



# Getting Started Kit: Prevent Harm from High-Alert Medications

## How-to Guide

### 5 Million Lives Campaign

We invite you to join the 5 Million Lives Campaign, a national initiative to dramatically improve the quality of American health care. The Institute for Healthcare Improvement (IHI) and its partners seek to engage thousands of U.S. hospitals in an effort to reduce harm for five million American patients between December 2006 and December 2008. This ambitious work builds upon the great energy and commitment shown by hospitals during the 100,000 Lives Campaign, a national, IHI-led initiative that focused on reducing unnecessary mortality and ran from December 2004 to June 2006. Complete details, including materials, contact information for experts, and web discussions, are on the web at <http://www.ihi.org/IHI/Programs/Campaign/>.

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*This How-to Guide is dedicated to the memory of David R. Calkins, MD, MPP (May 27, 1948 – April 7, 2006) -- physician, teacher, colleague, and friend -- who was instrumental in developing the Campaign's science base. David was devoted to securing the clinical underpinnings of this work, and embodied the Campaign's spirit of optimism and shared learning. His tireless commitment and invaluable contributions will be a lifelong inspiration to us all.*

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**Scientific Contributors**

Several organizations have generously offered advice and have made scientific contributions to this document. They include:

American Society for Health-System Pharmacists  
Institute for Safe Medication Practices

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**Goal:** Prevent harm from high-alert medications by implementing the changes in care recommended in this Guide.

**What Are High-Alert Medications?**

High-alert (or high-hazard) medications are medications that are most likely to cause significant harm to the patient, even when used as intended. The Institute for Safe Medication Practices (ISMP) reports that, although mistakes may not be more common in the use of these medications, when errors occur the impact on the patient can be significant.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), referring to ISMP's work, describes high-alert medications as those "that have the highest risk of causing injury when misused" ("[High-Alert Medications and Patient Safety](#)." Joint Commission *Sentinel Event Alert*. November 19, 1999).

Based on reports submitted to ISMP, a review of literature, and the experience of many hospitals around the country, the list of high-alert medications includes as many as 19 categories and 14 specific medications. Although it is important to improve management of all of these medications, some of them are used more frequently and the resulting harm from this subset may be more significant.

Based on the findings from use of the [Global Trigger Tool](#) and experience from hospitals that have participated in the Institute for Healthcare Improvement's (IHI's) Collaboratives, the Campaign has chosen to focus on four groups of high alert-medications — anticoagulants, narcotics and opiates, insulins, and sedatives — because they represent areas of greatest harm and greatest opportunity for improvement. The most common types of harm associated with these medications include hypotension, bleeding, hypoglycemia, delirium, lethargy, and bradycardia.

The Campaign recommends that teams begin improving processes with at least one of these medication groups and then expand to include all four groups.

## **Why Focus on Reducing Harm from High-Alert Medications?**

High-alert medications are more likely to be associated with harm than other medications. Although any medication used improperly can cause harm, high-alert medications cause harm more commonly and the harm they produce is likely to be more serious. The harm leads not only to patient suffering, but also to additional costs associated with care of these patients. Known safe practices can reduce the potential for harm.

- The Institute of Medicine (IOM) Committee on Identifying and Preventing Medication Errors estimated that at least 1.5 million preventable adverse drug events (ADEs) occur each year in the United States.

Committee on Identifying and Preventing Medication Errors. Aspden P, Wolcott J, Bootman JL, Cronenwett LR, Editors. *Preventing Medication Errors: Quality Chasm Series*. Washington, DC: National Academies Press; July 2006.

- Several studies have identified adverse drug events as the most frequent single source of health care mishaps, continually placing patients at risk of injury.

Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: A practical methodology for measuring medication-related harm. *Qual Saf Health Care*. 2003;12:194-200.

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

Bates DW, Cullen DJ, Laird NM, et al. Incidence of adverse drug events and potential adverse drug events: Implications for prevention. *JAMA*. 1995;274:29-34.

Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. *JAMA*. 1997;277:312-317.

Ebbesen J, Juajordet I, Erikssen J, et al. Drug-related deaths in a department of internal medicine. *Arch Intern Med*. 2001;161:2317-2323.

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- Based on a rate of 400,000 adverse drug events per year in hospitalized patients, the IOM Committee estimated that ADEs accounted for \$3.5 billion (in 2006 dollars) of additional costs incurred by hospitals.

Committee on Identifying and Preventing Medication Errors. Aspden P, Wolcott J, Bootman JL, Cronenwett LR, Editors. *Preventing Medication Errors: Quality Chasm Series*. Washington, DC: National Academies Press; July 2006.

