Implementation Guide to Reducing Harm from High-Alert Medications

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Adverse Drug Events (ADEs) Overview
Preventing Harm from High-Alert Medications

Background:

- Medications are the most common intervention in healthcare but are also most commonly associated with adverse events in hospitalized patients. At least 20% of all harm is associated with medication errors.
- High-alert medications are more likely to be associated with harm than other medications; they cause harm more commonly, the harm they produce is likely to be more serious, and they "have the highest risk of causing injury even when used correctly."
- Insulin, anticoagulants, narcotics and sedatives are the medications responsible for the majority of harm due to high-alert medications.

Suggested Aim:

Reduce the incidence of harm due to high-alert medications by 50% by December 31, 2013.

Potential Measures:

Outcome: Percent of high-alert medication (ADEs) per 1000 doses (aggregate, class or specific medication)
Percent of admissions with a high-alert medication (ADE)
Process: Percent of patients receiving a high-alert medication (aggregate, class, or specific med) that receive a reversal agent.

Primary Drivers	Secondary Drivers
Awareness, Readiness & Education	✓ Assess organizational capacity, readiness and willingness to implement systems to prevent ADEs ✓ Create awareness of high alert medications most likely to cause ADEs
Standardize Care Processes	✓ Implement ISMP quarterly action agendas where appropriate ✓ Develop standard order sets using safety principles ✓ Allow nurses to administer rescue drugs based on protocol ✓ Minimize interruptions during the process of medication distribution and administration ✓ Standardize concentrations and minimize or eliminate multiple drug strengths where possible ✓ Allow pharmacists to change anticoagulant doses based on lab values per protocol ✓ Include a pharmacist in direct clinical activities (ICU rounds, ambulatory medication decision making, etc.)
Decision Support	✓ Include pharmacists on rounds ✓ Monitor overlapping medications prescribed for a patient
Prevent Failure	✓ Minimize or eliminate nurse distraction during the medication administration process ✓ Standardize concentrations and minimize dosing options where feasible ✓ Timely lab results with effective systems to ensure review and action ✓ Use non-pharmacological methods of pain and anxiety management where appropriate
Identification and Mitigation of Failure	✓ Analyze dispensing unit override patterns ✓ Prompt real time learning from each failure
Smart Use of Technology	✓ Use "smart pumps" with up-to-date library or double check all IV infusions for high alert medications ✓ Understand errors that can occur from Patient Controlled Analgesic devices ✓ Use alerts wisely ✓ Use data/information from alerts and overrides to redesign standards ✓ Link order sets to recent lab values
Involve the Patient and Family	✓ Allow patient management of insulin where possible ✓ Provide patient education at a literacy level understandable by all

Making Changes:

- This intervention is in the Collaborative with Reducing Avoidable Readmissions **(Reduce RED Collaborative).** National meetings, webinars, monthly coaching calls, change packages and other tools will augment state hospital association activities.

Key Resources:

- Rashidee et al, High-Alert Medications: Error Prevalence and Severity, *Patient Safety & Quality Healthcare* 2009 July-Aug
- Institute for Safe Medication Practices: http://www.ismp.org/
- **IHI** : How to Guide Prevent Harm from High Alert Medications
- AHRQ Tools on Medication Reconciliation: http://www.ahrq.gov/qual/match/
- **IHI**: How to Guide Implementing Medication Reconciliation

Adverse Drug Event (High-Alert Medications) Driver Diagram

2012-2013

AIM: Reduce the Incidence of Harm from Adverse Drugs Events (ADEs) due to High-Alert Medications (HAMs) by 50% by 12/31/13

Primary Driver	Secondary Driver	Change Ideas
Awareness, Readiness & Education	• Assess organizational capacity, readiness and willingness to implement systems to prevent ADEs • Create awareness of HAMs most likely to cause ADEs	✓ Use Institute for Safe Medical Practices assessment tool[1] ✓ Assess clinical staff knowledge (pre-test); Educate; 6 week post test; Target gaps [2,3] ✓ HAMs – Insulin, Anticoagulants/Antithrombotics, Narcotics, sedatives
Standardized Care Processes	• Implement ISMP quarterly action agendas where appropriate[1] • Develop standard order sets using safety principles • Allow nurses to administer rescue drugs based on protocol without obtaining physician approval • Sequence implementation by drug class	✓ Review key literature [4,5,6,7,8] ✓ Analyze local ADE data to guide focus[9] ✓ Use IHI "How to Guides" and "Knowledge Center" [10] and ISMP guidelines[2] ✓ Pick HAM drug class with highest priority and begin practice implementation instead of tackling all simultaneously ✓ **INSULIN:** Reduce sliding scale variation (or eliminate sliding scales) ✓ **INSULIN:** Coordinate meal and insulin times ✓ **ANTICOAGULANTS:** Use protocol to discontinue or restart warfarin perioperatively
Avoid Errors During Care Transitions	• Implement effective medication reconciliation processes • Where appropriate, create ambulatory clinics for HAM follow-up	✓ Reconcile all medications at each transition ✓ Use flow sheets that follow the patient through the transitions of care (not unit based but patient based) ✓ **INSULIN:** Require new insulin orders when patient transitions from parenteral to enteral nutrition ✓ **ANTICOAGULANTS:** Transition patients to warfarin clinics
Decision Support	• Include pharmacists on rounds • Monitor overlapping medications given to a patient	✓ 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

