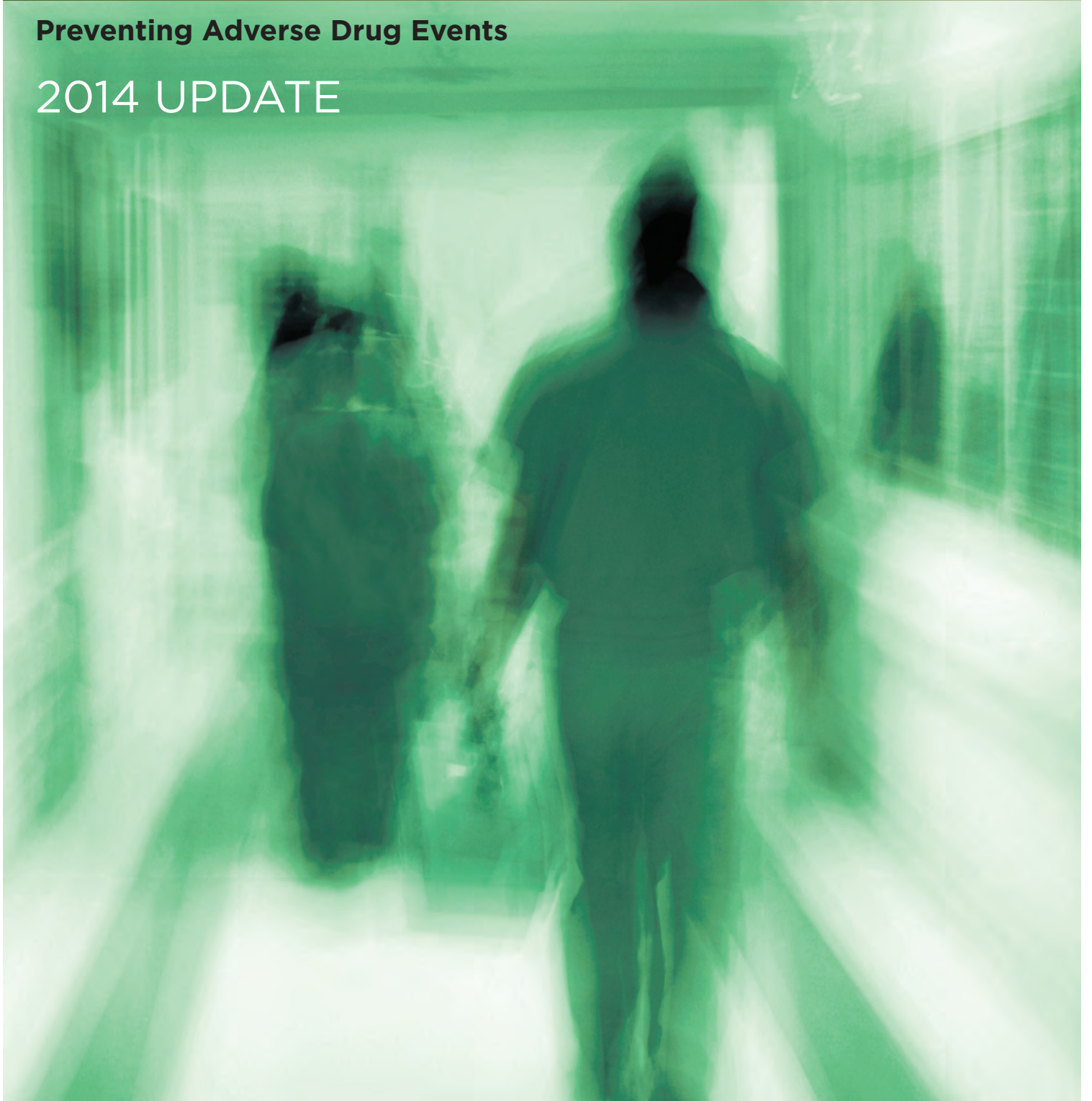


ADVERSE DRUG EVENT (ADE) CHANGE PACKAGE

Preventing Adverse Drug Events

2014 UPDATE



American Hospital
Association



HRET
HEALTH RESEARCH &
EDUCATIONAL TRUST
In Partnership with AHA

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The AHA/HRET HEN would like to acknowledge our partner, Cynosure Health, for their work in developing the Adverse Drug Event (ADE) Change Package.

WHAT'S NEW IN THIS EDITION?

- New detailed drivers, ideas to test and narrative sections on Patient and Family Engagement.
- New, narrower focus on warfarin, opioids, and insulin.
- Incorporates the 2013 ADA standards of diabetes care.
- Provides expanded change ideas, especially regarding opioids.
- Offers addenda with many tools for preventing ADEs with warfarin, opioid, and insulin use.
- Updated references.

OVERVIEW: ADVERSE DRUG EVENTS (ADE'S)

Preventing Harm from High-Alert Medications

Sample AIM and Measurement

Background

- Adverse events in hospitalized patients are most commonly associated with frequent interventions such as the prescription and administration of medications. At least 20% of all harm to hospitalized patients is associated with medication errors.
- High-alert medications (HAMs) are more likely to be associated with harm than other medications – they cause harm more frequently, the harm they produce is likely to be more serious, and they “have the highest risk of causing injury even when used correctly.”
- Anticoagulants, opioids, and insulin are responsible for the majority of harm due to High-Alert Medications.
- Warfarin is the most commonly prescribed anticoagulant.

Suggested AIM

Reduce the incidence of harm due to warfarin, opioids, and insulin by 40% by December 8, 2014.

Outcome Measures: (New Measures in Italics!)

All ADEs

Indicator Name: All Adverse Drug Events per 1,000 Patient Days (ADE-112)

Numerator: Number of Adverse Drug Events.

Denominator: Number of Patient Days.

Source: Intermountain HEN.

Indicator Name: Days Since Last ADE (New Measure) (Rural CAH Data Collection Tool)

Numerator: Days since last ADE.

Denominator: N/A

Anticoagulants

Indicator Name: Excessive Anticoagulation with Warfarin – Inpatients (ADE-12)

Numerator: All patients experiencing excessive anticoagulation with warfarin (“excessive” is organization-defined).

Denominator: Inpatients receiving warfarin anticoagulation therapy.

Insulin

Indicator Name: Hypoglycemia in Inpatients Receiving Insulin (ADE-13)

Numerator: Hypoglycemia in inpatients receiving insulin or other hypoglycemic agents (e.g. hypoglycemia defined as plasma glucose concentration of 50 mg per dl or less).

Denominator: Inpatients receiving insulin or other hypoglycemic agent.

Opioids

Indicator Name: ADE's due to Opioids (ADE-11)

Numerator: Number of patients treated with opioids who received naloxone during the review period.

Denominator: Number of inpatients and patients in hospital outpatient departments who received an opioid agent during the review period. Exclusion: ED patients; naloxone use for nausea or pruritus.

Suggested Process Measures

Anticoagulants: Percentage (or raw number) of patients on warfarin managed by pharmacy driven protocols. (ADE-123)

Insulin: Percentage (or raw number) of patients on insulin whose blood sugars registered <70 mg/dl at least once. (ADE-124)

Opioids: Percentage of patients receiving opioids who regularly receive a formal assessment (e.g. POSS or RASS) during therapy. (ADE-126)

KEY ELEMENTS IDEAS TO TEST

Patient and Family Engagement

- Provide patient education in a language and at a literacy level all can understand.
- Provide hypoglycemia rescue protocols to patients and families in a manner that they understand; use “teach back” to verify understanding.
- Provide oral concentrated glucose solutions for rescue.
- Ensure that patients and families thoroughly understand and can comply with appointments for follow up INR testing at regular intervals; if unable to do so, work with community resources to arrange transportation, or consider alternate medications.
- Obtain complete lists of all medications, including herbals and over the counter medications, and understand any dietary peculiarities, so that drug-drug and drug-food interactions can be minimized or avoided.
- Educate patients and families regarding potentially lethal layering effects of multiple opioids, or a single opioid with a hypnotic, anxiolytic, muscle relaxant, or alcohol.
- Educate patients and families regarding the potentially lethal effects of failure to dispose of fentanyl patches properly, especially in such a way as to keep them away from children.

