Prevention of Excessive Anticoagulation from Warfarin

STARTER PACK – WEBINAR #1
Why is it important to reduce the incidence of excessive INRs?
What is “Excessive Anticoagulation”?

- No national definition
- No CMS PfP standard definition
- Some HIIN’s define it as an INR > 5, some INR > 6
- Great Lakes defines it as an INR > 6
Why Excessive INR Reduction?

• Key Statistics
  – 150,000 hospital acquired excessive INRs annually
  – At an average of $8,000 per ADE, this equals $1.2B
  – 2004 study by Bond (2004):
    • 26,000 inpatient deaths annually in Medicare population...no pharmacy involvement

How does an high INR cost money?

• Delayed discharges
• Lab costs
• Bleeding related costs
Can we prevent excessive INRs, or... it is just a “cost of doing business”? 
Can It Be Done?

- Large Indiana hospital reduced high INRs by > 50%
  - Standard work
  - Standard labs
  - Pharmacist-driven monitoring and orders
Can It Be Done?

• Rural Kentucky hospital reduced high INRs by > 50%
  • Standard work
  • Standard labs
  • Pharmacist-driven monitoring and orders
And in 2016...

- Hospital based pharmacists reported that pharmacy driven warfarin management:
  - Reduced sub-therapeutic INRs (55% to 39%, RR 29%)
  - Reduced supra-therapeutic INRs > 5 (3.7% to 2.6%, RR 30%)
  - Reduced time to achieve therapeutic range by 0.5 days
  - Did increase supra-therapeutic INRs 3.5 – 4.9 (13% to 19%, RI 46%)

Can It Be Done?

[Image of a strong woman with the text "We Can Do It!"]
Getting Started
Project Goal

- HIIN goal: 20% reduction in excessive INR events
- Great Lakes is one of 16 HIINs working to achieve this bold goal!
First Things First

- Ask:
  - Are we ready?
  - Is there urgency?
  - Is there leadership support?
  - Who owns this effort?
  - What resources are needed?
  - What if we are not ready for full-scale change?

- Assess the readiness before you proceed
Establishing Your Team

• Successful teams are multi-disciplinary
• Who do you need on your team?
  • Executive Champion – senior leader who will provide support
  • Team Leader – a person with authority to test the change ideas
  • Team Members – pharmacists, physicians, nursing, lab specialists, dietary, IT, patient advocate
Tips for Effective Meetings

• Plan ahead
  – Set the agenda
  – Gather data/materials
  – Do pre-work
• Be brief
  – there is no rule that says a meeting needs to last an hour!
• Timed Agenda
• “Parking Lot”
• Take “actionable” minutes
• FOLLOW UP
Best Practices

WHAT WORKS
Summary of Best Practices

• Engage patients and families
• Make it easy to find the data and underlying themes of failures
• Pharmacy management of warfarin dosing
• Pharmacy tracks and trends all INRs
• All patients have INR drawn upon admission, even if chronically taking warfarin
• All patients on warfarin get daily INRs drawn
• Identify all drug-drug interactions and dietary preferences
• Identify patients not suited for warfarin therapy
Engage Patients and Families

• Explain risks/benefits/alternative
• Listen to, respect, understand and respond to patient concerns
• Identify work or hobby related risk factors
• Identify mobility challenges and fall risks
• Seek barriers to medication management and ability to obtain regular INRs once discharged
Make it easy to find the data and underlying themes of failures

• How often do you find a patient has an INR > 6 from anything other than warfarin?

• Do you really need to verify each event by opening the chart?

• Open a patient's chart to:
  – Validate...Look at 10 in depth and verify that at least 9 patients are/were receiving warfarin
  – While looking at those 10....look for themes...what is causing most cases of high INRs in your facility?
Pharmacy Management of Warfarin Dosing

• Becoming more common
• Pharmacy students are learning it
• Pharmacists on the job for years are learning it

• Data shows as good and often is better than “best usual care” (physician management)

Key Resources: Wong (2010), Donovan (2006), and Merrens (2008)
Warfarin Tampering: Process Capability 60%

