
Thursday, October 30, 2014
United States Institute of Peace
Washington, DC
Welcome

Don Wright
Deputy Assistant Secretary for Health
Office of the Assistant Secretary for Health
Welcome

Paul D. Hughes
Senior Advisor for International Security and Peacebuilding
United States Institute of Peace
Opening Remarks

Wanda K. Jones
Principal Deputy Assistant Secretary
Department of Health & Human Services
Introducing the National Action Plan For Adverse Drug Event (ADE) Prevention

Dale Hu, MD, MPH
Acting Director, Division of Health Care Quality, Office of Disease Prevention and Health Promotion
U.S. Department of Health & Human Services
Conference Overview

1) Introduction to the Action Plan
2) Drug Class-Specific Plenary Sessions
3) Afternoon Breakout Sessions

Objectives

• Coordination and collaboration in the initiative to reduce preventable ADEs
• Discuss and prioritize potential measures to track national progress in ADE prevention
ADEs - Opportunity for Impact

**INSIDE the Hospital**

- 1.9 million stays
- Increased length of stay

**OUTSIDE the Hospital**

- 3.5 million office visits
- 1 million ED visits

Most common post-discharge complication

A Call to Action

- 2010: Patient Protection and Affordable Care Act
- December 2011: Bipartisan Letter to HHS
- September 2012: OASH formed Federal Interagency Steering Committee
### Considerations in Targeting Drug Classes

<table>
<thead>
<tr>
<th>Medication Class</th>
<th>Common</th>
<th>Clinically Significant</th>
<th>Preventable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics</td>
<td>✓</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>Antineoplastics</td>
<td>✓</td>
<td>✓</td>
<td>?</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>✓</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Insulin/oral hypoglycemics</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Opioids/benzodiazepines</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
ADE Prevention
Federal Advisory Group

Federal Interagency Steering Committee for Adverse Drug Events (Chair – OASH)

Anticoagulants
- Workgroup Lead
  - CDC
- SME Consultant

Diabetes Agents
- Workgroup Leads
  - CMS & VA
- SME Consultant

Opioids
- Workgroup Leads
  - AHRQ & VA
- SME Consultant
National Action Plan Components

Executive Summary
Introduction
Section 1: Action Plan Scope and Development
Section 2: Surveillance Resources
Section 3: Prevention Approaches
Section 4: Incentives and Oversight Opportunities

Section 5: Anticoagulants
- Surveillance
- Evidence-Based Prevention Tools
- Incentives & Oversight
- Research (Unanswered Questions)
- Health IT

Section 6: Diabetes Agents
- Surveillance
- Evidence-Based Prevention Tools
- Incentives & Oversight
- Research (Unanswered Questions)
- Health IT

Section 7: Opioids
- Surveillance
- Evidence-Based Prevention Tools
- Incentives & Oversight
- Research (Unanswered Questions)
- Health IT
ADE Action Plan Timeline

OCT 2012
- Steering Committee Meeting 1

NOV 2012
- Steering Committee Meeting 2
  - Launch of workgroups

APR 2013
- Steering Committee Meeting 4
  - Progress update on Action Plan

SEP 2013
- Draft Action Plan published in Federal Register

APR 2014
- Develop eLearning tools related to ADEs

OCT 2014
- ADE Prevention Conference

AUG 2014
- ADE Action Plan Released
Preventing Anticoagulant Adverse Drug Events (ADEs) and Monitoring Progress

Nadine Shehab, PharmD, MPH
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
Financial Disclosures

• None to report
Objectives

• Provide a brief overview of the national epidemiology of anticoagulant adverse drug events (ADEs)

• Discuss key public health actions for advancing anticoagulation safety identified in the HHS National Action Plan for ADE Prevention

• Identify opportunities and challenges in monitoring national progress in advancing anticoagulation safety
Anticoagulant ADEs: Opportunity for Impact
Inpatient ADEs

- All ADEs
  - Affect ~1.9 million U.S. hospital stays annually (2008)
  - Drugs: most common causes of inpatient complications
  - ~3.5 billion (2006 USD) hospital costs

Inpatient ADEs: Contribution of Anticoagulants

- All ADEs
  - Affect ~1.9 million U.S. hospital stays annually (2008)
  - Drugs: most common causes of inpatient complications
  - ~3.5 billion (2006 USD) hospital costs

- Anticoagulant ADEs (excessive bleeding)
  - Most common ADE in a nationally representative sample of hospitalized Medicare beneficiaries (2008)
  - Contributed to 5 of 12 deaths due to all adverse events (drug and non-drug related)

Inpatient ADEs: Contribution of Anticoagulants (continued)

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Causes of Medication-Related Adverse Outcomes*</th>
<th>% of All Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hormones</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Corticosteroids</td>
<td>13.2</td>
</tr>
<tr>
<td>3</td>
<td>Insulin, oral hypoglycemics</td>
<td>2.1</td>
</tr>
<tr>
<td>4</td>
<td>Analgesics, antipyretics, antirheumatics</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Opioids</td>
<td>5.6</td>
</tr>
<tr>
<td>3</td>
<td>Agents that effects blood constituents</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Anticoagulants</td>
<td>10.2</td>
</tr>
<tr>
<td>4</td>
<td>Other systemic agents</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Antineoplastics, immunosuppressants</td>
<td>10.1</td>
</tr>
</tbody>
</table>

Outpatient ADEs

- Hospital Admissions: ~280,000
- Emergency Dept Visits: ~1 million
- Physician Office Visits: ~3.5 million

Annually

Outpatient ADEs (ED Visits): Contribution of Anticoagulants

- Warfarin second most commonly implicated drug in U.S. emergency department (ED) visits for ADEs (2004-2005)
  - ~60,000 ED visits for ADEs, annually (2006-2008)

Table 2. Number of Cases and National Estimates of ED Visits for Hemorrhage-Related Adverse Events From Clopidogrel Plus Aspirin and From Warfarin in Individuals Older Than 17 Years, by Adverse Event Description and Disposition—United States, 2006-2008

<table>
<thead>
<tr>
<th>Case Characteristic</th>
<th>Cases, No.</th>
<th>Annual National Estimate, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse event description</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute hemorrhage</td>
<td>2005</td>
<td>67.6 (60.3-74.8)</td>
</tr>
<tr>
<td>Central nervous system hemorrhage</td>
<td>82</td>
<td>3.2 (1.6-4.9)</td>
</tr>
<tr>
<td>Pulmonary hemorrhage</td>
<td>44</td>
<td>2.5 (1.3-3.8)</td>
</tr>
<tr>
<td>Gastrointestinal tract hemorrhage</td>
<td>493</td>
<td>22.8 (16.9-28.7)</td>
</tr>
<tr>
<td>Genitourinary hemorrhage</td>
<td>190</td>
<td>8.2 (6.4-10.1)</td>
</tr>
<tr>
<td>Epistaxis, skin, or other minor hemorrhage</td>
<td>1022</td>
<td>54.3 (48.6-60.0)</td>
</tr>
<tr>
<td>Other or unspecified hemorrhage</td>
<td>174</td>
<td>8.9 (6.7-11.1)</td>
</tr>
<tr>
<td><strong>Other adverse events</strong></td>
<td>745</td>
<td>26.7 (21.3-32.1)</td>
</tr>
<tr>
<td>Laboratory abnormality only</td>
<td>671</td>
<td>93.2 (88.3-98.0)</td>
</tr>
<tr>
<td>Fall/injury while taking antiplatelet/anticoagulant</td>
<td>74</td>
<td>6.8 (2.0-11.7)</td>
</tr>
<tr>
<td>Unspecified toxic effects</td>
<td>176</td>
<td>5.7 (1.6-9.9)</td>
</tr>
</tbody>
</table>

**Disposition**

<table>
<thead>
<tr>
<th>Disposition</th>
<th>Cases, No.</th>
<th>Annual National Estimate, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalized</td>
<td>1385</td>
<td>43.9 (38.1-49.8)</td>
</tr>
<tr>
<td>ED visits for acute hemorrhages only</td>
<td>877</td>
<td>40.1 (33.8-46.4)</td>
</tr>
</tbody>
</table>

~68% ED visits: acute hemorrhage (e.g., GI hemorrhage, epistaxis)

~27% ED visits: laboratory abnormalities (e.g. elevated INR), fall/injury while on warfarin

~40% ED visits for acute hemorrhage resulted in hospital admission
Anticoagulation Underutilization and Effectiveness Must be Addressed Alongside Safety

- Anticoagulants are underutilized in the U.S. population
  - Less than one-half of AF patients eligible for warfarin receiving it
  - Over 75% of patients with VTE may be non-adherent with warfarin

- Clinician & patient concerns around toxicity (bleeding) contribute to underutilization
  - Our goal: to help advance the field of anticoagulation safety to minimize these concerns


AF Atrial fibrillation; VTE Venous thromboembolism
Federal Interagency Workgroup for Anticoagulant ADEs
Federal Interagency Workgroup for Anticoagulant ADEs

Federal Interagency Steering Committee for Adverse Drug Events

- Convened from December 2012 to June 2013
- Participation by ~11 Federal agencies
- Lead non-Federal SME consultant: Scott Kaatz, DO
- Input from >15 SMEs/organizations (academia, hospital care, ambulatory care, long-term care, home care, state QIOs)

IT  Information Technology; SME  Subject Matter Expert; QIO  Quality Improvement Organization
Public Comments received:
- Cardiology/Hematology
  - Anticoagulation Forum
  - American Heart Association
  - American Society of Hematology
  - National Blood Clot Alliance
  - New York State Anticoagulation Coalition
- Geriatrics (American Geriatrics Society)
- Hospital associations/affiliates (e.g., Intermountain Healthcare, The Joint Commission)
- Individual physicians, nurses, pharmacists
- Industry
- Patient safety / Healthcare quality (e.g., American Health Quality Association, National Patient Safety Foundation, Pharmacy Quality Alliance)
- Pharmacy (e.g., Academy of Managed Care Pharmacy, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists)
To **minimize population harms** from anticoagulants, Federal partners will need to:

1. Support advancement of surveillance strategies that better identify **real-world burden and scope of anticoagulant ADEs**

2. Support **development, dissemination, and uptake** of optimal AC management strategies, especially in under-addressed settings such as **care transitions** and **long-term care** (e.g., nursing homes)

3. Support policies (e.g., quality measures, EHR standards) that incentivize optimal AC management and that minimize payment/coverage barriers to such management

4. Support research of **real-world management of non-warfarin oral anticoagulants** (e.g., drug selection, transitions among agents, adherence, laboratory testing, reversal strategies)

AC  Anticoagulation;  EHR  Electronic Health Record
Anticoagulant ADEs: Key Surveillance Issues
Q: How can federal resources facilitate better SURVEILLANCE of anticoagulant ADEs at the national level?

- Identify **adequacy of diagnostic (ICD) coding** for capturing anticoagulant-related bleeding events
  - ICD-9-CM
    - Specificity: probably high
    - Sensitivity: unknown
  - External Cause of Injury (E)-codes
    - Not sufficiently reliable
  - Impact of ICD-10?


Q: How can federal resources facilitate better SURVEILLANCE of anticoagulant ADEs at the local (hospital or clinic) level?

- Support development of standardized, validated tools for local quality improvement / facility benchmarking

- Health care-associated infections (HAIs) as an example?
  - CDC’s National Healthcare Safety Network (NHSN)
  - Allows medical facilities, states, regions, and the nation to:
    - identify infection prevention problems areas
    - benchmark progress of and gaps in prevention efforts
    - comply with state and federal public reporting mandates
  - Serves >12,000 medical facilities (inpatient, outpatient)*

*As of January 2014
http://www.cdc.gov/nhsn/about.html
Q: What challenges should be addressed in PREVENTION of anticoagulant ADEs?

