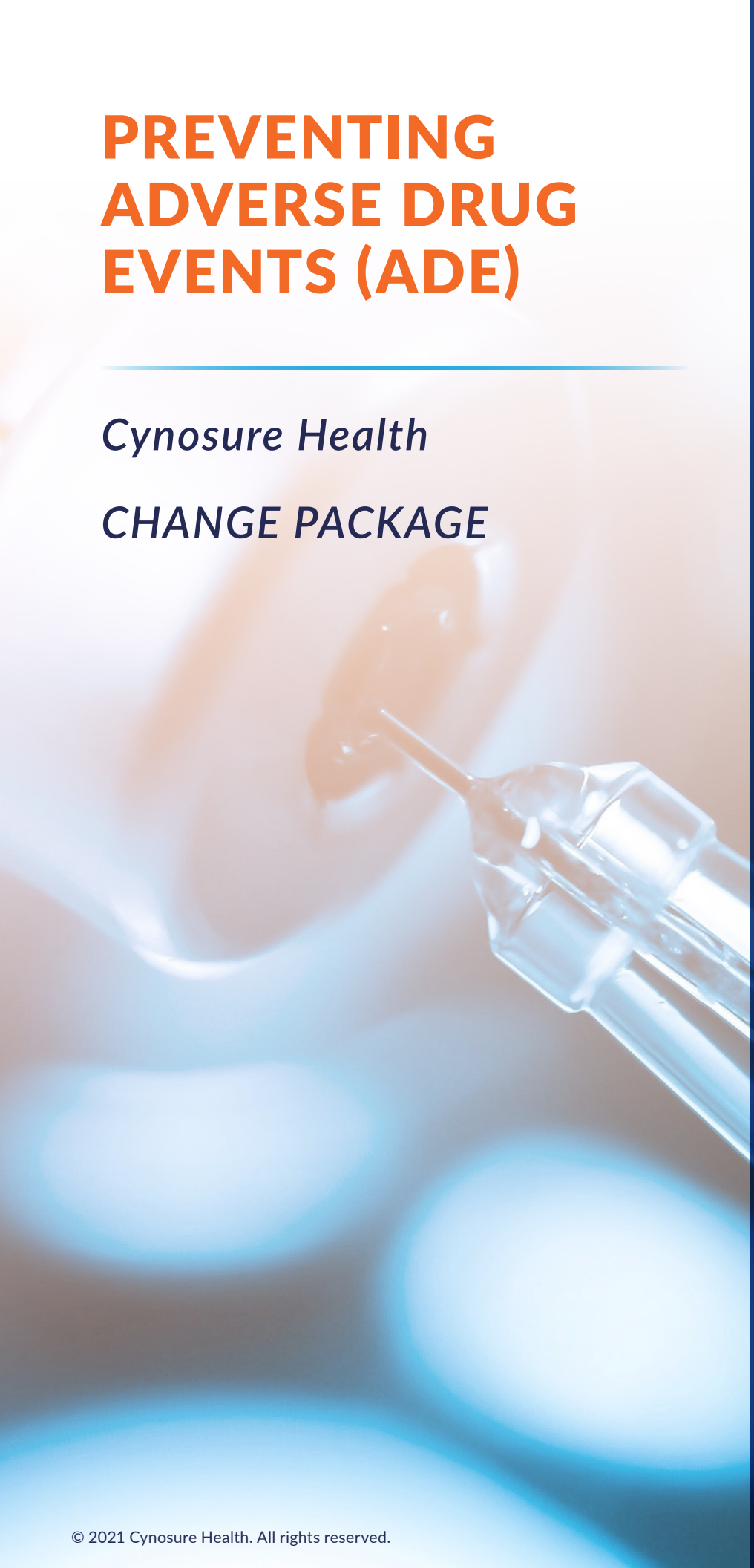
PREVENTING ADVERSE DRUG EVENTS (ADE)

Cynosure Health

CHANGE PACKAGE



HOW TO USE THIS CHANGE PACKAGE

ABOUT CYNOSURE

Cynosure Health is a nonprofit organization that works with diverse stakeholders to accelerate spread, implementation, and sustainable improvement in healthcare quality. Although our work spans multiple sectors in topics such as collaborative learning and care management, we specialize in working with hospitals, clinicians, health systems, and community-based coalitions on federal and statewide initiatives, regional collaboratives, and local partnerships. For over two decades, the Cynosure team has played a key role in developing and spreading proven strategies to improve outcomes, and we are committed to fostering innovative solutions to health care's toughest challenges.

ABOUT THIS CHANGE PACKAGE

Change Packages developed by our team of experts are tools to translate evidence into action, to help health care improvement teams make patient care safer and improve outcomes. In this Change Package, you will find best practices and ideas to test from other high performing health organizations. It was developed with contributions from subject matter experts, literature review, and sharing from health care organizations that have successfully implemented the identified practices. This change package helps to translate the evidence into a menu of strategies, change concepts and specific actionable items that any hospital can implement based on need or for purposes of improving patient quality of life and care.

Cynosure Health Change Packages are organized around a topic-specific Driver Diagram. Driver Diagrams are utilized to identify, organize, and prioritize improvement activities. Each primary driver for improvement in this Change Package has accompanying ideas to test for hospitals seeking to improve outcomes.

