

Improvement In Warfarin Patient Management Through Patient Self Testing (PST): Implications for Public and Private 3rd Party Payers and Public Health

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(Anticoagulation Forum: 12th National Conference on Anticoagulant Therapy, May 9-11, 2013 Phoenix, AZ)

Prevailing Market Conditions

Anticoagulation Management in U.S. – TABLE 1

Safe and effective anticoagulation (AC) management is essential to prevent blood clots that cause DVT/PE and stroke. We are entering a new age in AC management in the U.S. with the advent of

- a) new FDA-approved oral anticoagulants, and
- b) expanding patient self-testing (PST) for patients who use warfarin.

It is estimated that over 2.5 million patients are using “blood thinners”^{*} and about 80% of these patients use warfarin. While the percentage who use warfarin is expected to decrease, the overall demand is not expected to change dramatically due to the aging population as that cohort has an increased risk of atrial fibrillation (AF) as well as greater vulnerability to VTE blood clots.

^{*}Estimates are as high as 4 million.

INR Testing in U.S. – TABLE 2

It is essential that patients using warfarin be monitored through INR testing so that they maintain appropriate time in therapeutic range (TTR) to ensure that their risk of bleeding or clotting is minimized. Most patients receive INR testing at AC clinic, a physician’s office or independent laboratory. Given the inconvenience involved, many patients do not test regularly and are not in consistent TTR. PST should be available to most patients on warfarin because it improves the frequency of testing and the maintenance of TTR. However, relatively few patients (75,000^{*} out of 2.5+million patients on warfarin) take advantage of home testing. This is of major concern because studies have demonstrated that improved medical outcomes (as measured by TTR) are clearly associated with the use of PST. Patients on PST have fewer hospital readmissions, lower health care expenditures, and an improved quality of life since there is no need for routine clinic visits for INR testing.

^{*}Estimates are as high as 150,000.

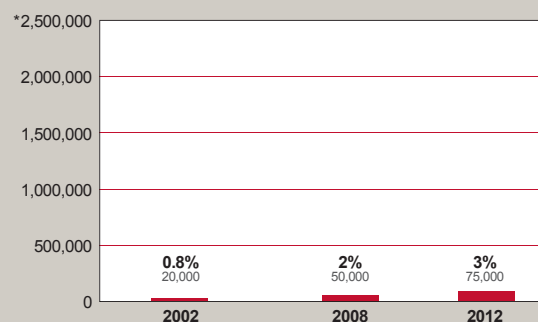
Patient Self-Testing Barriers – TABLE 3

1. Warfarin Market in the U.S.

Indication	Total Market	Estimated Population
Atrial Fibrillation	40-50%	1,125,000
VTE	30-40%	875,000
Other	20-30%	500,000
Total		2,500,000

^{*} Increased suitable population for VTE is based on younger age of patients

2. Estimated Growth of PST in the U.S.



^{*} Estimated chronic warfarin users, U.S.

3. PST Barriers

- PST Costs (POC equipment and test strips)
- Patient Reimbursement/Coverage - Public Sector (e.g. CMS)
- Patient Reimbursement/Coverage - Private Sector (e.g. BC/BS)
- Provider Reimbursement/Coding (clinics/phone calls/review and interpretation of results) - Public Sector
- Provider Reimbursement (clinics/phone calls/review and interpretation of results) - Private Sector
- Lack of patient/clinician awareness of value of PST (not for all patients-education/training required)

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Weight of Evidence

Overcoming Barriers – NBCA will take the following steps:

- **PST White Paper** - Develop a white paper – “PST Call to Action”
 - ▶ **Medical benefits of PST** – TABLE 4
 - ▶ **Cost effectiveness of PST** – TABLE 5
 - ▶ **Quality of life benefits of PST** – TABLES 6 & 7
 - ▶ Specific steps needed to overcome PST obstacles

Patient Self-Testing Opportunities

Expanding PST in the U.S. represents three important opportunities:

- Improved health outcomes for patients with clotting disorders and AF utilizing warfarin
- Reduced health care costs associated with DVT/PE and stroke resulting from suboptimal AC management and INR monitoring
- Improved quality of life as patients are freed up from numerous routine visits to clinics or doctors' offices for

4. Improvement in Health Outcomes/ Cost Effectiveness

Improvement in Warfarin Management in 10 Short Years

STUDIES:	1989-1993	2003-2011
Stroke rates:	2.09%/yr	1.66%/yr
TTR ≥60%:	2/6 trials (33%)	7/8 trials (88%)

