March 22, 2016

IV Medication & Blood Administration: Did your Hospital get the Memo?

Speaker

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- Email CMS: hospitalscg@cms.hhs.gov

Objectives

- Describe the changes CMS has issued to medication administration and safe opioid use.
- Explain the educational requirements for medication administration and safe opioid use.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

Introduction to the CMS Hospital CoPs on IV Medication and Blood and Blood Products

The Conditions of Participation (CoPs)

- Regulations first published in 1986 and many changes since
  - Revised section on IV and blood transfusions published advanced memo in March 14, 2014 and finalized June 6, 2014 and amended November 20, 2015 and many hospitals are still struggling with compliance
- First regulations are published in the **Federal Register** then CMS publishes the **Interpretive Guidelines** and some have **survey procedures** [2]
  - Hospitals should check this website once a month for changes

[1]www.gpoaccess.gov/fr/index.html [2]www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp

5

Location of CMS Hospital CoP Manuals

Medicare State Operations Manual

Appendix

Email CMS: hospitalscg@cms.hhs.gov

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.
- The appendices are in PDF format, which is the format generally used in the IOM to display files. Click on the red button in the 'Download' column to see any available file in PDF.
- To return to this page after opening a PDF file on your desktop, use the browser "back" button. This is because closing the file usually will also close most browsers

CMS Hospital CoP Manuals new address
www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

App. No.	Description	PDF File
A	Hospitals	2,185 KB
AA	Psychiatric Hospitals	606 KB

6

CoP Manual Also Called SOM

State Operations Manual
Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

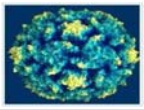
Table of Contents
(Rev. 151, 11-20-15)

Transmittals for Appendix A

Survey Protocol

Introduction
- Task 1 - Off-Site Survey Preparation
- Task 2 - Entrance Activities
- Task 3 - Information Gathering Investigation
- Task 4 - Preliminary Decision Making and Analysis of Findings
- Task 5 - Exit Conference
- Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module
Psychiatric Unit Survey Module
Rehabilitation Hospital Survey Module
Inpatient Rehabilitation Unit Survey Module
Hospital Swing-Bed Survey Module
Regulations and Interpretive Guidelines

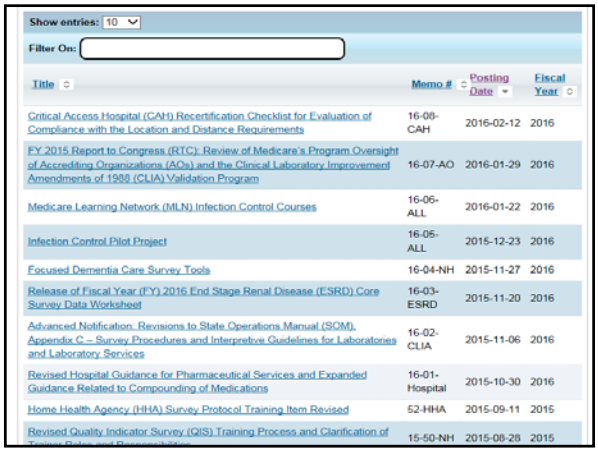


www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.p

Email questions **hospitalscg@cms.hhs.gov**

CMS Survey and Certification Website

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage



Show entries: 10

Filter On:

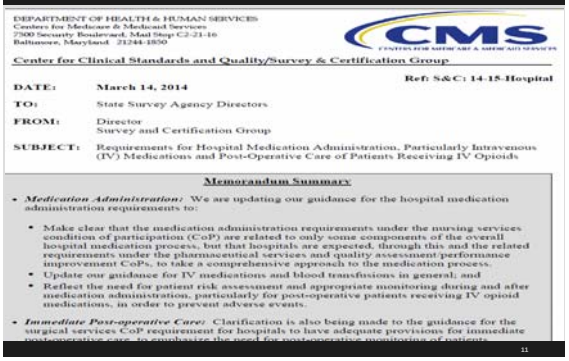
Title	Memo #	Posting Date	Fiscal Year
Critical Access Hospital (CAH) Recertification Checklist for Evaluation of Compliance with the Location and Distance Requirements	16-08-CAH	2016-02-12	2016
FY 2015 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program	16-07-AO	2016-01-29	2016
Medicare Learning Network (MLN) Infection Control Courses	16-06-ALL	2016-01-22	2016
Infection Control Pilot Project	16-05-ALL	2015-12-23	2016
Focused Dementia Care Survey Tools	16-04-NH	2015-11-27	2016
Release of Fiscal Year (FY) 2016 End Stage Renal Disease (ESRD) Core Survey Data Worksheet	16-03-ESRD	2015-11-20	2016
Advanced Notification: Revisions to State Operations Manual (SOM), Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services	16-02-CLIA	2015-11-06	2016
Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance Related to Compounding of Medications	16-01-Hospital	2015-10-30	2016
Home Health Agency (HHA) Survey Protocol Training Item Revised	52-HHA	2015-09-11	2015
Revised Quality Indicator Survey (QIS) Training Process and Clarification of	15-50-NH	2015-08-28	2015

IV Medication and Blood

- CMS issues an advanced 32 page memo on March 14, 2014
- CMS updates manual and makes it final on June 6, 2014 and issues final transmittal
- Amended Tag 405 on November 20, 2015
  - Addresses medication administration, safe opioid use, IV medications and blood transfusion
  - Must have a P&P
  - Must train staff
  - Must document process
  - **Questions to hospitalscg@cms.hhs.gov**

10

CMS Memo Med & Safe Opioid Use



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop: C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-15-Hospital

DATE: March 14, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

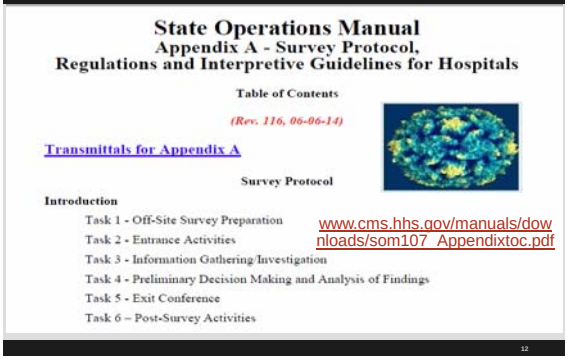
SUBJECT: Requirements for Hospital Medication Administration, Particularly Intravenous (IV) Medications and Post-Operative Care of Patients Receiving IV Opioids

Memorandum Summary

- ***Medication Administration:*** We are updating our guidance for the hospital medication administration requirements to:
  - Make clear that the medication administration requirements under the nursing services condition of participation (CoP) are related to only some components of the overall hospital medication process, but that hospitals are expected, through this and the related requirements under the pharmaceutical services and quality assessment performance improvement CoPs, to take a comprehensive approach to the medication process.
  - Update our guidance for IV medications and blood transfusions in general; and
  - Reflect the need for patient risk assessment and appropriate monitoring during and after medication administration, particularly for post-operative patients receiving IV opioid medications, in order to prevent adverse events.
- ***Immediate Post-operative Care:*** Clarification is also being made to the guidance for the surgical services CoP requirement for hospitals to have adequate provisions for immediate post-operative care, to emphasize the need for post-operative monitoring of patients

11

IV Medication, Blood, Safe Opioid Use



State Operations Manual
Appendix A - Survey Protocol,
Regulations and Interpretive Guidelines for Hospitals

Table of Contents

(Rev. 116, 06-06-14)

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www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

12

Final Transmittal Issued June 6, 2014

CMS Manual System
Pub. 100-07State Operations Provider Certification
Transmittal 116

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)
Date: June 6, 2014

SUBJECT: Revised State Operations Manual (SOM), Appendix A, Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for various provisions of 42 CFR 482.23(c), concerning medication administration, and 42 CFR 482.51(b)(4), concerning post-operative patient care.

NEW/REVISED MATERIAL - EFFECTIVE DATE: June 6, 2014
IMPLEMENTATION DATE: June 6, 2014

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A *if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0405/§482.23(c)/Standard: Preparation and Administration of Drugs
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0409/§482.23(c)(4)/Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0412/§482.23(c)(6)/The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.
R	Appendix A/Survey Protocol, Regulations and Interpretive Guidelines for Hospitals/A-0057/§482.51(b)(4)/There must be adequate provisions for immediate post-operative care.

www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R116SOMA.pdf

Amended Tag 405 Nov 29, 2015

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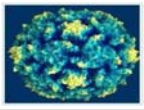


www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.p

Email questions **hospitalscg@cms.hhs.gov**

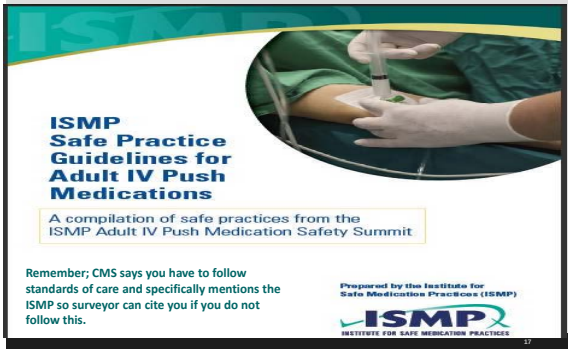
ISMP IV Push Medication Guidelines

ISMP IV Push Medications Guidelines

- ISMP has published a 26 page document called "ISMP Safe Practice Guidelines for Adult IV Push Medications
- The document is organized into factors that increase the risk of IV push medications in adults,
  - Current practices with IV injectible medications
  - Developing consensus guidelines for adult IV push medication and
  - Safe practice guidelines
  - About 90% of all hospitalized patients have some form of infusion therapy

16

IV Push Medicine Guidelines



17

IV Push Medications Guidelines

- Provide IV push medications in a ready to administer form
- Use only commercially available or pharmacy prepared prefilled syringes of IV solutions to flush and lock vascular access devices
- If available in a single dose vial then need to buy in single dose vial
- Aseptic technique should be used when preparing and administering IV medication
  - This includes hand hygiene before and after administration

18

IV Push Medications Guidelines

- The diaphragm on the vial should be disinfected even if newly opened
  - The top should be cleaned using friction and a sterile 70% isopropyl alcohol, ethyl alcohol, iodophor, or other approved antiseptic swab for at least ten seconds to it dry
  - Medication from glass ampules should be used with a filter needle unless the specific drug precludes this
- Medication should only be diluted when recommended by the manufacturer or in accordance with evidence based practice or approved hospital policies

19

IV Push Medications Guidelines

- If IV push medication needs to be diluted or reconstituted these should be performed in a clean, uncluttered, and separate location
- Medication should not be withdrawn from a commercially available, cartridge type syringe into another syringe for administration
- It is also important that medication not be drawn up into the commercially prepared and prefilled 0.9% saline flushes
  - This are to flush an IV line and are not approved to use to dilute medication

20

3.6 Do NOT dilute or reconstitute IV push medications by drawing up the contents into a commercially-available, prefilled flush syringe of 0.9% sodium chloride.

Discussion: Commercially available prefilled syringes of saline and heparin are regulated by the US Food and Drug Administration as *devices*, not as medications. These devices have been approved for the flushing of vascular access devices, but have NOT been approved for the reconstitution, dilution, and/or subsequent administration of IV push medications. Such use would be considered "off label" and not how manufacturers intended these products to be used, nor have prefilled flush syringes been tested for product safety when used in this manner.

Warnings intended to limit the use of prefilled syringes for medication preparation and administration appear on some syringe barrels, clearly stating "IV flush only." Some manufacturers have also limited or removed the gradation markings on the prefilled flush syringes in order to prevent measurement of a secondary medication in the flush syringe. When prefilled syringes are used in an off-label manner, the practitioner and employer bear the legal liability for any adverse events occurring from this practice.[21]

The mislabeling that occurs when medications are added to a prefilled syringe and a secondary label is not applied creates significant risk for errors. In many cases, the manufacturer's label is permanently affixed to the syringe barrel and contains product codes and a barcode as well as specific information about the fluid and its volume. When another medication is added to this syringe, there is no adequate method to amend the manufacturer's label, without covering the current information.[21] Thus, the syringe frequently remains labeled as 0.9% sodium chloride, when it also contains the diluted or reconstituted medication.

Although this unsafe practice is widespread, and many who use it mistakenly believe the risk of an error is insignificant—a belief clearly reinforced during public comment regarding this guidance statement—summit participants arrived at a consensus that the practice must be eliminated.

