AHC Media

New CMS CoP Changes on Medication Administration and Safe Opioid Use

Wednesday, July 23rd, 2014

Speaker

- Sue Dill Calloway RN, Esq. CPHRM, CCMSCP
- AD, BA, BSN, MSN, JD
- President of Patient Safety and Education Consulting
- Board Member
  Emergency Medicine Patient Safety Foundation
- 614 791-1468
- sdill1@columbus.rr.com

Learning Objectives

1. Explain the 32-page memo from CMS on medication administration and safe opioid use.

2. Review the three medication administration time frames.

3. Discuss CMS requirements for nurses giving IV medications or blood transfusions.

4. Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.

5. Evaluate compliance requirements and penalties.

The Conditions of Participation (CoPs)

- Regulations first published in 1986 and many changes since
  - Manual updated June 6, 2014 and 471 pages
  - Medication administration and Safe Opioid Use is effective on this date and also published in March 14, 2014 advanced memo
- 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

Location of CMS Hospital CoP Manuals

Medicare State Operations Manual

Appendix

- 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

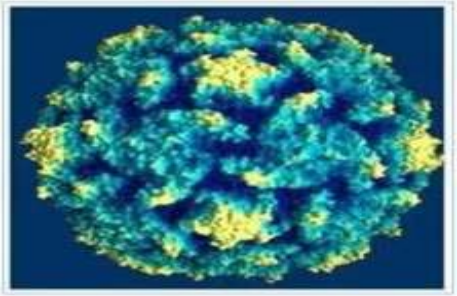
CMS Hospital CoP Manual

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

Table of Contents

(Rev. 116, 06-06-14)

Transmittals for Appendix A



Survey Protocol

Introduction

Task 1 - Off-Site Survey Preparation

Task 2 - Entrance Activities

Task 3 - Information Gathering/Investigation

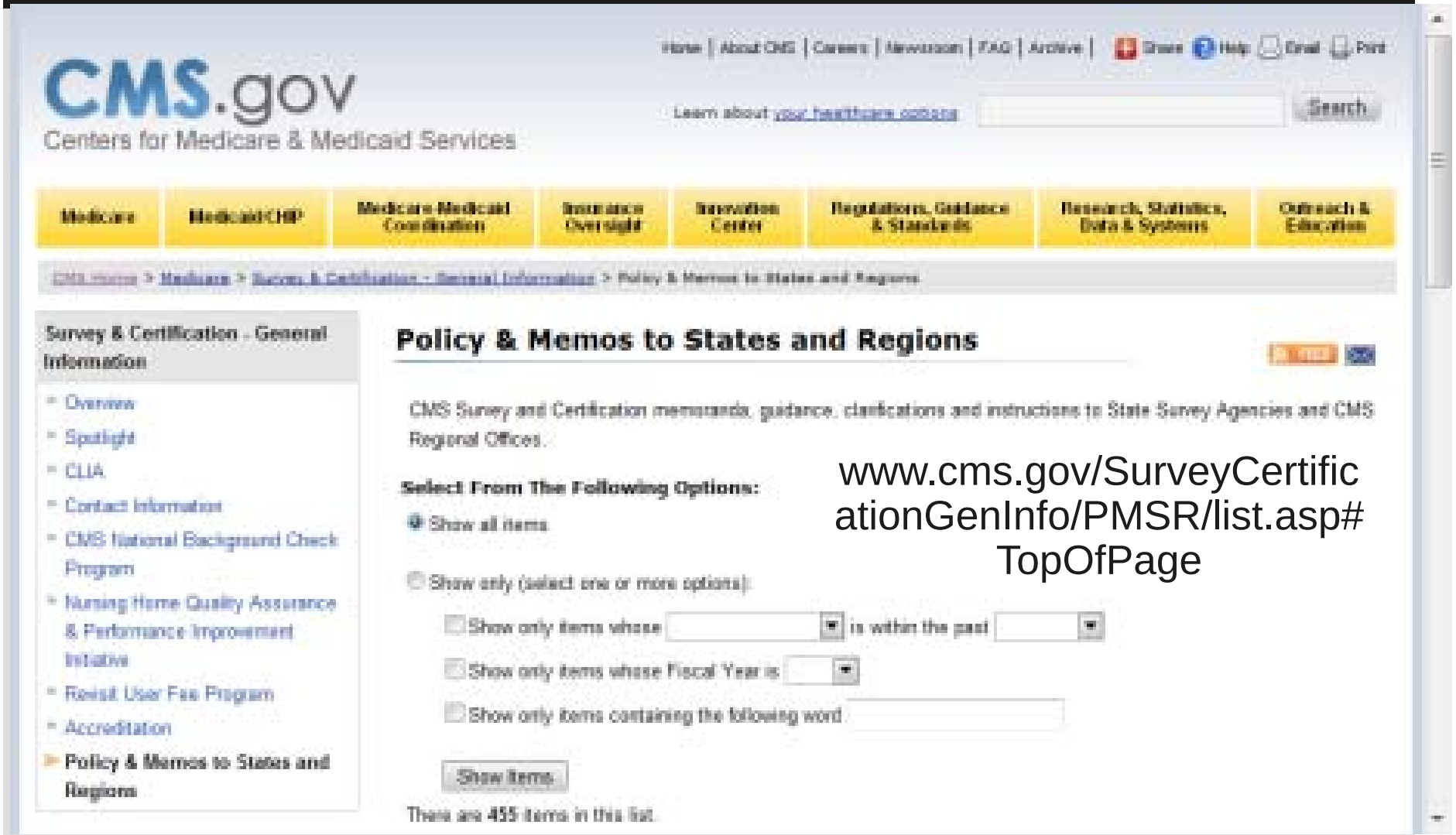
Task 4 - Preliminary Decision Making and Analysis of Findings

