Adverse Drug Events (ADE)

2016 UPDATE

Change Package

PREVENTING ADVERSE DRUG EVENTS







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TABLE OF CONTENTS

Part 1: Adverse Event Area (AEA) Definition and Scope	02
Part 2: Measurement	03
Part 3: Approaching your AEA	04
Part 4: Conclusion and Action Planning	18
Part 5: Appendices	19
Part 6: References	22

How to Use this Change Package

This change package is intended for hospitals participating in the Hospital Engagement Network (HEN) 2.0 project led by the Centers for Medicare & Medicaid Services (CMS) and Partnership for Patients (PFP); it is meant to be a tool to help you make patient care safer and improve care transitions. This change package is a summary of themes from the successful practices of high performing health organizations across the country. It was developed through clinical practice sharing, organization site visits and subject matter expert contributions. This change package includes a menu of strategies, change concepts and specific actionable items that any hospital can choose to implement based on need or for purposes of improving patient quality of life and care. This change package is intended to be complementary to literature reviews and other evidence-based tools and resources.

PART 1: ADVERSE EVENT AREA (AEA) DEFINITION AND SCOPE

An Adverse Drug Event (ADE) is an injury to a patient resulting from a medication intervention, which can occur in any health care setting.¹ The Office of Disease Prevention and Health Promotion (ODPHP) released The National Action Plan for ADE Prevention (ADE Action Plan) in October of 2014. The report focuses efforts on the group of ADEs that are: (1) common, clinically significant, preventable and measurable, (2) result from high-priority drug classes and (3) occur largely in high-risk populations.² Similarly, The Institute of Safe Medication Practice (ISMP) annually defines several medication classifications that are considered to be 'high alert medications' (HAMs).³ The Joint Commission describes HAMs as more likely to be associated with harm than other drugs-they cause harm more frequently, the harm they produce is likely to be more serious and they have the highest risk of causing injury when misused.⁴ Examples of ADEs include overdoses, allergic reactions and adverse drug reactions, including common and known side affects such as high international normalized ratios (INRs) moderate oversedation and hypoglycemia.⁵ For the purposes of the HEN project and the ADE Action Plan, the drug classes of focus for both adult and pediatric patients are⁶:

- Anticoagulants
- Diabetes agents
- Opioids

Magnitude of the Problem and Why this Matters

A study of Medicare beneficiaries by the U.S. Department of Health and Human Services (DHHS) found that 30 percent of inpatients experienced an ADE in 2011.⁷ The Agency for Healthcare Research and Quality (AHRQ) estimated that drug-related adverse events occurred in nearly 1.9 million inpatient stays, which include events where little to no harm is caused to those resulting in death.⁸ Studies show that greater the number of medications administered, the greater the likelihood of drug-drug and drug-disease interactions.^{9,10} Furthermore, older hospitalized patients are at highest risk for ADEs.¹¹ Older patients are more likely to be prescribed and given medications and more likely to have serious conditions such as kidney and liver disease that can affect the metabolism and excretion of the administered drugs.¹² Irrespective of medication or indication, preventable ADEs were estimated to cost \$3.5 billion in 2006.¹³

HEN 1.0 Progress:

From 2011 through 2014, over 1,400 hospitals participating in the AHA/HRET HEN worked to prevent adverse drug events.



Reduce the incidence of harm due to adverse drug events by 40 percent by September 23, 2016.

PART 2: MEASUREMENT

A key component to making patient care safer in your hospital is to track your progress towards improvement. This section outlines the nationally recognized process and outcome measures that you will be collecting and submitting data on as part of the AHA/HRET HEN. Collecting these monthly data points at your hospital will guide your quality improvement efforts as part of the Plan-Do-Study-Act (PDSA) process. Tracking your data in this manner will provide you with the valuable information you need to study your data across time and determine the effect your improvement strategies are having in your hospital at reducing patient harm. Furthermore, collecting these standardized metrics will allow the AHA/HRET HEN to aggregate, analyze and report its progress towards reaching the project's 40/20 goals across all Adverse Event Areas (AEAs).

Nationally Recognized Measures: Process and Outcome

Please download and reference the encyclopedia of measures (EOM) on the AHA/HRET HEN website for additional measure specifications and for any updates after publication at: http://www.hret-hen.org/audience/data-informatics-teams/EOM.pdf

HEN 2.0 EVALUATION MEASURES

- Excessive Anticoagulation with Warfarin Inpatients
- Hypoglycemia in Inpatients Receiving Insulin
- Adverse Drug Events due to Opioids

SUGGESTED PROCESS MEASURES

- Hypoglycemia Monitoring: percentage of patients on insulin whose blood sugars registered <80 mg/dl at least once
- Opioid Risk Assessment: percentage of patients receiving opioids who receive an opioid risk assessment prior to first opioid dose
- Formal Assessment during Opioid Therapy: percentage of patients receiving opioids who regularly receive a formal assessment (e.g., POSS or RASS) during therapy.

Suggested Bundles and Toolkits

- IHI How To Guide: Prevent Adverse Drug Events (Medication Reconciliation). Retrieved at: http://www.ihi.org/resources/ Pages/Tools/HowtoGuidePreventAdverseDrugEvents.aspx
- IHI Trigger Tool for Measuring Adverse Drug Events. Retrieved at: http://www.ihi.org/resources/Pages/Tools/ TriggerToolforMeasuringAdverseDrugEvents.aspx
- Multi-Center Medication Reconciliation Quality Improvement Study (MARQUIS) Toolkit. Retrieved at: https://innovations.
 ahrq.gov/qualitytools/multi-center-medication-reconciliation-quality-improvement-study-marquis-toolkit
- Military Health System Sustainment Guide for Adverse Drug Events. Retrieved at: http://www.health.mil/~/media/MHS/ General%20Files/PatientSafety/PfP/Sustainment%20Guides/ADE%20Sustainment%20Guide%20January%20 2014_final.ashx
- Road Map to a Medication Safety Program. Retrieved at: http://www.mnhospitals.org/Portals/0/Documents/ptsafety/ade/ Medication-Safety-Roadmap.pdf
- ISMP Guidelines for Safe Order Sets. Retrieved at: http://www.ismp.org/tools/guidelines/StandardOrderSets.asp
- Hypoglycemia Agent Adverse Drug Event Gap Analysis. Retrieved at: http://www.mnhospitals.org/Portals/0/Documents/ ptsafety/ade/Medication-Safety-Gap-Analysis-Hypoglycemic.pdf
- Reduce Adverse Drug Events Involving Insulin, Institute for Healthcare Improvement. Retrieved at: http://www.ihi.org/ resources/Pages/Changes/ReduceAdverseDrugEventsInvolvingInsulin.aspx
- Anticoagulation Agent Adverse Drug Event Gap Analysis. Retrieved at: http://www.mnhospitals.org/Portals/0/Documents/
 ptsafety/ade/Medication-Safety-Gap-Analysis-Anticoagulation-Agent.pdf
- Opioid Adverse Drug Event Prevention Gap Analysis. Retrieved at: http://www.mnhospitals.org/Portals/0/Documents/ ptsafety/ade/Medication-Safety-Gap-Analysis-Opioid.pdf
- Pennsylvania Patient Safety Authority Opioid Tools Retrieved at: http://patientsafetyauthority.org/EducationalTools/ PatientSafetyTools/opioids/Pages/home.aspx
- · For key tools and resources related to preventing and reducing ADEs, visit www.hret-hen.org