Awareness, Readiness, and Education

- Assess organizational capacity, readiness and willingness to implement systems to prevent ADEs.
- Create awareness of ADE harm due to insulin, anticoagulants and opioids.
- Assess staff understanding and knowledge.

Standardized Care Processes

- Implement ISMP quarterly action agendas where appropriate.
- Develop standard order sets using safety principles with physician and pharmacist input.
- Allow nurses to administer rescue drugs based on protocols.
- Minimize interruptions during the process of medication distribution and administration.
- Standardize concentrations and minimize or eliminate multiple drug formulations and concentrations wherever possible.
- Set dosing limits.
- Use standardized sedation-assessment scales.
- Allow pharmacists to change anticoagulant doses per protocol based on timely review of laboratory test results.
- Include a pharmacist in direct clinical activities (e.g. ICU rounds, ambulatory medication decision-making, etc.).

Decision Support

- Include pharmacists on rounds.
- Monitor overlapping multiple medications prescribed for patients.
- Use equianalgesic prompts and defaults (with an MD override option) for opioid-to-opioid transitions.

Prevent Failure

- Minimize or eliminate nurse distraction during the medication administration process.
- Standardize formulation concentrations and minimize dosing choices where feasible.
- Review lab results in a timely manner with effective systems to ensure necessary action.
- Use non-pharmacological methods of pain and anxiety management where appropriate.
- Use sedation-assessment scales to guide dosing in ALL care areas.

Identification and Mitigation of Failure

- Use multiple methods to identify ADEs, analyze findings, and use the analyses to re-design processes to minimize ADEs.
- Reduce staff intimidation and encourage reporting of errors and near-misses.
- Use a blame-free error reporting system to promote aggregate learning and the redesign of error prone processes.
- Use focused audits to identify practice patterns and system failures (e.g. D50 in ICU; naloxone in outpatient and inpatient procedure areas).
- Analyze dispensing unit override patterns.
- Prompt real-time learning from each failure.

Smart Use of Technology

- Use “smart pumps” with up-to-date libraries or double-checks for all IV infusions of high alert medications.
- Understand potential unintended consequences and errors that can occur with Patient Controlled Analgesic devices.
- Use alerts wisely.
- Use data/information from alerts and overrides to redesign standardized orders and protocols.
- Link order sets to recent lab test values and levels.
- Use the proper level of alerts with forcing functions and stops for drug, allergy, and diagnoses interactions.

Key Resources

- Rashidee et al, High-Alert Medications: Error Prevalence and Severity, Patient Safety & Quality Healthcare 2009 July-Aug
- Institute for Safe Medication Practices
- IHI How to Guide Prevent Harm from High Alert Medications
- AHRQ Tools on Medication Reconciliation

ADVERSE DRUG EVENT (HIGH-ALERT MEDICATIONS) DRIVER DIAGRAM 2013-2014

AIM: Reduce the Incidence of Harm from Adverse Drug Events (ADEs) due to High-Alert Medications (HAMs) by 50% by 12/8/14.

FOCUS: Insulin, Anticoagulants, and Opioids.

PRIMARY DRIVER	SECONDARY DRIVER	CHANGE IDEAS
Patient and Family Engagement	<ul style="list-style-type: none"> Recognize the patient and family as key partners in the campaign to reduce ADEs Educate patients and families regarding the risks and benefits of high alert medications. Explore and understand the patient's social situation, especially with regard to access to transportation and food. Educate patients and families regarding the importance of keeping high alert medications secured from small children and other vulnerable individuals. 	<ul style="list-style-type: none"> Provide patient education in a language and at a literacy level all can understand. INSULIN: Provide hypoglycemia rescue protocols to patients and families in a manner that they understand; use "teach back" to verify understanding. INSULIN: Provide oral concentrated glucose solutions for rescue. INSULIN: Allow hospitalized patient to perform self-management of insulin where safe and appropriate. ANTICOAGULANTS: Ensure that patients and families thoroughly understand and can comply with appointments for follow up INR testing at regular intervals; if unable to do so, work with community resources to arrange transportation, or consider alternate medications. ANTICOAGULANTS: Obtain complete lists of all medications, including herbals and over the counter medications, so that drug-drug interactions can be minimized or avoided. ANTICOAGULANTS: Obtain full understanding of any dietary peculiarities to help avoid drug-food interactions. OPIOIDS: Educate patients and families regarding potentially lethal layering effects of multiple opioids, or a single opioid with a hypnotic, anxiolytic, muscle relaxant, or alcohol. OPIOIDS: Educate patients regarding the potentially lethal effects of failure to dispose of fentanyl patches properly, especially in such a way as to keep them away from children.
Awareness, Readiness and Education	<ul style="list-style-type: none"> Assess organizational capacity, readiness and willingness to implement systems to prevent ADEs Create awareness of ADE harm due to insulin, anticoagulants and opioids Assess staff knowledge 	<ul style="list-style-type: none"> Use Institute for Safe Medical Practices assessment tool.¹ Use Opioid Adverse Drug Event Prevention Gap Analysis (Component of the Medication Safety Roadmap, Minnesota Hospital Assn, 2012).² Use Pennsylvania Patient Safety Authority Opioid Knowledge Self-Assessment tool.³
Standardized Care Processes	<ul style="list-style-type: none"> Implement ISMP quarterly action agendas where appropriate⁴ Develop standard order sets using safety principles Allow nurses to administer rescue drugs based on protocol without obtaining physician approval 	<ul style="list-style-type: none"> Review key literature.^{5,6,7,8,9} Analyze local ADE data to guide focus.¹⁰ Use IHI "How to Guides" and "Knowledge Center"¹¹ and ISMP guidelines.¹² INSULIN: Reduce sliding scale variation (or eliminate sliding scales). INSULIN: Coordinate meal and insulin times. INSULIN: Use insulin infusion per ADA recommendations in critically ill patients.¹³ INSULIN: Standardize concentrations. ANTICOAGULANTS: Use protocol to discontinue or restart warfarin peri-operatively. OPIOIDS: Use standard processes to effectively and manage pain.¹⁴ OPIOIDS: Use protocols and tables for equianalgesic transition from one opioid to another. OPIOIDS: Limit dosage strengths available in floor stock/ automated drug cabinets. OPIOIDS: Use standardized sedation assessment scales such as the Pasero Opioid-Induced Sedation Scale (POSS)¹⁵ or the Richmond Agitation Sedation Scale (RASS).¹⁶ OPIOIDS: Develop protocols to manage fentanyl patches to prevent overdose.

ADVERSE DRUG EVENT (HIGH-ALERT MEDICATIONS) DRIVER DIAGRAM 2013-2014 (CONTINUED)

AIM: Reduce the Incidence of Harm from Adverse Drug Events (ADEs) due to High-Alert Medications (HAMs) by 50% by 12/8/14.

FOCUS: Insulin, Anticoagulants, and Opioids.