**All Settings**

- Identify and promote adoption of standards that constitute high-quality AC management (e.g., “Anticoagulation Center of Excellence”)
  - Provider education
  - Dissemination of guidelines/tools/protocols
- Improve dissemination of results from large-scale, QI learning initiatives across facilities
- Better address safe use of non-warfarin anticoagulants in:
  - Provider/patient education
  - Clinical guidelines
  - Nationally recognized healthcare quality/patient safety measures

**Outpatient Settings**

- Improve uptake of evidence-based AC management models (AC clinic services, PST/PSM)
  - Incl. underserved/rural/homebound
- Address factors that contribute to inter-facility variability in AC services
- Address provider concerns around supratherapeutic INRs, resultant under-treatment
- Improve incorporation of AC-specific patient management into chronic disease education programs, other patient education/health literacy tools

**Inpatient Settings**

- Improve inpatient EHR tools to enable access to real-time, integrated, linked pharmacy-laboratory data
- Promote a multidisciplinary, coordinated, and systematic approach to AC management (e.g., “Anticoagulation Stewardship”)
- Better integrate AC-specific targets into current care transitions models

AC Anticoagulation; PSM Patient self-management; PST Patient self-testing; QI Quality Improvement
Antibiotic Stewardship as an Example

March 4, 2014:
“CDC recommends that all hospitals implement antibiotic stewardship programs that include, at a minimum, seven core elements”

1. Leadership
2. Accountability
3. Drug expertise
4. Tracking
5. Reporting
6. Education
7. Action

http://www.cdc.gov/getsmart/healthcare/pdfs/core-elements.pdf
March 4, 2014:
“CDC recommends that all hospitals implement antibiotic stewardship programs that include, at a minimum, seven core elements”
1. Leadership
2. Accountability
3. Drug expertise
4. Tracking
5. Reporting
6. Education
7. Action

8. Evaluate anticoagulation safety practices, take action to improve practices, and measure the effectiveness of those actions...

http://www.jointcommission.org/assets/1/6/HAP_NPSG_Chapter_2014.pdf
Anticoagulant ADEs: Key Incentives & Oversight Issues
Q: What actions can potentially advance healthcare POLICY strategies for preventing anticoagulant ADEs?

- **Payment / Coverage Challenges:**

<table>
<thead>
<tr>
<th>Area</th>
<th>Key Issues (Examples)</th>
</tr>
</thead>
</table>
| Anticoagulation Clinics | • Payments to non-physician providers  
                          | • Physician billing for anticoagulation management services       |
| Warfarin PST/PSM       | • Reimbursement/enrollment challenges                              |
| LTC, home care         | • Practice delivery model challenges                               |

- **Recommendation:** Explore and minimize potential barriers to improved and consistent use of evidence-based anticoagulation management practices

LTC Long-term care; PSM Patient self-management; PST Patient self-testing
Q: What actions can potentially advance health care POLICY strategies for preventing anticoagulant ADEs? (continued 1)

- **Health Care Quality Measures**
  - Current focus: *Are anticoagulants are being used when indicated?* (e.g., SCIP measures)
  - Less focused on: *Are anticoagulants being used safely?*
# NQF-Recognized

**Anticoagulation Quality Measures**

<table>
<thead>
<tr>
<th>NQF Measure ID</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>0218</strong></td>
<td>Surgery patients who receive <em>appropriate VTE prophylaxis</em> within 24 hours prior to surgery to 24 hours <em>after surgery</em></td>
</tr>
<tr>
<td><strong>0371 (0372)</strong></td>
<td>Patients who received <em>VTE prophylaxis</em> or have documentation why no <em>VTE prophylaxis was given</em> the day of or the day <em>after hospital (ICU) admission (or ICU transfer)</em> and the day of or the day after surgery</td>
</tr>
<tr>
<td><strong>0373</strong></td>
<td>Patients diagnosed with confirmed <em>VTE</em> who received an <em>overlap of parenteral anticoagulation and warfarin therapy</em></td>
</tr>
<tr>
<td><strong>0581 (0593)</strong></td>
<td>Patients with <em>DVT (or PE)</em> on anticoagulation for at least 3 months <em>after the diagnosis</em></td>
</tr>
<tr>
<td><strong>1525</strong></td>
<td>Prescription of warfarin or another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism <em>for all patients with nonvalvular atrial fibrillation</em> or atrial flutter at high risk for thromboembolism, according to CHADS2 risk stratification</td>
</tr>
</tbody>
</table>

DVT  Deep vein thrombosis;  ICU  Intensive Care Unit;  NQF  National Quality Forum;  PE  Pulmonary Embolism;  VTE  Venous thromboembolism

http://www.qualityforum.org/Measures_Reports_Tools.aspx
Q: What actions can potentially advance healthcare POLICY strategies for preventing anticoagulant ADEs? (continued 2)

- Health Care Quality Measures
  - Current focus: are anticoagulants are being used when indicated (e.g., SCIP measures)
  - Less focused on: are anticoagulants being used safely?

- **Recommendation:** Identify potential measures that address:
  - Safe use of anticoagulants
  - Non-warfarin oral anticoagulants
  - High-risk populations/settings (e.g., elderly, LTC)
  - Clinical outcomes vs. surrogate indicators

LTC Long-term care; SCIP Surgical Care Improvement Project
Anticoagulant ADEs: Key Research Issues
Q: What actions can potentially advance RESEARCH areas for anticoagulant safety?

All Agents

- Support development and evaluation of educational tools and programs on high-quality AC management for:
  - Providers
  - Patients
  - Caregivers

Warfarin

- Identify barriers to AC clinic, PST/PSM utilization and factors that facilitate broader uptake of evidence-based anticoagulant ADE prevention strategies
- Identify factors that contribute to inter-clinic variability among AC clinic services
- Identify any remaining areas where pharmacogenomics-guided AC management may be useful

Non-warfarin Oral Anticoagulants

- Development of guidance related to agent selection, transitions among agents, promoting adherence
- Development and interpretation of potential laboratory assays
- Real-world management of bleeding events
- Identification of pertinent emerging pharmacogenomic issues

AC Anticoagulation; PSM Patient self-management; PST Patient self-testing
Q: What actions can potentially advance RESEARCH areas for anticoagulant safety? (continued)

- **NOACs, NOACs, NOACs...** Federal support of:
  - Development of clinician and patient guidance
    - Patient-centered, individualized risk/benefit approaches to agent selection
    - Transitions among agents
    - Tools to promote adherence
  - Development and interpretation of potential laboratory assays
  - Real-world management of bleeding events, development of reversal protocols
Anticoagulant ADEs: Measuring Progress towards Prevention
### (Selected) Anticoagulant ADE Data Sources – *National Surveillance*

<table>
<thead>
<tr>
<th>System (Agency)</th>
<th>Data Element(s)</th>
<th>Methodology</th>
<th>Population</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inpatient</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| NIS (AHRQ)      | Hospital admissions with ICD or E-code diagnosis “anticoagulant poisoning” | Administrative claims | Nationally representative | • Accuracy of diagnostic coding?  
• Impact of conversion to ICD-10? |
| MPSMS/QSRS (AHRQ) | Bleeding events, laboratory abnormalities during hospitalization | Retrospective medical record review | Medicare patients with MI, CHF, PNA or requiring surgery | • Select patient population  
• System undergoing revision |
| **Outpatient**  |                 |             |            |             |
| NEISS-CADES (CDC) | Bleeding events, laboratory abnormalities resulting in ED visits, hospital admissions | Retrospective medical record review | Nationally representative | • Limited information on precipitating factors for ADEs |
### (Selected) Anticoagulant ADE Data Metrics – National Surveillance

<table>
<thead>
<tr>
<th>System (Agency)</th>
<th>Data Element(s)</th>
<th>Method</th>
<th>Population</th>
<th>Gaps</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inpatient</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HealthyPeople.gov</strong></td>
<td><strong>Medical Product Safety</strong></td>
<td><strong>MPS-5.1</strong></td>
<td>Reduce emergency department (ED) visits for overdoses from oral anticoagulants</td>
<td></td>
</tr>
<tr>
<td><strong>Outpatient</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NEISS-CADES (CDC)</strong></td>
<td><strong>Bleeding events, laboratory abnormalities resulting in ED visits, hospital admissions</strong></td>
<td><strong>Retrospective medical record review</strong></td>
<td><strong>Nationally representative</strong></td>
<td><strong>Limited information on precipitating factors for ADEs</strong></td>
</tr>
</tbody>
</table>
### (Selected) Anticoagulant ADE Metrics – Local Surveillance

#### Process Metrics

<table>
<thead>
<tr>
<th>Inpatient</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Implementation of <strong>TJC 2014 National Patient Safety Goal 03.05.01</strong> performance elements to reduce the likelihood of patient harm associated with anticoagulation therapy</td>
<td></td>
</tr>
<tr>
<td>• Number of patients diagnosed with confirmed <strong>VTE receiving unfractionated heparin</strong> therapy dosages with platelet count monitoring by nomogram or protocol (Previously NQF 0374)*</td>
<td></td>
</tr>
<tr>
<td>• Number of patients diagnosed with confirmed <strong>VTE discharged</strong> to home, home health, home hospice on warfarin with written discharge Instructions (Previously NQF 0375)*</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outpatient</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Average percentage of <strong>monthly intervals</strong> in which individuals with claims for warfarin do not receive an INR test (NQF 0555)</td>
<td></td>
</tr>
<tr>
<td>• Percentage of episodes with an <strong>INR test performed 3 to 7 days after a newly-started interacting anti-infective medication</strong> for Part D individuals receiving warfarin (NQF 0556)</td>
<td></td>
</tr>
<tr>
<td>• Average percentage of time in which patients aged 18 and older with <strong>atrial fibrillation</strong> who are on chronic warfarin therapy have <strong>INR test results within the therapeutic range (i.e., TTR)</strong> (CMS EHR Incentive Program 179v3 2014)</td>
<td></td>
</tr>
</tbody>
</table>

NQF National Quality Forum; PT Prothrombin time; INR International Normalized Ratio; VTE Venous thromboembolism
http://www.qualityforum.org/Measures_Reports_Tools.aspx
*No longer NQF-endorsed.
## Anticoagulant ADE Metrics – Gaps & Challenges

<table>
<thead>
<tr>
<th>Anticoagulant ADE Area</th>
<th>Measurement Challenges</th>
</tr>
</thead>
</table>
| **Non-warfarin oral anticoagulants** (e.g., dabigatran, rivaroxaban) | • Evolving and early science  
• Lack of well-established/studied intermediate laboratory markers |
| - Dosing, adherence, and transitions among agents           |                                                                                        |
| **Parenterally-administered anticoagulants** (esp. hospital uses) | • Lack of consensus, uniformity across facilities                                      |
| - Laboratory monitoring parameters                          |                                                                                        |
| **Outcomes**-based metrics                                 | • Limitations/unknowns in diagnostic (ICD) coding                                       |
| - Bleeding events                                           |                                                                                        |
| **Care transitions**-related metrics                       | • Complex processes  
• Limitations in health information exchange interoperability                          |
| - Communication and hand-off                               |                                                                                        |
| **Post acute-care** settings/populations                   | • Lack of surveillance systems or not captured by existing surveillance                  |
| - e.g., LTC, rural/remote, home care                       |                                                                                        |

ICD  International Classification of Diseases;  LTC  Long-term care
Measuring Progress –
Issues for Consideration

• What **metrics** could best inform progress on anticoagulant ADE prevention?
  – National vs. local levels
  – Currently available vs. require development?