Investigate Your Problem and Implement Best Practices

Driver diagrams: A driver diagram visually demonstrates the causal relationship between your change ideas, secondary drivers, primary drivers and your overall aim. A description of each of these components is outlined in the table below. This change package reviews the components of the driver diagram to first, help you and your care team identify potential change ideas to implement at your facility and second, to show how this quality improvement tool can be used by your team to tackle new process problems.

Aim	Primary Driver Primary Driver	Secondary Driver	Change Idea
		Secondary Driver	Change Idea
		Secondary Driver	Change Idea

AIM: A clearly articulated goal or objective describing the desired outcome. It should be specific, measurable and time-bound.

PRIMARY DRIVER: System components or factors that contribute <u>directly</u> to achieving the aim.

SECONDARY DRIVER: Action, interventions or lower-level components necessary to achieve the primary driver.

CHANGE IDEAS: Specific change ideas that will support and achieve the secondary driver.

Drivers in This Change Package

Prevent ADEs	Engage Patients and Families	Demonstrate the commitment to safety at all levels of the organization and patients	Change Ideas
		Build systems and processes that integrate patient and worker safety	Change Ideas
		Engage all team members in the commitment to safety; including patients and their families	Change Ideas
	Organizational Awareness, Readiness and Development	Support a culture that balances a systems approach and individual accountability	Change Ideas
		Create a reporting mechanism that is easy to use, meaningful and has a built in feedback process	Change Ideas
		Promote reflective learning and improvement	Change Ideas
	Standardize Care Processes	Design and ensure a safe work environment	Change Ideas
		Provide training on processes to support and improve patient and worker safety	Change Ideas
		Furnish staff with necessary equipment and supplies	Change Ideas
	Prevention of Failure	Implement an effective and efficient medication administration processes	Change Ideas
		Use forcing functions and redundancy for high risk processes	Change Ideas
		Implement an effective medication reconciliation process	Change Ideas
		Implement a culture of safety environment for improved error identification, mitigation and analysis	Change Ideas
	Decision Support	Use alerts wisely	Change Ideas
		Use of technology including but not limited to smart pumps, barcode technology and CPOE	Change Ideas

OVERALL AIMS: PREVENT ADEs

Primary Driver > Engage Patients and Families

By engaging patients and families in the care team, providers can further pursue the most effective paths of treatment, particularly once aware of the patient's home life and any relevant socio-economic situations. Furthermore when providers recognize the family as a partner, they become available to assist the care team with a patient's treatment regimen compliance, monitoring for side effects and enacting necessary lifestyle changes.

Secondary Driver > Acknowledge the patient and family as key partners in reducing harm from ADEs

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

Change Idea > Insulin-specific

- + Provide hypoglycemia rescue protocols to patients and families in a manner that they understand.
- + Use teach back to verify understanding.
- + Provide oral-concentrated glucose solutions and possibly glucagon for management of rescue events.
- + Allow hospitalized patients to perform self management when safe and appropriate.

Change Idea > Anticoagulant-specific

- + Ensure that patients and families thoroughly understand and can comply with appointments for follow-up INR testing at regular intervals.
- + If patients and families are unable to comply with discharge and follow-up instructions, work with community resources to arrange transportation or consider alternate medications.
- + Obtain a complete listing of all medications, including herbals and over-the-counter medications, so that drug interactions can be minimized or avoided.
- + Ensure patients have full understanding of any new dietary restrictions to help avoid drug-food interactions.

Change Idea > Opioid-specific

- + Educate patients and families regarding potentially lethal layering effects of multiple opioids, or a single opioid with a hypnotic, anxiolytic, muscle relaxant or alcohol.
- + Educate patients and families about the availability of naloxone in some states and its potential lifesaving effects.
- + Educate patients regarding the potentially lethal effects of failure to dispose of fentanyl patches properly.

Change Idea > Broadly applicable

+ Provide patient education in a language and literacy level all can understand.

Suggested Process Measures for Your Test of Change

- · Percent of patients discharged on insulin, warfarin or opioids who successfully performed a "read-back" during discharge medication counseling
- Percent of patients discharged on hypoglycemic agents who are also discharged with concentrated glucose solution as a home rescue agent
- Percent of patients discharged on hypoglycemic agents who needed to utilize their rescue concentrated glucose solution
- Percent of patients discharged on a Fentanyl patch who, through teach back, demonstrated understanding of the potentially fatal effect of this medication on children and the need to properly secure and dispose of these patches
- Percent of patients discharged on opioids who needed treatment in the emergency department due to an opioid ADE at home

Secondary Driver > Educate patients and families regarding the risks and benefits of HAMs

HAMs (e.g. anticoagulants, opioids and hypoglycemic agents) have high risk ratios: HAMs can be lifesaving or may mitigate intense pain, but can also be deadly. Providing information to patients and families that appropriately balances both risks and benefits to help arrive at the best path of treatment for each individual patient.

