



Body System: Patient-Based Care		
Session Topic: Drug Interactions and Prevention of Adverse Events		
Educational Format		Faculty Expertise Required
REQUIRED	Interactive Lecture	Expertise in the field of study. Experience teaching in the field of study is desired. Preferred experience with audience response systems (ARS). Utilizing polling questions and engaging the learners in Q&A during the final 15 minutes of the session are required.
OPTIONAL	Problem-Based Learning (PBL)	Expertise teaching highly interactive, small group learning environments. Case-based, with experience developing and teaching case scenarios for simulation labs preferred. Other workshop-oriented designs may be accommodated. A typical PBL room is set for 50-100 participants, with 7-8 each per round table. <u>Please describe your interest and plan for teaching a PBL on your proposal form.</u>
Professional Practice Gap	Learning Objective(s) that will close the gap and meet the need	Outcome Being Measured
<ul style="list-style-type: none"> • ADE's Account for an estimated 1 in 3 of all hospital adverse events; Affect about 2 million hospital stays each year; Prolong hospital stays by 1.7 to 4.6 days; ADEs account annually for: Over 3.5 million physician office visits; An estimated 1 million emergency department visits; Approximately 125,000 hospital admissions • Drug overdose in children has steadily been on the rise over the last two decades, particularly due to prescribing, dispensing, administering, or monitoring medication errors. • Family physicians have gaps in knowledge and performance in evaluating for potentially adverse drug events, among elderly patients receiving multiple medications. 	<ol style="list-style-type: none"> 1. Use evidence-based criteria to evaluate for potentially adverse drug events, among patients receiving multiple medications. 2. Disseminate best practices in safety strategies to decrease ADEs from high priority medications in primary care 3. Describe the different roles of different healthcare professions in managing patients' medications safely and effectively 4. Discuss the potential for misunderstandings and knowledge gaps between different professions, and the importance of continuing dialogue across the healthcare team 5. Identify system, team, and individual strategies for reducing the frequency of adverse drug events 	Learners will submit written commitment to change statements on the session evaluation, indicating how they plan to implement presented practice recommendations.



<ul style="list-style-type: none"> Family physicians have knowledge and performance gaps in developing collaborative care plans to address the needs of patients who have poor health literacy or reduced cognitive function, or those patients who have language barriers, in order to foster appropriate self-administration of medications. 		
ACGME Core Competencies Addressed (select all that apply)		
X	Medical Knowledge	Patient Care
	Interpersonal and Communication Skills	Practice-Based Learning and Improvement
	Professionalism	X Systems-Based Practice
Faculty Instructional Goals		
<p>Faculty play a vital role in assisting the AAFP to achieve its mission by providing high-quality, innovative education for physicians, residents and medical students that will encompass the art, science, evidence and socio-economics of family medicine and to support the pursuit of lifelong learning. By achieving the instructional goals provided, faculty will facilitate the application of new knowledge and skills gained by learners to practice, so that they may optimize care provided to their patients.</p> <ul style="list-style-type: none"> Provide up to 3 evidence-based recommended practice changes that can be immediately implemented, at the conclusion of the session; including SORT taxonomy & reference citations Facilitate learner engagement during the session Address related practice barriers to foster optimal patient management Provide recommended journal resources and tools, during the session, from the American Family Physician (AFP), Family Practice Management (FPM), and Familydoctor.org patient resources; those listed in the <u>References</u> section below are a good place to start <ul style="list-style-type: none"> Visit http://www.aafp.org/journals for additional resources Visit http://familydoctor.org for patient education and resources Review the purpose and goals of the "Reducing Adverse Drug Events (ADE) from High Priority Medications in Primary Care" project Provide strategies to help learners identify risk factors for ADEs from anticoagulants, diabetes agents (insulin and sulfonylureas) and opioids Describe preliminary clinical quality measures (CQMs) on ADEs from high priority medications Identify areas of high performance and areas for potential improvement from CQM audit and feedback reports Provide recommendations for gathering input from patient advisors and primary care practice teams (providers and clinical staff) on implementation of safety strategies to decrease ADEs Provide recommendations for planning and implementing practice-based safety 		



improvement interventions, including but not limited to report registries to identify patients at risk for ADEs and design outreach/case management, medication reconciliation, medication safety-focused patient and staff education/reminders, electronic health record decision support tools, refill and other practice policies to support safe medication use and monitoring

- Provide recommendations regarding guidelines for Medicare reimbursement.
- Provide recommendations to maximize office efficiency and guideline adherence to the prevention of adverse drug events.
- Provide an overview of newly available treatments, including efficacy, safety, contraindications, and cost/benefit relative to existing treatments.
- Provide instructions regarding the incorporation and use of the PCMH/ACO/Primary Care Core Measure Set into practice.

