Master Class
Patient Self-Testing

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Massachusetts General Hospital

Anticoagulation Forum
Master Class • April 20, 2017 • 11 – 11:30am
Disclosures

• Roche Diagnostics – advisory board
• Alere – educational services
Objectives

• Discuss benefits of patient self testing
• Facilitate discussion to promote PST in your clinic setting
How many patients in your clinic self test at home?

A. 0
B. 1-50
C. 51-100
D. 101-150
E. 151-200
F. 201-250
G. 251-300
H. >300
Based on the number of PSTers, what percent of your clinic population does this represent?

A. 1-4%
B. 5-9%
C. 10-14%
D. 15-20%
E. >20%
Top Indications for PST by INR range

![Bar chart showing top indications for PST by INR range. The bar chart indicates that AF/Af is the most common indication, followed by VTE, and then Heart Valve Replacements. The chart also shows data for Hypercoaguable States and other categories.]
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td># Patients</td>
<td>3049</td>
<td>4723</td>
<td>8413</td>
</tr>
<tr>
<td># studies</td>
<td>14</td>
<td>18</td>
<td>22</td>
</tr>
<tr>
<td>TE Events</td>
<td>OR 0.45 (95% CI 0.30-0.68)</td>
<td>RR 0.50 (95% CI 0.36-0.69)</td>
<td>OR 0.58 (95% CI 0.45-0.75)</td>
</tr>
<tr>
<td>Major Bleed Events</td>
<td>OR 0.65 (95% CI 0.42-0.99)</td>
<td>RR 0.87 (95% CI 0.66-1.16)</td>
<td>RR 0.87 (95% CI 0.75-1.05)</td>
</tr>
<tr>
<td>Mortality</td>
<td>OR 0.61 (95% CI 0.38-0.98)</td>
<td>RR 0.64 (95% CI 0.46-0.89)</td>
<td>OR 0.74 (95% CI 0.63-0.87)</td>
</tr>
</tbody>
</table>

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

Garcia-Alamino JM et al. Cochrane Database Syst Review. 2010:CD003839
INR performance: PST vs laboratory

Self Testers = 563 (all INR ranges, ~15% of clinic population)

### INR RANGE 2-3

<table>
<thead>
<tr>
<th>Testing</th>
<th># of PTs</th>
<th># of INRs</th>
<th>TTR</th>
<th># INRs 1.3 or below</th>
<th># INRs 5 or above</th>
<th># INRs 7 or above</th>
</tr>
</thead>
<tbody>
<tr>
<td>PST</td>
<td>462</td>
<td>6617</td>
<td>77.5</td>
<td>73 (1.1%)</td>
<td>22 (0.3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Laboratory</td>
<td>2945</td>
<td>25650</td>
<td>75.2</td>
<td>747 (2.9%)</td>
<td>176 (0.7%)</td>
<td>26 (0.1%)</td>
</tr>
</tbody>
</table>

### INR RANGE 2.5-3.5

<table>
<thead>
<tr>
<th>Testing</th>
<th># of PTs</th>
<th># of INRs</th>
<th>TTR</th>
<th># INRs 1.3 or below</th>
<th># INRs 5 or above</th>
<th># INRs 7 or above</th>
</tr>
</thead>
<tbody>
<tr>
<td>PST</td>
<td>88</td>
<td>1270</td>
<td>73</td>
<td>5 (0.4%)</td>
<td>14 (1.1%)</td>
<td>1 (0.1%)</td>
</tr>
<tr>
<td>Laboratory</td>
<td>220</td>
<td>2237</td>
<td>69</td>
<td>25 (1.1%)</td>
<td>30 (1.3%)</td>
<td>9 (0.4%)</td>
</tr>
</tbody>
</table>

Unpublished MGH AMS data 9/28/16 – 2/18/2017
Patient Eligibility

- Willing
- Able
- Reliable
- *Interested!*
Who trains patients on self testing?

