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Adverse Drug Event (ADE) Resource Guide

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INTRODUCTION

Medications offer great benefit to patients, but they can come with great risks when not administered or managed properly. The responsibility for managing these risks are shared by many federal agencies, drug manufacturers, pharmacies, hospitals, numerous healthcare professionals, healthcare insurers, patients, caregivers, and many others. So, there are substantial partners to collaborate on this problem. Although there are many initiatives involving some of these partners, there are more than 4 million visits to emergency departments, doctor's offices, or other outpatient settings each year due to adverse drug events (ADEs). There are also almost 10 ADEs per month for every 100 residents in long-term care (LTC). It is estimated that as much as 50% of injuries associated with medication use could be prevented with the knowledge currently available with as many as 1.5 million ADEs prevented across healthcare settings annually.[1]

Even if an ADE is not preventable, computerized systems can detect ADEs early so that health care providers can initiate interventions to mitigate the effects and lessen the severity of the reaction. Hospitals usually rely on hospital staff to complete manual, written incident reports in order to track adverse events, improve quality, and assess risk. However, only about 6% of ADEs are reported by this method. Automatic systems can improve detection considerably. Medication errors can occur at any point in the medication administration process. Some of the most frequent types of errors associated with ADEs include[2]:

- Missed dose
- Wrong technique
- Illegible order
- Duplicate therapy
- Drug-drug interaction

Computer systems are only part of the solution in preventing and reducing ADEs. Research studies on medication errors support other methods that improve the medication delivery system. These include[2]:

- Use FDA's MedWatch program to report serious ADE reactions
- Improve incident reporting systems
- Create a better atmosphere for healthcare providers to report ADEs where the person reporting the error does not fear punishment
- Rely more on pharmacists to advise physicians in medication prescription and healthcare provider education on medications
- Improve the nursing medication administration and monitoring systems

1 FDA's Safe Use Initiative Report

2 Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs (AHRQ)

Opportunities exist throughout federal agencies, state regulatory agencies, healthcare providers in all settings, insurers, and patients on national and community levels, to collaborate on solutions to reduce ADEs. There are several national agencies leading national efforts to bring communities together. Some of agencies and the collaboratives are:

- Health Resources and Services Administration (HRSA)
  - Patient Safety and Clinical Pharmacy Services Collaborative (PSPC)
- Agency for Healthcare Research and Quality (AHRQ)
  - Reducing and Preventing ADE
- Federal Drug Administration (FDA)
  - Safe Use Initiative

ABOUT THIS GUIDE

This resource guide provides an overview of some of the processes and strategies used by HRSA's PSPC. It is meant to serve as a resource to a broad overview of the collaborative action needed to form community groups to focus on ways to reduce ADEs in their communities. As with any team formation, it is necessary to pick the right multi-disciplinary team to begin work. It is important to maintain a focus on being patient-centered and make sure patients are represented in the teams. The list of additional resources contains many helpful links to expanded background information, education modules, literature, timelines, videos, and many helpful tools from current national collaborators, as well as the list of resources from previous work.

In particular, the additional resources for PSPC, should be visited for access to expanded guidelines, tools, and change packages outlined in this guide:

Patient Safety and Clinical Pharmacy Services Collaborative (PSPC) (HRSA)

DEFINITIONS[3]

Adverse Drug Events (ADE) – Events that result in harm or injury to the patient due to medication use – also see potential adverse drug events.

High Alert Drugs – Drugs that bear a heightened risk of causing significant harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. For more information on this list, see Institute for Safe Medication Practices.

Medical Errors - The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

Medical home – A Patient-Centered Medical Home is a team-based model of care led by a personal physician who provides continuous and coordinated care throughout a patient's lifetime to maximize health outcomes.

Medication Safety – Freedom from accidental injury during the course of medication use; activities to avoid, prevent, or correct adverse drug events which may result from the use of medications.

Medication Therapy Management (MTM) – MTM in pharmacy practice are distinct services or group of services that optimize therapeutic outcomes for individual patients. It includes 5 core elements: 1) Medication Therapy Review 2) Personal Medication Record 3) Medication Action Plan 4) Intervention and/or Referral 5) Documentation and Follow-up

Medication Use System – A combination of interdependent processes that share the common goal of safe, effective, appropriate, and efficient provision of drug therapy to patients. Major processes in the medication use system are: selecting and procuring, storage; prescribing; transcribing and verifying/reviewing; preparing and dispensing; administering and monitoring.

Potential Adverse Drug Event (pADE) – Potential harm that was identified and avoided with appropriate interventions before reaching the patient.

Example: Pharmacist catches an allergy to penicillin and calls the physician to change amoxicillin to azithromycin.

For more detail on these definitions, and others, please visit the PSPC Change Package.