• What **data sources** are currently available / would be needed for measurement?
  – Representativeness
  – Baseline and trends
  – Timeliness
  – Accuracy (sensitivity, specificity)

• What **public-private partnerships** could best advance progress on and monitoring of anticoagulant ADE prevention?
Acknowledgments

HHS Office of Disease Prevention and Health Promotion

• Don Wright MD, MPH
• Rebekah Rasooly, PhD
• Mishale Mistry, PharmD, MPH
• Christine Lee, PharmD, PhD
• Andrew York, PharmD

Centers for Disease Control and Prevention

• CAPT Dan Budnitz MD, MPH
• LCDR Andrew Geller, MD
• Mary George, MD, MSPH, FACS, FAHA
• Scott Grosse, PhD

Federal Steering Committee for ADEs and Federal Interagency Workgroup for Anticoagulant ADEs

and

Scott Kaatz, DO

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the Department of Health & Human Services.
Quality Improvement and Preventing Anticoagulant Adverse Drug Events

Anita Thomas, PharmD
Centers for Medicare and Medicaid Services
Overview

• Discuss Anticoagulant Related Adverse Drug Events (ADEs)
• Review Areas of Quality Improvement for Anticoagulant ADE Prevention
• Provide Overview of CMS Quality Improvement Organization (QIO) Program
• Reflect on Quality Improvement Success
• Describe CMS Quality Program Alignment with the National Action Plan on ADE Prevention
Anticoagulants: Most Common Causes of ADEs Across Health Care Settings

- **Inpatient**: One-third of identified ADEs
- **Outpatient**: Most frequent cause ADE leading to ER visits and admissions
- **Long Term Care/Home Care**: As many as 34,000 serious warfarin-related ADEs per year in Nursing Home Settings
Anticoagulants: Areas of Quality Improvement

- Communication and Coordination of Care
  - Provider communication
  - Patient and family engagement
- Medication Coordination
  - Medication reconciliation
  - Inpatient and outpatient medication variations
- Community Driven and Evidence-based Best Practices
- Identification and Resolution of Gaps
The QIO Program, one of the largest federal programs dedicated to improving health quality for Medicare beneficiaries, is an integral part of the U.S. Department of Health & Human Services' (HHS) National Quality Strategy for providing better care and better health at lower cost.
http://www.qioprogram.org
CMS Quality Improvement Organization Program Overview

**Aims**
- Better Health
- Better Care
- Lower Cost

**Foundational Principles:**
- Enable innovation
- Foster learning organizations
- Eliminate disparities
- Strengthen infrastructure and data systems

**Goals**
- Make care safer
- Strengthen person and family engagement
- Promote effective communication and coordination of care
- Promote effective prevention and treatment
- Promote best practices for healthy living
- Make care affordable
CMS QIO 10th Statement of Work (SOW) Success

- Improving Transitions of Care: Nearly $1 billion in cost savings
- Improving Health for Populations and Communities: 1,826 professionals recruited and assisted with PQRS EHR 2012 reporting potentially impacting 4.1 million Medicare beneficiaries
- Reducing Health Care Associated Infections: 85,149 fewer days with urinary catheters for Medicare beneficiaries
- Reducing Potential for Adverse Drug Events: 44,640 potential adverse drug events were prevented
- Preventing or Healing Pressure Ulcers in Nursing Homes: 3,374 pressure ulcers prevented or healed in 767 nursing homes
- Minimizing the Use of Physical Restraints in Nursing Homes: 6,250 Medicare beneficiaries in 981 nursing homes are now restraint free
- Partnering with More Nursing Homes: 5,021 nursing homes recruited to participate in national collaborative
- Improving the Lives of People with Diabetes: 20% absolute rate of improvement in controlling blood sugar levels among participants screened
CMS Quality Improvement Organization Program Framework

QIO 11th Statement of Work

Beneficiary and Family Centered Care (BFCC-QIO)

Quality Innovation Network (QIN-QIO)
QIN-QIO
11th SOW Task Overview

QIN-NCC-QIO

Task A Excellence in Operations
- Improving cardiac health & reducing cardiac disparities
- Reducing disparities in diabetes care
- Coordinating care through Immunization IS
- Coordinating prevention through Health Information Technology

Task B Better Health
- Improving cardiac health & reducing cardiac disparities
- Reducing disparities in diabetes care
- Coordinating care through Immunization IS
- Coordinating prevention through Health Information Technology

Task C Better Care
- Reducing care-associated infections
- Reducing care-acquired conditions
- Coordinating care to reduce readmits & adverse drug events

Task D Lower Costs
- Quality Improvement through Physician Value Modifier
- Local QIO Projects

Task E Technical Assistance
- Beneficiary and Family Centered Care
- Value Based Purchasing

Essential Functions
- Results-Oriented Quality Improvement Activities
- Community Learning and Action Networks
- Technical Assistance (i.e., QI Experts)
- Integrated Communications
QIN-QIO Key Roles

• Champion local-level, results-oriented change
  – Data driven
  – Active engagement of patients and other partners
  – Proactive, intentional innovation spread that improves and “sticks”

• Facilitate learning and action networks
  – Democratizing clinical quality improvement expertise so we “all teach, all learn”
  – Placing impetus for improvement at the bedside level

• Teach and advise as technical experts
  – Consultation and education
  – Knowledge management so learning is never lost

• Communicate effectively
  – Optimal learning, patient activation, and sustained behavior change
QIN-QIO

11th SOW Task: Coordination of Care

• Improve the quality of care for beneficiaries as they transition between providers
• Reduce hospital readmissions and admissions in the Medicare program
• Increase community tenure, as evidenced by increased number of nights spent at home, for at risk beneficiaries
• Reduce the prevalence of adverse drug events
QIN-QIO

11th SOW Task: Coordination of Care (Continued)

• Recruit communities and Medicare FFS Beneficiaries
• Perform community specific root cause
• Identify and implement appropriate community-level interventions across provider settings
• Collect data and determine measures to monitor community-level interventions that demonstrate improved outcomes across various populations of Medicare beneficiaries
QIN-QIO 11th SOW Task: Medication Safety and Adverse Drug Event Prevention

• Alignment with the ADE Action Plan
  – Targeting: Anticoagulants, Diabetes Agents, Opioids
• Alignment with Coordination of care, community focus
• Recruit Medicare beneficiaries, providers across continuum of care
QIN-QIO 11th SOW Task: Medication Safety and Adverse Drug Event Prevention (Continued)

- Implement new tools or utilizing existing tools and/or using Health Information technology to screen beneficiaries for adverse drug events
- Establish collaborations to coordinate medication management
- Develop or promote evidence-based or proven best practice adverse drug event prevention toolkits
- Identify barriers specific to the community
QIN-QIO 11th SOW Task: Examples of QIO Interventions for Anticoagulant ADE Prevention

- Empowering and educating patients and families, particularly at points of transition
- Development of toolkits with best practices specific to anticoagulant use across different care settings
- Medication reconciliation and management
- Identification of issues specific to communities using data analysis and root cause analyses
QIN-QIO 11th SOW Task: Data Driven Quality Improvement

• Analysis of Medicare Data
• Tracking of potential adverse drug events and adverse drug events
• Tracking of readmissions associated with adverse drug events
• Development of specific drug class evaluation measures
Anticoagulants
Adverse Drug Event Action Plan Conference

Scott Kaatz, DO, MSc
Chief Quality Officer, Hurley Medical Center
Clinical Associate Professor of Medicine, Michigan State University
Full Disclosure

• **Grant support**
  – Boehringer-Ingelheim
  – Bristol Myer Squibb
  – Bayer/Jansen/Johnson and Johnson
  – Eisai
  – Iverson Genetics Diagnostics/Medicare
  – National Institute of Health
  – Canadian Institute of Health Research
  – Blue Cross/Blue Shield of Michigan

• **Speaker honorarium**
  – Janssen
  – Boehringer-Ingelheim
  – Bristol Myer Squibb/Pfizer
  – CSL Behring

• **Consultant**
  – Boehringer Ingelheim
  – Bristol Myer Squibb/Pfizer
  – Janssen/Johnson and Johnson
  – Daiichi Sankyo

• **Board membership (non-profit)**
  – AC Forum
  – Thrombosis and Hemostasis Societies of North America
  – National Certification Board of Anticoagulation Providers
  – National Blood Clot Alliance Medical and Scientific Advisory Board
Anticoagulants ADE Action Plan

- Magnitude of the problem
- Current efforts
- Surveillance
- Roadmap for path forward
- Quality Improvement Organization Program
- Transitions of care
- Measures of success
  - Identify
  - Prioritize
- BLUF
- Inpatient
- Outpatient
- Extended care
• “Usual” care of anticoagulants is not safe
  – Many organization have gone to dedicated anticoagulation services
• Financial constraints limit the ability to have inpatient anticoagulation services
• Inability for anticoagulation clinics to receive insurance reimbursement limits their spread
• Similar constraint exist with extended care facilities
Inpatient Anticoagulation Services

• Integrated health care system hospitals
  – Can usually spread the cost among silos
  – Expense on the inpatient side can help with efficiencies and transitions and costs on the outpatient side

• Stand alone community hospitals
  – No realized efficiency/cost savings on the outpatient side
Inpatient Anticoagulation Service

Inpatient Anticoagulation Service

(continued 1)

• Cluster randomized trial
• Single institution
• Un-blinded

<table>
<thead>
<tr>
<th>TABLE 4. Transition of Care and Safety Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transition of Care</td>
</tr>
<tr>
<td>100% Communication bundle* compliance, % (n)</td>
</tr>
<tr>
<td>Appropriately enrolled in the AC clinic, % (n)</td>
</tr>
<tr>
<td>Communication: inpatient service and outpatient physician, % (n)</td>
</tr>
<tr>
<td>Communication: inpatient clinicians and AC clinic staff, % (n)</td>
</tr>
<tr>
<td>INR drawn within five days of hospital discharge, % (n)</td>
</tr>
<tr>
<td>30-Day Composite safety endpoint, % (n)</td>
</tr>
<tr>
<td>Inpatient + 30-day INR &gt;5, % (n)</td>
</tr>
<tr>
<td>Inpatient + 30-day major bleeding, % (n)</td>
</tr>
<tr>
<td>Inpatient + 30-day thrombosis, % (n)</td>
</tr>
</tbody>
</table>
Outpatient Anticoagulation Clinics

• Improve INR time in therapeutic range
  – RCT: 66.4%
  – Anticoagulation clinics: 65.6%
  – Community: 56.7%

• Well accepted management strategy
  – 95% of VA patients managed this way
  – Only about 30% of American managed this way

• Models and resources readily available
  – AC Forum Centers of Excellence
  – National Certification Board for Anticoagulation Providers
  – Indian Health Service 3 day training program

• Model to manage NOAC/TSOAC/DOAC/SODAs

van Walraven C. Chest. 2006 May;129(5):1155-66. PMID: 16685005
National Action Plan for Adverse Drug Event Prevention
Anticoagulation Forum  http://www.ACforum.org
National Certification Board for Anticoagulation Providers  http://www.NCBAP.org
Outpatient Anticoagulation Clinic Funding

• **Integrated health care system**
  – Can spread cost across the system
  – 1 FTE for each 250 – 300 patients
  – Example: 5000 patients would require approximately 20 FTEs
  – About $1.5 million uncompensated care

• **Stand alone community hospitals**
  – No system to spread losses
  – Any savings on outpatient care by private physicians is not realized by the hospital
    • Accountable care organization payments will evolve these calculations
Extended Care Facilities

• Little literature compared to outpatient anticoagulation services
• Could adapt to inpatient models
  – Smaller pool of expertise to draw upon with standalone facilities
• Outpatient anticoagulation clinic management now feasible
  – Shared EMR access allows anticoagulation clinics to manage remotely
  – Changes in reimbursement structure would be needed going forward
Anticoagulants ADE Action Plan

- **Inpatient**
  - Quality incentives robust enough to effect change

- **Outpatient**
  - Reimburse anticoagulation clinic care
    - Home INR monitoring with patient self testing as a model

- **Extended care**
  - Mechanism for anticoagulation clinics to manage
Overview and Prevention of Serious Hypoglycemic Events in Outpatient Settings

Leonard Pogach MD, MBA, FACP
National Director Medicine
Veterans Affairs Central Office
Office of Specialty Care/Office of Patient Care Services
Acknowledgements

Office of Disease Prevention and Health Promotion

• Donald Wright, MD, MPH
  Deputy Assistant Secretary for Health
  Director, Office of Disease Prevention and Health Promotion
  Office of the Assistant Secretary for Health

• Dale J. Hu, MD, MPH
  Chief Medical Officer and Acting Director
  Division of Health Care Quality
  Office of the Assistant Secretary for Health

• Yael Harris, PhD, MHS
  Former Director
  Division of Health Care Quality
  Office of the Assistant Secretary for Health

Federal Interagency Workgroup Co-Lead for Diabetes Agents

• Mary A. Andrawis, PharmD, MPH
  Senior Advisor, Center for Medicare and Medicaid Innovation
Contribution of Hypoglycemia to Health Burden of ADEs

