Management of Warfarin Patients Who Have Difficulty Getting INR Testing During COVID-19 Pandemic

Practical experiences and advice from the experts

Wednesday | March 25, 2020 | 8:00 PM ET

Expert Panel:

Scott Kaatz, DO, MSc
Arthur Allen, PharmD
Allison Burnett, PharmD
Geoff Barnes, MD, MSc

Nate Clark, PharmD
Tracy Minichiello, MD
Susan O’Neill, NP

Note: Please follow all advisories from the Centers for Disease Control and Prevention [www.cdc.gov](http://www.cdc.gov) and your local public health organizations.
Presenters

Scott Kaatz, DO, MSc
• President, AC Forum
• Medical Director for Professional Development and Research, Senior Staff Hospitalist, Henry Ford Hospital

Arthur Allen, PharmD
• Clinical Pharmacy Specialist, VA Salt Lake City Health Care System

Allison Burnett, PharmD
• Director, Inpatient Anticoagulation Management Service, University of New Mexico Health Sciences Center

Geoff Barnes, MD, MSc
• Assistant Professor of Medicine, Vascular and Cardiovascular Medicine, University of Michigan, Ann Arbor

Nate Clark, PharmD
• Clinical Pharmacy Supervisor, Kaiser Permanente Colorado

Tracy Minichiello, MD
• Professor of Medicine, University of California, San Francisco
• Chief of Anticoagulation and Thrombosis Services, San Francisco VA Medical Center

Susan O'Neill FNP-BC, CACP
• Family Nurse Practitioner, Anticoagulation Services, Northwell Health/Staten Island University Hospital
Potential conflicts of interest

• Scott Kaatz
  • Consultant
    • Janssen
    • Pfizer
    • Portola
    • Roche
    • Bristol Myer Squibb
  • Research funding (to institution)
    • Janssen
  • Board membership (non-profit)
    • AC Forum
    • Thrombosis and Hemostasis Societies of North America
    • National Blood Clot Alliance Medical and Scientific Advisory Board
Practical Management of Warfarin Patients Who Have Difficulty Getting INR Testing

- Extended INR intervals
- Lab testing
  - Drive through point of care testing
  - Laboratory testing
  - Home testing
- Switching to DOAC
  - Warfarin to DOAC, overlap, start DOAC at which INR
  - Free coupons
- Telehealth
- COVID-19 Sample Workflow
Extended INR Intervals

• Question: is 12 weeks INR testing interval as good as 4 weeks in stable patients?
• Design: randomized trial
• Patients: 250 patients at one site with no dose change in past 6 months
• Intervention: monthly INRs with real INR reported every 12 weeks and sham INRs reported for others. Extreme INRs were reported.
• Comparison: monthly INRs
• Outcomes:
  • Primary: time in therapeutic range
  • Secondary: extreme INRs per patient, dose change, bleeding, thromboembolic events and death
• Timeframe: 1 year

<table>
<thead>
<tr>
<th>Outcome</th>
<th>4-Week Group (n = 126)</th>
<th>12-Week Group* (n = 124)</th>
<th>Absolute Difference (CI), percentage points</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean time in study (SD), d</td>
<td>349 (72)</td>
<td>356 (56)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean PT tests (SD), n</td>
<td>11.9 (2.5)</td>
<td>12.4 (2.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean time in therapeutic range (SD), %</td>
<td>74.1 (18.8)</td>
<td>71.6 (20.0)</td>
<td>2.5 (7.3)†</td>
<td>0.020‡</td>
</tr>
<tr>
<td>Mean number of INRs in therapeutic range (SD)</td>
<td>8.4 (2.8)</td>
<td>8.4 (2.9)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Patients with extreme INRs, n (%)

| INR ≥4.5 | 15 (11.9) | 8 (6.5) |
| INR ≤1.5 | 12 (9.5) | 11 (8.9) |

Number of extreme INRs, n (%)

| 0 | 99 (78.6) | 107 (86.3) |
| 1 | 19 (15.1) | 12 (9.7) |
| 2 | 6 (4.8) | 4 (3.2) |
| 3 | 2 (1.6) | 1 (0.8) |
| ≥1 | 27 (21.4) | 17 (13.7) | 7.7 (−1.8 to 17.1)|| 0.11 |