3.7 When necessary to prepare more than one medication in a single syringe for IV push administration

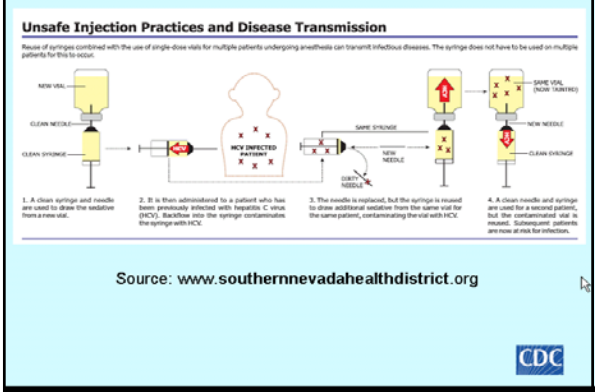
21

IV Push Medications Guidelines

- Combination of more than one medication is a single syringe is seldom necessary and could result in unwanted changes in the medication
- Never use IV solution or mini bags as a common source to flush an IV as to dilute for more than one patient
- Label syringes of IVP medication unless prepared and immediately given with no break
- Administer IV push medication at rate recommended by manufacturer or supported by evidenced based practices and often given too fast

22

Safe Injection Practices

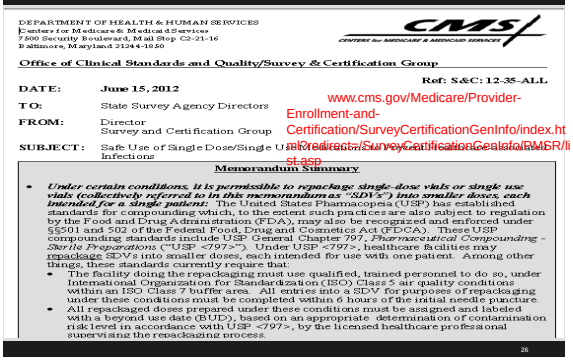


Safe Injection Practices

- Every hospital should have a policy on safe injection practices
- All staff should be trained on the policy including physicians and mid level providers
- Information should be included in orientation and periodically during skills lab or annual training
- CMS has a section on safe injection practices in the Infection Control worksheet
- CMS has issued a survey memo on this
- CDC has 10 safe injection practices

25

CMS Memo Safe Injection Practices



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS — CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-35-ALL

DATE: June 15, 2012

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Safe Use of Single Dose/Single Use Vials for Multiple Patients to Prevent Infections

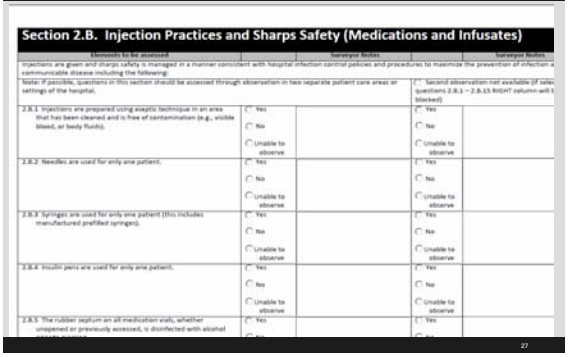
www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/index.html?redirect=/SurveyCertificationGenInfo/MBR/list.asp

Memorandum Summary

- ***Under certain conditions, it is permissible to repackage single-dose vials or single use vials (collectively referred to in this memorandum as "SDVs") into smaller doses, each intended for a single patient:*** The United States Pharmacopeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by the Food and Drug Administration (FDA), may also be recognized and enforced under §§501 and 502 of the Federal Food, Drug and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, *Pharmaceutical Compounding – Sterile Preparations* ("USP <797>"). Under USP <797>, healthcare facilities may repackage SDVs into smaller doses, each intended for use with one patient. Among other things, these standards currently require that:
  - The facility doing the repackaging must use qualified, trained personnel to do so, under International Organization for Standardization (ISO) Class 5 air quality conditions within an ISO Class 7 buffer area. All entries into a SDV for purposes of repackaging under these conditions must be completed within 6 hours of the initial needle puncture.
  - All repackaged doses prepared under these conditions must be assigned and labeled with a beyond use date (BUD), based on an appropriate determination of contamination risk level in accordance with USP <797>, by the licensed healthcare professional supervising the repackaging process.

26

CMS Worksheet Safe Injection Practices

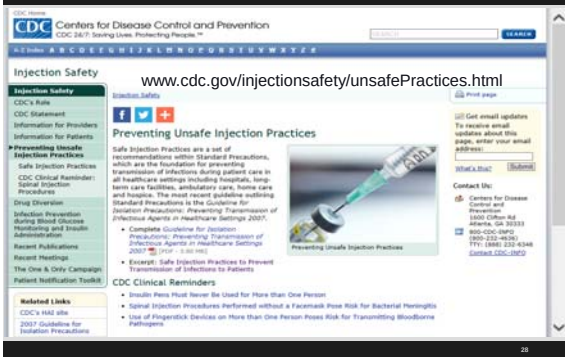


Section 2.B. Injection Practices and Sharps Safety (Medications and Infusates)

Elements to be assessed		Surveyor Notes		Surveyor Notes
injections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection a communicable disease including the following:				
Note: If possible, questions in this section should be assessed through observation in two separate patient care areas or settings of the hospital.			○ Second observation not available (if selec questions 2.B.1 – 2.B.15 RIGHT column will b blanked)	
2.B.1. Injections are prepared using aseptic technique in an area that has been cleaned and is free of contamination (e.g., visible blood, or body fluids).	○ Yes ○ No ○ Unable to observe		○ Yes ○ No ○ Unable to observe	
2.B.2. Needles are used for only one patient.	○ Yes ○ No ○ Unable to observe		○ Yes ○ No ○ Unable to observe	
2.B.3. Syringes are used for only one patient (this includes manufactured prefilled syringes).	○ Yes ○ No ○ Unable to observe		○ Yes ○ No ○ Unable to observe	
2.B.4. Insulin pens are used for only one patient.	○ Yes ○ No ○ Unable to observe		○ Yes ○ No ○ Unable to observe	
2.B.5. The rubber septum on all medication vials, whether unopened or previously accessed, is disinfected with alcohol	○ Yes		○ Yes	

27

CDC Preventing Unsafe Injection Practices

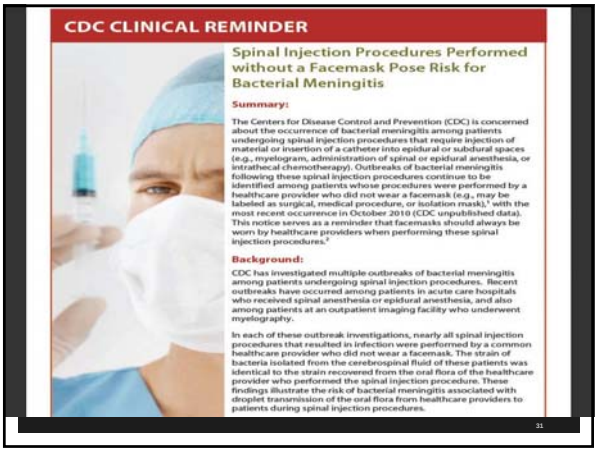


Safe Injection Practices

- If they make it in a single dose then you need to buy it in a single dose
- If they only make it in a multi-dose vial then try and use it only one patient
- Do not take the multi-dose vial into the patient rooms or into the OR
- Mark on the multi-dose that it expires in 28 days unless sooner by the manufacturer
- Clean off the top even if new since lid is just a dust cover

Safe Injection Practices

- Follow the CDC 10 safe injection practices
- Hand hygiene before starting an IV or giving an injection
- One needle and one syringe per patient
- Insulin pens are only for one patient
- IV bags and tubing is only for one patient
- Make sure sharps container is not past the fill line
- Wear a mask when putting in an epidural or spinal or doing a LP


CDC CLINICAL REMINDER

Spinal Injection Procedures Performed without a Facemask Pose Risk for Bacterial Meningitis

Summary:

The Centers for Disease Control and Prevention (CDC) is concerned about the occurrence of bacterial meningitis among patients undergoing spinal injection procedures that require injection of material or insertion of a catheter into epidural or subdural spaces (e.g., myelogram, administration of spinal or epidural anesthesia, or intrathecal chemotherapy). Outbreaks of bacterial meningitis following these spinal injection procedures continue to be identified among patients whose procedures were performed by a healthcare provider who did not wear a facemask (e.g., may be labeled as surgical, medical procedure, or isolation mask),[1] with the most recent occurrence in October 2010 (CDC unpublished data). This notice serves as a reminder that facemasks should always be worn by healthcare providers when performing these spinal injection procedures.[2]

Background:

CDC has investigated multiple outbreaks of bacterial meningitis among patients undergoing spinal injection procedures. Recent outbreaks have occurred among patients in acute care hospitals who received spinal anesthesia or epidural anesthesia, and also among patients at an outpatient imaging facility who underwent myelography.

In each of these outbreak investigations, nearly all spinal injection procedures that resulted in infection were performed by a common healthcare provider who did not wear a facemask. The strain of bacteria isolated from the cerebrospinal fluid of these patients was identical to the strain recovered from the oral flora of the healthcare provider who performed the spinal injection procedure. These findings illustrate the risk of bacterial meningitis associated with droplet transmission of the oral flora from healthcare providers to patients during spinal injection procedures.

31

Safe Injection Practices

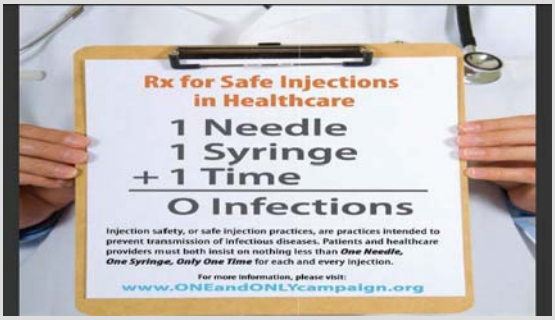
- Do not administer medications from single dose vials to multiple patients or combine left over contents for later use
- Pre-spiking of IV fluid is limited to **one hour**
- Pre-filled medication syringes should never be used on more than one patient
- A needle or other device should never be left inserted into a medication vial septum for multiple uses
  - This provides a direct route for microorganisms to enter the vial and contaminate the fluid

32

Not All Vials Are Created Equal

33

Safe Injection Practices Posters



34

Introduction to CMS CoPs on IV Medication

IV Medication & Transfusions

- CMS has pharmacy standards that impact nursing practice
  - Pharmacy section at tag **489-511** and 10 of 18 tag numbers rewritten November 20, 2015
- CMS wanted to make it clear that medication administration under nursing are only some of the ones that impact the overall medication process
- CMS states that the **pharmacy standards** and **QAPI** CoPs also impact medication administration, IV, blood administration and that nursing should be aware of this

36

Medication and Safe Opioid Use

- This memo updates the CMS guidance for IV medications and blood transfusions
- CMS also said the purpose of the memo was to reflect the need for patient risk assessment and appropriate monitoring during and after medication administration
  - Particularly for post-operative patients receiving IV opioid medications, in order to prevent adverse events
- So this is all about medication administration and safe opioid use
- CMS discusses the HHS National Action Plan for ADR Prevention

37

National Action Plan for ADR Prevention

Opioids One of 3 Most Common Errors

National Action Plan for ADR Prevention

- Hospital ADEs prolong the length of stay from 1.7 to 4.6 days
- HHS selected anticoagulants, diabetic medication, and opioid finding they are the most common medication errors
- CMS and HHS said also clinically significant, preventable, measureable, and there fore high-priority targets of the Action Plan
- Hospitals should review this action plan and consider these areas in their efforts to reduce medication errors and ADEs

39

National Action Plan for Adverse Drug Event Prevention

http://health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf

U.S. Department of Health and Human Services
Office of Disease Prevention and Health Promotion

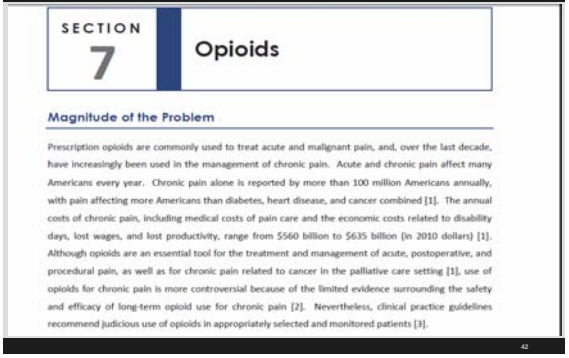
40

National Action Plan for ADR Prevention

- ADEs are an estimated one-third of all hospital adverse events
- ADEs account for over 3.5 million physician office visits and one million ED visits and 125,000 hospitalizations
- Looks at 3 common high alert and priority ADRs: **anticoagulants**, **diabetes agents**, and **opioids**
- Hospitals can expect an increase focus in the future of these 3 areas by CMS
- Final plan published Oct 30, 2014

41

Opioids Section 7



SECTION 7 Opioids

Magnitude of the Problem

Prescription opioids are commonly used to treat acute and malignant pain, and, over the last decade, have increasingly been used in the management of chronic pain. Acute and chronic pain affect many Americans every year. Chronic pain alone is reported by more than 100 million Americans annually, with pain affecting more Americans than diabetes, heart disease, and cancer combined [1]. The annual costs of chronic pain, including medical costs of pain care and the economic costs related to disability days, lost wages, and lost productivity, range from $560 billion to $635 billion (in 2010 dollars) [1]. Although opioids are an essential tool for the treatment and management of acute, postoperative, and procedural pain, as well as for chronic pain related to cancer in the palliative care setting [1], use of opioids for chronic pain is more controversial because of the limited evidence surrounding the safety and efficacy of long-term opioid use for chronic pain [2]. Nevertheless, clinical practice guidelines recommend judicious use of opioids in appropriately selected and monitored patients [3].

