The Military Health System's

PARTNERSHIP FOR PATIENTS CAMPAIGN

SAFE CARE SAVES LIVES

Sustainment Guide for Adverse Drug Events

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PARTNERSHIP FOR PATIENTS℠

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Contents

1 Introduction

The official National Partnership for Patients Program ended December 31, 2013. The lessons learned through the Military Health System (MHS) Adverse Drug Event (ADE) implementation process have led to the development of an improved Sustainment Guide. This sustainment guide includes the elimination of monitoring the therapeutic class of Sedatives, implementing processes to improve the integrity of data, clarification of definitions, and tracking data metrics to include clinically significant, preventable, and measurable harm associated with adverse drug events.

2 Adverse Drug Event (ADE) Prevention Evidence-Based Practices

2.1 ADEs – Background Information

According to the United States Department of Human and Health and Human Services (HHS), an adverse drug event is an injury resulting from the use of a drug. ADEs in hospitals can be caused by medication errors such as accidental overdoses or incorrect drug administration to a patient, or by adverse drug reactions to a normal dose, such as allergic reactions or excessive bleeding after treatment with the intended dose of a drug that prevents dangerous blood clots. For more information, visit: http://www.healthcare.gov/compare/partnership-for-patients/safety/ade.html.

The above is the original definition utilized for Partnership for Patients. Over time it was recognized that not all ADEs, according to this definition, are preventable. In this sustainment guide, preventable and non-preventable harm are differentiated.

An **adverse drug event (ADE)** is defined as "an injury resulting from medical intervention related to a drug." *Source:* Institute of Medicine (IOM).

An **adverse drug reaction (ADR)** is defined as "any response to a drug which is noxious and unintended which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function." *Source:* World Health Organization. Here are specific examples of methodology to distinguish between ADE and ADR:

- An event description of pain at the injection site, hives, itching, pruritus, and/or allergic symptoms with an onset appropriate to provide a reasonable causal relationship will be considered an **ADR.** Events will be considered an **ADE** if the allergy should have been known by the healthcare provider or was documented in the health records prior to ordering/dispensing/administering the drug to the patient. This would be viewed as a preventable harm.

- Breathing difficulties, unless directly associated to an allergic reaction (e.g., wheezing), remain as an **ADE** (reasoning; difficulty breathing or slowed breathing due to excess opioids could be considered preventable).

- Bleeding problems on anticoagulants will be considered an **ADE** since without any additional information; determination cannot be made supporting that these events were not preventable.

- Nausea and/or vomiting associated with oral administration of a narcotic would be considered a preventable **ADE** since concurrent food with oral administration of medications from this therapeutic class of drugs can often prevent nausea and/or vomiting from occurring.

A **Medication Error (ME)** is defined as "any **preventable** event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer." *Source:* National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). Identifying medication errors are important in understanding failure-prone aspects of health care delivery system and designing strategies to mitigate failures (IHI).

Specific examples of Medication Errors (ME) would include:

- A medication that was not prescribed / ordered appropriately.
- An order that was not transmitted appropriately.
- A drug that was not prepared / dispensed correctly.
- A drug that was not administered correctly.
- A drug that was not monitored and adjusted appropriately.

Harm represents clear clinical outcomes: impairment of the physical, emotional, or psychological function or structure of the body or pain and/or injury resulting thereof (IHI). For the purposes of this guide, Harm will be considered in alignment with DoD Harm Scale; Death, Severe Permanent Harm, Permanent Harm, Temporary Harm, or Additional Treatment, for each therapeutic category of focus; Heparin, Warfarin, Narcotics and Insulins.

ADE Burden of Illness

- More than 770,000 people are injured or die each year in hospitals from ADEs
- National hospital expenses to treat patients who suffer ADEs during hospitalization are estimated between $1.56-5.6 billion annually
- Patients who experienced ADEs were hospitalized an average of 8-12 days longer than patients who did not experience ADEs
- Nearly 120,000 patients each year need to be hospitalized for further treatment after emergency room visits for ADEs.
- Hospital inpatients with ADEs were on average 62 years old

Sources:

1. *Reducing and Preventing Adverse Drug Events To Decrease Hospital Costs*. Research in Action, Issue 1. AHRQ Publication Number 01-0020, March 2001. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/qual/aderia/aderia.htm Accessed 8/2/12
2. *Adults and Older Adult Adverse Drug Events.* Medication Safety Program, Program Focus and Activities, May 2011. http://www.cdc.gov/MedicationSafety/Adult_AdverseDrugEvents.html Accessed 8/2/12

ADEs encompass a wide variety of hospital-acquired conditions, and constitute more than 30 percent of Hospital-Acquired Conditions according to a 2010 study conducted by the HHS Office of Inspector General. The PfP estimates that 50 percent of the 1.9 million ADEs that occur in hospitals each year are preventable[1].