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[1] http://www.ismp.org/Newsletters/acutecare/actionagendas.asp
[2] http://www.ismp.org/Tools/guidelines/default.asp

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Primary Driver	Secondary Driver	Change Ideas
		✓ **NARCOTICS/SEDATIVES:** Use alerts to avoid over-sedation and respiratory arrest (with/without an Electronic Medical Record) ✓ **NARCOTICS/SEDATIVES:** Use alerts to avoid multiple narcotics/sedatives
Prevention of Failure	• Minimize or eliminate nurse distraction during medication administration process • Standardize concentrations and minimize dosing options where feasible • Timely lab results with 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., different locations, labels, alternate packaging)	✓ Perform independent double checks ✓ Use the "cone of silence" during medication administration ✓ Use visual cues like HAM specific flags at bedside ✓ **INSULIN:** Allow patient management of insulin where appropriate ✓ **INSULIN:** Set limits on high dose orders ✓ **ANTICOAGULANTS:** Use prepackaged heparin infusions; reduce the number of heparin concentrations in the hospital ✓ **ANTICOAGULANTS:** Use low molecular weight heparin 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 ✓ **NARCOTICS/SEDATIVES:** Use a table of drug to drug conversion doses ✓ **NARCOTICS/SEDATIVES:** Use fall prevention programs ✓ **NARCOTICS/SEDATIVES:** Use dosing limits
Identification and Mitigation of Failure	• Educate patients/families regarding risk of ADEs from "their" HAMs • Administer medications on time • Analyze dispensing unit override patterns • Transition to "Just Culture" environment for improved error analysis • Prompt real time learning from each failure	✓ Monitor, understand, and mitigate medication administration delays ✓ Assess culture with Agency for Healthcare Research and Quality Culture of Safety survey [11] ✓ Use error reporting system to allow aggregate learning to redesign error prone processes ✓ Use technology to alert (real time) key staff when rescue drug administered
Smart Use of Technology	• 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	✓ 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 ✓ Do not allow alert overrides without documented reason [12]

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[1] 2011 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Hospitals http://ismp.org/selfassessments/Hospital/2011/pdfs.asp

[2] Hsaio et al, Nurses' knowledge of high-alert medications: instrument development and validation, *Journal of Advanced Nursing* 66(1), 177-190

[3] Lu, M.-C.et al, Nurses' knowledge of high-alert medications, A randomized controlled trial, *Nurse Educ. Today* (2011)

[4] Institute for Healthcare Improvement High-Alert Medication Safety (Improvement Map)
http://app.ihi.org/imap/tool/#Process=b8541097-7456-4aab-a885-38c31950e6bf

[5] Institute for Safe Medication Practices High-Alert Medications http://ismp.org/Tools/highAlertMedications.asp

[6] California Hospital Association Medication Safety Committee High Alert Medication Guidelines for Select Anticoagulants
http://www.cshp.org/uploads/file/Shared%20Resources/2012/guideline_anticoagulants_2.21.12.pdf

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

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

[9] 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

[10] Institute for Healthcare Improvement High-Alert Medication Safety Knowledge Center http://www.ihi.org/explore/HighAlertMedicationSafety/Pages/default.aspx

[11] Agency for Healthcare Research and Quality Hospital Survey on Patient Safety Culture   http://www.ahrq.gov/qual/patientsafetyculture/hospsurvindex.htm

[12] Miller et al, Bar code Medication Administration Technology: Charcterization 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:

Medications are the most common intervention in health care and are also most commonly associated with adverse events in hospitalized patients.[1] Older hospitalized patients are at higher risk of adverse drug events[2] in part due to their increased use of medications and co-morbid conditions such as kidney and liver disease. An increase in the number of medications increases the likelihood of drug-drug and drug-disease interactions.[3]

Not all medications in clinical use are of equal risk to patients. Serious adverse events appear to be caused by relatively small number of medications.[4] The Institute of Medication Practice has identified a number of medications that they consider to be "high-alert medications."[5] These are defined by The Joint Commission as those medications which are more likely to be associated with harm than other medications—they cause harm more commonly, the harm they produce is likely to be more serious, and they "have the highest risk of causing injury when misused."[6]

Because of the complexity of attempting to identify and prevent all ADEs, focusing surveillance and prevention of high alert medications may be a more prudent approach.[7] The Institute for Healthcare Improvement's Five Million Lives campaign found that focusing on a few groups of high-alert medications: anticoagulants, narcotics and sedatives, and insulin would have the greatest impact. These medications, due to their high volume of use coupled with their inherent risks, are responsible for the majority of harm due to all high-alert medications.[8]

Why focus on anticoagulants?
- Lack of dosing guidelines and appropriate monitoring can lead to serious harm associated with this class of medications.[9]
- Anticoagulants account for 4% of preventable ADEs and 10% of potential ADEs.[10]
- Anticoagulation therapy is associated with serious and frequent ADEs in both inpatients and outpatients.[11]
- Warfarin is commonly involved in ADEs for a number of reasons:
  - the complexity of dosing and monitoring
  - patient compliance
  - numerous drug interactions
  - dietary interactions that can affect drug activity [12]
- There is considerable variation in ordering, dosing, and monitoring of patients on unfractionated heparin. Often, there is confusion over providing ongoing therapy while patients are receiving warfarin.[8]

Why focus on narcotics?
- Opioid overdose or underdose associated with respiratory depression or poor pain control was a contributing factor common in adverse events.[11]
- A collaborative of pediatric hospitals led by Child Health Corporation of America (CHCA) identified a rate of 5.2 narcotic-related ADEs for every 100 patients.[13]
- Patient-controlled analgesia (PCA) poses potential for harm. Episodes of respiratory depression are associated with drug interactions, continuous narcotic infusion, nurse- or physician-controlled analgesia, and inappropriate use of PCA by patients.[14]
- Mortality from user programming errors with PCA pumps have been estimated to be a low-likelihood event (ranging from 1 in 33,000 to 1 in 338,800), but relatively numerous in absolute terms (ranging from 65 to 667 deaths).[15]

Why focus on sedatives?
- Harm may result when clinicians are not aware of the onset of action, are titrating to effect without considering upper dose limits, and lack a process to address emergency situations such as respiratory depression and arrest.