42

Section 7 Opioids

- States chronic pain is reported by more than 100 million Americans annually
- Use has increased dramatically over the last decade with 201.5 million scripes in 2009
- Cost of this is $8.4 billion in 2010
- Cause many ADEs; over sedation, respiratory depression, nausea, vomiting, GI problems, pruritus, immunological and hormonal dysfunction, and constipation
  - CDC identified16,651 deaths from opioids in 2010 and 420,000 ED visits in 2011

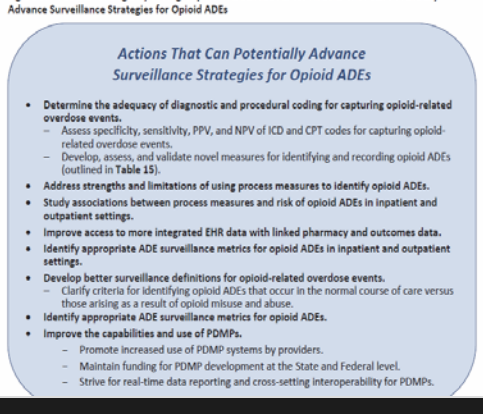
43

Section 7 Opioids

- Abuse is not addressed in the plan but mentions is a current target of the CDC, DEA, National Institute on Drug Abuse (NIDA), Substance Abuse and Mental Health Services Administration (SAMHSA) and the White House Office of National Drug Control Policy (ONDCP)
- Challenging to identify patients who drift from therapeutic use to misuse or abuse
- Includes a list of surveillance systems that monitor this and collect data on ADEs
- No outcome or process indicators on this

44

Figure 19. Federal Interagency Workgroup Recommendations for Actions That Can Potentially Advance Surveillance Strategies for Opioid ADEs



45

Figure 20. Federal Assets Related to Safe Management of Opioid Therapy, as Identified by the National Quality Strategy Priorities

Resources for Safer Care—Health Care Provider Knowledge

- DOD/VA:
  - **Opioid Prescribing Protocol/ Guidelines**—Includes recommendations for assessing patients for appropriate pain therapy.
  - **Education opportunities**—Provider education Web portal (Talent Management System [TMS]) offers several continuing education courses on pain management, including a course on **"Opioid Therapy for Acute and Chronic Pain."**
  - **Opioid Safe Program** at Womack Army Medical Center (Fort Bragg, North Carolina)—Primary care clinicians provide high-risk patients prescribed opioids with kits containing naloxone, along with training in identifying and responding to overdose symptoms.
- FDA:
  - **Risk Evaluation and Mitigation Strategies (REMS)**—Required strategy for extended-release and long-acting opioids; FDA developed a *Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics* and maintains a list of compliant continuing education (CE) programs for prescribers that include this curriculum.
  - **Opioid Dose Conversion Table**—Safe and reliable dose conversion table is based on updated evidence.
- IHS:
  - **TeleBehavioral Health Center of Excellence Pain and Addictions course**—15-series Webinar training program provides specialized training on how to treat pain and addictions.
  - **"Pain Champion" Training**—63-hour CE course trains local and regional experts, using the Project ECHO Model, which shares expertise by utilizing telehealth technology to connect an ECHO Team (primary care, specialists, and other providers integral to a patient-centered medical home team) to providers in rural and underserved locations.
- NIH:
  - **NIDAMED Physician Education Tools**—The National Institute on Drug Abuse (NIDA) created online tools and resources for medical professionals on safe pain management, including two classes entitled **"Safe Prescribing for Pain"** (2 CME/CE credits) and **"Managing Pain Patients Who Abuse Rx Drugs"**[el] (1.75 CME/CE

46

Safer Care	▪ Expand dissemination of evidence-based opioid guidelines/ protocols (e.g., dosing changes, management of high-risk individuals)
Patient and Family Engagement	▪ Promote patient education to improve the safety of care transition
Effective Communication and Coordination of Care	▪ Develop more optimal and integrated health IT opioid management tools ▪ Coordinate care through practices such as medication reconciliation and discharge counseling
Science-Driven Prevention and Treatment	▪ Promote systematic and coordinated care ▪ Promote safe practices at point of initiation of inpatient opioids ▪ Promote the use of evidence-based tools for morphine equivalent dose (MED) and transitions between formulations
Promotion of Best Practices Within Communities	▪ Use metrics to monitor the use of opioid safety "best practices" ▪ Promote the use of evidence-based guidelines for monitoring

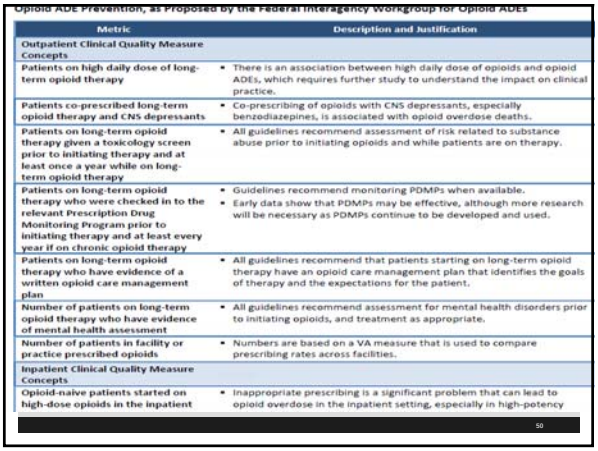
Abbreviations: MED = morphine equivalent dose

47

Slides Available Preventing Opioid ADEs

48

CDC Website on Rx Overdoses



Opioid ADE Prevention, as Proposed by the Federal Interagency Workgroup for Opioid ADEs

Metric	Description and Justification
Outpatient Clinical Quality Measure Concepts	
Patients on high daily dose of long-term opioid therapy	• There is an association between high daily dose of opioids and opioid ADEs, which requires further study to understand the impact on clinical practice.
Patients co-prescribed long-term opioid therapy and CNS depressants	• Co-prescribing of opioids with CNS depressants, especially benzodiazepines, is associated with opioid overdose deaths.
Patients on long-term opioid therapy given a toxicology screen prior to initiating therapy and at least once a year while on long-term opioid therapy	• All guidelines recommend assessment of risk related to substance abuse prior to initiating opioids and while patients are on therapy.
Patients on long-term opioid therapy who were checked in to the relevant Prescription Drug Monitoring Program prior to initiating therapy and at least every year if on chronic opioid therapy	• Guidelines recommend monitoring PDMPs when available. • Early data show that PDMPs may be effective, although more research will be necessary as PDMPs continue to be developed and used.
Patients on long-term opioid therapy who have evidence of a written opioid care management plan	• All guidelines recommend that patients starting on long-term opioid therapy have an opioid care management plan that identifies the goals of therapy and the expectations for the patient.
Number of patients on long-term opioid therapy who have evidence of mental health assessment	• All guidelines recommend assessment for mental health disorders prior to initiating opioids, and treatment as appropriate.
Number of patients in facility or practice prescribed opioids	• Numbers are based on a VA measure that is used to compare prescribing rates across facilities.
Inpatient Clinical Quality Measure Concepts	
Opioid-naive patients started on high-dose opioids in the inpatient	• Inappropriate prescribing is a significant problem that can lead to opioid overdose in the inpatient setting, especially in high-potency

50

Opioid Overdose Prevention Toolkit

51

1.1 Billion Funding Proposed Opioid Abuse

- President's budget proposes 1.1 billion to address prescription opioid abuse and heroin use epidemic
- These have taken a heartbreaking toll on too many Americans and their families
- 28,648 deaths from this in 2014
- Sharp increase in heroin deaths and increasing deaths from fentanyl
- President said this is a priority in his administration
- Substance use disorders are required to be covered by insurance

52

Briefing Room

Your Weekly Address
Speeches & Remarks
Press Briefings
Statements & Releases
White House Schedule
Presidential Actions
Executive Orders
Presidential Memoranda
Proclamations
Legislation
Pending Legislation
Signed Legislation
Vetoed Legislation
Nominations & Appointments
Disclosures

The White House
Office of the Press Secretary

For Immediate Release February 02, 2016

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FACT SHEET: President Obama Proposes $1.1 Billion in New Funding to Address the Prescription Opioid Abuse and Heroin Use Epidemic

President's Budget includes new mandatory funding to help ensure that all Americans who want treatment can get the help they need

Prescription drug abuse and heroin use have taken a heartbreaking toll on too many Americans and their families, while straining resources of law enforcement and treatment programs. More Americans now die every year from drug overdoses than they do in motor vehicle crashes. New data from the Centers for Disease Control and Prevention (CDC) show that opioids—a class of drugs that include prescription pain medications and heroin—were involved in 28,648 deaths in 2014. In particular, CDC found a continued sharp increase in heroin-involved deaths and an emerging increase in deaths involving synthetic opioids, such as fentanyl.

The President has made clear that addressing the opioid overdose

53

TJC Opioid Standards for Behavioral Health

- Recently, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued an update
- The update was to the 2007 Guidelines for the Accreditation of Opioid Treatment Programs
- TJC did a comparative analysis to make sure their standards were still consistent with SAMHSA
- TJC makes revisions effective July 1, 2016
- Discusses history, physical, assessment, testing, requirements of the opioid treatment program etc.

54

SAMHSA Opioid Treatment Guidelines

- The final revised guidelines for opioid treatment programs (OTP) were released March 15, 2015
- It is 82 pages long
- Called Federal Guidelines for Opioid Treatment Programs
- Has chapter on the new changes
- Includes section on the medication unit, human resource management, telemedicine, risk management, patient and staff emergencies, program sponsor, medical director, etc.

55

http://cdn.atforum.com/wp-content/uploads/Federal-Guidelines-For-Opioid-Treatment-Programs-March-2015.pdf

FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS

March 2015

56

TJC Opioid Standards for Behavioral Health

Standards Revisions for Opioid Treatment Programs

Applicable to Behavioral Health Care

Effective July 1, 2016

Care, Treatment, and Services (CTS)

Standard CTS.01.01.01

The organization accepts for care, treatment, or services only those individuals whose identified care, treatment, or service needs it can meet.

Note 1: ***For opioid treatment programs:*** *If an individual eligible for treatment applies for admission to a comprehensive maintenance treatment program but cannot be placed within 14 days in a program that is within a reasonable geographic area, an opioid treatment program's program sponsor may place the individual in interim maintenance treatment.*

Note 2: ***For opioid treatment programs:*** *There may be individuals in special populations who have a history of opioid use but are not currently physiologically dependent. Federal regulations waive the one-year history of addiction for these special populations, because these individuals are susceptible to relapse to opioid addiction, leading to high-risk behaviors with potentially life-threatening consequences. These populations include the following:*

- *Persons recently released from a penal institution*
- *Persons recently discharged from a chronic care facility*
- *Pregnant women*
- *Previously treated patients*

Standard CTS.02.01.07

The organization completes a physical health assessment, including a medical history and physical examination.

Note: *This standard does not apply to foster care and therapeutic foster care. (Refer to CTS.02.04.01, EP 1 for more information)*

Element of Performance for CTS.02.01.07

A 9. **For opioid treatment programs:** The program does not use telemedicine to substitute for a physical examination when one is needed. Telemedicine may be used to support the decision making of a physician, when a provider qualified to conduct physical examinations and make diagnoses is physically located with the patient.

Standard CTS.02.02.09

For opioid treatment programs: The organization has a process to provide medical histories, physical examinations, and diagnostic and laboratory tests.

Element of Performance for CTS.02.02.09

A 12. **For opioid treatment programs:** The program includes confirmation testing such as gas chromatography-mass spectrometry (GC-MS) or liquid chromatography-mass spectrometry (LC-MS) as part of its established procedures for addressing potentially false-positive and false-negative urine or other toxicology test results.

Please note that EP numbering for Standard CTS.02.02.09 reflects relocation of various requirements.

57

FDA News Release

Califf, FDA top officials call for sweeping review of agency opioids policies

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For Immediate Release

February 4, 2016

Release

In response to the opioid abuse epidemic, today Dr. Robert Califf, the FDA's Deputy Commissioner for Medical Products and Tobacco, along with other FDA leaders, called for a far-reaching action plan to reassess the agency's approach to opioid medications. The plan will focus on policies aimed at reversing the epidemic, while still providing patients in pain access to effective relief.

The FDA will:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;

58

AMA Calls for End to Opioid Epidemic

- Unacceptable that 30,000 die each year from misuse and abuse of prescription opioids and heroin
- Issues joint statement with National Governors Association
- Physicians should use prescription drug monitoring programs
- These databases can identify potential opioid abuse
- Physicians who prescribe need the most up to date information
- Guidelines are important tools

59

AMA Calls for End to Opioid Epidemic

60

CMS CoPs on IV Medication, Safe Opioids and Blood

IV Medication & Transfusions

- CMS states the medication process is a **shared** responsibility of the hospital nursing staff
  - This includes using a comprehensive system and compliance with the pharmacy standards and patient safety requirements under the QAPI section
  - The QAPI section was rewritten March 21, 2014
  - Remember the CMS QAPI worksheet
- Patient risk assessment and appropriate monitoring of patient response to medications, especially opioids, can reduce medication errors

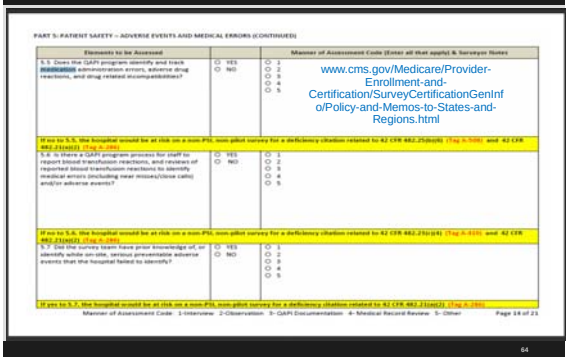
62

Medication Safety & IV Opioids

- CMS said updating their requirements to in order to better align with current acceptable standards of practice
- Every year there are many fatalities with the use of IV opioid medications in hospitals
- Opioid-induced respiratory depression deaths might be prevented with appropriate risk assessment and frequent monitoring of respiratory rate, oxygen, and sedation level
  - Also PCA is a form of self administration
- Added additional guidance or blue box advisories

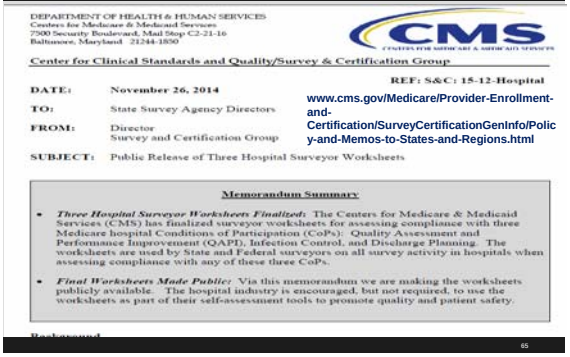
63

CMS QAPI Work Sheet ADE & Medical Errors



www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

Final CMS CoP Worksheets Published



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

REF: S&C: 15-12-Hospital

DATE: November 26, 2014
TO: State Survey Agency Directors
FROM: Director, Survey and Certification Group
SUBJECT: Public Release of Three Hospital Surveyor Worksheets

Memorandum Summary

- ***Three Hospital Surveyor Worksheets Finalized:*** The Centers for Medicare & Medicaid Services (CMS) has finalized surveyor worksheets for assessing compliance with three Medicare hospital Conditions of Participation (CoPs): Quality Assessment and Performance Improvement (QAPI), Infection Control, and Discharge Planning. The worksheets are used by State and Federal surveyors on all survey activity in hospitals when assessing compliance with any of these three CoPs.
- ***Final Worksheets Made Public:*** Via this memorandum we are making the worksheets publicly available. The hospital industry is encouraged, but not required, to use the worksheets as part of their self-assessment tools to promote quality and patient safety.

