

ADE Prevention: 2014 Action Plan Conference

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

- Most common post-discharge complication

- 3.5 million office visits
- 1 million ED visits



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

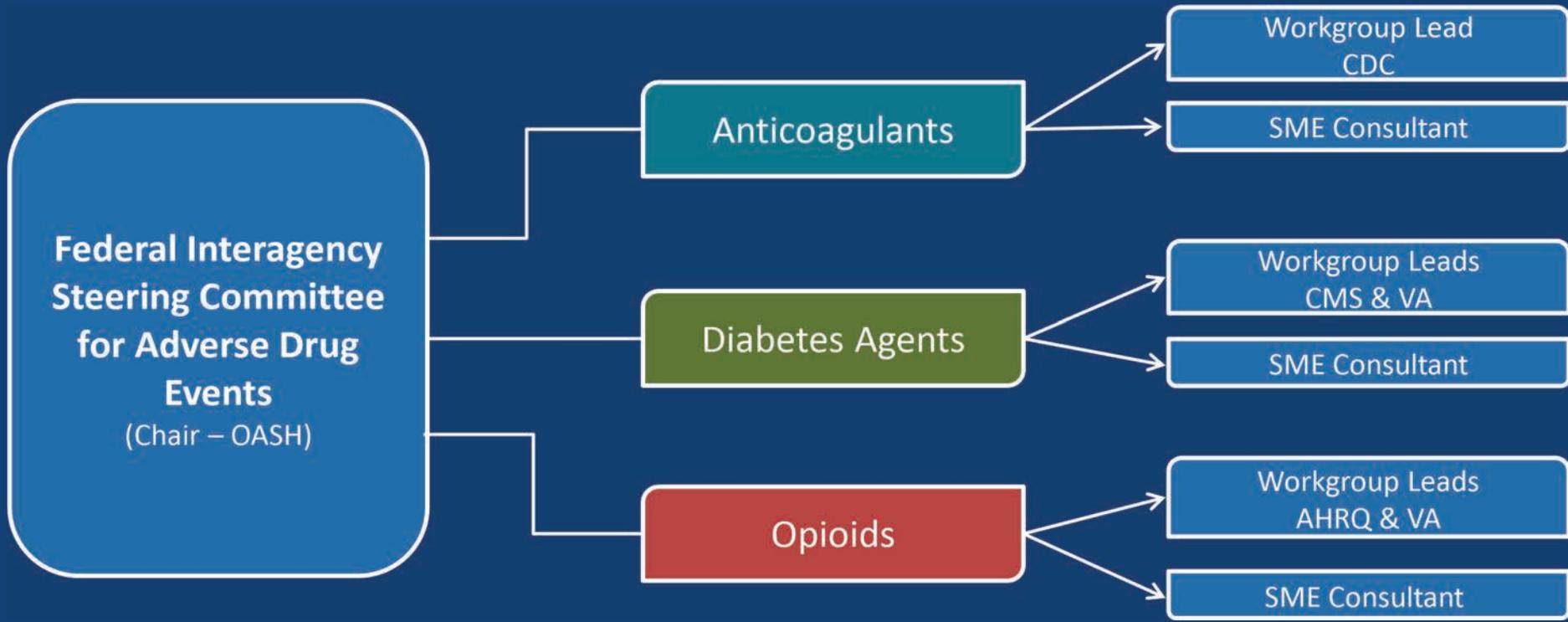


Considerations in Targeting Drug Classes

Medication Class	Nature of Harms		
	Common	Clinically Significant	Preventable
Antibiotics	✓	?	?
Antineoplastics	✓	✓	?
Corticosteroids	✓	?	?
Anticoagulants	✓	✓	✓
Insulin/oral hypoglycemics	✓	✓	✓
Opioids/benzodiazepines	✓	✓	✓



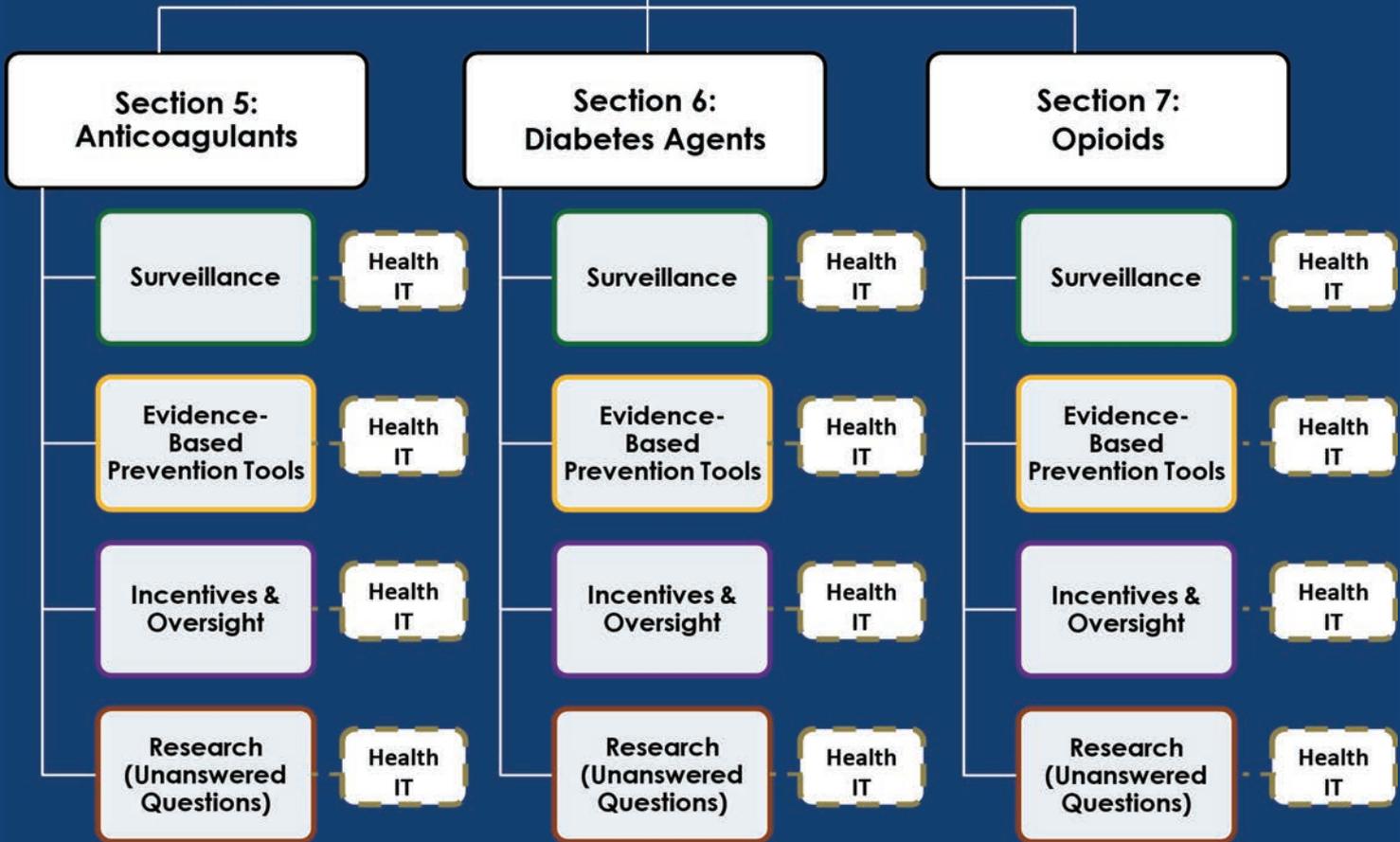
ADE Prevention Federal Advisory Group





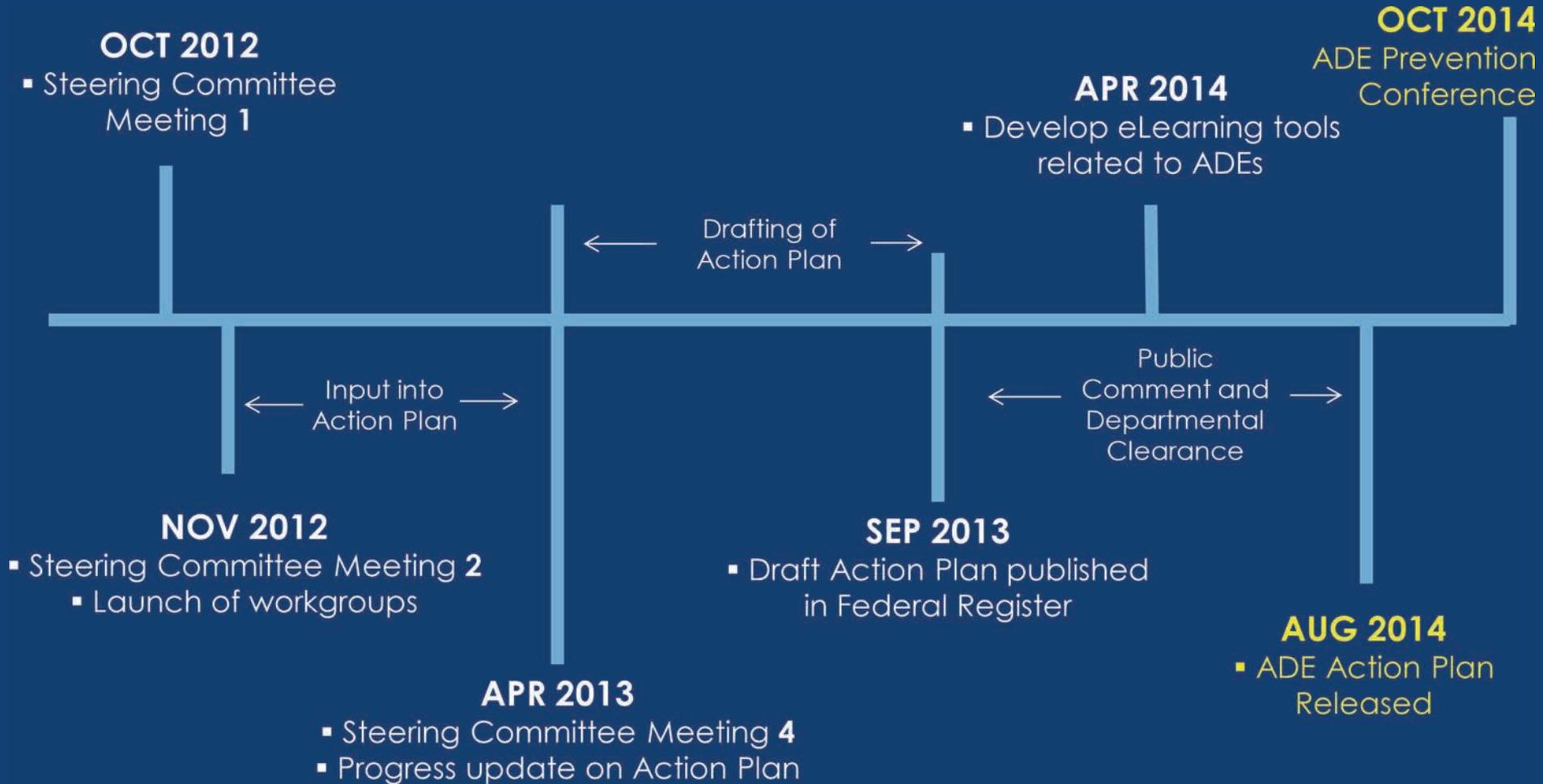
National Action Plan Components

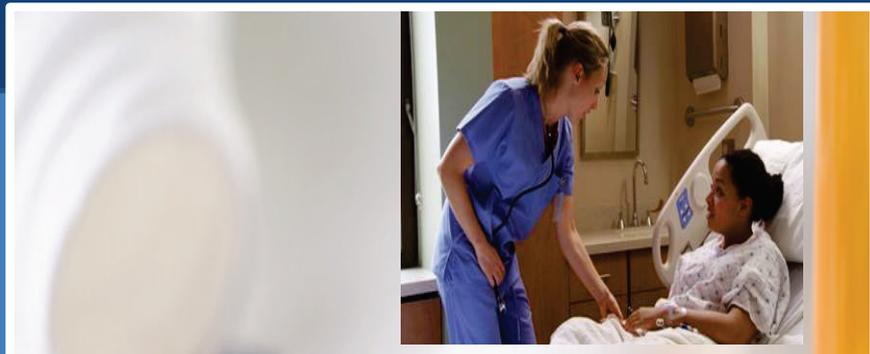
Executive Summary
Introduction
Section 1: Action Plan Scope and Development
Section 2: Surveillance Resources
Section 3: Prevention Approaches
Section 4: Incentives and Oversight Opportunities





ADE Action Plan **Timeline**





Preventing Anticoagulant Adverse Drug Events (ADEs) and Monitoring Progress

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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



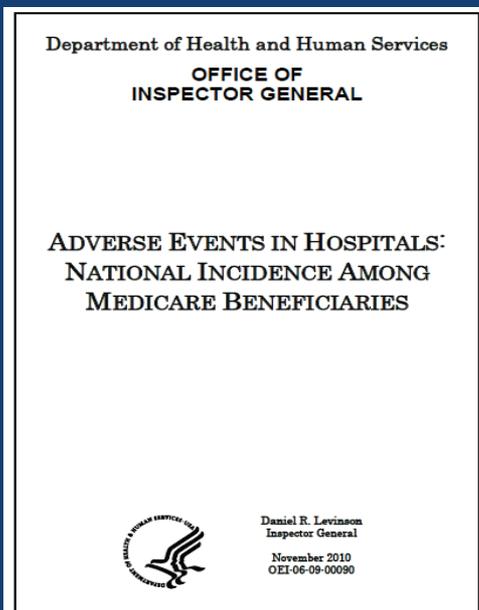
- All ADEs
 - Affect **~1.9 million** U.S. hospital stays annually (2008)
 - **Drugs: most common** causes of inpatient complications
 - **~3.5 billion** (2006 USD) hospital costs



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)*



April 2011
Medication-Related Adverse Outcomes in U.S. Hospitals and Emergency Departments, 2008

Jennifer Lucado, M.P.H., Kathryn Paetz, Ph.D., M.B.A., R.N., and Anne Elkhauser, Ph.D.