- Multiple sedative uses accounted for 42% of preventable ADEs in the intervention group.[16]
- Sedative use in the elderly is considered particularly high risk by the Institute of Safe Medication Practices. It has also been shown to be associated with a higher rate of falls among this group of patients.[17]

Why focus on insulin?
- The pharmacology of the drug, complexity of dosing, and variety of products all contribute to the potential for error and associated harm.
- Hypoglycemia is the most common complication of insulin therapy and is an extremely frequent adverse event in hospitals worldwide.[18]
- Even when hospitals use protocols and guidelines, there continue to be adverse events. Adjustments are not made to dosing to take into account stress caused by illness or a medical procedure, or when a patient may not have adequate food/caloric intake.[19]

Suggested Aims:
- Reduce the incidence of harm due to high-alert medications by 50% by December 31, 2013.
- Reduce high-alert triggers on the Medication Trigger Tool by 25% by December 31, 2013.

Awareness, Readiness & Education:

While medication errors have been on the radar of hospitals for the last two decades, the focus has been on administration by nurses. This focus has led to the campaign called The Five Rights: Right Patient, Right Drug, Right Dose, Right Route, and Right Time. The focus on these five rights has often led to the punishment of nurses for "their errors" rather than understanding the system failures that led to the error and redesign of those systems to prevent errors.

A "culture of blame" has not lead to improved medication safety. Given that realization, healthcare is starting to turn to a very different concept: "Just Culture." Developed by David Marx, "Just Culture" can be defined 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 that caregivers feel 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 the environment around them."[20]

Secondary Driver: Assess Organizational Capacity, Readiness and Willingness

Capacity is often thought of as number of people available to do a task. However, the organizational capacity, readiness and willingness to examine and change systems of care to prevent medication errors are truly about the culture of the organization. Assessing the culture globally, but also at the unit specific level or roles specific level can lead to insight as to the barriers that impede an organization from reaching optimal medication safety.

Secondary Driver: Create Awareness of HAMs Most Likely to Cause ADEs

Research has shown that creating and using a tool that assesses organizational practices and knowledge, using that assessment to educate and close gaps, then reassessing at a defined period in the future, can improve organizational knowledge and awareness of the risks of HAMs. It is then extrapolated that this increased knowledge and awareness will lead to fewer errors.

Change Ideas: Methods to Enhance Organizational Awareness
- Use Institute for Safe Medical Practices (ISMP) self-assessment too.l[21]
- Assess clinical staff knowledge (pre-test); Educate; 6 week post-test; Target gaps.[22,23]
- Use a well-developed patient safety culture survey instrument like the SAQ[24] or AHRQ Patient Safety Instrument.[25]

Suggested Process Measures:
- ISMP self-assessment results – focus on safe practices not widely implemented.
- Counts of high-alert medication triggers from the Medication Trigger Tool by drug class.
- The rate of high-alert triggers from the Medication Trigger Tool by class of drug per 100 patients receiving a drug in that class.
- The rate of high-alert triggers from the Medication Trigger Tool by class of drug per 1000 doses of a drug in that class.

"Hardwiring" Awareness, Readiness, & Education as part of Improvement Plan:

Regular assessments of performance are important for hardwiring awareness, readiness and education. Utilize the ISMP self-assessment tool at least annually and note progress in every section where weakness is identified.

Standardized Care Processes:

Standard work can create standard outcomes. Medicine is complex and not everything can be standardized, but to quote Brent James M.D. of the Intermountain Health, "Standardize what is standardizable and no more." Standard orders and protocols can be written so that they can incorporate specific patient characteristics such as kidney or liver disease, advanced age, or others. These customized approaches to individual HAMs can be a part of routine practice; they can be built in and systematized.

Secondary Drivers: Implement ISMP Quarterly Action Agendas Where Appropriate[26]

The ISMP quarterly action agendas synthesize the latest safe practices in a variety of areas based on self-report, queries and other mechanisms to identify unsafe medication practices. Not all are appropriate for every hospital (some are specific to medication uses only in sophisticated settings) and hospitals can focus on those representing high-alert medications.

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 in standard order sets.

Secondary Drivers: Allow Nurses to Administer Rescue Drugs Based on Protocol

Protocols for use of rescue medications, such as Narcan®, glucose, flumazenil can be established for non-physician use. Vitamin K is another rescue agent, as is Fresh Frozen Plasma and hematologic factors; however, its uses are best discussed with physician and possibly pharmacy participation for major bleeding issues.

Secondary Drivers: Sequence Implementation by Drug Class

Rather than address all high-alert medications, start with the drug class where the greatest opportunity for improvement exists and finish that class before beginning with another class. You can use the results from the ISMP self-assessment tool, Medication Trigger Tool or perhaps incident reports to determine which class should begin first. Another strategy is to pick the class with the least amount of complexity in an institution and implement all of the safety aspects with that class prior to starting another.