- According to a review of events in an adverse drug reaction database of 317 preventable ADEs, “analysis and categorization by type of error and outcome suggested that three high-priority preventable ADEs accounted for 50% of all reports: (1) overdoses of anticoagulants or insufficient monitoring and adjustments (according to laboratory test values) were associated with hemorrhagic events, (2) overdosing or failure to adjust for drug-drug interactions of opiate agonists was associated with somnolence and respiratory depression, and (3) inappropriate dosing or insufficient monitoring of insulins was associated with hypoglycemia.”

Winterstein AG, Hatton RC, Gonzalez-Rothi R, Johns TE, Segal R. Identifying clinically significant preventable adverse drug events through a hospital's database of adverse drug reaction reports. *American Journal of Health-System Pharmacy*. 2002 Sep;59(18):1742-1749.

- Eckman et al. estimated the cost of an inpatient major anticoagulation-related bleed as ranging from \$3,000 to \$12,000.

Eckman MH, Levine HJ, Salem DN, Pauker SG. Making decisions about antithrombotic therapy in heart disease: Decision analytic and cost-effectiveness issues. *Chest*. 1998;114:699-714.

Adverse drug events can be reduced significantly by implementing recognized safety measures, such as standardizing and simplifying core medication processes in known high-risk areas, redesigning delivery systems using proven human factors principles, partnering with patients, and creating safety cultures that minimize blame and maximize communication.

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Improving medication management entails not only reducing errors, but also implementing changes that reduce harm or adverse events. Not all harm is the result of errors. Some harm may be prevented by improving medication management, changing prescribing patterns, adding other therapies to minimize untoward side effects, and identifying harm soon enough to be able to mitigate it before it becomes serious.

Note: High-alert medications can also be linked to other care processes and Campaign interventions, such as medication reconciliation, care of the ventilated patient (DVT prophylaxis), and perioperative care. In some cases, rapid deterioration of a patient may be caused by, or aggravated by, medications.

Oral anticoagulation management and care of the diabetic patient spans the continuum of care. Improving the care of patients receiving these medications will necessitate examining larger system issues and partnering with patients.

## **Anticoagulants: The Evidence**

Anticoagulants such as intravenous heparin and oral warfarin are commonly used to treat cardiac disease and thromboembolism in both the inpatient and outpatient setting. Although anticoagulants are used widely, there continue to be errors and a lack of appropriate and consistent management for the treatment of these patients. The effects of warfarin, which has a narrow therapeutic index, are easily altered by interactions with other medications, herbals, OTC products, and food. Reliable processes are needed to achieve desired INR consistently, and to assure appropriate management of anticoagulated patients before and after surgery.

- Lack of dosing guidelines and appropriate monitoring can lead to serious harm associated with this class of medications.

Hull RD, Raskob GE, Hirsh J, 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.

- In a study by Bates et al., anticoagulants accounted for 4% of preventable ADEs and 10% of potential ADEs.

Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events: Implications for prevention. ADE Prevention Study Group. *JAMA.* 1995;274:29-34.

- A literature review by Kanjanarat et al. reports that anticoagulation therapy is associated with serious and frequent ADEs in both inpatients and outpatients.

Kanjanarat P, Winterstein AG, John TE, et al. Nature of preventable adverse drug events in hospitals: A literature review. *Am J Health-Syst Pharm.* 2003;60:1750-1759.

*Monitoring adverse drug events: Finding needles in the haystack.* Irving, TX: VHA; 2002.

- Warfarin and insulins, both of which typically require ongoing monitoring to prevent overdose or toxicity, caused one in every seven estimated adverse drug events treated in emergency departments (14.1%; 95% confidence interval 9.6%

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to 18.6%); and more than a quarter of all estimated hospitalizations (871 cases, 95% confidence interval 17.3% to 35.2%). In the elderly, insulin, warfarin, and digoxin were implicated in one in every three estimated adverse drug events treated in emergency departments (1,592 cases, 33.3%; 95% confidence interval 27.8% to 38.7%); and 41.5% of estimated hospitalizations (646 cases, 95% confidence interval 32.4% to 50.6%).

Budnitz DS, Pollock DA, Weidenbach KN, et al. National surveillance of emergency department visits for outpatient adverse drug events. *JAMA*. 2006;296:1858-1866.

- Warfarin is commonly involved in ADEs for a number of reasons. These include the complexity of dosing and monitoring, patient compliance, numerous drug interactions, and dietary interactions that can affect drug levels. Strategies to improve both the dosing and monitoring of these high-alert medications have potential to reduce the associated risks of bleeding or thromboembolic events.  
<http://www.ahrq.gov/clinic/ptsafety/pdf/chap9.pdf>

## **Narcotics and Opiates: The Evidence**

Pain management is an important component of patient care. Implementing appropriate pain management protocols not only ensures that patients receive pain relief, but also minimizes opportunities for errors and harm. Effective pain control is integral to good health and to recovery from injury, surgery, and illness. The goal of pain management is the control of pain to enable optimal function of the patient such as participation in rehabilitation activities, deep breathing to prevent atelectasis, and mobilization to prevent DVTs, as well as full participation in life for outpatients. Fear of addiction may be a concern for some clinicians when dealing with chronic pain management in any setting. At this time the Campaign interventions focus on appropriate pain management in the hospital setting.