Cynosure HEALTH

PART 1: DEFINITION AND SCOPE

Current definition of harm topic: 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 2014. The report focused efforts on the group of ADEs that are common, clinically significant, preventable and measurable. The three initial targets of the ADE Action Plan are:

- Anticoagulants (primary ADE of concern: bleeding)
- Diabetes agents (primary ADE of concern: hypoglycemia)
- Opioids (primary ADE of concern: accidental overdoses/over-sedation/ respiratory depression).[2]

Similarly, The Institute of Safe Medication Practice (ISMP) annually defines several medication classifications, including insulin, anticoagulants and opioids that, are considered to be 'high alert medications' (HAMs).[3] The Joint Commission describes HAMs as those more likely to be associated with harm than other drugs—as 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 related to HAMs include common side effects such as high International Normalized Ratios (INRs), moderate over-sedation and hypoglycemia.

Adverse drug events frequently occur among outpatients as well. Shehab et. al. recently reviewed nationally representative surveillance data and found an estimated four (4) ED visits for adverse drug events occurred per 1000 individuals annually, and among older adults (aged ≥65 years), anticoagulants, antidiabetic agents, and opioid analgesics were implicated in approximately 60 percent of ED visits for adverse drug events.[5]

Consistent with the national focus and priorities, this change package addresses the ADE subtopics of[6]:

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

PART 2: MEASUREMENT

A key component to making patient care safer in your hospital is to track your progress toward improvement. 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 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.

NATIONALLY RECOGNIZED MEASURES: PROCESS AND OUTCOME

Evaluation Measures

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

Suggested Process Measures

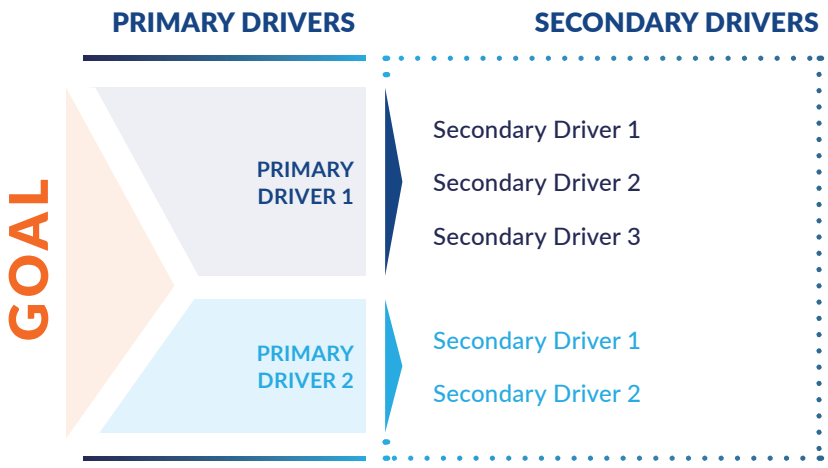
- Hypoglycemia Monitoring: percentage of patients on insulin whose blood sugars registered <80 mg/dl at least once
- Opioid Risk Assessment: percentage of patients receiving opioids who receive an opioid risk assessment prior to first opioid dose
- Formal Assessment During Opioid Therapy: percentage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

PART 3: HOW TO IMPROVE

INVESTIGATE YOUR PROBLEM AND IMPLEMENT BEST PRACTICES

Driver Diagrams

A driver diagram visually demonstrates the causal relationship between 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 is organized by reviewing the components of the driver diagram to (1) help your care team identify potential change ideas to implement at your facility and (2) show how this quality improvement tool can be used by your team to tackle new process problems.



Suggested bundles and toolkits

WARFARIN
Anticoagulation Agent Adverse Drug Event Gap Analysis

INSULIN
Hypoglycemic Agent Adverse Drug Event Gap Analysis

Society of Hospital Medicine Glycemic Control Implementation Guide

OPIOIDS
Opioid Adverse Drug Event Prevention Gap Analysis

Pennsylvania Patient Safety Authority Opioid Tools

BROADLY APPLICABLE
ISMP Guidelines for Safe Order Sets

Adverse Drug Event Top Ten Checklist

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 directly to achieving the aim.

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

CHANGE IDEAS: Specific change ideas which will support or achieve the secondary driver.