PRIMARY DRIVER	SECONDARY DRIVER	CHANGE IDEAS
Avoid Errors During Care Transitions	<ul style="list-style-type: none"> Implement effective medication reconciliation processes Implement pharmacist-driven ambulatory clinics for warfarin management 	<ul style="list-style-type: none"> Reconcile all medications at each transition. Use flow sheets that follow the patient through the transitions of care (and that are not unit based, but patient based). INSULIN: Require new insulin orders when patients are transitioned from parenteral to enteral nutrition. ANTICOAGULANTS: Transition patients to warfarin clinics.
Decision Support	<ul style="list-style-type: none"> Include pharmacists on rounds Monitor overlapping medications given to patients Use smart pumps and barcode technology 	<ul style="list-style-type: none"> Use alerts for dosage limits. ANTICOAGULANTS: Use pharmacists to assist with identification of alternatives when contraindications exist. ANTICOAGULANTS: Have pharmacists perform independent double-checks of all VTE prophylaxis orders. OPIOIDS: Use alerts to avoid over-sedation and respiratory arrest (with/without an Electronic Medical Record). OPIOIDS: Use alerts to avoid multiple narcotics/sedatives. OPIOIDS: Use alerts and dosage limits on concurrently prescribed opioid potentiators. OPIOIDS: Use equianalgesic prompts and defaults (with an MD override option) for opioid-to-opioid transitions.
Prevention of Failure	<ul style="list-style-type: none"> Minimize or Eliminate nurse distraction during medication administration process Standardize concentrations and minimize dosing options where feasible Use forcing functions and redundancy for high risk processes Provide timely lab results and implement an effective system to ensure review and action Use non-pharmacological methods of pain and anxiety management where appropriate Identify “look-alike, sound-alike” medications and create a mechanism to reduce errors (e.g., storing in different locations, clear labels, alternate packaging) Use multiple methods to identify ADEs, analyze the findings, and use the analyses to re-design processes to minimize ADEs 	<ul style="list-style-type: none"> Adopt an organization-wide definition and understanding of the practice of “independent double-checks,” then perform them on all HAMs. Use the “cone of silence” during medication administration. Use visual cues (HAM-specific bedside flags). INSULIN: Allow patient self-management of insulin where appropriate. INSULIN: Set limits on high dose orders. ANTICOAGULANTS: Use prepackaged heparin infusions; reduce the number of heparin concentrations available in the hospital. ANTICOAGULANTS: Use low molecular weight heparin or other agents instead of unfractionated heparin whenever clinically appropriate. ANTICOAGULANTS: Make lab results available within 2 hours. ANTICOAGULANTS: Perform automatic nutrition consults for all patients on warfarin to avoid drug-food interactions. OPIOIDS: Use a table of drug-to-drug conversion doses. OPIOIDS: Use fall prevention programs. OPIOIDS: Use dosing limits. OPIOIDS: Use sedation assessment scales to guide dosing in ALL care areas. OPIOIDS: Use tools to prevent overdose due to hydromorphone.¹⁷

ADVERSE DRUG EVENT (HIGH-ALERT MEDICATIONS) DRIVER DIAGRAM 2013-2014 (CONTINUED)

AIM: Reduce the Incidence of Harm from Adverse Drug Events (ADEs) due to High-Alert Medications (HAMs) by 50% by 12/8/14.

FOCUS: Insulin, Anticoagulants, and Opioids.

PRIMARY DRIVER	SECONDARY DRIVER	CHANGE IDEAS
Identification and Mitigation of Failure	<ul style="list-style-type: none"> Educate patients/families regarding risk of ADEs from 'their' HAMs Monitor and analyze use of reversal agents Analyze dispensing unit override patterns Transition to a "Culture of Safety" environment for improved error analysis Prompt real-time learning from each failure 	<ul style="list-style-type: none"> Assess the organizational culture with Agency for Healthcare Research and Quality Culture of Safety survey.¹⁸ Use a blame-free error reporting system to promote aggregate learning and to redesign error-prone processes. Use technology to alert (in real-time) key staff when rescue drugs are administered. Reassess and modify standing orders whenever rescue drugs are needed to prevent ADE recurrence in those patients. Use focused audits to identify practice patterns and system failures (e.g. D50 in ICU; naloxone in outpatient and inpatient procedure areas).
Smart Use of Technology	<ul style="list-style-type: none"> Use 'smart pumps' Understand errors that can occur from Patient Controlled Analgesic devices and other medication delivery devices Use alerts wisely Use data/information from alerts and overrides to redesign standardized processes Link order sets to recent lab values 	<ul style="list-style-type: none"> Educate staff regarding unintended consequences of device use/failure. Use proper level of alerts with forcing functions and stops for drug, allergy and diagnosis interactions Set dosing limits with CPOE. Do not allow alert overrides without documented reason.¹⁹

¹ 2011 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment* for Hospitals. Retrieved at <http://ismp.org/selfassessments/Hospital/2011/pdfs.asp>

² Website. Retrieved at <http://www.mnhospitals.org/Portals/0/Documents/ptsafety/ade/Medication-Safety-Gap-Analysis-Opioid.pdf>

³ Website. Retrieved at <http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/opioids/Documents/assessment.pdf>

⁴ Website. Retrieved at <http://www.ismp.org/Newsletters/acutecare/actionagendas.asp>

⁵ Institute for Healthcare Improvement High-Alert Medication Safety (Improvement Map). Retrieved at <http://app.ihc.org/imap/tool/#Process=b8541097-7456-4aab-a885-38c31950e6bf>

⁶ Institute for Safe Medication Practices High-Alert Medications. Retrieved at <http://ismp.org/Tools/highAlertMedications.asp>

⁷ California Hospital Association Medication Safety Committee High Alert Medication Guidelines for Select Anticoagulants. Retrieved at <http://www.calhospital.org/general-information/cha-medication-safety-guidelines-anticoagulants> (last accessed April 16, 2014)

⁸ Federico, Preventing Harm from High-Alert Medications, The Joint Commission Journal on Quality and Patient Safety, 33(9), 537-542

⁹ Graham et al, Implementation of a High-Alert Medication Program, The Permanente Journal, 12(2), 15-22

¹⁰ Stavroudis et al, NICU medication errors: identifying a risk profile for medication errors in the neonatal intensive care unit, Journal of Perinatology (2010) 30, 459-468

¹¹ Institute for Healthcare Improvement High-Alert Medication Safety Knowledge Center. Retrieved at <http://www.ihc.org/explore/HighAlertMedicationSafety/Pages/default.aspx>

¹² Website. Retrieved at <http://www.ismp.org/Tools/guidelines/default.asp>

¹³ American Diabetes Association, Standards of Medical Care in Diabetes-2013, Diabetes Care 36(S1), S45-46

¹⁴ The Joint Commission Sentinel Event Alert: The Safe Use of Opioids in Hospitals. Retrieved at http://www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf

¹⁵ Pasero, Assessment of Sedation During Opioid Administration for Pain Management, Journal of Perianesthesia Nursing, 24(3): 186-90. Retrieved at http://www.mghpcs.org/eed_portal/Documents/Pain/Assessing_opioid-induced_sedation.pdf

¹⁶ Retrieved at <http://www.icudelirium.org/docs/RASS.pdf>

¹⁷ Website. Retrieved at <http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/hydromorphone/Pages/home.aspx>

¹⁸ Agency for Healthcare Research and Quality Hospital Survey on Patient Safety Culture. Retrieved at <http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/index.html>

¹⁹ Miller et al, Barcode Medication Administration Technology: Characterization of High-Alert Medication Triggers and Clinician Workarounds, The Annals of Pharmacotherapy 2011 Feb, Vol. 45, 162-168

PREVENTION OF ADVERSE DRUG EVENTS (ADE) DUE TO HIGH ALERT MEDICATIONS (HAM)

Adverse events in hospitalized patients are most commonly associated with frequent interventions such as the prescription and administration of medications.

- Older hospitalized patients are at highest risk for adverse drug events.¹ These patients are more likely to be prescribed and given medications, and more likely to have serious conditions such as kidney and liver disease that can affect the metabolism and excretion of the administered drugs.²
- The greater the number of medications administered, the greater the likelihood of drug-drug and drug-disease interactions.³

Not all medications in clinical use present a risk to patients; serious adverse drug events appear to be caused by a relatively small number of medications.⁴ The Institute of Medication Practice has developed a list of medications considered to be “high-alert medications. (HAM)”⁵ As defined by The Joint Commission, “high-alert medications” are more likely to be associated with harm than other drugs – they cause harm more frequently, the harm they produce is likely to be more serious, and they “have the highest risk of causing injury when misused.”⁶

Attempting to identify and prevent all ADEs is complex and difficult; targeting high alert medications for surveillance may be a more prudent approach to prevent ADEs.⁷ The Institute for Healthcare Improvement’s “5 Million Lives” campaign recommends that focusing on a few groups of high alert medications (anticoagulants, opioids, and insulin) would have the greatest impact. These 3 groups of HAMS are responsible for the majority of harm, due to their inherent risks and high frequency of use.⁸

FOR 2014, THE AHA/HRET-HEN IS FOCUSING ITS ADE HARM REDUCTION ON THESE THREE GROUPS

Why anticoagulants?