Many patients may experience harm even with appropriate dosing of narcotics. The most common kinds of harm include over-sedation, respiratory depression, confusion, lethargy, nausea, vomiting, and constipation. Much of this harm can be prevented with appropriate dosing or choosing of a different method of pain relief.

- In a study by Kanjanarat et al., contributing factors to two common adverse outcomes were warfarin overdose and inappropriate monitoring resulting in hemorrhage, and opioid overdose or underdose associated with respiratory depression or poor pain control.

Kanjanarat P, Winterstein AG, John TE, et al. Nature of preventable adverse drug events in hospitals: A literature review. *Am J Health-Syst Pharm.* 2003;60:1750-1759.

- During a Collaborative of pediatric hospitals led by Child Health Corporation of America (CHCA), participating hospitals identified a rate of 5.2 narcotic-related ADEs for every 100 patients.

CHCA Improvement Case Study

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- Patient-controlled analgesia (PCA) also poses potential for harm. Looi-Lyons et al. identified that episodes of respiratory depression were associated with drug interactions, continuous narcotic infusion, nurse- or physician-controlled analgesia, and inappropriate use of PCA by patients.

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

- Vicente et al. reported that mortality from user programming errors with PCA pumps was 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).

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.

- The most common side effects in Chinese patients reported in a study by Tsui et al. included nausea (34.5%) and vomiting (18.2%). Bradypnea and oxygen desaturation occurred in 0.5% and 1.6% respectively.

Tsui SL, Wong WN, Irwin M, et al. The efficacy, applicability and side effects of postoperative intravenous patient-controlled morphine analgesia: An audit of 1233 Chinese patients. *Anaesthesia and intensive care.* 1996;24(6):658-664.

## **Insulins: The Evidence**

Insulins are effectively used to treat diabetics and elevated blood sugars in postoperative patients. The goal of therapy is to achieve control without causing immediate harm associated with hypoglycemia or long-term harm associated with hyperglycemia. The pharmacology of the drug, complexity of dosing, and variety of products all contribute to the potential for error and associated harm.

- Donihi et al. reported a rate of 55.9 hypoglycemia events per 100 treated days before implementation of a sliding-scale protocol.

Donihi AC, DiNardo MM, DeVita MA, Korytkowski MT. Use of a standardized protocol to decrease medication errors and adverse events related to sliding scale insulin. *Quality and Safety in Health Care*. 2006;15:89-91.

- Hypoglycemia is the most common complication of any insulin therapy and is an extremely frequent adverse event in hospitals worldwide.

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

## **Sedatives: The Evidence**

Sedatives are a necessary component of an armamentarium to treat patients in the hospital setting. Examples of medications in this class include midazolam and chloral hydrate. Patients in hospitals may require sedation prior to procedures and during the hospital stay. However, inappropriate use may result in over-sedation, hypotension, delirium, and lethargy, and may contribute to the risk of falling. An ISMP survey identified benzodiazepines in patients over 65 (e.g., alprazolam) as high alert.

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.

- In a study of sedation of children, 239 (20.1%) experienced adverse events related to sedation, including inadequate sedation in 150 (13.2%) and decrease in oxygen saturation in 63 (5.5%). Five of these children experienced airway obstruction and two became apneic.

Malviya S. Adverse events and risk factors associated with the sedation of children by nonanesthesiologists. *Anesth Analg*. 1997;85:1207-1213.

- Multiple sedative use accounted for 42% of preventable ADEs in the intervention group.

*Computerized Order Entry on Inpatient Services Reduces Adverse Drug Events.*  
[Department of Pediatrics and Communicable Diseases, University of Michigan Health System.](#)

## **General Principles for Reducing Harm from High-Alert Medications**

Hospitals and other care settings should employ the following principles of a safe system:

1. Design processes to *prevent* errors and harm.
2. Design methods to *identify* errors and harm when they occur.
3. Design methods to *mitigate* the harm that may result from the error.

### 1. Methods to *prevent* harm include:

- Develop order sets, preprinted order forms, and clinical pathways or protocols to reflect a standardized approach to treat patients with similar problems, disease states, or needs.  