Change Ideas:
- Review key literature [27,28,29,30,31]
- Create standard orders
  - Obtain example order forms and ask: "What would we need to modify to make this work here?"
  - Allow flexibility within the orders based on common patient characteristics.
  - Allow for "opt out": this allows the clinician to not use the standard orders because they do not "fit" the patient.
  - Capture the logic of the "opt-out" on the standard orders so the "opt-outs" can be aggregated, creating learning that leads to improvement.
  - Make it easier for a physician to use the standard orders than to write orders.
- Institute for Healthcare Improvement "How to Guides" and "Knowledge Center" [32] and ISMP guidelines[33]
- **INSULIN:** Reduce sliding scale variation.[34]
- **INSULIN:** Coordinate meal and insulin times.
- **ANTICOAGULANTS:** Use protocol to discontinue or restart warfarin perioperatively.[35]

Suggested Process Measures:
- The percent of patients for whom a protocol is used for perioperative warfarin.
- The percent of patients for whom a standardized risk screening for venous thromboembolism (VTE) tool is used.
- The percent of patients who receive protocol driven risk based VTE prophylaxis.
- The number of transfers to a higher level of care that occurred because of VTE prophylaxis.

"Hardwiring" Standardized Care Processes as Part of Improvement Plan:

The organization should make it easy for the clinician to perform the desired activity. Understanding the care process on the various units by involving local clinicians in the design of processes will increase effectiveness. For example, physicians should not only be involved in defining the order sets but also how the order sets will be prompted to them.

Avoid 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 error. [36,37] While solutions remain elusive, proven processes do exist that can prevent or mitigate errors.

Secondary Drivers: Implement Effective Medication Reconciliation Processes

While "easier said than done," getting the medication correct at each transition of care remains a critically important process. This is especially true on admission and discharge. Some hospitals use pharmacy technicians to aid in this process at both ends of the hospitalization.

Secondary Drivers: Where Appropriate, Create Ambulatory Clinics for HAM Follow-up

A large portion of HAM issues presents in the emergency department due to inadequate ambulatory medication management. A common presentation is a critically elevated INR due to excessive warfarin (Coumadin). Ambulatory Coumadin® clinics run by hospitals in some locations have reduced these problems dramatically and depend on local community resources and physician + lab availability. Ample evidence exists now that mid-level professionals who work from protocols and manage warfarin daily have outstanding results. [38] Many institutions are now using either their own post discharge warfarin clinics or providers within the community have created this within their own offices. Often they involve a pharmacist or nurse practitioner to provide adjustments to dosing based on a protocol.

Change Ideas:
- Reconcile all medications at each transition.
- Use medication tools that follow the patient through the transitions of care (not unit based but patient based).
- **INSULIN:** Require new insulin orders when patient transitioned from parenteral to enteral nutrition.
- **ANTICOAGULANTS:** Transition patients to warfarin clinics.

Suggested Process Measures:
- The percent of medications reconciled at each transition of care.
- The percent of patients receiving anti-coagulation therapy who are followed in focused anti-coagulation ambulatory centers.
- The percent of patients on insulin who receive new orders when removed from parenteral feedings to enteral feedings.

"Hardwiring" to Avoid Errors During Care Transitions as Part of Improvement Plan:

Medication reconciliation tools that serve for both ordering and reconciliation can help to hardwire this process. These can be created for both paper and electronic ordering systems. Standard discharge order sets with an automatic referral of patients on anticoagulation at discharge, facilitated by a nurse who handles these transitions, can help make this process a part of standard care. Also, exception reports regarding when reconciliation is incomplete can help identify problems with sustainability issues.

Decision Support:

Decision support provides additional information, problem solving, and controls to prevent adverse drug events. Decision support is a concept where just-in-time information helps clinicians make more informed and accurate decisions. Often, technology solutions provide decision support. For example, smart pumps make dosing adjustments and calculations available at the point of care. Alerts on electronic prescribing platforms can look for dosing errors and drug sensitivity data being available when prescribing antibiotics can decrease the use of incorrect agents. In fact, medication manuals on the nursing station are a form of decision support.

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 setting[39] and general medical units[40].

Secondary Drivers: Monitor Overlapping Medications Prescribed for a Patient (Multiple Narcotics, Sedatives, Anti-Psychotics)

Consider establishing criteria for clinical pharmacist intervention to include both specific medications and the number of total medications.

Secondary Drivers: Use Smart Pumps, Bar Code Technology

Hospitals have implemented the use of smart IV pumps to support appropriate dosing, flows and need to change medication bags. Smart pumps are not infallible, however, and can create unintended consequences. Some facilities also use barcode technology to reduce medication errors during administration. Although helpful, it does not detect all errors and can be overridden: often when appropriate, occasionally when it is not.

Change Ideas:
- Use alerts for dosage limits.
- Monitor override patterns for barcode, automated dispensing units and other technology tools that create forcing functions.

- ANTICOAGULANTS: Use pharmacists to assist with identification of alternatives when contraindications exist.
- ANTICOAGULANTS: Have pharmacists perform independent double checks of all VTE prophylaxis orders.
- NARCOTICS/SEDATIVES: Use alerts to trigger monitoring to prevent over-sedation and respiratory arrest (with/without an Electronic Medical Record).
- NARCOTICS/SEDATIVES: Use alerts to avoid multiple narcotics/sedatives.