DRIVERS IN THIS CHANGE PACKAGE

GOAL REDUCE ADES DUE TO INSULIN, WARFARIN AND OPIOIDS

PRIMARY DRIVERS	SECONDARY DRIVERS
ENGAGE PATIENTS AND FAMILIES	Educate patients and families regarding the risk and benefits of insulin, warfarin, and opioids. Educate and partner with patients to increase self-management.
FIND AND USE DATA TO DRIVE IMPROVEMENT	Use high probability logic; don't spend hours verifying the cause of every event. Review data for themes of failure and success. Make the data visible.
STANDARDIZE THE WORK: INSULIN	Target 140-180mg/dl glucose range, not normoglycemia. Identify all critically ill patients with severe hyperglycemia and treat with intravenous insulin infusion. Use basal bolus correction insulin on all patients prescribed insulin in hospitals. Eliminate sliding scale insulin as the sole means of glycemic control. Adjust the insulin regimen after a single episode of hypoglycemia (glucose <70mg/dl). Coordinate meal and insulin administration times. Use manual or electronic alerts to notify staff of every patient with a prior episode of hypoglycemia in the current (or previous) hospitalization. Trust well-controlled diabetic patients, especially Type 1 diabetic patients, to manage their insulin pump as inpatients.
STANDARDIZE THE WORK: WARFARIN	Have the pharmacy track and trend all INRs. Obtain an INR before the first inpatient dose, even on outpatients on chronic warfarin. Obtain daily INRs on all patients receiving warfarin, even if the patient has been on chronic outpatient warfarin. Consider non-warfarin oral anticoagulants in patients in whom INRs may be or are difficult to control.
STANDARDIZE THE WORK: OPIOIDS	Use structured approaches to manage dosing safely. Use available tools to identify patients at higher risk of harm before dosing. Use available tools and technology on patients receiving opioids. Avoid layering of multiple opioids or layering other respiratory depressants (e.g. benzodiazepines, hypnotics, muscle relaxants and antihisthamines with an opioid.)

Driver 1 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, the family becomes available to assist the care team with a patient's compliance with the treatment regimen, monitoring for side effects and enacting necessary lifestyle change.

ASK PATIENTS: "What matters to you?" in addition to "What's the matter?"

SECONDARY DRIVERS IN THIS SECTION

1. **Educate patients and families regarding the risks and benefits of insulin, warfarin and opioids.**
2. **Educate and partner with patients to increase self-management.**

1. Educate patients and families regarding the risks and benefits of insulin, warfarin and opioids.

Insulin, warfarin and opioids have high risk-benefit ratios. Providing information to patients and families that appropriately balance both risks and benefits helps all involved arrive at the best path of treatment for each individual patient.

Change Ideas – Insulin Specific

- Inform 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 the hospital.
- Inform patients not to self-medicate while in the hospital, unless their doctor has specifically written that order and the nurse and pharmacist are aware.

Change Ideas – Warfarin 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 and clotting times.

Change Ideas – Opioid Specific

- Educate patients that zero pain is not the goal; rather, decreased pain that allows for improved function is the goal.
- Educate patients and families about the importance of keeping potentially harmful medications secured from small children and other vulnerable individuals.
- Educate patients and families about the danger of pain relievers and that hospital staff may instead choose to employ non-pharmacological methods of pain and anxiety management to manage the patient's pain instead of opioids, when appropriate.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- Percent of patients and families/caregivers who, when surveyed, can correctly state the risks, benefits and alternatives to the suggested medications in their own words.
- Percent of patients who opt for a different option given the explanation of risks/benefits.

2. Educate and partner with patients to increase self-management.

Self-management is effective when patients and families are educated about and involved in both medication management and treatment both throughout their hospitalization and after discharge. Patients with increased self-management skills have been shown to have lower readmission rates.[7]

Change Ideas – Insulin Specific

- Educate patients and families regarding hypoglycemia rescue protocols. Use "teach-back" to check their understanding.
- Allow hospitalized patients to perform self-management when safe and appropriate.
- Listen to the patient. Experienced diabetics in good control know how their glucose levels react to certain foods. Many count carbs and know how much bolus or correction insulin is needed.

Change Ideas – Warfarin Specific

- Ensure that patients and families thoroughly understand and can keep appointments for follow-up laboratory appointments for 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.
- Ensure patients have full understanding of any new dietary restrictions to help avoid drug-food interactions.
- Work with the patient and family to obtain a complete listing of all medications, including herbals and over-the-counter medications, so that drug interactions can be minimized or avoided.
- Recognize that some patients may not be suited for safe warfarin therapy and explore alternative options.

Change Ideas – Opioid Specific

- Inform families that they 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.
- Educate patients and families about the availability of naloxone and its potential lifesaving capability.
- Educate patients and families regarding potentially lethal layering effects of multiple opioids or a single opioid combined with a hypnotic, anxiolytic, muscle relaxant antihistamine and/or alcohol.
- Educate patients regarding the potentially lethal effects of failure to dispose of fentanyl patches properly.

Change Ideas – Broadly Applicable

- Provide patient education in the primary language, at the appropriate literacy level, and using the patient's preferred learning method. Doing so has been shown to improve health outcomes.[8]
- Use "teach-back" to verify understanding.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- Percent of patients discharged on insulin, warfarin or opioids who successfully performed a "teach-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 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 required treatment in the emergency department due to an opioid ADE at home.

Hardwire the process

Patient and family engagement must become part of standard workflow. Capture complete social history, a complete list of prescribed, herbal and over-the-counter medications and personal preferences through conversations with the patient and family or caregiver. Provide opportunity for meaningful discussion of risks, benefits and alternatives. Institute teach-back at discharge. Anticipate "what might go wrong" that would lead to an ADE at home.