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

QAPI Questions Surveyor Will Ask

- Is there evidence of training or communication to convey expectations for patient safety related to reporting medication errors including near misses?
- Is there evidence that the hospital has adopted policies supporting a non-punitive approach to staff reporting of medical errors (including near misses/close calls), adverse events, and situations they consider unsafe?
- On every unit can staff describe what is meant by medical errors including medication errors, near misses and adverse events?

QAPI Questions Surveyor Will Ask

- Does the QAPI program identify and track medication administration errors, adverse drug reactions, and drug related incompatibilities?
- Is there a QAPI program process for staff to report blood transfusion reactions, and reviews of reported blood transfusion reactions to identify medical errors (including near misses/close calls) and/or adverse events ?
- Can the hospital provide evidence that medical errors, near misses, and adverse events are identified in staff reports or incident reports?

67

Follow National Standards of Care 405

- **Standard:** Medications must be prepared and administered with acceptable national standards of practice and mentions five organizations (405)
  - National Coordinating Council for Medication Error Reporting and Prevention
  - Institute for Healthcare Improvement
  - U.S Pharmacopeia
  - Institute for Safe Medication Practices
  - Infusion Nurses Society
  - CDC at www.cdc.gov
  - Also according to the TJC MM chapter, manufacturer's directions and hospital policy

68

Timing of Medication Administration Tag 405

- What are acceptable standards of care?
  - National organizations that are recognized in the field issue written statements and policies that direct patient care
- The hospital's P&Ps must be consistent with SOC
- Standards of care can be set by state pharmacy boards and national organizations like the ones mentioned by CMS
- Others include:
  - ASHP (American Society of Healthcare System Pharmacist), American Nurses Association (ANA), American Pharmacy Association (APA), APIC, etc.

69

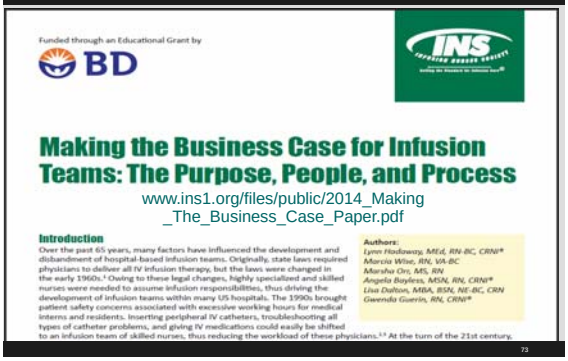
3 Time Frames for Administering Medication

- Time Critical Medicine
- 1 hour before or after
- 2 hours before or after

ISMP Institute for Safe Medication Practices

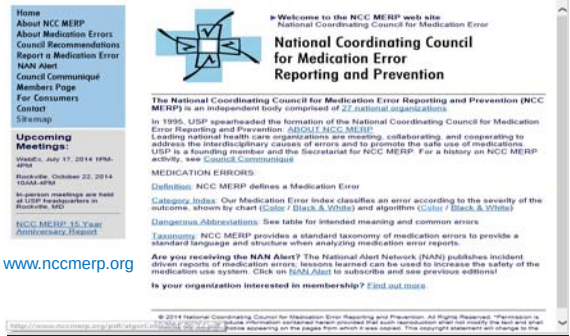
Infusion Nurses Society INS

Free Publication Business Case IV Teams

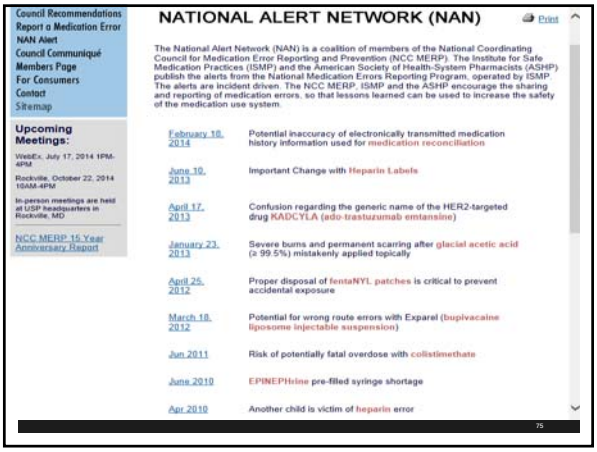


www.ins1.org/files/public/2014_Making_The_Business_Case_Paper.pdf

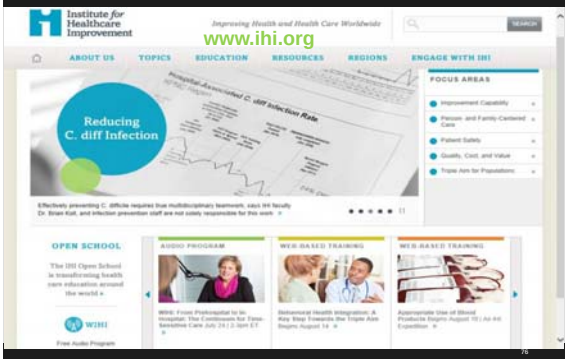
National Coordinating Council



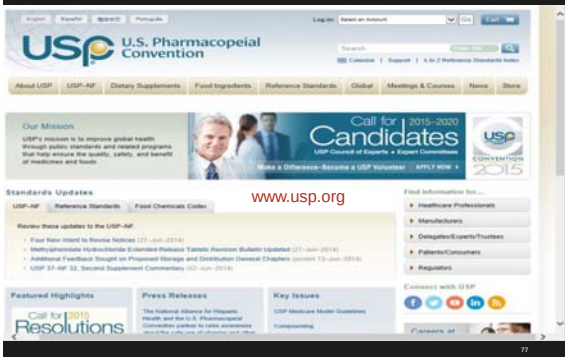
www.nccmerp.org



Institute for Healthcare Improvement IHI



USP U.S. Pharmacopeial



Centers for Disease Control & Prevention CDC

CDC IV Guidelines

- Every hospital should have the 2011 CDC Guidelines for the Prevention of Intravascular Catheter Related Infections
  - How to prep the skin for the peripheral IV
  - How to secure the needle
  - How long to change the dressing
  - How long do you change the IV tubing?

79

www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011

Naomi P. O'Grady, M.D.[1], Mary Alexander, R.N.[2], Lillian A. Burns, M.T., M.P.H., C.I.C.[3], E Patchen Dellinger, M.D.[4], Jeffery Garland, M.D., S.M.[5], Stephen O. Heard, M.D.[6], Pamela A. Lipsett, M.D.[7], Henry Masur, M.D.[1], Leonard A. Mermel, D.O., Sc.M.[8], Michele L. Pearson, M.D.[9], Issam I. Raad, M.D.[10], Adrienne Randolph, M.D., M.Sc.[11], Mark E. Rupp, M.D.[12], Sanjay Saint, M.D., M.P.H.[13], and the Healthcare Infection Control Practices Advisory Committee (HICPAC)[14].

1National Institutes of Health, Bethesda, Maryland
2Infusion Nurses Society, Norwood, Massachusetts
3Greenich Hospital, Greenwich, Connecticut
4University of Washington, Seattle, Washington
5Wheaton Franciscan Healthcare-St. Joseph, Milwaukee, Wisconsin
6University of Massachusetts Medical School, Worcester, Massachusetts
7Johns Hopkins University School of Medicine, Baltimore, Maryland
8Warren Alpert Medical School of Brown University and Rhode Island Hospital, Providence, Rhode Island
9Office of Infectious Diseases, CDC, Atlanta, Georgia
10MD Anderson Cancer Center, Houston, Texas
11The Children's Hospital, Boston, Massachusetts
12University of Nebraska Medical Center, Omaha, Nebraska
13Ann Arbor VA Medical Center and University of Michigan, Ann Arbor, Michigan

80

81

Safe Injection Practices

- Must ensure staff follow SOP to prevent HAI related to medication preparation
  - References infection control worksheet
  - Assessed under infection control section
- Compounded sterile preparations (CSP) can cause HAI if proper precautions not followed such as USP standards
- Nurses may prepare sterile medication for immediate use
- CMS mentions the following apply

82

Compounding 2016

- Must only involve simple transfer of not more than 3 commercially manufactured, sterile, nonhazardous products from the manufacturer's original container
- And not more that two entries into any one container including a vial or an IV bag
- Administration must be within one hour following the preparation
- Must follow aseptic technique during all phases of preparation

83

Compounding 2015

- Must label it unless your prepare it and immediately administer it to the patient
- CSP label must include: patient identification, name and amount of ingredients, name or initial of person who prepared it, and exact one hour BUD
- Drug is outdated after its expiration date or BUD
  - BUD is December 2017 but multi-dose vial expires in 28 days when opened unless sooner by manufacturer
- Need P&P to give clear directions to staff on how to determine BUD date if not available from manufacturer

84

Blood Transfusions and IVs

- **Standard:** Blood transfusions and IV medications must be administered with state law and MS P&P
  - This section has been changed five times over the past several years
- Use to require special training for this and there was a long list of things that nurses had to be trained on
- Added section on compounding to the nursing section along with a detailed section on the same in the pharmacy section

85

Blood Transfusions and IVs 409

- CMS eliminated the regulations mandating training for non-physicians who administer IV medication and blood and blood products
  - CMS says because this training is already standard practice
  - However, when the June 2013 interpretive guidelines were issued CMS said you must still be **competent** in those areas
  - So basically hospitals will want to train in these areas
  - Must follow your P&P and state scope of practice

86

Blood and IV Medication Training

- Must still follow **state law requirements**
  - In some states an LPN can not hang blood
  - Or the LPN can not push certain IV medications in some states
  - Must show they are competent
- Must still have approved **Medical Staff Policies** and Procedures in place
- Staff must follow these which have most of the things that were previously required

87

Blood and IV Medication Training

- CMS mentions that many of the medications given IV are included in the high risk or high alert medication category
- High alerts are those that if a mistake happens the patient is more likely to be injured or die
- CMS references several other areas in the CoP on high alert medications
  - Including that patients need be monitored when receiving high alert medications like opioids which is discussed later
  - TJC has section on high alert medication in MM.01.01.03

88

High Risk Medications

- Need P&P on high alert medications such as dosing limits, administration guidelines, packaging, labeling and storage to reduce medication errors (490)
  - Could be pediatric, geriatric or patients with renal or hepatic impairment
  - Need to have a system to minimize adverse drug events
  - There are several lists of high alert medications and may want to make sure list is posted in medication rooms even though hospital does not select all of them in their policy

89

High Risk Medications

- High risk medications may include (continued):
  - Such as checklists, dose limits, pre-printed orders, special packaging, special labeling, double-checks and written guidelines
  - Examples of high-risk drugs may include investigational drugs, controlled medications, medications not on the approved FDA list, medications with a narrow therapeutic range, psychotherapeutic medications and look-alike/sound-alike medications and those new to the market or new to the hospital

90

Policy on High Alert Medications

- Have a policy on high alert meds,
- Common ones include Digoxin IV, Heparin, adrenergic agonists, concentrated electrolytes and chemo have highest risk of injury (ISMP)
- Insulin, Warfarin, Opiates and Narcotics, injectible KCL, Heparin, Fentanyl patches, and NaCl over 0.9% were most commonly ones involved in error
- CMS amends CoPs and is focusing on safe use of **opioids** as a high risk medication

91

Policy on High Alert Medications

- If insulin have vials in different bins or sections of the box and not all thrown together
- Use tall man lettering such as NovaLog and Nova**LIN**
  - High alert may include; Epidural infusions, Fentanyl, Heparin over 1000 units, insulin, Lidocaine with Epi vials, neuromuscular blockers, PCA, TPN, moderate sedation, anesthetic agents (propofol), and adrenergic agonists (phenylephrine)

92

MODEL HIGH-ALERT MEDICATIONS POLICY & PROCEDURES

PURPOSE
- To provide guidance to acute care organizations for the safe handling and administration of medications designated as High Alert Medications.
- To increase awareness of High Alert Medications, thereby improving patient safety.

DEFINITION
High Alert Medications are drugs that bear a higher risk of causing significant patient harm when they are used in error.[1]

POLICY
A. The following medications are appropriate for inclusion in a High Alert Medications policy.
- Epidural infusions
- Fentanyl
- Heparin (>100 units, flushes exempt)
- Insulin (including regular, aspart, NPH, and glargine)
- Lidocaine with epinephrine vials
- Neuromuscular blocking agents (atracurium, cisatracurium, mivacurium, pancuronium, rapacuronium, rocuronium, succinylcholine, vecuronium, etc)
- Patient Controlled Analgesia (PCA) infusions of any medication
- Total Parenteral Nutrition (TPN) and Total Nutrient Admixture (TNA) solutions
- Oncologic agents
- Moderate sedation agents (e.g., midazolam)
- Anesthetic agents (e.g., propofol)
- [illegible]

B. The following medications may also be appropriate for inclusion in a High Alert Medication policy in addition to the medications above.
- Glycoprotein IIb/IIIa inhibitors (eptifibatide, abciximab, tirofiban)
- Iron Dextran
- Adrenergic antagonists agents (e.g., esmolol)
- Anticonvulsants

C. Concentrated electrolyte vials (e.g., potassium chloride) should not be stocked in patient care areas.

PROCEDURES
Safety procedures during the ordering, preparation, dispensing and administration of High Alert Medications include:

Prescribing
A. Verbal orders for High Alert Medications should be discouraged.
B. If possible, prescribing for High Alert Medications should be standardized using preprinted orders.

Preparation and dispensing
A. All storage locations should be clearly labeled and separated from regular stock. If High Alert Medications must be kept in patient care areas, locked storage areas should be used with a distinct High Alert Medication warning label visibly placed on the storage bin.

93

High Alert How to Guide IHI

www.ihi.org/NR/rdonlyres/8B2475CD-56C7-4D9B-B359-801F3CC3A8D5/0/HighAlertMedicationsHowToGuide.doc

94

95

Blood Transfusions and IVs

- Hospital P&P for blood and IV medication must be based on state law and MS P&P and must address the following:
  - Vascular access route such as central line, peripheral or implanted port and what medications can be given IV and via what type of access devices
  - Basic safety practices for medication administration
    - **Tracing line** and tubes prior to administration to be sure proper route
    - Verify proper programming of infusion devices

96

Why Trace the Lines?