Institute for Safe Medication Practices. Designing preprinted order forms that prevent medication errors. *ISMP Medication Safety Alert!* April 23, 1997.
- Minimize variability by standardizing concentrations and dose strengths to the minimal few needed to provide safe care.
- Consider pharmacist- or nurse-run anticoagulation services.
- Include reminders and information about appropriate monitoring parameters in the order sets, protocols, and flow sheets.
- Consider protocols for vulnerable populations such as the elderly.

### 2. Methods to *identify* errors and harm include:

- Include reminders and information about appropriate monitoring parameters in the order sets, protocols, and flow sheets.
- Ensure that critical lab information is available to those who need the information and can take action.
- Implement independent double-checks where appropriate.

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3. Methods to *mitigate* harm include:

- Develop protocols allowing for the administration of reversal agents without having to contact the physician.
- Ensure that antidotes and reversal agents are readily available.
- Have rescue protocols available.

## **Key Components of Appropriate Management of High-Alert Medications**

The following recommendations are based on published literature and on experience from hospitals that have participated in IHI Collaboratives on medication safety.

Although some of the recommended changes may not have undergone the rigors of double-blind studies, they have been gathered carefully and critically from hospitals with a demonstrated reduction in harm.

For each category of high-alert medications — anticoagulants, narcotics, insulin, and sedatives — we have grouped the recommended changes in the following categories:

- Suggested Changes: A sampling of the most effective changes for this medication
  
- Changes designed to ensure standardization (See “1: Design processes to *prevent* errors and harm” above.)
  
- Changes designed to ensure adequate monitoring (See “2: Design methods to *identify* errors and harm when they occur” above.)
  
- Changes designed to better partner with patients and families (See “3: Design methods to *mitigate* the harm that may result from the error” above.)

## **Changes to Improve Management of Anticoagulants**

### ALL ANTICOAGULANTS

#### Suggested Changes:

- Format anticoagulation flow sheet and orders to follow the patient through transitions from hospital to skilled care to home.
- Use an anticoagulant dosing service or "clinic" in inpatient and outpatient settings.

### HEPARIN

#### Suggested Changes:

- Implement weight-based heparin protocol; limit these to no more than one or two protocols.
- Use preprinted order forms or ordering protocols.
- Ensure that heparin dosing protocols account for the use of thrombolytics and GIIg/IIIa inhibitors.
- Ensure that heparin cannot be administered within 6-12 hours of a dose of LMWH.
- Use standard concentrations in OR, ER, and the ICUs.
- Separate like products when using or storing.
- Dispense the anticoagulant medication from pharmacy only.
- Use smallest size package, concentration, and dose for floor stock.

#### Changes Designed to Ensure Standardization:

- Implement standardize protocols and dosing.
- Establish guidelines to hold heparin and provide reversal therapy for heparin over-anticoagulation.
- Simplify by minimizing available concentrations.

## WARFARIN

### Suggested Changes:

- Because warfarin has such a narrow therapeutic index, appropriate dosing and monitoring are critical. Since ongoing therapy occurs in the ambulatory setting, engaging patients by ensuring that they understand how to take the medication, other medications that should be avoided, and identification of symptoms that indicate harm is critical.
- Simplify by minimizing available concentrations and strengths of oral formulations.

### Changes Designed to Ensure Standardization:

- Standardize protocols and dosing.
  - Standardized protocols for the initiation and maintenance of warfarin therapy including Vitamin K dosing guidelines.
  - Develop a protocol, based on evidence, to discontinue and restart warfarin perioperatively.
- Make information available; for example, improve access to lab results and/or use of point-of-care testing in order to determine doses.
- Ensure appropriate monitoring and dose management through a centralized anticoagulation service.

Standardizing the steps to initiate and maintain treatment reduces variation and makes the process easier for nurses and pharmacists to support. Studies have shown that strategies to improve prescribing and monitoring have the potential to reduce adverse events such as bleeding or thromboembolic events.

### Changes Designed to Ensure Adequate Monitoring:

- Make lab results available on the unit within two hours, or monitor at the bedside.
- Plot INR results versus dose changes on run chart or control chart.

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Changes Designed to Ensure Better Partnering with Patients and Families:

Randomized trials show that patient control of anticoagulation is as good as, or even better than, management by usual care or by an anticoagulation clinic. Although self-management may not be appropriate for all patients, motivated patients can successfully comply with monitoring and dosing protocols.

[Protocols for High-Risk Drugs: Reducing Adverse Drug Events Related to Anticoagulants](#)

- Engage patients by developing educational programs and training, at an appropriate literacy level, to include self-monitoring and how to avoid drug and food interactions.
- Use medication reconciliation to improve handoffs of medication information.
- Work with patients to carry an accurate list of medications all the time.

## **Changes to Improve Management of Narcotics**

Appropriate dosing of narcotics should provide appropriate pain relief with resulting adverse events. Factors that contribute to harm with narcotics include errors in calculation, errors in conversion of IV to PO, confusion in potency when changing drugs, and errors in delivery by the intravenous route.