- Anticoagulation therapy is associated with frequent and serious ADEs in both inpatients and outpatients.⁹
- Anticoagulants account for 4% of preventable ADEs and 10% of potential ADEs.¹⁰
- Lack of standardized dosing guidelines and appropriate monitoring can lead to serious harm associated with this class of medications.¹¹
- There is considerable variation in the dosing and monitoring of patients on unfractionated heparin.

- Additionally, continuing heparin therapy while patients are started on warfarin requires complex adjustments and can result in confusion and errors.⁸
- The anticoagulant warfarin is commonly involved in ADEs for a number of reasons, including:
 - the complexity of appropriate dosing and monitoring,
 - lack of patient adherence to recommendations,
 - interactions with other medications,
 - and dietary interactions that can affect drug activity.¹²

Why opioids?

A collaborative of pediatric hospitals led by the Child Health Corporation of America (CHCA), identified a rate of 5.2 narcotic-related ADEs for every 100 patients.¹³ Opioid use in older patients is considered particularly high-risk by the Institute of Safe Medication Practices, as drug metabolism can be reduced by aging and co-morbid disease. Opioid use in the elderly has also been shown to be associated with a higher rate of patient falls.

- 49.2% of all parenteral medication errors occur on the general nursing unit and 16.7% are due to opioid analgesics.¹⁴ Use of multiple opioids and sedatives accounted for 42% of preventable ADEs in the intervention group.¹⁵
- Opioid overdoses may be associated with respiratory depression. Harm results when clinicians are not familiar with opioids’ onset of action, are titrating opioids to achieve an effect without considering upper dose limits, and lack a process to address emergency situations such as respiratory depression and arrest.
- 0.5%¹⁶ to 1.1%¹⁷ of post-operative patients receiving opioids experience respiratory depression.
- Failure to rescue occurs in as great as 19.7% of all post-surgical patients experiencing a life-threatening complication for which early identification and intervention can reduce the risk of death.¹⁸
- 44% of cardiopulmonary arrests are identified as respiratory-related.¹⁹
- At a rate of 17.2 per 10,000 at-risk hospitalizations, post-operative respiratory failure results in \$1.96 billion in excess costs annually.²⁰
- Opioid under-dosing may be associated with poor pain control.⁹
- Patient-controlled analgesia (PCA) also poses a potential for harm. Episodes of respiratory depression have been associated with multiple drug interactions, continuous narcotic infusion, nurse- or physician-controlled analgesia, and inappropriate use

of PCS by patients.²¹ Patient-controlled analgesia (PCA) also poses a potential for harm. Episodes of respiratory depression have been associated with multiple drug interactions, continuous narcotic infusion, nurse- or physician-controlled analgesia, and inappropriate use of PCA by patients.

- Mortality from user programming errors with PCA pumps has been estimated to be a low-likelihood event (occurring in 1 in 33,000 to 1 in 338,800 patients). However, 65 to 667 deaths are reported per year.²²

Why insulin?

- The pharmacology of insulin, the complexity of its dosing, and the variety of its available formulations contribute to the potential for error and associated harm. In addition, some of the newer insulins have a rapid onset of action and can quickly lead to patient hypoglycemia.
- Hypoglycemia is the most common complication of insulin therapy and is an extremely frequent adverse event in hospitals around the world.²³
- Even when hospitals implement protocols and guidelines, adverse events continue to be reported. In these cases, necessary dosing adjustments may not be considered or made for reduced caloric intake, illness, medical and surgical procedures, and other sources of physiologic stress that can impact insulin requirements.²⁴

SUGGESTED AIMS

- Reduce the incidence of harm due to warfarin, opioids, and insulin by 40% by December 8, 2014.

PATIENT AND FAMILY ENGAGEMENT

Broad evidence continues to increase supporting what we all intuitively know: the treatment of medical conditions is not as simple as “disease – doctor – nurse – medication.” Failure to engage patients and families in health care leads to several types of errors, some of which can be described as (1) failure to pursue the most effective paths of treatment due to lack of awareness of the patient’s socio-economic situation (e.g. inability to afford certain medications, lack of transportation to follow up medical or laboratory appointments, dietary or religious preferences and practices, medications or herbals acquired from other sources), and (2) failure to recognize the family as a partner in assisting the patient with treatment regimen compliance, monitoring for side effects, and necessary life style changes.

Secondary Driver: Recognize the patient and family as key partners in the campaign to reduce ADEs.

As clinicians, we spend a very small amount of time with our patients during their course of treatment. While we are the “subject matter experts” of our chosen licenses and specialties, the patient and family are the “local knowledge experts” about themselves and their environment, we know that all successful change requires both of these components.

Secondary Driver: Educate patients and families regarding the risks and benefits of high alert medications.

These medications, notably anticoagulants, opioids, and hypoglycemic agents, have high risk ratios: they can be life saving or may mitigate intense pain, but can also be deadly. Providing information to patients and families that appropriately balances these risks and benefits helps arrive at the best path of treatment for each individual patient.

Secondary Driver: Explore and understand the patient’s social situation, especially with regard to access to transportation and food.

In particular, warfarin requires regular monitoring of INR levels. Lack of transportation to laboratory appointments leads to lack of drug effect monitoring, potentially leading to life threatening results from either over or under treatment. Diabetics on limited income have been known to become hypoglycemic when they have no money to purchase food, sometimes referred to as the “food cycle” of hypoglycemia.

Secondary Driver: Educate patients and families on the importance of keeping high alert medications secured from small children and other vulnerable individuals.

All high alert medications can cause severe harm or death. These medications should be stored in such a way as to be impossible for them to be taken by individuals other than the patient. Fentanyl patches in particular have been known to cause death in children when not properly disposed of, after having become attached to the child’s skin.

Change Ideas: Methods to engage patients and families

- Provide patient education in a language and at a literacy level all can understand.
- **INSULIN:** Provide hypoglycemia rescue protocols to patients and families in a manner that they understand; use “teach back” to verify understanding.
- **INSULIN:** Provide oral concentrated glucose solutions, and possibly even glucagon injection for rescue.

- **INSULIN:** Allow hospitalized patient to perform self-management of insulin where safe and appropriate.
- **ANTICOAGULANTS:** Ensure that patients and families thoroughly understand and can comply with appointments for follow up INR testing at regular intervals; if unable to do so, work with community resources to arrange transportation, or consider alternate medications.
- **ANTICOAGULANTS:** Obtain complete lists of all medications, including herbals and over the counter medications, so that drug-drug interactions can be minimized or avoided.
- **ANTICOAGULANTS:** Obtain full understanding of any dietary peculiarities to help avoid drug-food interactions.
- **OPIOIDS:** Educate patients and families regarding potentially lethal layering effects of multiple opioids, or a single opioid with a hypnotic, anxiolytic, muscle relaxant, or alcohol.
- **OPIOIDS:** Educate patients regarding the potentially lethal effects of failure to dispose of fentanyl patches properly, especially in such a way as to keep them away from children.

Suggested Process Measures

- Percent of patients discharged on warfarin who have a laboratory follow up appointment for INR check where transportation to that appointment is verified.
- Percent of patients discharged on a hypoglycemic agent who are also discharged with concentrated glucose solution as a home rescue agent.
- Percent of patients discharged on a Fentanyl patch who, through “teach back,” demonstrated understanding of the potentially fatal affect of this medication on children, and the need to properly secure and dispose of these patches.

“Hardwiring” Awareness, Readiness, & Education in Improvement Plans

Patient and Family Engagement must become part of standard workflow if it to become hardwired. Capturing complete social history along with a complete list of prescribed, herbal and over the counter medications will help avoid ADEs due to drug-drug, drug-food, and dietary or religious choices. Instituting “teach back” at discharge by the bedside nurse, discharging nurse, pharmacist, or physician will avoid post discharge ADEs.

AWARENESS, READINESS, AND EDUCATION

Medication errors have been on hospitals’ radars for the last two decades, but the focus for improvement has been on ensuring correct administration of drugs by nursing staff. This focus led to the QI campaign “The Five Rights: Right Patient, Right Drug, Right Dose, Right Route, Right Time.” Unfortunately, the campaign’s attention was directed solely towards the nursing component instead of on identifying and understanding system failures that led to medication errors and ADEs.

