Simple Steps for Quality Anticoagulation Therapy in LTC

Darren M. Triller, PharmD
February 28, 2013
CMS

- Leads a national healthcare quality improvement program, implemented locally by an independent network of QIOs in each state and territory.

IPRO

- The federally funded Medicare Quality Improvement Organization (QIO) for New York State, under contract with the Centers for Medicare & Medicaid Services (CMS).
The QIO Program

- Largest federal program dedicated to improving health quality at the local level,
- Trustworthy partners for the continual improvement of healthcare for all Americans,
- Focuses on three broad aims:
  - Better patient care,
  - Better population health,
  - Lower healthcare costs through improvement.
As the QIO for New York State, IPRO works to achieve the goals of the national QIO program by

- Convening communities of providers, practitioners and patients across the state to:
  - Share knowledge,
  - Spread best practices,
  - Achieve rapid, wide-scale improvements in patient care.
The QIO Program supports patients by:

- Providing information to help you better manage your own healthcare,
- Reviewing quality of care complaints,
- Working with local healthcare providers to make healthcare safer and “patient-centered,”
- Listening to you and learning from your experiences,
- Helping to remove roadblocks between you and better healthcare.
The QIO Program supports providers by:

- Managing and sharing evidence-based best practices, knowledge and tools for improving health quality, efficiency and value.
- Serving as a change agent for rapid, widespread and significant improvements that contribute to broader national healthcare goals.
- Facilitating collaborative learning and action that results in better, more patient-centered care.
- Encouraging beneficiaries to take a more active role in their own healthcare.
QIO Program Priorities 2011-2014

- Beneficiary- and Family-Centered Care
- Improving Individual Patient Care by Reducing
  - Healthcare-Associated Infections in Hospitals
  - Healthcare-Acquired Conditions in Nursing Homes
  - Adverse Drug Event
- and through Quality Reporting
- Integrating Care for Populations and Communities
- Improving Health for Populations and Communities
Background

March 14, 2012 Medline Industries announced 11 new Prevention Above All Discovery Grants awarding more than $500,000 in funding for research

Foundation for Quality Care, Inc. awarded $100,000 for the period January 1, 2012 through February 28, 2013 for research study on Warfarin Safety

Based on Omnicare Pilot conducted with IPRO
Study Partners

Foundation for Quality Care, Inc., an affiliate of NYSHFA

- Project Director, Karen Morris, RN, MS
- Sr. Director Resource Development, Gayle Farman, MPA
- Program Assistant, Melony Spock

IPRO, New York’s Quality Improvement Organization

- Principal Investigator, Darren Triller, Pharm.D.
- Data Analyst, Susan Wymer, BSN, RN, MS
Objectives

Discuss key elements of high quality anticoagulation management systems

Identify critical areas for improvement in the long term care setting

Describe available resources and expert guidance for improving anticoagulation-related quality in the LTC setting
Four medications or medication classes were implicated alone or in combination in 67.0% of hospitalizations: warfarin (33.3%), insulins (13.9%), oral antiplatelet agents (13.3%), and oral hypoglycemic agents (10.7%).
Priorities

Serious, life-threatening, or fatal events occurred at a rate of 2.49 per 100 resident months; 57% of these more severe events considered preventable. Errors resulting in preventable events occurred most often in the prescribing and monitoring stages of warfarin management.

The American Journal of Medicine (2007) 120, 539-544
3.5. (Best Practices Statement) We suggest that health-care providers who manage oral anticoagulation therapy should do so in a systematic and coordinated fashion, incorporating patient education, systematic INR testing, tracking, follow-up, and good patient communication of results and dosing decisions.
Thus, recommendations for delivering optimized anticoagulation therapy should apply to all clinicians involved in the care of outpatients receiving anticoagulation, regardless of the structure and setting in which that care is delivered.