- CMS issues survey memo regarding why they want nurses to trace the lines when getting out of report or before injecting medication into an IV line
- This has been a patient safety issues for many years
- Staff can connect two things together that do not belong together because the ends match
- It has been the subject of many reports including a sentinel event alert from TJC

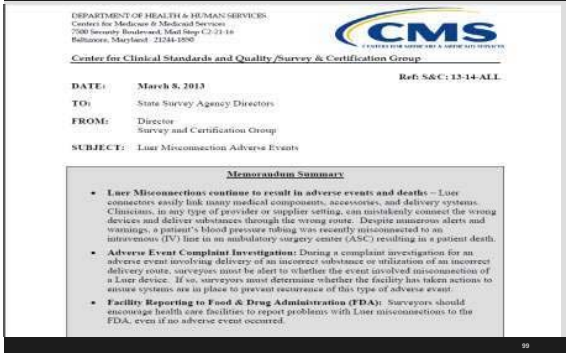
97

Luer Misconnections Memo

- A study found the Pa Patient Safety Authority found that it occurred once a month in their state and if you extrapolate that to the nation it could be 50 a month
- For example, a patient had the blood pressure cuff connected to the IV and died of an air embolism
- Nurse accidentally hangs a medication in the epidural line instead of the IV resulting in the patient's death
- Luer connections easily link many medical components, accessories and delivery devices

98

Luer Misconnections Memo



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-14-ALL

DATE: March 8, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Luer Misconnection Adverse Events

Memorandum Summary

- **Luer Misconnections continue to result in adverse events and deaths** – Luer connectors easily link many medical components, accessories, and delivery systems. Clinicians, in any type of provider or supplier setting, can mistakenly connect the wrong devices and deliver substances through the wrong route. Despite numerous alerts and warnings, a patient's blood pressure tubing was recently misconnected to an intravenous (IV) line in an ambulatory surgery center (ASC) resulting in a patient death.
- **Adverse Event Complaint Investigation:** During a complaint investigation for an adverse event involving delivery of an incorrect substance or utilization of an incorrect delivery route, surveyors must be alert to whether the event involved misconnection of a Luer device. If so, surveyors must determine whether the facility has taken actions to ensure systems are in place to prevent recurrence of this type of adverse event.
- **Facility Reporting to Food & Drug Administration (FDA):** Surveyors should encourage health care facilities to report problems with Luer misconnections to the FDA, even if no adverse event occurred.

99

PA Patient Safety Authority Article

Table. Tubing Misconnections Reported to the Pennsylvania Patient Safety Authority, January 2008 to September 2009

MISCONNECTION	NUMBER OF REPORTS
Secondary intravenous (IV) infusion connected to lower "Y" port of primary IV tubing set	8
Hemodialysis arterial and venous tubing lines reversed	5
G-tube and J-tube lines reversed	3
Incorrect tubing connection (no further explanation provided in reports)	3
Epidural and patient-controlled analgesia (PCA) tubing sets reversed	2
Nonhemodialysis arterial and venous tubing lines reversed	2
Cell saver tubing connected to cell saver reservoir	1
Feeding tube set connected to Broviac®	1
Feeding tube set connected to peripherally inserted central catheter (PICC) line	1
Feeding tube set connected to suction port	1
Imaging contrast tubing set connected to tracheostomy cuff	1
IV tubing set connected to dialysis catheter	1
IV tubing set connected to PICC line	1
IV tubing set connected to tracheostomy cuff	1
Knee irrigation connected to peripheral IV tubing	1
Miscommunication (arterial line noted in medical record as peripheral IV)	1
Oral medication delivered through peripheral IV line	1
Suction line connected to water seal	1
Suction and feeding tubing sets reversed	1
Total	**36**

100

ISMP Tubing Misconnections www.ismp.org

ISMP Medication Safety Alert!

PREVENTING CATHETER/TUBING MISCONNECTIONS: MUCH NEEDED HELP IS ON THE WAY

From the July 15, 2010 issue

Catheter/tubing misconnections remain a serious problem in healthcare. Just a few weeks ago we learned of another fatal event. Over Memorial Day weekend, a 19-month-old child, who was receiving treatment for a chronic gastrointesti disorder, died at a pediatric care center. A suspension of **QUESTRAN** (cholestyramine) was accidentally given via a central line intravenous catheter instead of through an enteral feeding tube.

In May 2010, another report was published about barium sulfate being administered via the superior vena cava during upper gastrointestinal study (Soghoian S, Hoffman RS, Nelson L. Unintentional IV injection of barium sulfate in a child. *J Health-Syst Pharm*. 2010;67:734-36). The patient, a 17-month-old child, had a central venous catheter (CVC) in place f antibiotic therapy. As the procedure began, approximately 3 mL of barium sulfate was injected into the CVC, which was mistaken as the child's gastrostomy tube. Fortunately, no respiratory distress developed and the child was discharged days later.

Luer connector systems, common to many healthcare catheters, tubes, administration sets, extension sets, and syringe have been at the heart of many catheter/tubing misconnections. At the center of one of the most commonly reported problems is the fact that some manufactured enteral catheters still have ports that only accept parenteral administratio sets and syringes. So, even if a liquid medication is prepared in an oral syringe, the medication must be transferred to parenteral syringe for administration via this type of enteral catheter port, risking the accidental administration of the drug via a parenteral line.

Below are examples of the type of reports we have received associated with catheter/tubing misconnections, all of whi we've described in this newsletter since publication began in 1996:

- IV infusions connected to epidural lines, and epidural solutions connected to IV lines
- Syringe containing IV medication given via an intrathecal catheter
- IV tubing connected to inflation balloon port of endotracheal tube or tracheostomy tube
- Sequential compression device tubing or pneumatic blood pressure cuff tubing attached to port of IV administrati set
- Oxygen tubing connected to port of IV administration set
- Breast milk intravenously infused into neonates
- Bladder irrigation solutions given IV, or TPN solutions administered via foley catheter port
- IV administration set spiked into enteral nutrition container, resulting in enteral nutrition administered IV.

101

TJC Sentinel Event Alert #36 www.jointcommission.org

The Joint Commission

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Topic Library Item

Sentinel Event Alert, Issue 36: Tubing misconnections—a persistent and potentially deadly occurrence

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102

New Standards Prevent Tubing Misconnections

- New and unique international standards being developed in 2014 for connectors for gas and liquid delivery systems
- To make it impossible to connect unrelated systems
- Includes new connectors for enteral, respiratory, limb cuff inflation neuraxial, and intravascular systems
- Phase in period for product development, market release and implementation guided by the FDA and national organizations and state legislatures
  - FAQ on small bore connector initiative

103

New standards to prevent tubing misconnections will have unprecedented impact on supply chain and patient safety

What if you could no longer connect any of the equipment that you have in stock to give enteral feedings (e.g., feeding sets, tubes, oral syringes). That is the likely scenario - once new standards to prevent tubing misconnections are released - without a carefully crafted implementation plan across all settings where care is delivered.

The very simple and universal design of most *connectors* in all of health care creates a serious risk that tubes from totally unrelated systems can be inadvertently connected leading to patient death or serious injury. This means that an enteral feeding tube could be accidentally connected to an IV line, delivering formula into a vein with fatal consequences. An international group of stakeholders are working together to solve this problem by developing unique design standards for every delivery system so that unrelated systems can never be mistakenly connected together.

What do these new standards mean for healthcare

New and unique international standards are being developed for connectors for each gas and liquid delivery system in healthcare to make it virtually impossible to connect unrelated systems[1]. These new connector standards will include new designs for connectors of enteral, respiratory, limb cuff inflation, neuraxial, and intravascular systems. It is anticipated that the standards for enteral connectors will be the first to be released in 2014. There will be a phase-in period for product development, market release and implementation guided by the FDA, existing state legislation, suppliers, and national organizations working together.

www.premierinc.com/tubingmisconnections/

104

A-0409
(Rev.)

§482.23(c)(4) - Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.

Interpretative Guidelines §482.23(c)(4)

Intravenous (IV) medications and blood transfusions must be administered in accordance with State law and approved medical staff policies and procedures. Further, many of the medications included in the high-alert categories are administered intravenously. (See also the discussion of high-risk/high-alert medications in the guidance for §482.23(b).) Hospital policies and procedures for blood transfusions and IV medications must be based on accepted standards of practice, and must address at least the following:

Vascular Access Route

Patients may require a form of vascular access to deliver blood or medications, either venous or arterial, based on the desired treatment plan. Safe administration of blood transfusions and IV medications includes the correct choice of vascular access. IV medications, such as fluids, antibiotics, and chemotherapy, may require specific types of access, such as peripheral or central catheters versus implanted port devices, based on the medication's chemical properties or safety concerns. Hospital policies and procedures must address which medications can be given intravenously via what type of access.

105

Blood Transfusions and IVs

- Patient Monitoring
  - Nursing staff must understand each medication and its monitoring requirement
  - Monitor for the effects of the medication since IV medications have a more rapid effect
  - Monitoring to include assessment of risk factors that would influence type and frequency of monitoring
  - Such as patient with renal failure on Vancomycin and dose is based on lab test

106

Blood Transfusions and IVs

- P&P expected to address
  - Monitoring for fluid and electrolyte balance
  - Monitor patients on high alert meds including **opioids** and evaluate for over-sedation and respiratory depression
    - Tag 405 discusses the assessment and monitoring of patients on opioids
  - Needs to address assessment of patients with risk factors that would influence the type and frequency of monitoring

107

Get Fluid & Electrolyte Balance Updates

Assessment & Monitoring of Patients

- Patients on medications needed to be carefully monitored (Tag 405)
  - May need clinical and lab data to evaluate medication
  - Monitor respiratory status, pulse ox BP, end tidal CO2 with patients on **opioids**
  - Evaluate clinical signs such as confusion, agitation, unsteady gait, itching etc.
  - Know **high risk medications** policy and safe practices
  - Know risk factors for ADE such as patient has liver or kidney failure, history of sleep apnea, obesity, smoking, drug-drug interaction and first time medication use

109

Assessment & Monitoring of Patients

- ADE, such as anaphylaxis or opioid-induced respiratory depression may require timely and appropriate (405)
- Post-medication monitoring in case of a high alert medication may include regular assessment of VS, pulse ox, and sedation levels of post surgery patient on PCA
- Such as Richmond agitation sedation scale (RASS) or the Pasero Opioid-Induced sedation scale (POSS), Inova Sedation Scale (ISS), Ramsey scale, Aldrete Scoring system

110

Pasero Opioid-induced Sedation Scale POSS

Pasero Opioid-induced Sedation Scale (POSS)

https://secure.tha.com/surveys/files/pasero-opioid-induced-sedation-scale-poss.pdf

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

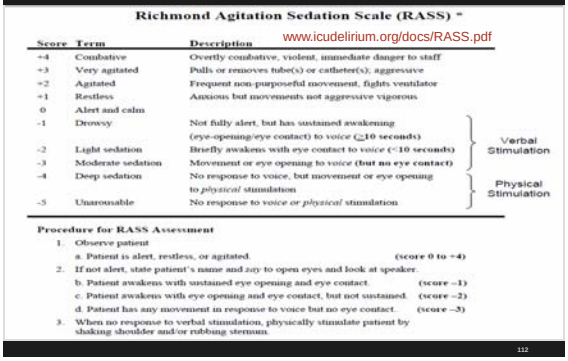
2. Slightly drowsy, easily aroused
Acceptable; no action necessary; may increase opioid dose if needed

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 naloxone; 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.

111

Richmond Agitation Sedation Scale RASS



Richmond Agitation Sedation Scale (RASS) "

www.icudelirium.org/docs/RASS.pdf

Score	Term	Description	
+4	Combative	Overtly combative, violent, immediate danger to staff	
+3	Very agitated	Pulls or removes tube(s) or catheter(s); aggressive	
+2	Agitated	Frequent non-purposeful movement, fights ventilator	
+1	Restless	Anxious but movements not aggressive vigorous	
0	Alert and calm		
-1	Drowsy	Not fully alert, but has sustained awakening (eye-opening/eye contact) to *voice* (≥10 seconds)	Verbal Stimulation
-2	Light sedation	Briefly awakens with eye contact to *voice* (<10 seconds)	Verbal Stimulation
-3	Moderate sedation	Movement or eye opening to *voice* **(but no eye contact)**	Verbal Stimulation
-4	Deep sedation	No response to voice, but movement or eye opening to *physical* stimulation	Physical Stimulation
-5	Unarousable	No response to *voice or physical* stimulation	Physical Stimulation

Procedure for RASS Assessment

1. Observe patient
   a. Patient is alert, restless, or agitated. **(score 0 to +4)**
2. If not alert, state patient's name and *say* to open eyes and look at speaker.
   b. Patient awakens with sustained eye opening and eye contact. **(score –1)**
   c. Patient awakens with eye opening and eye contact, but not sustained. **(score –2)**
   d. Patient has any movement in response to voice but no eye contact. **(score –3)**
3. When no response to verbal stimulation, physically stimulate patient by shaking shoulder and/or rubbing sternum.