Driver 2 FIND AND USE THE DATA TO DRIVE IMPROVEMENT

SECONDARY DRIVERS IN THIS SECTION

1. **Use high probability logic; reasonably limit time spent verifying the cause of the event.**
2. **Review data for themes of failure and success.**
3. **Make the data visible.**

1. Use high probability logic; reasonably limit time spent verifying the cause of the event.

While there can be several causes leading to severe hypoglycemia, excessively elevated INRs, or need for naloxone administration, experience in the typical hospital shows that 90-95 percent of these situations are due to very limited causes. Verifying each and every cause is time consuming and contributes little to improvement efforts. Resist the temptation to seek "perfect data." If you can avoid opening that chart you will save precious time for other improvement activities. Read below to find easy ways to identify numerators and denominators, and therefore rates.

Change Ideas – Insulin Specific

- Look at 10 severe hypoglycemia events. Remembering that some long-acting insulins can have an effect for 36 hours, what percent of these hypoglycemia events did not follow insulin administration? Once you are convinced that the percent is low…stop chasing every event to 'prove' it was due to insulin!

Change Ideas – Warfarin Specific

- Look at 10 high INR events. What percent of these events were due to causes other than warfarin administration? Once you are convinced that the percent is low…stop chasing every event to 'prove' it was due to warfarin!

Change Ideas – Opioid Specific

- Look at 10 naloxone events. What percent of these events did not follow opioid administration? Once you are convinced that the percent is low…stop chasing every event to 'prove' it was due to warfarin!"

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- Sample 10-20 of each of these events. Validate that the low glucose, high INR or naloxone administration were due to insulin, warfarin and opioids respectfully. If you have high concordance (>90 percent), then you know that, with confidence, you can proceed without further verification.

2. Review data for themes of failure and success.

Change Ideas – Insulin Specific

- What themes did you find? Common causes include an unexpected and sudden situation where the patient cannot eat or drink, or is not allowed to; poor appetite; lack of coordination of insulin administration and meal delivery; or recurrent hypoglycemic events, possibly due to targeting too low of a blood glucose.

Change Ideas – Warfarin Specific

- What themes did you find? Common causes include no INR prior to warfarin administration or too rapid warfarin loading.

Change Ideas – Opioid Specific

- What themes did you find? Common causes include the lack of assessment of the patient before each dose; excessive dosing for the elderly and frail; routine use of reversal agents in procedural areas or the operating room; or concomitant.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- Look at 5-10 charts each where harm occurred from insulin or warfarin or opioids. Do you find a common theme that may have ped to the harm? What was it? Why do you think that process failure commonly occurred?

3. Make the data visible.

Engage all staff necessary to improvement by visibly displaying the data. Data often starts a conversation. Discuss it during shift huddles, staff meetings, physician meetings and board meetings. Display it in your lobby! Your patients know your organization is not perfect. Engage them and harvest their improvement ideas.

Change Ideas – Insulin Specific

- Segment the data and use run charts to display the rates and most common causes of severe hypoglycemia by unit and prescriber.

Change Ideas – Warfarin Specific

- Use run charts to display the rates of excessive INRs and most common causes. In medical staff meetings, show the rates by physician.
- Compare physician-driven high INRs with those that occur through the pharmacy.

Change Ideas – Warfarin Specific

- Use run charts to display the rates and most common causes of naloxone use by unit and prescriber.
- Be sure to show the data from ambulatory procedure areas and crosswalk the need for naloxone with the interval between sedation dosing.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- What percent of your units display ADE rates and causes?
- In what percent of your physician meetings is ADE data shown and discussed?
- What percent of these discussions conclude with action steps?

Hardwire the Process

Be efficient with data. It is easy to get mired in it. Set a timer. Spend no more than 15-20 minutes in the chart exploring the record looking for causes. Resist the temptation to be distracted by other events you come across.

Be effective with data. Constantly display actionable data (e.g., run charts, control charts) and analyze the data with all involved parties. Make sure every agenda includes ample time for this event, whether a stand-up meeting or a traditional one. Put data high on the agenda, not at the end.

Driver 3 STANDARDIZE THE WORK: INSULIN

SECONDARY DRIVERS IN THIS SECTION

1. **Target 140-180mg/dl glucose range, not normoglycemia.**
2. **Identify all critically ill patients with severe hyperglycemia and treat with intravenous insulin infusion.**
3. **Use basal bolus correction insulin on all patients prescribed insulin in hospitals.**
4. **Eliminate sliding scale insulin as the sole means of glycemic control.**
5. **Adjust the insulin regimen after a single episode of hypoglycemia (glucose <70mg/dl).**
6. **Coordinate meal and insulin administration times.**
7. **Use manual or electronic alerts to notify staff of every patient with a prior episode of hypoglycemia in the current (or previous) hospitalization.**
8. **Trust well-controlled diabetic patients, especially Type 1 diabetic patients, to manage their insulin pump as inpatients.**

1. Target 140-180 mg/dl glucose range, not normoglycemia.

In 2009, the NICE SUGAR STUDY revealed that targeting normoglycemia in ill patients was risky. The authors concluded that, "our trial showed that a blood glucose target of less than 180 mg per deciliter resulted in lower mortality than a target of 81 to 108 mg per deciliter. On the basis of our results, we do not recommend use of the lower target in critically ill adults."[9]

The American Diabetes Association (ADA), in its 2020 Standards of Medical Care in Diabetes, acknowledges this and similar studies, and recommends a target glucose of 140-180 mg/dL in the hospitalized patient. Since some literature reports a modest reduction in surgical site infections with lower targets, the ADA finds target glucose of 110-140 mg/dL is acceptable, *provided that hypoglycemia can be avoided.*[10]

Change Ideas

- Discuss with your physicians, pharmacists, nurses and dieticians. Are they up to date?
- Review your order sets. Do they support overly aggressive management? Do they need to be altered?
- Review order entry alerts. At what glucose level do they fire?