A. Clinic personnel, bill using G0248
B. Clinic personnel, no billing
C. IDTF
D. Other
INR Meters in use today

Coaguchek XS

Coag-Sense
Working with Industry: Collaboration with IDTFs (Independent Diagnostic Testing Facilities)

- Advanced Cardio Services (under Lincare) ▪
  www.advancedcardioservices.com
- Agile Home Monitoring ▪
  www.agilehm.com
- Alere Anticoagulation Solutions ▪
  AlereCoag.com
- Cardiac Remote Services (under Lincare) (formerly Philips) ▪
  www.remotecardiacservices.com
- CardionetINR ▪
  www.cardionetinr.com
- mdINR (under Lincare) ▪
  www.mdinr.com
- Patient Home Monitoring - PHM ▪
  www.myphtm.com
- Real Time Diagnostics ▪
  www.rtdlabs.com
- Roche – Coaguchek Patient Services ▪
  www.coaguchek-usa.com
- US Healthcare LLC (DME, limited IDTF) ▪
  www.ushsnj.com
PST N = 578 (15% of clinic population)
March 16, 2017, unpublished data MGH AMS
Advantages of partnering with IDTFs

• Review/determine insurance benefit and patient’s out of pocket costs
• Provide in-home training and supplies (testing meter and strips)
• Communicate INR results to warfarin manager via fax/page/phone/web portal
• Ongoing support of patient compliance with prescribed testing frequency (if desired)
• Technical support and assistance for patients
Does your clinic receive revenue for review and interpretation of INR using billing code G0250?

A. Yes
B. No
What is the most common reason for not implementing PST in your clinic?

A. Insurance issues
B. Don’t believe patients can do this
C. Time involved
D. It would mean a loss in revenue to my clinic
E. Other
What INR testing frequency do you require for your PST population? (for stable patients)

A. Weekly
B. 2 weeks
C. 1 or 2 week intervals
D. 3 weeks
E. 4 weeks
F. Other
## INR Testing Frequency

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>HQACM</th>
<th>PST Every 4 wks</th>
<th>PST Weekly</th>
<th>PST Twice weekly</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>N at 1 yr</td>
<td>690</td>
<td>335</td>
<td>102</td>
<td>149</td>
<td>104</td>
<td></td>
</tr>
<tr>
<td>TTR %</td>
<td>62.1</td>
<td>60.8</td>
<td>59.9</td>
<td>63.3</td>
<td>66.8</td>
<td>.0068</td>
</tr>
<tr>
<td>% In-range INRs</td>
<td>57.5</td>
<td>54.8</td>
<td>53.5</td>
<td>61.5</td>
<td>64.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>% Extreme INRs ≤1.5 or ≥4.0</td>
<td>11.4</td>
<td>12.6</td>
<td>13.7</td>
<td>9.6</td>
<td>7.9</td>
<td>0.03</td>
</tr>
<tr>
<td>Mean DASS*</td>
<td>48</td>
<td>49.5</td>
<td>47</td>
<td>46.2</td>
<td>47</td>
<td>0.53</td>
</tr>
</tbody>
</table>

*DASS=Duke Anticoagulation Satisfaction Score, lower DASS score, higher satisfaction

- Conclusion from THINRS sub-study: “more frequent PST improved TTR and reduced the proportion of poorly managed patients”

Self-Testing Analysis Based on Long-term Evaluation (STABLE)

- Assessed 2 groups determined by testing frequency (TF):
  - Variable
  - Weekly
- 42 month observation

### Table:

<table>
<thead>
<tr>
<th>All TF</th>
<th>Variable TF</th>
<th>Weekly TF</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>Mean TTR %</td>
<td>SD</td>
<td>N</td>
</tr>
<tr>
<td>29,457</td>
<td>69.7</td>
<td>18.6</td>
<td>24,907</td>
</tr>
</tbody>
</table>

TTR by CoaguChek Patient Services

# Patients = 18,243 ▪ #INRs = 1,055,265 ▪ 2008-2015

- Mean TTR Variable = 70.2%
- Mean TTR Weekly = 72.8%
  p<0.0001

Fantz CR. The efficacy of patient self-testing to manage patients on warfarin. White paper published by Roche 2016
How to manage increased # INRs?

