SECTION 1

# National ADE Action Plan Scope and Development

## Scope of the National Action Plan for ADE Prevention

The *National Action Plan for Adverse Drug Events Prevention* addresses a defined group of ADEs that are considered to be common, clinically significant, preventable, and measurable; resulting from high-priority drug classes (i.e., anticoagulants, diabetes agents, and opioids); and occurring largely in high-risk populations (e.g., older adults). Preventable or ameliorable ADEs include medication errors (e.g., errors in the dose of drug administered) or adverse events that are outcomes resulting from harm caused by medical care that could have been mitigated in duration or severity by heightened monitoring or better health care management [1].

The ADE Action Plan is intended to address direct patient harms from prescribed medication use [2]. The ADE Action Plan seeks to identify, collate, and communicate opportunities and gaps within Federal systems and among external stakeholders. The ultimate goal is to strengthen and support health care systems and providers in their efforts to ensure the safest care of their patients with regard to preventing ADEs from a small group of high-priority drug classes. In addition, the ADE Action Plan provides some insights on current evidence-based best practices, so that greater consistency in the application of these practices can occur throughout the Nation, and identifies opportunities to drive improvement. The overriding focus of the ADE Action Plan begins with the most fundamental charge to health care systems and providers: "First, do no harm."

Considering the breadth of harms resulting from medication use, the Federal Interagency Steering Committee decided to narrow the focus of the ADE Action Plan, with the intent of expanding the plan to a wider array of topics and drug classes in the future. Thus, the ADE Action Plan does not address circumstances beyond the therapeutic use of medications, such as illicit or recreational drug use, drug withdrawal, or use of medications in acts of intentional self-harm (e.g., suicide or suicide attempts). Other important public health issues, such as nonadherence to medication regimens, undertreatment of diseases, and underutilization of chemo-prophylaxis are also excluded from the focus of the ADE Action

Plan. The ADE Action Plan is not intended to serve as a clinical document or guideline, or a replacement for currently established, evidence-based clinical- and laboratory-guided strategies for preventing or reducing ADEs.

## Framework for the National Action Plan for ADE Prevention

In designing an ADE Action Plan, the Steering Committee considered several models for ensuring a comprehensive focus in the effort to reduce ADEs. Leaders of each Federal Interagency Workgroup (FIW) agreed that the National Strategy for Quality Improvement (National Quality Strategy) addressed all of the challenges and incorporated all of the principles necessary to provide guidance in the development of ADE prevention strategies and advancement opportunities [3]. The National Quality Strategy (NQS), a requirement of the Affordable Care Act, is a nationwide effort to align public and private interests to improve the quality of health and health care for all Americans. Under the leadership of the Department of Health and Human Services (HHS), the NQS was developed using a collaborative process that solicited input from a wide range of stakeholders across the health care system. The strategy addresses health care delivered in all health settings and acknowledges the unique roles of the patient, his/her family, the health care provider, and the community (including State and local public health departments) in successfully achieving the goals. The NQS is defined by three aims (patient care, community health, and efficiency) and outlines six priorities to achieve these aims:

1) Safer Care
2) Informed Patient and Family Engagement
3) Communication and Care Coordination
4) Science-Driven Prevention and Treatment
5) Promoting Best Practices Within the Community
6) Innovative Delivery Models To Achieve Affordable Care

These priorities embody the principles and approaches that can effectively reduce ADEs and create a culture of safety around the effective use of medications. The first five NQS priorities have been used to frame each of the drug class-specific prevention sections of the ADE Action Plan. The sixth priority is included in the section on Incentives and Oversight Opportunities. One of the key principles in the ADE Action Plan is a focus on patient-centered care and patient participation in the delivery of health care.

This patient-oriented focus is essential to ensuring the successful management of chronic conditions that lead to the use of most prescribed medications. The NQS also addresses the unique nature of each patient's clinical history and acknowledges that many patients experience multiple chronic conditions and may need a more comprehensive and coordinated approach to avoid ADEs.