- **Ambulatory Patients**
  - Insulin 1\(^{st}\) most common drug implicated in ED visits for ADEs overall (\(\sim 8\%\)) \(^1\)
  - Insulin and oral diabetes drug implicated in \(\sim 25\%\) of emergent hospitalizations for ADEs in older adults \(^2\)

- **Hospitalized Patients**
  - Hypoglycemia was 3\(^{rd}\) most common ADE \(^3\)

- **Skilled Nursing Facility Patients**
  - Hypoglycemia was 1\(^{st}\) most common ADE \(^4\)

1. *JAMA*. 2006;296:1858-1866
3. Adverse Events in Hospitals, 2010, OEI-06-09-00090
Emergency Hospitalizations for Adverse Drug Events in Older Americans

Figure 1. Estimated Rates of Emergency Hospitalizations for Adverse Drug Events in Older U.S. Adults, 2007–2009.
FIW for ADEs—Diabetes Agents

Overview

Federal Interagency Steering Committee for Adverse Drug Events

<table>
<thead>
<tr>
<th>Topic</th>
<th>Gaps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider education</td>
<td>Understanding co-morbid risks</td>
</tr>
<tr>
<td></td>
<td>Understanding absolute benefits and harms</td>
</tr>
<tr>
<td></td>
<td>Adjust therapy in persons with Diabetes and with multiple chronic</td>
</tr>
<tr>
<td></td>
<td>conditions</td>
</tr>
<tr>
<td></td>
<td>Individualizing care</td>
</tr>
<tr>
<td></td>
<td>Shared Decision Making</td>
</tr>
<tr>
<td>Patient / caregiver</td>
<td>Educational material targeted for hypoglycemia prevention</td>
</tr>
<tr>
<td>education</td>
<td>Addressing health literacy and numeracy in decreasing hypoglycemia</td>
</tr>
<tr>
<td></td>
<td>events</td>
</tr>
<tr>
<td>Surveillance</td>
<td>Absence of rates of serious hypoglycemia in ambulatory care,</td>
</tr>
<tr>
<td></td>
<td>emphasis upon modifiable (Education, Health literacy) and non-</td>
</tr>
<tr>
<td></td>
<td>modifiable (age, chronic co-morbid conditions) risk factors.</td>
</tr>
<tr>
<td>Incentive &amp; Oversight</td>
<td>Overtreatment Measures</td>
</tr>
<tr>
<td></td>
<td>Addressing co-morbid conditions (exclusions and inclusions criteria)</td>
</tr>
<tr>
<td>Health Systems</td>
<td>Impact of care coordination on adverse drug events</td>
</tr>
<tr>
<td></td>
<td>Transitions of care:</td>
</tr>
<tr>
<td></td>
<td>-In the hospital between providers</td>
</tr>
<tr>
<td></td>
<td>-From hospital to home/rehab/nursing home</td>
</tr>
</tbody>
</table>
Diabetes Agents

Public Comments: Common Themes

**Surveillance**

*General concurrence:*
- Complexity in managing blood glucose in patients with comorbidities
  - Preventable vs. non-preventable ADEs
- Improve surveillance of hypoglycemic events to better monitor and understand risk factors for such events

**Incentives and Oversight**

*General concurrence:*
Incentivize programs that individualize Hgb A1c treatment targets for older adults, with penalties for overaggressive glycemic control

**Evidence-Based Prevention Tools**

*General concurrence:*
- Education material targeting prevention of hypoglycemia
- Patient-centered decisions that incorporate a risk/benefit assessment to select the ideal treatment for patients
- Collaborative partnership among health care professionals

**Health Information Technology**

*Gaps identified:*
- Challenges in capturing point-of-care testing data and related quality measures
- Improve linkages with pharmacists in order to help in the development of more robust EHR systems to identify and manage patients with diabetes / hypoglycemia

AC: anticoagulation; EHR: electronic health records; NOACs: new oral anticoagulants
ADE Action Plan: Four-Pronged Approach

- Surveillance
- Evidence-Based Prevention Tools
- Incentives & Oversight
- Research/Unanswered Questions

Health IT
FIW for ADEs—Diabetes Agents
Prevention

Patient Centered Care

“...the highly scientific development of this mechanistic age had led perhaps to some loss in appreciation of the individuality of the patient and to trusting largely to the laboratories and outside agencies which tended to make the patient not the hub of the wheel, but a spoke.” – Dr. Will Mayo
<table>
<thead>
<tr>
<th>Source</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADVANCE, ACCORD, VADT</td>
<td>Serious hypoglycemia strongly associated with cardiovascular morbidity/mortality. Association strongest in control arms.</td>
</tr>
<tr>
<td>Veteran Affairs-Department of Defense (VA-DoD)</td>
<td>Avoid using medications to achieve hemoglobin A1c &lt;7.5% in most adults age 65 and older; moderate control is generally better. There is no evidence that using medications to achieve tight glycemic control in older adults with type 2 diabetes is beneficial. Among non-older adults, except for long-term reductions in myocardial infarction and mortality with metformin, using medications to achieve glycated hemoglobin levels less than 7% is associated with harms, including higher mortality rates. Tight control has been consistently shown to produce higher rates of hypoglycemia in older adults. Given the long timeframe to achieve theoretic microvascular benefit of tight control, glycemic targets should reflect patient goals, health status, and life expectancy. Reasonable glycemic targets would be 7.0–7.5% in healthy older adults with long life expectancy, 7.5–8.0% in those with moderate comorbidity and a life expectancy &lt;10 years, and 8.0–9.0% in those with multiple morbidities and shorter life expectancy.</td>
</tr>
<tr>
<td>American Diabetes Association</td>
<td></td>
</tr>
<tr>
<td>American Geriatrics Society</td>
<td></td>
</tr>
</tbody>
</table>

**Table:** A1C target recommendations, %

<table>
<thead>
<tr>
<th>Major comorbidity or physiologic age</th>
<th>Microvascular complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent &gt; 10 years of life expectancy</td>
<td>&lt; 7</td>
</tr>
<tr>
<td>Present 5-10 years of life expectancy</td>
<td>&lt; 8</td>
</tr>
<tr>
<td>Marked &lt; 5 years of life expectancy</td>
<td>8.9%</td>
</tr>
</tbody>
</table>

**Table:** A Framework for Considering Treatment Goals for Glycemia, Blood Pressure, and Dyslipidemia in Older Adults with Diabetes

<table>
<thead>
<tr>
<th>Patient Characteristics/Health Status</th>
<th>Rationale</th>
<th>Reasonable A1C Goal</th>
<th>Fasting or Preprandial Glucose (mg/dL)</th>
<th>Blood Pressure</th>
<th>Lipids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy (No co-existing chronic illness, intact cognitive and functional status)</td>
<td>Longer remaining life expectancy</td>
<td>&lt;7.5%</td>
<td>90-130</td>
<td>110-180</td>
<td>&lt;140/80</td>
</tr>
<tr>
<td>Complex/or intermediate (Multiple co-existing chronic illnesses or ≥ 2 instrumental ADL impairments or mild to moderate cognitive impairment)</td>
<td>Intermediate remaining life expectancy, high treatment burden, hypoglycemia vulnerability, failure of treatment,</td>
<td>&lt;8.0%</td>
<td>90-160</td>
<td>110-180</td>
<td>&lt;140/80</td>
</tr>
<tr>
<td>Very complex/poor health (Long-term care or end stage chronic illnesses or moderate to severe cognitive impairment or ≥ 4 ADL dependencies)</td>
<td>Limited remaining life expectancy makes benefit uncertain</td>
<td>&lt;8.5%</td>
<td>100-160</td>
<td>110-200</td>
<td>&lt;150/90</td>
</tr>
</tbody>
</table>
American Diabetes Association, American Geriatrics Society, and VA/DoD recommend individualized targets and Shared Decision Making when choosing goals of therapy.

**Looser Glycemic Targets:**
- A1c 7.5 – 8% +
- Hypoglycemia prone
- Limited life expectancy
- Advanced complications
- Extensive co-morbid conditions
- Target difficult to attain

**Glycemic Target:** A1c <7% to 7.5%
For many patients, to ↓ incidence of clinically significant microvascular disease

**Tighter Glycemic Targets:**
- A1c 6 – 6.5%
- Short disease duration
- Long life expectancy
- No significant CVD
- If can be achieved without hypoglycemia
What Has Been Lacking

- The explicit recognition of the emergence of Diabetes with **Multiple Chronic Conditions (DwMCC)** as an additional, important level of complexity

- A framework that builds on elements identified and converts them into a set of specific, actionable, national-level strategies

- Such a framework would allow for identification of gaps in achieving prevention of ADE in persons with DwMCC and also opportunities for collaboration between the public and private sectors
Hypoglycemic ADEs
Opportunities for Advancing Prevention

**Safer Care**
- Improved uptake of **individualized glycemic goals**
- Development of tools to guide providers in engaging in **shared decision-making** with patients/caregivers
- Increase provider awareness of **previous hypoglycemic events to avoid reoccurrence**
- Wider dissemination of **evidence-based protocols** (e.g., dosing nomograms, order sets)

**Patient and Family Engagement**
- Increase use of **shared decision-making** in setting glycemic goals
- Improve incorporation of **hypoglycemia prevention in patient education/health literacy tools**

**Effective Communication and Coordination of Care**
- Promote increased integration of **health literacy/numeracy principles** in patient-provider interactions
- Promote **multidisciplinary and systematic approach to inpatient hypoglycemia prevention efforts**
- Integration of **medication reconciliation and other care transition models**

**Science-driven Prevention and Treatment**
- Address **inaccuracy of self-monitoring of blood glucose**
- Promote use of **root-cause analyses** for all inpatient hypoglycemic events
# Hypoglycemic ADEs

**Current Federal Assets Related to Prevention of Hypoglycemia**

<table>
<thead>
<tr>
<th>Federal Agency</th>
<th>Evidence-based Tool / Resource to Address Hypoglycemia Prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACL</td>
<td>• Stanford Diabetes Self-Management Program&lt;br&gt;• National Council on Aging Better Choices, Better Health-Diabetes&lt;br&gt;• HomeMeds℠ Medication Management System</td>
</tr>
<tr>
<td>AHRQ</td>
<td>• Medicines for Type 2 Diabetes: Research Review&lt;br&gt;• Premixed Insulin for Type 2 Diabetes: Adult Guide Blood Sugar: Research Review&lt;br&gt;• Re-Engineered (RED) Toolkit</td>
</tr>
<tr>
<td>BoP/DoD/VA</td>
<td>• Management of Diabetes Clinical Practice Guidelines</td>
</tr>
<tr>
<td>CDC</td>
<td>• Helping the Child with Diabetes Succeed</td>
</tr>
<tr>
<td>FDA</td>
<td>• Risk Evaluation and Mitigation (REM) Strategies&lt;br&gt;• Medication Guides</td>
</tr>
<tr>
<td>IHS</td>
<td>• Treatment Algorithms&lt;br&gt;• Quick Guide Cards&lt;br&gt;• Advancements in Diabetes Seminar</td>
</tr>
<tr>
<td>NIH</td>
<td>• National Diabetes Information Clearinghouse&lt;br&gt;• Hypoglycemia Resources &amp; Information Material</td>
</tr>
</tbody>
</table>
A1c Variability “Speedometer”
A1C Test and Diabetes
## Diabetes Agents Patient Engagement

### EP: Recommendation 1

<table>
<thead>
<tr>
<th>Objective</th>
<th>Select patient education materials on high risk medications that follow health literacy principles and meet language needs and confirm understanding</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommendations on EHR Functionality/Usability</strong></td>
<td>Provides pre-determined order set of patient education material(s) that follows health literacy principles (e.g., does not use jargon or vague terms, breaks down action steps into manageable explicit steps) according to patient’s preferred language.</td>
</tr>
</tbody>
</table>
Hypoglycemic ADEs
Opportunities for Advancing Surveillance Strategies

- Address gaps in standard surveillance definitions for hypoglycemic events
- Assess the adequacy of diagnostic and procedural coding for capturing hypoglycemic events
- Coordinate efforts across the federal government and with private sector to enhance inpatient monitoring of hypoglycemic events
- Improve access to more integrated EHR data linking pharmacy, laboratory, and outcomes data
- Improve efforts to collect additional information on hypoglycemic events in the ambulatory setting
Hypoglycemic ADEs
Currently Available Federal Surveillance Systems