Use innovation and technology to create solutions

– How patients report
  • Phone, keypad, web portal, mPOC*

– 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

Tailor approach to who benefits most from increased frequency

*mPOC – wireless connectivity from meter direct to CoaguChekXS ®
Clinical outcomes can be improved with better TTR and avoidance of very high or low INRs.

A. Agree
B. Disagree
C. Maybe
Practical tips to get started

• Utilize PST agreement (supplements general AMS agreement). Attach a copy to patient’s record.
• Practical / educational discussion with patient for expectations. Summarize in writing.
• Organize / streamline the process
  – referral entry and e-sign to IDTF
  – INR retrieval from website (eliminate faxes)
  – Electronic interface to eliminate faxes/manual entry
• Documentation in clinic and hospital records
More Practical Tips

• Physician Order for Patient Self Testing – use electronic form and pre-populate with your clinic details, who is credentialed to sign in clinic?

• Send insurance information with referral to IDTF (patient permission obtained and documented in advance)

• Keep patients actively involved – e.g. no action by clinic until signed PST agreement returned
Patient self testing of INRs at home.

I reviewed concepts and expectations for patient self testing (PST) at home with NAME. Patient's compliance in past is acceptable. NAME (or his/her significant other) seems able to perform and wishes to proceed. Permission was obtained to release contact information and insurance information to the Independent Diagnostic Testing Facility (IDTF) we will eventually work with.

I reviewed the purpose of the AMS Patient Agreement for PST and will send to patient. Patient understands we need this document signed and returned before the PST referral is initiated. Additionally, I stressed the importance of weekly testing in order to maximize the benefit to maintain therapeutic INRs. I reviewed expectations for testing, reporting INR values directly to the IDTF and our plan to communicate results and dose instructions to patient. This was summarized in writing and provided to NAME, he/she understands and agrees to our plan.
Determine what’s best for your clinic

Who will be testing?
Where to report?
  – Emphasize AM testing, Mon-Thu
  – Avoid weekends and holidays
Sample worksheet to stay organized

1. Discuss what PST entails, send PST agreement. Document in Epic
2. When above returned, complete referral
3. Place referral in Lynn’s mailbox to review and sign (or credentialed provider)
4. Fax to IDTF
5. Addend Epic PST note and update lab on patient record in DawnAC
Do you have a plan to increase the number of self testers in your clinic?

A. Yes  
B. No  
C. Maybe
MGH AMS – 578 PST patents – 15% of population

MGH AMS - 578 patient self-testers (15% of current active patient populations) 3/16/2017
Future Considerations

• Where does PST fit in the changing landscape with DOACs?
• How can you capitalize on technologies to be more efficient?
• How can you get data to demonstrate value self testing enables?
Resource Center

Overview

The Anticoagulation Centers of Excellence Resource Center is a comprehensive library for healthcare providers. Our multidisciplinary committee of physician, pharmacist, and nurse experts has assembled this collection of clinical tools. These resources are provided as examples from high-performing services. Many resources were submitted from Anticoagulation Forum members, and while all are instructive, some may not be directly applicable to your service. Our expansive collection of resources includes disease-specific algorithms, policies and procedures for running your service, guidelines for transitions of care, and patient education materials. In addition, we have included the latest information on the new target-specific oral anticoagulants.

If you have a resource that should be included in our Resource Center, please email it to excellence@acforum.org.

Browse by Pillar

- Drug Therapy Management
- Disease State Management
- Transition and Coordination of Care
- Service Operational Performance
- Patient and Family Education
- Comprehensive Toolkits
- Apps for Practitioners
- Additional Resources