This “culture of blame” did not lead to improved medication safety or encourage effective redesign of systems to prevent errors, so the healthcare industry is now adopting a very different concept: the “Just Culture.” Its developer, David Marx, defined “A Fair and Just Culture” as “one that learns and improves by openly identifying and examining its own weaknesses.” Organizations with a Just Culture are as willing to expose areas of weakness as they are to display areas of excellence. Of critical importance is caregivers’ perception that they are supported and safe when voicing concerns. Individuals know, and are able to articulate, that they may speak safely on issues regarding their own actions or those in their environment in an effort to identify problems and promote quality improvement.”²⁵

Secondary Driver: Assess organizational capacity, readiness, and willingness.

Capacity is often defined as the number of people available to do a task. However, true organizational capacity is determined by the culture of an organization, and its readiness and willingness to examine and change systems of care to promote quality improvement. Assessing the culture globally and at unit-specific and role-specific levels can lead to insights regarding the barriers that impede an organization from achieving optimal medication safety.

Secondary Driver: Create awareness of ADE harm due to insulin, anticoagulants and opioids.

Research has shown that organizational knowledge and awareness of the risks of HAMs is improved by creating and using tools that assesses organizational knowledge and practices, analyzing assessments to identify performance gaps and develop strategies to improve performance, educating relevant stakeholders regarding QI initiatives, and reassessing progress at a defined period in the future. This increased knowledge and awareness is expected to lead to new processes and systems and fewer errors.

Secondary Driver: Assess staff knowledge.

Studies have shown that most healthcare providers (physicians, pharmacists, or nurses) score lower than 50% on a standardized opioid knowledge assessment.²⁶ Assessment of staff knowledge can inspire active learning and guide targeted education and training. Education alone may not be sufficient to reduce ADEs due to opioids, but it does provide an important foundation for quality improvement in this area.

Change Ideas: Methods to enhance organizational awareness

- Use the Institute for Safe Medical Practices (ISMP) Self-Assessment Tool.²⁷
- Use the Opioid Adverse Drug Event Prevention Gap Analysis (A Component of the Medication Safety Roadmap, Minnesota Hospital Assn, 2012).²⁸
- Use the Pennsylvania Patient Safety Authority Opioid Knowledge Self-Assessment Tool.²⁶
 - Assess clinical staff knowledge via a pre-test
 - Identify and target gaps in knowledge and understanding
 - Educate staff and other appropriate stakeholders
 - Implement a 6-week post-test to assess effective learning.^{29,30}
- Use a well-developed patient safety culture survey instrument such as the SAQ³¹ or AHRQ Patient Safety Instrument.³²

Suggested Process Measures

- Analyze ISMP self-assessment results – focus on identifying safe practices not yet widely implemented and enhancing active safety programs.
 - Count high-alert medication triggers from the Medication Trigger Tool data by drug class.
 - Calculate the rate of high-alert triggers from the Medication Trigger Tool data by class of drug per 100 patients receiving a drug in that class.
 - Calculate the rate of high-alert triggers from the Medication Trigger Tool by class of drug per 1,000 doses of a drug in that class.

“Hardwiring” Awareness, Readiness, & Education in Improvement Plans

Regular assessments of performance are important for “hardwiring” awareness, readiness and education in an organization’s culture. Utilize the ISMP self-assessment tool at least annually and note progress in every section where weakness has been identified. Communicate the results of the assessments and provide necessary education and training to relevant stakeholders across the organization.

STANDARDIZED CARE PROCESSES

Standard work will create standard outcomes. However, medicine is complex, and not everything in healthcare can or should be standardized. Therefore, as noted by Brent James M.D. of Intermountain Health, “Standardize what is standardizable” and no more. Use standard orders and protocols which incorporate special safety precautions for target groups with specific patient characteristics such as advanced age or chronic conditions/diseases that could increase risk. These customized approaches can be built in for all patients using HAMs and become a systematized part of routine practice.

Secondary Drivers: Implement ISMP quarterly action agendas where appropriate.³³

The ISMP quarterly action agendas gather the most up-to-date safe practices in a variety of areas from self-reports, queries, and other surveys that identify unsafe medication practices. Not all best practices are appropriate for every hospital; for example, some are focused on medications used only in more intensive or complex settings. Hospitals can elect to implement specific recommendations that are relevant to their own high-alert medication utilization.

Secondary Drivers: Develop standard order sets.

Work with physicians and pharmacists to develop standard order sets for high-priority HAMs. Use well-described safety principles as resources to assist in the development of the standard order sets.

Secondary Drivers: Allow nurses to administer rescue drugs based on protocol.

Protocols for the use of rescue medications, such as naloxone to reverse over-sedation and glucose to reverse hypoglycemia, can be established for non-physician use. For major bleeding issues with anticoagulation, Vitamin K, Fresh Frozen Plasma, and other hematologic factors can serve as designated rescue agents, if approved in advance by staff physicians and pharmacists.

Change Ideas

- Review key literature.^{34,35,36,37,38}
- Create standard (standing) orders.
 - Obtain examples of order forms utilized at other institutions and ask: “What would we need to modify to make a standing order work here?”
 - Allow flexibility within orders to address specific patient characteristics that may increase risks.
 - Allow for “opt-outs”: permitting clinicians not to use standard orders when the standard orders don’t “fit” the patient.
 - Aggregate the “opt-outs” on the standard orders in categories based on indications for their use.
 - Study opt-out use data to assess if use is appropriate. Revise standing orders as necessary.
 - Make it easier for physicians to use standard orders rather than to write their own.
- Institute for Healthcare Improvement “How to Guides” and “Knowledge Center”³⁹ and ISMP guidelines.⁴⁰

ANTICOAGULANTS:

- Use a protocol to discontinue or restart warfarin peri-operatively.⁴¹
- Use standardized dosing protocols.

OPIOIDS:

- Use standard processes to effectively manage pain.¹⁶
- Use protocols and tables for equianalgesic transition from one opioid to another.
- Limit dosage strengths available in floor stock and automated drug cabinets.
- Use standardized sedation assessment scales such as the Pasero Opioid-Induced Sedation Scale (POSS)⁴² or the Richmond Agitation Sedation Scale (RASS).⁴³
- Develop protocols to manage fentanyl patches to prevent overdose.

INSULIN:

- Reduce sliding-scale variation.⁴⁴
- Coordinate meals and insulin administration times.
- Use insulin infusion as per ADA recommendations in critically ill patients.⁴⁵

Suggested Process Measures

- The percentage of patients for whom a protocol was used for peri-operative warfarin
- The percentage of patients with opioid orders for whom a standardized risk screening tool was used.
- The percentage of patients receiving opioids that received regular assessment using an assessment tool.
- The number of transfers to a higher level of care that occurred because of opioid over-sedation.
- The percent of patients with a blood glucose of <70 mg/dl (one or more times) who had their insulin orders modified.
- The percent of ICU patients with a blood glucose >180 mg/dl (one or more times) who received insulin infusions.

“Hardwiring” Standardized Care Processes in Improvement Plans

The organization should make it easy for the clinician to perform a desired activity. Involving local clinicians in the design of processes will enhance their understanding of the rationale behind improvement changes and increase the effectiveness of the changes. For example, physicians should not only be involved in defining the order sets but in determining how the order sets will be delivered and which prompts will be necessary to guide users.

AVOIDANCE OF ERRORS DURING CARE TRANSITIONS

Transitions of care, whether from nurse to nurse, physician to physician, or unit to unit are a common and dangerous source of errors.^{46,47} Though complete solutions remain elusive, improved processes have been identified that can prevent or mitigate errors.

Secondary Drivers: Implement effective medication reconciliation processes.

Providing the medications correctly at each point of transition of care, especially upon admission and discharge, remains a critically important component of these improvements – but is “easier said than done.” Some hospitals use pharmacy staff or technicians to assist with medication reconciliation during transitions and at both ends of hospitalization.

Secondary Drivers: Implement pharmacist driven ambulatory clinics for warfarin management.

