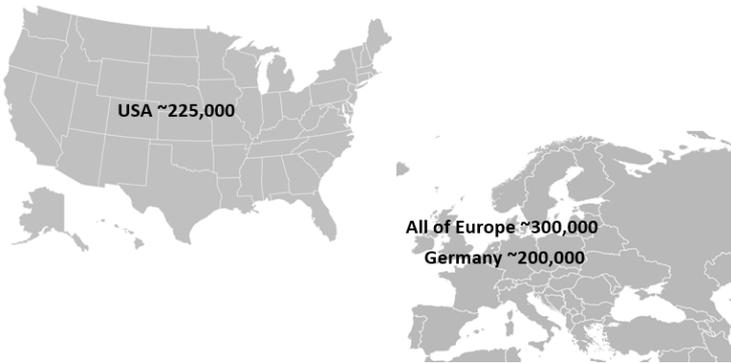


Patient self-testing at Massachusetts General Hospital AMS

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The map below shows the number of self-testing patients in the USA and Europe. Of the 300,000 patient self-testers in Europe, two-thirds of those are in Germany. 225,000 patients in the USA represents 5.6% of the warfarin population as self-testers.

A range of studies have been undertaken that look at the efficacy of self-testing for anticoagulation patients compared to Usual or Clinic Care and these generally show an improvement in

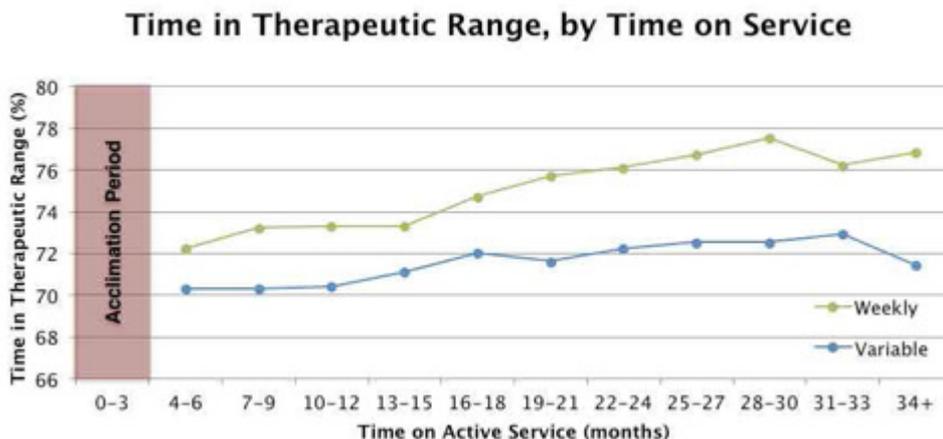
outcomes from TTR and bleeding events to mortality.

Summary of meta-analyses comparing PST/PSM to Usual or Clinic Care¹⁻³

	Heneghan et al Lancet 2006	Garcia-Alamino et al Cochrane 2010	Bloomfield et al Ann Intern Med 2011
# Patients	3049	4723	8413
# studies	14	18	22
TE Events	OR 0.45 (95% CI 0.30-0.68)	RR 0.50 (95% CI 0.36-0.69)	OR 0.58 (95% CI 0.45-0.75)
Major Bleed Events	OR 0.65 (95% CI 0.42-0.99)	RR 0.87 (95% CI 0.66-1.16)	RR 0.87 (95% CI 0.75-1.05)
Mortality	OR 0.61 (95% CI 0.38-0.98)	RR 0.64 (95% CI 0.46-0.89)	OR 0.74 (95% 0.63-0.87)

TE=Thromboembolic, OR=Odds Ratio, RR=Relative Risk, CI=Confidence Interval

TTR by CoaguChek Patient Services⁴



Number of Patients: 18,243

Number of INRs: 1,055,265

Time Range: 2008-2015

Mean TTR Variable = 70.2%

Mean TTR Weekly = 72.8%

A number of advantages of partnering with Independent Diagnostics Testing Facilities (IDTFs) were highlighted including:

- The ability to review/determine the insurance benefits and patient's out of pocket costs
- Providing in-home training and supplies (testing meter and strips)
- Communicating INR results to warfarin managers via fax/page/phone/web portal

- Ongoing support of patient compliance with prescribed testing frequency
- Technical support and assistance

As of September 2016, Massachusetts General Hospital AMS had a self-testing patient population of 560, using eight different IDTFs, and representing 14% of the clinic population. Patient self-testers are recorded within DAWN AC under the 'Patient Self-Testing lab' type and the top indications for this patient cohort are Atrial Fibrillation, VTE, Heart Valve Replacements and Hypercoagulable States.