## Development Process for the National Action Plan for ADE Prevention

To develop the ADE Action Plan, the FIWs followed a systematic approach in which they

- Facilitated discussions among the Federal partners to identify opportunities and gaps in cross-agency coordination and alignment in four areas: surveillance, prevention, incentives and oversight policies, and research (unanswered questions)
- Conducted an initial environmental scan of existing Federal resources, medical literature, and clinical guidelines that address the four areas
- Evaluated and catalogued resources and initiatives to determine their pertinence to ADE prevention
- Performed a gap analysis to identify the strengths and weaknesses of current resources and develop recommendations to strengthen existing resources
- Engaged non-Federal subject matter expert consultants in the FIW discussions, so that they could contribute their expertise in addressing ADEs in each of the three drug class areas, define best practices, and provide recommendations for enhancing resources in ways that could support health care systems and providers

Consequently, the ADE Action Plan reflects the perspectives of a broad group of Federal Agencies and non-Federal subject matter expert consultants, and identifies opportunities to leverage existing resources and initiatives in the field of ADE prevention.

### *Organization of the National Action Plan for ADE Prevention*

Using the model established by the Steering Committee for the National Action Plan To Prevent Healthcare-Associated Infections, the ADE Steering Committee identified key focus areas that corresponded to the most immediate areas for consideration in understanding and preventing ADEs associated with anticoagulants, diabetes agents, and opioids:

- **Surveillance**—Coordinate existing Federal surveillance resources and data to assess the health burden and rates of ADEs.
- **Prevention—**Share existing evidence-based prevention tools across Federal Agencies and with non-Federal health care providers and patients.
- **Incentives and Oversight**—Explore opportunities, including financial incentives and oversight authorities, to promote ADE prevention.
- **Research**—Identify current knowledge gaps and future research needs (unanswered questions) for ADE prevention.

Considerations for how health information technology (health IT) can be leveraged to advance ADE prevention are also incorporated throughout the ADE Action Plan. At the onset, the ADE Steering Committee and FIWs recognized the potential for health IT to support all aspects of the ADE Action Plan, including measurement, incentives, quality measure development and reporting, and prevention. Examples of how health IT can potentially support the ADE Action Plan are outlined in **Table 1**.

**Table 1. Examples of How Health Information Technology Can Support Goals of the ADE Action Plan**

| Focus Area | Health IT Feature | Impact |
|---|---|---|
| **Surveillance** | Electronic data transmission | ▪ Real-time data reporting<br>▪ Reduced provider burden<br>▪ Improved patient access to health information |
| **Prevention** | Clinical decision support | ▪ Flowsheets<br>▪ e-prescribing<br>▪ Patient panels<br>▪ Implementation of clinical guidelines<br>▪ Sharing best practices |
| **Incentives** | Electronic health records | ▪ Meaningful Use |
| **Research** | Data repositories | ▪ Answer research questions<br>▪ Identify best practices<br>▪ Develop new research questions |

Furthermore, leveraging health IT helps align the ADE Action Plan with goals outlined in the Federal Health Information Technology Strategic Plan. In November 2011, the HHS Office of the National Coordinator for Health IT (ONC) released the Federal Health Information Technology Strategic Plan, which identified "achieving rapid learning" as one of its five priority goals to advance by 2015 [4]. Through the establishment of a "Learning Health Care System," health IT could aid in the identification

of effective interventions to prevent ADEs and accelerate integration of ADE surveillance and prevention strategies into clinical practice. A Learning Health Care System also has the potential to answer additional research questions to help advance the field of medication safety.

The Medicare and Medicaid Electronic Health Record (EHR) Incentive Program (e.g. Meaningful Use), which provides incentive payments for eligible professionals and hospitals that meet certain requirements in the use of an EHR, also represents a tremendous opportunity to leverage health IT resources to further the prevention of ADEs, while increasing opportunities for measuring progress. Currently, very few medication safety-specific targets are included in stage 2 of meaningful use for the EHR Incentive Program—and even fewer are included that address the high-priority medication classes associated with the most preventable morbidity in inpatient and outpatient settings [**Table 2**]. The current Core Measure requirements under Meaningful Use only address the need for documentation in the EHR of a current patient medication list, and the remaining medication safety-related measures are categorized under Clinical Quality Measures (CQMs), from which professionals and hospitals must select a preset number of measures on a menu list. These measures are less likely than Core Measures to be implemented. Furthermore, some of the medication safety-related CQMs do not uniformly reflect the most recent evidence on the sources of the highest burden of medication-related harms (e.g., use of "high risk" [or "Beers Criteria"] medications may not be optimal choices for older adults, but other medications are far more likely to result in ADEs) [5, 6, 7].