A significant number of patients on warfarin present to emergency departments as a result of inadequate ambulatory warfarin management. Ambulatory warfarin clinics operated by some hospitals in partnership with local physicians and laboratories and funded by community resources have reduced ER utilization dramatically. Ample research evidence shows that mid-level professionals, including nurse practitioners and pharmacists, working from protocols to manage daily warfarin use, demonstrate care outcomes significantly superior to those obtained using models of traditional physician warfarin management.⁴⁸ Therefore, many institutions are now developing their own post-discharge warfarin clinics, or referring patients to providers within the community who have launched such clinics in their offices.

Change Ideas

- Reconcile all medications at each transition.
- Use medication tools that follow the patient throughout all the transitions of care, and that are not unit-based but patient-based.
- **INSULIN:** Require new insulin orders when a patient is transitioned from parenteral to enteral nutrition.
- **ANTICOAGULANTS:** Transition patients to warfarin clinics for follow-up.

Suggested Process Measures

- The percentage of medications reconciled at each point of transition of care
- The percentage of patients on insulin who receive new orders when they are removed from parenteral feedings and placed on enteral feedings
- The percentage of patients receiving warfarin therapy who are followed in specialized warfarin ambulatory centers

“Hardwiring” Error Avoidance During Care Transitions in Improvement Plans

Medication reconciliation tools that can be used for both ordering and reconciliation can help to “hardwire” this process. These “hardwires” can be created through both paper and electronic ordering systems. Standard discharge order sets with an automatic referral of patients on anticoagulation to ambulatory warfarin centers at discharge, facilitated by a nurse experienced in handling these transitions, can help make these processes routine. When reconciliation is incomplete, an exception report can be generated which may identify some of the challenges with sustaining the process.

DECISION-SUPPORT

Decision-support provides additional information, problem solving, and controls to prevent adverse drug events. Decision-support occurs when information is provided “at-just-the-right-time” to help clinicians make more informed and accurate decisions. Medication manuals at a nursing station are a form of decision-support. Technology solutions also provide decision-support. For example, smart pumps make dosing adjustments and calculations available at the point of care. Alerts on electronic prescribing platforms can pick up dosing errors and display drug allergy and sensitivity data which can decrease the use of inappropriate agents.

Secondary Drivers: Include pharmacists on rounds.

Pharmacist participation in medical rounds significantly reduces the rate of ADEs caused by prescribing errors, both in an ICU setting⁴⁹ and in general medical units.⁵⁰

Secondary Drivers: Monitor overlapping medications prescribed for a patient (multiple narcotics, sedatives, anti-psychotics).

Consider establishing criteria for clinical pharmacist intervention for both utilization of high-alert medications as well as for prescription of large amounts and high doses of all medications.

Secondary Drivers: Use smart pumps, barcode technology.

Many hospitals have implemented the use of smart IV pumps to facilitate appropriate dosing and flow, and to alert providers to change medication bags. Smart pumps are not infallible, however, and could support a wrong dose or rate of administration, creating unintended negative consequences for patients. Double-checking smart pump function remains important. Some facilities also use barcode technology to reduce medication errors during administration. Although helpful, barcode systems do not detect all errors and can be overridden, at times inappropriately.

Change Ideas

- Implement alerts for maximum dosage limits
- Monitor override patterns for barcodes, automated dispensing units, and other technological tools.
- **ANTICOAGULANTS:** Enlist pharmacists to assist with identification of medication alternatives when contraindications exist for the use of a specific medication.
- **ANTICOAGULANTS:** Have pharmacists perform independent double-checks of all VTE prophylaxis orders.

- **OPIOIDS:** Use alerts to avoid use of multiple narcotics/sedatives.
- **OPIOIDS:** Monitor activation of trigger alerts which prevent over-sedation and respiratory arrest.
- **OPIOIDS:** Implement alerts and dosage limits on concurrently prescribed opioid potentiators.
- **OPIOIDS:** Use prompts with defaults (with an MD override option) for administration of equianalgesic medications for opioid-to-opioid conversion.
- **INSULIN:** Standardize subcutaneous and intravenous insulin concentrations
- **INSULIN:** Use barcode technology and/or label U-500 as high risk to avoid accidental overdosing due to use of U-500 in lieu of U-100.

Suggested Process Measures

- Measure the rate of “overrides” for automated dispensing units, barcodes, and other technology. (NB. High rates or increasing rates over time can indicate a problem.)
- Measure the percentage of VTE prophylaxis orders that have had independent double-checks performed.

“Hardwiring” Decision-Support in Improvement Plans

Many of the interventions above are not only implementation strategies but also “hardwiring” strategies. Examples of hardwiring interventions include implementing alerts and having pharmacists attend rounds as a full member of the patient care team. Double-checks can be triggered by alerts which require regular monitoring of designated processes, by direct observation or by chart review. With technology solutions, hardwiring includes performing systematic audits to ensure that the technology is being used appropriately, as well as anticipating and preventing potential errors and inappropriate overrides that could generate unintended negative consequences.

PREVENTION OF FAILURE

Medication errors are the most frequent cause of adverse drug events.^{51,52} Effective system and process designs can decrease medication errors.

Secondary Driver: Minimize or eliminate nurse distraction during the medication administration process.

Most medication errors can be attributed to system failures, with distractions/interruptions as a major contributing factor.⁵³ One study reports observing as many as thirty interruptions in a single nursing shift.⁵⁴ Minimizing distractions can promote a safer work environment. Distraction reduction can be aided by implementing visual cues, such as a “medication sash,” for staff to display when administering drugs, and by using designated, clearly identified quiet areas for medication preparation. These visual cues should signal a “Cone of Silence” within which interruptions should be forbidden.

Secondary Driver: Standardize concentrations and minimize dosing options when feasible.

Multiple formulations of a medication and multiple dosing options can lead to errors. Over thirty years ago, two concentrations were available for regular insulin: 40 units/mL (U-40) or 100 units/mL (U-100). Many episodes of unintended hypoglycemic events occurred when patients who had been on U-40 were given the same ostensible “doses,” but were medicated by an insulin of U-100 concentration. Today, standard insulin is provided only in U-100 form to avoid this potential error. Similar principles apply to all high-alert medications. Having too many options (e.g. various heparin concentrations in adult ICUs) can lead to errors and ADEs.

Secondary Driver: Monitor HAM use and develop criteria and protocols for timely review and action.

An established plan for monitoring HAM use should be implemented with all high alert medications, and should include the type and frequency of audits. When laboratory results are used to monitor effects of HAMs, protocols for timely lab test ordering, reporting, review, and response to these results should be implemented.

Secondary Driver: Use non-pharmacological methods of pain and anxiety management when possible.

Patients' pain and anxiety can sometimes be managed by adjusting environmental factors, such as lowering bright lights, decreasing noise levels, and achieving optimal room temperature. Other helpful approaches could include the use of aromatherapy, distraction, music, and touch therapy.

Secondary Driver: Manage "look-alike, sound-alike" medications.

Hospitals should create a list of the look-alike/sound-alike medications they store, dispense, or administer, and implement strategies to minimize potential errors in their prescription and administration. Such strategies may include electronic prescriptions, TALLMAN Lettering, and separation of look-alikes on shelves and in unit-based dispensing machines.

Secondary Driver: Use multiple methods to identify ADEs, analyze findings, and use the analyses to revise and re-design processes to minimize ADEs.

Many strategies are available to identify ADEs. Passive methods include scanning data reports and reviewing unusual occurrence reports. Unfortunately, multiple studies have shown that these passive methods underreport ADEs by a factor of ten or more. Hospitals that wish to more effectively identify ADEs use active methods, such as collecting targeted data reports, studying automated drug unit real-time feedback/data, and implementing targeted staff interviews. For example, in order to better understand underlying causes, one institution interviews its Rapid Response Team members who have identified patients with over-sedation who required transfer to a higher level of care.

Change Ideas

- Develop an organization-wide standard for independent double-checks.
- Perform independent double-checks on all high-alert medication administrations.
- Use the "Cone of Silence" during medication administration.
- Use visual clues such as HAM specific flags at the bedside.
- **ANTICOAGULANTS:** Use pre-packaged heparin infusions; reduce the number of different heparin formulations in the hospital.
- **ANTICOAGULANTS:** Use low-molecular-weight heparin or other newer agents instead of unfractionated heparin whenever clinically appropriate.