2.2 Evidence-Based Practice Guidelines

To reduce the prevalence of ADEs, the Institute for Healthcare Improvement has developed strategies for reducing harm from three high-alert medication categories including anticoagulants, narcotics, and insulins. High-alert medications are medications that are most likely to cause significant harm to the patient, even when used as intended.

[1] *Preventing Adverse Drug Events*, http://www.healthcare.gov/compare/partnership-for-patients/safety/ade.html, accessed 8/2/12

Changes to Improve Management of Heparin

- Consistently use standardized weight-based heparin protocol throughout facility
  - Limit to no more than two protocols
  - Use preprinted order forms or ordering protocols
  - Establish guidelines to hold heparin and provide reversal therapy for heparin over-anticoagulation
  - Ensure protocol address how to evaluate and treat patients with heparin-induced thrombocytopenia (HIT)
  - Ensure heparin dosing protocols account for the use of thrombolytics and GIIb/IIIa inhibitors
  - Ensure heparin is not administered within 6-12 hours of a dose of LMWH
  - Ensure appropriate monitoring parameters are implemented and used reliably
- Implement standardized concentrations of heparin
- Use pre-mixed infusions and ready-to-administer products when available
- Remove high-concentration products from floor stock
- Separate look-alike/sound-alike (LASA) products (names and packaging) when using or storing
- Implement effective independent double checks
- Use smart pumps (if available) with accurate drug libraries to infuse heparin
- Administer boluses from pharmacy prepared syringes or set up smart pump libraries
- Make heparin-flush available only in syringes
- Do not accept heparin orders with unapproved abbreviations (i.e. U for units, etc.)
- Use LMWH when appropriate, instead of heparin
- Use auxiliary labels for high-alert medications consistently throughout the facility

Changes to Improve Management of Warfarin

- Consistently use standardized protocols and dosing
  - Use preprinted order forms or ordering protocols that are prominently labeled by indication (i.e. A. Fib, DVT, etc.)
  - Standardized protocols for the initiation and maintenance of warfarin therapy including, Vitamin K dosing guidelines
  - Develop an evidence-based protocol, to discontinue and restart warfarin preoperatively
  - Develop a evidence-based protocol, to bridge warfarin therapy with more rapidly-acting anticoagulants such as heparin or LMWH
- Use ONLY oral unit-dose products, when these products are available
- Ensure effective implementation of independent double checks
- Minimize available strengths of oral formulations to the essential few
- Ensure efficient access to laboratory results (i.e. available within 2 hrs) and/or use of point-of-care testing at the bedside
- Include a nutrition consult to avoid drug/food interactions and educate the patient about them
- Create daily CHCS report of patients on warfarin for nutrition education
- Use medication reconciliation to improve handoffs of medication information
- Engage patients by developing educational programs and training at an appropriate literacy level
- Implement system to properly verify inventory stocking in the Automated Dispensing Cabinets
- Utilize auxiliary labels for high-alert medications consistently within the organization

Changes to Improve Management of Narcotics

- Consistently use standardized protocols for initiation and maintenance of pain management
    - Use protocols and pre-printed orders (CPOE order sets) where possible for PCA, postoperative, epidural, and intrathecal pain management
    - Include dose calculations, maximum bolus doses, prescribed dose, monitoring guidelines, and options for non-opioid analgesics
    - Establish standard naloxone regime which can be given prior to contacting physician, based on a protocol signed by a physician
- Standardize monitoring protocols including documentation of vital signs and pain score following each dose
- Use appropriate monitoring for adverse effects of narcotics and opiates
- Minimize multiple drug strengths
- Implement standard concentrations of narcotics/opiates
- Establish formulas for narcotic dose-equivalences
- Widely circulate formulas for narcotic dose-equivalences to all staff
- Prepare narcotic/opiate infusions in the pharmacy ONLY
- Use smart pumps with accurate drug libraries
- Label distal end of all access lines to distinguish IV from EPIDURAL
- Use tubing without injection ports for EPIDURAL
- Standardize to single drug as opiate of choice for PCA or use dose equivalencies for multiple drug choices
- Consult a pain specialist if physician are not knowledgeable about pain control
- Increase use of non-pharmacologic intervention for pain and anxiety
- Educate patient/family about PCA use before surgical procedure
- Dose narcotics to a pain score mutually agreed upon by patient & provider prior to procedure
- Use medication reconciliation to improve handoffs of medication information
- Educate patients regarding hypotension and dizziness upon rising
- Anticipate and schedule toileting for high-risk patients