Introduction

The use of pharmaceuticals is an essential element of the American health care system, helping to treat acute illnesses and maintain control of chronic conditions in many people. However, medication use can result in morbidity and mortality from many types of adverse outcomes. Adverse outcomes can include side effects of prescribed drugs that are taken as directed, unintentional overdosing by the patient, and medication errors such as incorrect prescribing and dosing. The rates of medication-related adverse outcomes are increasing over time—a trend likely to continue with the aging of the population, the growth in the number of comorbidities, and polypharmacy.^{1,2,3,4}

This Statistical Brief presents data from the Healthcare Cost and Utilization Project (HCUP) on medication- or drug-related adverse outcomes that were seen in hospitals in 2008, updating previously published information on inpatient stays in 2004.⁵ In addition, we provide information on these occurrences in treat-and-release emergency department (ED) visits.

The following types of medication-related adverse outcomes are coded in these hospital and ED data:

- "drug poisoning (overdose or wrong drug given or taken in error) or accidental poisoning (accidental

Highlights

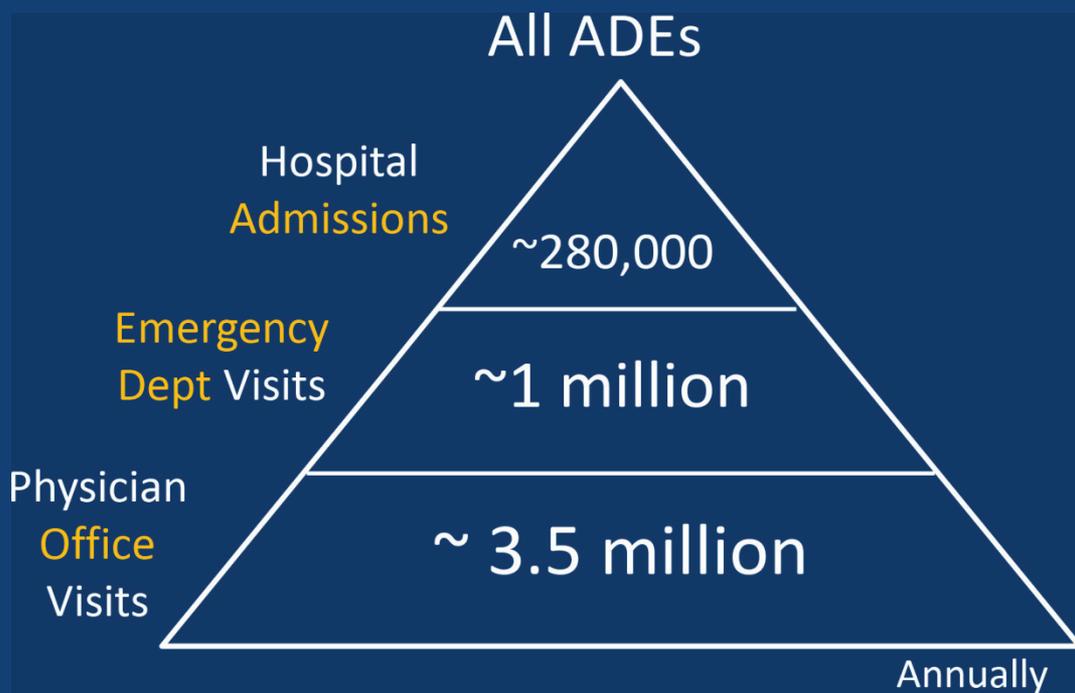
- In 2008, drug-related adverse outcomes were noted in nearly 1.9 million inpatient hospital stays (4.7 percent of all stays), and 838,000 treat-and-release ED visits (0.8 percent of all visits).
- Over the five years between 2004 and 2008, there was a 52 percent increase in drug-related adverse outcomes in the inpatient setting—more than half of this increase was due to corticosteroids, anticoagulants, and sedatives and hypnotics.
- In the inpatient setting, corticosteroids, such as prednisone, caused 13.2 percent of all drug-related adverse outcomes.
- Analgesics, antipyretics, and antirheumatics were the second most common general cause of drug-related adverse outcomes for both inpatient and treat-and-release ED events, accounting for 12.5 percent and 11.8 percent of events, respectively. Within this category, opiates were the most common specific cause of drug-related adverse outcomes, responsible for 5.8 percent of all inpatient events and 4.4 percent of treat-and-release ED events.
- Over 53 percent of all inpatient stays with a drug-related adverse outcome were for patients 65 or older. Only 18.5 percent of treat-and-release ED visits with a drug-related adverse outcome were for elderly patients.
- Among treat-and-release ED visits involving drug-related adverse outcomes, analgesics and antibiotics were common causes of events for all age groups. Psychotropics were another common drug-related adverse outcome for all age groups younger than 65. Agents affecting the blood (such as anticoagulants) were a common drug-related adverse outcome for those 65 and older.

¹ Budnitz DS, Pollock DA, Weidenbach KM, Mendelsohn AB, Schroeder TJ, Annet JL. "National Surveillance of Emergency Department Visits for Outpatient Adverse Drug Events." JAMA. 2006; 296(15):1926-1930.
² Hug BL, Wilkowitz DJ, Seo CM, Kochane CA, Seger DL, Yoon C, Matheny ME, Bates DM. "Adverse Drug Event Rates in Six Community Hospitals and the Potential Impact of Computerized Physician Order Entry for Prevention." Journal of General Internal Medicine. 2010; 25(1): 21-30.
³ Bourgeois FT, Shannon MW, Vallin C, Mandl KD. "Adverse Drug Events in the Outpatient Setting: An 11-year Analysis." Pharmacotherapy and Drug Safety. 2010; 30(9): 901-910.
⁴ Sicker HC, Rajgopalakrishnan R, MacDonald D, Barrett S, Collins KD, Dorman J, Gadag V. "Adverse Drug Events in Adult Patients Leading to Emergency Department Visits." The Annals of Pharmacotherapy. 2010; 44(4): 541-546.
⁵ Elkhauser A, and Owens P (AHRQ). Adverse Drug Events in U.S. Hospitals, 2004. HCUP Statistical Brief #26. April 2007. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.hcup-a.ahrq.gov/stat/statbriefs/sb26.pdf>

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



Outpatient ADEs





Outpatient ADEs (ED Visits): Contribution of Anticoagulants



JAMA The Journal of the American Medical Association

National Surveillance of Emergency Department Visits for Outpatient Adverse Drug Events

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Thomas J. Schroeder, MS
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Context: Adverse drug events are common and often preventable causes of medical injuries. However, timely, nationally representative information on outpatient adverse drug events is limited.

Objective: To describe the frequency and characteristics of adverse drug events that lead to emergency department visits in the United States.

Design, Setting, and Participants: Active surveillance from January 1, 2004, through December 31, 2005, through the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance project.

- 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^a

Case Characteristic	ED Visits for Adverse Events	
	Warfarin	
	Cases, No.	Annual National Estimate, % (95% CI)
Adverse event description		
Acute hemorrhage ^b	2005	67.6 (60.3-74.8)
Central nervous system hemorrhage	82	3.2 (1.6-4.9)
Pulmonary hemorrhage	44	2.5 (1.3-3.8)
Gastrointestinal tract hemorrhage	493	22.8 (16.9-28.7)
Genitourinary hemorrhage	190	8.2 (6.4-10.1)
Epistaxis, skin, or other minor hemorrhage	1022	54.3 (48.6-60.0)
Other or unspecified hemorrhage	174	8.9 (6.7-11.1)
Other adverse events	745	26.7 (21.3-32.1)
Laboratory abnormality only	671	93.2 (88.3-98.0)
Fall/injury while taking antiplatelet/anticoagulant	74	6.8 (2.0-11.7) ^d
Unspecified toxic effects ^c	176	5.7 ^d (1.6-9.9)
Disposition		
Hospitalized ^e		
All ED visits	1385	43.9 (38.1-49.8)
ED visits for acute hemorrhages only	877	40.1 (33.8-46.4)

~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



Federal Interagency Workgroup for Anticoagulant ADEs



Federal Interagency Workgroup for Anticoagulant ADEs

Federal Interagency Steering Committee for Adverse Drug Events

Workgroup 1 ANTICOAGULANTS



- 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)



Draft National Action Plan for ADE Prevention Published Sep 4, 2013

National Action Plan for Adverse Drug Event Prevention



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The Daily Journal of the United States Government

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Notice

Solicitation of Written Comments on Draft National Action Plan for Adverse Drug
Event Prevention

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)



U.S. Department
of Health & Human Services



B. L. U. F.

(Bottom Line Up Front)

- To minimize population harms from anticoagulants, Federal partners will need to:

Surveillance

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

Evidence-Based Prevention Tools

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

Incentives & Oversight

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

Research (Unanswered Questions)

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



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>



Anticoagulant ADEs: Key Prevention Issues



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 suprathreshold 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

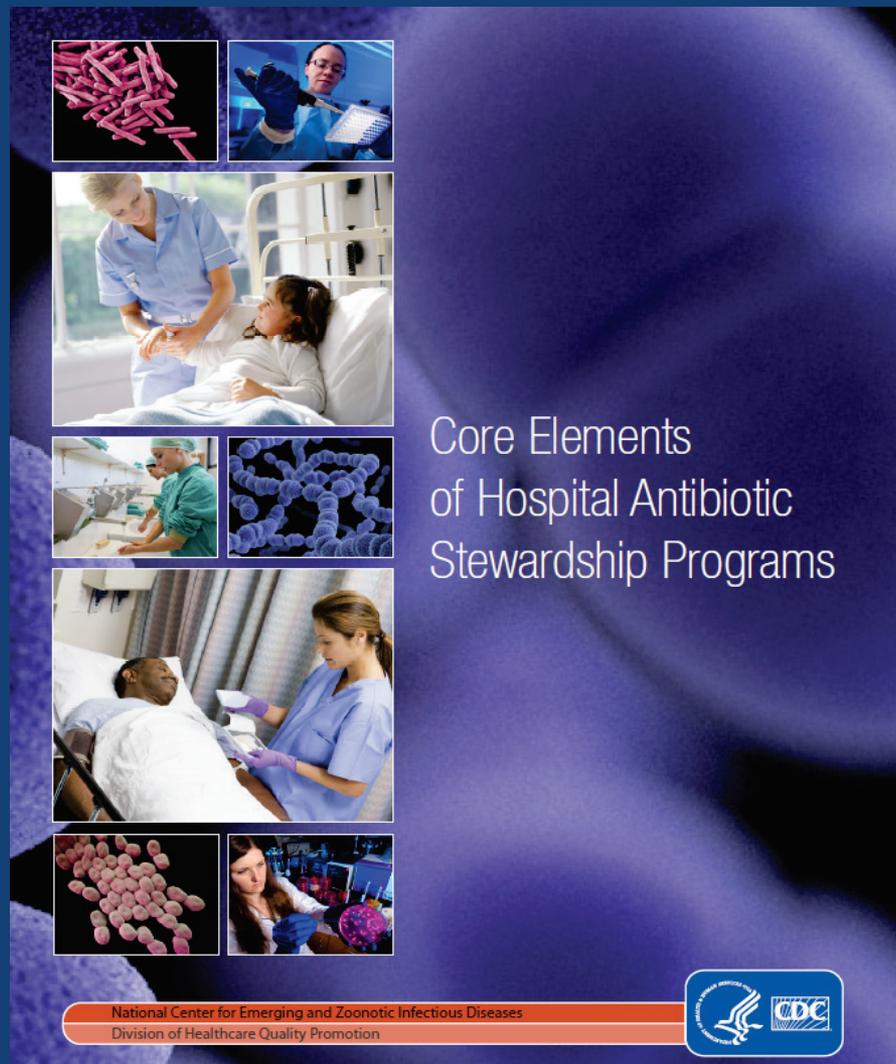


Antibiotic Stewardship as an Example

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





Advancing the Concept of Anticoagulation Stewardship

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

Can the same be achieved for Anticoagulation?