112

Comparison of Sedation Scales Medscape

Pain Management Nursing

Comparsion of Selected Sedation Scales for Reporting Opioid–Induced Sedation Assessment

Abstract and Introduction
Nurse Assessment of Sedation Using a Sedation Scale
Study Aims and Methods
Results
Limitations
Summary Recommendations
References

Study Aims and Methods

EDITORS' RECOMMENDATIONS

Vital Signs: Overdoses of Prescription Opioid Pain Relievers and Other Drugs Among Women

Deaths and Severe Adverse Events Associated With Anesthesia-Assisted Rapid Opioid Detoxification

Chronic Pain Treatment With Opioid Analgesics

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113

Blood Transfusions and IVs

- **Risk factors** for patients receiving opioids include
  - Snoring or history of sleep apnea
  - No recent opioid use or first-time use of IV opioids
  - Increased opioid dose requirement or opioid habituation
  - Longer length of time receiving general anesthesia during surgery
  - Receiving other sedating drugs, such as benzodiazepines, antihistamines, sedatives, or other CNS depressants
  - Preexisting pulmonary or cardiac disease
  - Thoracic or other surgical incisions that may impair breathing

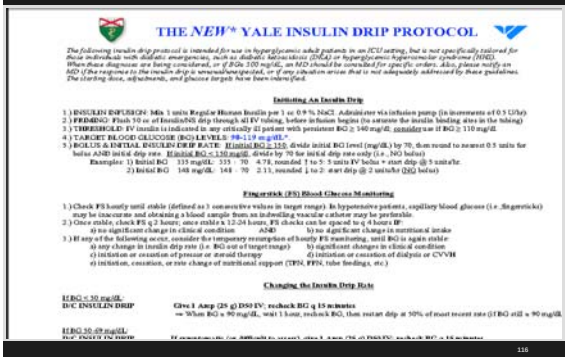
114

Blood Transfusions and IVs 409

- Hospital P&P is expected to address:
  - Monitoring for fluid and electrolyte balance
    - Policy must address monitoring and treatment for fluid and electrolyte imbalances that may occur with blood transfusions and IV medications
  - Monitoring patients for high alert medications including IV opioids
    - Policy must include the list the hospital selected as their high risk medications
    - Must include how to monitor for them such as 2 nurses check insulin or use bar coding and how often monitoring of patient on IV insulin and how often glucose checks

115

Insulin Drip Monitoring Protocol



THE *NEW** YALE INSULIN DRIP PROTOCOL

The following insulin drip protocol is intended for use in hyperglycemic adult patients in an ICU setting, but is not specifically tailored for those individuals with diabetic emergencies, such as diabetic ketoacidosis (DKA) or hyperglycemic hyperosmolar syndrome (HHS). When these diagnoses are being considered, or if BGs 500 mg/dL, an MD should be consulted for specific orders. Also, please notify an MD if the response to the insulin drip is unwarranted/unexpected, or if any situation arises that is not adequately addressed by these guidelines. The starting dose, adjustments, and glucose targets have been intensified.

Initiating An Insulin Drip

1.) INSULIN INFUSION: Mix 1 units Regular Human Insulin per 1 cc 0.9 % NaCl. Administer via infusion pump (in increments of 0.5 U/hr)
2.) PRIMING: Flush 50 cc of Insulin/NS drip through all IV tubing, before infusion begins (to saturate the insulin binding sites in the tubing)
3.) THRESHOLD: IV insulin is indicated in any critically ill patient with persistent BG ≥ 140 mg/dL (consider use if BG ≥ 110 mg/dL
4.) TARGET BLOOD GLUCOSE (BG) LEVELS: 90-119 mg/dL*
5.) BOLUS & INITIAL INSULIN DRIP RATE: If initial BG ≥ 150, divide initial BG level (mg/dL) by 70, then round to nearest 0.5 units for bolus AND initial drip rate. If initial BG < 150 mg/dL, divide by 70 for initial drip rate only (i.e., NO bolus)
Examples: 1) Initial BG 335 mg/dL: 335 ÷ 70 = 4.78, rounded ↑ to 5: 5 units IV bolus + start drip @ 5 units/hr.
2) Initial BG 148 mg/dL: 148 ÷ 70 = 2.11, rounded ↓ to 2: start drip @ 2 units/hr (NO bolus)

Fingerstick (FS) Blood Glucose Monitoring

1.) Check FS hourly until stable (defined as 3 consecutive values in target range). In hypotensive patients, capillary blood glucose (i.e., fingersticks) may be inaccurate and obtaining a blood sample from an indwelling vascular catheter may be preferable.
2.) Once stable, check FS q 2 hours; once stable x 12-24 hours, FS checks can be spaced to q 4 hours IF:
a) no significant change in clinical condition AND b) no significant change in nutritional intake
3.) If any of the following occur, consider the temporary resumption of hourly FS monitoring, until BG is again stable:
a) any change in insulin drip rate (i.e. BG out of target range) b) significant changes in clinical condition
c) initiation or cessation of pressor or steroid therapy d) initiation or cessation of dialysis or CVVH
e) initiation, cessation, or rate change of nutritional support (TPN, PPN, tube feedings, etc.)

Changing the Insulin Drip Rate

If BG < 50 mg/dL:
D/C INSULIN DRIP
Give 1 Amp (25 g) D50 IV; recheck BG q 15 minutes
⇒ When BG ≥ 90 mg/dL, wait 1 hour, recheck BG, then restart drip at 50% of most recent rate (if BG still ≥ 90 mg/dL

If BG 50-69 mg/dL:

116

Blood Transfusions and IVs 409

- Expected to address monitoring for over-sedation and respiratory depression for safe opioid use
  - Can erroneous assume patient is asleep when they are having progressive symptoms of respiratory compromise
  - Factors that put patients at high risk include snoring, history of sleep apnea, first time use of IV opioids, increased opioid dose, longer length of time receiving general anesthesia, pulmonary or cardiac disease or thoracic or surgical incisions

117

Assess and Monitor Patients

- Need to assess and monitor the effects of the medications
- To allow for early identification of adverse effects
- Some may need to use clinical and lab data to evaluate efficacy of medication therapy
  - For **opioids** may need to monitor respiratory status, Vitals signs such BP, O_2 sat, pain level, sedation scale, and carbon dioxide levels
- Evaluate symptoms such as confusion, agitation, unsteady gait, pruritus, somnolence etc.
- Be aware of high alert medications as discussed

118

Blood Transfusions and IVs

- **P&P** must include who can conduct the assessments
- The frequency and duration of the assessments
- Under what circumstances practitioners prescribing IV opioids are allowed to establish protocols that differ from hospital P&P
- **Assessment** includes VS (TPR and BP), pain level, respiratory status, sedation level and $ETCO_2$
- Also mentions APSF(Anesthesia Patient Safety Foundation) monitoring of opioids including $ETCO_2$

119

APSF Website Mentioned by CMS

120

Whitepaper and Workshop Dangers Opioids

Dangers of Postoperative Opioids

APSF Workshop and White Paper Address Prevention of Postoperative Respiratory Complications

by Matthew B. Weinger, MD

www.apsf.org/newsletters/html/2007/winter/01_opioids.htm

Executive Summary

In response to concerns about the safety of the use of patient-controlled analgesia (PCA) in the postoperative period, the Anesthesia Patient Safety Foundation (APSF) held a workshop in San Francisco on October 13, 2006, that was attended by over 100 clinicians, scientists, and medical industry representatives. The attendees listened to a range of relevant expert presentations, broke into small groups to discuss specific issues, and then reconvened to present and discuss the findings. The workshop focused on improved detection of postoperative opioid-induced respiratory depression. Robert K. Stoelting, MD, APSF President, opened with a statement of the workshop goals: 1) reviewing the evidence regarding the risks of PCA; 2) evaluating the value of continuous monitoring of postoperative patients receiving PCA; and 3) developing recommendations that could be promulgated to advance patient safety. He noted that the APSF believed that opioid-induced postoperative respiratory depression is a preventable cause of morbidity and mortality. He further stated that the recognition of patients at increased risk for respiratory depression and utilization of appropriate monitors to detect this side effect of parenteral opioids could significantly improve patient safety.

The available evidence suggests that there is a significant and underappreciated risk of serious injury from PCA and neuraxial opioids in the postoperative period. While some patient populations (notably those patients with obstructive sleep apnea) appear to be at higher risk, there is still a low but unpredictable incidence of life-threatening, opioid-induced respiratory depression in young healthy patients. Moreover, life-threatening, opioid-induced respiratory depression also occurs with intermittent parenteral injections of opioid analgesics. Data and clinical experience suggest that, while continual respiratory monitoring could detect many cases of life-threatening, opioid-induced depression, current monitoring technologies and clinical practices are insufficiently reliable with both false positives (e.g., monitor false alarms) and false negatives (e.g., low sensitivity to SpO_2 in the presence of supplemental oxygen administration). Nevertheless, the status quo while awaiting the perfect monitor(s) is not acceptable, and the APSF advocates the routine use of continuous postoperative respiratory monitoring in at-risk patients receiving PCA or neuraxial opioids. Although pulse oximetry will monitor oxygenation, it has reduced sensitivity as a monitor of hypoventilation when supplemental oxygen is administered. When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations.

121

Table 1. Summary of Opinions about Current Methods of Detecting Opioid-Induced Respiratory Depression

Method	Primary Measures	Sensitivity[a]	Specificity[b]	Reliability[c]	Response Time	Frequency of Measurement	Cost	Comments
Clinical observation[d]	Oxygenation & Ventilation	Variable	Variable	Variable	Variable	Intermittent	Variable	Depends on observer skill and observation frequency
Chest wall impedance	Ventilation	Low	Low	Low	Moderate	Continuous	Modest	May be non-specific in airway obstruction
Respiratory rate	Ventilation	Low	Moderate	Moderate	Moderate	Intermittent/ Continuous	Variable	May not be helpful in patients with obstructive sleep apnea (OSA)
Tidal volume	Ventilation	Moderate	Moderate	Low	Moderate	Continuous	Modest	Unreliable technology
SpO_2 (when giving supplemental FiO_2)	Oxygenation	Low	Moderate	High	Slow	Continuous	Modest	Desaturation may be late and then very rapid
Venous blood gas	Oxygenation & Ventilation	High	Modest	High	Slow	Intermittent	High	Depends on prior clinical observation or fortuity
Arterial blood gas	Oxygenation & Ventilation	Very High	Very High	Very High	Slow	Intermittent	High	Depends on prior clinical observation or fortuity
Minute ventilation	Ventilation	Moderate	Moderate	Low	Moderate	Continuous	Modest	Unreliable technology
SpO_2 (without supplemental FiO_2)	Oxygenation & Ventilation	High	High	High	Fast	Continuous	Modest	Alveolar gas equation predicts a drop in SpO_2 even with modest hypoventilation
$PrCO_2$ (unintubated)	Ventilation	Moderate	High	Moderate	Fast	Continuous	Modest	High $PrCO_2$ significant but dependent on sampling. Underestimates $PaCO_2$. Some believe only reliable as measure of respiratory rate
$PrCO_2$ (intubated)	Ventilation	Very High	Very High	High	Fast	Continuous	Modest	Not viable option on ward

[a] Sensitivity is test positivity in the presence of abnormality (i.e., [True positives]/[True positives + False negatives]).
[b] Specificity is test negativity in the absence of abnormality (i.e., [True negatives]/[True negatives + False positives]).
[c] Reliability is the consistency of meaningful data, particularly when abnormalities are present.
[d] Clinical observation includes signs of sedation, decreased level of consciousness, respiratory rate, depth, and pattern, airway obstruction, cyanosis, etc.

122

ISMP Use a Standard Sedation Scale

For Information – Not Required/Not to be Cited

In addition to assessing risk for respiratory depression, the Institute for Safe Medication Practices recommends hospitals use a standard sedation scale when assessing patients receiving PCA. Scales such as the Richmond Agitation Sedation Scale, Pasero, Ramsey, or Glasgow Coma Scale are useful in assessing sedation.

Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen…Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013

123

For Information – Not Required/Not to be Cited

Institute for Safe Medication Practices Guidelines for PCA Monitoring

Assessment of Opioid Tolerance	Vital Signs	Pain	Sedation	Respiratory		
				Rate	Quality	SPO_2* &/or $ETCO_2$**
Baseline Assessment before PCA	X	X	X	X	X	X
PCA Initiation or Change in Drug/Syringe Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
PCA Dose Change or Bolus Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
Adverse Event or Patient Deterioration (e.g., adverse change in sedation score) Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
Hand-offs/Shift Change	X	X	X	X	X	X

Institute for Safe Medication Practices (ISMP). Medication Safety Alert – Fatal PCA Adverse Events Continue to happen…Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013 ISMP adapted these recommendations from the San Diego Patient Safety Council

* SPO_2: Saturation of peripheral oxygen via pulse oximetry

124

Safe Opioid Use & Safe Medication Use

- Patients at great risk for adverse events include age, liver or kidney failure, history of sleep apnea, history of smoking, drug-drug interaction, first time medication use and weight
  - Obesity could increase apnea and smaller patients could more sensitive to dose levels of medications
- **Risk factors** need to be considered in determining how often to monitor and what type of monitoring
- Must communicate important information in hand-offs such as change of shift

125

Safe Opioid Use & Safe Medication Use

- ADR, such as opioid-induced respiratory depression require timely intervention as per established hospital protocols
- Must also report to physician or LIP immediately
- High alert medications would want to check VS, O_2 sat, (ETCO2), and sedation levels to prevent respiratory depression and arrest
- Staff are expected to include patient's reports of his experience of the medication's effects
- Educate the patient and family about notifying staff if difficulty breathing

126

Safe Opioid Use & Safe Medication Use

- Hospital policy is expected to address the manner and frequency of monitoring
- Hospital P&P is expected to include information to be communicated at shift change
- It is important to document order, medication record, lab reports, vital signs etc.
- Document after actual administration of medication and no documentation in advance
- Surveyor will make sure staff is knowledgeable about intervention protocol if ADE occurs

127

Anesthesia Patient Safety Foundation

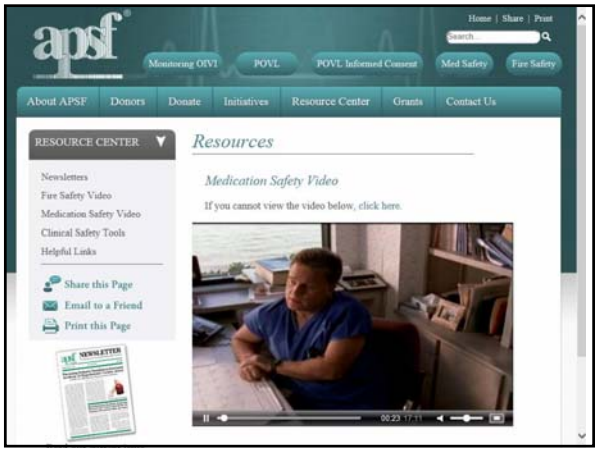
Anesthesia Patient Safety Foundation

- *APSF calls for every patient receiving postoperative opioid analgesics to be managed based on the following clinical considerations*:*
  - *Individualize the dose and infusion rate of opioid while considering the unique aspects of each patient's history and physical status.*
  - *Make continuous monitoring of oxygenation (pulse oximetry) the routine rather than the exception.*
  - *Assess the need for supplemental oxygen, especially if pulse oximetry or intermittent nurse assessment are the only methods of identifying progressive hypoventilation.*
  - *When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations. Continuous monitoring is most important for the highest risk patients, but depending on clinical judgment, should be applied to other patients.*

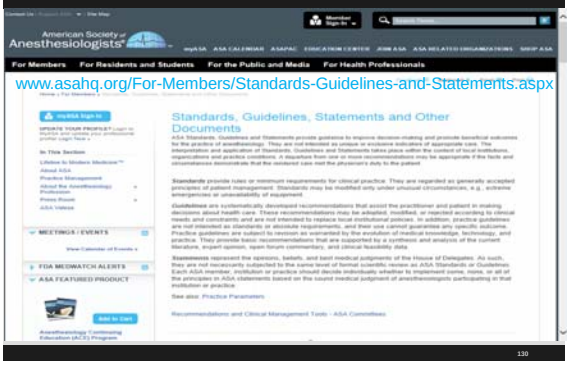
When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations. Continuous monitoring is most important for the highest risk patients, but depending on clinical judgment, should be applied to other patients.