Change Idea > Insulin-specific

- + Instruct patients that glucose targets in the hospital may be higher than what they have been taught by their doctor. This is because it is easier to become hypoglycemic in hospitals.
- + Inform patients not to self-medicate while in the hospital, unless their doctor has specifically written that order and the nurse is aware.

Change Idea > Anticoagulant-specific

+ Inform patients and families that anticoagulants like warfarin can help prevent life threatening blood clots in hospitalized patients and that compliance with dietary instructions are important in maintaining proper drug levels.

Change Idea > Opioid-specific

- + Educate patients and families about the danger of pain relievers and that hospital staff may instead chose to employ non-pharmacological methods of pain and anxiety management to manage the patient's pain instead of opioids, when appropriate.
- + In addition, families can help manage a patient's pain and anxiety by adjusting environmental factors such as lowering bright lights, decreasing noise levels and achieving optimal room temperature, as well as being empathetic.

Change Idea > Broadly applicable

+ Educate patients and families about the importance of keeping HAMs secured from small children and other vulnerable individuals.

Suggested Process Measure for Your Test of Change

• Percent of patients who experience an ADE related to undirected self-medication while in the hospital

Secondary Driver > Explore and understand the patient's social situation

Through engagement and communication with patients and families, providers are often able to obtain information about a patient's access to transportation and food, which may impact adherence to discharge instructions. The inability to secure transportation to laboratory appointments may lead to lack of drug effect monitoring and can potentially lead to life threatening results from either over or under treatment. Diabetics on limited income may become hypoglycemic when they have no money to purchase food, a situation sometimes referred to as the "food cycle" of hypoglycemia.¹⁴ Additionally, warfarin requires regular monitoring of INR levels.

Change Idea > Insulin-specific

+ Patients may have very different dietary habits at home. Low-income patients have been shown to have high carbohydrate diets. Blood glucoses may drop precipitously when admitted to the hospital due to illness and changes in appetite or diet occur. Families should be discouraged from bringing food from home to the patient.

Change Idea > Anticoagulant-specific

+ Families should be discouraged from bringing food from home to the patient as certain foods can alter the drug labels of warfarin and make it ineffective or cause bleeding.

Change Idea > Opioid-specific

+ Families and friends must understand that no medications can be brought from home to help alleviate the patient's pain. These medications, coupled with medication prescribed in the hospital, may cause catastrophic events. Families should be instructed that if the patient appears in pain, work with the doctor and nurse to manage it.

Change Idea > Broadly applicable

+ Encourage patients and families to support their care team in identifying areas of potential harm, including where family provided meals and home medications may impact care.

Suggested Process Measure for Your Test of Change

• Percent of patients and families who perform an accurate teach back, that is, confirming the patient's understanding of the instructions and the concept by having the patient explain them back

Hardwire the Process

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

Primary Driver > Organizational Awareness, Readiness and Development

ADEs do not happen in a vacuum. Previous QI campaigns like the "The Five Rights: Right Patient, Right Drug, Right Dose, Right Route, Right Time" were directed solely towards the necessity of changing hospital staff behaviors to address medical errors instead of on identifying and understanding system failures that lead to medication errors and ADEs. A culture of safety is integral to improved medication safety and supports the effective redesign of systems to prevent errors.

Secondary Driver > Assess organizational capacity and readiness

Capacity is the number of people available to do a task. However, true organizational capacity is determined by the culture of an organization and its readiness and willingness to examine and change systems of care to promote quality improvement. Assess capacity at the global, unit and individual levels for insight into barriers that impede optimal medication safety.

Change Idea > Insulin-specific

- + Assess current policies, procedures and order sets for prevention of hypoglycemia.
 - > Determine the organization's target glucose ranges.
 - > Assess relevant data; i.e., number of severe hypoglycemia events or the number of events requiring rescue D50 that have occurred.

Change Idea > Anticoagulant-specific

- + Assess current policies, procedures and order sets for warfarin management.
- > Determine pharmacist and physician receptiveness for pharmacy management of warfarin via validated protocols.

Change Idea > Opioid-specific

- + Assess current policies and procedures of sedation practices and sedation monitoring.
- + Use the Opioid Adverse Drug Event Prevention Gap Analysis.¹⁵

Change Idea > Broadly applicable

- + Use the Institute for Safe Medical Practices (ISMP) Self-Assessment Tool.¹⁶
- + Use a patient safety culture survey instrument such as the Safety Attitudes Questionnaire (SAQ)¹⁷ or AHRQ Patient Safety Instrument.¹⁸

Suggested Process Measure for Your Test of Change

• Analyze ISMP self-assessment results and identify the number of safe practices not yet implemented or active safety programs that need to be enhanced

Secondary Driver > Assess staff knowledge

Analyze organizational assessments to identify performance gaps, develop strategies to improve performance and educate relevant stakeholders. Repeat the organizational assessments in the future and make necessary adjustments. Increased knowledge and awareness will lead to new processes and systems and fewer errors.

Studies show that most health care providers (e.g. physicians, pharmacists or nurses) score lower than 50% on a standardized opioid knowledge assessment.¹⁹ Assessment of staff knowledge can inspire active learning and guide targeted education and training. Education alone may not be sufficient to reduce ADEs due to opioids, but education does provide an important foundation for quality improvement in this area.

Change Idea > Insulin-specific

+ Hold discussions with nurses and physicians regarding hypoglycemia. Do they consider it just a "cost of doing business?" Do they understand the risks of severe hypoglycemia and know that it is often avoidable?

Change Idea > Anticoagulant-specific

+ Assess the knowledge of pharmacists and physicians in the management of warfarin. If the INR is trending up but not yet out of range, is there concern or an urgency to modify the dosage?

Change Idea > Opioid-specific

- + Use the Opioid Adverse Drug Event Prevention Gap Analysis.
- + Use the Pennsylvania Patient Safety Authority Opioid Knowledge Self-Assessment Tool.
 - > Assess clinical staff knowledge via a pre-test.

- > Identify and target gaps in knowledge and understanding.
- > Educate staff and other appropriate stakeholders.
- + Implement a six-week post test to assess effective learning.^{21,22}

Change Idea > Broadly applicable

- + Incorporate practical testing of ADE knowledge as part of annual competency testing for nurses.
- + Use medical staff and pharmacy peer review mechanisms to provide feedback to professionals regarding opportunities for knowledge improvement.