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- In your random sample of cases with severe hypoglycemia, what percent appeared to have aggressive glucose management? What percent had more than one event?

2. Identify all critically ill patients with severe hyperglycemia and treat with insulin i.v. infusion.

Several authors and the ADA recommend that critically ill patients with glucose levels greater than 180 mg/dL be managed with insulin drips.[11] This is not limited to diabetics, and many ill patients may have glucose intolerance, insulin resistance or have undiagnosed diabetes.

Change Ideas

- Find a champion physician and nurse in the intensive care unit who can, working with pharmacy, test an insulin drip protocol on one patient.
- Reach out to others and obtain insulin drip protocols.
- If already using insulin drips at times, explore the barriers to spread so that every receives optimum care.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- What percent of critically ill patients with two or more glucose readings greater than 180 mg/dL were started on insulin drips?"

3. Use basal bolus correction insulin on all patients receiving insulin.

All patients with adequate oral intake should be managed with a combination of basal + bolus (meals) + correction. All patients with who are NPO should be managed with a combination of basal + correction. The use of correction only (also called sliding scale insulin) causes wide variations in glucose levels, sometimes called the "roller-coaster effect."

Change Ideas

- Look to see if you have standard insulin orders that allow for patient variation.
- Ask the nurses about how much physician variation in insulin orders exists on their unit.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- What percent of patients on insulin who were eating received basal, bolus (nutritional), and correction insulin?
- How many different correction orders did you find? Can you standardize into just two or three?

4. Eliminate "sliding scale insulin" as the sole means of glycemic control.

As noted above, sliding scale insulin as the sole means of glycemic control can lead to great variation and increased risks of severe hyperglycemia and hypoglycemia. The ADA recommends that all patients on insulin receive basal insulin + correction.[12,13]

Change Ideas

- Look at your charts and talk to the nurses. Are physicians using "sliding scale insulin" alone? If so, how much variability do you see in glycemic control in those patients treated with sliding scale insulin alone?

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- What percent of patients on insulin who were eating received correction "sliding scale" insulin alone?

5. Alter the insulin regimen after a single episode of hypoglycemia (glucose <70 mg/dl).

Current standards strongly recommend a change in insulin orders after a single hypoglycemia episode (blood glucose less than 70 mg/dl). Patients who have hypoglycemia events in the hospital are more likely to have additional hypoglycemia or severe hypoglycemic events.[14]

Change Ideas

- Survey your physician and nursing staff to assess their understanding of the of an inpatient hypoglycemia event and subsequent risk of additional events.
- Develop scripts for nurses to use to contact physicians for order changes.
- Role play scripting with nurse and physician champions.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- What percent of patient who experience a hypoglycemia event have their insulin orders changed following the event?

6. Coordinate meals and insulin.

Modern short acting insulin can reduce glucose levels in a few minutes. Often nurses give insulin at near meal-time, but the meal has not arrived to the patient. When short acting insulins are given, glucose levels can plummet before the meal arrives.

Change Ideas

- Verify that the meal has arrived and that the patient has an appetite before administering meal-based bolus short acting insulin.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- Monitor a sample of patients receiving insulin with their meals. What percent of patients receive their insulin within a window of time from 15 minutes before the meal arrives until 15 minutes after the meal arrives?

7. Use manual or electronic alerts to notify staff of every patient with a prior episode of hypoglycemia in the current (or previous) hospitalization.

Change Ideas

- During shift change huddles, report any patient who had a hypoglycemic event on the prior shift, and if and how the insulin orders were changed in response to that event.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- Compare the rate of recurrent hypoglycemic events in patients whose initial events were reported at shift change versus those whose initial events were not reported.

8. Trust well controlled diabetics, especially Type 1's, to manage their insulin pump as inpatients.

Well-controlled diabetics, especially Type 1 diabetics on insulin pumps with cutaneous glucose monitors, have deep experience managing their glucose levels in a variety of situations. Under certain circumstances these patients can be allowed to manage their insulin safely with supervision. Patients meeting the following criteria should be considered:

1. Cognitive and physical skills needed to successfully self-administer insulin
2. Adequate oral intake
3. Be proficient in carbohydrate estimation
4. Use multiple daily insulin injections or continuous subcutaneous insulin infusion pump therapy
5. Have stable insulin requirements
6. Understand sick-day management

Change Ideas

- Assess your policies and procedures. How can they be updated to allow for self-management?
- Find a qualified candidate. Test it once. Debrief. Learn. Try it again.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- Measure the number of patients admitted with insulin pumps in a 30 day period. In a sample of ten, count how many would meet the required characteristics.

Hardwire the Process

On admission, capture the six key criteria listed above in all diabetics regarding appropriateness of self-management in the hospitals.