 The Joint Commission

National Patient Safety Goals Effective January 1, 2014

Hospital Accreditation Program

NPSG.03.05.01

Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.

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



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



Anticoagulant ADEs: Key Incentives & Oversight Issues



Q: What actions can potentially advance healthcare POLICY strategies for preventing anticoagulant ADEs?

- **Payment / Coverage Challenges:**

Area	Key Issues (Examples)
Anticoagulation Clinics	<ul style="list-style-type: none">• Payments to non-physician providers• Physician billing for anticoagulation management services
Warfarin PST/PSM	<ul style="list-style-type: none">• Reimbursement/enrollment challenges
LTC, home care	<ul style="list-style-type: none">• Practice delivery model challenges

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



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

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



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



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



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

System (Agency)	Data Element(s)	Methodology	Population	Limitations
Inpatient				
NIS (AHRQ)	Hospital admissions with ICD or E-code diagnosis “anticoagulant poisoning”	Administrative claims	Nationally representative	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Limited information on precipitating factors for ADEs



(Selected) Anticoagulant ADE Data Metrics – *National Surveillance*

System (Agency)	Data Element(s)	Method	Population	Gaps
<i>Inpatient</i>				
				<ul style="list-style-type: none"> Accuracy of diagnostic coding? Impact of conversion to ICD-10?
Medical Product Safety				<ul style="list-style-type: none"> Select patient population
MPS-5.1		Reduce emergency department (ED) visits for overdoses from oral anticoagulants		
<i>Outpatient</i>				
NEISS-CADES (CDC)	Bleeding events, laboratory abnormalities resulting in ED visits, hospital admissions	Retrospective medical record review	Nationally representative	<ul style="list-style-type: none"> Limited information on precipitating factors for ADEs



(Selected) Anticoagulant ADE Metrics – *Local* Surveillance

Process Metrics

Inpatient

- Implementation of **TJC 2014 National Patient Safety Goal 03.05.01 performance elements to reduce the likelihood of patient harm associated with anticoagulation therapy**
- Number of patients diagnosed with confirmed **VTE receiving unfractionated heparin** therapy dosages **with platelet count monitoring** by nomogram or protocol (Previously NQF 0374)*
- Number of patients diagnosed with confirmed **VTE discharged** to home, home health, home hospice on warfarin **with written discharge instructions** (Previously NQF 0375)*

Outpatient

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



Anticoagulant ADE Metrics – Gaps & Challenges

Anticoagulant ADE Area	Measurement Challenges
<ul style="list-style-type: none">• Non-warfarin oral anticoagulants (e.g., dabigatran, rivaroxaban)<ul style="list-style-type: none">– Dosing, adherence, and transitions among agents	<ul style="list-style-type: none">• Evolving and early science• Lack of well-established/studied intermediate laboratory markers
<ul style="list-style-type: none">• Parenterally-administered anticoagulants (esp. hospital uses)<ul style="list-style-type: none">– Laboratory monitoring parameters	<ul style="list-style-type: none">• Lack of consensus, uniformity across facilities
<ul style="list-style-type: none">• Outcomes-based metrics<ul style="list-style-type: none">– Bleeding events	<ul style="list-style-type: none">• Limitations/unknowns in diagnostic (ICD) coding
<ul style="list-style-type: none">• Care transitions-related metrics<ul style="list-style-type: none">– Communication and hand-off	<ul style="list-style-type: none">• Complex processes• Limitations in health information exchange interoperability
<ul style="list-style-type: none">• Post acute-care settings/populations<ul style="list-style-type: none">– e.g., LTC, rural/remote, home care	<ul style="list-style-type: none">• Lack of surveillance systems or not captured by existing surveillance



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?



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- Scott Grosse, PhD

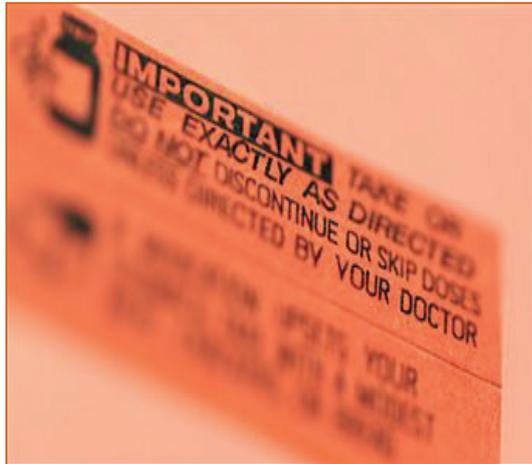
Federal Steering Committee for ADEs and Federal Interagency Workgroup for Anticoagulant ADEs and Scott Kaatz, DO

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



CMS Quality Improvement Organization Program

- 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>

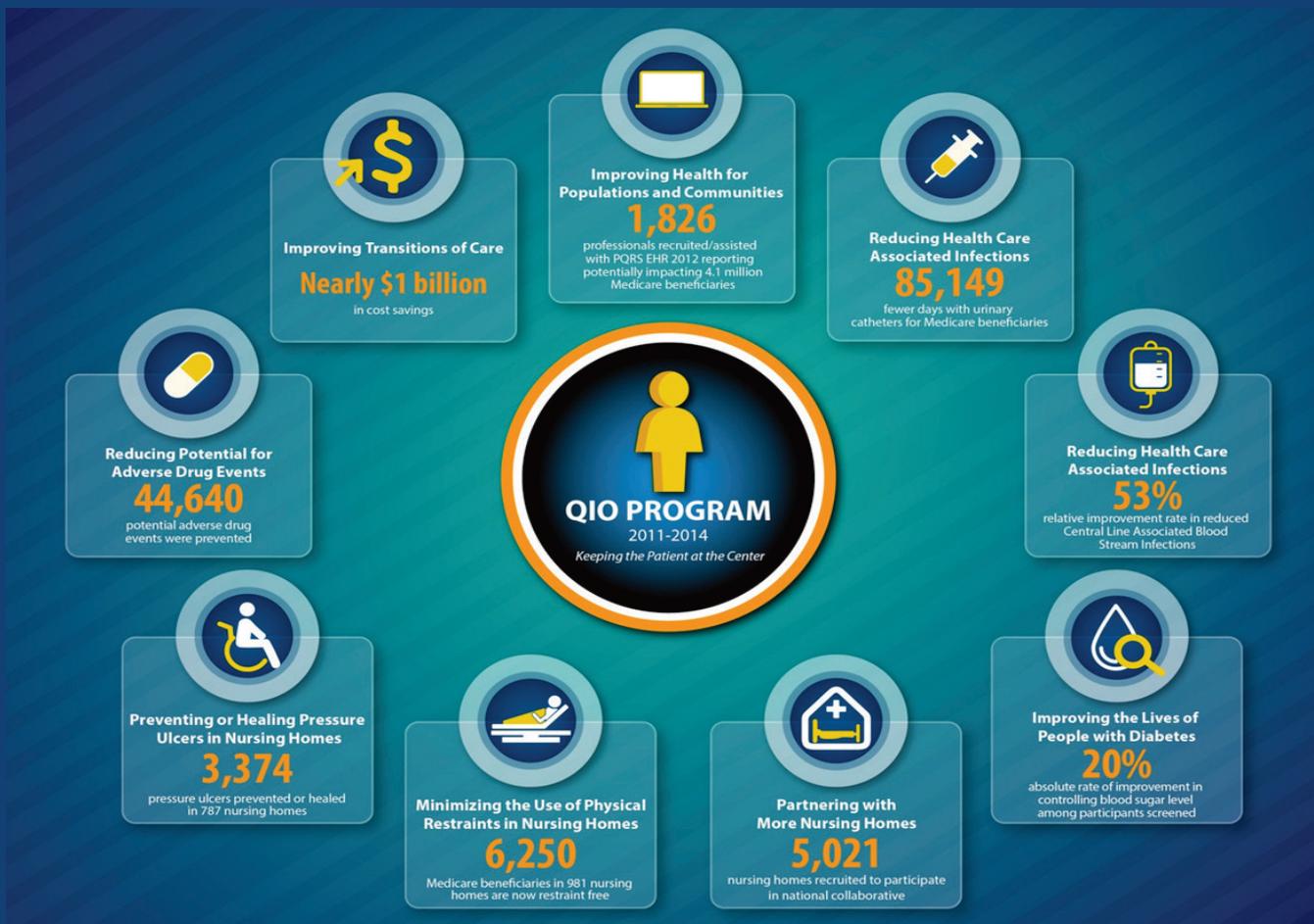


CMS Quality Improvement Organization Program Overview





CMS QIO 10th Statement of Work (SOW) Success





CMS Quality Improvement Organization Program Framework

QIO 11th Statement of Work





QIN-QIO

11th SOW Task Overview

QIN-NCC-QIO

Task A Excellence in Operations

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

Essential Functions

- Results-Oriented Quality Improvement Activities
- Community Learning and Action Networks
- Technical Assistance (i.e., QI Experts)
- Integrated Communications

Task C Better Care

- Reducing care-associated infections
- Reducing care-acquired conditions
- Coordinating care to reduce readmits & adverse drug events

Task E Technical Assistance

- Beneficiary and Family Centered Care
- Value Based Purchasing

Task D Lower Costs

- Quality Improvement through Physician Value Modifier
- Local QIO Projects



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



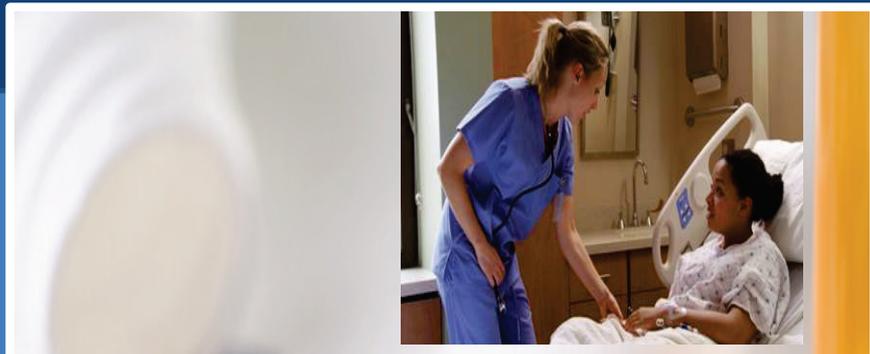
QIN-QIO 11th SOW Task: Examples of QIO Interventions for Anticoagulant ADE Prevention

- 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

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 - Boehringer-Ingelheim
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 - Eisai
 - Iverson Genetics Diagnostics/Medicare
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 - 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**



Bottom Line Up Front (BLUF)