Adapted from Brent James MD / Courtesy of Larry Staker MD/ Dimitri Lerner, PharmD UCSD
Warfarin Untampered: Process Capability 94%
Adapted from Brent James MD / Courtesy of Larry Staker MD / Dimitri Lerner, PharmD UCSD
Warfarin Dosing by Pharmacy

• Infrastructure:
  – Mandatory order sets: steer providers toward involving pharmacist
    • Contains all required elements: indication, goal of tx, monitoring
  – Standardized initiation
    • Baseline labs
    • Dosing guidelines/nomograms
    • Previous warfarin history
    • Problem list/DDI screen
    • Bleeding risk assessment
# Initial Dosing: Decision Support

<table>
<thead>
<tr>
<th></th>
<th>African American</th>
<th>Hispanic / Caucasian</th>
<th>Asian</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &lt; 70</td>
<td>7.5 mg</td>
<td>5 mg</td>
<td>2.5 mg</td>
</tr>
<tr>
<td>Age ≥ 70</td>
<td>5 mg</td>
<td>Females: 2.5 mg</td>
<td>2.5 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Males: 5 mg</td>
<td></td>
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</tbody>
</table>

- Consider **REDUCING** your starting dose by 2.5 mg or 50% (whichever is less) for the following patient characteristics:
  - Debilitation, weight < 45 kg
  - Baseline INR > 1.3
  - Vitamin K deficiency / malnutrition
  - Serum albumin < 3 gm/dL
  - Liver disease
  - Catabolic conditions (i.e. Recent major surgery, untreated hyperthyroidism, decompensated heart failure, pneumonia / febrile illness)
  - Concurrent medications (CYP P450 inhibitors): azole antifungals, metronidazole, trimethoprim – sulfamethoxasole (Septra, Bactrim), current outpatient amiodarone use

- Consider **INCREASING** your starting dose by 2.5 mg or 50% (whichever is less) for the following patient characteristics:
  - Weight > 90 kg
  - Untreated hypothyroidism
  - Receiving enteral feeds
  - Concurrent medications (CYP P450 inducers): rifampin, carbamazepine, dicloxacillin, phenobarbital, bosentan
# Warfarin Adjustment

- **Dose 1**: give in the evening and check the PT/INR in the morning
- **Dose 2**: should be the same as dose 1
  - **EXCEPTION**: reduce the dose if the PT/INR rose ≥ 0.5 the morning after dose 1
- **Dose 3**: use the guideline in Step 5 to determine the dose 3
- **Dose 4**: should be the same as the dose 3
  - **EXCEPTION**: reduce the dose if a large increase in PT/INR occurs in the morning after dose 3 and the PT/INR became therapeutic.

*All adjustments are suggestions – do not substitute for physician/pharmacist judgment*

<table>
<thead>
<tr>
<th>Day of Warfarin Therapy</th>
<th>INR</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>As determined in Step 3 above</td>
</tr>
<tr>
<td>2</td>
<td>&lt; 1.5</td>
<td>Continue starting dose</td>
</tr>
<tr>
<td></td>
<td>≥ 1.5</td>
<td>Decrease or hold dose a</td>
</tr>
<tr>
<td>3</td>
<td>= 1.2</td>
<td>Increase dose a</td>
</tr>
<tr>
<td></td>
<td>&gt; 1.2 and &lt; 1.7</td>
<td>Continue same dose</td>
</tr>
<tr>
<td></td>
<td>≥ 1.7</td>
<td>Decrease dose a</td>
</tr>
<tr>
<td>4 (or until therapeutic)</td>
<td>Daily increase &lt; 0.2</td>
<td>Increase dose a</td>
</tr>
<tr>
<td></td>
<td>Daily increase 0.2-0.3</td>
<td>Continue same dose</td>
</tr>
<tr>
<td></td>
<td>Daily increase 0.4-0.6</td>
<td>Decrease dose a</td>
</tr>
<tr>
<td></td>
<td>Daily increase ≥ 0.7</td>
<td>Hold dose</td>
</tr>
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</table>
Pharmacists track and trend all INRs

• If the organization is not yet ready for pharmacist driven warfarin management then:

• Partner with the physicians
  – Track and trend all INRs
  – It makes a difference when pharmacists do it

Key Resources: Metersky (2016)
All patients have INR drawn upon admission, even if chronically taking warfarin

