



National Action Plan for Adverse Drug Event Prevention

Quality Insights Quality Innovation Network

Wednesday, February 25, 2015

2:00 p.m. – 3:15 p.m. ET / 1:00 p.m. – 2:15 p.m. CT

Quality Insights Quality Innovation Network



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Polling Question #1

- I am a:
 - a. Pharmacist
 - b. Pharmacy technician
 - c. Nurse/nurse practitioner
 - d. Physician
 - e. Physician's assistant
 - f. Administrator
 - g. Other

Please enter your response to this question in the Polling box, located on the right of your screen, where this question is posted.

National Action Plan for Adverse Drug Event Prevention



U.S. Department of Health and Human Services
Office of Disease Prevention and Health Promotion

<http://www.health.gov/hai/ade.asp#action-plan>

Definition of Adverse Drug Event

Adverse Drug Event (ADE)

“an injury resulting from medical intervention related to a drug”¹

1. Kohn, LT, et al. (Institute of Medicine). To err is human: building a safer health system. Washington, DC: National Academy Press, 2000.

How Common are ADEs?

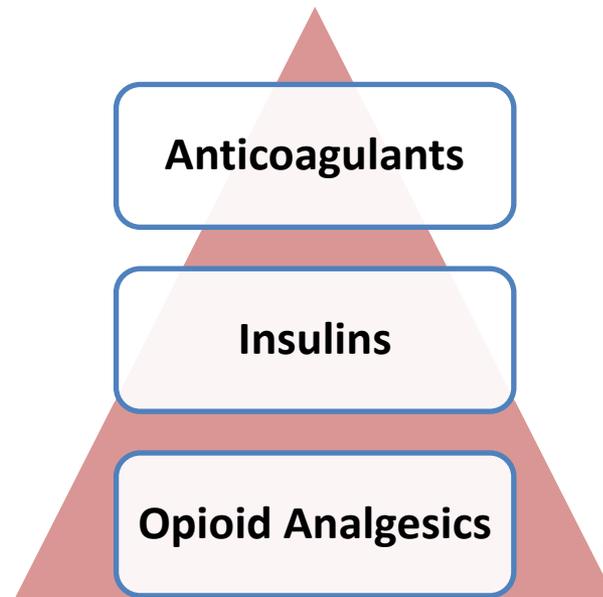
- ADEs occur in any health care setting (inpatient and outpatient)
 - Cause 1/3 of all hospital related adverse events²
 - Cause an estimated 1 million emergency dept visits and 125,000 hospital admissions each year³
- Likelihood increases during transitions of care
 - 2/3 of complications within three weeks of hospital discharge related to adverse drug events⁴

2. US Dept of HHS Office of Inspector General. Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. Washington DC.2010 Nov. Report No.: OEI-06-09-00090.

3.CDC unpublished data: Updated numbers for: Budnitz, DS, et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA. 2006;296(15):1858-66.

4. Forster, AJ et al. The incidence and severity of adverse events affecting patients after discharge from the hospital. Ann Intern Med. 2003; 138(3):161-7.

What Drugs Cause ADEs?

