic provides comprehensive management and education to over 4000 patients receiving anticoagulant therapy. The AMS leadership includes Medical Director, Robert Hughes, MD, Nursing Director, Walter Moulaison, RN, MSN, NE-BC, and Nursing Practice Specialist, Lynn Oertel, RN, MSN, NP-C, CACP. Care is provided by thirteen Clinical Nurses supported by administrative support personnel.

The goals of oral anticoagulant therapy are to treat and prevent thromboembolism and to minimize the risk of bleeding complications by achieving and maintaining the International Normalized Ratio (INR) within a specified target range. Regular INR monitoring is necessary for patients who are receiving anticoagulation therapy in order to determine dose adjustments required to maintain the INR in an established therapeutic range.

The Anticoagulation (AC) Forum, founded in 1991, is an interdisciplinary, national organization of health care professionals that strives to improve the quality of care for patients taking antithrombotic medications. It provides educational and networking opportunities; facilitates research; promotes the clinical application of evidence-based practice; and impacts healthcare policy by informing regulatory agencies and industry about best practices. Although the AC Forum is an interdisciplinary professional organization, nurses play a prominent role in the organization and have been instrumental in developing standards for safe and effective anticoagulation care since its inception.

MGH AMS leadership and clinical nurses have actively participated in the AC Forum activities for a number of years. Moulaison, Oertel, and 100% of the AMS Clinical Nurses are members of the organization. In addition, Oertel served as a member of the AC Forum Board of Advisors from 1997 to 2015 and is currently on the Advisory Council.
The AC Forum presents a bi-annual national education and research conference. MGH AMS nurses have regularly attended these conferences and they have participated in providing educational sessions and posters presentations. The AC Forum also conducts interactive webinar presentations followed by discussions that connect anticoagulation care providers across the country. As participants in this ongoing dialogue, MGH AMS nurses help to shape the organization's guidelines and consensus statements on important and timely topics. Members of the AC Forum also receive periodic e-newsletters that contain practice-specific information. In the past, Oertel has co-authored a column in the newsletter featuring patient case vignettes that present clinical practice issues encountered at MGH with related interventions to optimize patient care.

To guide anticoagulation practice, the AC Forum publishes consensus guidelines which are available on their website (attachment EP6a.a). In 2008, they published “Delivery of Optimized Anticoagulant Therapy: Consensus Statement from the Anticoagulation Forum” (attachment EP6a.a). The article provided recommendations for delivering optimal anticoagulation therapy in nine key areas:

1. Qualifications of personnel
2. Supervision
3. Care management and coordination
4. Documentation
5. Patient education
6. Patient selection and assessment
7. Laboratory monitoring
8. Initiation and stabilization of therapy
9. Maintenance therapy

In October of 2008, four members of the AC Forum, including Oertel, that participated in developing this first set of consensus guidelines, also contributed to publishing "Oral Anticoagulation Patient Self-Testing: Consensus Guidelines for Practical Implementation" which was published in Managed Care and widely distributed to AC Forum members (attachment EP6a.b). Considered seminal publications, the recommendations continue to be applicable to care provided by anticoagulation clinics today. In 2013, they published “Delivery of Optimized Anticoagulation Therapy: Consensus Statement from the Anticoagulation Forum”, focusing on anticoagulation care in the inpatient setting. The guidelines referred to an emerging "extensive body of evidence supporting the efficacy, safety and improved quality of life associated with Patient Self Testing.” In addition, they called for a wider use of PST. Subsequently, the topic was included in multiple AC Forum educational forums, such as sessions at National Conferences, published articles, and in AC Forum newsletters.

MGH AMS physicians and nurses have incorporated the standards and guidelines from the AC Forum consensus statements in their delivery of anticoagulation patient care. Of note, is the recognition of the MGH AMS as a “Center of Excellence in Anticoagulation” by the AC Forum in 2013-2015 and 2015-2017.
History of Patient Self Testing at MGH

One example of AMS nurses incorporating AC Forum specialty standards/guidelines into the delivery of care is seen in their promotion and support of a Patient Self Testing (PST) option for patients. Similar to home blood-glucose monitoring by patients with diabetes, PST for anticoagulation, consists of INR testing using a home testing device and reporting their INR value to AMS clinic care team. Testing is done weekly for most patients and AMS clinic clinical nurses provide instruction back to the patient about any dose adjustments that may be needed. Patients selected for PST are most often taking anticoagulants for a long-term condition or indefinitely, and must be:

- under the care of a provider who prescribes the PST system and monitors the therapy
- willing to participate in training on the proper use and care of PST meter and reporting procedures
- able to participate in face-to-face training and follow the procedures for testing
- physically capable of performing the test after receiving training
- able to understand and retain the testing procedure instructions
- willing to follow the provider’s recommendations for testing frequency and reporting, including access to a telephone or other communication device, and
- compliant with dose adjustments.