Needs Assessment

*Note – the focus of this education is on the prevention of adverse drug events in hospitals

Primary care is increasingly responsible for the care of patients with long-term, multi-morbid conditions; however, polypharmacy increases the danger of adverse drug reactions.^{1,2} Many new drugs are introduced every year, and new interactions between medications are increasingly reported.³ Recognizing drug interactions is a frequent challenge for family physicians, and remembering all potential interactions has become virtually impossible. Most pharmacies have drug-interaction software programs with their dispensing package. However, these programs tend to “flag” all interactions, making it difficult for the pharmacist to interpret clinical significance. As a result, the pharmacist generally consults with the prescribing physician.⁴ An adverse drug event (ADE) is defined as harm experienced by a patient as a result of exposure to a medication, and ADEs account for nearly 700,000 emergency department visits and 100,000 hospitalizations each year. ADEs affect nearly 5% of hospitalized patients, making them one of the most common types of inpatient errors; ambulatory patients may experience ADEs at even higher rates. Transitions in care are also a well-documented source of preventable harm related to medications.⁵

ADEs make up the single largest category of adverse events experienced by hospitalized patients, accounting for nearly 19% of all injuries.⁶ Between 2004 and 2008, there was a 52 percent increase in the number of ADEs reported in U.S. hospitals. Adverse drug events increase the risk of death, the length of hospitalization, and the cost of care.⁷ The Office of Disease Prevention and Health Promotion (ODPHD) summarizes the magnitude of the problem as:⁸

- In inpatient settings, ADEs:
 - Account for an estimated 1 in 3 of all hospital adverse events
 - Affect about 2 million hospital stays each year
 - Prolong hospital stays by 1.7 to 4.6 days
- In outpatient settings, ADEs account annually for:
 - Over 3.5 million physician office visits
 - An estimated 1 million emergency department visits
 - Approximately 125,000 hospital admissions



Highlights from the 2008 *Medication-Related Adverse Outcomes in U.S. Hospitals and Emergency Departments* Statistical Brief #109:⁹

- 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 5.6 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.

Deaths from drug overdose have been rising steadily over the last two decades in the U.S., with nearly 9 out of 1 poisoning deaths caused by drugs.¹⁰ Medication errors are common among patients who are being treated for multiple chronic conditions.^{11,12} Medication errors are also common among pediatric patients, who are at higher risk of experiencing medication errors than adults because of the need for a dose calculation based on a patient's age, weight (mg/kg), body surface area (mg/m²), and clinical condition.^{13,14} Adverse effects from drug interactions affect patients of all ages, and in both ambulatory and hospital settings.

Unintentional poisoning killed 838 U.S. children in 2010; and in 2011, U.S. poison centers received more than 1.4 million calls involving poison exposures for children 19 and younger, with nearly 80 percent of these calls involving children under 6, and roughly half of them involved exposures to medications.¹⁵ Prescribing, dispensing, administering, or monitoring medication errors are among the most common types of medical errors for pediatric patients.^{13,16} In fact, the American Academy of Pediatrics (AAP) suggests that parents' use of nonstandard measurement instruments (i.e. nonstandard kitchen spoon use) significantly contributes to medication dosing errors.¹⁷

Among older Americans, aged 60 and over, more than 76% used two or more prescription drugs and 37% used five or more.¹⁸ The risk of adverse drug events is considerable in older patients, leading to one in six hospital admissions because of an adverse drug event.¹⁹ In fact, polypharmacy has been shown to increase a patient's risk for falls and postoperative hip fracture,



precipitate confusion, and incontinence.²⁰⁻²² Polypharmacy associated with multi-morbidity is burdensome for patients, likely leads to a reduction of overall drug benefit, and is an additive effect of harms and side effects.²³ Older adults are often negatively impacted by polypharmacy and are at greater risk for adverse drug events due to metabolic changes, drug-drug interactions, prescribing cascades, and are at greater risk for hip fractures.^{19,24} Unintentional weight loss in older adults may also be due to medication use as polypharmacy can interfere with taste or cause nausea.²⁵