A performance improvement project to determine if TTR improved for patient self-testers was carried out by the AMS, the results of which are below and which were also included in a poster presentation at the ACF conference in May 2011.

ANALYSIS OF TTR PRE AND POST PST											
	Pre					Post					P value
	Mean	SD	Median	Q1	Q3	Mean	SD	Median	Q1	Q3	
F/U days*	693.8	439.7	769	253	1135	297	260.7	187	100	454	
INRs_30 days	2.8	2.9	2	1.5	3.2	3.7	1.3	3.9	3	4.3	<0.0001
Interval	15.2	8.1	15.1	9.9	19.2	14.5	48.1	8.1	7.3	11	<0.0001
TTR	69.5	16.1	72.9	60.7	79.5	74.6	18.8	77.6	64.4	88.8	<0.001

*F/U days = # treatment days from first to last INR, INRs_30 days = # INRs every 30 days, Interval = intervals between INRs, TTR calculated using Rosendaal method

Further as yet unpublished data from the AMS from December 2014 to March 2015 looks at INR performance in patient self-testers versus laboratory testing for a therapeutic range of 2-3.

Testing	# of PTs	# of INRs	TTR	# INRs 1.3 or below	# INRs 5 or above	# INRs 7 or above
PST	413	3,450	75	164 (4.75%)	21 (0.6%)	2 (0.06%)
Laboratory	3,457	18,018	73.9	1,175 (6.5%)	156 (0.87%)	33 (0.18%)

Frequency of INR testing for patient self-testers is 7 days at the start of treatment and increasing to no more than 14 days once established. This frequency is set within the patient's Treatment Plan in DAWN AC.

The AMS needed to be innovative and embrace new technology to create solutions for dealing with increased numbers of INRs for patient self-testers who tested more frequently than Usual Care patients, whilst tailoring their approach to those who benefitted most from increased frequency. This involved looking at:

- **Incoming INRs to clinic**
 - From patient (dedicated phone line, interactive voice-response system, web portal, mobile app)
 - From IDTF (Fax, phone, page, web portal retrieval)
- **Outgoing communication to assess and/or inform patients**
 - Telephony services
 - Email or mail (USPS mail has time delay)
 - Smart phones
 - Mobile apps
 - Web portals

Self-testing brings a number of benefits to provider and patients alike including:

- Empowerment – patients are actively engaged in their care and disease management
- Achieve more time in therapeutic range – therefore more likely to reduce adverse events and the associated health care costs
- Convenience – removes limitations associated with getting to a laboratory
- Preference for fingerstick over venous puncture (poor venous access)
- Improve quality of life – less time spent with travelling to/from laboratories, doctor's office etc.
- Maintains consistent lab for patient – mobile lifestyle, frequent traveller

In summary, the right patient selection and right educational support, makes patient self-testing an attractive option for routine INR testing by achieving a greater percent of time in therapeutic range and limiting the times INRs get in the danger zones. Actively engaging patients in their health care management offers many benefits and reinforces compliance.

A number of practical tips were outlined both at the clinic level and for getting started with PST.

At the clinic level:

- Utilize PST agreement (supplements general AMS agreement). Scan and attach to DAWN AC Documents Tab
- Practical / educational discussion with patient for expectations and practicalities
- Organize / streamline the process
- Document in clinic and hospital records

Getting started:

- Physician Order for Patient Self Testing (IDTF referral)
- Patient Authorization Form (not all IDTFs require this) for patient's signature to release healthcare information to determine benefit coverage
- Use ICD-10 codes for approved diagnoses [include: Z79.01 Long term (current) use of anticoagulants]

The presentation was brought to a close with a list of reasons explaining the introduction/growth of patient self-testing within anticoagulation services:

- Patients prefer it for many reasons
- Improves the quality of INR control, avoids danger zones
- Likely to reduce poor outcomes with better control
- Right option for the right patient
- This is patient-focused – engages patients in their health care management

References:

1. Heneghan C et al. *Lancet* 2006;367:404-411
2. Garcia-Alamino JM et al. *Cochrane Database Syst Review*. 2010:CD003839
3. Bloomfield HE et al. *Ann Intern Med* 2011. 154:472-482
4. Fantz CR. *The efficacy of patient self-testing to manage patients on warfarin. White paper published by Roche 2016*