Task 5 - Exit Conference

Task 6 – Post-Survey Activities

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

CMS Survey and Certification Website



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

Medication and Safe Opioid Use

- CMS issues 32 page memo on medication administration and safe opioid use advanced memo and issued final one June 6, 2014
  - Risk and patient safety need to review this besides nursing, pharmacy, MEC, and nurse educator
- Concerned about the number of patients with adverse events when taking opioids
- Must have a P&P
- Must train staff and include information that must be in the assessment
- Must document process
  - **Questions to hospitalscg@cms.hhs.gov**

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

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

Final Transmittal Issued June 6, 2014

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

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 116 | **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-0957/§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

4 Tag Numbers and Changes in Effect Now

A-0409

(Rev.116, Issued: 06-06-14 Effective: 06-06-06-14, Implementation 06- 06-14)

§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 §482.25(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

Medication and Safe Opioid Use

- CMS has pharmacy standards that impact nursing practice
  - Pharmacy section at tag **490-511**
- 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 and that nursing should be aware of this

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

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
- Draft plan and final one expected summer 2014

www.health.gov/hai/pdfs/ade-action-plan.pdf

National Action Plan for Adverse Drug Event Prevention

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

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 non-cancer pain (CNCP). Acute and chronic pain affects many Americans every year. Chronic pain alone is reported by over 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 CNCP is more controversial due to the limited evidence surrounding the safety and efficacy of long-term opioid use for CNCP [2]. Nonetheless, opioids are recommended for treatment of CNCP in

Figure 18. Federal Interagency Workgroup Recommendations for Actions that Can Potentially Advance Surveillance Strategies for Opioids ADEs

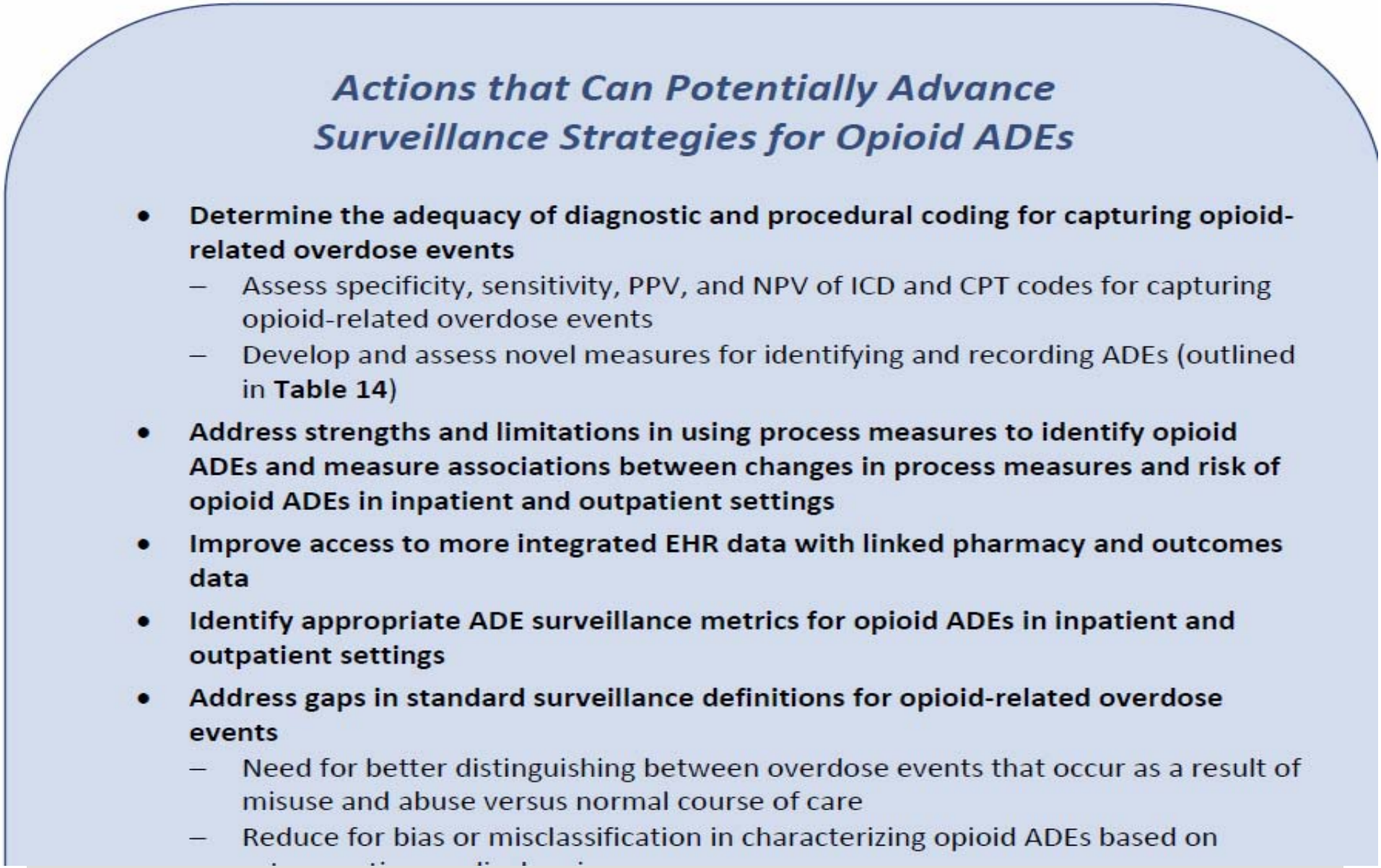


Figure 19. Current and Potential Federal Assets Related to Safe Management of Opioid Therapy as Identified by National Quality Strategy Priorities

