Ambulatory Medication Safety Matters

Susan Paparella MSN, RN
Vice President
Institute for Safe Medication Practices (ISMP)
spaparella@ismp.org
Objectives

• Understand the national landscape of medication and vaccine errors in ambulatory settings

• Describe high-alert medication-related events in ambulatory practice sites and related recommendations for prevention

• Describe vaccine-related events in ambulatory practice sites and related recommendations for prevention
Disclosure

• Susan Paparella declares no conflicts of interest, real or apparent and no financial interests in any company, product, or service mentioned in this program.
True or False

The incidence of adverse drug events in ambulatory care is more frequent than in inpatient care:

A  True
B  False
Ambulatory Medication Errors

• Ghandi, et al.- review of 1,200 outpatient prescriptions, patient interviews, along with chart review to determine the rates types, severity, and preventability of adverse events¹

• 25% had an adverse event
• 13% serious
• Serotonin reuptake inhibitors, beta blockers, ACE inhibitors, NSAIDS
• 20% preventable
Incidence of ADEs in Ambulatory Care

Adverse Drug Events in U.S. Adult Ambulatory Medical Care

Urmimala Sarkar, M.D., M.P.H., Andrea López, B.S., Judith H Maselli, M.S.P.H., and Ralph Gonzales, M.D., M.S.P.H.

Author information ▶ Copyright and License information ▶
Emergency Hospitalizations for Adverse Drug Events in Older Americans


ESTIMATED 99,628 EMERGENCY HOSPITALIZATIONS A YEAR FOR ADVERSE DRUG EVENTS IN US FOR ADULTS 65 AND OLDER

• 48% 80 YEARS OR OLDER
• 65% UNINTENTIONAL OVERDOSE
• Medications Implicated: (alone or in combination)

  • Warfarin
  • insulins
  • oral antiplatelet agents
  • oral hypoglycemic agents

© 2018 ISMP
Pediatric Patients are Vulnerable

• 70% of pediatric care takes place in ambulatory settings
• 17.5 % of errors occur in patients under 14 years of age
  – 5% result in hospital admission

• Unique risks include:
  – Weight-based dose calculation
  – Drug dilution before dosing and administration
  – Inability for children to articulate if experiencing adverse events
What key system issues found commonly in a variety of ambulatory care locations can increase the risk for medication errors?
Key Elements of the Medication Use System™

- Patient Information
- Drug Information
- Communication of Drug Information
- Labeling, Packaging, and Nomenclature
- Drug Storage, Stock, Standardization, and Distribution
- Device Acquisition and Use
- Environmental Factors
- Patient Education
- Staff Competency and Education
- Quality Processes and Risk Management
Key System Issues Impacting Medication Safety in Ambulatory Care

• No designated/planned oversight for medication use
  – Pharmacy is not involved; consulted
• Lack IT infrastructure, integration, or ongoing support
• Inadequate, nonstandard policies development/oversight related to medication use
  – Nonstandard patient identification processes
  – Nonstandard procedures for monitoring and follow up
• Nonstandard communication of drug information
Key System Issues Impacting Medication Safety in Ambulatory Care

• Outdated devices/limited oversight for devices
• Medication preparation and administration by non-licensed individuals
• Lack of knowledge/competency evaluation of staff involved in medication use
• Unspecified security practices for controlled substances; limited oversight for safe practice
  – Anesthesia work rooms propped open
  – Narcotics unlocked, no regular accounting for controlled substances and prescription blanks
Key System Issues Impacting Medication Safety in Ambulatory Care

• Nonstandard (and possibly unsafe) injection practices
• Lack of policies and historical practices for error reporting
• Unsafe storage practices
• Altered perception of risk
Case Report: Ambulatory Surgical Care

• Teenage opioid-naïve patient – tonsillectomy in hospital-based outpatient surgical center
• Surgeon reported to patient’s family the patient “did well” after surgery
• One hour later patient died from respiratory depression from fentanyl in recovery room
• Patient not monitored for over 25 min
• Causative factors:
  – PACU nurse taking care of another patient at the time
  – Anesthesia administered a dose without a handoff
  – Patient not identified as opioid-naïve
  – Alarm fatigue – nurses muted all monitor alarms

© 2018 ISMP
Chemotherapy Surprise?
Drug Labeling
Best Practice?