Suggested Process Measures:
- The rate of "overrides" for automated dispensing units, bar codes and other technology (Note: there is no "ideal" override rate but high rates can indicate a problem as well as growing rates over time).
- The percent of VTE prophylaxis orders that have independent double checks performed.

"Hardwiring" Decision Support as Part of Improvement Plan:

Many of the interventions are not only implementation strategies but also hardwiring strategies. Including pharmacists in rounds as a full member of the patient care team and implementing alerts are examples of hardwired interventions.

Hardwiring the double check process may include regular monitoring, both by chart review and observation. For technology solutions, hardwiring means ensuring that the technology is being used appropriately, with a systematic audit process, as well as anticipating unintended consequences that generate overrides.

Prevention of Failure:

Medication errors are the most frequent cause of adverse drug events.[41,42] Effective system and process designs can decrease medication errors.

Secondary Driver: Minimize or Eliminate Nurse Distraction During Medication Administration Process

Most medication errors are commonly attributed to system failures, with distractions/interruptions as a contributing factor.[43] One study cites as many as 30 interruptions in a single nursing shift.[44] Minimizing distractions is part of creating a safe work environment. Implementing visual cues, such as a "medication sash" or designated, clearly identified areas for medication preparation can reduce the number of distractions. These visual cues signal a "cone of silence," i.e. the nurse should not be interrupted.

Secondary Driver: Standardize Concentrations and Minimize Dosing Options Where Feasible

Multiple concentrations and multiple dosing options can lead to error. One of the first nationwide changes occurred over thirty years ago when there were two concentrations 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 where given the same doses but of the U-100 concentration. These same principles apply to all high-alert medications. Too many options in dosing may lead to failure and sometime catastrophe (e.g., adult heparin in NICUs).

Secondary Driver: Timely Lab Results With Effective System to Ensure Review and Action

An established plan for monitoring should be implemented with all high alert medications, including type and frequency of monitoring. When laboratory values are used to monitor effects of HAMs, protocols for ordering, reviewing, and reporting these values should be implemented.

Secondary Driver: Use Non-Pharmacological Methods of Pain and Anxiety Management Where Appropriate

Changing environmental factors (lowering bright lights, decreasing noise levels, and achieving optimal temperature) can help manage a patient's pain and/or anxiety. Other ideas include the use of aromatherapy, distractions, music and touch therapy.

Secondary Driver: Manage "Look-Alike, Sound-Alike" Medications

Hospitals should create a list of look-alike/sound-alike medications it stores, dispenses, or administers and implement strategies to minimize potential errors for each. Such strategies include TALLMAN Lettering, separation on shelves and in unit based dispensing machines.

Change Ideas:
- Perform independent double checks.
- Use the "cone of silence" during medication administration.
- Use visual clues like HAM specific flags at bedside.
- INSULIN: Allow patient management of insulin where appropriate.
- INSULIN: Set limits on high dose orders.
- ANTICOAGULANTS: Use prepackaged heparin infusions; reduce the number of heparin concentrations in the hospital.
- ANTICOAGULANTS: Use low molecular weight heparin instead of unfractionated heparin whenever clinically appropriate.
- ANTICOAGULANTS: Make lab results available within 2 hours; create a closed system for elevated lab result management.
- ANTICOAGULANTS: Perform automatic nutrition consults for all patients on warfarin to avoid drug-food interactions.
- NARCOTICS/SEDATIVES: Use a table of drug-to-drug conversion doses.

Suggested Process Measures:
- The percent of critical inpatient lab results for patients receiving selected HAMs that have no documented action (failure rate).
- Medication pass (distribution) errors – observational.
- The number of interruptions during medication administration processes.
- The percentage of patients prescribed narcotics/sedatives that also receive non-pharmacological methods of pain and anxiety management.

"Hardwiring" Prevention of Failure as a Part of the Improvement Plan:

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

Hardwiring for ADE prevention may include routine reminders for double checks at the bedside by two licensed caregivers. Observations and chart reviews may also be used. If using an electronic medical record, implement a hard stop for the documentation of the double check.

Identification and Mitigation of Failure:

Once an ADE does happen, prompt identification and mitigation can reduce adverse outcome for the patient. Identification can also provide opportunities for learning and system redesign.

Secondary Drivers: Educate Patients/Families Regarding Risk of ADEs

Patients and families can be an ally with medication safety. In addition to staying alert for early warning signs, helping them to understand the benefits and potential risks of medications in their care will activate their role upon discharge. Education regarding self-management is much easier if the patient and caregiver are involved throughout the hospitalization with their medication management.

Secondary Driver: Transition to "Just Culture" for Improved Error Analysis

As previously mentioned, a "culture of blame" has not led to improved medication safety. As organizations become more successful implementing the "Just Culture," they concomitantly see improvements in reporting, more comprehensive error analysis and a greater likelihood of adopting system changes that lead to sustainable reductions in errors.

Secondary Driver: Prompt real time learning from each failure

Hospitals that learn rapidly and thoroughly from each failure and substantive "near miss" during medication management issues are better able and positioned to successfully implement safe practices. Understanding the actions and events shortly after an error occurs reduces memory bias. However, it is also a time that can be emotionally charged due to individual responses to errors and relating to patients, families, even colleagues. Yet, understanding failure and taking a broad systems view is crucial to reduction medication errors. Many recommend asking at least five "whys" when investigating an accident to force respondents to think about other influences that had an impact.