- “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



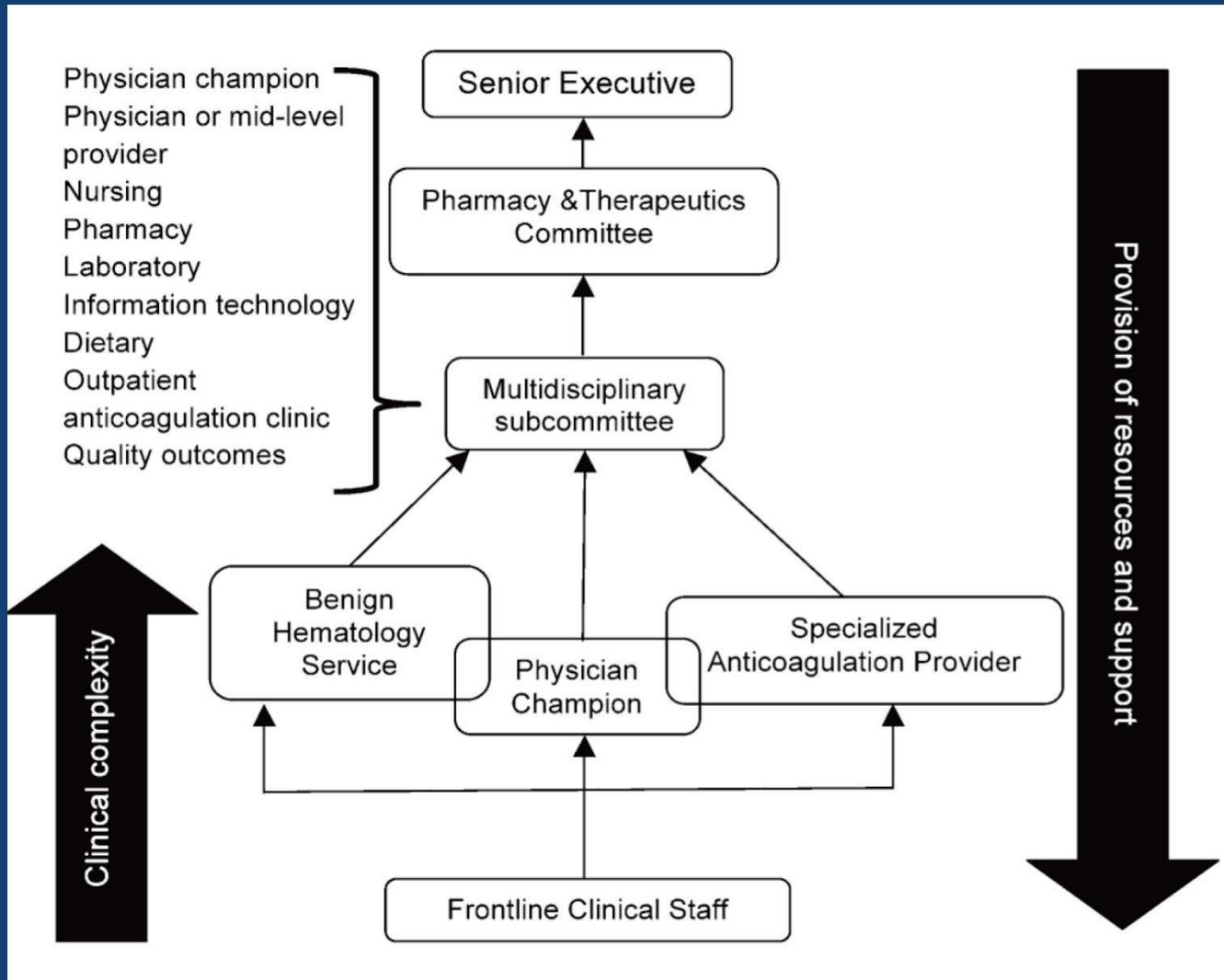
Inpatient Anticoagulation Services

- **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



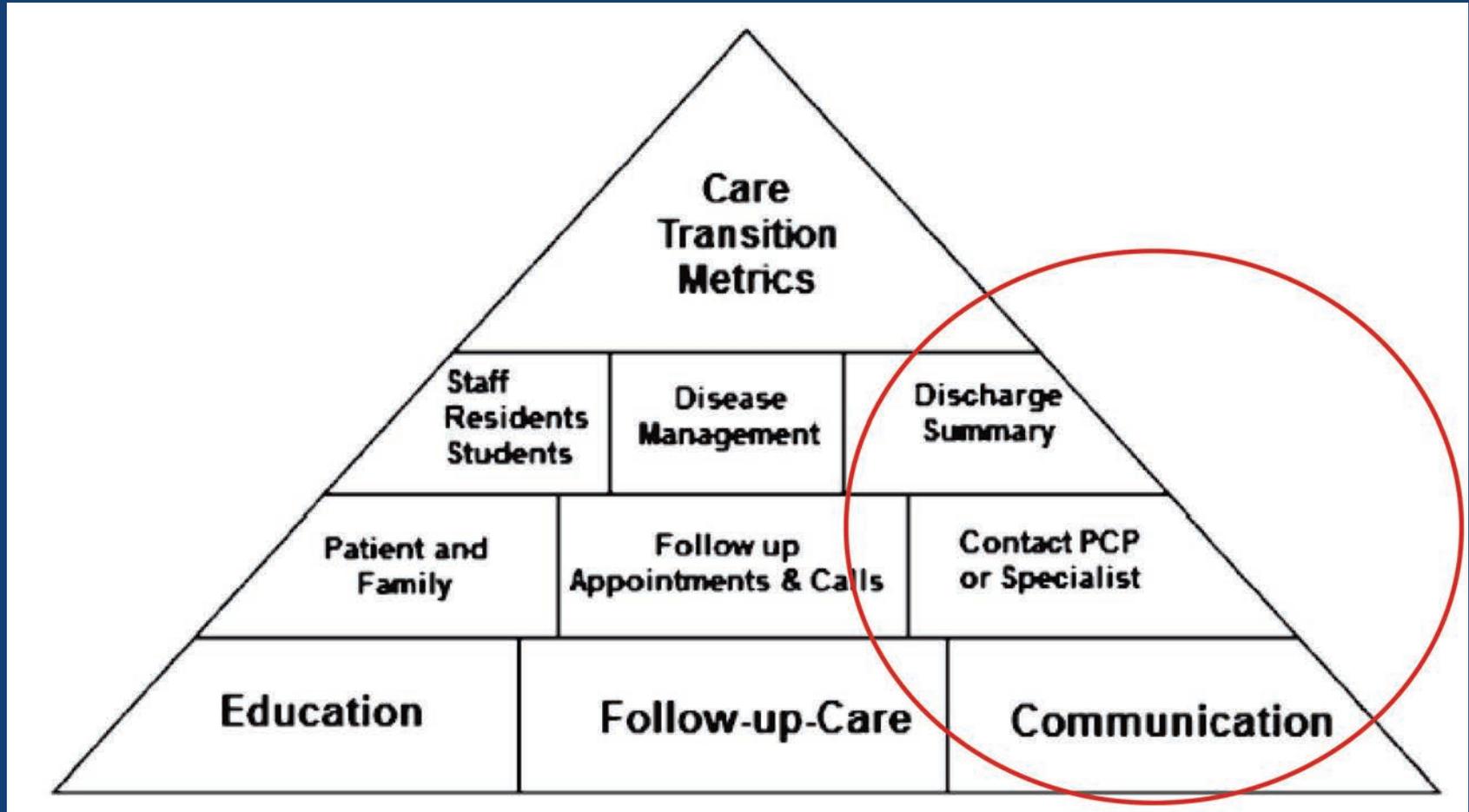
Inpatient Anticoagulation Service





Inpatient Anticoagulation Service

(continued 1)





Inpatient Anticoagulation Service

(continued 2)

- Cluster randomized trial
- Single institution
- Un-blinded

TABLE 4. Transition of Care and Safety Results

Transition of Care	PDAS (n = 250)	Control (n = 250)	P Value
100% Communication bundle* compliance, % (n)	75.6% (189)	2.8% (7)	<0.001
Appropriately enrolled in the AC clinic, % (n)	97.2% (243)	95.2% (238)	0.242
Communication: inpatient service and outpatient physician, % (n)	99.6% (249)	12.4% (31)	<0.001
Communication: inpatient clinicians and AC clinic staff, % (n)	98.8% (247)	14.8% (37)	<0.001
INR drawn within five days of hospital discharge, % (n)	78.4% (196)	66.4% (166)	0.003
30-Day Composite safety endpoint, ¹ % (n)	10.0% (25)	14.8% (37)	0.103
Inpatient + 30-day INR >5, % (n)	9.6% (24)	14.8% (37)	0.076
Inpatient + 30-day major bleeding, % (n)	0.8% (2)	0.4% (1)	0.563
Inpatient + 30-day thrombosis, % (n)	0% (0)	0% (0)	N/A



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



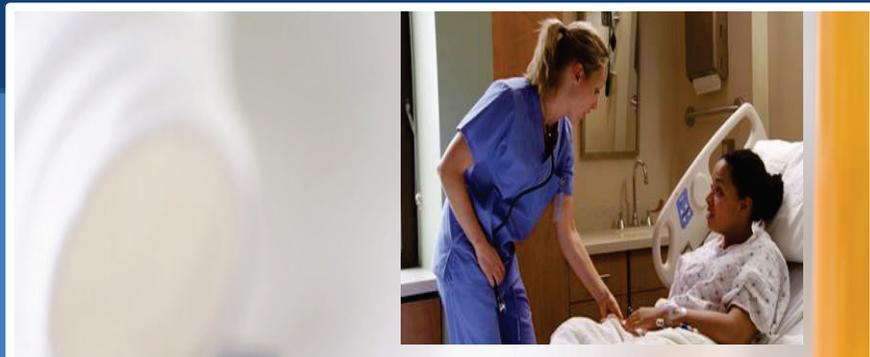
Special Thanks To





Questions?





Overview and Prevention of Serious Hypoglycemic Events in **Outpatient Settings**

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Office of the Assistant Secretary for Health
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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 1st most common drug implicated in ED visits for ADEs overall (~8%) ¹
 - Insulin and oral diabetes drug implicated in ~25% of emergent hospitalizations for ADEs in older adults ²
- Hospitalized Patients
 - Hypoglycemia was 3rd most common ADE ³
- Skilled Nursing Facility Patients
 - Hypoglycemia was 1st most common ADE ⁴

1. *JAMA*. 2006;296:1858-1866

2. *N Engl J Med*. 2011;365:2002-2012

3. Adverse Events in Hospitals, 2010, OEI-06-09-00090

4. Adverse Events in Skilled Nursing Facilities, 2014, OEI-06-11-00370



Emergency Hospitalizations for Adverse Drug Events in Older Americans

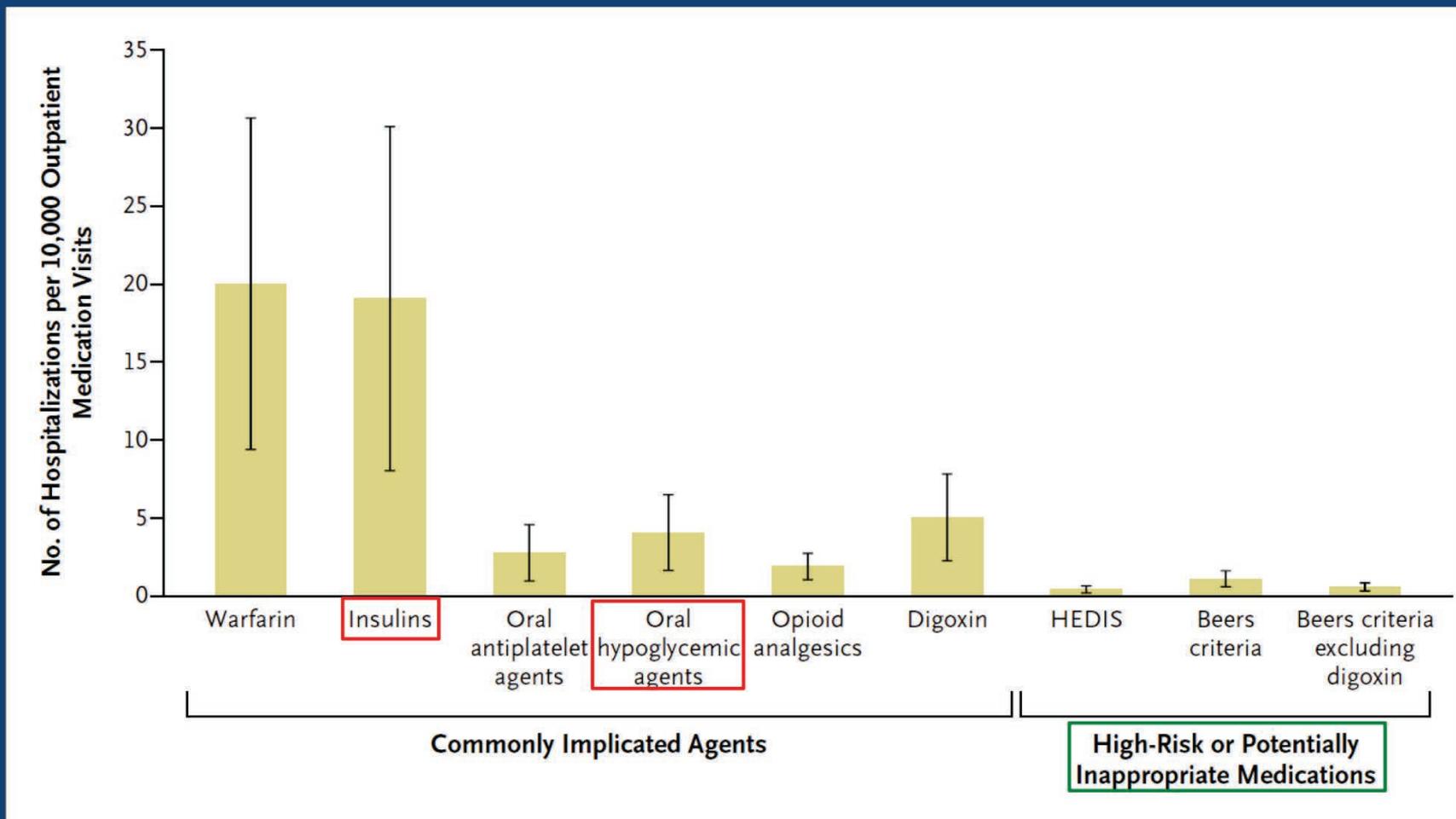


Figure 1. Estimated Rates of Emergency Hospitalizations for Adverse Drug Events in Older U.S. Adults, 2007–2009.