[3] Patient Safety and Clinical Pharmacy Services Collaborative (PSPC) (HRSA)

READINESS ACTION

Collaborative communities can be established to work on specific ADEs, or with a broader vision. Once the vision is established, then team development should take place. These communities should have representation from many levels of clinicians and professionals to patients, families, and caregivers in both public and private sectors. The following assessment can be used to assess readiness to begin action and is included in HRSA PSPC Change Package:

1. Perform quick self-assessment using change package

- What are the relationships I need to develop to perform on each strategy?
- Who should we partner with?
- What are the assets we have to carry out each strategy?
- What are the assets we need to line up?
- Who are the people to move this forward?
- What will show it is working?

2. Organize information on the need for, and the benefits of, clinical pharmacy services (CPS)

- Have a case for the need for change
- Use success story from another community
- Identify acknowledged problem situations that would be improved by CPS
- Use readily available data to make case for CPS

3. Reach out and set communications with other interested parties up front

- Use training to engage Senior Leaders
- Identify individual provider interests
- Talk to IT early and understand capacity for improvement through IT
- Identify physician champions
- Introduce case for CPS in strategic and operational planning
- Ask leadership to charter the effort

4. Move partners and champions into place (organizations and providers)

- Convene people that “want a change, have ideas for change”
- Involve interested providers
- Involve patients and families on a planning committee
- Discuss information on benefits to CPS
- Document and share needs and interests
- Prepare for “first things first”

5. Identify potential high-risk populations of focus and map CPS

- Survey staff on what health status and medication risks to focus on
- Develop estimates of baseline patient flows
- Draft referral criteria
- Draw CPS as a workflow integrated into current practice

STRATEGIES TO PROMOTE SAFE MEDICATION USE – PSPC[4]

High performing organizations and many successful PSPC teams have used the following strategies to build teams to implement the following strategies to achieve breakthrough improvements:

1. Get leadership commitment: develop organizational relationships that promote safe medication-use systems and optimal health outcomes

2. Track for measurable improvement: Achieving change using the value and power of data-driven improvements

3. Make care delivery integrated: Build an integrated health care system across providers and settings that produces safety and optimal health outcomes

4. Develop safe medication use systems: Develop and operate by safe medication-use practices

5. Practice patient-centered care: Build a patient-centered medication-use system

[4] Patient Safety and Clinical Pharmacy Services Collaborative (PSPC) (HRSA)

RESOURCES FROM PREVIOUS WORK

PIM, DDI, and PDP

Understanding and Utilizing National Drug Codes- Pharmacy QIOSC

FDA's National Drug Code Directory

Medicare Part D Prescription Drug Event (PDE) Data Elements

An Intervention to Improve Secondary Prevention of Coronary Heart Disease

Evidence for the Effectiveness of Techniques to Change Physician Behavior

Physician Tools

Beers List

Improving Drug Safety in OK – The SPOkE Project

PIM Recommendation

Spoke Project

TMF Health Quality Institute – Warfarin DDI Project

Beneficiaries/Caregivers

Patient Medication Worksheet – DADE IPRO (NY)

Drug Interaction Checker – website for caregivers

Therapeutic Drug Levels

Your Guide to Coumadin®/Warfarin Therapy

AHRQ Pill Cards

Iowa Healthcare Collaborative – Patient Medication Card

What You Need To Know About Med Errors

Consumer Drug Information from ASHP

General Resource List

Current MTM contact list

Prescription Drug Event Record Layout

Patient Safety Tools Available through AHRQ

AHRQ Guide to Warfarin Therapy

AHRQ Patient Safety Network – Computerized Provider Order Entry Patient Safety Primer

ConsumerMedSafety.org

Report - Electronic Prescribing: Becoming Mainstream Practice

FDA Center for Drug Evaluation and Research: Drug Safety Initiative

FDA Drug Interactions: What You Should Know

FDA Managing Drug Safety Issues Q&A

Medline Plus: Drug Safety

Medline Plus: Drugs and Supplements Listing

Potentially Inappropriate Medications for the Elderly According to the Revised Beers Criteria

Express Scripts® Drug Digest

The Institute for Safe Medication Practices

Pharmacy Support

American Society of Health-System Pharmacists

American Pharmacist Association

National Association of Boards of Pharmacy

ADDITIONAL RESOURCES

ADE Regions and Coaches

Agency for Healthcare Research and Quality

Agency for Healthcare Research and Quality – Patient Safety Network for literature/tools

BeMedWise – a resource for FAQs, quizzes, and other patient education

FDA - Safe Use Initiative

FDA – Patient Safety Newsletter

Healthcare Communities

HRSA – PSPC resources and change package

Improving Individual Patient Care (IIPC) National Coordinating Center (NCC)

IIPC SDPS ListServe

Institute for Safe Medication Practices (ISMP) – resource for many tools, assessments, guidelines and much more for clinicians and consumers

Institute for Safe Medication Practices (ISMP) – Patient Safety Videos

National Council on Patient Information and Education (NCPIE) – resource for patient education