Change Ideas:
- Use clinical pharmacists to educate patient/family on their HAM(s).
- Monitor, understand, and mitigate medication administration delays.
- Assess culture with Agency for Healthcare Research and Quality Culture of Safety survey.[11]
- Use error-reporting system to allow aggregate learning to redesign error prone processes.
- Conduct an interdisciplinary failure modes and effects analysis (FMEA) in a non-punitive manner on prior ADE events to learn system breakdowns, knowledge gaps, and opportunities to correct for system re-design.
- Use technology to alert (real time) key staff when a rescue drug is administered.

Suggested Process Measures:
- Counts of "triggers" form the Medication Trigger Tool for HAMs.
- Percentage of patients re-admitted due to ADE complication.
- Medication pass (distribution) errors – observational.

"Hardwiring" Identification and Mitigation of Failure as Part of Improvement Plan:

Many of the interventions are not only implementation strategies but also hardwiring strategies. Hardwiring for ADE prevention includes:
- Routine reminders for double checks at the bedside of HAMs by two licensed caregivers .
(If using an electronic medical record, implement a hard stop for the documentation of the double check)
- Automatic notification of a pharmacist when rescue medications are administered.
- Routine review of anticoagulant orders by clinical pharmacists for appropriate dosage based on patient age and laboratory results.

Smart Use of Technology:

Utilizing technology effectively will help to identify and to mitigate errors. Technologies such as physician order entry, physician decision support, bar code scanning, and smart pumps, to name a few, have been demonstrated to improve drug safety.[45,46] Technologies such as these can: be used to identify errors made, identify steps leading

to those errors, prevent prescribing errors by using approved dosages and decision support, and prevent administration errors in any of the '5 Rights..[47]

Secondary Driver: Understand Potential Errors That Can Occur From Medication Delivery Devices

Automated devices, such as Patient Controlled Analgesia (PCA) pumps and smart pumps, can have unintended consequences. Since they are often used with HAMs, understanding the potential for errors for these devices is crucial to mitigating harm. Working with device manufacturers, reviewing the SMP website, and other literature and reports about potential errors gives a starting point to anticipating potential device errors.

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 be unsafe.

Secondary Driver: Use Data/Information From Alerts and Overrides to Redesign Standardized Processes

Requiring documentation for overriding makes the clinician think twice about going outside of guidelines and protocols. Furthermore, the "override reason" data can be mined to target education or improve the protocol. Additionally, measuring the override rate can provide clues about trends and patterns.

Secondary Driver: Link Order Sets to Recent Lab Values

Lab values for anticoagulants and antithrombotic agents need to be linked to a closed loop mechanism to ensure that they are seen, evaluated, and acted upon; this includes reevaluating the current treatment based on the lab values. Another option is to create a pharmacy driven protocol that allows for more immediate adjustment without a physician's order.

Change Ideas:
- 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
- Do not allow alert overrides without documented reason [48]

Suggested Process Measures:
- The device override rate (Note: An absolute "correct" rate is a myth; rather high-rates or increasing rates may indicate a potential safety problem or workflow issues causing more overrides)

"Hardwiring" Smart Use of Technology as Part of Improvement Plan:

Soft stops, hard stops, and alerts are all examples of hardwiring. A soft stop is a reminder that requires no action. It can be passed by pressing a key or clicking the mouse. A hard stop requires action. It cannot be passed without an appropriate action.

Potential Barriers:

- Recognize that for many physicians this will be a change in their practice. The use of alerts and stops and decision support may be new and invoke feelings of loss of control and "being told how to practice medicine." The recruitment of a physician champion or two that are well-respected among their physician colleagues will be crucial to help engage physicians in new processes and use of technology.
- These processes may be new territories for many physicians, nurses, and pharmacists. Technology involves a learning curve. Different practitioners will adapt at different rates.
- Physicians may resist standard orders, believing they are "cookbook medicine." Educating the physicians as to the actual nature of standard order sets, including both the built-in options for customization as well as the option for "opt out" can mitigate this resistance and increase adoption. Nurses may have many

fears in giving rescue medications by protocol without specific physician order. These fears may include creating patient harm, being disciplined, or receiving negative feedback from physicians. It is important that both nursing and physician leadership support these nurse driven orders and intercede when inappropriate behavior occurs.

- Some physicians are very uncomfortable reconciling medications ordered by other physicians. When asked about this hesitancy, medical legal liability along with lack of knowledge of certain drugs is the most common answer.
- Additionally, physicians may be circumspect about protocol operated by pharmacists, nurses or nurse practitioners. Some may have had a long track record of successful management of warfarin while many simply may be unaware of the advantages of these clinics.
- Technology for installing dosage and multiple (duplicative) therapy alerts may not be available at every facility.
- Resistance to the "cone of silence" may occur. Physicians' and other caregivers' workflow may be impacted if they need to wait to talk with a patient's nurse. The urge to interrupt with a "quick question" may be difficult to suppress.
- Nurses maybe uncomfortable providing rescue interventions based on a protocol without calling the physician first. Support by physician and nurse leadership and education on the benefits of such protocols could help to mitigate this resistance.