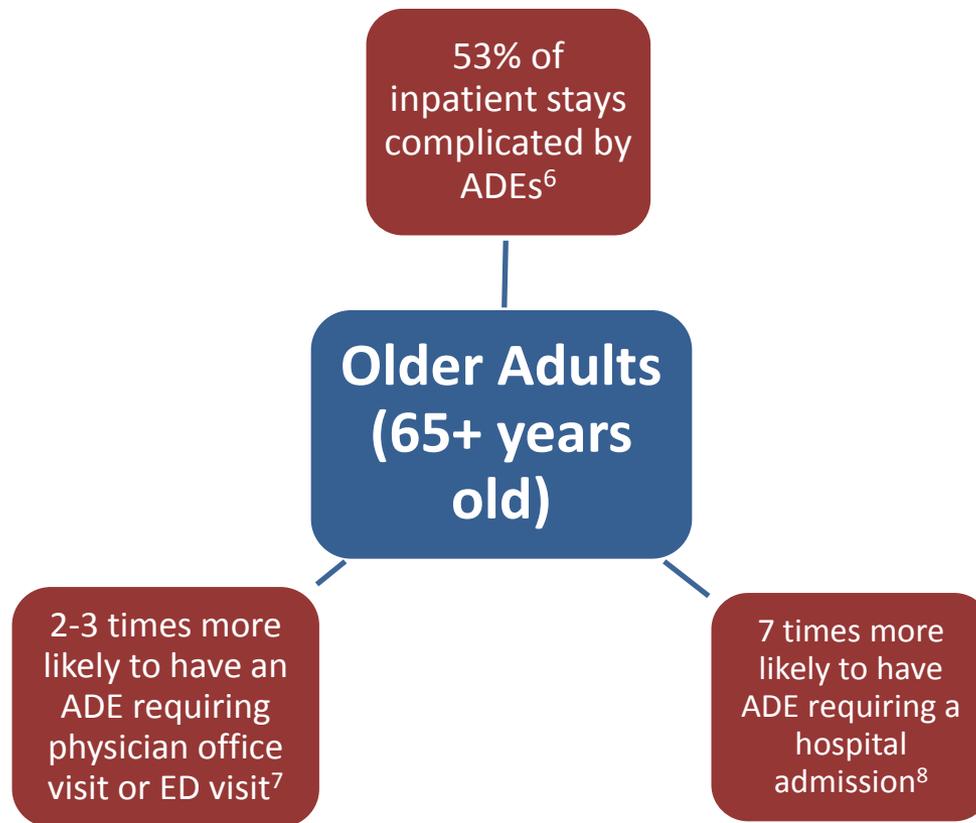


Are top drugs implicated in emergency department (ED) visits & ED visits that lead to hospitalizations⁵

(antibiotics and anti-neoplastics round out the top 5)

5. Budnitz, DS, et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA. 2006;296(15):1858-66.

Who is Most Vulnerable?



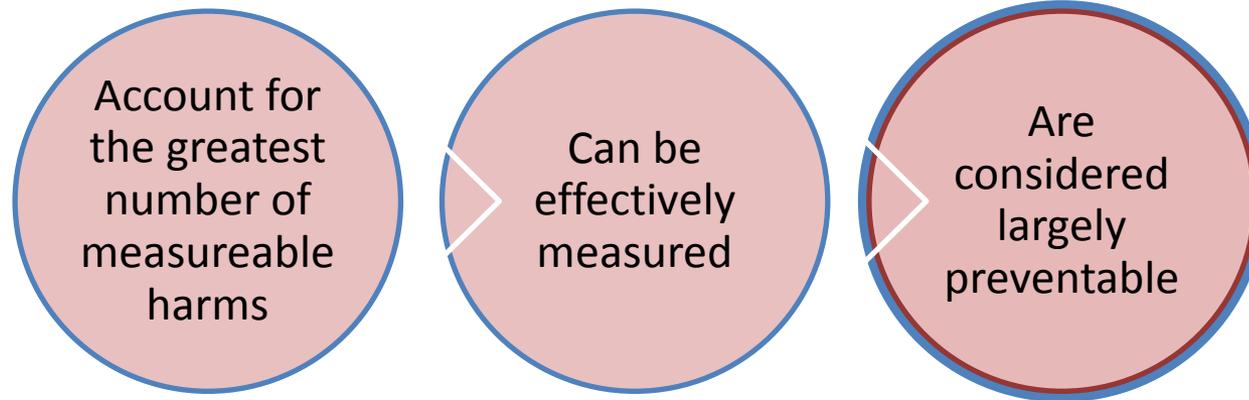
6. Lucado, J. (Social & Scientific Systems, Inc.), Paez, K. (Social & Scientific Systems, Inc.), and Elixhauser A. (AHRQ). Medication-Related Adverse Outcomes in U.S. Hospitals and Emergency Departments, 2008. HCUP Statistical Brief #109. April 2011. Agency for Healthcare Research and Quality, Rockville, MD. Available from: <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb109.pdf>

7. Institute of Medicine Committee on Identifying and Preventing Medication Errors. Preventing Medication Errors: Quality Chasm Series. Washington, DC: The National Academies Press, 2006.