Matthew Grissinger, RPh, FISMP, FASCP
Senior Patient Safety Analyst

Rabih Dabiz, PharmD, FISMP
Patient Safety Analyst

Pennsylvania Patient Safety Authority
PA Ambulatory Surgical Facility (ASF) Errors: June 2004- December 2010

• 502 medication error reports
• 91% of the events reached the patient
• 3.6% harm index = E to I
• 40.2% involved the elderly
• 11% of reports involved the pediatric population
  – More than double the percentage of pediatric patients treated in ASFs

© 2018 ISMP
PA-ASF Omission Errors

- Antibiotics (53.7%, $n = 72$)
  - preoperative stage (60.4%)
  - postoperative stage (17.9%)
- ceFAZolin the most commonly omitted within that class (70% of all antibiotics, $n = 35$)
- Benzodiazepines (6%, $n = 8$)
  - Midazolam accounting for the majority of the omitted benzodiazepines$^5$
Strategies to Avoid Antibiotic Omissions

- Use of prompts in the perioperative EHR/CPOE regarding prophylactic antibiotics
- Preoperative standing order forms for select surgical diagnoses
- A routine process to screen preoperative antibiotic orders according to national guidelines and immediately notifying physicians of problems
- Change the preoperative processes for antibiotic administration
  – Administration begun at time of handoff to anesthesia
Strategies to Reduce Risk with ASF Errors

- Establish best practice protocols and expectations for communication of patient and drug information
- Involve pharmacy in drug storage oversight
- Implement bedside bar-code scanning for drug and patient ID
- Label all prepared syringes
- Standardization of handoffs
- Establish a Quality/Safety Team
Ambulatory Clinics
Medication Safety Challenges

• Lack of pharmacy oversight
• Clinic leadership may not have a clinical background
• Lack of an integrated EHR with other systems
• Non-standard patient identification practices
• Storage issues
• Management of samples
Ambulatory Clinics
Medication Safety Challenges

• Medications may not be prepared or administered by nurses
  – No competency validations; no formal education
• Transitions of care; coordination of care
  – Challenges with medication reconciliation
• E-prescribing
• High volume; rapid patient turnover
• Procedural-based concerns
  – Moderate sedation
  – Failure to rescue
What at-risk behaviors are common in ambulatory practice that can seriously impact medication safety?
At-Risk Behaviors

- Working outside scope of practice
- Using unlabeled syringes
- Excessive use of verbal orders
- Administering medications without an order
- Managing unfamiliar medications
- Compounding products outside of a sterile field with BUD for longer than immediate use
- Incomplete documentation
- Nonstandard handoffs
- Unsafe injection practices
Las Vegas Outbreak - 2008

- Cluster of 3 acute HCV infections identified in Las Vegas
- All 3 patients underwent procedures at the same endoscopy clinic during the incubation period\(^6\)
And the Risk Continues- 2018

About 160 syringes reused at Minn. clinic; nurse practitioner fired

By S. M. Chavey / St. Paul Pioneer Press on Mar 5, 2018 at 6:43 pm

Is there a lack of practitioner knowledge regarding safe injection practices?
Which of the following is an unsafe injection practice?

A. Reuse of a syringe on more than one patient after changing the needle
B. Reuse of a single dose vial on more than one patient
C. Reuse of an insulin pen on more than one patient after applying a needle
Unsafe Injection Practices Also Include…

• Using a multiple dose vial on more than one patient
• Using the same tubing, or same syringe, on multiple patients after changing the needle
• Using a large volume IV bag as a common source for preparing IV flushes
High-cost, but Single Use Only
Prefilled 0.9% sodium chloride syringes are not for preparation/compounding

www.ismp.org/guidelines/iv-push
Vaccine administration errors (VAEs) are preventable events that could lead to reduced vaccine effectiveness or adverse patient outcomes, mainly patients who are unprotected.

Existing data on vaccine-related errors (VAERS- FDA and CDC) lacks sufficient detail.

Identifying trends could result in targeted efforts to prevent errors, including changes to product labeling, name, or design that contribute to errors.
2017 ISMP VERP Reports

Facilities

- Medical Clinic (outpatient): 211
- Physician Practice: 177
- Public Health Immunization Clinic: 76
- Other: 41
- Hospital (ambulatory): 36
- Hospital (inpatient): 17
- Community Pharmacy: 13
- Military Locations: 3
- Pharmacy-based Health Clinic: 1
2017 ISMP VERP Reports

Practitioners

- Medical Assistant: 310
- Registered Nurse (RN): 114
- LVN/LPN: 80
- Pharmacist: 19
- Physician: 19
- Nurse Practitioner: 14
- Other: 11
- Physician Assistant: 6
- Student (e.g., medicine, nursing, pharmacy): 2
Vaccine Error Types

- Wrong vaccine: 130
- Wrong age: 95
- Contaminated or deteriorated vaccine: 55
- Expired vaccine: 53
- Extra dose: 50
- Wrong timing/interval: 47
- Event type not listed: 45
- Wrong dose - over dosage: 37
- Wrong dose - under dosage: 20
- Wrong route of administration: 13
- Vaccine/component omission - One component given: 13
- Vaccine/component omission - Diluent given: 10
- Wrong patient: 5
- Wrong administration site: 2
What is the most common vaccine involved in error in the ambulatory care setting?