Use Administrative Leadership and Sponsorship to Help Remove or Mitigate Barriers:

- Executive, clinical, and human resource leaders must lead this effort. Leaders who employ blame and shame for errors drive them underground. It is critical that human resources and legal staff understand the new approach.
- Senior physician, senior nursing, and senior pharmacy management will be critical to the success of new innovations like we have discussed in the section. These may be perceived as something punitive (*timeliness audits*), something new and unfamiliar (*Consult a pharmacist? What's a hard stop?*), or additional work (independent double checks before administering a HAM).
- Physician leadership will be key. The data regarding the efficacy of both medication reconciliation and protocol driven warfarin clinics, coupled with the literature which supports these activities, and finalized by stories of the effects on patients when the when the traditional processes fail, will help overcome these barriers. As these processes prove to be in the best interest of patients (and in some cases easier for physicians), more and more physicians will adopt them until a critical mass is reached, transforming the quality of care.
- Senior leadership and pharmacy management support is critical to the implementation of double check requirements, as it may be seen solely as additional work.
- Purchasing and implementing new technology takes resources. Administrative leadership's support for securing the necessary resources to achieve goals in prevention of ADEs is essential. Phasing in capital purchases to the areas with highest yield can improve leadership willingness to support ADE programs.

This is Not Just a Change in Practice but May Also be a Change in Culture:

- This now should be obvious: improving medication safety is a clear move from a culture of blame to a culture of learning and system improvement. It is not, however, a creation of a blame-free environment. Reckless and unjustified behavior should not be tolerated.
- Standard processes work. As healthcare providers become more comfortable with them, the culture in fact changes. Clinicians can then focus on the patient characteristics that require deviation from standard work. Collectively, this combination of processes has been shown to outperform traditional methods.[49,50]

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- Including pharmacists in patient rounds and as consultants may require a change in culture. The concept of teaming is an important one to understand and that changes may be necessary. The change in practice may require education/in-services/simulation to improve caregivers' communication and conflict resolution skills.
- This is an example of an innovation that will require small test of changes and a planned spread driven by success. The ideal end result is the development of team based care where each member of the team (physician, nurse, respiratory therapist) contributes to better and safer patient care.

Tips for How to Use the Model for Improvement:

- Start safe. Trust is slowly earned. Consider beginning with the ARQH Culture of Safety tool [51] and the Institute of Safe Medication Practices self-assessment tool. [21]
- Create a multi-disciplinary team representing key stakeholder groups. Pick a HAM based on one of these common classes or your own data.
- 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 successes of this pilot to accelerate adoption.
- Pilot a program to minimize distraction during the medication administration process. Use data (# of interruptions, # of errors) to gain buy-in from physicians and other caregivers.
- Implement the double check policy of HAMs incrementally, reviewing for actual/potentials issues (e.g. delay of treatment), resources required and resource constraints.
- Design a small pilot on the unit where the lead physicians and nurses are comfortable with testing these medication administration design changes and protocols. To cite one study where they tried it in one unit, "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."[42]

References

[1]Leape, et al, The nature of adverse events in hospitalized patients, Results of the Harvard Medical Practice Study II. *New England Journal of Medicine*, 323, 377 – 384.

[2]Classen, et al, Adverse drug events in hospitalized patients: Excess length of stay, extra cost, and attributable mortality. *JAMA* 277:301 – 306, Jan. 22 – 29, 1997.

[3]Thomas and Brennan, The incidence and types of preventable adverse events in elderly population-based review of medical records. *BMJ* 320:741 – 744, Mar. 18, 2000.

[4]Budnitz, et al, Medication use leading to emergency department visits for adverse drug events in older adults. *Ann Intern Med*, 147:755 – 765, Dec. 4, 2007.

[5]Smetzer, et al, Findings from the IIS MP medication safety self-assessment for hospitals, *Jt. Comm J QualSaf*, 29:586-597, Nov. 2003

[6] The Joint Commission: The .Joint Commission announces the 2008 National Patient Safety Goals and Requirements. *Jt. CommPerspect*. 27:1, 9-22, Jul. 2007.

[7]Classen, et al, Adverse drug events among hospitalized Medicare patients: Epidemiology and national estimates from a new approach to surveillance. *Jt. Comm J QualSaf*, 36 (1):12-20, Jan. 2010.

[8] Getting Started Kit: Prevent Harm from High-Alert Medications How-to Guide. http://www.ihi.org/knowledge/Pages/Tools/HowtoGuidePreventHarmfromHighAlertMedications.aspx(last accessed March 8, 2012).

[9]Hull, et al. Continuous intravenous heparin compared with intermittent subcutaneous heparin in the initial treatment of proximal-vein thrombosis. *N Engl J Med*. 1986;315:1109-1114.

[10]Bates, et al. Incidence of adverse drug events and potential adverse drug events: Implications for prevention. ADE Prevention Study Group. *JAMA*. 1995;274:29-34

[11]Kanjanarat, et al. Nature of preventable adverse drug events in hospitals: A literature review. *Am J Health-Syst Pharm*. 2003;60:1750-1759.

[12]http://www.ahrq.gov/clinic/ptsafety/pdf/chap9.pdf (last accessed March 8, 2012).

[13] CHCA Improvement Case Study

[14]Looi-Lyons LC, Chung FF, Chan VW, McQuestion M. Respiratory depression: An adverse outcome during patient-controlled analgesia therapy. *J ClinAnesth*. 1996;8(2):151-156.

[15]Vicente KJ, Kada-Bekhaled K, Hillel G, Cassano A, Orser BA. Programming errors contribute to death from patient-controlled analgesia: Case report and estimate of probability. *Canadian Journal of Anesthesia*. 2003;50:328-332.