8. Budnitz DS, Pollock DA, Weidenbach KN, Mendelsohn AB, Schroeder TJ, Annett JL. National surveillance of emergency department visits for outpatient adverse drug events. *JAMA*. 2006;296(15):1858-66.

Why focus on 3 drug classes?

The National Action Plan for ADE Prevention found anticoagulants, diabetes agents and opioids cause ADEs that:



ADE Action Plan: Surveillance

- Ways that the burden and rates of ADEs can be measured to monitor progress (reduction) at population-based level
- Active vs. passive surveillance

Active	Passive
<ul style="list-style-type: none">• Small sample size, limited to a specific setting (e.g. hospital), claims based• MPSMS, NEISS-CADES	<ul style="list-style-type: none">• Reporting is voluntary• FDA FAERS

Abbreviations:

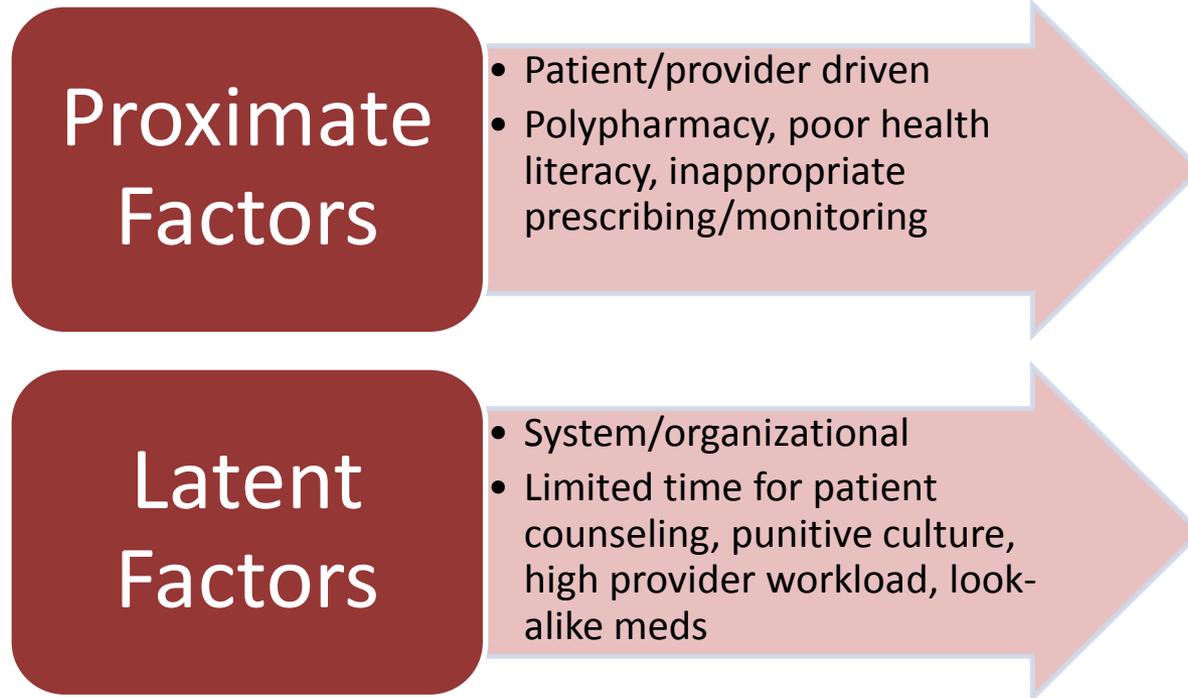
MPSMS -Medicare Patient Safety Monitoring System

NEISS-CADES -National Electronic Injury Surveillance System-Cooperative Adverse Drug Events Surveillance System

FDA FAERS- Food & Drug Administration Federal Adverse Event Reporting System

ADE Action Plan: Prevention

- Perform root cause analysis to investigate factors that contribute to ADEs
- Distinguish between proximate factors and latent factors



ADE Action Plan: Incentives/Oversight

Support incentives and oversight that promote ADE prevention

- Quality measures – Sentinel events, EHR measures (medication reconciliation, warfarin), NQF measures (diabetes)
- Regulatory oversight (hospital conditions of participation, long term care regs);
- Value based purchasing - “Pay for reporting”, ACO models, community-based care transitions programs, Partnership for Patients, PQRS
- Other – QIO program; Medicare coverage of home INR and glucose testing

Polling Question #2

- My practice setting routinely monitors adverse drug event rates for one or more of the 3 high risk categories:
 - a. Yes
 - b. No

Please enter your response to this question in the Polling box, located on the right of your screen, where this question is posted.