Suggested Process Measure for Your Test of Change

· Percent of staff showing improvement on post-test assessment after education or training

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

Research shows that creating and using tools that assess organizational knowledge and practices improves the organizations awareness of the risks of HAMS. Analysis of organizational assessments helps to identify performance gaps, develop strategies to improve performance and educate relevant stakeholders. Organizational assessments should be repeated in the spirit of continuous improvement leading to increased knowledge and awareness, new processes and systems and fewer errors. Vertical and horizontal communication of the assessment findings and actions taken will spread and sustain organizational improvements.

Change Idea > Insulin-specific

+ Educate nurses and physicians about hypoglycemia and the fact that it is not an unavoidable result of insulin therapy.

Change Idea > Anticoagulant-specific

+ Alert the pharmacy to track and trend INRs, and intervene before they represent excessive anticoagulation.

Change Idea > Opioid-specific

+ Educate staff about the risks of over-sedation, especially in the frail elderly and those at risk for sleep apnea.

Change Idea > Broadly applicable

+ Show the data! Track and trend hypoglycemic, excessive anticoagulation and over-sedation events. Find and tell stories of harm.

Suggested Process Measures for Your Test of Change

- Percent increase in the number of ADEs reported by staff in patients prescribed anticoagulants, opioids and insulin
- Percent of patients readmitted due to ADE complications

Hardwire the Process

Regular assessments of performance are important for hardwiring awareness, readiness and education into an organization's culture. Utilize the ISMP self-assessment tool and AHRQ Culture of Safety Surveys at least annually and note progress in every section. Communicate the results of the assessments and provide necessary education and training across the organization.

Primary Driver > Standardize Care Processes

Standardizing a work process will lead to more standard outcomes. However, medicine is complex, and not everything in health care can or should be standardized. Use standard orders and protocols to incorporate special safety precautions for target groups that have specific patient characteristics, such as advanced age or chronic conditions or particular high-risk diseases. Customize approaches for all patients who are prescribed HAMs and in doing so, make that action a systematized or routine practice.

Secondary Driver > Implement ISMP quarterly action agendas where appropriate

The ISMP quarterly action agendas (available on https://www.ismp.org/newsletters/acutecare/actionagendas.aspx) gather together the most up-to-date safe medicine practices within a variety of areas from self-reports queries and other surveys that identify unsafe medication practices. Not all best practices are appropriate for every hospital; for example, some are focused on medications used only in more intensive or complex settings. Hospitals can elect to implement specific recommendations that are relevant to their own HAM utilization.

Change Idea > Insulin-specific

+ Consider using insulin pens only under special circumstances. (ISMP Quarterly Action Agenda, Oct-Dec. 2014)

Change Idea > Anticoagulant-specific

+ Conduct an interdisciplinary Failure Modes and Effects Analysis (FMEA) to identify sources of risk that are specific to an organization related to the use of anticoagulants and further individualize improvements needed to reduce the risk of errors. (ISMP Quarterly Action Agenda, Jan-Mar. 2007)

Change Idea > Opioid-specific

+ Only allow basal Patient Controlled Analgesia (PCA) doses for opioid tolerant patients. (ISMP Quarterly Action Agenda, Apr-June 2015)

Change Idea > Broadly applicable

+ Review ISMP action plans at www.ismp.org and implement as appropriate.

Suggested Process Measure for Your Test of Change

• (Yes/No) ISMP action plans are reviewed on a regular basis by care team

Secondary Driver > Develop standard order sets using safety principles

Work with the health care team including physicians and pharmacists to develop standard order sets for HAMs. Use safety principles as resources to assist in the development of the standard order sets. Consider using relevant professional societies as resources in development of standard order sets.

Change Idea > Insulin-specific

- + Reduce or eliminate sliding-scale variation.
- + Coordinate meals and insulin administration times.
- + Use insulin infusion per ADA recommendations in critically ill patients.

Change Idea > Anticoagulant-specific

+ Use a protocol to discontinue or restart warfarin perioperatively.

Change Idea > Opioid-specific

- + Use protocols and tables for equianalgesic transition from one opioid to another.
- + Limit dosage strengths available in floor stock and automated drug cabinets.

Change Idea > Broadly applicable

- + Include clinical informatics representative on the improvement team to integrate order sets, alerts and documentation in the EMR.
- + Create standard (standing) orders:
 - > Obtain examples of order forms utilized at other institutions and ask: "What would we need to modify to make a standing order work here?"
 - > Allow flexibility within orders to address specific patient characteristics that may increase risks.
 - > Allow clinicians to opt-out of standard orders when the standard orders don't "fit" the patient.
 - > Aggregate the opt-outs on the standard orders in categories based on indications for their use.
 - > Study opt-out use data to assess situational appropriateness. Revise standing orders as necessary.
 - > Consider including IT in the design and development of physician order sets making it easier and more likely that physicians will utilize them consistently.

Suggested Process Measures for Your Test of Change

- Percent of patients with a blood glucose of <70 mg/dL (one or more times) who had their insulin orders modified
- · Percent of patients who are transitioned from one opioid to another with equianalgesic orders
- · Percent of patients for whom a protocol was used for peri-operative warfarin

Secondary Driver > Implement targeted standard work

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

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

Change Idea > Insulin-specific

+ Implement standard processes to ensure coordination of short acting insulin administration and meal delivery.

Change Idea > Anticoagulant-specific

+ Implement pharmacy driven INR trending with targeted interventions when the rate of rise is too fast or exceeds optimal range for the clinical indication.

Change Idea > Opioid-specific

- + Use standardized sedation assessment scales such as the POSS or RASS (see Appendix II and III).
- + Develop protocols to manage fentanyl patches to prevent overdose.

Change Idea > Broadly applicable

- + Allow nurses to administer rescue drugs based on protocol without obtaining physician approval.
- + Run reports that are available from automated tools and systems and decide how that information can be incorporated into the performance improvement process.