- AHRQ Medicare Patient Safety Monitoring System (MPSMS)
- CDC National Electronic Injury Surveillance System – Cooperative Adverse Drug Event Surveillance System (NEISS-CADES)
- FDA Adverse Event Reporting System (FAERS)
- AHRQ Healthcare Cost and Utilization Project (HCUP)
- Nationwide Emergency Department Sample (NEDS)
- BOP, DOD Patient Safety Reporting System, IHS Resource and Patient Management System (RPMS-EHR), VHA Integrated Databases / VA ADERS
## Diabetes Agents

### EHR Recommendations: Eligible Providers

<table>
<thead>
<tr>
<th>Category</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Elements</td>
<td>- Record co-morbid conditions</td>
</tr>
<tr>
<td>Patient Lists</td>
<td>- Stratify patients by specific lab values and certain risk factors</td>
</tr>
<tr>
<td>Quality Measure Concepts</td>
<td>- Overtreatment measure</td>
</tr>
<tr>
<td>Clinical Decision Support (CDS)</td>
<td>- Addressing potential risk for hypoglycemia</td>
</tr>
<tr>
<td></td>
<td>- Shared Decision Making</td>
</tr>
<tr>
<td></td>
<td>- Action Plan for prevention of hypoglycemia</td>
</tr>
</tbody>
</table>
### Data Elements & Patient Lists

<table>
<thead>
<tr>
<th>Existing Data Elements</th>
<th>New Data Elements to Capture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive impairment / dementia</td>
<td>Prior hypoglycemic reactions</td>
</tr>
<tr>
<td>Advanced microvascular diabetes complications</td>
<td></td>
</tr>
<tr>
<td>Limited life expectancy</td>
<td></td>
</tr>
<tr>
<td>Current substance use</td>
<td></td>
</tr>
<tr>
<td>Recent discharge from inpatient setting</td>
<td></td>
</tr>
</tbody>
</table>

#### Generate lists of diabetic patients with A1c level and key risk factors

| For all patients with diabetes, patient panels should be generated with the following information | • Most recent A1c value  
• Age  
• Cognitive impairment  
• Advanced microvascular diabetes complications | • Cardiovascular complications  
• Limited life expectancy  
• Alcohol or substance abuse  
• Recent discharge  
• Prior hypoglycemic reactions |
# Clinical Decision Support # 1

<table>
<thead>
<tr>
<th>Rule Title</th>
<th>Identification of patients at risk for hypoglycemia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective</strong></td>
<td>Identify patients at high risk for hypoglycemia and outline recommended action steps</td>
</tr>
<tr>
<td><strong>Risk Group</strong></td>
<td>Persons with diabetes</td>
</tr>
<tr>
<td><strong>Triggering Condition</strong></td>
<td>Risk factors that place a person with diabetes at risk for hypoglycemic events</td>
</tr>
<tr>
<td>Rule Title</td>
<td>Shared Decision Making between physician and patient on target A1c values</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Objective</td>
<td>Use CDS to improve performance in persons with diabetes (a high-priority health condition)</td>
</tr>
<tr>
<td>Risk Group</td>
<td>Persons with diabetes</td>
</tr>
<tr>
<td>Triggering Condition</td>
<td>When A1c value is reported to the physician’s office</td>
</tr>
</tbody>
</table>
Proposed CDS Display

A1c value: Pre-populated

Target A1c value as determined by BOTH physician and patient:

Insert TARGET lab value here after

Reasons to why TARGET lab value was chosen:

<table>
<thead>
<tr>
<th>Patient has the following risk factors for hypoglycemia (check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Older than 65</td>
</tr>
<tr>
<td>Cognitive impairment/dementia</td>
</tr>
<tr>
<td>Advanced microvascular diabetes complications</td>
</tr>
<tr>
<td>Cardiovascular complications</td>
</tr>
<tr>
<td>Limited life expectancy (active treatment of non-squamous, basal cell malignancies; end-stage hepatic, pulmonary disease)</td>
</tr>
<tr>
<td>Alcohol or substance abuse</td>
</tr>
<tr>
<td>Transition inpatient to outpatient</td>
</tr>
<tr>
<td>Prior hypoglycemic reactions.</td>
</tr>
<tr>
<td>Other please state ________________</td>
</tr>
</tbody>
</table>
FIW for ADEs—Diabetes Agents
Incentives and Oversight

Federal Interagency Steering Committee for Adverse Drug Events

<table>
<thead>
<tr>
<th>Workgroup</th>
<th>DIABETES AGENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surveillance</td>
<td></td>
</tr>
<tr>
<td>Evidence-Based Prevention Tools</td>
<td></td>
</tr>
<tr>
<td>Incentives &amp; Oversight</td>
<td></td>
</tr>
<tr>
<td>Research (Unanswered Questions)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Current Incentive Measure</th>
<th>Modification / Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>NQF 0729: Composite (All or Nothing Scoring) Diabetes Mellitus: Hemoglobin A1c control (&lt;8%)</td>
<td>Stratify by age, insulin, co-morbid conditions, significant risk, decreased life expectancy Addressing: highest risk individuals, advanced age, co-morbid conditions</td>
</tr>
<tr>
<td>NQF 0059: Diabetes Mellitus: Hemoglobin A1c poor control (&gt;9%)</td>
<td>CONCEPT MEASURE: Overtreatment treatment measure to balance under-treatment measure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Numerator</th>
<th>Denominator</th>
<th>Exclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td># of pts with A1c: &lt;7% (primary outcome)</td>
<td>Patients on sulfonylurea or insulin tx with chronic co-morbid conditions and / or age &gt;65 years</td>
<td>Younger (&lt;65 years old) not on hypoglycemic agents without specified co-morbid conditions</td>
</tr>
</tbody>
</table>
# Hypoglycemic ADEs

## Opportunities for Advancing Research Areas

<table>
<thead>
<tr>
<th>Topic Area</th>
<th>Gap</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Provider Education</strong></td>
<td>• Comorbidities</td>
</tr>
<tr>
<td></td>
<td>• Risk-benefit analysis for prescribing</td>
</tr>
<tr>
<td></td>
<td>• Individualized care and shared decision-making</td>
</tr>
<tr>
<td><strong>Patient/Caregiver Education</strong></td>
<td>• Impact of increased health literacy / numeracy in the prevention of hypoglycemic ADEs</td>
</tr>
<tr>
<td></td>
<td>• Hypoglycemia-related patient education materials</td>
</tr>
<tr>
<td><strong>Surveillance</strong></td>
<td>• Stratification of hypoglycemic events in ambulatory settings by risk factors</td>
</tr>
<tr>
<td></td>
<td>• Impact of hypoglycemic events on quality of life</td>
</tr>
<tr>
<td><strong>Incentives &amp; Oversight</strong></td>
<td>• Overtreatment of diabetes measure</td>
</tr>
<tr>
<td></td>
<td>• Addressing comorbidities (via exclusions and inclusions criteria) and impact on rates of hypoglycemia</td>
</tr>
<tr>
<td><strong>Health Systems</strong></td>
<td>• Current prevention tools in transitions of care</td>
</tr>
<tr>
<td></td>
<td>• EHRs to facilitate monitoring over time</td>
</tr>
<tr>
<td></td>
<td>• Linked EHR-pharmacy systems to identify patients with diabetes/hypoglycemia</td>
</tr>
<tr>
<td></td>
<td>• Medication management interventions recorded in EHRs and impact on patient outcomes</td>
</tr>
<tr>
<td></td>
<td>• Telephonic diabetes management for specific patient populations</td>
</tr>
</tbody>
</table>
The physician must be able to tell the antecedents, know the present, and foretell the future – must mediate these things, and have two special objects in view with regard to disease, namely, to do good or to do no harm. The art consists in three things – the disease, the patient, and the physician. The physician is the servant of the art, and the patient must combat the disease along with the physician.
Prevention of Serious Hypoglycemic Events in Inpatient Settings

Mary Andrawis, PharmD, MPH
Senior Advisor
Centers for Medicare and Medicaid Services, Innovation Center
National Data Source on ADEs
AHRQ - MPSMPS

Medicare Patient Safety Monitoring System (MPSMS)
• Trained abstracters extract information from sample of 800 charts every year

2010 Data From MPSMS on Adverse Drug Events associated with:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digoxin</td>
<td>12,000</td>
</tr>
<tr>
<td>Hypoglycemic Agents</td>
<td>930,000*</td>
</tr>
<tr>
<td>IV Heparin</td>
<td>170,000**</td>
</tr>
<tr>
<td>LMWH and Factor Xa Inhibitor</td>
<td>340,000**</td>
</tr>
<tr>
<td>Warfarin</td>
<td>170,000**</td>
</tr>
<tr>
<td>Total Adverse Drug Events</td>
<td>1,621,000</td>
</tr>
</tbody>
</table>

*57% are hypoglycemic agents
**42% are anticoagulants (combined)

MPSMS 2011 Data: 33,967 Hospital Discharges

Patient was receiving insulin/oral hypoglycemics or both during hospital stay

Yes: 12,394 cases

No: 706 cases excluded

Glucose tested and documented during the stay

Yes: 11,888 cases

No: 11,209 cases

Glucose ≤ 50 mg/dl

No: 9,367 cases excluded

Yes: 1,521 cases

Glucose ≤ 70 mg/dl but > 50 mg/dl

No: 9,367 cases

Yes: 679 cases

There was documentation the day of the serum glucose that patient(s) experienced one or more of the following:

- 1,082 Administrations of D 50
- 42 Administrations of glucagon
- 1,017 Administrations of juice and/or sugar
- 46 Anxiety
- 9 Code Blues/CPR
- 113 Confusion
- 14 Deaths
- 120 Drowsiness
- 77 Sweating
- 147 Weakness
- 11 Trembling
- 123 Increased heart rates
- 11 Irritability
- 0 Seizures
- 1 Stroke
- 0 Transient ischemic attack (TIA)
- 1 Myocardial Infarction
- 16 Comas/Losses of consciousness

1,305 cases did not experience an adverse event the same day they had a serum glucose equal or less than 70 mg/dl

Note: Patient(s) may have experienced more than one incidence of an adverse event during the hospital stay. Thus, the incidences of adverse events are greater than the number of cases that had at least one adverse event.

1,216/11,888 = 10.23% of patients who received a hypoglycemic agent during the hospital stay and had a blood glucose level documented during the stay experienced an adverse event.
ADEs as Causes of Inpatient Complications

- ~63% of ADEs:
  1. Excessive bleeding (anticoagulants)
  2. Delirium or change in mental status (opioids, benzodiazepines)
  3. Hypoglycemic event (insulin, oral hypoglycemics)

- ~50% of ADEs judged to be preventable

ADEs as Result of Care Transitions

- Most common causes of post-discharge complications
  - Comprise ~two-thirds of post-discharge complications*
  - Comprise ~one-half of preventable post-discharge complications

*Within 3 weeks of hospital discharge.