- **ANTICOAGULANTS:** Make laboratory results available within 2 hours; create a closed loop/system for management of elevated/unexpected test results/levels.
- **ANTICOAGULANTS:** Perform automatic nutrition consults for all patients on warfarin to avoid drug-food interactions.
- **OPIOIDS:** Use sedation scales to guide dosing in ALL care areas.
- **OPIOIDS:** Use dosing limits.
- **OPIOIDS:** Use tools to prevent overdose due to hydromorphone.⁵⁵
- **OPIOIDS:** Use a table of drug-to-drug conversion doses.
- **OPIOIDS:** Implement fall prevention programs.
- **INSULIN:** Allow patient management of insulin dosing where appropriate.
- **INSULIN:** Set limits on high dose orders.

Suggested Process Measures

- The percent of patients on opioids who are regularly assessed using a sedation scale.
- The percent of patients who are transitioned from one opioid to another with equianalgesic orders.
- Measure the percentage of critical inpatient lab results for patients receiving anticoagulants, opioids, and insulin for which a documented action or response was not evidenced. (Failure rate).
- Measure the number of observed medication distribution errors.
- Measure the number of interruptions during medication administration.

"Hardwiring" Prevention of Failure in an Improvement Plan

Many of the interventions above are not only implementation strategies but also hardwiring strategies. Standardizing concentrations, setting dosing limits, and using pre-packaged heparin for infusion are examples of hardwiring interventions.

Hardwiring for ADE prevention may include providing routine reminders for double-checks by two licensed care givers at the bedside. Observations and chart reviews may also be used. If an electronic medical record is being used, a "hard stop" can be implemented to force documentation of the double-check.

IDENTIFICATION AND MITIGATION OF FAILURES

Once an ADE does occur, prompt identification and mitigation can reduce adverse outcomes for the affected patient. Identification can also provide opportunities for institutional learning and system revision and redesign.

Secondary Drivers: Educate patients/families regarding risk of ADEs.

Patients and families can be allies in the promotion of medication safety. Helping patients and families to understand the benefits and potential risks of prescribed medications will allow them to be alert for early warning signs of an ADE after discharge. Self-management is facilitated when patients and families are educated about and involved with their medication management and treatment throughout the hospitalization and after discharge.

Secondary Driver: Monitor and Analyze Use of Reversal Agents.

Monitoring the use of reversal agents allows the assessment of situations that may cause harm to patients. While some isolated events of high INRs, over-sedation, and hypoglycemia are likely unavoidable, a review of patterns of these ADEs can help to uncover and identify system failures. During the last decade, when tight control of blood glucose was recommended for diabetic treatment, reviews of treatment history data often revealed patterns in which the same patient received multiple ampules of D50. Pattern analysis also identified high usage rates of D50 throughout ICU's, leading to the recognition that tight control was harmful. The American Diabetes Association (ADA) now recommends that the treating physician be notified for every occurrence of a blood glucose <100 mg/dl in patients receiving insulin; the physician should consider adjusting the insulin regimen. The ADA also recommends that even one instance of a blood glucose <70 mg/dl in a diabetic should prompt a change in insulin orders.⁵⁶ Such low blood glucose values are considered an early warning sign for avoidable severe hypoglycemia (glucose < 50 mg/dl).

Secondary Driver: Analyze Dispensing Unit Override Patterns.

Many individual reasons exist for overrides to occur, but patterns of overrides suggest possible system failures. These failures could range from human errors to inadequate order sets. Analysis of override patterns may identify care areas that are likely to require process improvement.

Secondary Driver: Transition to a “Culture of Safety” for improved error identification and quality improvement.

As previously mentioned, a “Culture of Blame” did not lead to reduced ADEs. Organizations that have successfully implemented a “Culture of Safety,” and transitioned to improvements in reporting, comprehensive error analysis, and subsequent system revisions, have demonstrated sustainable reductions in errors.

Secondary Driver: Prompt real-time learning from each failure.

Hospitals that rapidly and thoroughly study and learn from each medication management failure and substantive “near-miss” are better able to successfully implement new safety practices and promote quality improvement. Understanding failure is necessary to reduce medication errors; investigating errors shortly after they occur reduces memory bias. However, if an ADE leads to serious morbidity or mortality, patients, families, and healthcare professionals may not be as receptive to or able to respond to an acute investigation. Explaining the value of investigations in preventing future ADEs, and reassuring staff and patients that investigators will be avoiding a “Culture of Blame” and instead taking a broad systems view to promote quality improvement can be helpful in encouraging participation. When investigating an accident, asking at least 5 “whys” invites respondents to reflect and report on multiple negative influences that may have contributed to the ADE and that could be mitigated in the future. The 5 “whys” is a method of drilling down to core causes by sequentially exploring each answer provided.

Change Ideas

- Assess organizational culture with the Agency for Healthcare Research and Quality Culture of Safety survey.³²
- Monitor, identify, understand, and mitigate medication administration errors and delays.
- Use error-reporting systems that aggregate data to enhance learning and direct the redesign of error-prone processes.
- Conduct an interdisciplinary Failure Modes and Effects Analysis (FMEA) in a non-punitive manner on prior ADE events to identify system breakdowns, knowledge gaps, and opportunities to re-design processes and systems.
- Use technology to alert key staff in real-time when a rescue drug is administered.
- Reassess and modify standing orders whenever a rescue drug is needed for a patient to prevent an ADE recurrence in the same patient.

- Use focused audits to identify high risk practice patterns, ADEs, and system failures (e.g. administration of D50 in insulin-treated ICU patients or naloxone in outpatient and inpatient procedure areas).
- Use clinical pharmacists to educate patients/families about their HAM(s).

Suggested Process Measures

- Medication distribution errors observed
- Percentage of patients/families who perform an accurate ‘teach back’, that is, confirming patient understanding of instructions and concept by having the patient explain them back
- Percent increase in the number of ADEs reported by staff in patients prescribed anticoagulants, opioids, and insulin
- Percentage of patients re-admitted due to ADE complications.

“Hardwiring” Identification and Mitigation of Failure in Improvement Plans

Many of the interventions above are not only implementation strategies but also hardwiring strategies. Hardwiring for ADE prevention includes:

- Routine reminders for double-checks of HAMs at the bedside by two licensed providers. If using an electronic medical record, implement a hard stop for the documentation of the double-check.
- Automatic notification of a pharmacist whenever rescue medications are administered.
- Routine review of anticoagulant orders by clinical pharmacists to ensure appropriate dosage based on patient age and laboratory test results.

SMART USE OF TECHNOLOGY

Utilizing technology effectively will help to identify and mitigate errors. Advancements such as electronic physician order entry, computerized physician decision-support, barcode scanning, and smart pumps have improved drug safety.^{57,58} Technologies such as these can be used to identify errors made, and can prevent prescribing mistakes by providing pre-approved dosage prompts and decision-support. Additionally, these technologies can prevent administration errors in the ‘5 Rights’ domains mentioned above.⁵⁹

Secondary Driver: Understand potential errors that can occur from medication delivery devices.

Unfortunately, automated devices, such as Patient Controlled Analgesia (PCA) pumps and smart pumps, can also have unintended negative consequences. Since they are often used to deliver HAMs, understanding the potential mishaps that may occur with these devices is crucial to mitigating harm. Identifying and anticipating potential device errors can begin by consulting with device manufacturers, and reviewing the SMP web site and other literature regarding reported cases.

Secondary Driver: Use alerts wisely.

Overuse of alerts and hard stops can cause alert fatigue and frustration. This frustration can lead to the use of work-arounds that may increase risk and reduce safety.

Secondary Driver: Use data/information from alerts and overrides to redesign standardized processes.

Requiring documentation for an override spurs the clinician to think twice about stepping outside the recommended guidelines and protocols. The “override reason” documentation can then be reviewed to help improve protocols and identify education and training needs. Additionally, monitoring the override rate can provide clues about trends and patterns in processes and systems.

Secondary Driver: Link order sets to recent lab values.

Laboratory tests ordered to assess the effectiveness of anti-coagulants and anti-thrombotic agents need to be processed via a closed-loop mechanism to ensure the lab results are seen, evaluated, and acted upon in an appropriate and timely manner. Lab values can guide physicians in making treatment decisions, e.g. should the current treatment be continued without change?