Change Idea > Suggested Process Measures for Your Test of Change

- · Percent of patients with opioid orders for whom a standardized risk screening tool was used
- Percent of patients with opioids that received regular assessment using a tool such as POSS or RASS
- · Percent of transfers to a higher level of care that occurred because of opioid over sedation
- Number of nurse administered rescue drugs recorded

Hardwire the Process

Involving providers of all levels in the design of processes will enhance their understanding of the rationale behind improvement changes as well as increase the effectiveness of the changes. For example, physicians should not only be involved in defining the order sets but also in determining how the order sets will be delivered and which prompts will be necessary to guide users. Standardizing concentrations, setting dosing limits and using pre-packaged heparin for infusion are examples of hardwiring interventions. Hardwiring for ADE prevention may include providing routine reminders that two licensed caregivers should double check orders at the bedside. Observations and chart reviews may also be used. If an electronic medical record is being used, a hard stop can be implemented to force the documentation of the double check.

Primary Driver > Prevention of Failure

Medication errors are the most frequent cause of adverse drug events.^{23,24} Effective system and process designs can decrease medication errors. Transitions of care between staff or along the health care continuum can become dangerous source of errors. Though complete solutions remain elusive,^{25,26} improved processes have been identified that can prevent or mitigate errors by reducing variation in care process.

Secondary Driver > Implement effective and efficient medication administration processes

Most medication errors can be attributed to system failures during the administration process, with distractions and interruptions being a major contributing factor.²⁷ One study reported nurses observing as many as thirty interruptions during a single nursing shift.²⁸ Minimizing distractions can promote a safer work environment. Furthermore, pharmacist participation in medical rounds significantly reduces the rate of ADEs caused by prescribing errors, both in an ICU setting²⁹ and in general medical units.³⁰

Multiple formulations of a medication and multiple dosing options can lead to errors. Over 30 years ago, only two concentrations were available for regular insulin: 40 units/mL (U-40) or 100 units/mL (U-100). Many examples of unintended hypoglycemic events have occurred when patients who had been on U-40 were given the same doses, but were medicated by insulin of U-100 concentration. Today, standard insulin is provided only in U-100 form to avoid this potential error. Similar principles apply to all HAMs. Having too many options (e.g. various heparin concentrations in adult ICUs) can lead to errors and ADEs. Another strategy to minimize potential errors in ordering and administration, is to create a list of the 'look-alike/ sound-alike' medications they as they store, dispense or administer medications.

Change Idea > Insulin-specific

+ Allow patients' self-management of insulin dosing when appropriate. Set limits on high dose orders.

Change Idea > Anticoagulant-specific

- + Use prepackaged heparin infusions; reduce the number of different heparin formulations in the hospital.
- + Use low-molecular weight heparin or other newer agents instead of unfractionated heparin whenever clinically appropriate.
- + Make laboratory results available within two hours; create a closed loop or system for the management of elevated or unexpected test results and levels.
- + Perform automatic nutrition consults for all patients on warfarin to avoid drug-food interactions.

Change Idea > Opioid-specific

- + Use sedation assessment scales to guide dosing in all care areas.
- + Use dosing limits.
- + Use tools to prevent overdose due to hydromorphone.
- + Use a table of drug-to-drug conversion doses.
- + Implement fall prevention programs.

Change Idea > Broadly applicable

- + Adopt an organization wide standard for independent double checks.
- + Perform independent double checks on all HAM administrations.
- + Include pharmacists on rounds it significantly reduces the rate of ADEs caused by prescribing errors, both in the ICU setting and in general medical units.
- + Minimize and eliminate nurse distractions during medication administration process especially during care transitions along the care continuum. Implement visual cues, such as a medication sash and designated quiet areas.
- + Standardize concentrations and minimize dosing options where feasible.

Suggested Process Measures for Your Test of Change

- Number of interruptions by fellow staff during medication administration during each shift
- Number of interruptions by patients or families during medication administration during each shift
- Number of observed medication distribution errors
- Number of order adjustments suggested by pharmacy during rounds
- Number of medication errors related to look-alike, sound-alike medications

Secondary Driver > Use forcing functions and redundancy for high risk processes

When used smartly and judiciously, forcing functions can help prevent adverse drug events. Forcing functions, like the change ideas below, can help recognize and avoid events due to hyper and hypoglycemia, over-anticoagulation and over sedation. These built-in checks can be set to require regular monitoring of designated processes by direct observation or by chart review.

Change Idea > Insulin-specific

+ Require the acknowledgement that the meal tray is on the way or present at the bedside before insulin can be removed from the automated dispensing cabinet.

Change Idea > Anticoagulant-specific

+ Require an INR be drawn and results evaluated before any inpatient receives a dose of warfarin, even if it one of the patient's chronic medications.

Change Idea > Opioid-specific

+ Implement standard processes for opioid ordering to prevent duplicate layered opioids or opioids with benzodiazepines.

Change Idea > Broadly applicable

+ Hard and soft stops, that are properly designed and implemented, lead clinicians to "do the right thing" and help prevent them from "doing the wrong thing".

Suggested Process Measures for Your Test of Change

- Number of patients who become hypoglycemic while awaiting their meals
- Percent of critical inpatient lab results for patients receiving anticoagulants, opioids and insulin for which a documented action or response was not evidenced (failure rate)

Secondary Driver > Implement an effective medication reconciliation process

Providing medications correctly at each point that transition of care occurs, especially upon admission and discharge, is a critical component of medication management. Some hospitals use pharmacy staff or technicians to assist with medication reconciliation occurs during admission, transitions and discharge.

Change Idea > Insulin-specific

+ Require new insulin orders when patients transition from parenteral to enteral nutrition.

Change Idea > Anticoagulant-specific

+ Confirm all medications on admission, transfer and discharge to minimize drug-drug interactions that would affect INR levels.

Change Idea > Opioid-specific

+ Assess the patient's opioid history to determine if the patient is opioid naïve (<60 mg morphine equivalence per day for the last seven days) or opioid tolerant (> or = to 60 mg morphine equivalence per day for the last seven days).

Change Idea > Broadly applicable

- + Reconcile all medications at each transition.
- + In the absence of an EMR, use flowsheets that follow the patient throughout the transitions of care.
- + Use pharmacy staff or technicians to assist with medication reconciliation during admission, transitions and discharge.