  Utilize auxiliary labels for high-alert medications consistently within the organization

Changes to Improve Management of Insulin

- Consistently use standardized pre-printed diabetic and insulin infusion orders
- When prescribing insulin, include or refer to defined standards for laboratory testing and clinical monitoring of patients
- Ensure appropriate monitoring through more rapid testing of blood glucose
- Use a diabetic management flow sheet to track blood glucose values, carbohydrate intake and insulin administration
- Eliminate or limit the use of sliding insulin dosage scales; if used standardize it through use of a protocol/preprinted order form or computer order set that clearly designates the specific increments of insulin coverage
- Standardize to a single concentration of IV-infusion insulin
- Prepare all infusions in the pharmacy
- Do not accept insulin orders with unapproved abbreviations (i.e. U for units, trailing zero, etc.)
- Implement different means to separate LASA insulins (i.e. individual bins) and to make them look different or call attention to important information (i.e. auxiliary/colored labels, highlighter, etc.)
- Utilize Tallman lettering to distinguish LASA insulins
- Do not dispense insulin in original container only; label the vial with patient's name and expiration date. Use vial for single patient use ONLY
- Use smart pumps with accurate drug libraries
- Implement effective independent double checks
- Consider patient's usual time for meals and timeframe for insulin administration
- Consider unique delivery devices such as insulin pen with proper safeguards (i.e. dispensed by pharmacy ONLY, label each pen with patient's name, auxiliary label for single patient use, identified authorized staff to administer it, etc.)
- Allow and encourage patient self-management (or parents for young pediatric patients) when patients and parents are capable and willing
- Encourage patients to question doses and timing of insulin administration
- Utilize auxiliary labels for high-alert medications consistently within the organization

2.3 Proven Strategies

Additional strategies cited by the Agency for Healthcare Research and Quality (AHRQ) and the General Accounting Office (GAO) to improve the medication delivery system include:[2,3]

- Improve incident reporting systems (i.e., Patient Safety Reporting System)

[2] *Reducing and Preventing Adverse Drug Events To Decrease Hospital Costs, op cit.*
[3] *Adverse Drug Events: The Magnitude of Health Risk is Uncertain Because of Limited Incidence Data.* Government Accounting Office Report to Congressional Requesters, January 2000. www.gao.gov/new.items/he00021.pdf

- Create a better atmosphere for health care providers to report ADEs so that the person reporting the error does not fear repercussions or punishment
- Rely more on pharmacists to advise providers in prescribing medications and promote education on medications
- Improve nursing medication administration and monitoring systems
- Implement a standardized medication reconciliation form
- Improve communication between providers and patients about risks and benefits of medication
- Dispense drugs from pharmacy in single-unit/single-dose packages
- Install automated dispensing systems
- Barcode hospital medications
- Institute Look-Alike/Sound-Alike alerts
- Include pharmacists in hospital rounds
- Use the FDA's MedWatch program to report serious adverse drug reactions

2.4 MHS Inpatient ADEs Performance Measures

In order to collect and interpret data that documents success in reducing the incidence of ADEs, it is imperative that outcome measures be utilized. The MHS has committed to using the measures listed below. MTFs are expected and encouraged to report facility-wide ADEs and near-misses in the Patient Safety Reporting System.

Description	Data Source	Metric
• Number of clinically significant, preventable, and measurable inpatient ADEs, per calendar year resulting in harm (defined as DoD Harm Scale Categories; Death, Severe Permanent Harm, Permanent Harm, Temporary Harm, or Additional Treatment) for each category (Anticoagulants (only Heparin and Warfarin), Narcotics, and Insulins)	PSR	Outcome Measure

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