Driver 4 STANDARDIZE THE WORK: WARFARIN

SECONDARY DRIVERS IN THIS SECTION

1. **Have the pharmacy track and trend all INRs.**
2. **Obtain an INR before the first inpatient dose, even on outpatients on chronic warfarin.**
3. **Obtain daily INRs on all patients receiving warfarin, even if the patient has been on chronic outpatient warfarin.**
4. **Consider non-warfarin oral anticoagulants in patients in whom INRs may be or are difficult to control.**

1. Have the pharmacy track and trend all INRs.

Pharmacy management of warfarin is increasingly common and results in equal, and at times better, control.[15,16] Allowing for increased pharmacy participation using proven algorithms, either alone or in partnership with physicians, can reduce high INRs.

Change Ideas

- Identify champion pharmacists and physicians willing to try pharmacist-driven warfarin management.
- Train champion pharmacists with warfarin management training modules/programs.[17]
- Have pharmacists manage warfarin with physicians as partners.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- What is the percent of pharmacists' warfarin management recommendations that is accepted by physicians?
- What percent of pharmacist-managed warfarin patients are 'in-range' versus those patients who are physician-managed?

2. Obtain an INR before the first inpatient dose, even in outpatients on chronic warfarin.

Since warfarin effectiveness can vary based on albumin levels, diet and medications, even patients who have been stable on outpatient warfarin can have altered INRs on admission. Both patients who are new to warfarin and those who have been taking it should have an INR ordered and reviewed before given the first inpatient dose.[18]

Change Ideas

- Set a hard stop at the time of the first inpatient warfarin dose administration to require verification and acknowledge of INR upon admission.
- Confirm all medications on admission, transfer and discharge to minimize drug-drug interactions that would impact INR levels.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- Sample 20 recent patients given inpatient warfarin. What percent of patients had an INR performed before the first inpatient warfarin dose?

3. Obtain daily INRs on all patients on warfarin, even if the patients have been on chronic outpatient warfarin.

A common failure point in inpatient warfarin management is failure to obtain a daily INR.[19]

Change Ideas

- Include daily INR testing in warfarin order sets.
- Implement real time alerts to the physician-pharmacist team whenever an INR is trending above 3.5.
- Use a protocol to discontinue or restart warfarin peri-operation.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- Sample 20 recent patients given inpatient warfarin. What percent of patients had a daily INR performed?

4. Consider non-warfarin oral anticoagulants in patients in whom INRs may be or are difficult to control.

Warfarin is not appropriate for some patients, especially those with the inability to undergo regular laboratory testing. Furthermore, patients on other medications that may interfere with or potentiate warfarin's effect, and those with irregular diets may be prone to lability in their INR results.

Change Ideas

- Implement a screening tool to assess patient specific risks for warfarin that include those relating to the ability to follow up, manage medications and stabilize diet.
- Perform automatic nutrition consults for all patients on warfarin to avoid drug-food interactions.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- Look a sample of patients on warfarin. In what percent is the documentation about their likelihood go comply with follow up care? If the patient was unlikely to be able to successfully participate in follow up care, was an alternative anti-coagulant offered?

Hardwire the Process

Implement order sets for warfarin that include INRs before first dose, daily INRs and risk profiles. Standardize peri-operative management of warfarin by using protocols.

Driver 5 STANDARDIZE THE WORK: OPIOIDS

SECONDARY DRIVERS IN THIS SECTION

1. **Use structured approaches to manage dosing safely.**
2. **Use available tools to identify patients at higher risk of harm before dosing.**
3. **Use available tools and technology on patients receiving opioids.**
4. **Avoid layering of multiple opioids or layering other respiratory depressants (e.g., benzodiazepines, hypnotics, muscle relaxants and antihisthamines with an opioid.)**

1. Use structured approaches to manage dosing safely.

Structured approaches can reduce error. Hospitals have used several of these to prevent over-sedation.

Change Ideas

- Limit dosage strengths available in floor stock and automated drug cabinets.
- Use protocols and tables for equi-analgesic transition from one opioid to another.
- Assess the patient's opioid history to determine if the patient is opioid naïve (less than 60 mg morphine equivalence per day for the last seven days) or opioid tolerant (greater than or equal to 60 mg morphine equivalence per day for the last seven days).[20]
- Set alerts for hydromorphone doses based on patient risk of over-sedation.
- Implement standard processes for opioid ordering to prevent duplicate layered opioids or opioids with benzodiazepines, hypnotics, muscle relaxants or antihistamines.
- Only allow basal Patient Controlled Analgesia in patients who are opioid tolerant.
- Develop protocols to manage fentanyl patches to prevent overdose.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- In what percent of patients is opioid tolerance or intolerance documented?
- Of those identified as "tolerant", what percent met established criteria for opioid tolerance?
- What percent of patients > age 65 receive more than 1 mg of hydromorphone in a single dose?

2. Use available tools to identify patients at higher risk before dosing.

Risk varies due to age, illness, opioid tolerance/intolerance, obesity and other factors. Using standard tools to assessment each patient's risk before the first dose can lead to safer opioid administration.

Change Ideas

- Use the STOP BANG checklist on each patient to identify risk of airway obstruction during sedation or opioid administration.[21,22]
- Assess the current awareness of opioid risk among your health care professionals using the Pennsylvania Opioid Knowledge Self Assessment tool.[23]

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- What percent of patients receive a STOP BANG assessment prior to their first dose of opioids?
- What percent of physicians scored 80% of higher on the Pennsylvania Opioid Knowledge Self-Assessment Test? What percent of pharmacists and nurses did so?