APSF also has issued a video on opioid induced ventilatory impairment: http://apsf.org/resources_video4.php

128



ASA Standards and Guidelines



www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx

130

Blood Transfusions

- HHS says there were 13,785,000 units of whole blood and red blood cells were transfused in the US
- Collection, testing, preparation, and storage of blood and blood components are regulated by the FDA
- However, CMS standards govern administration of blood and blood products
- Transfusion errors can be fatal
- Has a number of things that must be in P&Ps

131

Blood Transfusions

- Confirm correct patient
- Verify correct blood product
- Standard calls for two qualified persons, one who is administering the transfusion
  - TJC NPSG allows one person hanging blood if use bar coding
- Document monitoring
- P&P include how frequent you monitor the patient and do vital signs
- How to identify and treat and report any adverse transfusion reaction

132

Blood Components and Blood Administration Procedures

According to the U.S. Department of Health and Human Services, 13,785,000 units of whole blood and red blood cells were transfused in the United States in 2011[5]. The collection, testing, preparation, and storage of blood and blood components are regulated by the Food and Drug Administration. However, administration of blood products via transfusion is governed by §482.23(c)(4). Blood transfusions can be life-saving. However, like IV medications, blood transfusions are not without risk of harm to patients. Transfusion reactions and/or errors can be fatal.

In addition to the safe practices and other safety considerations that apply to all IV medication administration, policies and procedures must address blood administration procedures that are consistent with accepted standards of transfusion practice, including but not limited to:

- *Confirming the following prior to each blood transfusion:*
  - *the patient's identity*
  - *verification of the right blood product for the right patient*

  The standard of practice calls for two qualified individuals, one of whom will be administering the transfusion, to perform the confirmation.
- *Requirements for patient monitoring, including frequency and documentation of monitoring*

Blood Transfusions

- Staff must be **competent** in venipuncture
- Competent in using vascular access devices
- Trained in early detection and intervention for opioid over-sedation
- Must document competency
- So make sure nursing education is aware and staff trained in orientation periodically
- Make sure staff educated on P&P

134

Survey Procedure

- Interview nursing staff on different units who administer IV medications and blood transfusions. Are staff knowledgeable with respect to:
  - Venipuncture techniques
  - Safe medication administration practices, including general practices applying to all types of medications and practices concerning IV tubing and infusion pumps
  - Maintaining fluid and electrolyte balance
  - Patient assessment for risk related to IV medications and appropriate monitoring
  - Early detection and intervention

135

Survey Procedure

- Will look to see if any blood transfusions
- To review staff files for evidence of competency in administering IV medication and blood products
- Surveyor encouraged to watch staff hang blood or observe IV medication given
  - Were safe injection practices followed
  - Was appropriate access for IV medication
  - Are patients monitored for adverse reactions
  - Were transfused patients correctly identified and correct blood administered?

136

Incident Reports A-410

- Standard: There must be procedure for reporting transfusion reactions, adverse drug reactions (ADRs) and errors in administration of drugs
- See tag 508 which was amended 11-20-2015 in the pharmacy section which affects nursing
- Important for staff to be versed in the blood and blood products policy and the symptoms of a transfusion reaction

137

A-0410

(Rev.)

§482.23(c)(5) - There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

Interpretive Guidelines §482.23(c)(5)

Adverse drug reactions and drug administration errors

There is a similar but more detailed and prescriptive requirement concerning internal hospital reporting of adverse drug reactions, drug administration errors and incompatibilities under the Pharmaceutical Services CoP at §482.25(b)(6). Therefore, it is not necessary for hospitals to establish a different procedure in the case of adverse drug reactions and drug administration errors for such events when nurses administer drugs or transfusions. Consult the guidance for §482.25(b)(6) to see what must be reported, to whom, and in what timeframe. Failure to make required reports concerning adverse drug reactions and errors in administration of drugs should be cited under §482.23(c)(5) when the drug was administered by a nurse, as well as under §482.25(b)(6).

Transfusion reactions

Transfusion reactions can occur during or after a blood transfusion. A patient's immune system recognizes the foreign blood product and attempts to destroy the transfused cells. Incompatible blood products are typically the cause of transfusion reactions. Symptoms may include back pain, bloody urine, hives, chills, fainting, dizziness, fever, flank pain, and skin flushing. More serious complications may include acute kidney failure, anemia, respiratory distress, shock and even death.

Transfusion reactions are serious and can be life-threatening. The hospital must have policies and procedures in place for the internal reporting of transfusion reactions. The policies must

138

Transfusion Reactions, ADEs, Drug Errors

- Establish a procedure in the case of ADEs and drug errors when nurses administer drugs or transfusions
  - Refers back to tag 508 regarding reporting these into the PI system
  - Often done on an incident report and document in chart and document physician or LIP notified
- Transfusion reactions can be serious and life threatening
  - Discussed the symptoms of a transfusion reaction: chills, hives, back pain, bloody urine, dizziness, fever, flank pain, skin flushing, kidney failure, anemia, shock, respiratory failure or death

139

Transfusion Reactions

- Transfusion reactions can occur during or after a blood transfusion
- Patient's immune system recognized the foreign blood product and attempts to destroy the infused cells
- Incompatible blood products are typically the cause of the transfusion reaction
  - Symptoms may include back pain, bloody urine, hives, chills, fainting, dizziness, fever, flank pain, and skin flushing. More serious complications may include acute kidney failure, anemia, respiratory distress, shock and even death.

140

Transfusion Reactions

- Must have P&P to ensure transfusion reactions are reported
- Must be reported immediately to practitioner
- Must be documented in the chart
- Must be reported to the QAPI program
- Surveyor is suppose to look at the hospital P&P and internal reports of transfusion reactions
- Will ask to see any incident reports

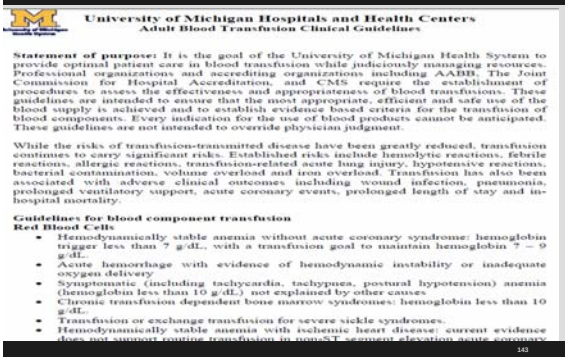
141

Survey procedure

- Request policy for reporting of transfusion reactions
- They may review the incident reports or other documentation through QAPI program
- Surveyor is told to interview the nursing staff responsible for administering blood to be sure they are familiar with and complying with the policies
- Surveyor instructed to ask for transfusion related incident reports and determine if reported to the PI program and to the practitioner responsible for the patient's care

142

So What's in Your Policy?



University of Michigan Hospitals and Health Centers
Adult Blood Transfusion Clinical Guidelines

Statement of purpose: It is the goal of the University of Michigan Health System to provide optimal patient care in blood transfusion while judiciously managing resources. Professional organizations and accrediting organizations including AABB, The Joint Commission for Hospital Accreditation, and CMS require the establishment of procedures to assess the effectiveness and appropriateness of blood transfusions. These guidelines are intended to ensure that the most appropriate, efficient and safe use of the blood supply is achieved and to establish evidence based criteria for the transfusion of blood components. Every indication for the use of blood products cannot be anticipated. These guidelines are not intended to override physician judgment.

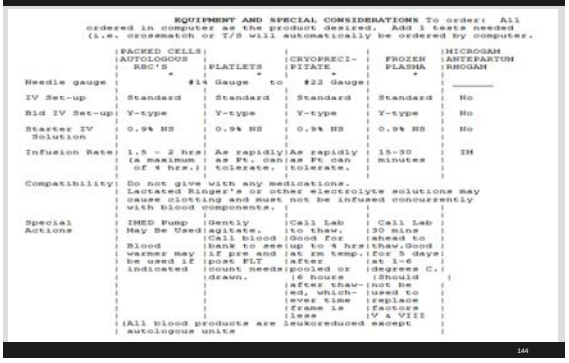
While the risks of transfusion-transmitted disease have been greatly reduced, transfusion continues to carry significant risks. Established risks include hemolytic reactions, febrile reactions, allergic reactions, transfusion-related acute lung injury, hypotensive reactions, bacterial contamination, volume overload and iron overload. Transfusion has also been associated with adverse clinical outcomes including wound infection, pneumonia, prolonged ventilatory support, acute coronary events, prolonged length of stay and in-hospital mortality.

Guidelines for blood component transfusion
Red Blood Cells

- Hemodynamically stable anemia without acute coronary syndrome: hemoglobin trigger less than 7 g/dL, with a transfusion goal to maintain hemoglobin 7 – 9 g/dL.
- Acute hemorrhage with evidence of hemodynamic instability or inadequate oxygen delivery
- Symptomatic (including tachycardia, tachypnea, postural hypotension) anemia (hemoglobin less than 10 g/dL) not explained by other causes
- Chronic transfusion dependent bone marrow syndromes: hemoglobin less than 10 g/dL.
- Transfusion or exchange transfusion for severe sickle syndromes.
- Hemodynamically stable anemia with ischemic heart disease: current evidence does not support routine transfusion in non-ST segment elevation acute coronary

143

So What's In Your Policy?



EQUIPMENT AND SPECIAL CONSIDERATIONS To order: All ordered in computer as the product desired. Add 1 tests needed (i.e. crossmatch or T/S will automatically be ordered by computer.

	PACKED CELLS AUTOLOGOUS RBC'S	PLATELETS	CRYOPRECIPITATE	FROZEN PLASMA	NICROGAM ANTEPARTUM RHOGAM
Needle gauge	#14 Gauge to		#22 Gauge		
IV Set-up	Standard	Standard	Standard	Standard	No
Bld IV Set-up	Y-type	Y-type	Y-type	Y-type	No
Starter IV Solution	0.9% NS	0.9% NS	0.9% NS	0.9% NS	No
Infusion Rate	1.5 - 2 hrs (a maximum of 4 hrs.)	As rapidly as Pt. can tolerate.	As rapidly as Pt can tolerate.	15-30 minutes	IM
Compatibility	Do not give with any medications. Lactated Ringer's or other electrolyte solutions may cause clotting and must not be infused concurrently with blood components.				
Special Actions	IMED Pump May Be Used Blood warmer may be used if indicated	Gently agitate. Call blood bank to see if pre and post PLT count needs drawn.	Call Lab to thaw. Good for up to 4 hrs at rm temp. after pooled or (6 hours after thawed, whichever time is less	Call Lab 30 mins ahead to thaw. Good for 5 days at 1-6 degrees C. Should not be used to replace factors V & VIII	
(All blood products are autologous units			leukoreduced except		

144

Title: Blood/Blood Component Transfusion

Infiltration	Clamp the IV line; restart new IV line and continue infusing blood / blood products.

* If necessary, a 20 gauge or 22 gauge may be used.

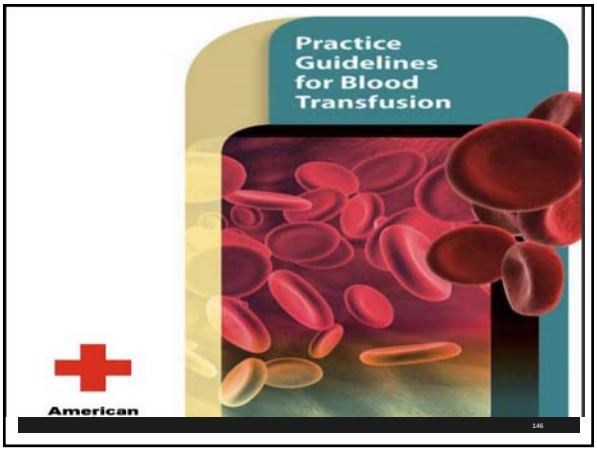
PROCEDURE:

I. Prior to obtaining blood from lab:
- A. Check chart for M.D. orders.
- B. Check that a "Consent for Transfusion of Blood and Blood Products for Medical Patients" has been signed. For patient receiving multiple transfusions over the year, a consent form is good for one year for the same diagnosis. If a patient signs a "Surgical Treatment or Therapeutic Procedure," no blood consent is needed.
- C. When platelets are being transfused, call the lab to see if the patient needs to be drawn for a pre-platelet count. A post platelet count must also be drawn after platelets are transfused.