- **A** Diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV)
- **B** Influenza (IIV3, IIV4, RIV3, ccIIV3, or LAIV4)
- **C** Hepatitis B (HepB)
- **D** MMR-V
### Frequent Vaccine Error Types and Contributing Factors

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>% of All Reports</th>
<th>Top Contributing Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Influenza Virus</strong>&lt;br&gt;Trivalent, Types A and B</td>
<td>16</td>
<td>Age-dependent formulation of same vaccine (19%)&lt;br&gt;Not familiar with dosing of the product (7%)&lt;br&gt;Patient age not verified before administration (6%)</td>
</tr>
<tr>
<td><strong>DTaP-IPV</strong>&lt;br&gt;Diphtheria and Tetanus Toxoids, Acellular Pertussis Adsorbed, and Inactivated Poliovirus</td>
<td>13</td>
<td>Not familiar with indicated ages for product (32%)&lt;br&gt;Age-dependent formulation of same vaccine (17%)&lt;br&gt;Patient age not verified before administration (4%)</td>
</tr>
<tr>
<td><strong>HepA</strong>&lt;br&gt;Hepatitis A, Inactivated</td>
<td>12</td>
<td>Age-dependent formulation of same vaccine (40%)&lt;br&gt;Not familiar with dosing of the product (31%)&lt;br&gt;Patient chart not checked prior to administration (6%)</td>
</tr>
<tr>
<td><strong>Tdап</strong>&lt;br&gt;Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Adsorbed</td>
<td>10</td>
<td>Similar vaccine abbreviations (18%)&lt;br&gt;Not familiar with product(s) (8%)&lt;br&gt;Similar generic names (8%)</td>
</tr>
<tr>
<td><strong>HPV4</strong>&lt;br&gt;Human Papillomavirus (Types 6, 11, 16, 18), Recombinant</td>
<td>8</td>
<td>Stored at temperature greater than recommended (17%)&lt;br&gt;Stored at temperature lower than recommended (13%)&lt;br&gt;Not familiar with product(s) (11%)</td>
</tr>
</tbody>
</table>
Name or Abbreviation Confusion

- Pneumovax 23/Prevanar 13 and Fluzone high-dose / Fluzone Quadrivalent
- DTaP-Tdap
- Adacel (Tdap) - Daptacel (DTaP)
- Kinrix (DTaP/Polio) – Pediarix (DTaP/Polio/hepatitis B)
- Hep B – Hib
- HPV - “HBV”
- Varicella virus vaccine – varicella zoster immune globulin (VZIG)
- Varivax – Zostavax
Types of Vaccine Errors\textsuperscript{10}

- Mistakes in choosing age-specific formulations of vaccines intended to prevent the same diseases
- Unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and a vaccine’s components (e.g., combination vaccines; diluent and powder)
- Failure to check or verify the vaccination schedule and the patient’s age, health record, or state immunization information system to avoid invalid doses administered too soon, or missed opportunities to vaccinate
Packaging Issues: Only one component of two components administered

Menveo container labels identical
Bar codes identical
Packaging Issue – RotaTeq vs. Rotarix

- Rotarix injected instead of given orally

Which one is oral?

Rotarix between other vaccines that ARE injectables
Look-alike Packaging and Labeling
15 Syrian children die after measles vaccinations

BEIRUT – At least 15 children died after receiving vaccinations in rebel-held parts of northwestern Syria, while the death toll from two days of government airstrikes on a central city climbed to nearly 50, a heavy toll even by the vicious standards of the country’s civil war, activists said.

The children, some just babies, all exhibited signs of “severe allergic shock” about an hour after they were given a second round of measles vaccinations in Idlib province on Tuesday, with many suffocating to death as their bodies swelled, said Dr. Abdullah Ajjal, who administered the vaccinations in a medical center in the town of Jarjanaz.
What safety strategies are effective for reducing the risk of vaccine errors in ambulatory clinic settings?
Strategies to Address Errors with Vaccines

- Make Immunization Schedules Available
- Provide VIS Before Vaccination
- Establish Protocols
- Educate Staff
- Maintain Cold Storage
- Separate Vaccines
- Avoid Storing Pre-drawn Syringes
- Use Full Names or Standard Abbreviations

- Label All Prepared Syringes
- Keep Vaccines with Diluents
- Discard Cartons
- Purchase Oral Vaccine in Safest Packaging
- Involve Patient/ Parent/ Caregiver in Verification
Defined Process for Administering Vaccines
Key Takeaways

• Risk associated with medication use is high in ambulatory care sites, but can be reduced:
  – Design safe systems for high-alert medications
  – Coach at-risk behaviors
• Evidence-based practices; set expectations
• Unsafe injection practices put patients at risk
• Oversight is key!
• Vaccine errors are more common than once recognized
  – Steps should be taken to reduce all error types
  – Report all vaccine errors
• Involve patients and families in care
• Give same level of safety attention to vaccine safety
Thank you for making ambulatory medication safety a practice priority! Questions?
References

8. Centers for Disease Control and Prevention One and Only Campaign. Available at: http://www.oneandonlycampaign.org
10. ISMP Vaccine Error Reporting Program 2018