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 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.

<table>
<thead>
<tr>
<th>Indication</th>
<th>Total Market</th>
<th>Estimated Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial Fibrillation</td>
<td>40-50%</td>
<td>1,125,000</td>
</tr>
<tr>
<td>VTE</td>
<td>30-40%</td>
<td>875,000</td>
</tr>
<tr>
<td>Other</td>
<td>20-30%</td>
<td>500,000</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>2,500,000</td>
</tr>
</tbody>
</table>

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

2. Estimated Growth of PST in the 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
- (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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4. Improvement in Health Outcomes/ Cost Effectiveness

Improvement in Warfarin Management in 10 Short Years

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke rates:</td>
<td>2.09%/yr</td>
<td>1.86%/yr</td>
</tr>
<tr>
<td>TTR ≥60%:</td>
<td>2/6 trials (33%)</td>
<td>7/8 trials (88%)</td>
</tr>
</tbody>
</table>

Agarwal, S. 2012. Archives of Internal Medicine

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

<table>
<thead>
<tr>
<th>TTR</th>
<th>Costs</th>
<th>Major hemorraghes</th>
<th>Deaths</th>
<th>Total Events</th>
<th>Cost, $ millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>TTR</td>
<td>80%</td>
<td>15%</td>
<td>15%</td>
<td>30%</td>
<td>45%</td>
</tr>
<tr>
<td>75%</td>
<td>15%</td>
<td>20%</td>
<td>20%</td>
<td>40%</td>
<td>60%</td>
</tr>
<tr>
<td>70%</td>
<td>15%</td>
<td>30%</td>
<td>30%</td>
<td>60%</td>
<td>90%</td>
</tr>
</tbody>
</table>


5. Cost Effectiveness of Patient Self-testing

"Anticoagulation clinic testing is not only associated with improved health outcomes but also cost savings to provider organizations moving from Usual care to AC clinic testing."

"There seems little reason not to organize an AC mgmt. clinic"

"Once AC clinic care is in place, moving to PST affords not only additional health advantages but also decreases the financial burden on patients and caregivers."

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."

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.”


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.

Bloomfield, H. 2011. Annals of Internal Medicine

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

2010, NEJM, THINRS Trial

82% Preferred PST over clinic care, 84% satisfied with self-testing process, 88% willing to continue 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.


“PST Call to Action” and Coalition – TABLE 9

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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Total Market</th>
<th>Estimated Population</th>
<th>PST Suited</th>
<th>Target</th>
<th>3 Year Target</th>
<th>5 Year Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial Fibrillation</td>
<td>40-50%</td>
<td>1,125,000</td>
<td>50%</td>
<td>562,500</td>
<td>10%</td>
<td>20%</td>
</tr>
<tr>
<td>VTE</td>
<td>30-40%</td>
<td>875,000</td>
<td>60%*</td>
<td>525,000</td>
<td>15%</td>
<td>25%</td>
</tr>
<tr>
<td><strong>Subtotal:</strong></td>
<td></td>
<td><strong>2,000,000</strong></td>
<td>54.4%</td>
<td>1,087,500</td>
<td><strong>135,000</strong></td>
<td><strong>243,750</strong></td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>20-30%</td>
<td>500,000</td>
<td>***</td>
<td>***</td>
<td>***</td>
<td>***</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>2,500,000</strong></td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

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