Resources for Safer Care – Health Care Provider Knowledge

- **DOD/VA:**
  - **Opioid Prescribing Protocol/ Guidelines**—includes recommendations for assessing patients for appropriat 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 acut and chronic pain"
  - **Opioid Safe Program** at Fort Bragg—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)**— created strategy for extended release and long-acting opioids; FDA developed a "Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioi Analgesics," and maintains a list of compliant Continuing Education (CE) programs that include this provider curriculum
  - **Opioid Dose Conversion Table**—effort to develop safe and reliable dose conversion table based on updated evidence
- **IHS:**
  - **TeleBehavioral Health Center of Excellence Pain and Addictions course**—15 series webinar trainig program providing specialized training on how to treat pain and addictions
- **NIH:**
  - **NIDAMED Physician Education Tools**— the National Institute on Drug Abuse hosts a website with tools an resources for medical professionals for safe pain management including two classes entitled "Safe Prescribing for Pain" and "Managing Pain Patients Who Abuse Rx Drugs"[i]

Resources for Patients and Family Engagement

- **ACL:**
  - **Chronic Disease Self-Management Education Programs**—provides education and tools to older adults an adults with disabilities with education and tools to help them better manage chronic conditions including

CDC Website on Rx Overdoses

CDC Home

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

SEARCH

A-Z Index A B C D E F G H I J K L M N O P Q R S T U V W X Y Z #

Injury Prevention & Control www.cdc.gov/homeandrecreationalsafety/rxbrief/index.html

Home & Recreational Safety
- Prescription Drug Overdose
  - Get the Facts
  - Research & Activities
  - Publications
  - Opioid Prescribing Guidelines Review
  - **Policy Impact**
  - State Rx Drug Laws
- Heads Up: Concussion in Sports
- Falls – Older Adults
- Falls – Children
- Water-Related Injuries
- Poisoning
- Fires
- Playground Injuries
- Bicycle-Related Injuries
- Dog Bites

Injury Center Topics
- Saving Lives & Protecting People
- Home & Recreational Safety
- Motor Vehicle Safety
- Traumatic Brain Injury

Injury Center > Home & Recreational Safety > Prescription Drug Overdose

Recommend Tweet Share

Policy Impact: Prescription Painkiller Overdoses

What's the Issue?

In a period of nine months, a tiny Kentucky county of fewer than 12,000 people sees a 53-year-old mother, her 35-year-old son, and seven others die by overdosing on pain medications obtained from pain clinics in Florida.[1] In Utah, a 13-year-old fatally overdoses on oxycodone pills taken from a friend's grandmother.[2] A 20-year-old Boston man dies from an overdose of methadone, only a year after his friend also died from a prescription drug overdose.[3]

These are not isolated events. Drug overdose death rates in the United States have more than tripled since 1990 and have never been higher. In 2008, more than 36,000 people died from drug overdoses, and most of these deaths were caused by prescription drugs.[4]

Policy Impact: Prescription Painkiller Overdoses [460KB, 12 pages]

Order Printed Copies

100 people die from drug overdoses every day in the United States.[4]

Email page link
Print page
Get email updates
Subscribe to RSS

Get email updates
To receive email updates about this page, enter your email address:
What's this%? Submit

Contact Us:

Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333

800-CDC-INFO
(800-232-4636)
TTY: (888) 232-6348

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

Medication and Safe Opioid Use

- 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

Medication and Safe Opioid Use

- 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

CMS QAPI Work Sheet ADE & Medical Errors

PART 5: PATIENT SAFETY – ADVERSE EVENTS AND MEDICAL ERRORS (CONTINUED)

Elements to be Assessed		Manner of Assessment Code (Enter all that apply) & Surveyor Notes
5.5 Does the QAPI program identify and track medication administration errors, adverse drug reactions, and drug related incompatibilities?	○ YES ○ NO	○ 1 ○ 2 ○ 3 ○ 4 ○ 5 www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html
If no to 5.5, the hospital would be at risk on a non-PSI, non-pilot survey for a deficiency citation related to 42 CFR 482.25(b)(6) (Tag A-508) and 42 CFR 482.21(a)(2) (Tag A-286)		
5.6 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?	○ YES ○ NO	○ 1 ○ 2 ○ 3 ○ 4 ○ 5
If no to 5.6, the hospital would be at risk on a non-PSI, non-pilot survey for a deficiency citation related to 42 CFR 482.23(c)(4) (Tag A-410) and 42 CFR 482.21(a)(2) (Tag A-286)		
5.7 Did the survey team have prior knowledge of, or identify while on-site, serious preventable adverse events that the hospital failed to identify?	○ YES ○ NO	○ 1 ○ 2 ○ 3 ○ 4 ○ 5
If yes to 5.7, the hospital would be at risk on a non-PSI, non-pilot survey for a deficiency citation related to 42 CFR 482.21(a)(2) (Tag A-286)		

Manner of Assessment Code: 1-Interview 2-Observation 3- QAPI Documentation 4- Medical Record Review 5- Other Page 14 of 21

CMS CoPs on Nursing Administration and Safe Opioid Use

Changes to Nursing Tag Numbers 405, 409, and 412

Preparation/Admin of Drugs 405 2014

- Standard: Drugs must be prepared and administered according to state and federal law
  - Amended Dec 2011, June 7, 2013 and June 6, 2014
- Standard: Need an practitioner's **order**
  - Important issue with CMS to have an order for all medications administered or standing order
  - Make sure order is documented in the medical record
  - Surveyor will observe nurse prepare and pass medications