Another option to process laboratory results is to create a medical staff approved protocol for the pharmacy that allows for an immediate adjustment of anti-coagulant dosage.

Change Ideas

- Educate staff regarding unintended consequences of device use/failure.
- Set dosing limits with CPOE.
- Use the proper level of alerts with forcing functions and stops (within limits) for drug, allergy and diagnoses interactions.
- Do not allow alert overrides without obtaining a documented reason.⁶⁰

Suggested Process Measures

• The device override rate

—NB: an “ideal override rate” is a myth. Instead, high rates or increasing rates may indicate a potential safety problem or workflow issue.

“Hardwiring” Smart Use of Technology in Improvement Plans

Soft stops, hard stops, and alerts are all examples of hardwiring. A soft stop is a reminder that requires no action. The health care provider can proceed simply by pressing a key or clicking the mouse. A hard stop requires a specific and appropriate action before the provider is allowed to proceed.

POTENTIAL BARRIERS

- Recognize that, for many physicians, technology will demand changes in their practice. The use of alerts and stops and decision-support may be new and invoke perceptions of a loss of control and of “being told how to practice medicine.” To help engage physicians in the use of technology, recruit one or two early-adopting physician champions to serve as ambassadors and mentors for these changes.
- Technology involves a learning curve. Different practitioners will adapt to new technologies and processes at different rates. Provide adequate training and support for practitioners unfamiliar with new systems and technologies.
- Physicians may resist using standard orders, believing they represent “cookbook medicine”. Educating physicians regarding the proven value of standard order sets in reducing errors can mitigate this resistance and increase adoption. Presenting the options for customization and “opt-out” for patients with special needs can promote acceptance.
- Nurses may be hesitant to provide rescue medications via protocols without specific physician orders. They may fear harming patients, working beyond their training or scope, making errors, or receiving negative feedback from physicians. It is important that both nursing and physician leadership openly support these nurse-driven orders, provide adequate training and support, and intercede if inappropriate or uncivil encounters occur as a result of following protocols.

- Some physicians are very uncomfortable reconciling medications ordered by other physicians, and commonly describe concerns about medico-legal liability along with lack of knowledge about or familiarity with the drugs prescribed. Inviting physicians to work together to develop broadly approved protocols may mitigate some of these concerns.
- Physicians may be cautious about supporting protocols implemented by pharmacists, nurses, or nurse practitioners in ambulatory centers. Some MDs may be unaware of the positive safety records and advantages of these clinics. Educating physicians about the advantages of such protocols and including physicians in the protocol development process can be reassuring.
- The technology to install dosage and multiple (duplicative) therapy alerts may not be available at every facility. Updating senior managers about the value of new technology may persuade them to consider providing resources to support technology upgrades.
- Resistance to a “Cone of Silence” may develop if physicians’ and other care providers’ workflow is impacted by waiting to talk with a patient’s nurse. The urge to interrupt with a “quick question” may be difficult to suppress.
- Nurses may be uncomfortable providing rescue interventions based on a protocol without first calling the ordering physician. Education on the benefits of such protocols and support by physicians and nurse leadership for such empowerment could reduce nurses’ hesitation.

Use administrative leadership and sponsorship to help remove or mitigate barriers to error review and prevention

- Executive, clinical, and human resource leaders must lead the effort to prevent and reduce errors. Leaders who employ “blame and shame” when dealing with errors merely drive them underground. It is critical that an organization’s senior management, team leaders, human resources department, and legal staff understand this new “Culture of Safety” approach.
- Senior physician, nursing, and pharmacy management will be critical players in promoting the success of new innovations such as those noted above. Some improvement efforts may be initially perceived as punitive (e.g. timeliness audits), new and unfamiliar (“Consult a pharmacist? What’s a hard stop?”), or burdensome (e.g. independent double-checks before administering a HAM).

- Physician leadership will be the key to success. The literature has provided excellent data supporting the efficacy of both medication reconciliation and protocol-driven warfarin clinics. As physicians observe that these processes prove to be in the best interest of patients (and, in some cases, easier for the physicians to practice), more and more doctors will adopt them until a tipping point is reached, transforming the culture of the entire organization.
- Purchasing and implementing new technology requires resources. Senior leadership should understand the benefits of such upgrades and drive the efforts to obtain the necessary resources to achieve the outlined strategic goals for ADE prevention. Productive financial investments in these efforts can be directed towards the units demonstrating the greatest quality improvements and can promote broader adoption of these change ideas and best practices.

Not just a change in practice but a change in culture

- Improving medication safety requires a significant shift from a “Culture of Blame” to a “Culture of Learning and System Improvement.” It does not require, however, the establishment of an entirely blame-free environment; reckless and negligent behavior should, of course, never be tolerated.
- Standard processes and standing orders work. Collectively, this combination of processes has been shown to outperform traditional care methods.^{61,62} As healthcare providers become more comfortable with standard processes, clinicians can focus on the occasional patient situations that require deviation from the standard.
- Including pharmacists as consultants on the healthcare team during patient rounds may require a change in culture. The concept of multi-disciplinary teaming may require clinician education, in-services, or simulations to build or improve care providers’ communication, team function, and conflict resolution skills.
- Implementation of these innovations should begin with small tests of change and, when successful, disseminated to the larger organization. The eventual goal is for the entire organization to develop successful team-based care that improves quality and safety for patients.

TIPS ON HOW TO USE THE MODEL FOR IMPROVEMENT

- Start slowly to earn the trust of the involved professionals. Consider beginning with the AHRQ Culture of Safety Tool³² and the Institute of Safe Medication Practices Self-Assessment Tool to assess the current status of the relevant staff in the organization.²⁷
- Then, share the results of the assessments and the analyses, conclusions, and recommendations with champions for each stakeholder unit.
- Create a multi-disciplinary team with the champions and representatives from key stakeholder groups. Pick a HAM-based trial from one of these three common classes or from other areas at risk identified by your own collected data.
- Design a small pilot on a unit where the lead physicians/ champions and nurses are comfortable with testing medication administration design changes and protocols. One unit’s reported after their pilot, “The presence of a pharmacist on rounds as a full member of the patient care team in a medical ICU was associated with a substantially lower rate of ADEs caused by prescribing errors. Nearly all changes [99%] were readily accepted by physicians.”⁵²
- Additional suggestions for pilot testing include:
 - Trial the use of a new smart pump on one unit where pumps are used frequently, e.g. an intensive care unit.
 - Pilot the use of pharmacists in clinical rounds on one unit or with one physician. Utilize the success of the pilot to promote broader adoption of this best practice.
 - Pilot a program to minimize distractions during the medication administration process. Use data (e.g. # of interruptions, # of errors) to demonstrate improved outcomes and gain buy-in from physicians and other care providers.
 - Implement the double-check policy for HAMs incrementally, reviewing implementation for resource needs and constraints and other actual/potential issues (e.g. delay of treatment).
- Analyze the results of testing and disseminate successful processes and changes to the executive leadership and the larger institution.
- Continue to monitor the effectiveness of these processes and make necessary periodic revisions to enhance performance.

Appendix I: Adverse Drug Event (ADE) Top Ten Checklist

Adverse Drug Event (ADE) Top Ten Checklist

TOP TEN, EVIDENCE BASED INTERVENTIONS				
PROCESS CHANGE	IN PLACE	NOT DONE	WILL ADOPT	NOTES (RESPONSIBLE AND BY WHEN?)
Identify "look-alike, sound-alike" medications and create a mechanism to reduce errors (e.g., store in different locations, use clear labels, use alternate packaging)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Standardize concentrations and minimize dosing options where feasible	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Set dosing limits for insulin and opioids	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Implement pharmacist-driven warfarin management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Use alerts to avoid multiple prescriptions of opioids/sedatives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Use effective tools to reduce over-sedation from opioids (e.g. risk assessment tools, sedation assessment tools)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reduce sliding scale variation (or eliminate sliding scales)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Minimize or eliminate pharmacist or nurse distraction during the medication fulfillment/administration process	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Use data/information from alerts and overrides to redesign standardized processes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Coordinate meal and insulin times	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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