PST became a possibility for many AMS patients after 2008, when Medicare expanded coverage to include Prothrombin Time (PT) and International Normalized Ratio (INR) monitoring done in the home for patients with atrial fibrillation, deep vein thrombosis and pulmonary emboli. The insurance coverage change served to expand the options for patients requiring on-going testing for anticoagulation

Based on the AC Forum guidelines, the MGH began to offer a PST program to a small group of selected patients. Moulaison and Oertel were cautious about expanding too quickly and wanted to ensure that the patients who elected PST would have clinical outcomes that were at least as good as those patients monitored using traditional phlebotomy and laboratory testing. Oertel led the development and approval of the MGH AMS Patient Self Testing Policy, and a formalized PST Patient Agreement was implemented in 2010. In 2013, they conducted a retrospective review of AMS PST patients, using data from their software system, to evaluate the INR Time in Therapeutic Range (TTR). The review indicated that TTR for PST patients exceeded the average for the clinic as a whole.

It is also significant that other professional organizations have published information supporting the benefits of PST. For example, the American College of Chest Physicians presented evidence-based clinical practice guidelines for anticoagulation therapy (Evidence-Based Management of Anticoagulant Therapy, Chest, 2012 Feb; 141 (2 Suppl) and included the recommendation that for patients “who are motivated and can demonstrate competency in self-management strategies, including the self-testing equipment, we suggest patient self-management (PSM) rather than usual outpatient
INR monitoring”. In 2014, the U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion presented a National Action Plan for Adverse Drug Event Prevention and identified PST and PSM as part of a national action plan to prevent adverse drug events.

Anticoagulation management is, by nature, interdisciplinary. Nurses, physician medical directors, and pharmacists work collaboratively to develop dosing protocols and treatment algorithms that are used on a daily basis by the clinical nurses who interact with patients. Patient education is essential to the success of anticoagulation management, as patient adherence and outcomes are enhanced when patients fully understand their care. AMS clinical nurses have the primary responsibility for patient education and follow up. PST patients require even more intervention from clinical nurses as the teaching is more extensive, the testing is more frequent, and the on-going follow-up involves more coaching and support. At the same time, meeting these patient care needs highlights the unique and valuable contribution of nurses in maintaining the health of this population.

The MGH AMS uses DAWN AC® Anticoagulation Software to support the management of anticoagulation care. This computerized, anticoagulation tracking application uses clinically validated algorithms to support decision making involved in the various phases of anticoagulation treatment (e.g. induction, maintenance, and bridging). It facilitates access to patient information demonstrating anticoagulation quality outcomes, such as time-in-therapeutic-range, rates of major bleeding, and thromboembolic events. The software also provides reports relevant to patient visits (e.g. missed appointments or testing), and trends in the number of patients managed in the clinic and cared for by each nurse.

Example: Initiative to Increase Patient Self Testing

Despite the documented success of anticoagulation PST at MGH, the number of patients managed through PST remained relatively small. As a reference, in July – September of 2013, the total number of PST patients receiving maintenance therapy was 586 or about 13.3% of AMS patients (attachment EP6a.c).

Moulaison and Oertel took a critical look at the number of AMS patients in PST and began a series of interventions aimed at increasing the number electing PST. The interventions included:

- Maintaining an ongoing focus on PST at AMS Staff Meetings
  - Staff meeting minutes from 6/9/2014 are an example (attachment EP6.a.d)

- Obtaining approval for Oertel to be a credentialed provider at MGH in September 2014
  - This change allowed Oertel to place the initial order for the change to PST from phlebotomy testing which resulted in a streamlined workflow for AMS clinical nurses
• Presenting educational materials promoting PST
  o For example, an overview by Oertel of the highlights from the Anticoagulation Forum’s 13th National Conference on Anticoagulation Therapy, April 23-25, 2015, including the plenary lecture “Patient Self Testing for Warfarin Therapy: Working with Industry, Achieving Reimbursement and Current Best Practices