Patients with dose changes, n (%)

| 0 dose changes | 56 (44.4) | 78 (62.9) |
| 1 dose change | 38 (30.2) | 19 (15.3) |
| 2 dose changes | 13 (10.3) | 17 (13.7) |
| 3 dose changes | 11 (8.7) | 6 (4.8) |
| ≥4 dose changes | 8 (6.3) | 4 (3.2) |
| ≥1 dose change | 70 (55.6) | 46 (37.1) | 18.5 (6.1 to 30.0)|| 0.004 |

Clinical events, n (%)

| Major bleeding event | 1 (0.8) | 2 (1.6) | −0.8 (−4.9 to 2.9)|| 0.55 |
| Verified thromboembolic event | 1 (0.8) | 0 (0) | 0.8 (−2.3 to 4.4)|| 0.32 |
| Death | 5 (4.0) | 2 (1.6) | 2.4 (−2.3 to 7.5)|| 0.25 |
• Implementation study
• 6 anticoagulation clinics
• Each clinic decided on extended timeframe

## Extended INR Intervals

<table>
<thead>
<tr>
<th></th>
<th>Extended INR testing interval ($n = 2479$)</th>
<th>No extended INR testing interval ($n = 1615$)</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total follow-up time (days)</td>
<td>118 368</td>
<td>39 609</td>
<td></td>
</tr>
<tr>
<td>Length of INR testing interval (days), median (IQR)</td>
<td>42 (42–55)</td>
<td>28 (21–29)</td>
<td></td>
</tr>
<tr>
<td>Next INR value out-of-range, no. (%)</td>
<td>677 (27.3)</td>
<td>458 (28.4)</td>
<td>0.46</td>
</tr>
<tr>
<td>Next INR value extreme, no. (%)</td>
<td>158 (6.4)</td>
<td>124 (7.7)</td>
<td>0.11</td>
</tr>
<tr>
<td>Major bleeding (no.)</td>
<td>5 (0.02 per patient-year)</td>
<td>1 (0.01 per patient-year)</td>
<td></td>
</tr>
<tr>
<td>CRNM bleeding (no.)</td>
<td>6 (0.02 per patient-year)</td>
<td>10 (0.09 per patient-year)</td>
<td></td>
</tr>
<tr>
<td>Emergency department visits (no.)</td>
<td>23 (0.07 per patient-year)</td>
<td>21 (0.19 per patient-year)</td>
<td></td>
</tr>
<tr>
<td>Thromboembolic events (no.)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>
Venous Thromboembolism Guidelines

• American Society of Hematology
  • For patients receiving maintenance VKA therapy for treatment of VTE, the ASH guideline panel suggests using a longer (6-12 weeks) INR recall interval rather than a shorter (4 weeks) INR recall interval during periods of stable INR.

• Anticoagulation Forum
  • During the first three months of warfarin therapy for VTE we suggest that INR recall intervals not exceed 6 weeks.
  • For patients demonstrating consistently stable INRs after three months of warfarin therapy for VTE we suggest that INR recall intervals can be extended up to 12 weeks.

Atrial Fibrillation and Other Guidelines

• 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation (and the 2019 update)
  • Among patients treated with warfarin, the INR should be determined at least weekly during initiation of antithrombotic therapy and at least monthly when anti-coagulation (INR in range) is stable. (Level of Evidence: A)
    • None of the 3 references provided in support of this recommendation compared monthly to every 3 month INR intervals.