ADE Prevention: 2014 Action Plan Conference

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



<http://www.health.gov/hai/pdfs/2014-ADE-Action-Plan-Conference-Slides.pdf>

Anticoagulants (AC)

- **Surveillance** – support strategies that better identify the real world burden and scope of AC ADEs
- **Evidence-based Prevention Tools** – support development and uptake of optimal AC management strategies especially during care transitions and in long-term care
- **Incentives and Oversight** – support policies that incentivize optimal AC management & minimize payment/coverage barriers
- **Research** – support research of real world management of non-warfarin oral anticoagulants

Anticoagulants (AC) cont'd.

- “Anticoagulation Stewardship”
- “Anticoagulation Center of Excellence”
- Provider education, use of guidelines/tools/protocols
- Increase use of evidence-based AC management models
 - AC clinic services
 - Patient self-testing/patient self-monitoring
 - Incorporate AC management into chronic disease education programs
 - Better long term care/home care/coordination of care across settings
 - Improve EHRs to get real-time data, link pharmacy-laboratory data

Anticoagulants (AC) cont'd

- New (non-warfarin) Oral Anticoagulants (NOACs)
 - NOACs are NOT “set it and forget it” drugs
 - Recent JAMA article⁹ – relative risk of any bleeding with dabigatran 30 percent higher than warfarin; 58 percent higher for major bleeding
 - Patients on NOACs can benefit from an AC management service
 - Develop guidance for drug selection/dosing, transitions between agents, adherence, peri-procedural management
 - Develop potential laboratory assays
 - Management of bleeding events, reversal protocols
 - Identify pharmacogenomic issues

9. Hernandez, I. Risk of bleeding with dabigatran in atrial fibrillation. *JAMA Intern Med* online 2014; Nov 3. Available from: <http://archinte.jamanetwork.com/article.aspx?articleid=1921753>

Diabetes Agents

- **Surveillance** – improve surveillance of hypoglycemic events to better monitor & understand risk factors for such events
- **Evidence-based prevention tools** – educational materials focused on hypoglycemia prevention; collaboration amongst health care professions; use evidence-based patient centered tools such as diabetes self management programs
- **Incentives and oversight** – incentive programs that individualize HbA1c (glycosylated hemoglobin) goals for older adults, discourage overaggressive HbA1c lowering in elderly
- **Health Information Technology** – capture point-of-care testing data, utilize related quality measures; improve linkages with pharmacists to develop more robust EHRs

Diabetes Agents cont'd

- Avoid using medications to achieve HbA1c goals <7.5 percent in most older adults ≥ 65 years old, moderate control is generally better¹⁰
- Top predictors of hypoglycemia:
 - Nutritional interruption
 - Prior hypoglycemic event
 - Inappropriate prescribing
- Recommendations
 - basal/bolus insulin protocol - eliminate sliding scale
 - Implement nurse-driven protocols for hypoglycemia management
 - Coordinate mealtime blood glucose testing, insulin administration and meals

10. The American Geriatrics Society. [Choosing Wisely®: Five Things Physicians and Patients Should Question: An Initiative of the ABIM Foundation.](#)

Opioids

- **Surveillance** – outcome and process measures related to opioid ADEs are lacking, developing prescription drug monitoring programs to track use across care settings
- **Evidence-based prevention tools** – DOD/VA opioid prescribing protocol/guidelines & patient education tools; FDA-REMS program for providers addressing long-acting opioid use; SAMHSA-opioid overdose prevention toolkit
- **Incentives and oversight** – prospective and retrospective drug utilization reviews of pharmacy claims; data sharing among pharmacies
- **Health Information Technology**