### Table 3. Anticoagulation Management Issues for Which Established Policies and Procedures May Be Useful

- Assessing the risks and benefits of anticoagulation therapy
- Documenting patient's understanding of anticoagulation therapy
- Indications for anticoagulation therapy
- Indication-specific target INR values
- Determining the planned duration of anticoagulation therapy
- Initiating anticoagulation therapy
- Managing therapeutic and nontherapeutic INR values
- Determining monitoring intervals for INR and other laboratory parameters pertinent to anticoagulation therapy (eg, complete blood cell counts, urinalysis)
- Defining and documenting adverse events (eg, major bleeding, thromboembolism, death)
- Defining the mechanism by which missed appointments will be flagged
- Establishing a system for the timely reporting of laboratory results
- Managing noncompliance to blood tests or clinic visits
- Managing transitions between care settings (eg, outpatient to skilled nursing, outpatient to inpatient)
- Defining criteria for discharging patients from a dedicated AMS
- Reimbursement procurement
- Defining and assessing quality measures
- Interrupting anticoagulation for invasive procedures
- Managing anticoagulation therapy during pregnancy
- Coordination of anticoagulation therapy during travel
- Defining eligibility criteria and follow-up requirements for patient education

AMS = anticoagulation management service; INR = international normalized ratio
Table 1.2 describes a stepwise process for the prudent management of antithrombotic therapy in frail elderly patients. This approach complies with good geriatric care as well as with the intent of regulatory oversight.

**TABLE 1.2. Steps in the Management of Antithrombotic Therapy in Elderly Patients**

<table>
<thead>
<tr>
<th>Step</th>
<th>Task(s)</th>
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<tbody>
<tr>
<td>1</td>
<td>Identify patients with conditions that may benefit from platelet-active medications (e.g., CAD, PAD, TIA, stroke).</td>
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<tr>
<td>2</td>
<td>Identify patients with conditions that may benefit from anticoagulant medications (e.g., AF, valvular heart disease, high risk for DVT or PE).</td>
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<td>3</td>
<td>Record the diagnosis that justifies antiplatelet or anticoagulant therapy.</td>
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<td>If warfarin is prescribed, establish and record target INR and INR range.*</td>
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<td>If possible, estimate the patient’s risk of a thrombotic event without antithrombotic treatment.*</td>
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<td>6</td>
<td>If possible, estimate the reduction in the risk of a thrombotic event with effective antithrombotic treatment.*</td>
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<td>7</td>
<td>Review the patient’s history for absolute and relative contraindications to therapy.*</td>
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<td>8</td>
<td>Perform a baseline laboratory evaluation if one has not recently been completed (e.g., CBC, creatinine, glucose, INR, fecal occult blood test, urinalysis for blood). Consider optional stool test for Helicobacter pylori antigen.</td>
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<td>9</td>
<td>Assess the patient for modifiable risk factors that increase the risk of bleeding during NSAIDs, H. pylori-associated ulcer, untreated urinary tract infection).</td>
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<td>Reduce modifiable risk factors (e.g., stop NSAIDs, treat H. pylori infection, prescribe PPI to reduce the risk of gastrointestinal bleeding caused by antiplatelet medication).</td>
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<td>11</td>
<td>Review the benefits and potential adverse effects of antithrombotic therapy with the authorized representative and decide whether to begin therapy.</td>
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<td>12</td>
<td>Monitor therapy for effectiveness (e.g., INR), if appropriate.</td>
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<td>13</td>
<td>Monitor the patient for adverse effects of therapy (e.g., bleeding signs or symptoms, LMWH: low-molecular-weight heparin; NSAID: nonsteroidal anti-inflammatory medications; TIA: transient ischemic attack).</td>
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<tr>
<td>14</td>
<td>Determine the appropriate duration of therapy and record a stop date.</td>
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AF: atrial fibrillation; CAD: coronary artery disease; CBC: complete blood count; DVT: deep venous thrombosis; INR: international normalized ratio; LMWH: low-molecular-weight heparin; NSAID: nonsteroidal anti-inflammatory medications; TIA: transient ischemic attack.

* See Appendix 5, Baseline Anticoagulant Risk/Benefit Assessment
† See Appendix 12, Absolute Contraindications to Anticoagulation
Evaluation of Prescribing and Monitoring

Prescribing: Time in therapeutic range (TTR)
Monitoring: Timeliness of INR monitoring after initiation of antibiotics
What is a quality program?