• Many things are different when admitted
  – Usually ill, often quite ill
  – Catabolic; low albumin levels
  – New medications and antibiotics
  – Different diet

Key Resources: Metersky (2016)
All patients on warfarin get daily INRs drawn

- And after the patients have been admitted...more happens...
  - More medications, especially antibiotics
  - More catabolic; dropping albumin levels
  - They might not eat their greens! (*Or it might be the first time they’ve been served them in a long time!*)
  - Dosing anomalies
  - Loading

Key Resources: Metersky (2016)
Identify all drug-drug interactions and dietary preferences

• The DDI interactions you already check for
  – Do you use a system?
  – How many do you identify? How many do you miss?

• Do you know if the patient is eating or not?

• Or what the patient is eating...more Vit K, less Vit?

• Some systems (UC San Diego) feed this data to the pharmacist through the EHR
The UCSD Warfarin Pharmacy Flowsheet
The UCSD Warfarin Pharmacy Flowsheet
Identify patients not suited for warfarin therapy

- Significant potential drug-drug interactions
- Significant and inconsistent warfarin-diet interactions
- Fall/bleeding risk...is the benefit of any anticoagulant worth the risk?
- Likely barriers to regular INR tests
Develop Your Learning Loop
PDSA...PDSA...PDSA...

• Small tests of Change/Rapid Cycle
Learning Loop Ideas

- Invite champion pharmacists and physicians
- Support the training of pharmacists
- Co-manage a few patients with the pharmacist driving the decisions
- Look at the results
- Compare pharmacist managed “in range” INRs (test group) with physician managed (control group)
Keep Learning as You Spread

- Few
- Unit
- Whole Hospital
- Outpatients
Key Resources for More Information

• Anticoagulation Agent Adverse Drug Event Gap Analysis

• AHA/HRET HEN 2.0 Adverse Drug Event Change Package
Key Resources for Information on Pharmacy Driven Warfarin Management


Key Resources for Information on Pharmacy Driven Warfarin Management


Understanding the Measures

HOW WILL YOU KNOW THAT YOU’RE MAKING A DIFFERENCE?
# ADE: MHA/IHA/WHA HIIN Evaluation Measure

**Adverse Drug Events (ADE) related to Anticoagulation Safety: Inpatients experiencing excessive anticoagulation with warfarin**

<table>
<thead>
<tr>
<th>Measure type</th>
<th>Outcome</th>
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<tbody>
<tr>
<td>Numerator</td>
<td>Number of inpatients experiencing excessive anticoagulation with warfarin (INR greater than 6)</td>
</tr>
<tr>
<td>Denominator</td>
<td>Number of inpatients receiving warfarin anticoagulation therapy</td>
</tr>
<tr>
<td>Exclusions</td>
<td>Patients with INR greater than 6, present on admission</td>
</tr>
</tbody>
</table>
| Rate calculation      | \[
number of patients with INR > 6 
\]
|                       | \[
number of patients receiving warfarin anticoagulation therapy x 100
\] |

**Specifications/definitions**
- Available from: [ISMP Trigger Alert List](#)

**Data source (s)**
- **Hospital Reported**: Submit to Keystone Data System (KDS)

**Automatic transfer from**
- n/a

**Baseline period**
- Returning HEN 2.0 Hospitals: 2016 Q1
- New GLPP HIIN Hospitals: 2016 Q4

**Data collection period**
- Monthly, beginning 2016 Q4

**KDS Survey Name**
- ADE – Anticoagulation & Glucose

**KDS Measure ID(s)**
- KDS-HIIN-ADE-2

**PfP Measure Name**
- INR_6
Gap Analysis
WHAT IT IS AND HOW YOU USE IT
What is the Current State of Excessive INR Prevention?
What and How

• A tool that will help you understand what’s currently in place and not in place in your facility
• Check items that are in place
• Prioritize gaps based on learnings
Excessive INR Reduction Gap Analysis

- **Domains**
  - Contact info
  - Foundation
  - HIT
  - Best practices
  - Help