Suggested Process Measures for Your Test of Change

- · Percent of patients on insulin who receive new orders when they are removed from parenteral feedings and placed on enteral feedings
- · Percent of patients whose opioid history was assessed prior to prescription of opioids

Secondary Driver > Implement a culture of safety environment for improved error identification, mitigation and analysis

Medication errors need to be recognized and reported in order to be addressed. A culture of blame will not lead to reduced ADEs.³¹ Organizations that have successfully implemented a culture of safety and transitioned to improvements in reporting, comprehensive error analysis and subsequent system revisions, have demonstrated sustainable reductions in errors.³²

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

Change Idea > Insulin-specific

+ Reward nurses for reporting hypoglycemic events and severe hypoglycemic events, as well as contacting physicians to obtain new orders the first time a hypoglycemic event occurs with a given patient.

Change Idea > Anticoagulant-specific

+ Acknowledge physicians and pharmacists who report excessive anticoagulation events and who work collaboratively to develop and implement processes to minimize high INRs.

Change Idea > Opioid-specific

+ Support nurses who resist physician attempts to sedate patients too quickly. Reward all staff for reporting any over-sedation events, no matter how trivial they might appear.

Change Idea > Broadly applicable

- + Assess organizational culture with the Agency for Healthcare Research and Quality Culture of Safety survey.
- + Monitor, identify, understand and mitigate medication administration errors and delays. Use blame free, error reporting systems to promote learning and to direct the redesign of error-prone processes.
- + Conduct an interdisciplinary FMEA in a non-punitive manner on prior ADE events to identify system breakdowns, knowledge gaps and opportunities to redesign processes and systems.
- + Reassess and modify standing orders whenever a rescue drug is needed for a patient or to prevent an ADE recurrence in the same patient.
- + Use focused audits to identify practice patterns, ADEs and system failures (e.g., administration of D50 in insulin-treated ICU patients or naloxone in outpatient and inpatient procedure areas).
- + Prompt real-time learning from each failure.
- + Monitor and analyze use of reversal agents to uncover and identify system failures.
- + Analyze dispensing unit override patterns.
- + Implement review and action based on timely, key lab results.

Suggested Process Measure for Your Test of Change

• Percent increase in the number of ADEs reported by staff in patients prescribed HAMs after interventions related to culture

Hardwire the Process

Medication ordering and reconciliation tools can help to hardwire this process. Tools can be created through both paper and electronic ordering systems. Standardized discharge order sets with an automatic referral of patients on anticoagulation to ambulatory warfarin centers at discharge, facilitated by clinicians experienced in handling these transitions, can help make these processes routine.

Primary Driver > Decision Support

Decision support provides additional information, problem solving and controls to prevent adverse drug events. Decision support occurs when information is provided at the right time to help clinicians make more informed and accurate decisions. Medication manuals at a nursing station are a form of decision support. Technology solutions also provide decision support. Alerts on electronic prescribing platforms can pick up dosing errors and display both drug allergy and sensitivity data. This can decrease the use of inappropriate agents.

Secondary Driver > Use alerts wisely

Overuse of alerts and hard stops can cause alert fatigue and frustration. This frustration can lead to the use of work-arounds that may increase risk and reduce safety. Requiring documentation for an override spurs the clinician to think twice about stepping outside the recommended guidelines and protocols. The documented override reason can then be reviewed to help improve protocols and identify education and training needs. Additionally, monitoring the override rate can provide clues about trends and patterns in processes and systems.

Change Idea > Insulin-specific

+ Implement real time alerts to notify nurse shift leaders when D50 is pulled from the automated drug cabinet.

Change Idea > Anticoagulant-specific

+ Implement real time alerts to the care team whenever an INR is greater than 5.0.

Change Idea > Opioid-specific

+ Implement real time alerts to notify nurse shift leaders when naloxone is pulled from the automated drug cabinet.

Change Idea > Broadly applicable

- + Use data from alerts and overrides to redesign standardized processes.
- + Assess responses to alerts to determine if alert needs to be strengthened, modified or eliminated.
- + Monitor overlapping medications given to patients.
- + Consider establishing criteria for clinical pharmacist intervention for both the utilization of HAMs, as well as for the prescription of large amounts and high doses of all medications.

Suggested Process Measures for Your Test of Change

- Rate of alert overrides without documented reason
- Rate of alert overrides with documented reason

Secondary Driver > Use of technology including but not limited to smart pumps, barcode technology and CPOE

Utilizing technology effectively will help to identify and mitigate errors. Advancements such as computerized physician order entry (CPOE), computerized physician decision-support, barcode scanning and smart pumps have improved drug safety.^{33,34} Technologies such as these can be used to identify errors made and can prevent prescribing mistakes by providing preapproved dosage prompts and decision support.

Many hospitals have implemented the use of smart IV pumps to facilitate appropriate dosing and flow and to alert providers to change medication bags. They can be used to make dosing adjustments and calculations available at the point-of-care. Smart pumps are not infallible however and could support a wrong dose or rate of administration creating unintended negative consequences for patients. Double checking smart pump function remains important.

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

Some facilities also use barcode technology to reduce medication errors during administration. Although helpful, barcode systems do not detect all errors and can be overridden, at times inappropriately.³⁵

Change Idea > Insulin-specific

- + Standardize subcutaneous and intravenous insulin concentrations.
- + Create alert for nurse prior to administration of insulin if most recent blood glucose was <100 mg/dl.

Change Idea > Anticoagulant-specific

- + Enlist pharmacists to assist with the identification of alternatives when contraindications exist.
- + Laboratory tests ordered to assess the effectiveness of anti-coagulants and anti-thrombotic agents need to be processed via a closed-loop mechanism to ensure the lab results are seen, evaluated and acted upon in an appropriate and timely manner. Lab values can guide physicians and pharmacists in making treatment decisions.
- + Have pharmacists perform independent double checks of all venous thromboembolism (VTE) prophylaxis orders.

Change Idea > Opioid-specific

- + Use alerts to avoid the use of multiple narcotics or sedatives.
- + Use alerts to avoid over-sedation and respiratory arrest.
- + Use alerts and dosage limits on concurrently prescribed opioid potentiators.
- + Use prompts and defaults (with a physician override option) for administration of equianalgesic medications for opioid-to-opioid conversion.

Change Idea > Broadly applicable

- + Implement alerts for dosing limits. Monitor override patterns for barcodes, automated dispensing units and other technological tools.
- + Link order sets to recent lab values.