Mean TTR for the entire sample was 58%. Site-observed TTR varied from 38% to 69% or from poor to excellent.
Outstanding LTC Management

Figure 2 Percent of time spent in therapeutic range

Papaioannou et al. BMC Geriatrics 2010, 10:38
Advantages of LTC Environment

Minimize variation

• Adherence
• Diet

Cohesive care plan

Standardized communication among disciplines/specialities

Routine patient assessment

Rapid responsiveness

Single source of policies and procedures
Baseline study findings (NY)

**Mean TTR (Rosendaal method)**

- Quality Gap of 40%!

*For Quality Improvement Organizations 10th Statement of work
** Achieved across 6 facilities in intervention study*
Warfarin/Antibiotic Monitoring

Pilot:
• Baseline 55%
• Completion: 97%

Medline study:
• Baseline: 66.09%
## Baseline Evaluation of Policies/Procedures

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Explaining the Quality Gap

Best practices have been defined
• ACCP guidelines
• Anticoagulation Forum
• American Medical Directors Association

Institutions have achieved excellence

Poor performing facilities lack key organizational elements necessary to achieve excellence
• Stated target INR for indication
• Valid dose adjustment strategies
• Quality reporting/improvement strategy
#1: Stated INR Target for Indication

4.1 For patients treated with VKAs, we recommend a therapeutic INR range of 2.0 to 3.0 (target INR of 2.5) rather than a lower (INR<2) or higher (INR 3.0-5.0) range (Grade 1B).
Several such evidence-based guidelines from appropriate specialty societies, including the ACCP Practice Guidelines 9th Ed, were consulted during the preparation of this Information Tool Kit.
Specific AMDA Recommendations

“Maintain therapeutic INR range 2.0-3.0 (target 2.5)”

• Acute DVT treatment
• Pulmonary embolism treatment

The target INR for stroke prevention in patients with AF is 2.5 (range 2.0-3.0).
• Warfarin maintained at an INR below 2.0 does not decrease bleeding risk, but does increase stroke risk.
• Stroke risk rises dramatically when INR is at or below 1.8
• Stroke risk double when INR is at or below 1.7
• Stroke risk triples when INR is at or below 1.5
SPAF III Results: Event Rate Per Year in High-Risk Cohort (N=1,044)

*P*=.0001

Aspirin (325 mg/day) plus fixed-dose warfarin (INR, 1.2–1.5)
Adjusted-dose warfarin (INR, 2–3)

Impact of target INR on population TTR

We had three main findings:
• Mean site INR varied widely
• Proportion of patients near 2.5 varied widely by site
• A higher proportion near 2.5 was strongly associated with higher site-level TTR
3.7 For dosing decisions during maintenance VKA therapy, we suggest using validated decision support tools (paper nomograms or computerized dosing programs) rather than no decision support.
The authors found that site-level adherence to a relatively simple algorithm regarding when to change the dose of warfarin and when not to change the dose predicted fully 87% of between-center variance.

Each 10% increase in center algorithm-consistent dosing independently predicted a 6.12% increase in TTR and an 8% decrease in rate of composite clinical outcome.”
APPENDIX 9. INR-Based Guide for Warfarin Monitoring and Dose Adjustment to Maintain Target INR 2.0–3.0

INR below 2.0
Check Warfarin/INR Flow Sheet (Appendix 7) to determine if patient suffered an acute DVT or PE within past 3 mo.

INR below 1.5
Scenario A: If patient has had a DVT or PE within 3 mo and INR is below 1.5
- Contact attending physician to determine if patient requires heparin or LMWH until INR is therapeutic.

Scenario B: If no DVT or PE within 3 mo and INR is below 1.5
- Contact attending physician to choose from recommendations and monitoring.

Option 1
If no DVT or PE within 3 mo and
- Last 3 INRs between 2.0 and 3.0 and
- No recent missed dose, acute illness, dietary changes
- Continue current dose and recheck INR in 1 wk

Appendices 5-10 offer sample policies, templates, and other guidance to assist the practitioner in managing warfarin use in the LTC setting.
APPENDIX 5. Sample Facility Policy on Safe and Effective Warfarin Use

**Purpose:** To assure safe and effective use of warfarin in all facility patients.

**Policy:**

- **Patient identification**
  Charts of patients receiving warfarin will be labeled in a way that makes it easy to identify patients who are taking warfarin.