### Suggested Changes:

- Standardize protocols for the initiation and maintenance of pain management.
- Use appropriate monitoring for adverse effects of narcotics and opiates.
- Make available protocols and reversal agents that can be administered without additional physician orders.
- Consult a pain specialist if the managing physicians are not knowledgeable about pain control. Pain specialists vary in different settings; they may be specially trained nurses, pharmacists, physicians, or others.
- Increase the use of non-pharmacologic intervention for pain and anxiety.
- Set up all pumps to be programmed with an independent double-check from pharmacy or nursing staff.
- Perform independent double-checks on the unit for PCA and epidural narcotics.
- Minimize or eliminate multiple drug strengths where possible.

### Changes Designed to Ensure Standardization:

- Use protocols and pre-printed orders where possible for PCA, postoperative pain management, and sedation, as well as for epidural, intrathecal pain management.
  - Include dose calculations, maximum bolus doses, monitoring guidelines, and options for non-opioid analgesics.
- Establish a standard naloxone regime that can be given before calling physician.

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Changes Designed to Ensure Adequate Monitoring:

- Standardize monitoring protocols (including documentation) of vital signs and pain score following each dose. Serious over-sedation is seldom due to overt error but is nonetheless quite preventable. Efforts must be interdisciplinary and include anesthesia and recovery room.

Changes Designed to Ensure Better Partnering with Patients and Families:

- Dose narcotics to a pain score mutually agreed upon by patient and clinicians prior to procedures. Patients may have unrealistic expectations of zero pain post-operatively. There may also be a disconnect between the expectations of the clinician and those of the patient regarding post-op pain. Establishing mutual expectations pre-operatively can be a valuable way to reduce over-sedation without minimizing pain relief.
- Use medication reconciliation to improve handoffs of medication information.

## **Changes to Improve Management of Insulin**

Injectable insulin has improved the quality of life and longevity of diabetic patients. However, poor management can lead to hyperglycemia or hypoglycemia, each of which can cause harm to the patient. A number of suggested strategies can decrease errors and related harm.

### Suggested Changes:

- Require an independent double-check of the drug, concentration, dose, pump settings, route of administration, and patient identity before administering all IV insulin.
- Use pre-typed diabetic and insulin infusion orders.
- Separate look-alikes and sound-alikes by labeling, by time, and by distance.
- Prepare all infusions in the pharmacy and standardize to a single concentration of IV-infusion insulin.
- Have patients manage their own insulin if they are capable.
- Coordinate meal and insulin times.

### Changes Designed to Ensure Standardization:

- Eliminate the use of sliding insulin dosage scales; if a sliding scale is used, standardize it through the use of a protocol and preprinted order form or computer order set that clearly designates the specific increments of insulin coverage.
- Standardize to single concentration of IV infusion insulin.
- Use a diabetic management flow sheet.

### Changes Designed to Ensure Adequate Monitoring:

- Ensure appropriate monitoring through more rapid testing of blood sugars.
- When prescribing insulin, include or refer to defined standards for laboratory testing and clinical monitoring of patients.

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Changes Designed to Ensure Better Partnering with Patients and Families:

- Allow and encourage patient self-management (or parents for young pediatric patients) when patients and parents are capable and willing.
- Encourage patients to question doses and timing of insulin administration.

## **Changes to Improve Management of Sedatives**

### Suggested Changes:

- Stock and prescribe only one concentration of oral moderate sedation agents.
- Establish preprinted order forms for ordering narcotics and sedatives.
- Monitor all children who have received chloral hydrate for pre-operative sedation before, during, and after the procedure.
- Have age- and size-appropriate resuscitation equipment and reversal agents available wherever the medications are administered, and during procedures that are performed when the patient is under sedation.

### Changes Designed to Ensure Standardization:

- Use dosing protocols and automatic dose reductions for benzodiazepines and other sedatives and hypnotics in target populations.

### Changes Designed to Ensure Adequate Monitoring:

- Monitor patients for respiratory depression, as evidenced by decreased oxygen saturation or increased CO<sub>2</sub> levels, by using pulse oximeters and capnographers.
- Integrate documentation of medications and patient vital sign data to recognize predictable and preventable trends reflected by vital signs, patient lab values, and drug interactions (respiratory rate, hypotension, increased level of sedation).

### Changes Designed to Ensure Better Partnering with Patients and Families:

- Educate patients regarding hypotension and dizziness upon rising.
- Provide adequate lighting, especially at night.
- Anticipate and schedule toileting for high-risk patients.
- Evaluate medication list with patient for additive risk of sedation.