Data from a recent American Academy of Family Physicians (AAFP) CME Needs Assessment survey indicate that family physicians have statistically significant and meaningful gaps in the medical skill necessary to provide optimal management polypharmacy and medication interactions.²⁶ CME outcomes data from 2015 AAFP FMX *Polypharmacy in the Elderly* sessions suggest that physicians have knowledge and practice gaps with regard to consistent communication with patients about the medications they are currently taking; systematically performing medication audits; and communication with other members of the health care team regarding medications.²⁷

Physicians should also be aware of the recent literature regarding drug interactions, and adverse reactions and warnings. Including, but not limited to:

- Pregnancy risk with progestin-releasing implants in HIV-infected women using efavirenz^{28,29}
- Oritavancin interference with coagulation tests³⁰
- Morphine interference with antiplatelet effect of P2Y12 receptor blockers in patients with acute MI³¹⁻³³
- Canagliflozin (Invokana, Invokamet) and Dapagliflozin (Farxiga, Xigduo XR): Drug Safety Communication - Strengthened Kidney Warnings Revised warnings in the drug labels to include information about acute kidney injury and added recommendations to minimize this risk. Posted 06/14/2016³⁴
- Zecuity (sumatriptan) Migraine Patch: Drug Safety Communication - FDA Evaluating Risk of Burns and Scars UPDATED 06/13/2016: Health care professionals should discontinue prescribing Zecuity, and patients should stop using any remaining patches and contact their prescribers for an alternative migraine medicine. Originally posted 06/02/2016³⁴
- May 2016 Drug Safety Labeling Changes includes 86 products with revisions to Prescribing Information. Posted 06/10/2016³⁴
- Nature Made (Various Products) by Pharmavite LLC: Recall - Possible Health Risk Salmonella can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Posted 06/08/2016³⁴

Physicians should consider the National Action Plan for ADE Prevention from the Office of Disease Prevention and Health Promotion (ODPHP), on behalf of the Federal Interagency Steering Committee for Adverse Drug Events.⁸

The ADE Action Plan addresses a defined group of ADEs that are considered to be common, clinically significant, preventable, and measurable; resulting from high-priority drug classes; and occurring largely in high-risk populations.



Three key drug classes identified as initial targets for the ADE Action Plan include:

1. **Anticoagulants** (primary ADE of concern: bleeding)
2. **Diabetes agents** (primary ADE of concern: hypoglycemia)
3. **Opioids** (primary ADE of concern: accidental overdoses, over-sedation, respiratory depression)

To align the efforts of federal health agencies to reduce patient harms from these specific ADEs nationally, the ADE Action Plan identifies a four-pronged approach:

- **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.

The American Academy of Family Physicians Academy has participated in the Core Measures Collaborative (the Collaborative) convened by America's Health Insurance Plans (AHIP) since August 2014. The Collaborative is a multi-stakeholder effort working to define core measure sets of various specialties promoting alignment and harmonization of measure use and collection across both public and private payers.

Participants in the Collaborative included Centers for Medicare and Medicaid Services (CMS), the National Quality Forum (NQF), private payers, provider organizations, employers, and patient and consumer groups. This effort exists to decrease physician burden by reducing variability in measure selection, specifications and implementation— making quality measurement more useful and meaningful for consumers, employers, as well as public and private clinicians.

With significant AAFP input, a PCMH/ACO/Primary Care Core Measure Set has been developed for primary care. The goal of this set is to decrease burden and allow for more congruence between payer reporting programs.³⁵

Resources: Evidence-Based Practice Recommendations/Guidelines/Performance Measures

- National Action Plan for Adverse Drug Event Prevention⁸
- Reducing the risk of adverse drug events in older adults¹⁹
- Using medications appropriately in older adults²²
- American Geriatric Society: Care of Older Adults with Multi-morbidity²³
- American Geriatric Society: updated BEERS criteria³⁶
- Minimizing adverse drug events in older patients²⁴
- Appropriate use of polypharmacy for older patients³⁷
- Engaging Patients in Collaborative Care Plans³⁸
- Medication adherence: we didn't ask and they didn't tell¹¹
- FamilyDoctor.org - Seniors: Managing Your Medications (patient resource)³⁹
- Caregiver Resource – FCA: Caregivers' Guide to Medications and Aging⁴⁰