[16]*Computerized Order Entry on Inpatient Services Reduces Adverse Drug Events*.   Department of Pediatrics and Communicable Diseases, University of Michigan Health System. (last accessed March 8, 2012).

[17]Fonad E, et al. Falls and fall risk among nursing home residents. *J ClinNurs*. 2008;17:126-134.

[18]Runciman WB, Roughead EE, Semple SJ, Adams RJ.Adverse drug events and medication errors in Australia. *Int J Qual Health Care*. 2003;15Suppl 1:i49-59.

[19]Magee MF, Hospital protocols for targeted glycemic control: Development, implementation, and models for cost justification, *Am J Health-Syst Pharm*., Vol 64 May 15, 2007 Suppl 6

[20]http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1955339/(last accessed March 14, 2012).

[21] 2011 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Hospitals

[22]Hsaio et al, Nurses' knowledge of high-alert medications: instrument development and validation, *Journal of Advanced Nursing* 66(1), 177-190.

[23] Lu, M.-C.et al, Nurses' knowledge of high-alert medications, A randomized controlled trial, *Nurse Educ. Today* (2011).

[24] Safety Attitudes Questionnaire http://www.uth.tmc.edu/schools/med/imed/patient_safety/questionnaires/registration.html (accessed April 16, 2012)

[25] AHRQ Patient safety Instrument http://www.ahrq.gov/qual/patientsafetyculture/hospsurvindex.htm

[26]http://www.ismp.org/Newsletters/acutecare/actionagendas.asp (last accessed March 16, 2012)

[27] Institute for Healthcare Improvement High-Alert Medication Safety (Improvement Map) http://app.ihi.org/imap/tool/#Process=b8541097-7456-4aab-a885-38c31950e6bf (last accessed March 16, 2012)

[28] Institute for Safe Medication Practices High-Alert Medications http://ismp.org/Tools/highAlertMedications.asp (last accessed March 16, 2012)

[29] California Hospital Association Medication Safety Committee High Alert Medication Guidelines for Select Anticoagulants

http://www.cshp.org/uploads/file/Shared%20Resources/2012/guideline_anticoagulants_2.21.12.pdf (last accessed March 16, 2012)

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

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

[32] Institute for Healthcare Improvement High-Alert Medication Safety Knowledge Center
http://www.ihi.org/explore/HighAlertMedicationSafety/Pages/default.aspx (last accessed March 16, 2012)

[33] http://www.ismp.org/Tools/guidelines/default.asp (last accessed March 16, 2012)

[34] Hirsch, I, Sliding Scale Insulin: Time to Stop Sliding, *JAMA*, 2009;301(2):213-214

[35] Guyatt, et al, Executive Summary: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* February 2012: 141:2 suppl 7S-47S

[36] Solet, et al, Lost in Translation: Challenges and Opportunities in Physician-to-Physician Communication During Patient Handoffs, *Academic Medicine*: December 2005; 80 (12):1094-1099

[37] Patterson, et al, Patient Handoffs: Standardized and Reliable Measurement Tools Remain Elusive, *Joint Commission Journal on Quality and Patient Safety*; 36 (2), February 2010 :52-61

[38] Nutescu, E, Anticoagulation Management Services: Entering a New Era, *Pharmacotherapy*: Volume 30, 2010, 327-329.

[39] Leape, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit, *JAMA* 282(3):267-270, 1999.

[40] Kucukarslan, et al. Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medicine units. *Arch Intern Med* 163:2014-2018, 2003.

[41] **Leape LL**, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients.Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991;**324**:377–84.

[42] **Bates DW**, Boyle DL, Vander Vliet MB, et al. Relationship between medication errors and adverse drug events. *J Gen Intern Med* 1995;**10**:199–205.

[43] Agency for Healthcare Research and Quality. Medication administration safety. In: Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville, MD: Agency for Healthcare Research and Quality; 2008: chap 37. *AHRQ* publication 08–0043.

[44] Anthony, K., Wiencek, C., Bauer, C., No interruptions please: impact of a no interruption zone on medication safety in intensive care units. *Crit Care Nurse* 30(3): 21-29, June 2010.

[45] Bates DW.Using information technology to reduce rates of medication errors in hospitals.*BJM*. 2000;320:788.

[46] Ammernwerth E, Schjnell-Inderst P, Machan C, Siebert U. The effect of electronic prescribing on medication errors and adverse drug events: A systematic review. *J Am Med Informatics Assoc*. 2008;15(5):585-600.

[47] Crane J, Crane FG. Preventing medication errors in hospitals through a systems approach and technological innovation: A presecription for 2010.*Hosp Top.* 2006 Fall;84(4):3-8.

[48] Miller et al, Bar Code Medication Administration Technology: Characterization of High-Alert Medication Triggers and Clinician Workarounds, *The Annals of Pharmacotherapy* 2011 Feb Vol 45, 162-168

[49] Protocol Based Care, Quality and Service Improvement Tools, National Health Service Institute for Innovation and Improvement
http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/protocol_based_care.html (last accessed March 17, 2012)

[50] Society of Hospital Medicine Glycemic control Resource Room
http://www.hospitalmedicine.org/ResourceRoomRedesign/html/12Clinical_Tools/01_Insulin_Orders.cfm (last accessed March 17, 2012)

[51] Agency for Healthcare Research and Quality Hospital Survey on Patient Safety Culture
http://www.ahrq.gov/qual/patientsafetyculture/hospsurvindex.htm (last accessed March 16, 2012)