Suggested Process Measures for Your Test of Change

- Measure the percent of VTE prophylaxis orders that have had independent double checks performed
- Rate of overrides for automated dispensing units
- Rate of overrides in barcode systems
- Number of ADEs related to smart pumps
- Number of ADEs related to PCAs

Hardwire the Process

Soft stops, hard stops and alerts are all examples of hardwiring. A soft stop is a reminder that requires no action. The health care provider can proceed simply by pressing a key or clicking the mouse. A hard stop requires a specific and appropriate action before the provider is allowed to proceed. Beware though, alerts not chosen wisely can create alert fatigue and ultimately interfere with the process and cause harm. With technology solutions, hardwiring includes performing systematic audits to ensure that the technology is being used appropriately. Additionally, it is important to anticipate and prevent potential errors and inappropriate overrides that could generate unintended negative consequences.

PDSA IN ACTION | TIPS ON HOW TO USE THE MODEL FOR IMPROVEMENT

Choice of Tests and Interventions for ADE Reduction

- There are interventions that can be effective in reducing the risks of ADEs. Improvement teams should begin their efforts by asking: "What is the greatest need at our facility? Where can we have the greatest impact?" Suggested tests of change include:
 - > Trial the use of a new smart pump on one unit where pumps are used frequently (e.g., an intensive care unit).
 - > Pilot the use of pharmacists in clinical rounds on one unit or with one physician. Utilize the success of the pilot to promote broader adoption of this best practice.
 - > Pilot a program to minimize distractions during the medication administration process. Use data (e.g., number of interruptions, number of errors) to demonstrate improved outcomes and gain buy-in from physicians and other care providers.
 - > Implement the double check policy for HAMs incrementally, reviewing implementation for resource needs and constraints and other actual or potential issues (e.g. delay of treatment).

Implement Small Tests of Change

Test a medication administration design change.

PLAN

Design a small pilot on a unit where the lead physicians, clinical champions and nurses are comfortable with testing medication administration design changes and protocols.

DO

Keep the scale of an initial test small. Begin with one nurse, on one shift. Then test with a few more nurses of varying experience levels and a small number of patients.

STUDY

Analyze the results of testing and disseminate successful processes and changes to the executive leadership and the larger institution.

ACT

Continue to monitor the effectiveness of these processes and make necessary periodic revisions to enhance performance.

Potential Barriers

- Recognize that, for many physicians, technology will demand changes in their practice. The use of alerts, hard and soft stops and decision support may be new and may invoke perceptions of a loss of control and the idea that they're being told how to practice medicine. To help engage physicians in the use of technology, recruit one or two early-adopting physician champions to serve as ambassadors and mentors for these changes.
- Technology involves a learning curve. Different practitioners will adapt to new technologies and processes at different rates. Provide adequate training and support for practitioners unfamiliar with new systems and technologies.
- Physicians may resist using standard orders, believing they represent cookbook medicine. Educating physicians regarding the proven value of standard order sets in reducing errors can mitigate this resistance and increase adoption. Presenting the options for customization and opt-out for patients with special needs can promote acceptance.
- Nurses may be hesitant to provide rescue medications via protocols without specific physician orders. They may fear harming
 patients, working beyond their scope, making errors or receiving negative feedback from physicians. It is important that
 both nurse and physician leaders openly support these nurse-driven protocols, provide adequate training and support and
 intercede if inappropriate or uncivil encounters occur as a result of following protocols.
- Some physicians are uncomfortable reconciling medications ordered by other physicians and commonly describe concerns about medico-legal liability along with lack of knowledge about or familiarity with the drugs prescribed. Organizations should develop processes, approved by the medical staff, that outline responsibilities for all parts of discharge medication reconciliation. Often primary care physicians or hospitalists can perform this role.
- Physicians may be cautious about supporting protocols implemented by pharmacists, nurses or nurse practitioners in ambulatory centers. Some physicians may be unaware of the positive safety records and advantages of these clinics. Education about the advantages of such protocols and including physicians in the protocol development process can be reassuring.
- The ability to use technology to install dosage and multiple (duplicative) therapy alerts may not be available at every facility.
- Updating senior managers about the value of new technology may persuade them to consider providing resources to support technology upgrades.
- Resistance to a uninterrupted medication administration may develop if physicians' and other care providers' workflow is
 impacted by waiting to talk with a patient's nurse. The urge to interrupt with a "quick question" may be difficult to suppress.

Enlist Administrative Leadership as Sponsors to Help Remove or Mitigate Barriers

- Executive, clinical and human resource leaders must lead the effort to prevent and reduce errors. Leaders who employ blame and shame when dealing with errors are likely to decrease their staff's willingness to report an error from which they could learn. It is critical that an organization's senior management, team leaders, human resources department and legal staff understand this new culture of safety approach.
- Senior physician, nurse and pharmacy management will be critical players in promoting the success of new innovations such as those noted above. Some improvement efforts may be initially perceived as punitive (timeliness audits), new and unfamiliar ("Consult a pharmacist? What's a hard stop?") or burdensome (independent double checks before administering a HAM).
- Physician leadership will be the key to success. The literature provides evidence supporting the efficacy of both medication reconciliation³⁶ and protocol-driven warfarin clinics. As physicians observe that these processes prove to be in the best interest of patients, and in some cases easier for the physicians to practice, more and more doctors will adopt them until a tipping point is reached, transforming the culture of the entire organization.
- Purchasing and implementing new technology requires resources. Senior leadership should understand the benefits of such upgrades and drive the efforts to obtain the necessary resources to achieve the outlined strategic goals for ADE prevention. Productive financial investments in these efforts can be directed towards the units demonstrating the greatest quality improvements and can promote broader adoption of these change ideas and best practices.

Change not only "The Practice," but also "The Culture"

- Improving medication safety requires a significant shift from a culture of blame to a culture of learning and system
 improvement. It does not require, however, the establishment of an entirely blame-free environment; reckless or negligent
 behavior should never be tolerated.
- Standard processes and standing orders work. Collectively, this combination of processes has been shown to outperform traditional care methods.^{37,38} As health care providers become more comfortable with standard processes, clinicians can focus on the occasional patient situations that require deviation from the standard.
- Including pharmacists as consultants on the health care team during patient rounds may require a change in culture. The concept of multi-disciplinary teaming may require clinician education, in-services or simulations to build or improve care providers' communication, team function and conflict resolution skills.
- Implementation of these innovations should begin with small tests of change and when successful disseminated to the larger organization. The eventual goal is for the entire organization to develop successful team-based care that improves quality and safety for patients.