3. Use standard validated tools and technology on patients receiving opioids.

Standard, validated tools exist for assessing patients' response to opioid administration both after each dose and before the subsequent dose. End tidal capnography, the most accurate indicator of adequate respirations, alerts caregivers should respirations be depressed and carbon dioxide levels rising.

Change Ideas

- Use the Pasero Opioid-Induced Sedation Scale (POSS) on all patients receiving opioids in the peri-operative period and on the general medical/surgical units.[24] See **Appendix II**.
- Use the Richmond Agitation Sedation Scale (RASS) on all intensive care unit patients.[26] See **Appendix III**.
- Use end tidal capnography in patients requiring more than pre-defined threshold opioid doses, or in those at risk for over-sedation as defined by risk assessment tools.[25]

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- What percent of patients who received opioids were monitored by either the POSS or the RASS?

4. Avoid layering of multiple opioids or layering other respiratory depressants (e.g., benzodiazepines, hypnotics, muscle relaxants and antihistamines) with an opioid.

Layering can occur in two forms: when a patient has multiple active opioid orders or when other respiratory depressants are added to opioids. These combinations can lead to respiratory depression.

Change Ideas

- Implement patient specific, not physician specific order sets.
- Develop opioid order sets based on risk stratification of over-sedation.
- Offer non-opioid alternative analgesia and build the options into order sets.
- Disallow hypnotics, muscle relaxants and antihistamines in patients on opioids.
- Disallow orders for prn benzodiazepines in patients on opioids unless they have been regularly taking benzodiazepines.
- If two opioids are ordered for different levels of pain, which opioid is to be used for each pain level should be clearly defined, along with the minimum interval between doses when transitioning to higher opioid potency.

SUGGESTED PROCESS MEASURES FOR YOUR TEST OF CHANGE

- What percent of patients who had over-sedation events had received opioids PLUS benzodiazepines, hypnotics, muscle relaxants, or antihistamines?
- What percent of patients have more than one provider simultaneously writing opioid orders?

Hardwire the Process

Require an opioid risk assessment prior to the first dose. Implement and require the use of opioid safe order sets. Assess every patient administered opioids before and after every dose per the POSS or RASS protocol.

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 reviewing recent events to better understand what the greatest needs are in their facility. Suggested tests of change include:

- Pharmacy track and trend daily INRs of the next ten patients started on warfarin, with daily feedback to physicians.
- Nurse-physician dyad trial of nurse scripts to notify the physician of a hypoglycemia event and request new insulin orders.
- Trial the use of the Pasero Opioid-Induced Sedation Scale with one or two nurses in the post-op surgery unit.

IMPLEMENT SMALL TESTS OF CHANGE

Implement the ADE Bundle

PLAN Begin by promoting early detection and recognition of sepsis and septic shock via screening. If you are already screening for sepsis in the emergency department, begin screening at-risk inpatients in a medical or surgical unit. Don't reinvent the wheel; adopt and revise a proven screening tool.

DO Enlist a receptive, early-adopter physician on your improvement committee to test these changes with his/ her next few patients in the emergency department or in the inpatient unit. Ask a receptive nurse and/ or ED technician on your sepsis committee to test the screening tool as well. Test small: coordinate with the physician champion to test the screening tool on one patient, with one nurse, and/or one ED technician.

STUDY Ask the physician and/or nurse the following questions:

- "What happened?"
- "What went well?"
- "What didn't go well?"
- "What do we need to revise for next time?"

ACT Do not wait for the next committee meeting to make necessary changes. Revise the protocols and retest the revisions with the same physician, the same nurse, and/or the same ED technician. Monitor quality improvement by collection and analysis of data from sepsis screening and bundle compliance in the care of patients with sepsis and septic shock. Use variance/risk reports and coded data to identify missed sepsis cases and opportunities for improvement. Providing timely feedback for all members of the sepsis team care promotes immediate change and understanding.

COMMON CHALLENGES TO IMPROVEMENT

CHALLENGE 1

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.

CHALLENGE 2

Physicians may be cautious about supporting protocols implemented by pharmacists, nurses or nurse practitioners. Some physicians may be unaware of the positive safety records and advantages of these approaches. Education about the advantages of such protocols, inclusion of physicians in the protocol development process, and data capture within your organization of small samples showing superiority or lack of inferiority can help breakthrough this barrier.

CHALLENGE 3

The technology to install dosage and multiple (duplicative) therapy alerts may not be available at every facility.

SOLUTIONS

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 new and unfamiliar, or burdensome.
- Physician leadership will be the key to success. The literature cited in this change package provides a basis for engaging physician leaders in change.

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

- To achieve the organization's improvement goals, everyone involved with the care of sepsis patients must be included in the development and implementation of the elements in this bundle. The processes, protocols and order sets must be carefully scripted and standardized; tested, reviewed and revised; and, to promote staff awareness and commitment, communicated to all employees by the senior leadership.