FIW for ADEs—Diabetes Agents Overview

Federal Interagency Steering Committee for Adverse Drug Events

Workgroup **DIABETES AGENTS**

Surveillance

Evidence-Based
Prevention Tools

Incentives &
Oversight

Research
(Unanswered
Questions) and
GAPS

Topic	Gaps
Provider education	<ul style="list-style-type: none"> Understanding co-morbid risks Understanding absolute benefits and harms Adjust therapy in persons with Diabetes and with multiple chronic conditions Individualizing care Shared Decision Making
Patient / caregiver education	<ul style="list-style-type: none"> Educational material targeted for hypoglycemia prevention Addressing health literacy and numeracy in decreasing hypoglycemia events
Surveillance	<ul style="list-style-type: none"> Absence of rates of serious hypoglycemia in ambulatory care, emphasis upon modifiable (Education, Health literacy) and non-modifiable (age, chronic co-morbid conditions) risk factors.
Incentive & Oversight	<ul style="list-style-type: none"> Overtreatment Measures Addressing co-morbid conditions (exclusions and inclusions criteria)
Health Systems	<ul style="list-style-type: none"> Impact of care coordination on adverse drug events Transitions of care: <ul style="list-style-type: none"> -In the hospital between providers -From hospital to home/rehab/nursing home



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

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

Incentives and Oversight

General concurrence:

Incentivize programs that individualize Hgb A1c treatment targets for older adults, with penalties for overaggressive glycemetic control

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



ADE Action Plan: Four-Pronged Approach





FIW for ADEs—Diabetes Agents Prevention

Diabetes Agents

**Evidence-
Based
Prevention
Tools**

Health IT

Patient Centered Care

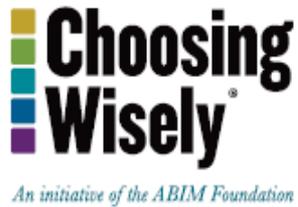
“....the highly scientific development of this mechanistic age had led perhaps to some loss in appreciation of the individuality of the patient and to trusting largely to the laboratories and outside agencies which tended to make the patient not the hub of the wheel, but a spoke.” – *Dr. Will Mayo*

Source

Evidence

ADVANCE, ACCORD, VADT

Serious hypoglycemia strongly associated with cardiovascular morbidity/mortality. Association strongest in control arms.



3

Avoid using medications to achieve hemoglobin A1c <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 theorized microvascular benefits 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 < 10 years, and 8.0 – 9.0% in those with multiple morbidities and shorter life expectancy.

Veteran Affairs-
Department of Defense
(VA-DoD)

Table: A1c target recommendations, %⁶

Major comorbidity ^a or physiologic age	Microvascular complications		
	Absent or mild ^b	Moderate ^c	Advanced ^d
Absent > 10 years of life expectancy	< 7	< 8	8-9 ^e
Present ^f 5-10 years of life expectancy	< 8	< 8	8-9 ^e
Marked ^g < 5 years of life expectancy	8-9 ^e	8-9 ^e	8-9 ^e

American Diabetes
Association

American Geriatrics Society

Table 1. A Framework for Considering Treatment Goals for Glycemia, Blood Pressure, and Dyslipidemia in Older Adults with Diabetes

Patient Characteristics/ Health Status	Rationale	Reasonable A1C Goal (A Lower Goal May Be Set for an Individual if Achievable without Recurrent or Severe Hypoglycemia or Undue Treatment Burden)	Fasting or Preprandial Glucose (mg/dL)	Bedtime Glucose (mg/dL)	Blood Pressure (mmHg)	Lipids
Healthy (Few coexisting chronic illnesses, intact cognitive and functional status)	Longer remaining life expectancy	<7.5%	90-130	90-150	<140/80	Statin unless contraindicated or not tolerated
Complex/intermediate (Multiple coexisting chronic illnesses ^a or 2+ instrumental ADL impairments or mild to moderate cognitive impairment)	Intermediate remaining life expectancy, high treatment burden, hypoglycemia vulnerability, fall risk	<8.0%	90-150	100-180	<140/80	Statin unless contraindicated or not tolerated
Very complex/poor health (Long-term care or end-stage chronic illnesses ^b or moderate to severe cognitive impairment or 2+ ADL dependencies)	Limited remaining life expectancy makes benefit uncertain	<8.5% ^c	100-180	110-200	<150/90	Consider likelihood of benefit with statin (secondary prevention more so than primary)



Shared Decision Making

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**

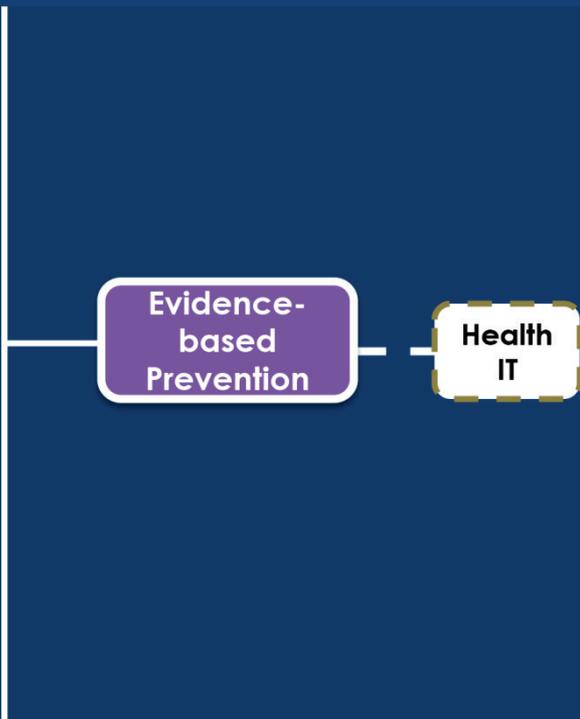
Science-driven Prevention and Treatment

- 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



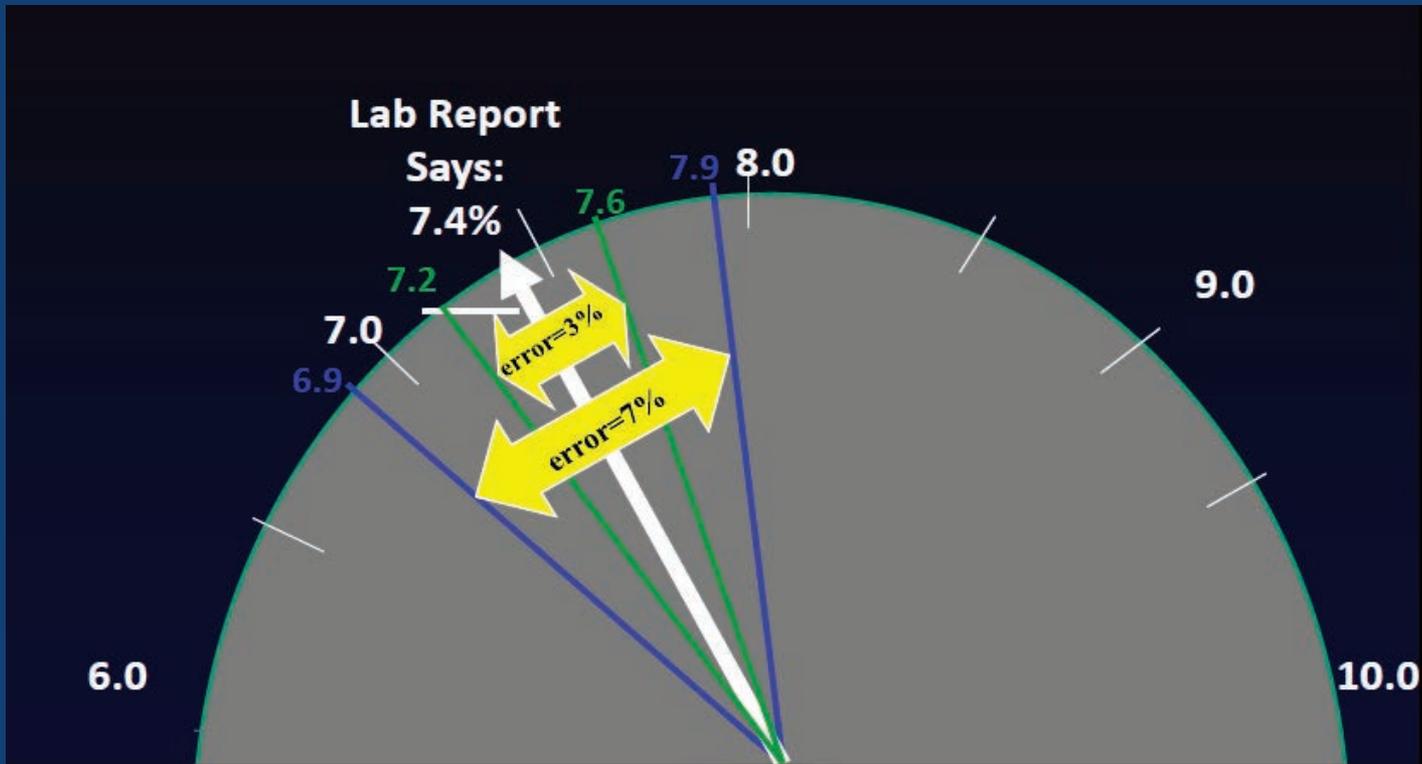
Federal Agency	Evidence-based Tool / Resource to Address Hypoglycemia Prevention
ACL	<ul style="list-style-type: none"> Stanford Diabetes Self-Management Program National Council on Aging Better Choices, Better Health-Diabetes HomeMedsSM Medication Management System
AHRQ	<ul style="list-style-type: none"> Medicines for Type 2 Diabetes: Research Review Premixed Insulin for Type 2 Diabetes: Adult Guide Blood Sugar: Research Review Re-Engineered (RED) Toolkit
BoP/DoD/VA	<ul style="list-style-type: none"> Management of Diabetes Clinical Practice Guidelines
CDC	<ul style="list-style-type: none"> Helping the Child with Diabetes Succeed
FDA	<ul style="list-style-type: none"> Risk Evaluation and Mitigation (REM) Strategies Medication Guides
IHS	<ul style="list-style-type: none"> Treatment Algorithms Quick Guide Cards Advancements in Diabetes Seminar
NIH	<ul style="list-style-type: none"> National Diabetes Information Clearinghouse Hypoglycemia Resources & Information Material



A1c Variability “Speedometer”

A1C Test and Diabetes

<http://diabetes.niddk.nih.gov/dm/pubs/A1CTest/>





Diabetes Agents Patient Engagement

EP: Recommendation 1

Objective	Select patient education materials on high risk medications that follow health literacy principles and meet language needs and confirm understanding
Recommendations on EHR Functionality/ Usability	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.