Drugs & Biologicals 405

- Drugs and biologicals may be administered on orders of other practitioners:
  - Allowed by state law
  - State scope of practice act
  - Hospital P&P and
  - MS bylaws and R/R (Rules and Regulations)
- Must not only be within acceptable standards of practice (SOP) but done under the supervision of nursing
- CMS has blue box advisories which are not to be cited

Pharmacy Should Prepare Piggybacks & IVs

For Information – Not Required/Not to be Cited

Although the regulation addresses both preparation and administration of drugs and biologicals and does not prohibit preparation of drugs by nursing staff, to improve patient safety it is generally preferable for hospitals to avoid nurse preparation of drugs in patient care areas, and instead rely upon pharmacy IV admixture systems and/or commercially available unit dose products.

Preparation/Administration of Drugs 405

- Standard: Medications must be prepared and administered with acceptable national standards of practice and mentions five organizations
  - 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

Timing of Medication Administration Tag 405

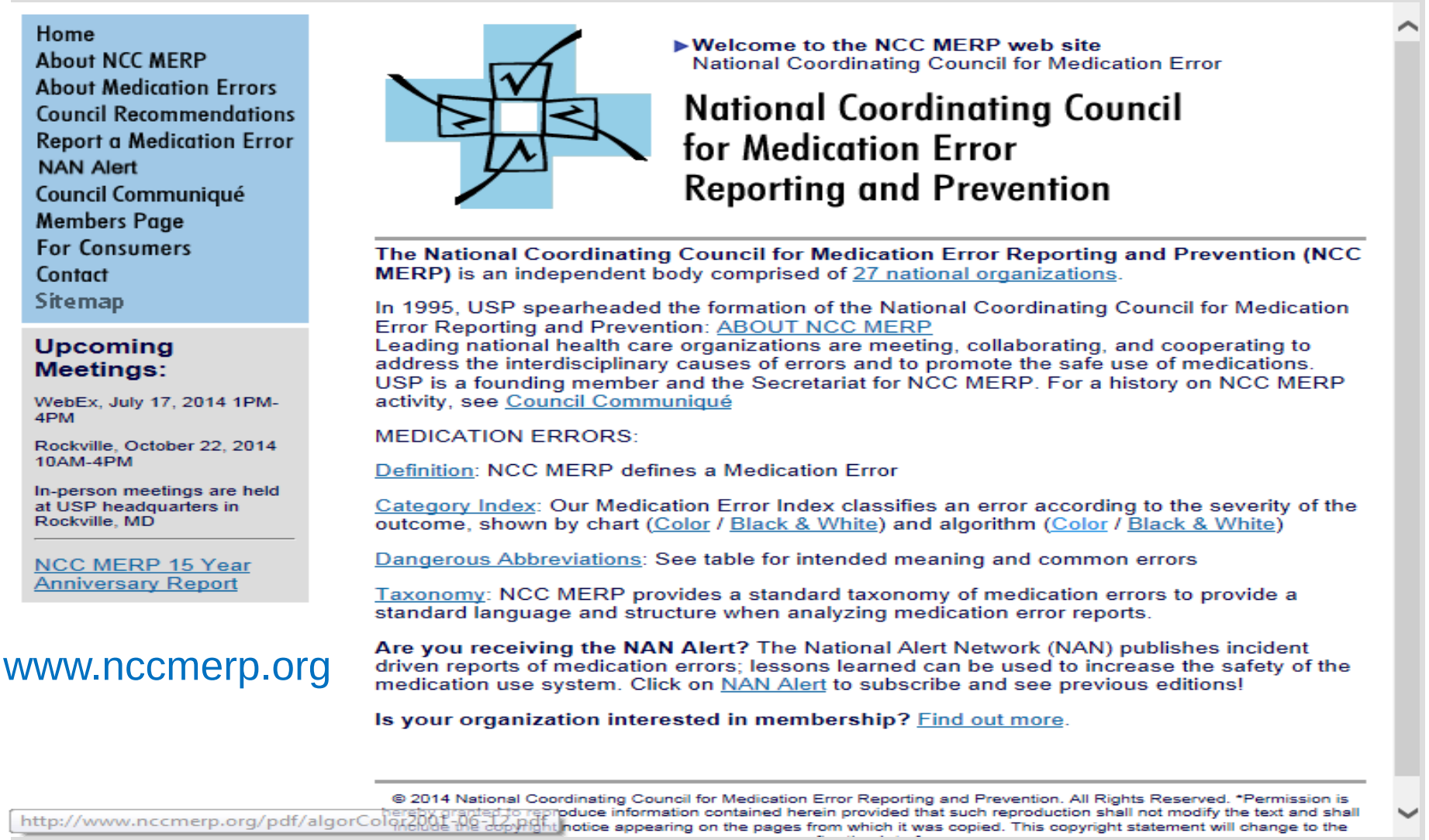
- What are acceptable standards of care?
  - National organizations that are recognized in the field issue written statements and policies that direct patient care
- The hospital's P&Ps must be consistent with SOC
- Standards of care can be set by state pharmacy boards and national organizations like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

ISMP Institute for Safe Medication Practices

Infusion Nurses Society INS

www.ins1.org

National Coordinating Council



Upcoming Meetings:

WebEx, July 17, 2014 1PM-4PM

Rockville, October 22, 2014 10AM-4PM

In-person meetings are held at USP headquarters in Rockville, MD

NCC MERP 15 Year Anniversary Report

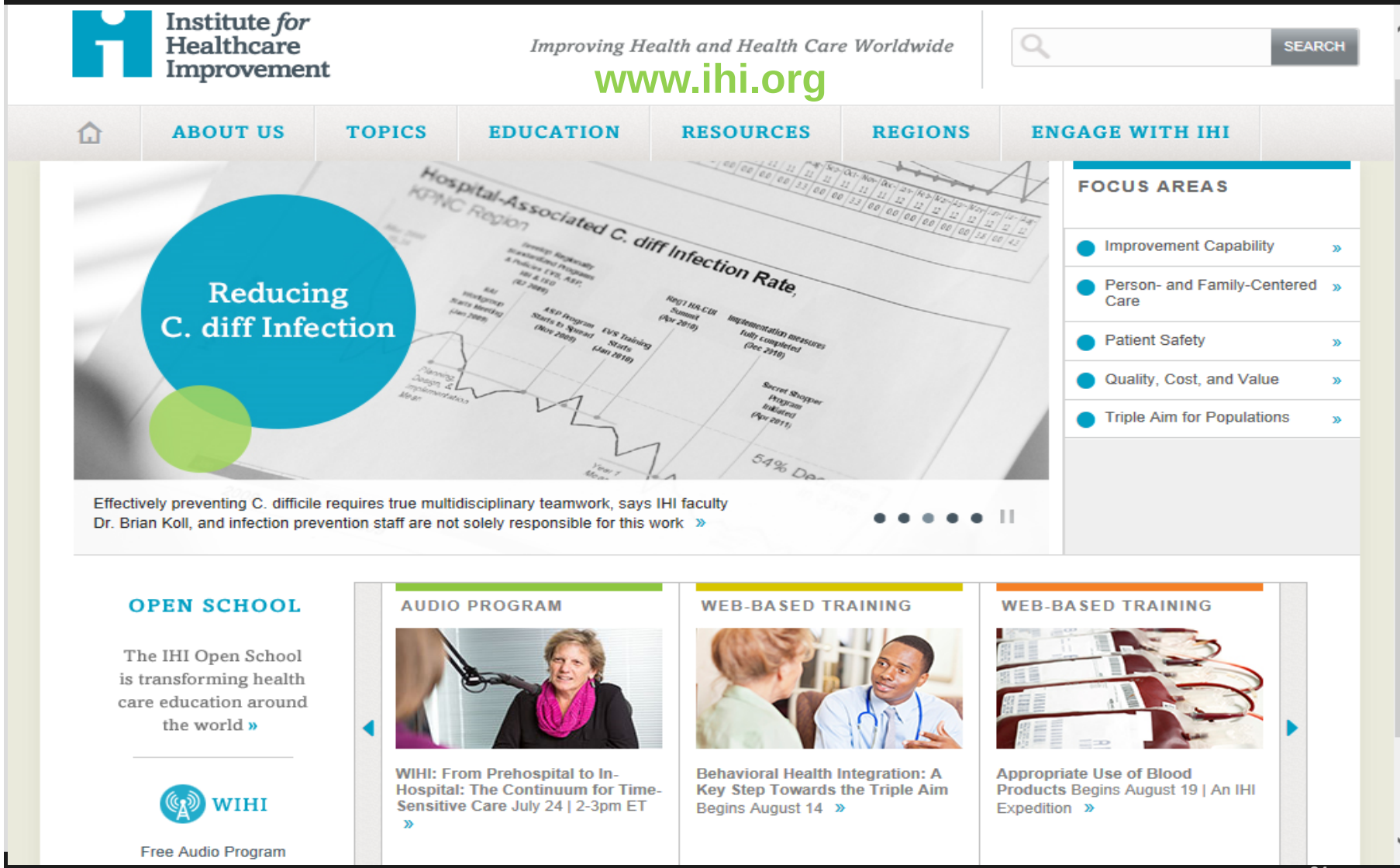
NATIONAL ALERT NETWORK (NAN)

Print

The National Alert Network (NAN) is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP) publish the alerts from the National Medication Errors Reporting Program, operated by ISMP. The alerts are incident driven. The NCC MERP, ISMP and the ASHP encourage the sharing and reporting of medication errors, so that lessons learned can be used to increase the safety of the medication use system.

February 18, 2014	Potential inaccuracy of electronically transmitted medication history information used for **medication reconciliation**
June 10, 2013	Important Change with **Heparin Labels**
April 17, 2013	Confusion regarding the generic name of the HER2-targeted drug **KADCYLA** (**ado-trastuzumab emtansine**)
January 23, 2013	Severe burns and permanent scarring after **glacial acetic acid** (≥ 99.5%) mistakenly applied topically
April 25, 2012	Proper disposal of **fentaNYL patches** is critical to prevent accidental exposure
March 18, 2012	Potential for wrong route errors with Exparel (**bupivacaine liposome injectable suspension**)
Jun 2011	Risk of potentially fatal overdose with **colistimethate**
June 2010	**EPINEPHrine** pre-filled syringe shortage
Apr 2010	Another child is victim of **heparin** error

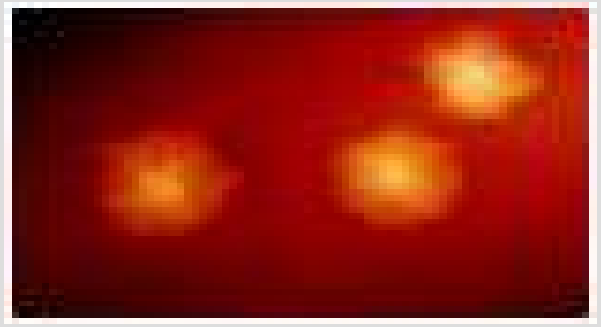
Institute for Healthcare Improvement IHI