## **Forming the Team and Setting Your Aim**

Before starting any improvement work, it is always wise to establish the aim of the work. In this Campaign intervention, the aim is to prevent harm and save lives by improving the prescribing and management of specific categories of high-alert medications.

A team should develop an aim. **The aim statement** should include 1) a clear statement of purpose, 2) a measurable goal, 3) a description of how this will be done, and 4) a specific timeframe.

The overall goal of this Campaign intervention is to *prevent all harm from high-alert medications*. Hospitals may set specific aim statements in pursuit of this overall goal. These aim statements might target specific medications, specifying percentage reductions within a set timeframe. A sample aim statement follows: “Decrease the incidence of adverse events associated with warfarin by 50% on the medical patient care unit within nine months.”

Note: This is only meant to be an example; your team should develop its own aim statement so that the team will feel ownership and support it. If your organization is enrolled in the Campaign, the wording may be very similar to the example, but be sure the team discusses and adopts it first.

From the suggested interventions, teams should select key stakeholders in the organization who have essential roles in ensuring that patients receive the medication appropriately. An example of a team follows:

- Physician who regularly prescribes anticoagulants or narcotics
- Nurse from the patient care unit
- Pharmacist

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One person, not necessarily the physician, should serve as the team's day-to-day leader who can apply expertise to (or acquire expertise in) using Plan-Do-Study-Act cycles and testing changes on a small scale.

Additional team members might also include:

- Quality Director
- Risk Manager
- Representative from Information Technology

(Note: In addition, consider including a patient or family member on the team.)

In order to be most effective, a core team of no more than five to seven people should oversee the work. As different changes are tested, other key people in the organization can be included on an ad hoc basis, especially if they can offer some special expertise that is limited to one area of the work. For example, if your hospital has a computerized order entry system, you may want to include a representative from Information Technology. (It would not be necessary to include that person in all meetings about anticoagulation care, since not all of the work will apply to that department.)

Another approach to the improvement work is to create sub-teams to work on specific components of anticoagulation management. One sub-team might deal with patient education. Another sub-team might work on reviewing patient education materials and testing the timing of when a patient should receive that information. Another group might focus on a high-risk process such as medication distribution or storage. These are just a few examples of sub-teams, which can be an effective way to divide the work and achieve improvement more quickly. The sub-teams should report their work and results to the core team, which oversees the entire project and ensures coordination.

## **Using the Model for Improvement**

In order to move this work forward, IHI recommends using the Model for Improvement. Developed by Associates in Process Improvement, the Model for Improvement is a simple yet powerful tool for accelerating improvement that has been used successfully by hundreds of health care organizations to improve many different health care processes and outcomes.

The model has two parts:

- Three fundamental questions that guide improvement teams to 1) set clear aims, 2) establish measures that will tell if changes are leading to improvement, and 3) identify changes that are likely to lead to improvement.
  
- The Plan-Do-Study-Act (PDSA) cycle to conduct small-scale tests of change in real work settings — by planning a test, trying it, observing the results, and acting on what is learned. This is the scientific method, used for action-oriented learning.

Implementation: After testing a change on a small scale, learning from each test, and refining the change through several PDSA cycles, the team can implement the change on a broader scale — for example, for an entire pilot population or on an entire unit.

Spread: After successful implementation of a change or package of changes for a pilot population or an entire unit, the team can spread the changes to other parts of the organization or to other organizations.

You can learn more about the Model for Improvement on [www.IHI.org](http://www.IHI.org).

### **Sample First Test of Change**

In the Model for Improvement, teams conduct small tests of change to start improvement work. With this approach, team members can learn quickly what works or how changes need to be refined before full implementation.

#### Example: Implementing a warfarin dosing protocol

Goal: Reduce harm associated with warfarin initiation.

Change: Develop and implement a warfarin dosing protocol.

Scale: 1 physician, 1 nurse, 1 patient

#### Plan:

1. Educate staff about the small test of change.
2. Either develop a protocol or use one developed by another organization.
3. Identify who, what, where, and when of the test.
4. Complete the test.
5. Huddle with the team to discuss.

When preparing a test, include your predictions of what will happen. After you conduct the test, answer questions about your predictions; for example, in this case:

Physician will be able to use the protocol easily.      Yes or No

The protocol fits into the flow of our work.      Yes or No

The protocol does not add any time to the process.      Yes or No

If the answer to any question is “No,” find out why and modify the protocol and retest.

## **Measurement Strategies for High-Alert Medications**

Successful measurement is a cornerstone of successful improvement. In order to make measurement meaningful:

- Use sampling to make measurement efficient.
- Integrate measurement into people's daily routine.
- Plot data on the measures over time, and post your results so that teams can see their progress.

When thinking about your measurement strategy and picking measures, it is useful to consider two types of measures: process and outcome. Process measures tell you what your care delivery system is doing. Outcome measures describe the results of that system. A good measurement scheme should include both process and outcome measures.