- FamilyDoctor.org. Caregiving: Caring for an Elderly Relative - Managing Medicines (patient resource)⁴¹
- FamilyDoctor.org: Poisoning (patient education)⁴²

References

1. Hasler S, Senn O, Rosemann T, Neuner-Jehle S. Effect of a patient-centered drug review on polypharmacy in primary care patients: study protocol for a cluster-randomized controlled trial. *Trials*. 2015;16:380.
2. Panagioti M, Stokes J, Esmail A, et al. Multimorbidity and Patient Safety Incidents in Primary Care: A Systematic Review and Meta-Analysis. *PloS one*. 2015;10(8):e0135947.
3. Ansari JA. Drug Interaction and Pharmacist. *Journal of young pharmacists : JYP*. Jul-Sep 2010;2(3):326-331.
4. Ament PW, Bertolino JG, Liszewski JL. Clinically significant drug interactions. *American family physician*. Mar 15 2000;61(6):1745-1754.
5. Agency for Healthcare Research and Quality (AHRQ). Medication Errors. *Patient Safety Primer* 2015; <https://psnet.ahrq.gov/primers/primer/23/medication-errors>. Accessed June, 2016.
6. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *The New England journal of medicine*. Feb 7 1991;324(6):377-384.
7. Weiss AJ, Elixhauser A, Bae J, Encinosa W. Origin of adverse drug events in US hospitals, 2011. 2013.
8. The Office of Disease Prevention and Health Promotion (ODPHP). National Action Plan for ADE Prevention. 2014; <http://health.gov/hcq/ade-action-plan.asp>. Accessed June, 2016.
9. Lucado J, Paez K, Elixhauser A. Medication-related adverse outcomes in US hospitals and emergency departments, 2008. 2011.
10. Centers for Disease Control and Prevention. Prescription Drug Overdose. 2014; <http://www.cdc.gov/homeandrecreationalafety/overdose/>. Accessed July, 2014.
11. Brown M, Sinsky CA. Medication adherence: we didn't ask and they didn't tell. *Family practice management*. Mar-Apr 2013;20(2):25-30.
12. Koper D, Kamenski G, Flamm M, Bohmdorfer B, Sonnichsen A. Frequency of medication errors in primary care patients with polypharmacy. *Family practice*. Jun 2013;30(3):313-319.
13. Aseeri MA. The impact of a pediatric antibiotic standard dosing table on dosing errors. *The journal of pediatric pharmacology and therapeutics : JPPT : the official journal of PPAG*. Jul 2013;18(3):220-226.
14. National Safety Council. Poisoning. 2014; http://www.nsc.org/safety_home/HomeandRecreationalSafety/Poisoning/Pages/Poisoning.aspx. Accessed July, 2014.