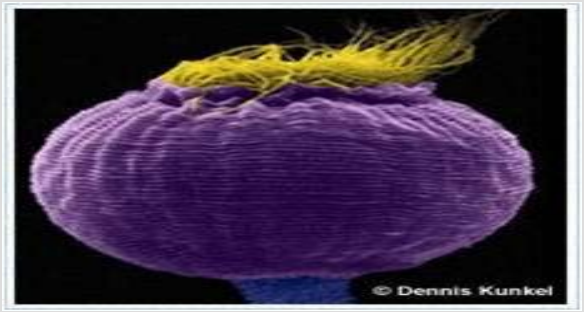


USP U.S. Pharmacopeial

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

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

CDC 10 Recommendations

- The CDC has a page on Injection Safety that contains the excerpts from the Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- Summarizes their 10 recommendations for safe injection practices
- CMS expects hospitals to follow the CDC guidelines
  - Available at http://www.cdc.gov/ncidod/dhqp/injectionSafetyPractices.html

10 CDC Standards Safe Injection Practices

Injection Safety

- **Injection Safety**
- CDC's Role
- CDC Statement
- Information for Providers
- Information for Patients
- Preventing Unsafe Injection Practices
- ▶**Safe Injection Practices**
  - CDC Clinical Reminder: Spinal Injection Procedures
- Infection Prevention during Blood Glucose Monitoring and Insulin Administration
- Recent Publications
- Recent Meetings
- The One & Only Campaign

Related Links

- One & Only Campaign
- HICPAC

Injection Safety > Preventing Unsafe Injection Practices

Email page link
Print page

Recommend 7 Tweet Share

Safe Injection Practices to Prevent Transmission of Infections to Patients

Download the complete 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings [PDF - 3.80 MB]

III.A.1.b. Safe Injection Practices The investigation of four large outbreaks of HBV and HCV among patients in ambulatory care facilities in the United States identified a need to define and reinforce safe injection practices 453. The four outbreaks occurred in a private medical practice, a pain clinic, an endoscopy clinic, and a hematology/oncology clinic. The primary breaches in infection control practice that contributed to these outbreaks were 1) reinsertion of used needles into a multiple-dose vial or solution container (e.g., saline bag) and 2) use of a single needle/syringe to administer intravenous medication to multiple patients. In one of these outbreaks, preparation of medications in the same workspace where used needle/syringes were dismantled also may have been a contributing factor. These and other outbreaks of viral hepatitis could have been prevented by adherence to basic principles of aseptic technique for the preparation and administration of parenteral medications 453, 454. These include the use of a sterile, single -use, disposable needle and syringe for each injection given and prevention of

Contact Us:

Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333

800-CDC-INFO
(800-232-4636)
TTY: (888) 232-6348
Contact CDC–INFO

Medication Errors Tag 405

- CMS talks about the studies that show the large number of medication errors in hospitals
- Institute of Medicine said drug related adverse outcomes in 1.9 million inpatient hospital stays
- This is 4.7% of all patient stays
- There are 838,000 patient who are treated and released for drug related AE
- This is 0.8% of all visits
- Despite CPOE, ePHI, scanning and other technologies

Drugs & Biologicals 405

- CMS would allow them to document and sign the order
- For example, the above practitioners would be permitted as allowed by the state scope of practice such as by the state pharmacy board and if the hospital has granted them privileges
  - A PharmD manages the Anticoagulant Clinic or works with diabetic patients in managing their insulin
  - The MS approved the INR chart for patients on warfarin (coumadin)
  - Pharmacists changes dose and writes and signs off order

Drugs and Biologicals 405

- CMS calls them drugs and biologicals
  - Joint Commission calls them medications
  - Each state law differs on scope of practice on what PA, NP, CRNA, Pharm.D etc. can do so be aware of your state specific law
  - July 11, 2014 regulation where MS can C&P certain non-physician providers
- Drugs and biologicals must be administered by or under the supervision of nursing or other personnel as allowed by law, P&Ps, and MS bylaws and R/Rs

Standing Orders and Outpatient Orders

- Drugs must be administered in response to an order from a practitioner or concerning standing orders
- This includes ordering outpatient services for practitioners who are not privileged but are permitted by hospital & MS P&P to order
- Exception is for flu and pneumovac
  - Need physician approved protocol after assessment of contraindications

CMS Changes to Medication Administration

- CMS issued a survey and certification memo with changes to Tag 405 on December 22, 2011, June 7, 2013 and March 14, 2014 memo and June 6, 2014 manual
  - Tag 405 use to say that all medications must be given within 30 minutes of the scheduled time
  - Now three blocks of time to give medications
  - Thanks to efforts of the ISMP
  - Included section on standing orders all but one sentence moved to tag 457

Tag 405 Revised June 7, 2013

A-0405

(Rev.)

§482.23(c) Standard: Preparation and Administration of Drugs

---

(1) **Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.**

(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations….

(2) **All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.**

Interpretive Guidelines §§482.23(c)*(1), (c)(1)(i)* and (c)(*2*)

According to the Institute of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people each year.[1] *It has been estimated that drug-related adverse outcomes were noted in nearly 1.9 million inpatient hospital*

Transmittal Medication Admin Dec 22, 2011

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

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 77	(Advance Copy)	Date: December 22, 2011

SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for 42 CFR 482.23(c), concerning medication administration.