• 2012 Evidence-Based Management of Anticoagulant Therapy: 9th ed: American College of Chest Physicians Guidelines
  • For patients with consistently stable INRs, we suggest and INR testing frequency of up to 12 weeks rather than every 4 weeks (Grade 2B)

January CT. J Am Coll Cardiol 2014;64:e1–76
Holbrook A. Chest. 2012 Feb;141(2 Suppl):e152S-e184S
Extended INR Panel Discussion
Drive Through POC-INR Testing

Guest Speaker: Susan O’Neill, MS, FNP-BC, CACP
Staten Island University Hospital Northwell Health

Purpose: Maximize safety and minimize exposure of staff and patients.
Define Criteria of patient selected for this drive through POC-INR testing
Process: Anticoagulation Center Nurse Practitioner (NP) will:

- Review the patient on an individual basis and perform an assessment of the risks and benefits of bringing the patient for the drive through INR-POC. Also, NP will screen the patient with regards to risk of infection with COVID-19.
- NP will interview the patient over the phone and provide a time for the drive through POC-INR testing
- Upon patient arrival, NP will perform the POC-INR testing using the Coagucheck XS Machine (finger stick requiring 30 -60 seconds)
- NP will complete the Anticoagulation visit and schedule the next appointment via drive through POC-INR
Lab Testing Panel Discussion
DOAC Conversion

• Guideline-based appropriate patient selection
• Barriers to switching
• Things to be careful about (e.g., 30-day free DOAC cards)
• Timing of warfarin to DOAC switch
• How do you operationalize the switch to be most efficient?
Anticoagulation Services – Outpatient Clinic
Transitioning from Warfarin to a DOAC

YES

APPROVED DOAC INDICATION

Brief discussion of pros/cons of warfarin vs DOAC with patient (may be telephonic)

☐ Importance of adherence with DOAC
☐ Improved safety and convenience of DOAC
☐ Minimal need for lab monitoring with DOAC
☐ Agreement to manage by PCP/Cardiology
☐ Possible higher co-pay amount/cost with DOAC

Patient prefers to pursue DOAC

NO

Maintain warfarin therapy

Non-clinical criteria met
(Patient Care Coordinator)

☐ Insurance coverage confirmed
☐ Affordable co-pay long-term

Clinical criteria met
(Pharmacist)

☐ Adequate renal function (exceptions may apply)
☐ Adequate hepatic function (no severe cirrhosis)
☐ No major drug interactions
☐ History of good adherence
☐ No extremes of weight (<50kg or >120kg, BMI >40)
☐ No absolute contraindications (mech valve, pregnancy, breastfeeding, etc)

If PCP/Cardiology to follow, they agree with DOAC therapy management & are willing to:

☐ Prescribe refills
☐ Manage peri-procedurally
☐ Monitor renal function
☐ Evaluate for drug interactions
☐ Periodic review of risks/benefits

Schedule and complete a NPV (may be telephonic)

☐ Comprehensive education & counseling
☐ Check INR and transition to DOAC, accordingly
☐ Prescribe sufficient refills (if necessary)

Forward progress note to Anticoagulation Clinic Medical Director

Forward progress note to PCP (or fax if non-UNM)

Forward progress note to Cardiology (or fax if non-UNM)

*N see "Direct Oral Anticoagulant (DOAC) Patient Selection Algorithm" for additional guidance
* see "Direct Oral Anticoagulants (DOACs) Clinical Guideline" for additional guidance
* see "Switching Between Anticoagulants" for additional guidance