II. Obtaining the blood/blood components from the Laboratory:
- A. Order blood/blood components from the Laboratory. The availability of products can be reviewed in P.C.I.
- B. Lab technician (when available) will select appropriate bag of blood/blood component.
- C. Check the blood for any signs of jaundice, hemolysis, gas bubbles, abnormal color, or cloudiness. Check for the following information:
  1. Patient's name
  2. Unit number
  3. Blood type/group and RH
  4. Patient's Medical Record number
  5. Expiration date and time to be sure unit is not outdated
  6. Type of product
- D. The RN and Lab personnel will review and compare the information on the "Unit Issue Card"/"Unit Transfusion Card" and the unit of blood/blood component. One will read the information on the unit of blood and then the other will read the information from the unit transfusion card. The RN and Lab personnel both sign the "Unit Issue Card" after verifying patient/unit data. The "Unit Issue Card" remains in the blood bank, the "Unit Transfusion Card"/crossmatch slip goes to the floor with the unit of blood/blood component.

NOTE: Only one unit may be taken out at a time, unless there is an emergency situation. Blood that is not to be given to the patient within 20 minutes of leaving the lab, must

145



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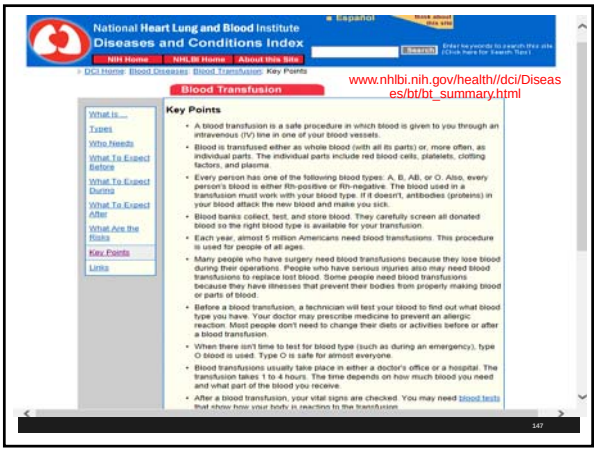
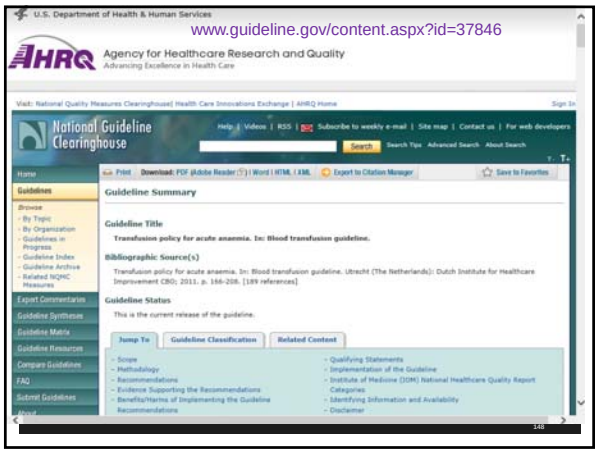
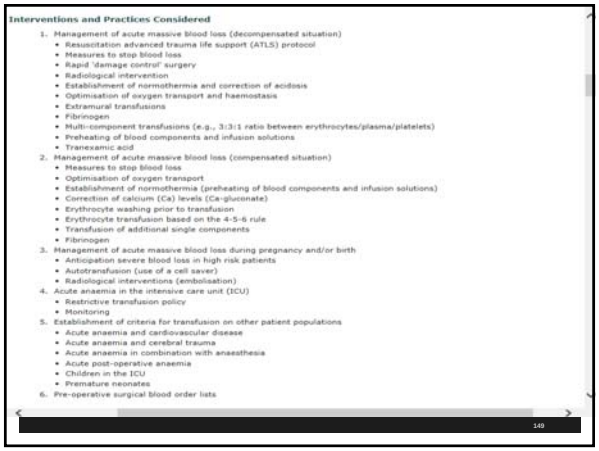


www.nhlbi.nih.gov/health//dci/Diseases/bt/bt_summary.html

147


www.guideline.gov/content.aspx?id=37846
U.S. Department of Health & Human Services
AHRQ
Agency for Healthcare Research and Quality
National Guideline Clearinghouse
Guideline Summary
Guideline Title
Transfusion policy for acute anaemia. In: Blood transfusion guideline.
Bibliographic Source(s)
Guideline Status
This is the current release of the guideline.
148


Interventions and Practices Considered
1. Management of acute massive blood loss (decompensated situation)
• Resuscitation advanced trauma life support (ATLS) protocol
• Measures to stop blood loss
• Rapid 'damage control' surgery
• Radiological intervention
• Establishment of normothermia and correction of acidosis
• Optimisation of oxygen transport and haemostasis
• Extramural transfusions
• Fibrinogen
• Multi-component transfusions (e.g., 3:3:1 ratio between erythrocytes/plasma/platelets)
• Preheating of blood components and infusion solutions
• Tranexamic acid
2. Management of acute massive blood loss (compensated situation)
• Measures to stop blood loss
• Optimisation of oxygen transport
• Establishment of normothermia (preheating of blood components and infusion solutions)
• Correction of calcium (Ca) levels (Ca-gluconate)
• Erythrocyte washing prior to transfusion
• Erythrocyte transfusion based on the 4-5-6 rule
• Transfusion of additional single components
• Fibrinogen
3. Management of acute massive blood loss during pregnancy and/or birth
• Anticipation severe blood loss in high risk patients
• Autotransfusion (use of a cell saver)
• Radiological interventions (embolisation)
4. Acute anaemia in the intensive care unit (ICU)
• Restrictive transfusion policy
• Monitoring
5. Establishment of criteria for transfusion on other patient populations
• Acute anaemia and cardiovascular disease
• Acute anaemia and cerebral trauma
• Acute anaemia in combination with anaesthesia
• Acute post-operative anaemia
• Children in the ICU
• Premature neonates
6. Pre-operative surgical blood order lists
149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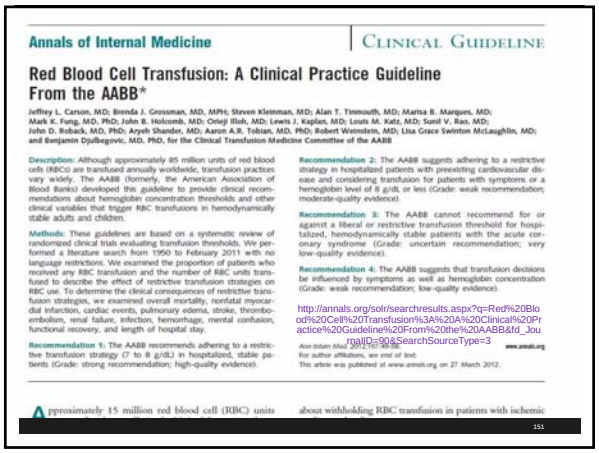


Annals of Internal Medicine | CLINICAL GUIDELINE

Red Blood Cell Transfusion: A Clinical Practice Guideline From the AABB*

Jeffrey L. Carson, MD; Brenda J. Grossman, MD, MPH; Steven Kleinman, MD; Alan T. Tinmouth, MD; Marisa B. Marques, MD; Mark K. Fung, MD, PhD; John B. Holcomb, MD; Ortenji Illoh, MD; Lewis J. Kaplan, MD; Louis M. Katz, MD; Sunil V. Rao, MD; John D. Roback, MD, PhD; Aryeh Shander, MD; Aaron A.R. Tobian, MD, PhD; Robert Weinstein, MD; Lisa Grace Swinton McLaughlin, MD; and Benjamin Djulbegovic, MD, PhD, for the Clinical Transfusion Medicine Committee of the AABB

Description: Although approximately 85 million units of red blood cells (RBCs) are transfused annually worldwide, transfusion practices vary widely. The AABB (formerly, the American Association of Blood Banks) developed this guideline to provide clinical recommendations about hemoglobin concentration thresholds and other clinical variables that trigger RBC transfusions in hemodynamically stable adults and children.

Methods: These guidelines are based on a systematic review of randomized clinical trials evaluating transfusion thresholds. We performed a literature search from 1950 to February 2011 with no language restrictions. We examined the proportion of patients who received any RBC transfusion and the number of RBC units transfused to describe the effect of restrictive transfusion strategies on RBC use. To determine the clinical consequences of restrictive transfusion strategies, we examined overall mortality, nonfatal myocardial infarction, cardiac events, pulmonary edema, stroke, thromboembolism, renal failure, infection, hemorrhage, mental confusion, functional recovery, and length of hospital stay.

Recommendation 1: The AABB recommends adhering to a restrictive transfusion strategy (7 to 8 g/dL) in hospitalized, stable patients (Grade: strong recommendation; high-quality evidence).

Recommendation 2: The AABB suggests adhering to a restrictive strategy in hospitalized patients with preexisting cardiovascular disease and considering transfusion for patients with symptoms or a hemoglobin level of 8 g/dL or less (Grade: weak recommendation; moderate-quality evidence).

Recommendation 3: The AABB cannot recommend for or against a liberal or restrictive transfusion threshold for hospitalized, hemodynamically stable patients with the acute coronary syndrome (Grade: uncertain recommendation; very low-quality evidence).

Recommendation 4: The AABB suggests that transfusion decisions be influenced by symptoms as well as hemoglobin concentration (Grade: weak recommendation; low-quality evidence).

http://annals.org/solr/searchresults.aspx?q=Red%20Blood%20Cell%20Transfusion%3A%20A%20Clinical%20Practice%20Guideline%20From%20the%20AABB&fd_JournalID=90&SearchSourceType=3

Ann Intern Med. 2012;157:49-58. www.annals.org
For author affiliations, see end of text.
This article was published at www.annals.org on 27 March 2012.

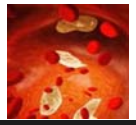
Approximately 15 million red blood cell (RBC) units ... about withholding RBC transfusion in patients with ischemic

151

http://www.itxm.org

CAH Conditions of Participation (CoPs) Nursing: IV Medication and Blood

Manual Updated April 7, 2015



Medication Assessment 297 2015

- **Assessment of Patients on Medications**
- Very concerned about patient having respiratory depression or ADR from opioids
- Must carefully monitor
- May include respiratory status, BP, pulse ox and $ETCO_2$
- Evaluate for confusion, agitation, unsteady gait, itching, lethargy, etc.
- Opioids are considered high risk medications

154

ISMP List of High Alert Medication

ISMP's List of *High-Alert* Medications

Printer friendly version

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies like improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; standardizing the ordering, storage, preparation, and administration of these products; and employing redundancies such as automated or independent doublechecks when necessary. (Note: manual independent double-checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list).

Classes/Categories of Medications	Specific Medications
adrenergic agonists, IV (e.g., EPINEPHrine, phenylephrine, norepinephrine)	epoprostenol (Flolan), IV
adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)	magnesium sulfate injection
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)	methotrexate, oral, non-oncologic use
antiarrhythmics, IV (e.g., lidocaine, amiodarone)	opium tincture
antithrombotic agents, including:	oxytocin, IV
▪ anticoagulants (e.g., warfarin, low-molecular-weight heparin, IV unfractionated heparin)	nitroprusside sodium for injection
▪ Factor Xa inhibitors (e.g., fondaparinux)	potassium chloride for injection concentrate
▪ direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran etexilate, lepirudin)	potassium phosphates injection
	promethazine, IV
	vasopressin, IV or intraosseous

155

Medication Assessment 297 2015

- **Assessment of Patients on Medications**
- Factors that put patients at greater risk for adverse events and respiratory depression
  - Liver or kidney failure
  - History of sleep apnea or snoring
  - Age, thoracic or other surgical incisions
  - History of smoking, pulmonary or cardiac disease
  - First time medication use, receiving benzodiazepines, antihistamines
  - Asthma, Patient weight

156

Medication Assessment 297 2015

- Need to communicate in report and hand offs
- High alert medications would want to assess sedation level
- Staff are expected to include patient reports of their experience of medication's effects
- Educate the patient and family to notify nurse if any difficulty breathing or ADEs
- P&P must discuss manner and how frequent to monitor patient

157

IV Medication & Blood 297 2015

- Need correct choice of vascular access devise to deliver blood and medications
- Peripheral catheters, PICC, midlines, central lines, implanted ports and other types of devices
- Need P&P to address which ones can be given IV and via what type of access
- Trace lines and tubes for correct connections and prior to giving meds
- Verify IV pump is properly programmed

158

IV Medication & Blood 297 2015

- P&P expected to address:
  - Monitoring for fluid and electrolyte imbalance
    - –Electrolyte imbalance can occur with IV meds or blood
  - Monitoring of patients receiving high alert medication including opioids
    - –How often and what devices such as pulse ox or ETCO2, and document pain level, VS, respiratory status and sedation level
  - Monitoring for over-sedation and respiratory depression related to opioid in post-op patients

159

Comparison of Sedation Scales Medscape

www.medscape.com/viewarticle/708387_3

160

ISMP Use a Standard Sedation Scale

For Information – Not Required/Not to be Cited

In addition to assessing risk for respiratory depression, the Institute for Safe Medication Practices recommends hospitals use a standard sedation scale when assessing patients receiving PCA. Scales such as the Richmond Agitation Sedation Scale, Pasero, Ramsey, or Glasgow Coma Scale are useful in assessing sedation.

Institute for Safe Medication Practices (ISMP). Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen…Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013

161

Blood Transfusions 297 2015

- Confirm correct patient
- Verify correct blood product
- Standard calls for two qualified persons, one who is administering the transfusion
  - TJC NPSG allows one person hanging blood if use bar coding
- Document monitoring
- P&P include how frequent you monitor the patient and do vital signs
- How to identify and treat and report any adverse transfusion reaction

162

This presentation is intended solely to provide general information and does not constitute legal advice. Attendance at the presentation or later review of these printed materials does not create an attorney-client relationship with the presenter(s). You should not take any action based upon any information in this presentation without first consulting legal counsel familiar with your particular circumstances.

163

Thanks for attending! Questions??

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164