



National Action Plan for Adverse Drug Event Prevention—Diabetes Agents

Adverse Drug Events (ADEs) –Background

- Adverse drug events (ADEs) are the most common cause of health care-related harm, affecting approximately two million hospital stays, and accounting for an estimated 3.5 million physician office visits, one million emergency department (ED) visits, and 280,000 hospital admissions every year
- Owing to the morbidity and mortality associated with their harms and their amenability for prevention, the Department of Health & Human Services (HHS) identified ADEs as a critical patient safety and public health challenge that should be addressed in an aligned and coordinated fashion across the Federal Government

National Action Plan for ADE Prevention

- The **ADE Action Plan** is a Federal, inter-agency effort that was developed with the following key objectives:
 - Identify high-priority targets for Federal efforts, with a focus on three high- priority drug classes that cause ADEs and are considered to be common, clinically significant, preventable, and measurable: **anticoagulants, diabetes agents, and opioids**
 - Use a four-pronged approach: **Surveillance, Prevention, Incentives and Oversight, and Research** to identify the highest priority strategies and opportunities for advancement, which will have the greatest impact on reducing ADEs
 - Align the efforts of Federal health agencies and non-Federal stakeholders to reduce patient harms from these specific ADEs nationally
 - Implement these strategies to promote safer and higher quality health care services, reduce health care costs, inform and engage consumers, and, ultimately, improve health outcomes

Diabetes Agents ADE –Background

- The ADE Action Plan targets hypoglycemia as the most severe, and largely preventable, diabetes agent ADE
 - **Inpatient settings:** Hypoglycemia was identified as the third most common ADE identified among Medicare beneficiaries hospitalized in 2008; nearly all identified cases in this population were considered to be preventable
 - **Outpatient settings:** Insulin and oral diabetes agents are among the most common medication classes resulting in U.S. emergent hospitalizations for ADEs; from 1999-2010, rates of hospital admissions for hypoglycemic events among Medicare beneficiaries increased by approximately 22.3% while the rates of hospital admissions for hyperglycemia significantly decreased.

Diabetes Agents ADEs –Selected Key ADE Action Plan Recommendations

- **Surveillance:** Improve capture of diabetes agent-related ADEs in inpatient , outpatient, long-term care settings, and care transitions to better understand the true burden
- **Prevention:** Promote a multi-factorial risk mitigation approach to the prevention of hypoglycemic events, including the identification of patient and iatrogenic risk factors; promote the individualization of target glycemic goals based upon life expectance, comorbid conditions, social support, and personal preference
- **Incentives & Oversight:** Improve access to more robust Electronic Health Record (HER) systems that facilitate clinical quality measures and clinical decision support tools that support individualization of glycemic targets
- **Research:** Promote research that identifies if and how individualized glycemic goals and shared decision-making are being utilized in clinical treatment decisions of patients with diabetes

Outcome & Process Measures

SCOPE	MEASURE/DATA ELEMENTS	AGENCY	DATA SYSTEM/BRIEF DESCRIPTION	
INPATIENT	NATIONAL	1. Incidence of hypoglycemic events	AHRQ a. HCUP-Inpatient stays with ICD-9 codes and E-codes from administrative claims and/or EHR data b. MPSMS-Inpatient stays with combination of laboratory triggers and clinical triggers from medical record review	
		2. Incidence of hypoglycemic events in Federal Health System Populations	a. IHS b. VA a. Resource and Patient Management System (RPMS-EHR)-EHR entry in the Problem List of "hypoglycemia" b. Integrated Databases-ADE identification by ICD-9 codes, primary hospitalizations, ED or clinic visits, and laboratory values	
	LOCAL/FACILITY-LEVEL	3. Rate of hypoglycemic events following administration of an anti-diabetic agent (NQF 2363)	CMS	a. Electronic clinical data-EHR, laboratory, pharmacy
		4. Rate of all-cause unplanned readmission (NQF 1789)	CMS	a. MedPAR-Medicare Part A Claims for readmissions within 30 days of hospital discharge
		5. Admission rates for diabetes short-term complications (NQF 0272)	AHRQ	a. HCUP State Inpatient Database-discharges for short-term diabetes complications (ketoacidosis, hyperosmolarity, coma)
		6. Proposed Meaningful Use Measures (Stage 3)		a. Hyperglycemia (balancing measure) b. Mild hypoglycemia (<70mg/dL) c. Recurrent hypoglycemia d. Documentation of etiology of hypoglycemic event (clinical decision support)
INPATIENT & OUTPT.	SPONTANEOUS REPORTS			
	7. Rates of clinician-diagnosed or patient-reported hypoglycemia	a. DOD b. FDA c. VA	a. Patient Safety Reporting System b. FAERS c. VA ADERS	
OUTPATIENT	NATIONAL	8. Incidence of hypoglycemic events	a. FDA b. CDC c. AHRQ a. Sentinel, Mini-Sentinel-ED visits, hospitalizations for hypoglycemic events from administrative claims/HER b. NEISS-CADES-ED visits, emergent hospitalizations, diagnosed hypoglycemic events from medical record review c. NEDS-ED visits with hypoglycemia as first-listed diagnosis	
		9. Incidence of hypoglycemic events in Federal Health System Populations	a. DOD b. VA c. IHS a. Pharmacovigilance Defense Application System-outpatient clinic visits, ED visits, ICD-9/CPT codes b. Integrated Databases- ADE identification by ICD-9 codes, primary hospitalizations, ED or clinic visits, and laboratory values c. Resource and Patient Management System (RPMS-EHR)-EHR entry in the Problem List of "hypoglycemia"	
	LOCAL/FACILITY-LEVEL	10. Rates of patients with HbA1c poor control	NCQA	a. HEDIS-data from HMO's and PPO's. Poor control defined as HbA1c >9%
		11. Rates of patients with HbA1c control	NCQA	a. HEDIS-data from HMO's and PPO's. Control defined as HbA1c <8% or, <7% for subset younger than 65 years old
		12. Percentage of diabetic patients ≥65 years with HbA1c <7% (NQF 3476-MUC)	CMS	a. Proposed Meaningful Use Measure (Stage 3)

Note: AHRQ = Agency for Healthcare Research and Quality; CMS = Centers for Medicare and Medicaid Services; DOD = Department of Defense; FAERS = FDA Adverse Event Reporting System; FDA = Food and Drug Administration; HCUP = Healthcare Cost and Utilization Project; HEDIS = Healthcare Effectiveness Data and Information Set; IHS = Indian Health Service; MedPar = Medicare Provider Analysis and Review; MUC = Measures Under Consideration; NCQA = National Committee for Quality Assurance; NEDS = Nationwide Emergency Department Sample; NEISS-CADES = National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance Project; VA = Veterans Affairs; VA ADERS = VA Adverse Event Reporting System