CONCLUSION & 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 <50mg/dL and naloxone use. Once you have identified an area of opportunity, engage the front-line staff by asking their ideas. Then, 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

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

1. Standardize concentrations and minimize dosing options where feasible.
2. Set dosing limits for insulin and opioids.
3. Set target glucose levels at 140-180 mg/dL in the hospitalized patient.
4. Eliminate "sliding scale" insulin as the sole method of glycemic management. Manage all patients with basal+bolus+correction if eating, and basal+bolus if not.
5. Seek new insulin orders for any patient with a single episode of inpatient hypoglycemia (less than 70 mg/dL).
6. Coordinate meal and insulin times.
7. Implement pharmacist-driven warfarin management.
8. Use standard opioid equi-analgesic conversion tables.
9. Use standard order sets to avoid multiple concurrent prescriptions of opioids and sedatives.
10. 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 OPIOID-INDUCED SEDATION SCALE (POSS)

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

Reference: Pasero, Chris. Assessment of sedation during opioid administration for pain management. Journal of Perianesthesia Nursing, 24:186-90, 2009. Retrieved HERE on December 19, 2020.

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%[1] or notify prescriber[2] 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

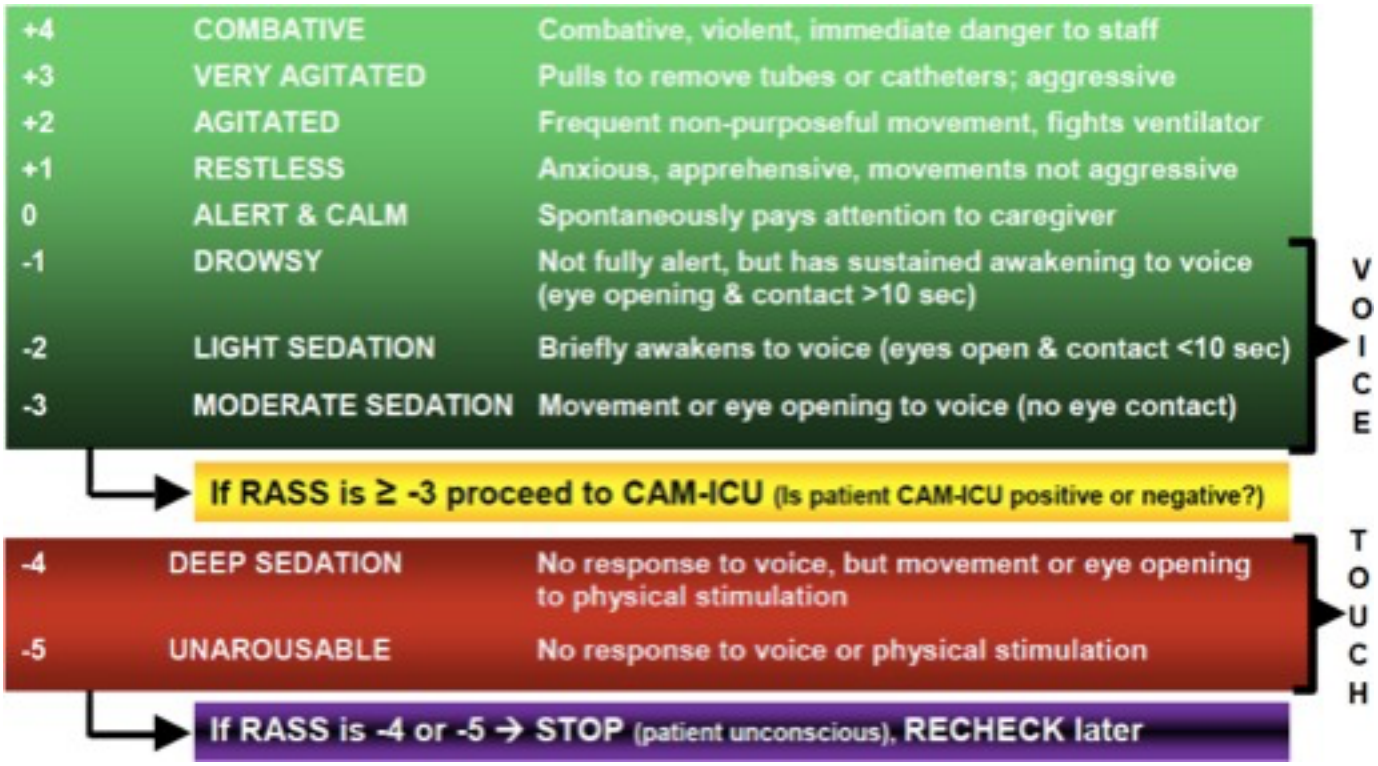
Unacceptable; stop opioid; consider administering naloxone[3,4]; notify prescriber[2] or anesthesiologist; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory.

*Appropriate action is given in *italics* at each level of sedation.

APPENDIX III:
RICHMOND AGITATION SEDATION SCALE (RASS)

Purpose of Tool: To assess the level of consciousness and agitation in Intensive Care Unit patients to guide sedation and assist in communication among care providers.

Reference: Curtis N. Sessler, Mark S. Gosnell, Mary Jo Grap, Gretchen M. Brophy, Pan 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. 166:1338-1344, 2002. Accessed HERE on December 19, 2020.



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