Agarwal, S. 2012. Archives of Internal Medicine

Improvement in TTR Reduces Health Care Costs, Improves Quality of Life

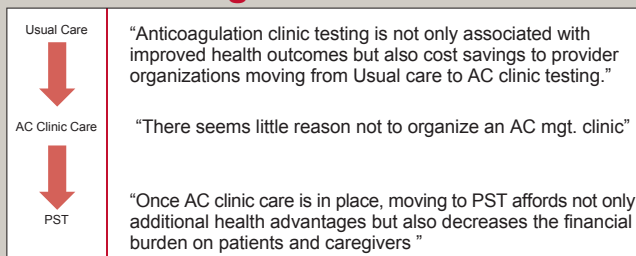
Scenario	Ischemic Strokes (95% CI)	Major Hemorrhages (95% CI)	Deaths (95% CI)	Total Events (95% CI)	Cost, \$ Millions (95% CI)	Utility, QALYs (95% CI)
Status Quo	3872 (3749–3994)	3318 (3218–3429)	8285 (8109–8449)	15 475 (15 275–15 678)	368 (358–377)	121 685 (121 472–121 888)
Change in TTR						
Estimated Adverse Events Averted, Costs Saved, or QALYs Added by Improving TTR						
+2.5%	96 (-74 to 258)	136 (-24 to 289)	332 (126–554)	584 (302–883)	8.1 (-4.0–20.9)	458 (161–748)
+5%	183 (8–348)	269 (118–416)	663 (405–869)	1115 (825–1389)	15.9 (3.2–28.4)	893 (575–1154)
+7.5%	259 (91–421)	396 (251–548)	964 (722–1194)	1619 (1315–1912)	22.9 (10.9–35.2)	1255 (862–1528)
+10%	332 (171–499)	523 (377–685)	1233 (1000–1457)	2088 (1811–2364)	29.7 (16.7–41.7)	1606 (1138–1900)
+15%	454 (280–628)	755 (607–910)	1711 (1480–1931)	2920 (2630–3200)	41.3 (28.9–54.3)	2224 (1570–2224)
+20%	557 (394–720)	965 (826–1120)	2092 (1857–2307)	3614 (3320–3882)	51.5 (39.5–63.7)	2721 (2430–2983)

95% CIs are calculated by bootstrapping with 1000 iterations. Utilities are given in QALYs. Some of the estimates of benefit from the smallest TTR improvement that we modeled (2.5%) cannot be distinguished from zero at the 95% confidence level.

67,000 patients model

Rose, A. 2011. Circulation

5. Cost Effectiveness of Patient Self-testing



For Those Patients Well-suited for PST

“The consensus agrees that there are several points in favor of PST (PSM)... a higher degree of medical safety, increased patient education, improved response to changes in lifestyle, increased independence for the patient and improved quality of life”

Lafata, J. (2000). Anticoagulation clinics and patient self testing for patients on chronic warfarin therapy: a cost-effectiveness analysis. Journal of Thrombosis and Thrombolysis, 9, S13-S19.

Ansell J, Jacobson A, Levy J, Voller H, Hasenkamp JM; International consensus guidelines prepared by International Self-Monitoring Association for Oral Anticoagulation (ISMAAP). Journal of Cardiology, 2005; 99:37-45.

6. Patients Suitability for Patient Self-testing (Patients at 28 VA Medical Centers)

Self-testing a Practical Solution for Many Warfarin Patients

80%	“A high proportion of a diverse group of patients achieved competency of INR self-testing either on their own or with the aid of care provider.”
87%	“Adherence of weekly self-testers within 2 days of goal.”

Matchar, D. (2010). NEJM, 363:17

7. Patient Satisfaction Higher with PST, Clinical Trials, Real-world

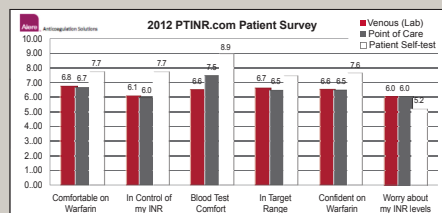
Patient satisfaction with anticoagulation, as measured by the DASS, was greater in the self-testing group than in the clinic-testing group.

2010. NEJM, THINRS Trial

8 of 11 clinical studies found that patient satisfaction, quality of life, or both was better in the PST or PSM group than in the usual care group.

Bloomfield, H. 2011. Annals of Internal Medicine

1,921 Real-world Warfarin Patients Preferred Self-testing



2012 data on file, Alere

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Targeting Future Growth

Chest Guidelines Support PST Expansion – **TABLE 8**

8. Chest Guidelines

3.6. For patients treated with VKAs 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 (2B). For all other patients, we suggest monitoring that includes the safeguards in our best practice statement 3.5.

Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines, February 2012.

“PST Call to Action” and Coalition – **TABLE 9**

9. PST Target Impact in the U.S. Market

Indication	Total Market	Estimated Population	PST Suited	Target	3 Year Target	5 Year Target
Atrial Fibrillation	40-50%	1,125,000	50%	562,500	10%	20%
					56,250 patients	112,500 patients
VTE	30-40%	875,000	60%*	525,000	15%	25%
					78,750 patients	131,250 patients
Subtotal:	—	2,000,000	54.4%	1,087,500	135,000**	243,750**
Other	20-30%	500,000	***	***	***	***
Total	—	2,500,000	—	—	—	—

*Higher “PST suited” percent projected for VTE is based on younger age of VTE patients in contrast with AF patients.

** Conservative growth estimates

*** Other indications for warfarin use beyond the scope of NBCA projections

For these reasons, NBCA is seeking to increase PST in the U.S. to 10-15% of suitable patients (>135,000) within 3 years and 20-25% (>240,000) of all suitable patients using warfarin within 5 years.

- **PST Call to Action** - Develop a PST Development Strategic Plan to implement the “PST Call to Action” to overcome obstacles to expanding PST
- **PST Coalition** - Form and mobilize a coalition of patients, clinicians, 3rd party payers and industry to expand PST with legal/health policy and health economics expertise

13 additional citations are available at this poster session or upon request from the National Blood Clot Alliance (info@stoptheclot.org)

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