REVISED MATERIAL - EFFECTIVE DATE*: December 22, 2011
IMPLEMENTATION DATE: December 22, 2011

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/§482.23(c) Standard: Preparation and Administration of Drugs/A-0405

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

A-0405

(Rev.77, Issued: 12-22-11, Effective/Implementation: 12-22-11)

www.cms.gov/Transmittals/01_overview.asp

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

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

June 6, 2014 Final Changes to Tag 405

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

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 116

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.

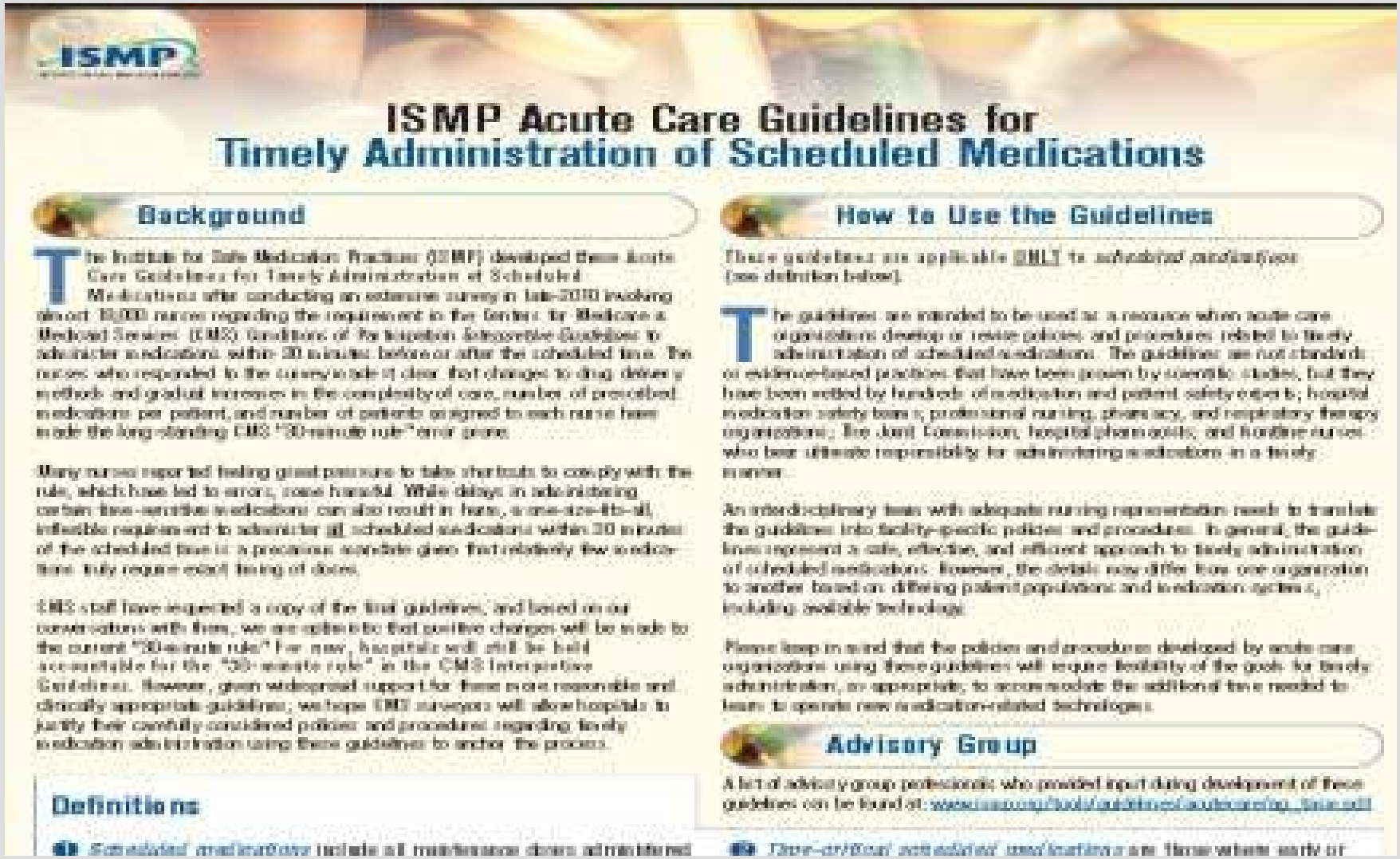
NEW/REVISED MATERIAL - EFFECTIVE DATE: June 6, 2014
IMPLEMENTATION DATE: June 6, 2014

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

ISMP New Guideline www.ismp.org



ISMP

ISMP Acute Care Guidelines for Timely Administration of Scheduled Medications

Background

The Institute for Safe Medication Practices (ISMP) developed these Acute Care Guidelines for Timely Administration of Scheduled Medications after conducting an extensive survey in late-2010 involving about 10,000 nurses regarding the requirement in the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation *Interpretive Guidelines* to administer medications within 30 minutes before or after the scheduled time. The nurses who responded to the survey made it clear that changes to drug delivery methods and gradual increases in the complexity of care, number of prescribed medications per patient, and number of patients assigned to each nurse have made the long-standing CMS "30-minute rule" error prone.

Many nurses reported feeling great pressure to take shortcuts to comply with the rule, which have led to errors, some harmful. While delays in administering certain time-sensitive medications can also result in harm, a one-size-fits-all, inflexible requirement to administer all scheduled medications within 30 minutes of the scheduled time is a precarious yardstick given that relatively few medications truly require exact timing of doses.