However, if you're just starting, it makes sense to ask some basic yes-or-no questions before starting measurement in earnest. These questions can tell you a lot very quickly, before you invest the time to set up a more rigorous, long-term measurement structure. For high-alert medication work, ask the following yes-or-no questions:

1. Have you developed a protocol or order set for all appropriate medications?
2. Is the protocol or order set being used?
3. If you have developed forms, are the forms being used as designed?
4. Have you developed dose-conversion charts to minimize errors when changing from one medication to another? For pain medications?
5. If you have developed dose conversion charts, are they being used?

To answer these questions, use a sample of, at most, ten charts per week on the unit where you are testing the new process. The information you gather from this relatively easy exercise can focus your work at the beginning of an improvement project and

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allow the team to identify areas for improvement quickly. Once you've started to address these initial issues you can begin more rigorous measurement in earnest.

Recommended Measures

In Appendix A you will find a list of measures that the Campaign recommends for measuring the progress of your improvement work. They are divided into process and outcome measures.

You need not use all of these measures, and you may choose measures that are not listed, as appropriate for your setting. These measures are designed to provide you and your team with the tools necessary to support your own improvement work, not necessarily to allow comparison of your hospital to other hospitals or to create a national benchmark.

Process Measures

The recommended process measures begin with a set of four measures—one for each category of high-alert medication—that track whether medications are ordered, received, and managed in compliance with the appropriate protocol:

- Percent of Patients Receiving Narcotic with Treatment Appropriately Managed According to Protocol;
- Percent of Patients Receiving Anticoagulant with Treatment Appropriately Managed According to Protocol;
- Percent of Patients Receiving Insulin with Treatment Appropriately Managed According to Protocol; and
- Percent of Patients Receiving Sedative with Treatment Appropriately Managed According to Protocol.

We recommend that these measures serve as the core of your process measurement within each high-alert medication category. If the results are at 80% or less, you do not

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have a reliable process; you have chaos. The goal is to be at a level of performance where all patients who are eligible for treatment are treated according to the protocol.

We have also listed two measures—really two ways of looking at the same process—used in the 100,000 Lives Campaign Medication Reconciliation intervention, which also have relevance in High-Alert Medication improvement projects: Percent of Unreconciled Medications, and Unreconciled Medications per 100 Admissions. A working medication reconciliation process is an important contributor to high-alert medication improvement.

#### Outcome Measures

Adverse drug events present the single greatest risk of harm to patients in hospitals. Traditional efforts to detect ADEs have focused on voluntary reporting and tracking of errors. However, public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients. Hospitals need a more effective way to identify events that do cause harm to patients, in order to select and test changes to reduce harm. Tracking harm related to high-alert medications—rather than errors—is a useful way to tell if changes the team is making are improving the safety of the medication system.

As the primary measure of outcomes, we recommend use of the [IHI Global Trigger tool](#)—focusing on triggers associated with ADEs—to detect ADEs associated with the four categories of high-alert medications. Similar to the measurement of compliance on the process side, we recommend four measures, one for each category of high-alert medications:

- Adverse Drug Events Related to Narcotic per 100 Admissions with Narcotic Administered;
- Adverse Drug Events Related to Anticoagulant per 100 Admissions with Anticoagulant Administered;
- Adverse Drug Events Related to Insulin per 100 Admissions with Insulin Administered; and

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- Adverse Drug Events Related to Sedatives per 100 Admissions with Sedative Administered.

The IHI Global Trigger Tool is a chart review aid that, when combined with appropriate sampling, allows an organization to efficiently uncover harm. The triggers in the Medication Module and the Care Module of the Global Trigger Tool should be used for this measure, which focuses on ADEs rather than all harm. Strategies for appropriate sampling and targeting of patient populations relevant to high-alert medication improvement work are discussed in the Measure Information Form (MIF) linked to in Appendix A.

We also recommend a set of measures that are sensitive to the individual categories of high-alert medications targeted by this intervention:

- Percent of Patients Receiving Warfarin with INR Outside Protocol Limits;
- Percent of Patients Receiving Heparin with aPPT Outside Protocol Limits;
- Percent of Patients Receiving Insulin with Blood Glucose Level Outside Protocol Limits;
- Percent of Patients Receiving Narcotic Who Receive Subsequent Treatment with Naloxone; and
- Percent of Patients Receiving Sedative Who Receive Subsequent Treatment with Flumazenil.

While these measures do not measure harm directly, they can serve as more-easily-collected proxies for negative clinical outcomes associated with high-alert medications. Additionally, because they identify patients with undesirable conditions, these measures can and should be used as starting points in case-by-case investigations of how the care system may have failed.