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

National ADE reporting system based on medical record review

- AHRQ Medicare Patient Safety Monitoring System (**MPSMS**)
- CDC National Electronic Injury Surveillance System – Cooperative Adverse Drug Event Surveillance System (**NEISS-CADES**)

Passive national ADE reporting systems

- FDA Adverse Event Reporting System (**FAERS**)

Identification of ADES from administrative claims meta-databases

- AHRQ Healthcare Cost and Utilization Project (**HCUP**)
- Nationwide Emergency Department Sample (**NEDS**)
- FDA Sentinel Initiative, Mini-Sentinel Pilot
- National Health Interview Survey (**NHIS**)

Federal integrated health networks

- 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

Data Elements	<ul style="list-style-type: none">• Record co-morbid conditions
Patient Lists	<ul style="list-style-type: none">• Stratify patients by specific lab values and certain risk factors
Quality Measure Concepts	<ul style="list-style-type: none">• Overtreatment measure
Clinical Decision Support (CDS)	<ul style="list-style-type: none">• Addressing potential risk for hypoglycemia• Shared Decision Making• Action Plan for prevention of hypoglycemia



Data Elements & Patient Lists

Existing Data Elements	New Data Elements to Capture
Cognitive impairment / dementia	Prior hypoglycemic reactions
Advanced microvascular diabetes complications	
Limited life expectancy	
Current substance use	
Recent discharge from inpatient setting	

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

Rule Title	Identification of patients at risk for hypoglycemia
Objective	Identify patients at high risk for hypoglycemia and outline recommended action steps
Risk Group	Persons with diabetes
Triggering Condition	Risk factors that place a person with diabetes at risk for hypoglycemic events



Clinical Decision Support # 2

Rule Title	Shared Decision Making between physician and patient on target A1c values
Objective	Use CDS to improve performance in persons with diabetes (a high-priority health condition)
Risk Group	Persons with diabetes
Triggering Condition	When A1c value is reported to the physician's office



Proposed CDS Display

A1c value

Target A1c value as determined by BOTH physician and patient:

Insert TARGET lab value here after

Reasons to why TARGET lab value was chosen:

Patient has the following risk factors for hypoglycemia (check all that apply)

<input type="checkbox"/>	Older than 65
<input type="checkbox"/>	Cognitive impairment/dementia
<input type="checkbox"/>	Advanced microvascular diabetes complications
<input type="checkbox"/>	Cardiovascular complications
<input type="checkbox"/>	Limited life expectancy (active treatment of non-squamous, basal cell malignancies; end-stage hepatic, pulmonary disease)
<input type="checkbox"/>	Alcohol or substance abuse
<input type="checkbox"/>	Transition inpatient to outpatient
<input type="checkbox"/>	Prior hypoglycemic reactions.
<input type="checkbox"/>	Other please state _____



FIW for ADEs—Diabetes Agents Incentives and Oversight

Federal Interagency Steering Committee for Adverse Drug Events

Workgroup **DIABETES AGENTS**

Surveillance

Evidence-Based
Prevention
Tools

Incentives &
Oversight

Research
(Unanswered
Questions)

Current Incentive Measure

NQF 0729: Composite (All or Nothing Scoring)
Diabetes Mellitus: Hemoglobin A1c control (<8%)

NQF 0059:
Diabetes Mellitus: Hemoglobin A1c poor control (>9%)

Modification / Recommendations

Stratify by age, insulin, co-morbid conditions, significant risk, decreased life expectancy
Addressing: highest risk individuals, advanced age, co-morbid conditions

CONCEPT MEASURE: Overtreatment treatment measure to balance under-treatment measure

Numerator	Denominator	Exclusions
# of pts with A1c: <7% (primary outcome)	Patients on sulfonylurea or insulin tx with chronic co-morbid conditions and / or age >65 years	Younger (<65 years old) not on hypoglycemic agents without specified co-morbid conditions



Hypoglycemic ADEs

Opportunities for Advancing Research Areas

Topic Area	Gap
Provider Education	<ul style="list-style-type: none"> • Comorbidities • Risk-benefit analysis for prescribing • Individualized care and shared decision-making
Patient/ Caregiver Education	<ul style="list-style-type: none"> • Impact of increased health literacy / numeracy in the prevention of hypoglycemic ADEs • Hypoglycemia-related patient education materials
Surveillance	<ul style="list-style-type: none"> • Stratification of hypoglycemic events in ambulatory settings by risk factors • Impact of hypoglycemic events on quality of life
Incentives & Oversight	<ul style="list-style-type: none"> • Overtreatment of diabetes measure • Addressing comorbidities (via exclusions and inclusions criteria) and impact on rates of hypoglycemia
Health Systems	<ul style="list-style-type: none"> • Current prevention tools in transitions of care • EHRs to facilitate monitoring over time • Linked EHR-pharmacy systems to identify patients with diabetes/hypoglycemia • Medication management interventions recorded in EHRs and impact on patient outcomes • Telephonic diabetes management for specific patient populations

Research

Health
IT



Of the Epidemics: Hippocrates

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

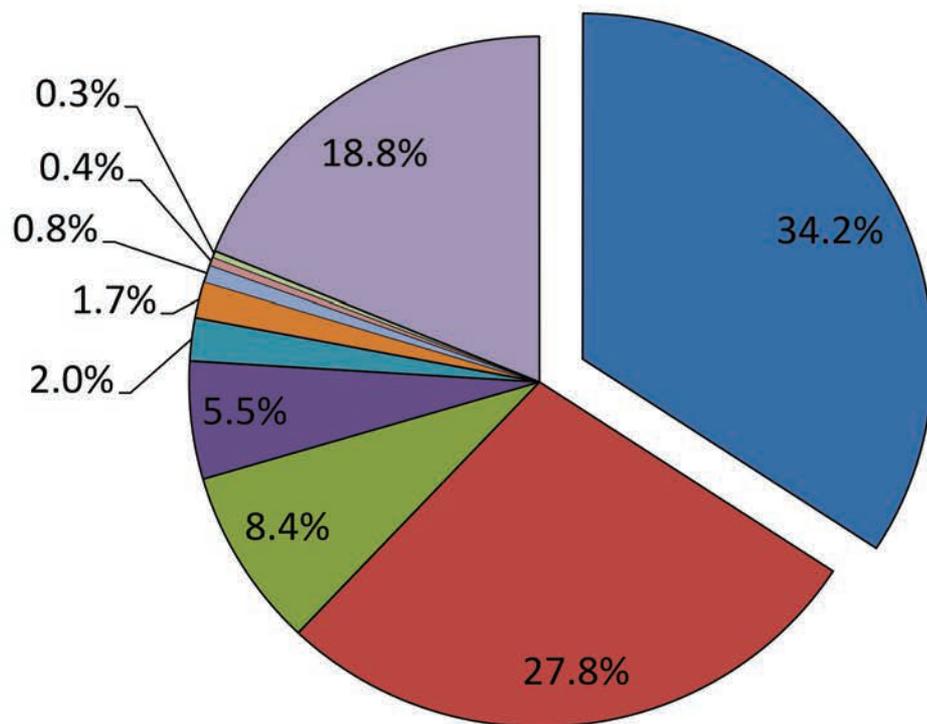
Mary Andrawis, PharmD, MPH
Senior Advisor
Centers for Medicare and Medicaid Services, Innovation Center





National Data Source on ADEs – AHRQ - MPSMPS

Percent of Total Measured HACs— PFP 2010 Baseline (4.745M)



■ Adverse Drug Events (57% Hypoglycemic Events & 42% Anticoagulant Drug Events)

■ Pressure Ulcers

■ Catheter-Associated Urinary Tract Infections

■ Falls

■ Surgical Site Infections

■ Obstetric Adverse Events

■ Ventilator-Associated Pneumonia

■ Central Line-Associated Bloodstream Infections

■ Venous Thromboembolism

■ All other HACs—based on 14 other specific measures (from C diff Infection to Contrast Nephropathy)



National Data Source on ADEs

AHRQ - MPSMPS

Medicare Patient Safety Monitoring System (MPSMS)

- Trained abstractors extract information from sample of 800 charts every year

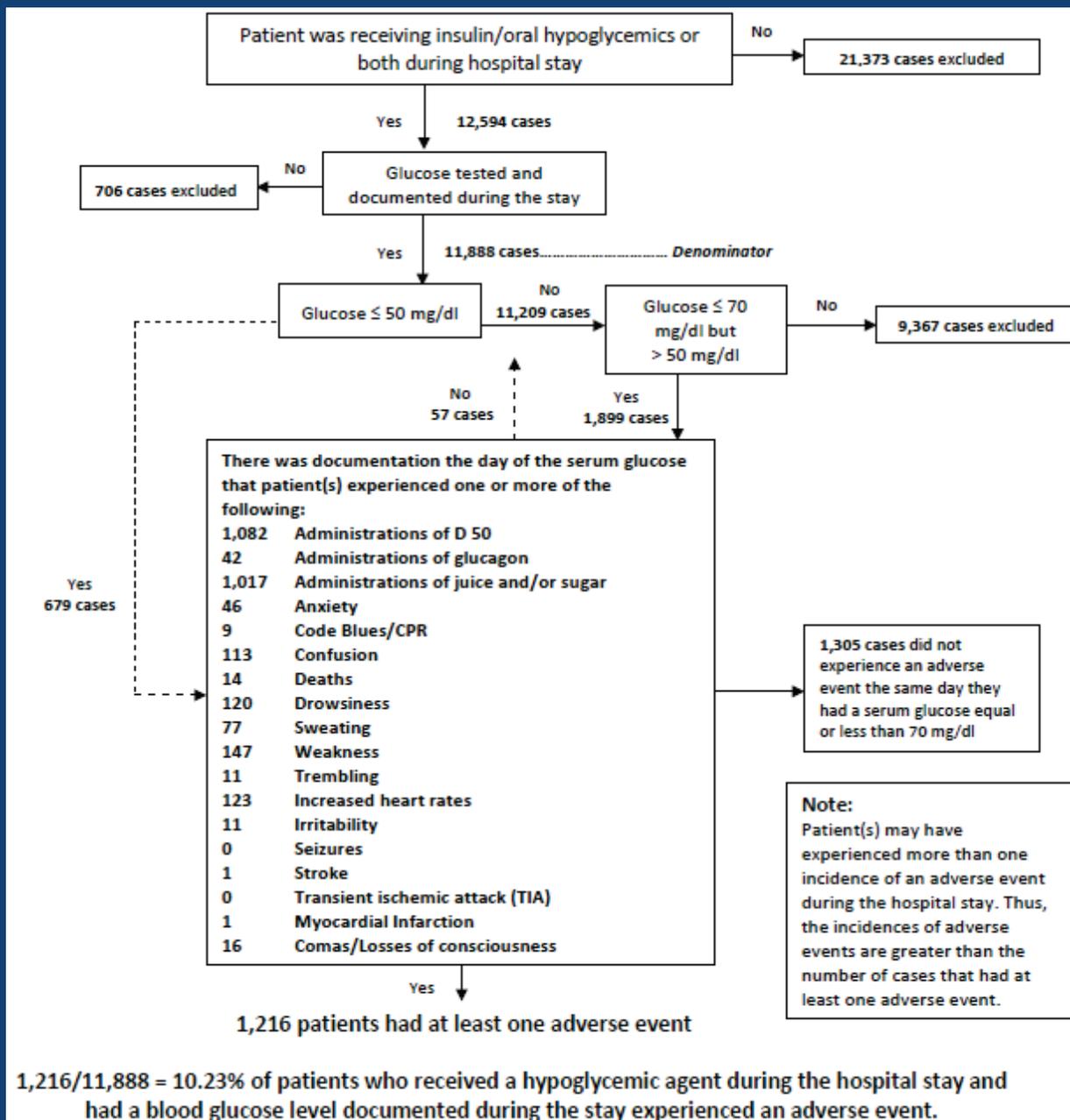
2010 Data From MPSMS on Adverse Drug Events associated with:

Digoxin	12,000
Hypoglycemic Agents	930,000*
IV Heparin	170,000**
LMWH and Factor Xa Inhibitor	340,000**
Warfarin	170,000**
<hr/>	
Total Adverse Drug Events	1,621,000

*57% are hypoglycemic agents

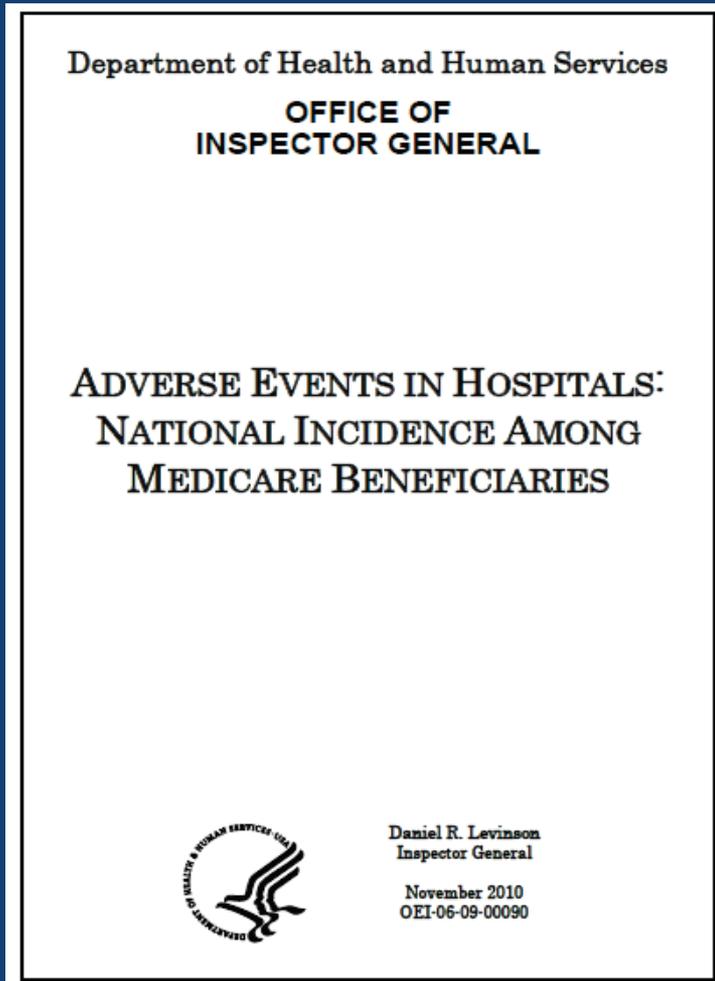
**42% are anticoagulants (combined)