Inpatient Hypoglycemia

Patient Risk Factors
- Low BMI
- Cachexia
- Advanced Malignancy
- Age
- Liver
- Kidney disease
- CHF

Iatrogenic
- Insulin/oral agents Risk Magnified with inappropriate use or failure to react/anticipate preventable problems
- Overly aggressive target
- Inappropriate prescribing

Top Predictors:
1. Nutritional Interruption
2. Prior hypoglycemia
3. Inappropriate prescribing
Inpatient Glycemic Control: Challenges

No Standard Definition of Serious/Severe/Clinically Significant Hypoglycemia

- Blood glucose <40 mg/dL
- Requiring third-party assistance (e.g., from a family member and/or medical personnel, or leading to an emergency department visit or hospital admissions)
Unclear Ideal Glycemic Targets

- Uncontrolled hyperglycemia associated with poor outcomes
- Use of intensive insulin therapy associated with reductions in mortality in ventilated ICU patients
- Results not replicated in NICE-SUGAR study, in which intensive insulin therapy associated with serious hypoglycemia/increased mortality
Inpatient Glycemic Control: Challenges (continued 2)

• Professional society-recommended upper-level glycemic targets in the ICU setting range from 150 mg/dL (Society of Critical Care Medicine) to 200 mg/dL (American College of Physicians)

• Careful balance in managing risks associated with hyperglycemia and hypoglycemia

Target values for glycemic control recommended by the Federal sector and multiple private and public stakeholder agencies should be individualized
Inpatient Glycemic Control: Challenges (continued 3)

Lack of Systematic Identification of Patients at Risk

- Failure to adjust insulin/diabetes regimens in response to decreases in oral intake (e.g. unexpected interruption of tube feedings or other sources of nutrition)
- Failure to respond appropriately to an initial hypoglycemic event (>40% of patients who experience one episode go on to suffer at least one additional hypoglycemic episode)

*Federal partners should facilitate the use of systems that enhance recognition and documentation of risk factors, including prior hypoglycemic events, that contribute to inpatient hypoglycemic events*
Barriers to Multidisciplinary Coordination

• Information should be shared across all health care providers and shifts; includes documentation of nutritional intake, coordination of meal time/blood glucose testing, and changes in normal routine (e.g., reduced dietary intake or use of parenteral nutrition)

• The use of EHR, order sets, and hypoglycemic management protocols can support tracking this information
# Measure Recommendations

<table>
<thead>
<tr>
<th>Metric</th>
<th>Description and Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Quality Measure Concepts—Eligible Hospitals (Inpatient Settings)</strong></td>
<td></td>
</tr>
<tr>
<td>7. Hypoglycemic events, serious</td>
<td>Total number of hypoglycemic events, divided by the number of patients administered a diabetes agent.</td>
</tr>
<tr>
<td>Rationale</td>
<td>Calculates percent of hypoglycemic events for all inpatients receiving diabetes agents.</td>
</tr>
<tr>
<td>8. Hyperglycemia</td>
<td>Total number of hyperglycemic hospital days (defined as elevated glucose level), divided by all individuals with a diagnosis of diabetes mellitus who were administered antidiabetic agents (except metformin)</td>
</tr>
<tr>
<td>Rationale</td>
<td>- Calculates percent of hyperglycemic events for all inpatients receiving diabetes agents.</td>
</tr>
<tr>
<td></td>
<td>- Serves as balancing measure to hypoglycemia measure.</td>
</tr>
<tr>
<td>9. Hypoglycemia, mild</td>
<td>Total number of days in which any hypoglycemic event (&lt;70 mg/dL) reported, divided by total number of hospital days for patients receiving a diabetes agent.</td>
</tr>
<tr>
<td>Rationale</td>
<td>Currently no system to effectively track and monitor episodes of hypoglycemia that do not result in need for third-party assistance.</td>
</tr>
<tr>
<td>10. Recurrent Hypoglycemia</td>
<td>Patients suffering at least one recurrent hypoglycemic event on a subsequent hospital day during the same hospital stay.</td>
</tr>
<tr>
<td>Rationale</td>
<td>Patients suffering at least one recurrent hypoglycemic event on a subsequent hospital day during the same hospital stay.</td>
</tr>
</tbody>
</table>
# New NQF-Endorsed Measures

**Inpatient glycemic control measures**

<table>
<thead>
<tr>
<th>Measure Title/Description</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Implementation Guidance</th>
<th>Measure Developer/Endorsement Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe hypoglycemia</td>
<td>Total number of hypoglycemic events (&lt;40 mg/dL) that were preceded by administration of short-acting insulin within 12 hours or an antidiabetic agent other than short-acting insulin within 24 hours, were not followed by another glucose value greater than 80 mg/dL within five minutes, and were at least 20 hours apart</td>
<td>Total number of hospital days with at least one antidiabetic agent administered</td>
<td>Threshold may be adjusted if needed</td>
<td>CMS/NQF endorsed: NQF# 2363</td>
</tr>
<tr>
<td>Hyperglycemia</td>
<td>Sum of the percentage of hospital days in hyperglycemia (≥2 elevated blood glucose values (&gt;200 mg/dL) at least 6 hours apart, a single elevated blood glucose measurement if only 1 value is available that day, or no blood glucose level was measured that day and the preceding 2 days were not normoglycemic days) for each admission in the denominator</td>
<td>Total number of admissions with diagnosis of diabetes mellitus, at least one administration of insulin or any antidiabetic medication except metformin, or at least one elevated blood glucose value (&gt;200 mg/dL [11.1 mmol/L]) at any time during the entire hospital stay</td>
<td>Threshold may be adjusted if needed</td>
<td>CMS/NQF endorsed: NQF# 2362</td>
</tr>
</tbody>
</table>
### EHR Functionality/Usability
**Recommendation—Eligible Hospitals (Inpatient Settings)**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>11.</td>
<td>Documentation of etiology of hypoglycemic event</td>
</tr>
</tbody>
</table>

**Rationale**
Captures etiology and actions to take (checklist) to prevent future events

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>12.</td>
<td>Alert to potential risk for hypoglycemic events</td>
</tr>
</tbody>
</table>

**Rationale**
- When there is a patient with repeated blood glucose values of $<70 \text{ mg/dL}$, provider should be alerted for potential risk.
- Provider should be provided list of options to prevent future episodes or document why no action taken.
What Can Safer Care Look Like at the Front Line?

• Adopt a basal/bolus insulin protocol and eliminate sliding scale insulin
• Institute a nurse-driven protocol for hypoglycemia management
• Ensure the coordination of mealtime blood glucose testing, insulin administration, and meals
Dignity Health System (35 Hospitals)
Rate: BG<40 / Total POC Results

Decrease of 51.7% from Baseline to Current

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Jun-12</th>
<th>Jul-12</th>
<th>Aug-12</th>
<th>Sep-12</th>
<th>Oct-12</th>
<th>Nov-12</th>
<th>Dec-12</th>
<th>Jan-13</th>
<th>Feb-13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numerator</td>
<td>8,798</td>
<td>7,272</td>
<td>598</td>
<td>447</td>
<td>405</td>
<td>382</td>
<td>322</td>
<td>343</td>
<td>331</td>
<td>300</td>
</tr>
<tr>
<td>Denominator (Total POC Results)</td>
<td>3,067,470</td>
<td>2,641,303</td>
<td>197,915</td>
<td>199,960</td>
<td>195,670</td>
<td>201,919</td>
<td>205,596</td>
<td>209,882</td>
<td>234,646</td>
<td>208,707</td>
</tr>
<tr>
<td>Number of Hospitals</td>
<td>35</td>
<td>35</td>
<td>35</td>
<td>35</td>
<td>35</td>
<td>35</td>
<td>35</td>
<td>35</td>
<td>35</td>
<td>35</td>
</tr>
</tbody>
</table>
Surveillance

LCDR Andrew I. Geller, MD
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
Surveillance and the ADE Action Plan

- Identify **existing federal systems** for ADE surveillance

- Identify **gaps and future opportunities**
  - Describe considerations for choosing surveillance data sources and surveillance metrics
  - Review operating characteristics of existing federal surveillance systems

- For each ADE focus area, identify opportunities for advancing surveillance to drive improvement
  - Match surveillance **metrics** with **existing data sources**

Considerations in Selecting Data Source & Metrics

- General Considerations
  - Quantification vs. Signal Detection
  - Active Surveillance vs. Passive / Voluntary Reporting
  - Actual Harms vs. Potential Problems
    - (Injuries vs. Errors)
Considerations in Selecting Data Source & Metrics (continued)

- Specific Considerations
  - Adverse “Drug” Events
  - Medication Use / Drug Denominators
  - Severity
  - Setting
  - Scope
  - Timeliness
  - Intervention Patterns?
# Federal Data Sources
## Active Systems

<table>
<thead>
<tr>
<th>AHRQ</th>
<th>CDC</th>
<th>AHRQ</th>
<th>FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>System Name</strong></td>
<td>MPSMS</td>
<td>NEISS-CADES</td>
<td>HCUP</td>
</tr>
<tr>
<td><strong>ADE Identification</strong></td>
<td>ADE-specific Active Case-finding</td>
<td>ADE specific Active Case-finding</td>
<td>Database Query</td>
</tr>
<tr>
<td><strong>Population</strong></td>
<td>Sample of Medicare FFS</td>
<td>Sample of U.S. EDs</td>
<td>State-based sample of US</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>Inpatient</td>
<td>ED</td>
<td>Inpatient &amp; ED</td>
</tr>
<tr>
<td><strong>Data Source(s)</strong></td>
<td>Inpatient medical records</td>
<td>ED medical records</td>
<td>Hospital Discharge Administrative Data</td>
</tr>
</tbody>
</table>

AHRQ, Agency for Healthcare Research and Quality  
CDC, Centers for Disease Control and Prevention  
FDA, Food and Drug Administration
# Federal Data Sources

## Passive Systems

<table>
<thead>
<tr>
<th>System Name</th>
<th>BOP</th>
<th>DOD</th>
<th>FDA</th>
<th>IHS</th>
<th>VA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>System Name</strong></td>
<td>N/A</td>
<td>Patient Safety Reporting System/ Pharmacovigilance Defense Application System</td>
<td>FAERS</td>
<td>RPMS-EHR</td>
<td>VA ADERs / VA Integrated Databases</td>
</tr>
<tr>
<td><strong>Population</strong></td>
<td>Inmates at federal prisons</td>
<td>Active military, retirees, and their families (MTFs)</td>
<td>U.S. &amp; Foreign</td>
<td>American Indians/ Alaskan Natives (IHS facilities)</td>
<td>Veterans (VHA facilities)</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>Outpatient &amp; Inpatient</td>
<td>Outpatient &amp; Inpatient</td>
<td>Any Setting</td>
<td>Outpatient &amp; Inpatient</td>
<td>Outpatient &amp; Inpatient</td>
</tr>
<tr>
<td><strong>Data Source(s)</strong></td>
<td>ADE Reports</td>
<td>ADE reports / EHR &amp; Administrative Data</td>
<td>ADE reports &amp; Clinical trials</td>
<td>ADE reports / EHR &amp; Administrative Data</td>
<td>ADE reports / EHR &amp; Administrative Data</td>
</tr>
</tbody>
</table>

**BOP**, Bureau of Prisons  
**DOD**, Department of Defense  
**IHS**, Indian Health Service  
**VA**, Veterans Administration
Data Sources Specific to Hypoglycemia

- **Ambulatory Patients**
  - National Health Interview Survey (NHIS)\(^1\)
    - Number of Americans diagnosed with diabetes
    - Treatment with insulin and/or oral diabetes agents

- **Hospitalized Patients**
  - Medicare Patient Safety and Monitoring System (MPSMS) / Quality & Safety Reporting System (QSRS)\(^2\)
    - Percent of patients administered hypoglycemic agents with an episode of hypoglycemia requiring intervention
  - MPSMS (through 2013) / QSRS (beginning 2015)\(^3\)

1. [http://www.cdc.gov/nchs/nhis/about_nhis.htm](http://www.cdc.gov/nchs/nhis/about_nhis.htm)
Existing Hypoglycemia Metrics

- **Ambulatory Patients**
  - **Healthy People 2020 Medical Product Safety – 5.2**
    - Reduce emergency department (ED) visits for overdoses from injectable anti-diabetic agents (per 10,000 outpatient prescription visits)

- **Hospitalized Patients**
  - **National Quality Forum (NQF) Endocrine Measure – 2363**
    - Rate of hypoglycemic events (<40 mg/dL) following the administration of an anti-diabetic agent
  - Paired with a hyperglycemia metric (NQF 2362)

2. [http://www.qualityforum.org](http://www.qualityforum.org)
Questions to Run On

- Additional data sources & metrics?
  - Inpatient / Outpatient / Other settings
  - Process or Outcome metrics
  - National Progress or Quality Improvement
  - Timeliness / Trending

- Gaps in data sources / metrics?
Questions?
Preventing Opioid ADEs and Monitoring Progress

Robert Kerns, PhD
Director, Pain Research, Informatics, Multimorbidities and Education
(PRIME) Center; Special Advisor for Pain Research
Federal Interagency Workgroup for Adverse Drug Events - Opioids

