Evidence-Based Best Practices for Outpatient Management of Warfarin

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Disclosures for Sara Vazquez

- Editorial consultant for UptoDate, Inc.
Why quality improvement for warfarin management?

• It’s our job to keep patients safe!
• Evidence shows that
  better warfarin management = better outcomes for patients
• How much does it really count?
  • In a VA study of 67,077 AF patients, with a 2-year time horizon:

<table>
<thead>
<tr>
<th>Improving TTR by 5%</th>
<th>Improving TTR by 10%</th>
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<tbody>
<tr>
<td>Prevented 1114 adverse events including 663 deaths</td>
<td>Prevented 2087 adverse events including 1233 deaths</td>
</tr>
<tr>
<td>Gained 863 quality-adjusted life-years</td>
<td>Gained 1606 quality-adjusted life-years</td>
</tr>
<tr>
<td>Saved $15.9 million</td>
<td>Saved $29.7 million</td>
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Design, Setting, Sponsorship

• Quality Improvement Study

• Veterans Affairs (VA) health systems across the United States

• Study funded by the RAND Corporation and the VA Health Services Research and Development Service

## Donabedian Structure-Process-Outcome Model

<table>
<thead>
<tr>
<th>Structure</th>
<th>Process</th>
<th>Outcome</th>
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<tr>
<td>• Conditions under which care delivery takes place</td>
<td>• Specific actions performed for a patient</td>
<td>• Effect of health care on a patient</td>
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Outcomes

**Definitive Outcome**
- Directly affects the patient
- Thrombosis, bleeding, death

**Intermediate Outcome**
- Does not directly affect the patient but has been linked to definitive outcomes
- Time in Therapeutic Range (TTR)

- Outcomes require risk adjustment
  - Accounts for differences in clinical complexity

vs

instead of

Establishing the Baseline of the Quality of Anticoagulation Control within the VA

- Developed a **risk adjustment model** for anticoagulation control
- Profiled 100 VA centers using TTR as an intermediate outcome
- Average TTR of VA patients on warfarin for ≥ 6 months = 58%
- Centers varied from < 50% TTR to ~70% TTR

1. **Time Until Next INR After a VERY LOW INR (≤ 1.5) or VERY HIGH INR (≥4.0)**
   - What is the optimal INR recheck interval following an extreme INR?
   - VA: mean 6-18 day recheck interval after a VERY HIGH INR
   - VA: mean 10-24 day recheck interval after a VERY LOW INR
   - For every additional day in the follow-up interval after a high or low INR, the site mean risk-adjusted TTR was 1.1 percentage points lower

**GOAL:** follow-up interval of 7 days or less after extreme INR in at least 80%, stretch 90% of patients
Process Measures-2 and 3

2. Rate of Loss to Follow-Up While Receiving Warfarin
   • Does a longer gap between monitoring predict poor TTR?
   • How many gaps of > 56 days between INR tests?
   • VA: 0.19 to 1.78 gaps per patient-year
   • For each additional 0.1 gaps per patient-year, site mean risk-adjusted TTR was 0.9 percentage points lower

3. Mean Site INR
   • Proportion of patients at a site with INR between 2.3-2.7 (who, per guidelines, should have an INR goal of 2-3)
   • VA: 30-64%
   • For every additional 10% of patients in this range, site mean risk-adjusted TTR was 3.8 percentage points higher

## Summary of Process Measures

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<th>Process Measure</th>
<th>Pre-Intervention Assessment Outcome in the VA</th>
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</table>
| **Time until next INR after a Low INR ≤1.5 or a High INR ≥ 4.0**  
Goal should be ≥ 80% of patients having at least 7-day follow-up after low or high INR | For every additional day in the follow-up interval after a high or low INR, the site mean risk-adjusted TTR was 1.1 percentage points lower |
| **Rate of Loss to Follow-Up While Receiving Warfarin**  
Goal should be to minimize gaps of > 56 days between INR tests | For each additional 0.1 gaps per patient-year, site mean risk-adjusted TTR was 0.9 percentage points lower |
| **Mean Site INR**  
Proportion of patients at a site with INR between 2.3-2.7 (who, per guidelines, should have an INR goal of 2-3)  
Goal should be to achieve the highest percentage of patients possible meeting this criterion | For every additional 10% of patients in this range, site mean risk-adjusted TTR was 3.8 percentage points higher |

Qualitative Assessment

• Site visits
• Staff interviews
• Observations of care delivery

• 3 VA sites among the **best** risk-adjusted TTRs
• 3 VA sites among the **worst** risk-adjusted TTRs

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**6 Key Structures of Care Associated with High Anticoagulation Clinic Performance**

| Adequate levels of staffing, including both pharmacists and pharmacy technicians in a supporting role |
| Deliberate efforts to standardize clinical practice around **evidence-based guidelines** |
| The presence of a **quality champion** for the anticoagulation clinic |
| **Higher staff qualifications** (use of residency-trained pharmacists, as opposed to pharmacists without such training) |
| A climate of **ongoing group learning**, with frequent informal consultation among colleagues |
| **Internal efforts to measure performance**, whether through TTR or a less-sophisticated measure such as proportion of values in range each month |

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The Intervention: Dashboard

- 4-year intervention, piloted in VISN 1 of the VA (New England)
- Dashboard Measures (site-level and patient-level):
  1. TTR
  2. Time to next INR after low INR
  3. Time to next INR after high INR
  4. Gaps in monitoring
  5. Mean INR values
- Used to assess site-level improvement, compare among other VISN 1 sites
- Real-time patient-level assessment to target patients for intervention
- In addition to using the dashboard, sites were encouraged to implement the features characterizing high-performing sites

Post-Intervention Outcomes

• VISN 1 improved TTR by 2.8% vs 0.5% in other VA sites not in the pilot (p < 0.001)
• VISN 1 sites that improved more on process measures improved more on TTR
• In 2017 the dashboard was implemented by the VA nationwide

Application Beyond the VA

• Measure your own performance
• Have a working registry
• Try to emulate the aspects of structure of care associated with higher TTR

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Questions for Discussion

• Role of extended-interval monitoring (i.e., up to 12 weeks between INR checks)
• Describe “adequate levels of staffing”
• Applications to non-pharmacist based AC clinics?
• Describe some examples of efforts to apply evidence-based guidelines
• Elaborate on the rationale for higher staff qualifications-was residency the only component assessed or others? i.e., board-certification or CACP?
• Were there barriers to implementation of the dashboard?
• Is the amount of effort and funding required to implement these measures justified for only a 2.8% improvement in TTR?
• Comment on potential quality improvement measures for DOACs?