Abbreviations: DOD/VA-Department of Defense/Veteran's Administration; FDA-REMS-Food and Drug Administration-Risk Evaluation and Mitigation Strategies; SAMHSA-Substance Abuse and Mental Health Services Administration

Opioids cont'd

- Opioid prescribing has skyrocketed in recent years; opioid overdose death has similarly increased (majority accidental)
- ADEs related to illicit/recreational opioid use, medication withdrawal, intentional harm, non-adherence not included in action plan

Recommendations

- Use surveillance to identify patients at risk (dose thresholds, duplications, etc.) and patterns of use that suggest overutilization
- Perform a behavioral health assessment prior to prescribing opioids
- Develop metrics to identify high risk patients and prescribers
- Optimize clinical decision support systems to guide dosage, etc.
- Improve availability and uptake of safe opioid prescribing practices and patient education tools
- Promote patient-centered, team based and coordinated care

Polling Question #3

- My practice setting has a protocol/best practices in place to prevent/manage adverse drug events for one or more of the three high risk categories:
 - a. Yes
 - b. No

Please enter your response to this question in the Polling box, located on the right of your screen, where this question is posted.

Quality Insights' Call to Action

- Already working with communities throughout our 5 state region on improving care coordination, reducing readmissions, etc.
 - Expanding our assistance to new communities
- Encourage communities to implement interventions to prevent adverse drug events associated with high-risk drugs
 - Improve patient education
 - Improve/increase screening patients for adverse drug events
 - Collect/track data to monitor ADE rates over time
 - Involve pharmacies/pharmacists in the process of medication safety especially as part of care coordination process
 - Develop multi-disciplinary coalitions to promote best practices and interventions across care settings to reduce ADEs associated with high risk drugs

ADE State Leads

- 1. Delaware - Sally Jennings**
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- 2. Louisiana - Chris Gatlin**
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- 3. New Jersey - Nicole Skyer-Brandwene**
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- 5. West Virginia - Jill Aliff**
 - jaliff@wvmi.org, 800.642.8686, ext. 4247

1



2



3



4



5



Upcoming Events

- **Alzheimer's Disease and Related Dementias (ADRD) Webinar Series**
 - Quality Insights is partnering with the West Virginia Geriatric Education Center to offer this **FREE** webinar series to address Alzheimer's Disease and Related Dementias (ADRD). Patients with ADRD are at higher risk for being hospitalized and readmitted. Recognizing and managing ADRD is important for providing coordinated care for individuals and reducing hospitalizations and readmissions.
 - **Dates/Times**
 - March 11, 2:00 – 3:15 ET [REGISTER NOW](#)
 - March 25, 2:00 – 3:30 ET [REGISTER NOW](#)
 - April 8, 2:00 – 3:30 ET [REGISTER NOW](#)
 - **Contacts**
 - Biddy Smith, 304.346.9864, ext. 3252, bsmith@wvmi.org
 - Jill Aliff, 304.346.9864, ext. 4247, jaliff@wvmi.org

Questions?



www.qualityinsights-qin.org

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References

1. Kohn, LT, et al. (Institute of Medicine). To err is human: building a safer health system. Washington, DC: National Academy Press, 2000.
2. US Dept of HHS Office of Inspector General. Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. Washington DC.2010 Nov. Report No.: OEI-06-09-00090.
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6. Lucado, J. (Social & Scientific Systems, Inc.), Paez, K. (Social & Scientific Systems, Inc.), and Elixhauser A. (AHRQ). Medication-Related Adverse Outcomes in U.S. Hospitals and Emergency Departments, 2008. HCUP Statistical Brief #109. April 2011. Agency for Healthcare Research and Quality, Rockville, MD. Available from: <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb109.pdf>
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<http://archinte.jamanetwork.com/article.aspx?articleid=1921753>

10. The American Geriatrics Society. Choosing Wisely®: Five Things Physicians and Patients Should Question: An Initiative of the ABIM Foundation. Available from:

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