PART 4: CONCLUSION AND ACTION PLANNING

Despite progress over the last few years, adverse drug events still remain the most common of all adverse events with warfarin, insulin and opioids having the greatest incidence of harm. This change package offers knowledge, strategies and ideas ready for you to test and implement within your organization.

First, assess your own organization by seeking out your ADEs. Do not rely on occurrence reports as they likely underrepresent the actual occurrence of ADEs. Start by searching for INRs >5, glucoses <50 mg/ dl and naloxone use. Once you have identified an area of opportunity, engage the front line staff by asking their ideas. Next, find physician, nurse, pharmacy and administrative champions. Finally, start with small, time limited tests of change. Learn from each of these tests and try again. It is important to make sure the new process is workable before you spread, but do not wait until you have a perfect process.

PART 5: APPENDICES

APPENDIX I: ADVERSE DRUG EVENTS (ADE) TOP TEN CHECKLIST

Associated Hospital/Organization: AHA/HRET HEN 2.0

Purpose of Tool: A checklist to review current or initiate new interventions to prevent ADEs in your facility

Reference: www.hret-hen.org

ADE Top Ten Checklist				
Process Change	In Place	Not Done	Will Adopt	Notes (Responsible and By When?)
Standardize concentrations and minimize dosing options where feasible.				
Minimize or eliminate pharmacist or nurse distraction during the medication fulfillment and administration process.				
Use data and information from alerts and overrides to redesign standardized processes.				
Set dosing limits for insulin and opioids.				
Reduce sliding scale variation (or eliminate sliding scales).				
Coordinate meal and insulin times.				
Target inpatient blood glucoses to safe levels: 140-180 mg/dl (some surgical patients may have net benefit at 100-180 mg/dl). No patient should have a glucose target <100.				
Implement pharmacist-driven warfarin management.				
Use alerts to avoid multiple prescriptions of opioids and sedatives.				
Use effective tools to reduce over-sedation from opioids (e.g. risk assessment tools such as "STOP BANG" and sedation assessment tools such as the Richmond Agitation Sedation Scale or the Pasero Opioid-Induced Sedation Scale).				

APPENDIX II: PASERO SCALE

Associated Hospital/Organization: Not applicable

Purpose of Tool: To assess sedation levels of patients who are receiving opioids to prevent over-sedation and respiratory depression

Reference: Pasero. Assessment of sedation during opioid administration for pain management. *Journal of Perianesthesia Nursing*, 24:186-90, 2009. Retrieved at http://www.mghpcs.org/eed_portal/Documents/Pain/Assessing_opioid-induced_ sedation.pdf

Pasero Opioid-induced Sedation Scale (POSS)

S = Sleep, easy to arouse

Acceptable; no action necessary; may increase opioid dose if needed

- 1. Awake and alert
- > Acceptable; no action necessary; may increase opioid dose if needed
- 2. Slightly drowsy, easily aroused
 - > Acceptable; no action necessary; may increase opioid dose if needed
- 3. Frequently drowsy, arousable, drifts off to sleep during conversation
 - > Unacceptable; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory; decrease opioid dose 25% to 50% or notify prescriber or anesthesiologist for orders; consider administering a non-sedating, opioid-sparing nonopioid, such as acetaminophen or an NSAID, if not contraindicated.
- 4. Somnolent, minimal or no response to verbal or physical stimulation
 - > Unacceptable; stop opioid; consider administering nalaxone; notify prescriber or anesthesiologist; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory

APPENDIX III: RICHMOND AGITATION-SEDATION (RASS) SCALE

Associated Hospital/Organization: Not applicable

Purpose of Tool: To assess the level of consciousness and agitated behavior in ICU patients that can be used to guide sedation and assist in communication among care providers

Reference: Curtis N. Sessler, Mark S. Gosnell, Mary Jo Grap, Gretchen M. Brophy, Pam V. O'Neal, Kimberly A. Keane, Eljim P. Tesoro, and R. K. Elswick "The Richmond Agitation–Sedation Scale", *American Journal of Respiratory and Critical Care Medicine*, Vol. 166, No. 10 (2002), pp. 1338-1344. Retrieved at: http://www.atsjournals.org/doi/full/10.1164/rccm.2107138#. VwwGDxMrLOS

Richmon	Richmond agitation sedation scale				
Score	Term	Description			
	Combative	Overtly combative or violent; immediate danger to staff			
	Very agitated	Pulls on or removes tube(s) or catheter(s) or has aggressive behavior toward staff			
	Agitated	Frequent non-purposeful movement or patient-ventilator dyssynchrony			
	Restless	Anxious or apprehensive but movements not aggressive or vigorous			
	Alert and calm				
	Drowsy	Not fully alert, but has sustained (more than 10 seconds) awakening, with eye contact, to voice			
	Light sedation	Briefly (less than 10 seconds) awakens with eye contact to voice			
	Moderate sedation	Any movement (but no eye contact) to voice			
	Deep sedation	No response to voice, but any movement to physical stimulation			
	Unarousable	No response to voice or physical stimulation			

Procedure

- 1. OBSERVE PATIENT. Is patient alert and calm (score 0)?
- Does patient have behavior that is consistent with restlessness or agitation (score +1 to +4 using the criteria listed above, under DESCRIPTION)?
- 2. IF PATIENT IS NOT ALERT, in a loud speaking voice, state patient's name and direct patient to open eyes and look at speaker.
- Repeat once if necessary. Can prompt patient to continue looking at speaker.
- Patient has eye opening and eye contact, which is sustained for more than 10 seconds (score -1).
- Patient has eye opening and eye contact, but this is not sustained for 10 seconds (score -2).
- Patient has any movement in response to voice, excluding eye contact (score -3).
- 3. IF PATIENT DOES NOT RESPOND to voice, physically stimulate patient by shaking shoulder and then rubbing sternum if there is no response to shaking shoulder.
- Patient has any movement to physical stimulation (score -4).
- Patient has no response to voice or physical stimulation (score -5).

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