- D. Nelson – ACL/AOA
- D. Cousins – AHRQ
- D. Perfetto – AHRQ*
- H. Wong – ASPE
- D. Boyle – BOP
- D. Budnitz – CDC
- A. Geller – CDC
- C. Jones – CDC*
- N. Shehab – CDC
- J. Cooper – CMS
- M. Ketcham – CMS
- D. Krauss – CMS
- A. Levitt – CMS
- J. Lyles – CMS
- D. McNally – CMS
- K. Nakano – CMS

- S. Rubio – CMS
- T. Coster – DOD*
- D. Myers – DOD
- J. Racoosin – FDA
- D. Slavin – FDA
- L. Tilman – HIS
- H. Huentelman – HIS
- K. Baker – NIH
- B. Goldspiel – NIH
- J. Skapik – ONC
- F. Cunningham – VA
- R. Kerns – VA*
- J. Trafton – VA
- R. Chou – Non-Federal
- J. Eadie – Non-Federal
- P. Kreiner – Non-Federal

* Presenting
Pain management and the role of opioid medications

Essential tool in the management of acute, post-operative, and procedural pain and in palliative care

Growing controversy regarding use in the management of chronic pain
Opioids for chronic low back pain

Figure 2. Results of meta-analysis of opioid efficacy with nonopioids or placebo comparisons

<table>
<thead>
<tr>
<th>Study, Year (Reference)</th>
<th>Standardized Mean Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kuntz and Brosel, 1996 (40)</td>
<td>-0.04 (-0.96 to 0.87)</td>
</tr>
<tr>
<td>Richards et al., 2002 (21)</td>
<td>-0.3 (-0.68 to 0.08)</td>
</tr>
<tr>
<td>Jamison et al., 1998 (44)</td>
<td>-0.02 (-0.82 to 0.78)</td>
</tr>
<tr>
<td>Hale et al., 2005 (41)</td>
<td>-0.4 (-0.74 to -0.07)</td>
</tr>
<tr>
<td><strong>Pooled</strong></td>
<td><strong>-0.19 (-0.49 to 0.11)</strong></td>
</tr>
</tbody>
</table>

Favors Opioid  Favors Placebo

Figure 3. Results of meta-analysis of opioid efficacy with opioid comparisons

<table>
<thead>
<tr>
<th>Study, Year (Reference)</th>
<th>Standardized Mean Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gammaitoni et al., 2003 (48)</td>
<td>-0.66 (-1.19 to -0.12)</td>
</tr>
<tr>
<td>Ringe et al., 2002 (50)</td>
<td>-1.13 (-1.55 to -0.7)</td>
</tr>
<tr>
<td>Schofferman, 1999 (49)</td>
<td>-0.69 (-1.23 to -0.15)</td>
</tr>
<tr>
<td>Simpson et al., 1997 (51)</td>
<td>-0.04 (-0.44 to 0.35)</td>
</tr>
<tr>
<td>Thurel et al., 1991 (45)</td>
<td>-2.12 (-2.89 to -1.35)</td>
</tr>
<tr>
<td><strong>Pooled</strong></td>
<td><strong>-0.93 (-1.89 to 0.03)</strong></td>
</tr>
</tbody>
</table>

Pain Reduction  Pain Increase

Increase in opioid prescribing

Source: Automation of Reports and Consolidated Orders System, US DEA, slide adapted from A Gilson
38,329 drug overdose deaths in 2010

16,651 (43%) involved opioid analgesics

Key summary points:

- “Clinicians may consider a trial of chronic opioid therapy if chronic non-cancer pain is moderate or severe, pain is having an adverse impact on function or quality of life, and potential therapeutic benefits outweigh or are likely to outweigh potential harms (strong recommendation, low-quality evidence).”

- Structured monitoring: Continue if safe and effective, discontinue if unsafe or ineffective
Limited Scope

• Limited focus to ADEs in the context of therapeutic use

• Not included:
  – Illicit/recreational use
  – Medication withdrawal
  – Intentional self-harm
  – Non-adherence
Surveillance
Opioid Adverse Event Plan

Christopher M. Jones, PhD, PharmD, MPH
CDR, US Public Health Service
Office of Public Health Strategy and Analysis
Office of the Commissioner
Food and Drug Administration
Outline

- Importance of surveillance in ADE prevention
- Outcomes and measures to track
- Examples of surveillance systems
- Recommended actions to improve surveillance
- Conclusions
Importance of Surveillance

• Need accurate, timely, and adequately representative information to understand trends in opioid injuries and safe prescribing practices
• Basis for measuring progress
• Inform future program or policy revision or development
Types of outcomes to track

• Clinical or primary outcomes
  – ED visits, deaths

• Intermediate or surrogate outcomes
  – Clinical or laboratory values that precede or lead to clinical outcomes
  – These are less relevant for opioid ADEs; not clearly established in context of opioid ADE prevention

• Process measures
  – Indicators of actions aimed at mitigating risk for primary or surrogate outcomes
What type of surveillance systems exist for opioid ADEs

- Federal
- State
- Facility-level
- Some surveillance systems can provide information on one or more levels
### Surveillance for clinical outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Data Source</th>
<th>Agency</th>
<th>Overview</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>National Vital Statistics System (NVSS)</td>
<td>CDC</td>
<td>Data from all death certificates in the U.S., including deaths involving drugs. Based on ICD-10 codes to identify the underlying cause of death as well as contributing causes</td>
</tr>
<tr>
<td>ED Visits</td>
<td>Drug Abuse Warning Network (DAWN)</td>
<td>SAMHSA</td>
<td>Data on drug-related ED visits from a nationally representative sample of EDs. Discontinued data collection in 2011 – now transitioning to a new system at CDC (in partnership with SAMHSA)</td>
</tr>
<tr>
<td>ED Visits</td>
<td>National Electronic Injury Surveillance System Cooperative Adverse Drug Event Surveillance (NEISS-CADES)</td>
<td>CDC</td>
<td>Collects data on ED visits for opioid overdose and other ADEs not related to misuse or abuse.</td>
</tr>
<tr>
<td>Outcome</td>
<td>Data Source</td>
<td>Agency</td>
<td>Overview</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>--------------------------------------------------</td>
<td>----------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>ED Visits Hospitalizations</td>
<td>Health Care Utilization Project (HCUP)</td>
<td>AHRQ</td>
<td>Largest all-payer emergency department (ED) database. Based on ICD-9 CM codes</td>
</tr>
<tr>
<td>Broad range of adverse events</td>
<td>FDA Adverse Event Reporting System (FAERS)</td>
<td>FDA</td>
<td>Database that contains information on adverse event and medication error reports submitted to FDA.</td>
</tr>
<tr>
<td>Broad range of adverse events</td>
<td>Mini-Sentinel (Sentinel Initiative)</td>
<td>FDA</td>
<td>Uses a variety of health-related electronic data (administrative claims data, electronic health records, drug dispensing data, etc.) to identify safety signals</td>
</tr>
<tr>
<td>Broad range of adverse events</td>
<td>Federal Health System Databases (VA, DOD, IHS, etc.)</td>
<td>Various</td>
<td>Monitor patient visits, ED visits, hospitalizations based on claims and administrative data</td>
</tr>
</tbody>
</table>
# Surveillance for process measures

<table>
<thead>
<tr>
<th>Measures</th>
<th>Data Source</th>
<th>Agency</th>
<th>Overview</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribing and use patterns</td>
<td>Prescription Behavioral Surveillance System (PBSS)</td>
<td>CDC, FDA, BJA,</td>
<td>Collects de-identified data from multiple state PDMPs. Longitudinal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Brandeis CoE</td>
<td>database for surveillance and evaluation</td>
</tr>
<tr>
<td>Prescribing and use patterns</td>
<td>Prescription Drug Monitoring Programs</td>
<td>Various state</td>
<td>Collects information on patient, prescriber, dispenser, drug, dose,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>agencies</td>
<td>quantity.</td>
</tr>
<tr>
<td>Controlled substance distribution</td>
<td>Automation of Reports and Consolidated Orders System (ARCOS)</td>
<td>DEA</td>
<td>Monitors flow of certain controlled substances from their point of</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>manufacture through distribution to the dispensing/retail level</td>
</tr>
<tr>
<td>Treatment and prescribing</td>
<td>Federal Health System Databases and EHRs (VA, DOD, IHS, BOP)</td>
<td>Various</td>
<td>Data on clinical interactions, tests conducted, prescriptions ordered,</td>
</tr>
<tr>
<td>patterns</td>
<td></td>
<td></td>
<td>etc.</td>
</tr>
</tbody>
</table>
Actions to advance surveillance for opioid ADEs

• Determine the adequacy of diagnostic and procedural coding for capturing opioid-related overdose events

• Address strengths and limitations in using process measures to identify opioid ADEs and measure associations between changes in process measures and risk of opioid ADEs in inpatient and outpatient settings

• Improve access to more integrated EHR data with linked pharmacy and outcomes data
Actions to advance surveillance for opioid ADEs (continued)

- Identify appropriate ADE surveillance metrics for opioid ADEs in inpatient and outpatient settings
- Address gaps in standard surveillance definitions for opioid-related overdose events
- Promote increased use of PDMP systems by providers and maintenance of funding for PDMP development at the state and federal level
Conclusions

• Surveillance is the cornerstone of not only our understanding of the problem, but also of tracking progress of change efforts

• Current surveillance systems are not optimal for opioid ADE surveillance

• Opportunities exist to develop clinical outcome and process measures, standardize definitions for opioid ADEs, and conduct research to validate candidate metrics

• Collaborations can be taken to improve our current surveillance of opioid ADEs
Evidence-Based Prevention Tools
Opioid Adverse Event Plan
Outline

• Overview of evidence-based prevention tools
• Examples of prevention tool resources
• Opportunities to advance opioid ADE prevention
• Charge to federal agencies
• Conclusions
Overview

- Federal agencies and others have implemented a number of strategies to reduce opioid ADEs
- Tools may differ depending on practice setting and types of ADEs
  - Inpatient: system-wide changes targeting medication and prescribing errors may be the most appropriate target
  - Outpatient: safer prescribing and closer monitoring by providers are likely best targets
<table>
<thead>
<tr>
<th>Resource</th>
<th>Agency</th>
<th>Overview</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid prescribing guidelines</td>
<td>DOD/VA</td>
<td>Includes recommendations for assessing patients for appropriate pain therapy, guidance on treatment options to consider, and patient monitoring</td>
</tr>
<tr>
<td>ER/LA Opioid Risk Evaluation and Mitigation Strategy (REMS)</td>
<td>FDA</td>
<td>Continuing education courses provided to interested providers based on FDA’s Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics</td>
</tr>
<tr>
<td>TeleBehavioral Health Center of Excellence in Pain and Addictions Course</td>
<td>IHS</td>
<td>Webinar training program that provides specialized information on how to treat pain and addiction</td>
</tr>
<tr>
<td>NIDAMED</td>
<td>NIDA</td>
<td>Website with tools and resources for medical professionals for safe pain management including two classes entitled “Safe Prescribing for Pain” and “Managing Pain Patients who Abuse Rx Drugs”</td>
</tr>
</tbody>
</table>
# Federal resources for patients and families

<table>
<thead>
<tr>
<th>Resource</th>
<th>Agency</th>
<th>Overview</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Disease Self-Management Education Programs</td>
<td>ACL</td>
<td>Education and tools to older adults and adults with disabilities to help them better manage chronic conditions, including chronic pain</td>
</tr>
<tr>
<td>ER/LA Opioid Risk Evaluation and Mitigation Strategy (REMS)</td>
<td>FDA</td>
<td>Patient counseling document available for providers to help guide education on risk and opioid management for patients receiving extended-release or long-acting opioids</td>
</tr>
<tr>
<td>Taking Opioids Responsibly</td>
<td>VA</td>
<td>Patient education tool titled “Taking opioids responsibly: for your safety and the safety of others”. Provides patients with information to help guide long-term opioid therapy for chronic pain</td>
</tr>
</tbody>
</table>
Federal resources to promote systems best practices and improve care coordination