Revised 03/2020
DOAC Conversion Panel Discussion
# Telehealth CMS Toolkit

<table>
<thead>
<tr>
<th>TYPE OF SERVICE</th>
<th>WHAT IS THE SERVICE?</th>
<th>HCPCS/CPT CODE</th>
<th>Patient Relationship with Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MEDICARE TELEHEALTH VISTIS</strong></td>
<td>A visit with a provider that uses telecommunication systems between a provider and a patient.</td>
<td>Common telehealth services include: • 99201-99215 (Office/outpatient visits) • G0425-G0427 (Telehealth consultations, emergency department or initial inpatient) • G0406-G0408 (Follow-up inpatient telehealth consultants to patients in hospitals or SNFs) <a href="https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes">https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes</a></td>
<td>For new* or established patients *To extent 1135 waiver requires established relationship, HHS will not conduct audits to ensure prior relationship existed for claims submitted during this public health emergency</td>
</tr>
<tr>
<td><strong>VIRTUAL CHECK-IN</strong></td>
<td>A check in with practitioner to decide whether office visit or other service is needed. A remote evaluation of recorded video and/or images submitted by established patient.</td>
<td>• HCPCS code G2012 • HCPCS code G2010</td>
<td>For established patients</td>
</tr>
<tr>
<td><strong>E-VISITS</strong></td>
<td>Communication between patient and provider through online patient portal.</td>
<td>• 99421 • 99422 • 99423 • G2061 • G2062 • G2063</td>
<td>For established patients</td>
</tr>
</tbody>
</table>

Telehealth and Lessons Learned

- Conversion of point to care clinic to telehealth
- Tips to keep your patients out of the emergency room (e.g. bruising, epistaxis)
COVID-19 Anticoagulation (AC) Preparedness

In-hospital/at discharge

- Optimize AC management of COVID-19 AC patients to minimize RN exposure
  - Use DOAC or LMWH instead of IV UFH
  - Use once daily dosing of LMWH or DOAC when possible
  - Group timing of meds

- DOAC for all new-start eligible patients
  - Evidence for DOAC use*
  - Good organ function
  - Lack of major DDIs or contraindications (mech. valves, APS)
  - Likely to be adherent
  - Longitudinal access confirmed

- VTE patients
  - Assess provoked vs. unprovoked event and intended duration of therapy
  - Consider discontinue AC if at or past intended completion date

- Established warfarin patients
  - Assess for DOAC eligibility** using criteria above

In clinic

- Warfarin
  - Non-valvular afib
  - VTE
  - Other indications

- Due/overdue to stop AC? (provoked/unprovoked, intended DOT, etc)
  - Continue warfarin therapy
  - Consider stop therapy through SDM

- Eligible for DOAC??
  - TTR >65% and on AC for ≥ 3 months?
    - Increase INR interval to 12 weeks
    - Willing/able to go to lab for INR check
    - -Identify lab site conducting COVID-19 symptom testing
    - -Direct patient to lab for INR check
    - -Telephonically manage
    - -Telephonically screen patient for COVID-19 symptoms

- Discharged on warfarin
  - Ensure 90-day supply when possible and appropriate
  - Mail order whenever possible
  - Schedule first follow-up accordingly based on new vs. established patient
  - Consider telephonic follow up

- Discharged on DOAC
  - Ensure 90-day supply when possible and appropriate
  - Mail order whenever possible
  - Schedule first follow-up for ≥ 1 month
  - Consider telephonic follow up
  - Avoid free 30-day supply cards unless absolutely necessary
  - Petition 3rd-party payers to waive warfarin step-through if exists

- Defer labs if possible
  - ≥ 65 yrs and stable: 12 months
  - <65 yrs and stable: flag for 3-6 months

- Schedule/reschedule INR in clinic
  - OR
  - employ other means such as drive-through INRs/HHC/PST as feasible

* Off-label use must be discussed with patient/caregiver and provider(s)
Φ Shared decision-making (SDM) should be employed in all anticoagulant conversions

Contact information via Tiger Connect: John Togami, PharmD (Outpatient Clinic); Allison Burnett (Inpatient Stewardship)

Last updated 3.20.20
Resources

• Centers for Disease Control
  www.cdc.gov/coronavirus/2019-nCoV

• Anticoagulation Centers of Excellence Resource Center
  acforum-excellence.org/Resource-Center

• References for Extended INR Intervals:
This webinar is brought to you, in part, by the support of the following companies: