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How-to Guide: Prevent Harm from High-Alert Medications

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

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Contents

Introduction

What is the Institute for Healthcare Improvement (IHI)?

The Institute for Healthcare Improvement (IHI) is a not-for-profit organization leading the improvement of health care throughout the world. IHI helps accelerate change by cultivating promising concepts for improving patient care and turning those ideas into action. Thousands of health care providers participate in IHI's groundbreaking work.

What is a How-to Guide?

IHI's How-to Guides address specific health care interventions hospitals and/or entire health systems can pursue to improve the quality of health care. These interventions align with several national initiatives of the IOM, AHRQ, CMS, Joint Commission, CDC, as well as the Department of Health and Human Services' "Partnership for Patients" initiative.

This material was developed for the IHI 100,000 Lives Campaign (2004-2006) and the 5 Million Lives Campaign (2006-2008), both voluntary initiatives to protect patients from medical harm. Both Campaigns involved thousands of hospitals and communities from around the United States in specific interventions.

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Contributors

Several organizations have generously offered advice and have made scientific contributions to this document. They include the American Society for Health-System Pharmacists and the Institute for Safe Medication Practices.

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 do occur, the impact on the patient can be significant.

The Joint Commission, referring to ISMP's work, describes high-alert medications as those "Medications that bear a heightened risk of causing significant harm to individuals when they are used in error."[1]

Based on reports submitted to ISMP, a review of the 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.[2] Although it is important to improve management of all of these medications, some of them have been associated with harm more frequently than others.

Based on findings from the use of the IHI Global Trigger Tool and the experience of hospitals that have participated in the Institute for Healthcare Improvement's (IHI's) Collaboratives, this How-to Guide focuses 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 oversedation.

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

[1] The Joint Commission E-dition. https://e-dition.jcrinc.com/Frame.aspx. Accessed November 18, 2011.

[2] The ISMP's List of High-Alert Medications. http://ismp.org/Tools/highalertmedications.pdf. Accessed November 18, 2011.

Why Focus on Reducing Harm from High-Alert Medications?

High-alert medications are more likely than other medications to be associated with harm. Although any medication used improperly can cause harm, high-alert medications cause harm more frequently 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.
- Several studies have identified ADEs as the most frequent single source of health care mishaps, continually placing patients at risk of injury. [3,4,5,6,7]
- Based on a rate of 400,000 ADEs 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.[8]
- 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."[9]

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[3] 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.

[4] 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.

[5] 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.

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

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

[8] 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.

[9] 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. *Am J Health Syst Pharm*. 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.[10]
- In 2008, drug-related adverse outcomes were noted in nearly 1.9 million inpatient hospital stays (4.7% of all stays), and 838,000 treat-and-release emergency department (ED) visits (0.8% of all visits). Opiates were the most common specific cause of drug-related adverse outcomes, responsible for 5.6% of all inpatient events.[11]
- A review of costs associated with errors related to patient-controlled analgesia (PCA) and device-related narcotic errors found that each error cost $552 – $733; harmful errors were 120 – 250 times more costly than those without harm. The authors estimated an annual rate of 407 PCA-related and 17 device-related errors per 10,000 people in the United States.[12]
- The Pennsylvania Patient Safety Authority reports that from January 2008 to June 6, 2009, Pennsylvania health care facilities submitted 2,685 event reports that mentioned medication errors involving the use of insulin products. The most common types of medication error associated with insulin were drug omission (24.7%) followed by wrong-drug errors (13.9%). More than 52% of the reported events led to situations in which a patient possibly or definitely received the wrong dose or no dose of insulin (e.g., dose omissions, wrong dose/overdosage, wrong dose/underdosage, extra dose, wrong-rate errors), which could lead to difficulties in glycemic control.[13]

The Pennsylvania Patient Safety Authority also reports that between 2004 and 2008, Pennsylvania health care facilities reported 591 serious events associated with anticoagulation.[14]

The number of ADEs 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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[10] Eckman MH, Levine HJ, Salem DN, Pauker SG. Making decisions about antithrombolytic therapy in heart disease: Decision analytic and cost-effectiveness issues. *Chest*. 1998;114:699-714.

[11] Lucado J, Paez K, Elixhauser A. *Medication-Related Adverse Outcomes in US Hospitals and Emergency Departments*. Healthcare Cost and Utilization Project, Statistical Brief #109. Rockville, MD: Agency for Healthcare Research and Quality; 2008. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb109.pdf. Accessed November 18, 2011.

[12] Meissner B, Nelson W, Hicks R, et al. The rate and costs attributable to intravenous patient-controlled analgesia errors. *Hosp Pharm*. 2009;44:312-324.

[13] Medication Errors with the Dosing of Problems across the Continuum. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Mar7(1)/Pages/09.aspx. Updated March 7, 2010. Accessed November 18, 2011.

[14] Anticoagulation Management Service: Safer Care, Maximizing Outcomes. http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Sep5(3)/Pages/81.aspx. Updated September 5, 2008. Accessed November 18, 2011.

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 in time to mitigate it before it becomes serious.

Note: High-alert medications can also be linked to other care processes and interventions, such as medication reconciliation, care of the ventilated patient (deep venous thrombosis [DVT] prophylaxis), and perioperative care. In some cases, medications may cause or aggravate the rapid deterioration of a patient. Drugs such as hydromorphone have been associated with deterioration of patients, resulting in calls to the Rapid Response Team.

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, over-the-counter products, and food. Reliable processes are needed to achieve desired international normalized ratio (INR) consistently, and to ensure appropriate management of anticoagulated patients before and after surgery. Safe therapy includes achieving desired levels of anticoagulation in a sufficiently rapid manner to prevent harm from clots while minimizing potential for bleeding.

- Lack of dosing guidelines and lack of appropriate monitoring can lead to serious harm associated with this class of medications.[15]
- In a study by Bates et al., anticoagulants accounted for 4% of preventable ADEs and 10% of potential ADEs.[16]
- A literature review by Kanjanarat et al. reports that anticoagulation therapy is associated with serious and frequent ADEs in both inpatients and outpatients.[17,18]
- Warfarin and insulins, both of which typically require ongoing monitoring to prevent overdose or toxicity, caused one in every seven estimated ADEs treated in emergency departments (14.1%; 95% confidence interval 9.6% 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 ADEs 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%).[19]

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[15] 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.

[16] 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.

[17] 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.

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

[19] 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 reasons include the complexity of dosing and monitoring, lack of patient adherence, numerous drug interactions, and dietary interactions that can affect drug activity. 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.[20]
- The Pennsylvania Patient Safety Authority also reports that between 2004 and 2008, Pennsylvania health care facilities reported 591 serious events associated with anticoagulation.[9]
- There is considerable variation in ordering, dosing, and monitoring of patients on unfractionated heparin. Often, there is confusion about providing ongoing therapy while patients are receiving warfarin.
- The Joint Commission recognized the importance of safe anticoagulation management and selected Anticoagulation Therapy as a National Patient Safety Goal.[21]

[20] Gandhi TK, Shojania KG, Bates DW. "Chapter 9: Protocols for High-Risk Drugs: Reducing Adverse Drug Events Related to Anticoagulants." In: *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. Evidence Report/Technology Assessment, No. 43. AHRQ Publication No. 01-E058. Rockville, MD: Agency for Healthcare Research and Quality; July 2001. http://www.ahrq.gov/clinic/ptsafety/pdf/chap9.pdf. Accessed November 18, 2011.

[21] The Joint Commission. http://www.jointcommission.org. Accessed November 18, 2011.

Narcotics: 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 functioning of the patient, including 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 interventions in this How-to Guide focus on appropriate pain management in the hospital setting. Appropriate pain management includes rapid and effective pain control without placing the patient at risk for harm.

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

- A study by Kanjanarat et al. identified contributing factors to two common adverse outcomes: warfarin overdose and inappropriate monitoring resulted in hemorrhage; and opioid overdose and underdose were associated with respiratory depression or poor pain control.[22]
- 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

- 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.[23]
- 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 high in absolute terms (ranging from 65 to 667 deaths).[24]

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[22] 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.

[23] 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.

[24] 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.[25]
- Using naloxone administration as a trigger, one community hospital calculated a rate of serious narcotic oversedation of 0.45/1,000 discharges.[26]

[25] 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.

[26] Meisel S, Phelps P, Meisel M. Case study: Reducing narcotic oversedation across an integrated health system. *Jt Comm J Qual Patient Saf*. 2007;33:543-548.

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 available 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.[27]
- Hypoglycemia is the most common complication of any insulin therapy and is an extremely frequent adverse event in hospitals worldwide.[28]
- Even when hospitals use protocols and guidelines, adverse events continue to occur. The reasons are that adjustments are not made to dosing to take into account stress caused by illness or a medical procedure, or patients may not have adequate food/caloric intake.[29]
- In the intensive care unit, even mild hypoglycemia is associated with increased mortality.[30]

[27] 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. *Qual Saf Health Care*. 2006;15:89-91.

[28] 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.

[29] Magee MF, Hospital protocols for targeted glycemic control: Development, implementation, and models for cost justification. *Am J Health-Syst Pharm*. 2007 May 15;42:Suppl 6.

[30] Egi M, Bellomo R, Stachowski E, et al. Hypoglycemia and outcome in critically ill patients. *Mayo Clinic Proceedings.* 2010;85:217-224.

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 benzodiazepines and chloral hydrate. Patients in hospitals may require sedation prior to procedures and during the hospital stay. However, inappropriate use may result in oversedation, hypotension, delirium, and lethargy, and may contribute to the risk of falling. When administered together, sedatives and narcotics have a synergistic effect, depressing the central nervous system. 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/or lack a process to address emergency situations such as respiratory depression and arrest.

- Older patients on benzodiazepines had a 2.9% higher rate of falls.[31]
- 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.[32]
- Use of multiple sedatives accounted for 42% of preventable ADEs in the intervention group.[33]
- The Minnesota Department of Health reports that roughly half of all patients who had a serious fall were on one or more "culprit medications," medications known to increase fall risk, within 24 hours in advance of their fall. Narcotics or other pain medications, anti-psychotic medications, anti-anxiety medications, hypertension medications, and sedatives were the most common culprit medications. Fifteen percent of patients who suffered a serious fall were on multiple culprit medications.[34]

[31] Fonad E, Wahlin TB, Winblad B, Emami A, Sandmark H. Falls and fall risk among nursing home residents. *J Clin Nurs*. 2008;17:126-134.

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

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

[34] Adverse Health Events in Minnesota Seventh Annual Public Report. http://www.health.state.mn.us/patientsafety/ae/2011ahereport.pdf. Updated January 2011. Accessed November 18, 2011.

General Principles for Reducing Harm from High-Alert Medications:

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

- Design processes to prevent errors and harm.
- Design methods to identify errors and harm when they occur.
- 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 establish a standardized approach to treating patients with similar problems, disease states, or needs.[35]
- Minimize variability by standardizing concentrations and dose strengths to the minimum needed to provide safe care.
- Consider centralized pharmacist- or nurse-run anticoagulation, insulin management, and pain management services.
- Include reminders and information about appropriate monitoring parameters in the order sets, protocols, and flow sheets.
- Consider protocols for vulnerable populations such as elderly, pediatric, and obese patients.
- Adopt TALL man lettering for pharmacy produced labels to differentiate drug names with potential for mix-up.

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.
- Instruct patients on symptoms to monitor for side effects and when to contact a health care provider for assistance.

[35] ISMP Guidelines for Standard Order Sets. http://ismp.org/Tools/guidelines/StandardOrderSets.asp. Accessed November 18, 2011.

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.

ISMP recommends conducting an interdisciplinary failure modes and effects analysis (FMEA) within your facility to identify organization-specific sources of failure with the use of high-alert medications.

Additional prospective risk assessments can be taken with insulin using a self-assessment tool developed by the American Society of Health-System Pharmacists.

A self-assessment tool for anticoagulants developed by ISMP is also available.

One suggestion is to review the literature to learn about serious adverse events that may have occurred at other institutions. Examine your own processes and ask, "Can that event happen here? What do we have in place to ensure that we minimize the risk for such an event?"

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, and recommendations developed by the Institute for Safe Medication Practices of Health-system Pharmacists. 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 demonstrated reductions 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

The changes listed are intended to help ensure safe anticoagulation management. The Joint Commission National Patient Safety Goal requires the following:

> The term "defined anticoagulant management program" means a program, specified in writing, for individualizing anticoagulation therapy that involves the use of standardized practices and patient involvement, and which is specifically designed to reduce the risk of ADEs associated with the use of heparin (unfractionated), low molecular weight heparin (LMWH), warfarin, and other anticoagulants.

- See The 2011 National Patient Safety Goals and FAQs.

A review of current anticoagulant and antiplatelet medications— including usual dose, recommendations for holding prior to surgery and spinal anesthesia/epidurals, and reversals—is included in **Appendix A**. This resource was produced by Jenna Minton Huggins and Erin Allender at WakeMed Health & Hospitals.

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.
- To reduce compounding and labeling errors, ensure that the organization uses ONLY oral unit-dose products and pre-mixed infusions, when these products are available.
- Ensure that staff undertaking anticoagulant duties are trained and competent.
- Conduct an ISMP Antithrombotic Therapy Self-Assessment.

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 a single standard concentration of heparin infusion across the institution.
- Separate like products when using or storing.
- Dispense the anticoagulant medication from pharmacy only.
- Allow only flush solutions on floor stock; send all other doses in a patient-specific form.
- Use LMWH in lieu of unfractionated heparin.
- Remove high-concentration products from floor stock.
- Make hep-flush available only in pre-filled syringes.
- Use saline instead of heparin for line flushes.
- Use smart pumps with pre-built minimum and maximum dose limits.
- Use smart pumps that safely allow for programming and administering bolus doses without the need to draw a dose from a vial.
- Develop and implement a pharmacy-based heparin dosing service.
- Monitor patients using Heparin Xa levels instead of aPPT.
- Ensure that appropriate monitoring parameters are implemented and used reliably.

Changes Designed to Ensure Standardization:

- Implement standardized protocols and dosing.
- Establish guidelines to hold heparin and provide reversal therapy for heparin over-anticoagulation.
- Simplify by minimizing availability of concentrated heparin products.

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, it is essential to engage patients by ensuring that they understand how to take the medication, which other medications should be avoided, and how to identify symptoms that indicate harm.
- Include a nutrition consult to educate patients on warfarin about drug/food interactions.
- Develop a robust communication plan to share information and to ensure timely follow-up with the next provider of care when a patient is discharged from the hospital.

Changes Designed to Ensure Standardization:

- Standardize protocols and dosing:
    - Standardize 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.
    - Develop a protocol, based on evidence, to bridge warfarin therapy with more rapidly-acting anticoagulants such as heparin and LMWH.
- Make information available; for example, improve access to lab results and/or use of point-of-care testing in order to determine doses.
- Initiate patient self-testing of their INR and self-adjustment of their doses.[36]
- Ensure appropriate monitoring, patient education, follow-up, 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 follow. Studies have shown that strategies to improve prescribing and monitoring have the potential to reduce adverse events such as bleeding or thromboembolic events.

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[36] Bloomfield H, Krause A, Greer N, et al. Meta analysis: Effect of patient self-testing and self-management of long-term anticoagulation on major clinical outcomes. *Ann Intern Med*. 2011;154:472-482.

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 a run chart or control chart.

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.

- Engage patients by developing educational programs and training, at an appropriate literacy level, to include self-monitoring and ways to avoid drug and food interactions.
- Most materials are not written for the appropriate literacy level. Engage patients to help identify materials that best meet their needs.

Examples of patient materials:

- Guide to Warfarin Therapy, Fairview Health Services.
- AHRQ patient brochure, "Blood Thinner Pills: Your Guide to Using Them Safely."
- Patient/family education includes the importance of follow-up monitoring, compliance issues, dietary restrictions, potential for adverse drug reactions, and food- and illness-drug interactions.
- Use medication reconciliation to improve handoffs of medication information.
- Work with patients to carry accurate lists of medications at all times.

As new anticoagulants are introduced into the market, ensure that all staff are:

- Familiar with dosing recommendations.
- Updating protocols and templates.
- Monitoring guidelines.
- Understand impact on laboratory practices.
- Understand impact on drug distribution and administration.
- Receiving education and training.

- Providing patient and family education.
- Aware of the existence of reversal agents.

Any drug that alters coagulation will have an impact on the patient and may have the potential to cause serious harm.

Changes to Improve Management of Narcotics

Appropriate dosing of narcotics should provide appropriate pain relief without adverse events. Factors that contribute to harm with narcotics include errors in calculation, errors in conversion of intravenous (IV) to per oral (PO), confusion about potency when changing drugs, and errors in delivery by the intravenous route.

Suggested Changes:

- Standardize protocols for the initiation and maintenance of pain management.
- Set standards for frequently monitoring vital signs for adverse effects of narcotics and opiates.
- Use capnography to detect hypoventilation (oximetry may be used as an alternate if a patient is a CO_2 retainer and is not on supplemental oxygen).
- Make available protocols that include the administration of reversal agents if needed as part of treatment plan. Contact the physician after the administration of the reversal agent.
- Consult a pain specialist if the managing physicians are not knowledgeable about pain control. The backgrounds of 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 nursing or nursing staff or use "smart pumps."
- Perform independent double-checks on the unit for PCA and epidural narcotics.
- Minimize or eliminate multiple drug strengths and concentrations where possible.
- Repackage injectable hydromorphone into unit-dose syringes of 0.2 or 0.4 mg.
- Minimize override capabilities of automated dispensing machines.
- Create alerts in the computer system for duplicate narcotics, high doses for age/weight, renal function, doses administered too frequently, and narcotics ordered or administered via multiple routes.
- Use an epidural pump and delivery system that makes it impossible to administer the epidural analgesic intravenously or an intravenous medication epidurally.
- Establish and widely circulate to all staff information and formulas for narcotic dose-equivalencies.
- Disallow dose ranges more than 2-fold.
- Consider all significant oversedation events as sentinel events subject to root cause analysis.

- Disallow the routine use of sedatives as an adjunct to pain management, unless the patient is also experiencing anxiety.

Changes Designed to Ensure Standardization:

- Use protocols and preprinted orders 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 regimen that can be given before calling a physician, based on a protocol signed by a physician.

Changes Designed to Ensure Adequate Monitoring:

- Standardize monitoring protocols (including documentation) of vital signs and pain score following each dose. Serious oversedation 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 postoperatively. There may also be a disconnect between the expectations of the clinician and those of the patient regarding post-op pain. Establishing common expectations pre-operatively can be a valuable way to reduce oversedation without minimizing pain relief.
- Use medication reconciliation to improve handoffs of medication information.
- Educate patients regarding hypotension and dizziness upon rising.
- Provide adequate lighting, especially at night.
- Anticipate and schedule toileting for high-risk patients.

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 preprinted 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; consider administering rapidly-acting insulin with or immediately after the meal.
- Place safeguards on high-dose insulin concentration.
- Consider unique delivery devices such as insulin pens with proper safeguards and syringe pumps for IV infusions.
- Implement a pharmacy- or nurse-driven diabetes management team.
- Create rules in the computer systems that alert for NPO status, changing steroid doses, changing TPN or enteral feedings, and other drug/disease interactions.
- Complete an insulin-safety self-assessment.[37]
- Institute clear monitoring protocols with triggers to administer glucose.
- Draw-to-dose all insulin doses in the pharmacy; disallow any insulin from floor-stock.
- Treat as a sentinel event and conduct a root cause analysis every time a patient has an insulin-related blood sugar < 40 mg/dl.
- Remove tuberculin syringes from floor stock so they cannot erroneously be used for insulin.

[37] Professional Practice Recommendations for Safe Use of Insulin in Hospitals. http://www.ashp.org/s_ashp/docs/files/Safe_Use_of_Insulin.pdf. Accessed November 18, 2011.

- Consider continuous blood sugar monitoring devices.
- Develop and default to a defined protocol with clear monitoring guidelines when insulin is used to treat hyperkalemia.
- Consider computer-assisted dosing adjustment program.

Changes Designed to Ensure Standardization:

- Eliminate the use of sliding insulin dosage scales; convert to basal/bolus insulin dosing. 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.

Changes Designed to Ensure Better Partnering with Patients and Families:

- Allow and encourage patient self-management (or parental management 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

Sedatives may be used alone or in combination with narcotics to manage patients with pain and post-surgically. Alone or in combination, this group of drugs can contribute to lethargy, confusion, respiratory depression, and falls.

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. Ensure that chloral hydrate is administered in the hospital where the patient can be monitored and not at home prior to arrival.
- Have age- and size-appropriate resuscitation equipment and reversal agents available wherever the medications are administered, and during procedures performed when the patient is under sedation.

Changes Designed to Ensure Standardization:

- Use dosing protocols and automatic dose reductions for benzodiazopines and other sedatives and hypnotics in target populations.
- Develop and deploy mild-, moderate-, and deep-sedation protocols that include scientifically based dosing and best practices. Develop and deploy triggers in the electronic record that monitor for the use of multiple sedatives, sedatives given too close together, and sedatives given with narcotic analgesics.
- Disallow the routine use of sedatives as an adjunct to pain management, unless the patient is also experiencing anxiety.

Changes Designed to Ensure Adequate Monitoring:

- Monitor patients for respiratory depression, as evidenced by decreased oxygen saturation or increased CO_2 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).
- Develop a program that includes fall prevention strategies for patients receiving medications in this group.

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. For the recommended interventions in this How-to Guide, the aim is to prevent harm and save lives by improving the prescribing and management of specific categories of high-alert medications.

There are two types of teams in health care: one that provides patient care, and one that improves processes. These do not necessarily include the same members. The team described below focuses on improvement.

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 goal will be achieved, and 4) a specific timeframe.

The overall goal of recommended interventions in this How-to Guide 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. The wording of your team's aim 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

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.)

For maximum effectiveness, 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. It 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 whether changes are leading to improvement, and 3) identify changes that are likely to lead to improvement; and
- 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 at 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 by 50% by December 2012.

Change: Develop and implement a warfarin dosing protocol.

Scale: 1 physician, 1 nurse, and 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 other staff 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 includes 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:

- Have you developed a protocol or order set for all appropriate medications?
- Is the protocol or order set being used?
- Have you developed dose-conversion charts to minimize errors when changing from one medication to another? For pain medications?
- If you have developed dose conversion charts, are they being used?
- Are patients monitored using established protocols?

To answer these questions, use a sample of, at most, ten patient 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 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.

How to Determine the Reliability of the Process

A simple measurement strategy to answer the questions above is to select five patient charts or records at the end of the day. Determine the answers to the above questions using those charts. If the answer is not "Yes" to each question for all five selected charts, then the system in place is not working as designed. If a patient is not treated as expected, but there is a valid reason for this, then that chart should not be counted.

Another measure is to ask five front-line staff members to describe the care process for one of the high-alert medications. If the five individuals do not describe the process in the same way, then it is likely that the system has not been standardized.

Drill-down or Enriched Sample

In order to determine if harm has been reduced with one of the high-alert medications, it may be helpful to drill down or collect an enriched sample. For example, if working with warfarin, select only patients receiving warfarin.

Based on the extent of your improvement efforts, the number of harm events in your sample may be small. Some organizations are using even more selective criteria, such as INR greater than a certain value or blood glucose lower than a certain value. The chances of finding harm will be greater in these situations. The information derived from these samples will be more helpful in identifying opportunities for improvement.

Recommended Measures

In the Measurement section at the end of this document, you will find a list of measures IHI 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 Narcotic Administrations Appropriately Managed According to Protocol;
- Percent of Anticoagulant Administrations Appropriately Managed According to Protocol;
- Percent of Insulin Administrations Appropriately Managed According to Protocol; and
- Percent of Sedative Administrations 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 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% of errors are ever reported and, of those, 90% to 95% cause no harm to patients. Hospitals need a more effective way to identify events that 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 Narcotics per 100 Patients with a Narcotic Administered;
- Adverse Drug Events Related to Anticoagulants per 100 Patients with an Anticoagulant Administered;
- Adverse Drug Events Related to Insulin per 100 Patients with Insulin Administered; and
- Adverse Drug Events Related to Sedatives per 100 Patients with a 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 the Measurement section.

Some hospitals have identified very few harm events when using a random sample of patients receiving a particular medication. In order to drill down, suggestions include selecting patients whose INR is greater than a certain value or whose blood glucose is lower than 50 or another hospital-determined value. This method should not be used to measure harm over time. Instead, this method allows hospitals to select those patients most likely to be experiencing harm from the medication. This is not a hospital rate; it is a focused sampling intended to help identify opportunities for improvement. Once improvements have been implemented, a different cohort of patients may be selected. Hospitals may wish to continue to use the

trigger tool review of randomly selected charts as an overall measure of medication-related harm over time.

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 a PPT 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 Require 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. Some hospitals have used these measures as their overall metric of harm. Following case review, the numerator is the number of patients with a true ADE; the denominator is the number of patients who received the target drug. If 100% of the triggers are captured in this manner, the ADE rate can be reliably tracked over time.

Tips for Getting Started

Improving the management of high-alert medications can seem like an overwhelming challenge. Many 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:

- 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.
- 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 it cannot control, such as the patient transferred from another facility. Don't start with the exceptions; start with the cases for which you can control most of the factors and bring in the rest later.
- Use small tests of change to test the design. (See the Model for Improvement.)
- Measure the process; if the science is right, the outcomes will follow.
- 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.

Suggestions for Developing Protocols:

- Obtain support from administrative and clinical leadership.
- Design your process improvement and standardization according to evidence-based medicine.
- Find a champion.
- Education and training are necessary, but are not sufficient alone to ensure reliable application of a protocol.
- Engage front-line staff in designing the process.
- Use the Model for Improvement or some other proven improvement methodology.

An example of one hospital's journey:

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

Supporting Material

- Anticoagulant Toolkit
    - This toolkit is intended for use by health care providers and institutions to provide effective and safe anticoagulation therapy and practices in all care settings.
- IHC Anticoagulation Toolkit
    - Iowa Healthcare Collaborative (IHC), in cooperation with health care providers across the state, has developed the following Anticoagulation Toolkit. The toolkit is a compilation of resources to ensure effective and safe long-term anticoagulation therapy.
- Cedar Rapids Healthcare Alliance: A comprehensive list of tools to implement the Anticoagulation Management System (AMS)

Measurement

Measure compliance with each of the key components of evidence-based high-alert medication care. Document whether each component of care was provided or contraindicated; these are "process measures." While improvements in individual measures indicate the processes surrounding those care elements have improved, improvement in actual patient outcomes requires improvement in all component measures.

IHI recommends the use of some or all of the following measures, as appropriate, to track your progress. In selecting your measures, consider the following:

- Whenever possible, use measures you are already collecting for other programs.
- Evaluate your choice of measures in terms of the usefulness of the final results and the resources required to obtain them; try to maximize the former while minimizing the latter.
- Try to include both process and outcome measures in your measurement scheme.
- You may use different measures or 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'.
- 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 exciting.

Different strategies for collecting the data needed to calculate this measure are outlined in the Measure Information.

Process Measures

Percent of Narcotic Administrations Appropriately Managed According to Protocol

- Measure Information

Percent of Anticoagulant Administrations Appropriately Managed According to Protocol

- Measure Information

Percent of Insulin Administrations Appropriately Managed According to Protocol

- Measure Information

Percent of Sedative Administrations Appropriately Managed According to Protocol

- Measure Information

Percent of Unreconciled Medications

- Measure Information

Unreconciled Medications per 100 Admissions

- Measure Information

Outcome Measures

Adverse Drug Events Related to Narcotic per 100 Admissions with Narcotic Administered

- Measure Information

Adverse Drug Events Related to Anticoagulant per 100 Admissions with Anticoagulant Administered

- Measure Information

Adverse Drug Events Related to Insulin per 100 Admissions with Insulin Administered

- Measure Information

Adverse Drug Events Related to Sedative per 100 Admissions with Sedative Administered

- Measure Information

Percent of Patients Receiving Warfarin with INR Outside Protocol Limits

- Measure Information

Percent of Patients Receiving Heparin with aPPT Outside Protocol Limits

- Measure Information

Percent of Patients Receiving Insulin with Blood Glucose Level Outside Protocol Limits

- Measure Information

Percent of Patients Receiving Narcotic Who Require Subsequent Treatment with Naloxone

- Measure Information

Percent of Patients Receiving Sedative Who Require Subsequent Treatment with Flumazenil

- Measure Information

Alignment with Other Measure Sets

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

Appendix A: Review of Anticoagulants and Antiplatelets

Review of Anticoagulants and Antiplatelets

JENNA MINTON HUGGINS, PHARMD, BCPS AND J. ERIN ALLENDER, PHARMD, BCPS

Generic name (Brand name)	Medication Class	Usual dose and route of administration	Renal Dosing No adjustment necessary	Elimination half-life	Recommendations for holding prior to major procedures or surgery	Recommendations for holding for spinal anesthesia/epidurals	Reversal
clopidogrel (Plavix)	antiplatelet	75 mg daily; PO	No adjustment necessary	~6 hours; platelet function restored in ~5 days	hold 5-10 days prior to procedure; may restart 24 hours after surgery if hemostasis achieved	hold 7 days prior to procedure; no recommendations with regard to administration while catheter in place or after catheter removal	no specific reversal agent; supportive care (platelet infusions)
dabigatran (Pradaxa)	anticoagulant; oral direct thrombin inhibitor	75 or 150 mg twice daily; PO	CrCl 15-30 ml/min: 75 mg PO BID CrCl < 15 ml/min: Use not recommended	12-17 hours (up to 34 hours in renally impaired)	hold 1 to 2 days (CrCl ≥50 mL/min) or 3 to 5 days (CrCl <50 mL/min) prior to procedure, potentially longer for spinal surgery/puncture or other major surgery; may restart when full anticoagulation deemed safe (therapeutic anticoagulation will occur 0-2 hours after administration)	hold a minimum of 5 days (longer if patient renally impaired) prior to spinal puncture or insertion of catheter; avoid use while catheter in place; may restart when full anticoagulation deemed safe, usually 8 hours after atraumatic puncture/removal or 24 hours after traumatic procedures (therapeutic anticoagulation will occur 0-2 hours after administration)	no specific reversal agent; consider hemodialysis if major hemorrhage or overdose; supportive care (anecdotal reports of Factor VIIa, PCC use)
enoxaparin (Lovenox)	anticoagulant; anti-Xa and anti-IIa	variable; SQ	CrCl < 30 ml/min: dose once daily instead of BID	7 hours (longer if renally impaired)	hold 24 hours prior to procedure; may restart 24-72 hours after surgery if hemostasis achieved	hold prophylactic doses at least 12 hours and therapeutic doses at least 24 hours prior to needle placement; avoid use while catheter in place; may restart 2 hours after removal of the catheter	protamine neutralizes ~60% of the drug; consider hemodialysis if major hemorrhage, overdose; supportive care