15. Centers for Disease Control and Prevention. A National Action Plan for Child Injury Prevention: Reducing Poisoning Injuries in Children. 2013; <http://www.cdc.gov/safekid/nap/overviews/poison.html>. Accessed July, 2014.
16. McPhillips H SC, Smith D, et al.,. Methodological Challenges in Describing Medication Dosing Errors in Children. In: Henriksen K BJ, Marks ES, et al., , ed. Vol 2. Rockville MD: Agency for Healthcare Research and Quality; 2005. Accessed July 2014.
17. Yin HS, Dreyer BP, Ugboaja DC, et al. Unit of Measurement Used and Parent Medication Dosing Errors. *Pediatrics*. 2014. Accessed July 15, 2014.
18. Centers for Disease Control and Prevention. NCHS Data Brief: Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007-2008. 2010; <http://www.cdc.gov/nchs/data/databriefs/db42.htm>. Accessed July, 2013.
19. Pretorius RW, Gataric G, Swedlund SK, Miller JR. Reducing the risk of adverse drug events in older adults. *American family physician*. Mar 1 2013;87(5):331-336.
20. Ziere G, Dieleman JP, Hofman A, Pols HA, van der Cammen TJ, Stricker BH. Polypharmacy and falls in the middle age and elderly population. *British journal of clinical pharmacology*. Feb 2006;61(2):218-223.
21. Lai SW, Liao KF, Liao CC, Muo CH, Liu CS, Sung FC. Polypharmacy correlates with increased risk for hip fracture in the elderly: a population-based study. *Medicine*. Sep 2010;89(5):295-299.
22. Willlams CM. Using medications appropriately in older adults. *American family physician*. Nov 15 2002;66(10):1917-1924.
23. American Geriatrics Society, Expert Panel on the Care of Older Adults with Multimorbidity. Guiding principles for the care of older adults with multimorbidity: an approach for clinicians. 2012; <http://www.guideline.gov/content.aspx?id=39322&search=polypharmacy>. Accessed 7/17/2013.
24. Pham CB, Dickman RL. Minimizing adverse drug events in older patients. *American family physician*. Dec 15 2007;76(12):1837-1844.
25. Gaddey HL, Holder K. Unintentional weight loss in older adults. *American family physician*. May 1 2014;89(9):718-722.
26. AAFP. 2012 CME Needs Assessment: Clinical Topics. American Academy of Family Physicians; 2012.
27. American Academy of Family Physicians (AAFP). AAFP FMX CME Outcomes Report. Leawood KS: AAFP; 2015.
28. Scarsi KK, Darin KM, Nakalema S, et al. Unintended Pregnancies Observed With Combined Use of the Levonorgestrel Contraceptive Implant and Efavirenz-based Antiretroviral Therapy: A Three-Arm Pharmacokinetic Evaluation Over 48 Weeks. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. Mar 15 2016;62(6):675-682.
29. Patel RC, Onono M, Gandhi M, et al. Pregnancy rates in HIV-positive women using contraceptives and efavirenz-based or nevirapine-based antiretroviral therapy in Kenya: a retrospective cohort study. *The lancet. HIV*. Nov 2015;2(11):e474-482.
30. U.S. Food and Drug Administration. ORBACTIV (oritavancin) for injection, for intravenous use. *FDA package insert* 2016; http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206334s002lbl.pdf. Accessed June, 2016.



31. Kubica J, Adamski P, Ostrowska M, et al. Morphine delays and attenuates ticagrelor exposure and action in patients with myocardial infarction: the randomized, double-blind, placebo-controlled IMPRESSION trial. *European heart journal*. Jan 14 2016;37(3):245-252.
32. Hobl EL, Stimpfl T, Ebner J, et al. Morphine decreases clopidogrel concentrations and effects: a randomized, double-blind, placebo-controlled trial. *Journal of the American College of Cardiology*. Feb 25 2014;63(7):630-635.
33. Parodi G, Valenti R, Bellandi B, et al. Comparison of prasugrel and ticagrelor loading doses in ST-segment elevation myocardial infarction patients: RAPID (Rapid Activity of Platelet Inhibitor Drugs) primary PCI study. *Journal of the American College of Cardiology*. Apr 16 2013;61(15):1601-1606.
34. U.S. Food and Drug Administration (FDA). MedWatch: The FDA Safety Information and Adverse Event Reporting Program. 2012; <http://www.fda.gov/Safety/MedWatch/default.htm>. Accessed August, 2012.
35. American Academy of Family Physicians (AAFP). PCMH/ACO/Primary Care Core Measure Set. 2016; <http://www.aafp.org/practice-management/improvement/measures.html>. Accessed May, 2016.
36. By the American Geriatrics Society Beers Criteria Update Expert P. American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc*. Nov 2015;63(11):2227-2246.
37. Hitzeman N, Belsky K. Appropriate use of polypharmacy for older patients. *American family physician*. Apr 1 2013;87(7):483-484.
38. Mauksch L, Safford B. Engaging Patients in Collaborative Care Plans. *Family practice management*. 2013;20(3):35-39.
39. FamilyDoctor.org. Seniors: Managing Your Medications. 2013; <http://familydoctor.org/familydoctor/en/seniors.html>. Accessed July, 2013.
40. Family Caregiver Alliance. Caregivers' Guide to Medications and Aging. 2013; http://www.caregiver.org/caregiver/jsp/content_node.jsp?nodeid=1104. Accessed July, 2013.
41. FamilyDoctor.org. Caregiving: Caring for an Elderly Relative - Managing Medicines. 2012; <http://familydoctor.org/familydoctor/en/seniors/caring-for-an-elderly-relative/managing-medicines.html>. Accessed August, 2013.
42. FamilyDoctor.org. Poisoning. 2009; <http://familydoctor.org/familydoctor/en/prevention-wellness/staying-healthy/first-aid/poisoning.html>. Accessed July, 2014.