<table>
<thead>
<tr>
<th>Resource</th>
<th>Agency</th>
<th>Overview</th>
</tr>
</thead>
<tbody>
<tr>
<td>VA National Pain Management Strategy</td>
<td>VA</td>
<td>Outlines best practices for pain management, including the use of facility-level pain management committees to provide oversight, and coordination of pain management activities to align actual care practices with best practices</td>
</tr>
<tr>
<td>Project Red</td>
<td>AHRQ</td>
<td>Provides information on a number of medication-related best practice strategies such as active medication reconciliation, and medication teaching for patients and caregivers</td>
</tr>
<tr>
<td>Sole Provider Program</td>
<td>DOD</td>
<td>The Sole Provider Program, developed as a risk mitigation program, identifies high-risk patients and assigns a single provider and one alternate provider who is authorized to prescribe opioids.</td>
</tr>
<tr>
<td>Mobile Application for Pain</td>
<td>VA</td>
<td>VA is piloting a mobile application designed to provide tools to help patients set personal goals for pain management; track their symptoms, functions, and self care behaviors over time; and provide guidance on pain management strategies for patients and caregivers</td>
</tr>
</tbody>
</table>
Opportunities to advance opioid ADE prevention - Inpatient
Using the National Quality Strategy Priorities

- **Safer Care**: Expand dissemination of evidence-based opioid guidelines/protocols (e.g. dosing changes, management of high-risk individuals)
- **Patient and Family Engagement**: Promote patient education to improve the safety of care transition
- **Effective Communication and Coordination of Care**: Develop more optimal and integrated Health IT opioid management tools
- **Science-driven Prevention and Treatment**: Promote “systematic and coordinated care”
  - Promote safe practices around initiation of opioids
  - Promote the use of evidence-based tools for morphine equivalent dose and transitions between formulations
- **Promote Best Practices within Communities**: Use metrics to monitor the use of opioid safety “best practices”
  - Promote the use of evidence-based guidelines for monitoring
# Opportunities to advance opioid ADE prevention - Outpatient

Using the National Quality Strategy Priorities

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safer Care</strong></td>
<td>Expand dissemination of evidence-based opioid guidelines/protocols. Improve availability and uptake of safe opioid prescribing practices.</td>
</tr>
<tr>
<td><strong>Patient and Family Engagement</strong></td>
<td>Develop and distribute patient education materials and strategies using the principles of health literacy. Spread public health message promoting safe opioid storage, use, disposal and not sharing opioids with friends or family.</td>
</tr>
<tr>
<td><strong>Effective Communication and Coordination of Care</strong></td>
<td>Develop more optimal and integrated Health IT opioid management tools. Integrate opioid-specific targets into care transition models.</td>
</tr>
<tr>
<td><strong>Promote Best Practices within Communities</strong></td>
<td>Use metrics to monitor the use of opioid safety best practices. Promote effective strategies identified by federal agencies that engage in patient care.</td>
</tr>
</tbody>
</table>
Charge to federal agencies

#1

- Federal agencies should explore ways to improve uptake of evidence-based strategies for safe opioid prescribing
  - Increase use of opioid prescribing guidelines
  - Appropriate provider training through didactic training, continuing education, and training at key points in the clinical training
Charge to federal agencies

#2

• Federal agencies should promote patient-centered, multimodal, team-based care to:
  – Personalize pain management
  – Properly manage patients with high-risk medical and mental co-morbidities
  – Intensively manage patients at high risk for opioid overdose
Charge to federal agencies #3

• Federal agencies should develop and encourage the use of patient education materials and tools
  – Materials should be developed using health literacy principles
  – Empower the patient to use opioids safely
  – Encourage patient engagement
Charge to federal agencies #4

- Leverage and learn from federal agencies involved in patient care
  - Agencies can play an important role in assessing and promoting best practices for pain management and opioid safety
  - Incubators of innovation
  - Dissemination of successes and challenges is essential
Conclusions

• Numerous tools exist to help improve the safe and appropriate use of opioids and to reduce opioid ADEs
• Many are not well implemented
• Federal agencies that provide patient care have been and can continue to be incubators of innovation for best practices
• Federal agencies charged to support the uptake and implementation of best practices.
Opioids: Incentives & Oversight and Research Needs

COL Trinka Coster, MD, MS
DA Director, Pharmacovigilance Program
Department of Defense
Disclaimer

The Department of Defense, to include the Defense Health Agency, Army, Navy, Air Force and Coast Guard, does not necessarily endorse, support, sanction, encourage, verify or agree with the comments, opinions, or statements presented. Any information are the views and responsibility of those making the comments and do not necessarily represent the views of the Department of Defense, the United States Government or its third party service providers.
Incentives & Oversight to Address Risk Factors for Opioid ADEs

• **Perform Drug Utilization Reviews & Monitor Administrative &/or Point of Sale Data to Identify At-Risk Patients**
  - Flag for maximum dose threshold, refill restriction, pill quantities, therapeutic duplication, drug-disease contraindications & incorrect duration of treatment
  - Identify patterns that suggest drug overutilization:
    - ✓ Prescribing patterns: # of prescribers &/or pharmacies in a unit of time
    - ✓ Cumulative dose monitoring: Morphine equivalent dose >120 mg
  - Data-sharing among pharmacies/practices to prevent unsafe opioid prescribing/dispensing

• **Advance Health Policy Strategies for Preventing Opioid ADEs**
  - Inpatients:
    - ✓ Expand health care quality reporting measures to include multi-disciplinary models of pain management (e.g., criteria for clinical pharmacist intervention, behavioral health intervention)
    - ✓ Validate metrics to monitor: patients on PCA opioid Rx or initiating high dose opioids/high potency formulations
Incentives and Oversight to Address Risk Factors for Opioid ADEs (continued)

• **Advance Health Policy Strategies for Preventing Opioid ADEs**
  o **Outpatient Strategies:**
    ✓ Metrics for process measures that identify high-risk patients
    ✓ Address financial barriers to use evidence-based prevention strategies, multi-disciplinary teams and multi-modal treatments for pain management
    ✓ Metrics for identifying high-risk patients and high-risk prescribers using administrative data and PDMP that lead to abuse/misuse
  o **Transitions of Care/Coordinated Care Strategies:**
    ✓ Address barriers to facilitate integrated pain management therapy

• **Standardizations of EHR for Opioid Therapy**
  o Strategies to Incentivize Clinical Support Systems: appropriate opioid starting dose, MEDs, & best practices/clinical guideline suggestions
  o Strategies to Incentivize: assessment, documentation, team pain management, risky behavior & opioid ADE prevention
Table 14. Measure Considerations for EHR (Stage 3) MU Requirements That Can Potentially Advance Opioid ADE Prevention, as Proposed by the Federal Interagency Workgroup for Opioid ADEs

<table>
<thead>
<tr>
<th>Metric</th>
<th>Description and Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outpatient Clinical Quality Measure Concepts</strong></td>
<td></td>
</tr>
<tr>
<td>Patients on high daily dose of long-term opioid therapy</td>
<td>▪ There is an association between high daily dose of opioids and opioid ADEs, which requires further study to understand the impact on clinical practice.</td>
</tr>
<tr>
<td>Patients co-prescribed long-term opioid therapy and CNS depressants</td>
<td>▪ Co-prescribing of opioids with CNS depressants, especially benzodiazepines, is associated with opioid overdose deaths.</td>
</tr>
<tr>
<td>Patients on long-term opioid therapy given a toxicology screen</td>
<td>▪ All guidelines recommend assessment of risk related to substance abuse prior to initiating opioids and while patients are on therapy.</td>
</tr>
<tr>
<td>Patients on long-term opioid therapy</td>
<td>▪ Guidelines recommend monitoring PDMPs when available.</td>
</tr>
<tr>
<td>Patients on long-term opioid therapy who were checked in to the</td>
<td>▪ Early data show that PDMPs may be effective, although more research will be necessary as PDMPs continue to be developed and used.</td>
</tr>
<tr>
<td>relevant Prescription Drug Monitoring Program prior to initiating</td>
<td></td>
</tr>
<tr>
<td>therapy and at least every year if on chronic opioid therapy</td>
<td></td>
</tr>
<tr>
<td>Patients on long-term opioid therapy who have evidence of a written</td>
<td>▪ All guidelines recommend that patients starting on long-term opioid therapy have an opioid care management plan that identifies the goals of therapy and the expectations for the patient.</td>
</tr>
<tr>
<td>opioid care management plan</td>
<td></td>
</tr>
<tr>
<td>Number of patients on long-term opioid therapy who have evidence of</td>
<td>▪ All guidelines recommend assessment for mental health disorders prior to initiating opioids, and treatment as appropriate.</td>
</tr>
<tr>
<td>mental health assessment</td>
<td></td>
</tr>
<tr>
<td>Number of patients in facility or practice prescribed opioids</td>
<td>▪ Numbers are based on a VA measure that is used to compare prescribing rates across facilities.</td>
</tr>
<tr>
<td>Inpatient Clinical Quality Measure Concepts</td>
<td></td>
</tr>
<tr>
<td>Opioid-naive patients started on high-dose opioids in the inpatient</td>
<td>▪ Inappropriate prescribing is a significant problem that can lead to opioid overdose in the inpatient setting, especially in high-potency formulations.</td>
</tr>
<tr>
<td>setting</td>
<td></td>
</tr>
<tr>
<td>Clinical Decision Support (CDS) Rule Concepts</td>
<td></td>
</tr>
<tr>
<td>Clinical decision support rules to support all measure concepts</td>
<td>▪ There should be supporting clinical decision support to promote best practices and improve measured processes.</td>
</tr>
</tbody>
</table>

Abbreviations: ADE = adverse drug event; CNS = central nervous system; IV = intravenous; PCA = patient-controlled analgesia; PDMP = Prescription Drug Monitoring Program
Research & Unanswered Questions

- Prevention Strategy Effectiveness (e.g., UDS, MED, Max dose, single provider)
- Definitions: to identify/define ADEs, aberrant behavior, misuse, abuse, overdose
- Best Practices: on management of high risk patient & adherence to CPG
- Outcomes: when using PDMP, sole provider, pain management teams & plans
- Coordination: of care (among a team or settings) and sharing data
- Overdose: differentiate accidental overdose vs. misuse/abuse
- Quality of Life: standard methods of assessing impact of pain
- Treatment: Biochemical/genetic markers for chronic pain, safety/efficacy of long term opioid Rx, pharmacogenomics and metabolism of opioids, new drug development for abuse resistant opioid formulations & starting, titrating and maximum effective dose
- Surveillance: coordination of surveillance system addressing ADEs and high- risk patients and prescribers
- Non-Drug Interventions: effectiveness of adjunctive and behavioral modalities for pain management and reduction in opioid use
Thank You!
Opioids: Measure and Metrics

Deborah Perfetto, PharmD
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality
Measures and Metrics: Current

Outcome:

National ADE Incidence/Rate:

- HCUP
- MPSMS
- QSRS (in development)
- ED visits
- Part D Claims- outpatient prescribing
- NEISS-CADES- ED visits for opioid overdose
- DAWN- ED visits for opioid overdose
Measures and Metrics: Current (continued)

Process:
National ADE Incidence/Rate:
• ARCOS- opioids sold to retail registrants

Quality Improvement:
Regional/Facility ADE Incidence/Rate:
• DOD- Outpatient clinic, ED visits, hospitalizations
• ATHENA
• VA- Outpatient clinic, ED visits, hospitalizations
• PDMP
• Partnership for Patients
• PSO

Spontaneous Reports:
• FDA Clinician-diagnosed or patient-reported ADE
Measures and Metrics: Proposed/meaningful Use Criteria

Outpatient:

- High daily dose long-term opioids
- Co-prescribed long-term opioids and CNS depressants
- Toxicology screen for long-term therapy
- PDMP check prior to and yearly for long-term therapy
- Written opioid care management plan
- Mental health assessment for long-term therapy
- Number of patients prescribed opioids in facility or practice
Measures and Metrics: Proposed/Meaningful Use Criteria

Inpatient:

• Monitoring of patients on PCA opioid therapy
• Prescribing high dose opioids in opioid-naïve patients

Clinical Decision Support:

• Clinical decision support rules to support measures concepts
Questions?

Breakout Sessions Wrap-Up and Closing Plenary
Questions?