- **INR reporting**
  - Nursing staff will record pertinent information about a patient's clinical status and INR results in the patient's chart.
  - Attending physician or licensed designee.
  - Nurse is responsible for assuring that an order is obtained and recorded.
  - Report is reported to a practitioner.

- **INR testing frequency**
  - Patients receiving warfarin will have an INR tested at least every 4 weeks.
  - Testing may occur more frequently depending on the clinical situation.

- **Antibiotic therapy**
  - If antibiotics are prescribed for a patient taking warfarin, the nurse will contact the attending physician for recommendations about INR testing frequency.
  - Practitioners may use the Facility Recommendations for Warfarin Dosing and Monitoring While on Antibiotics (see below).

Check INR at initiation of antibiotic therapy. Give usual warfarin dose and check INR every other day while patient remains on antibiotics. Check INR 5-7 days after discontinuation of antibiotics.
3.5 We suggest that health-care providers who manage anticoagulation therapy should do so in a systematic and coordinated fashion, incorporating patient education, systematic INR testing, tracking, follow-up, and good patient communication of results and dosing decisions.
TABLE 1.3. Improving the Safety of Therapeutic Anticoagulation: Joint Commission National Patient Safety Goals 2012

- Use only oral unit-dose products and prefilled syringes when these types of products are available.
- Use approved protocols for the initiation and maintenance of anticoagulant therapy.
- Assess the patient’s anticoagulation status before initiating warfarin therapy.
- For all patients receiving warfarin, adjust therapy on the basis of a current INR value.
- Use authoritative resources to manage potential food and drug interactions in patients receiving warfarin.
- Develop and implement a written policy to address baseline and ongoing laboratory tests required to monitor patients on anticoagulant therapy.
- Educate prescribers, staff, patients, and families on the importance of anticoagulation therapy. (This may include the following:
  - Importance of follow-up monitoring
  - Importance of adherence to therapy
  - Drug-food interactions
  - Potential for adverse drug reactions)

- Evaluate anticoagulation safety practices, take action to improve these practices, and measure the effectiveness of those actions in a time frame determined by the facility.

INR, international normalized ratio.

Adapted from: The Joint Commission25

Evaluate anticoagulation safety practices, take action to improve these practices, and measure the effectiveness of those actions in a time frame determined by the facility.
Poor performance is not consistent with best practices

Mean TTR (Rosendaal method)*

Quality Gap of 40%!

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**Achieved across 6 facilities in intervention study
Poor performance is due to a small number of specific system deficiencies

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Outstanding care can be achieved in LTC

Figure 2 Percent of time spent in therapeutic range

Papaioannou et al. BMC Geriatrics 2010, 10:38
Resources are available to guide rapid, wide-scale improvements

American Medical Directors Association  www.amda.com
ACCP Guidelines  www.chestnet.org
Anticoagulation Forum  www.acforum.org
National Blood Clot Alliance  www.stoptheclot.org
CMS Quality Improvement Organizations  www.qualitynet.org
Barriers

Fear of warfarin target INR (2.5), range 2.0-30

• Data supports increased efficacy
• Valid dosing strategy minimizes variation and risk
• Under-dosing not supported by consensus
• Consensus-based policy minimizes facility, prescriber risk
Barriers

Loss of prescriber autonomy

• Medicine plays central role in selection and implementation of strategy
• Prescriber autonomy maintained within structure of expert guidance tools
• CQI process provides physician with improved perspective of system performance and patient outcomes
Barriers

Improvement Implementation Burdensome/Costly

• AMDA toolkit designed for LTC setting
• Anticoagulation services/software available (e.g. POC vendors)
• Assistance available through QIOs, FQC, pharmacy provider, etc
• Costs of low performance are considerable
Will your organization take the first step?
This material was prepared by IPRO, the Medicare Quality Improvement Organization for New York State, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents do not necessarily reflect CMS policy. 10SOW-NY-AIM7.3-13.03
For more information

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