MPSMS 2011 Data: 33,967 Hospital Discharges





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

From
INSIDE
to
OUTSIDE
the
hospital

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



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)



Inpatient Glycemic Control: Challenges *(continued 1)*

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



Inpatient Glycemic Control: Challenges *(continued 4)*

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

Metric	Description and Justification
Clinical Quality Measure Concepts—Eligible Hospitals (Inpatient Settings)	
7. Hypoglycemic events, serious	Total number of hypoglycemic events, divided by the number of patients administered a diabetes agent
Rationale	Calculates percent of hypoglycemic events for all inpatients receiving diabetes agents.
8. Hyperglycemia	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)
Rationale	<ul style="list-style-type: none"> ▪ Calculates percent of hyperglycemic events for all inpatients receiving diabetes agents. ▪ Serves as balancing measure to hypoglycemia measure.
9. Hypoglycemia, mild	Total number of days in which any hypoglycemic event (<70 mg/dL) reported, divided by total number of hospital days for patients receiving a diabetes agent
Rationale	Currently no system to effectively track and monitor episodes of hypoglycemia that do not result in need for third-party assistance.
10. Recurrent Hypoglycemia	Patients suffering at least one recurrent hypoglycemic event on a subsequent hospital day during the same hospital stay
Rationale	Patients suffering at least one recurrent hypoglycemic event on a subsequent hospital day during the same hospital stay.



New NQF-Endorsed Measures

Measure Title/Description	Numerator	Denominator	Implementation Guidance	Measure Developer/ Endorsement Status
<i>Inpatient glycemic control measures</i>				
Severe hypoglycemia	Total number of hypoglycemic events (<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	Total number of hospital days with at least one antidiabetic agent administered	Threshold may be adjusted if needed	CMS/NQF endorsed: NQF# 2363
Hyperglycemia	Sum of the percentage of hospital days in hyperglycemia (≥ 2 elevated blood glucose values (>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	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 (>200 mg/dL [11.1 mmol/L]) at any time during the entire hospital stay	Threshold may be adjusted if needed	CMS/NQF endorsed: NQF# 2362



EHR Recommendations

EHR Functionality/Usability Recommendation—Eligible Hospitals (Inpatient Settings)

11. Documentation of etiology of hypoglycemic event	Total number of hypoglycemic events, divided by all patients administered a diabetes agent
--	--

Rationale

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

12. Alert to potential risk for hypoglycemic events	Clinical reminder and documentation of risk mitigation steps taken (checklist) when patient has experienced two or more blood glucose values of <70 mg/dL
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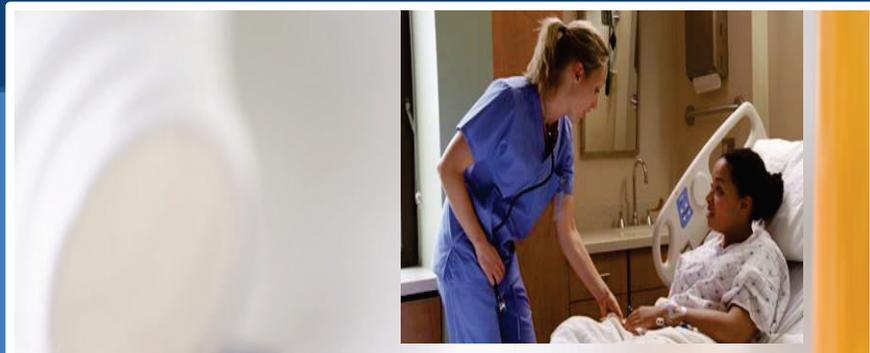
Rationale

- When there is a patient with repeated blood glucose values of <70 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



Surveillance

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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

	AHRQ	CDC	AHRQ	FDA
System Name	MPSMS	NEISS-CADES	HCUP	Sentinel
ADE Identification	ADE-specific Active Case-finding	ADE specific Active Case-finding	Database Query	Database Query
Population	Sample of Medicare FFS	Sample of U.S. EDs	State-based sample of US	U.S. Data Partners (private insured)
Setting	Inpatient	ED	Inpatient & ED	Inpatient & Outpatient
Data Source(s)	Inpatient medical records	ED medical records	Hospital Discharge Administrative Data	Insurance Claims Administrative Data



Federal Data Sources

Passive Systems

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



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) / QRS (beginning 2015) ³

1. http://www.cdc.gov/nchs/nhis/about_nhis.htm
2. *Jt Comm J Qual Patient Saf.* 2010;36:12-21

3. HIT Patient Safety Action & Surveillance Plan, 2013
http://www.healthit.gov/sites/default/files/safety_plan_master.pdf



Existing Hypoglycemia Metrics

■ Ambulatory Patients

– Healthy People 2020 Medical Product Safety – 5.2¹

- 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 – 2363²

- Rate of hypoglycemic events (<40 mg/dL) following the administration of an anti-diabetic agent

– Paired with a hyperglycemia metric (NQF 2362)

1. <http://www.healthypeople.gov>

2. <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

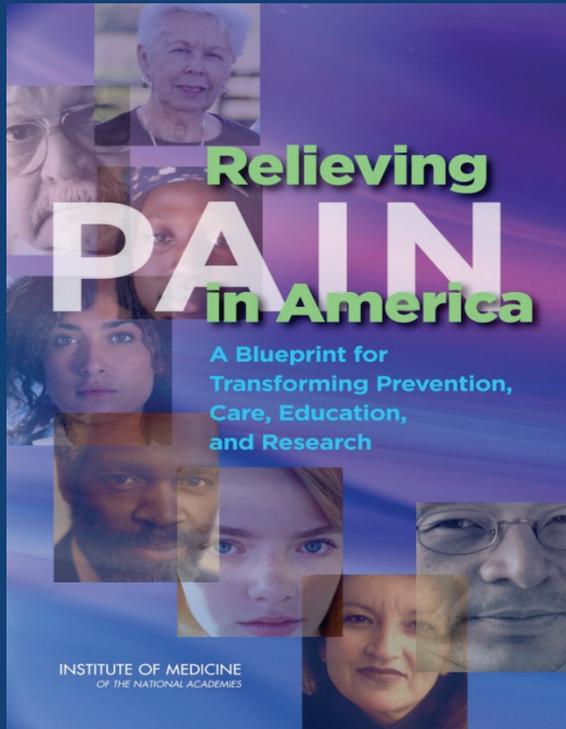




Federal Interagency Workgroup for Adverse Drug Events - Opioids

- 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



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

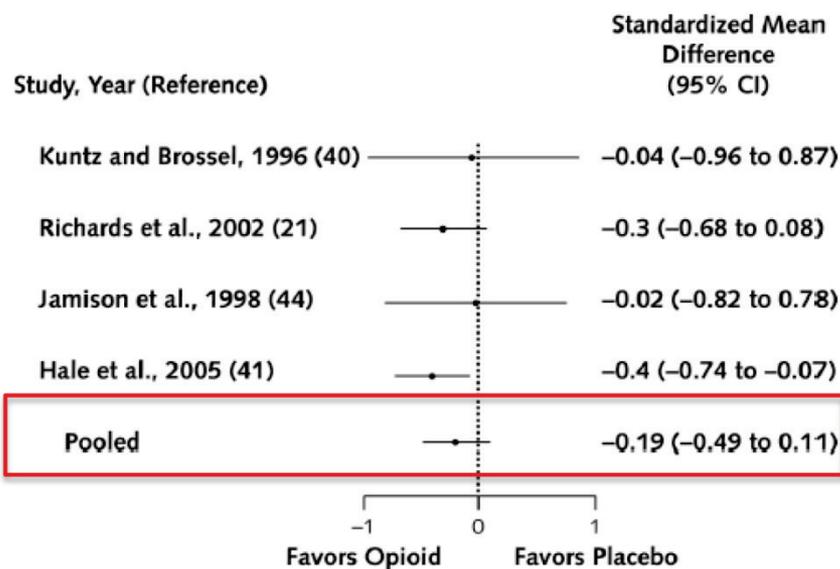
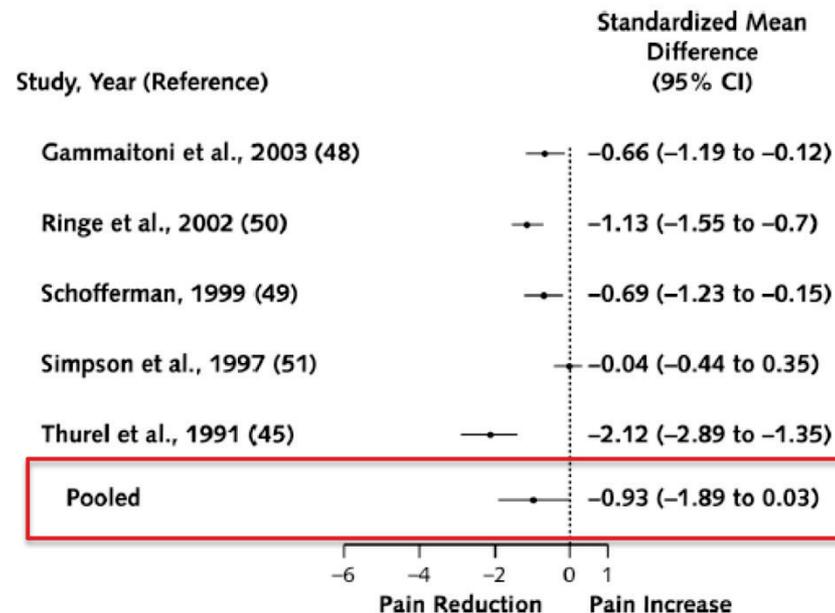
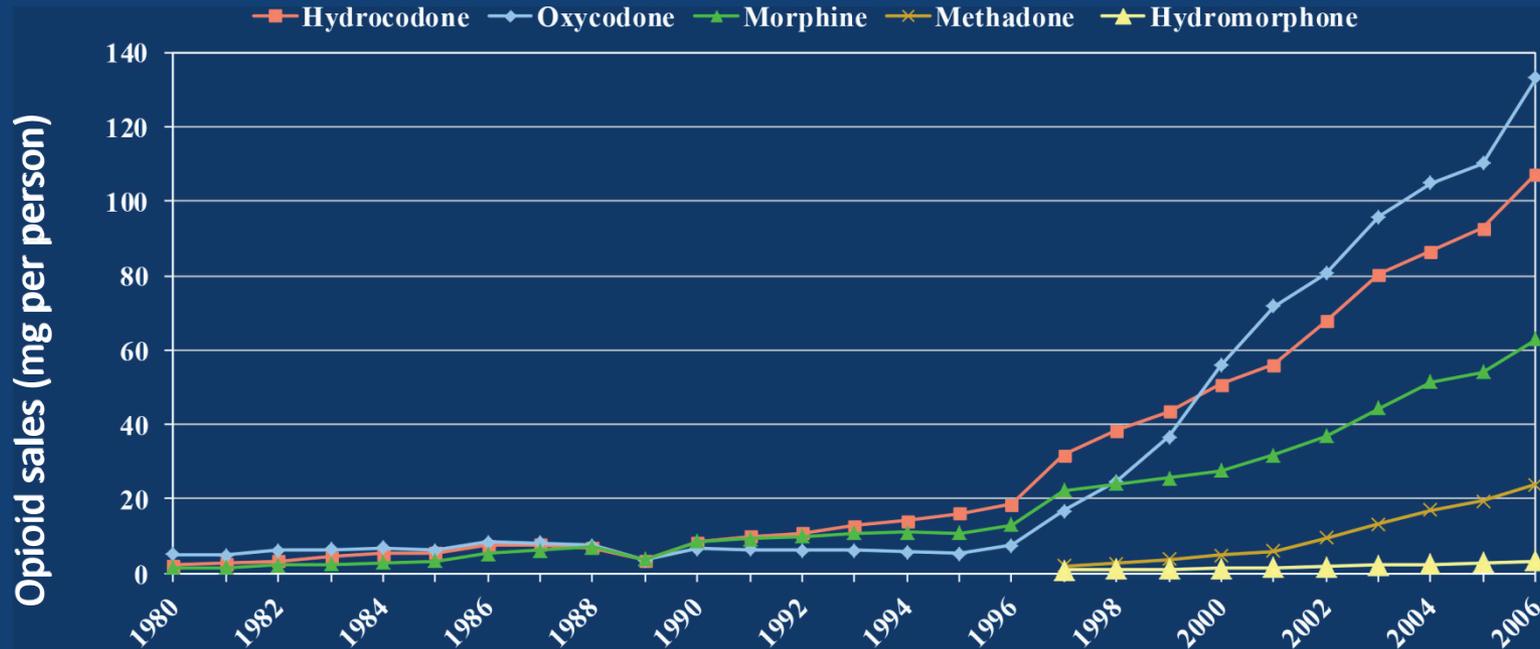