<table>
<thead>
<tr>
<th>Contact information:</th>
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<tbody>
<tr>
<td>The foundation:</td>
</tr>
<tr>
<td>1. Has an executive champion been named to support this work? Y/N</td>
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<tr>
<td>2. Has a measurable organizational AIM been established? Y/N</td>
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<tr>
<td>3. Has a multi-disciplinary team been identified? Y/N</td>
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<tr>
<td>4. Does team meet regularly (at least monthly)? Y/N</td>
</tr>
<tr>
<td>5. Has INR data analysis been obtained or performed internally? Y/N</td>
</tr>
<tr>
<td>6. Are excessive INR events reviewed using case review to determine if dosing or other process failures occurred? Y/N</td>
</tr>
<tr>
<td>7. Does monthly tracking of the excessive INR rate occur? Y/N</td>
</tr>
<tr>
<td>8. Does monthly tracking of key processes occur? Y/N</td>
</tr>
<tr>
<td>9. Is the monthly excessive INR event data shared with all staff? Y/N</td>
</tr>
<tr>
<td>10. Does the organization prioritize improvement efforts based upon learnings from data and analysis? Y/N</td>
</tr>
<tr>
<td>11. Is there a written description of your warfarin management reduction program? Y/N</td>
</tr>
<tr>
<td>12. Do you track and compare feedback to the medical and pharmacy staff the rates of excessive INRs with physician versus pharmacist management Y/N</td>
</tr>
<tr>
<td>13. Are physicians allowed to continue to manage warfarin even if their “in range” and excessive INR rates are much worse than pharmacist managed rates? Y/N</td>
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<thead>
<tr>
<th>Health information technology:</th>
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<tr>
<td>1. Do you require the use of standard orders sets (paper or electronic) that contain every one of the following key elements: indication, INR goal, routine monitoring, baseline labs, dosing guidelines/protocols, previous warfarin therapy, problem list and medication list, and bleeding risk assessment? Y/N</td>
</tr>
<tr>
<td>2. Do you use an EHR for physician order entry? (if No/skip to Question 12) Y/N</td>
</tr>
<tr>
<td>3. Does the EHR have the capacity to track and trend INRs and provide high/low alerts as well as alerts for rapid rising or falling trends? Y/N</td>
</tr>
<tr>
<td>4. Does the EHR have the capacity fire an alert if an INR has not been done before the first inpatient dose of warfarin? Y/N</td>
</tr>
<tr>
<td>5. Does the EHR have the capacity fire an alert if an INR has not been done in the prior 24 hours in a patient on warfarin? Y/N</td>
</tr>
<tr>
<td>6. Does the EHR have the capacity to provide active decision support for warfarin dosing? Y/N</td>
</tr>
<tr>
<td>7. Does the EHR have the capacity to fire alerts when dangerous INR trends occur or when dosing is possibly suboptimal? Y/N</td>
</tr>
<tr>
<td>8. Does the EHR have the capacity to fire alerts when other medications known to interact with warfarin dosing are ordered? Y/N</td>
</tr>
<tr>
<td>9. Does the EHR have the capacity to fire alerts when the patient’s diet changes, or she is switched to or from an NPO status? Y/N</td>
</tr>
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Your First/Next Steps

GET GOING
Stop Talking. Start Doing.

“The way to get started is to quit talking and begin doing.”

- Perform your Gap Analysis
- Access the Resources provided - make notes and ask questions
- View Webinar #2
  - How to engage and involve stakeholders
  - Learn about PDSA and Small Tests of Change
- Decide the next level of HIIN support
  - Onsite assistance
  - Improvement Action Network
  - Other
Where to find the Resources

Keystone Center Quality Initiatives

Folders
- Keystone Center Quality Initiatives
  - General HIIN information
  - Adverse Drug Events (ADE)
  - Antibiotic Stewardship (AMS)
    - AMS Starter Pack
    - AMS Resources
  - Clostridium difficile (C Diff)
    - C.Diff/AMS Starter Pack
    - C.Diff/AMS Resources
  - Catheter-associated Urinary Tract Infections (CAUTI)
    - CAUTI Starter Pack
    - CAUTI Resources
  - Central Line-associated Blood Stream Infections (CLABSI)
    - CLABSI Starter Pack
    - CLABSI Resources

Folder Contents
- GAP Analysis
- Webinar 1
- Webinar 2