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Generic name (Brand name)	Medication Class	Usual dose and route of administration	Renal Dosing No adjustment necessary	Elimination half-life	Recommendations for holding prior to major procedures or surgery	Recommendations for holding for spinal anesthesia/epidurals	Reversal
fondaparinux (Arixtra)	anticoagulant; anti-Xa	variable; SQ	CrCl < 30 ml/min: Contraindicated	17-21 hours (longer if renally impaired)	hold 24 hours prior to procedure; may restart 24-72 hours after surgery if hemostasis achieved	hold a minimum of 24-36 hours prior to procedure; avoid use while catheter in place; may restart 2 hours after catheter removal (if placement was atraumatic and single-pass) or 12 hours after catheter removal that does not meet these criteria	no specific reversal agent; consider hemodialysis if major hemorrhage or overdose; supportive care
heparin	anticoagulant; anti-Xa, antithrombin III and others	variable; IV or SQ	adjust according to aPTT	1.5 hours (IV)	hold 4-6 hours prior to procedure; may restart when hemostasis achieved	hold 4-6 hours prior to procedure (consider sending aPTT); patients may receive 5000 units twice daily for DVT prophylaxis while an epidural is in place; if a patient is receiving therapeutic doses of IV heparin, discontinue 2-4 hours before removing neuraxial catheter (consider sending aPTT prior to removal); may restart 1 hour after removal of the catheter	protamine; supportive care
prasugrel (Effient)	antiplatelet	10 mg daily; PO	No adjustment necessary	~7 hours; platelet function restored in ~7 days	hold 7-10 days prior to procedure; no official recommendations for restarting	hold at least 7 days prior to procedure; no recommendations with regard to administration while catheter in place or after removal	no specific reversal agent; supportive care (platelet infusions)
rivaroxaban (Xarelto)	anticoagulant	variable; PO	Afib: CrCl 15-50 ml/min: 15 mg PO daily CrCl < 15 ml/min: Avoid Use PostOp Px: CrCl <50 ml/min:No adjustment provided. Use with caution CrCl < 30 ml/min: Avoid Use	5-9 hours; 11-13 hours in elderly	hold at least 24 hours prior to procedure; may restart 6-10 hours after surgery if hemostasis achieved	hold at least 24 hours prior to procedure; avoid use while catheter is in place but if the drug is given, an epidural cathether should not be removed earlier than 18 hours after a dose of rivaroxaban; may restart 6 hours after removal of the catheter if placement was traumatic or 24 hours after traumatic punctures	no specific reversal agent; supportive care (anecdotal reports of PCC use)

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Generic name (Brand name)	Medication Class	Usual dose and route of administration	Renal Dosing No adjustment necessary	Elimination half-life	Recommendations for holding prior to major procedures or surgery	Recommendations for holding for spinal anesthesia/epidurals	Reversal
ticagrelor (Brilinta)	antiplatelet	90 mg twice daily; PO	No adjustment necessary	7-9 hours; platelet function restored in ~5 days	hold a minimum of 5 days prior to procedure; no official recommendations for restarting	no official recommendations from manufacturer; consider holding 7 days prior to procedure; no recommendations with regard to administration while catheter in place or after catheter removal	no specific reversal agent; supportive care (platelet infusions)
ticlopidine (Ticlid)	antiplatelet	250 mg twice daily; PO	No adjustment necessary	4-5 days	hold 10-14 days prior to procedure; no official recommendations for restarting	hold a minimum of 14 days prior to procedure; no recommendations with regard to administration while catheter in place or after catheter removal	no specific reversal agent; supportive care (platelet infusions)
warfarin (Coumadin; Jantoven)	anticoagulant	variable; PO	No adjustment necessary	7 days	hold 5 days prior to procedure; monitor INR and utilize short-acting bridging agents (e.g. IV heparin) when appropriate; may restart immediately after surgery	hold 4-5 days prior to procedure; INR must normalize prior to needle insertion; may restart low-dose warfarin post-procedure but remove catheter while INR < 1.5	vitamin K; FFP; cryoprecipitate; PCC; supportive care

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