• Frequently updating and communicating relevant PST vendor information
  o Home testing vendors and their contact information change over time. Oertel revises the contents with a focus on contact names and numbers, providing the AMS clinical nurses with accessible and up to date information which expedites PST initiation. A section of the vendor information list, updated in October 2016, is provided as an example below:

<p>| AMS Independent Diagnostic Testing Facilities |</p>
<table>
<thead>
<tr>
<th>IDTF</th>
<th>Contact &amp; E-Mail</th>
<th>Phone</th>
<th>Fax</th>
<th>Number Patient Calls to Report Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alere</td>
<td>Kim Marcantonio, <a href="mailto:Kim_Marcantonio@alere.com">Kim_Marcantonio@alere.com</a> (formerly Tapestry and QAS) (Bruce Aiken-860-608-9688)</td>
<td>877-262-4669</td>
<td>925-806-9678</td>
<td>877-262-4669, select option 2, listen and follow prompts</td>
</tr>
<tr>
<td>Remote Cardiac Services (RCS) [Delight Medicals] (formerly Philips)</td>
<td>Mark Russell, Territory Account Manager MA, <a href="mailto:mrusse11@remotecardiacservice.com">mrusse11@remotecardiacservice.com</a> Robert Syrbe (Rsyrbe)</td>
<td>603-321-7239</td>
<td>877-618-2754</td>
<td>800-804-0002 (direct)</td>
</tr>
<tr>
<td>Roche (CoaguChek Patient Services)</td>
<td>Gretchen Kuklish, <a href="mailto:gretchen.kuklish@roche.com">gretchen.kuklish@roche.com</a> (#1) Richard Howenstein, <a href="mailto:richard.howenstein@roche.com">richard.howenstein@roche.com</a> (#2)</td>
<td>317-521-0255</td>
<td>866-849-9120</td>
<td>800-780-0675 or web or automated phone</td>
</tr>
</tbody>
</table>

• Assigning PST articles to all AMS nurses and adding them to the AMS unit-based orientation materials
  o For example The Efficacy of Patient Self-Testing to Manage Patients on Warfarin, Corinne R. Fantz, PhD., DABCC, 2016)

• Posting of all PST vendor newsletters for AMS clinical nurses

The efforts of the AMS nurses were successful in increasing the number of patients electing PST, and the number increased to 632 in the by the last quarter of CY 2016. The increase in number of PST patients from quarter 3 of CY 2013 to the quarter 4 of CY 2016 was approximately 7.8 %, and the overall percentage of MGH AMS PST patients increased to 15.5%. Note that the slight dip in the number of PST patients in CY 2016 Quarter 3 is explained by the planned reduction in establishing new PST patients during the training and immediate aftermath of eCare implementation (attachment EP6a.c).
Hoping to achieve even greater gains, in December 2016 Moulaison and Oertel summarized data for the number of PST patients and encouraged the MGH AMS clinical nurses to propose a “stretch” goal for a desired percentage of PST patients in the clinic. The AMS nurses decided that they should set a goal of attaining 25% of patients being managed through PST.

In January 2017, Moulaison launched a “Performance Measures and Report Card Initiative” which presented metrics such as Time in Therapeutic Range, the number and percentage of PST patients, and a summary of communication methods used with patients by each clinic nurse. His letter to the clinical nurses explained the purpose of the initiative as promoting continuous improvement of care to the MGH AMS patients (attachment EP6.a.e). While this effort does identify high performers, it’s greatest value lies in its contribution to promoting discussion and sharing of best practices among AMS clinical nurses.

The MGH AMS nurses have incorporated the specialty standards and specific recommendations for PST that are included in the Consensus Statements for Anticoagulation and the specific Consensus Guidelines for PST from the AC Forum in the delivery of their patient care. They continue to use strategies to increase the number of patients electing PST while also ensuring that AMS patient outcomes are optimal.

In January 2017, Oertel presented “Changing Landscapes & Options for Patients: Self Testing & Management with VKA therapy or DOACs” indicating the continued focus on promotion of PST, combined with the newer focus on the MGH AMS role in management of patients receiving Vitamin K Antagonists (VKA) and Direct Oral Anticoagulants (DOACs).