Figure 3. Results of meta-analysis of opioid efficacy with opioid comparisons

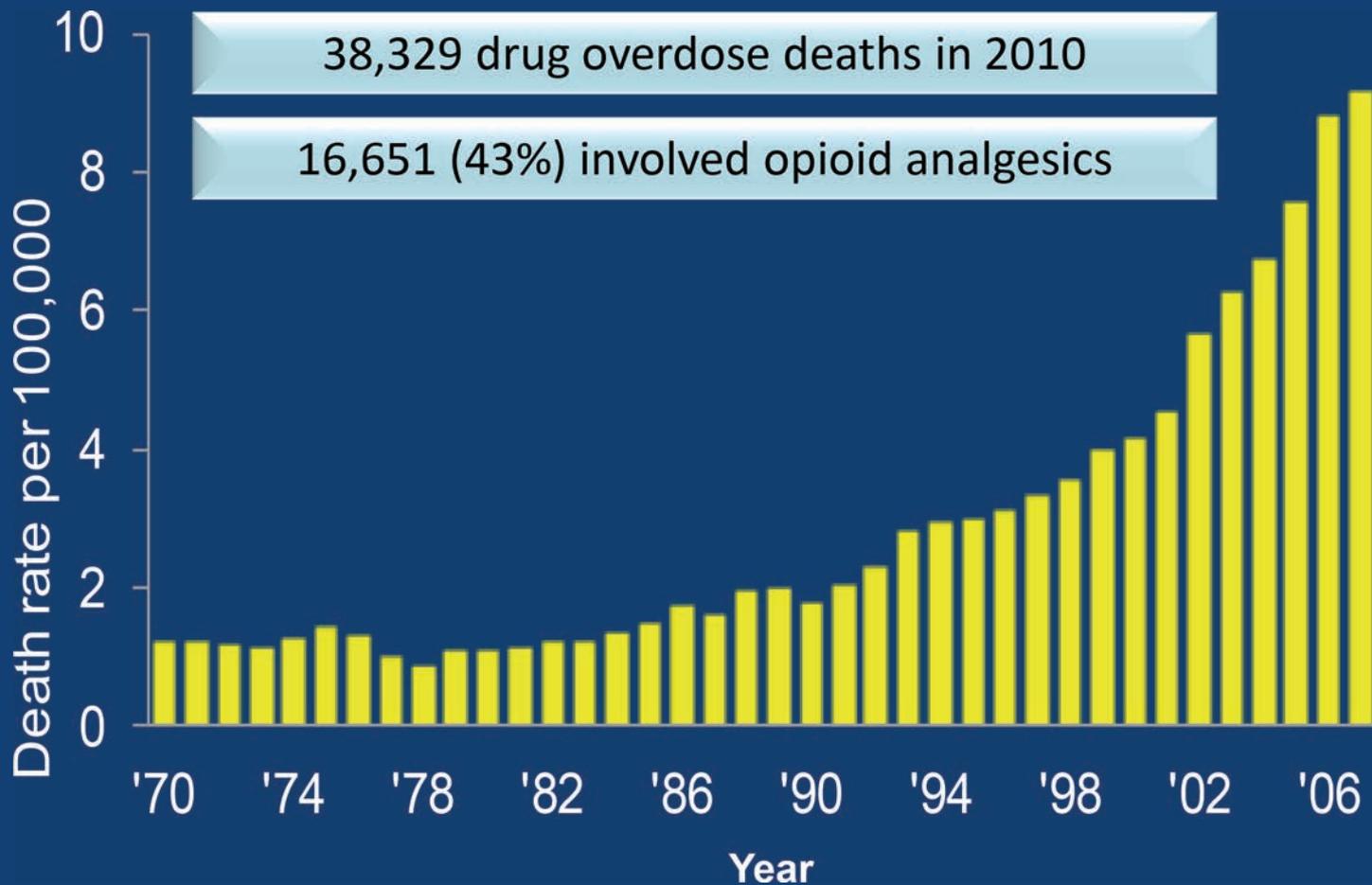




Increase in opioid prescribing



Source: Automation of Reports and Consolidated Orders System, US DEA, slide adapted from A Gilson





ELSEVIER

The Journal of Pain, Vol 10, No 2 (February), 2009: pp 113-130
Available online at www.sciencedirect.com

Opioid Treatment Guidelines

Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain

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

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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

Outcome	Data Source	Agency	Overview
Death	National Vital Statistics System (NVSS)	CDC	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
ED Visits	Drug Abuse Warning Network (DAWN)	SAMHSA	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)
ED Visits	National Electronic Injury Surveillance System Cooperative Adverse Drug Event Surveillance (NEISS-CADES)	CDC	Collects data on ED visits for opioid overdose and other ADEs not related to misuse or abuse.



Surveillance for clinical outcomes

(continued)

Outcome	Data Source	Agency	Overview
ED Visits Hospitalizations	Health Care Utilization Project (HCUP)	AHRQ	Largest all-payer emergency department (ED) database. Based on ICD-9 CM codes
Broad range of adverse events	FDA Adverse Event Reporting System (FAERS)	FDA	Database that contains information on adverse event and medication error reports submitted to FDA.
Broad range of adverse events	Mini-Sentinel (Sentinel Initiative)	FDA	Uses a variety of health-related electronic data (administrative claims data, electronic health records, drug dispensing data, etc.) to identify safety signals
Broad range of adverse events	Federal Health System Databases (VA, DOD, IHS, etc.)	Various	Monitor patient visits, ED visits, hospitalizations based on claims and administrative data



Surveillance for process measures

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



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



Federal resources for Health Care Providers

Resource	Agency	Overview
Opioid prescribing guidelines	DOD/VA	Includes recommendations for assessing patients for appropriate pain therapy, guidance on treatment options to consider, and patient monitoring
ER/LA Opioid Risk Evaluation and Mitigation Strategy (REMS)	FDA	Continuing education courses provided to interested providers based on FDA's Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics
TeleBehavioral Health Center of Excellence in Pain and Addictions Course	IHS	Webinar training program that provides specialized information on how to treat pain and addiction
NIDAMED	NIDA	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"



Federal resources for patients and families

Resource	Agency	Overview
Chronic Disease Self-Management Education Programs	ACL	Education and tools to older adults and adults with disabilities to help them better manage chronic conditions, including chronic pain
ER/LA Opioid Risk Evaluation and Mitigation Strategy (REMS)	FDA	Patient counseling document available for providers to help guide education on risk and opioid man agent for patients receiving extended-release or long-acting opioids
Taking Opioids Responsibly	VA	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



Federal resources to promote systems best practices and improve care coordination

Resource	Agency	Overview
VA National Pain Management Strategy	VA	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
Project Red	AHRQ	Provides information on a number of medication-related best practice strategies such as active medication reconciliation, and medication teaching for patients and caregivers
Sole Provider Program	DOD	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.
Mobile Application for Pain	VA	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



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

Safer Care

Expand dissemination of evidence-based opioid guidelines/protocols
Improve availability and uptake of safe opioid prescribing practices

Patient and Family Engagement

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

Effective Communication and Coordination of Care

Develop more optimal and integrated Health IT opioid management tools
Integrate opioid-specific targets into care transition models

Science-driven Prevention and Treatment

Promote systematic and coordinated care
Promote use of evidence-based strategies for managing risk factors for opioid overdose
Increase availability of mental health/substance use disorder treatment for patients on opioid therapy
Promote the use of Health IT tools to identify high-risk opioid practices

Promote Best Practices within Communities

Use metrics to monitor the use of opioid safety best practices
Promote effective strategies identified by federal agencies that engage in patient care



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

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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**
 - 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
 - Transitions of Care/Coordinated Care Strategies:
 - ✓ Address barriers to facilitate integrated pain management therapy
- **Standardizations of EHR for Opioid Therapy**
 - Strategies to Incentivize Clinical Support Systems: appropriate opioid starting dose, MEDs, & best practices/clinical guideline suggestions
 - 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

Metric	Description and Justification
Outpatient Clinical Quality Measure Concepts	
Patients on high daily dose of long-term opioid therapy	<ul style="list-style-type: none"> There is an association between high daily dose of opioids and opioid ADEs, which requires further study to understand the impact on clinical practice.
Patients co-prescribed long-term opioid therapy and CNS depressants	<ul style="list-style-type: none"> Co-prescribing of opioids with CNS depressants, especially benzodiazepines, is associated with opioid overdose deaths.
Patients on long-term opioid therapy given a toxicology screen prior to initiating therapy and at least once a year while on long-term opioid therapy	<ul style="list-style-type: none"> All guidelines recommend assessment of risk related to substance abuse prior to initiating opioids and while patients are on therapy.
Patients on long-term opioid therapy who were checked in to the relevant Prescription Drug Monitoring Program prior to initiating therapy and at least every year if on chronic opioid therapy	<ul style="list-style-type: none"> Guidelines recommend monitoring PDMPs when available. Early data show that PDMPs may be effective, although more research will be necessary as PDMPs continue to be developed and used.
Patients on long-term opioid therapy who have evidence of a written opioid care management plan	<ul style="list-style-type: none"> 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.
Number of patients on long-term opioid therapy who have evidence of mental health assessment	<ul style="list-style-type: none"> All guidelines recommend assessment for mental health disorders prior to initiating opioids, and treatment as appropriate.
Number of patients in facility or practice prescribed opioids	<ul style="list-style-type: none"> Numbers are based on a VA measure that is used to compare prescribing rates across facilities.
Inpatient Clinical Quality Measure Concepts	
Opioid-naive patients started on high-dose opioids in the inpatient setting	<ul style="list-style-type: none"> Inappropriate prescribing is a significant problem that can lead to opioid overdose in the inpatient setting, especially in high-potency formulations.
Clinical Decision Support (CDS) Rule Concepts	
Clinical decision support rules to support all measure concepts	<ul style="list-style-type: none"> There should be supporting clinical decision support to promote best practices and improve measured processes.

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

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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

(continued)

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



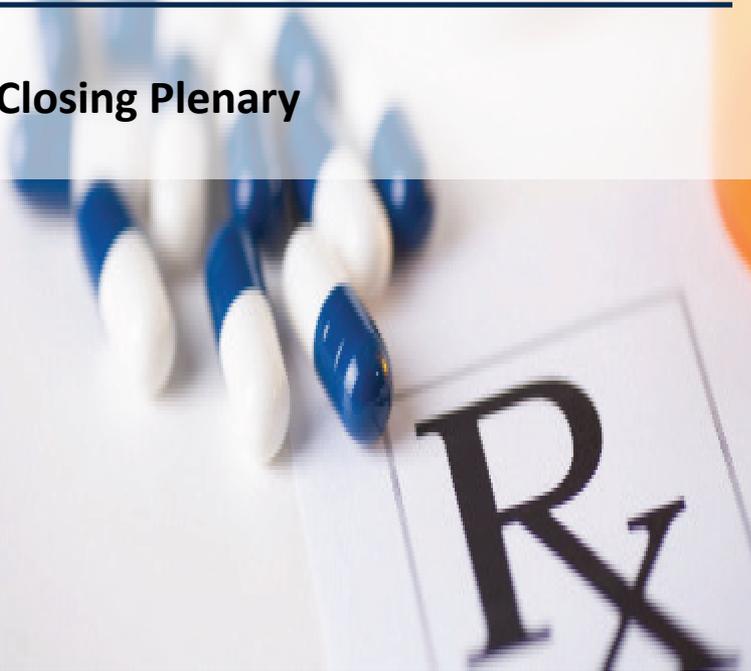
Questions?





ADE Prevention: 2014 Action Plan Conference

Breakout Sessions Wrap-Up and Closing Plenary





Questions?