## **Tips for Getting Started**

Improving the management of high-alert medications can seem like an overwhelming challenge. Many Campaign hospitals may have already made changes; others may still be struggling. Even if you have made changes, have you been able to sustain the improvement?

If your team tries to do everything all at once, it may well prove overwhelming. Here are a few tips we have learned from other quality improvement work and from those who have already achieved success in reducing harm from high-alert medications:

1. Segment the population. Rather than trying to improve care for every patient at the same time, begin by working with patients whose treatment is initiated in-house. This does not imply that all patients should not receive the same care. It is an approach to speed up the improvement process for those patients where you are the most likely to succeed. Once your team has implemented improvements with this group, spread the improvements to other groups.
2. Start by designing for a homogeneous population and control as many variables as possible to test the design. There will always be exceptions that your team feels they cannot control, such as the patient transferred from another facility. Don't start with the exceptions; start with those for which you can control most of the factors and bring in the rest later.
3. Use small tests of change to test the design. (See the Model for Improvement.)
4. Measure the process; if the science is right, the outcomes will follow.
5. Use standard approaches such as order sets, but remember that these alone will not accomplish the goal. Develop the order sets using evidence-based medicine and society guidelines.

## **Appendix A: Recommended Intervention-Level Measures**

The following measures are relevant for this intervention. The Campaign recommends that you use some or all of them, as appropriate, to track the progress of your work in this area. In selecting your measures, we offer the following advice:

1. Whenever possible, use measures you are already collecting for other programs.
2. Evaluate your choice of measures in terms of the usefulness of the results they provide and the resources required to obtain those results; try to maximize the former while minimizing the latter.
3. Try to include both process and outcome measures in your measurement scheme.
4. You may use measures not listed here, and, similarly, you may modify the measures described below to make them more appropriate and/or useful to your particular setting; however, be aware that modifying measures may limit the comparability of your results to others'. (Note that hospitals using different or modified measures should not submit those measure data to IHI.)
5. Remember that posting your measure results within your hospital is a great way to keep your teams motivated and aware of progress. Try to include measures that your team will find meaningful, and that they would be excited to see.

*Process Measure(s):*

<b>Percent of Patients Receiving Narcotic with Treatment Appropriately Managed According to Protocol</b>
Owner: <b>IHI</b>
Owner Measure ID: <b>N/A</b>
Measure Information: <a href="#">[Campaign MIF]</a>
Comments:

<b>Percent of Patients Receiving Anticoagulant with Treatment Appropriately Managed According to Protocol</b>
Owner: <b>IHI</b>
Owner Measure ID: <b>N/A</b>
Measure Information: <a href="#">[Campaign MIF]</a>
Comments:

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<b>Percent of Patients Receiving Insulin with Treatment Appropriately Managed According to Protocol</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments:

<b>Percent of Patients Receiving Sedative with Treatment Appropriately Managed According to Protocol</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments:

<b>Percent of Unreconciled Medications</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments: <ul style="list-style-type: none"><li>• Note that this measure is the same as that used in the 100,000 Lives Campaign.</li><li>• This measure is also a recommended intervention-level measure for another Campaign intervention, Medication Reconciliation.</li></ul>

<b>Unreconciled Medications Per 100 Admissions</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments: <ul style="list-style-type: none"><li>• Note that this measure is the same as that used in the 100,000 Lives Campaign.</li><li>• This measure is also a recommended intervention-level measure for another Campaign intervention, Medication Reconciliation.</li></ul>

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*Outcome Measure(s):*

<b>Adverse Drug Events Related to Narcotic per 100 Admissions with Narcotic Administered</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments:

<b>Adverse Drug Events Related to Anticoagulant per 100 Admissions with Anticoagulant Administered</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments:

<b>Adverse Drug Events Related to Insulin per 100 Admissions with Insulin Administered</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments:

<b>Adverse Drug Events Related to Sedative per 100 Admissions with Sedative Administered</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments:

<b>Percent of Patients Receiving Warfarin with INR Outside Protocol Limits</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments:

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<b>Percent of Patients Receiving Heparin with aPPT Outside Protocol Limits</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments:

<b>Percent of Patients Receiving Insulin with Blood Glucose Level Outside Protocol Limits</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments:

<b>Percent of Patients Receiving Narcotic Who Receive Subsequent Treatment with Naloxone</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments:

<b>Percent of Patients Receiving Sedative Who Receive Subsequent Treatment with Flumazenil</b>
Owner: <b>IHI</b> Owner Measure ID: <b>N/A</b> Measure Information: <a href="#">[Campaign MIF]</a> Comments:

*Alignment with Other Measure Sets:*

No known use of these measures in other national measure sets (e.g., JCAHO, CMS, CDC, NQF, etc.)