**Table 2. 2014 EHR Incentive Program Core and Clinical Quality Measures Related to Medication Safety [8, 9, 10]**

| | |
|---|---|
| **Core Measures** | ▪ Use computerized provider order entry (CPOE) for medication orders (**EP Core 1**)<br>▪ Medication reconciliation (**EP Core 14**) |
| **Clinical Quality Measures** | ▪ Use of high-risk medications in the elderly (**CMS156v1**) (EP)<br>▪ Documentation of current medications in the medical record (**CMS68v2**) (EP)<br>▪ Warfarin Time in Therapeutic Range (TTR) (**CMS179v1**) (EP)<br>▪ VTE patients receiving unfractionated heparin with dosages/platelet count monitoring by protocol (or nomogram) (**CMS eMeasure ID 109**) (EH)<br>▪ VTE patients receiving warfarin discharge instructions (**CMS eMeasure ID 110**) (EH) |

**Abbreviations:** EHR = electronic health record; EH = eligible hospital; EP = eligible professional; VTE = venous thromboembolism

### *Limitations of Health Information Technology*

Throughout the ADE Action Plan, health IT is considered a tool, not a stand-alone solution for advancing ADE prevention efforts. Access to health IT is a valuable resource for health care providers and their patients across all health care settings, but there are a number of challenges associated with its

successful and more widespread adoption, such as costs of implementation and current limitations in data exchange and interoperability [11]. These limitations are acknowledged in the ADE Action Plan, and use of health IT is viewed as one of several strategies that can be implemented to enhance, not replace, delivery of optimal clinical care to prevent ADEs.

## References


1. Agency for Healthcare Research and Quality. Adverse Drug Event (ADE), in Patient Safety Network: Glossary. Available from: http://psnet.ahrq.gov/glossary.aspx.
2. Nebeker JR, Barach P, Samore MH. Clarifying adverse drug events: a clinician's guide to terminology, documentation, and reporting. *Ann Intern Med* 2004;140(10):795-801.
3. U.S. Department of Health and Human Services. Report to Congress: National Strategy for Quality Improvement in Health Care. Washington (DC): The Department, March 2011.
4. Office of the National Coordinator for Health Information Technology (ONC). Federal Health IT Strategic Plan. 2011. Available from: http://www.healthit.gov/policy-researchers-implementers/health-it-strategic-planning.
5. Budnitz DS, Lovegrove MC, Shehab N, Richards CL. Emergency hospitalizations for adverse drug events in older Americans. *N Engl J Med* 2011;365:2002–12.
6. Budnitz DS, Shehab N, Kegler SR, Richards CL. Medication use leading to emergency department visits for adverse drug events in older adults. *Ann Intern Med* 2007;147:755-65.
7. Smith HS, Lesar TS. One more Beers? It's time to STOPP! The need for better tools to guide medication prescribing. *Pain Physician* 2011;14:E501-4.
8. Centers for Medicare and Medicaid Services. Stage 2 Eligible Hospital and Critical Access Hospital (CAH): Meaningful Use Core and Menu Objectives. October 2012. Available from: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Stage2_MeaningfulUseSpecSheet_TableContents_EligibleHospitals_CAHs.pdf.
9. Centers for Medicare and Medicaid Services. Clinical Quality Measures for 2014 CMS EHR Incentive Programs for Eligible Professionals. January 2013. Available from: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EP_MeasuresTable_Posting_CQMs.pdf.
10. Centers for Medicare and Medicaid Services. Clinical Quality Measures finalized for Eligible Hospitals and Critical Access Hospitals Beginning with FY2014. 2013. Available from: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2014_CQM_EH_FinalRule.pdf.

11. DePhillips III HA. Initiatives and barriers to adopting health information technology: a US perspective. *Dis Manage Health Outcomes*. 2007;15(1):1-6.