CMS staff have requested a copy of the final guidelines, and based on our conversations with them, we are optimistic that positive changes will be made to the current "30-minute rule." For now, hospitals will still be held accountable for the "30-minute rule" in the CMS Interpretive Guidelines. However, given widespread support for these more reasonable and clinically appropriate guidelines, we hope CMS surveyors will allow hospitals to justify their carefully considered policies and procedures regarding timely medication administration using these guidelines to anchor the process.

Definitions

Scheduled medications include all maintenance doses administered

How to Use the Guidelines

These guidelines are applicable ONLY to *scheduled medications* (see definition below).

The guidelines are intended to be used as a resource when acute care organizations develop or revise policies and procedures related to timely administration of scheduled medications. The guidelines are not standards or evidence-based practices that have been proven by scientific studies, but they have been vetted by hundreds of medication and patient safety experts; hospital medication safety teams; professional nursing, pharmacy, and respiratory therapy organizations; the Joint Commission; hospital pharmacists; and frontline nurses who bear ultimate responsibility for administering medications in a timely manner.

An interdisciplinary team with adequate nursing representation needs to translate the guidelines into facility-specific policies and procedures. In general, the guidelines represent a safe, effective, and efficient approach to timely administration of scheduled medications. However, the details may differ from one organization to another based on differing patient populations and medication systems, including available technology.

Please keep in mind that the policies and procedures developed by acute care organizations using these guidelines will require flexibility of the goals for timely administration, as appropriate, to accommodate the additional time needed to learn to operate new medication-related technologies.

Advisory Group

A list of advisory group professionals who provided input during development of these guidelines can be found at: www.ismp.org/tools/guidelines/acutecare/tg_team.pdf

Time-critical scheduled medications are those where early or

Practitioner Order Requirements 2014

- Name of the patient
- Age and weight of the patients to facilitate dose calculation requirements
  - Must have P&P to address for children and use only Kg or Grams for newborns
  - Other circumstances like as weight on elderly patient with history of renal failure and is being prescribed antibiotics
  - Hospitals must specify a unified approach
- Date and time of the order

Use Kg and Not Pounds for Children

Acetaminophen Dosing Chart

Acetaminophen (Tylenol) Dose every 4 to 6 hours *Maximum 5 doses in 24 hours*		Infants' Concentrated Drops 80 mg/ 0.8 mL	Children's Suspension Liquid 160 mg/ 5 mL	Children's Soft Chews Chewable 80 mg each	Junior Strength Chewable 160 mg each	Adult Regular Strength 325 mg each
		Dropperful (Use only the dropper provided)	Teaspoon (tsp)	Tablet	Tablet	Tablet
Weight	Age					
6-11 lbs	0-3 mos	½ = 0.4 mL				
12-17 lbs	4-11 mos	1 = 0.8 mL	½ tsp			
18-23 lbs	12-23 mos	1 ½ = 0.8+ 0.4mL	¾ tsp			
24-35 lbs	2-3 yrs	2 = 0.8 + 0.8 mL	1 tsp	2	1	
36-47 lbs	4-5 yrs		1 ½ tsp	3	1 ½	
48-59 lbs	6-8 yrs		2 tsp	4	2	
60-71 lbs	9-10 yrs		2 ½ tsp	5	2 ½	1
72-95 lbs	11 yrs		3 tsp	6	3	1 ½
96 lbs +	12 yrs +		4 tsp	8	4	2

Ibuprofen Dosing Chart

Ibuprofen (Motrin, Advil) Dose every 6 to 8 hours *Maximum 4 doses in 24 hours*		Infants' Concentrated Drops 50 mg/ 1.25 mL	Children's Suspension Liquid 100 mg/ 5 mL	Children's Chews Chewable 50 mg each	Junior Strength 100 mg each	Adult Regular Strength 200 mg each
		Dropperful (Use only the dropper provided)	Teaspoon (tsp)	Tablet	Tablet	Tablet
Under 6 mos		*Consult Your Child's Provider*				
Weight	Age					
12-17 lbs	6-11 mos	1=1.25 mL				
18-23 lbs	12-23 mos	1 ½ =1.875 mL				
24-35 lbs	2-3 yrs		1 tsp	2		
36-47 lbs	4-5 yrs		1 ½ tsp	3		
48-59 lbs	6-8 yrs		2 tsp	4	2	
60-71 lbs	9-10 yrs		2 ½ tsp	5	2 ½	
72-95 lbs	11 yrs		3 tsp	6	3	
96 lbs +	12 yrs +		4 tsp	8	4	2

Practitioner Order Requirements 2014

- Drug name
- Dose, frequency, and route
- Dose calculation requirements
- Exact strength or concentration, when applicable
- Quantity and/or duration, when applicable
- Specific instructions for use, when applicable and
- Name of the prescriber

Medical Staff Approved P&P 2014

- MS must approve the P&P for medication administration
  - Should be part of PI process
  - Should be done in consultation with nurses and pharmacists
  - Drugs must be administered under supervision of nursing or other personnel
- CMS has many specifics which must be included in this MS approved P&P
- Needs to be consistent with state law and the scope of practice

P&P Requirements

- Must identify the categories of licensed personnel who can prepare and administer
  - For example, Ohio allows RNs and LPNs who have passed a pharmacy course to prepare and administer
- Must include the types of medications they are allowed to prepare and administration
  - For example, the Ohio Board of Nursing does not allow a LPN to hang blood or give certain IV medications
- Must address education or training requirements and CMS has some recommendations

Education Recommendation

- CMS recommend training in orientation and as part of continuing education
- Training **may** include the following;
  - Safe handling and preparation of authorized medications
  - Knowledge of the indications, side effects, drug interactions, compatibility, and dose limits of administered medications
  - Equipment, devices, special procedures, and/or techniques required for medication administration (IV pumps, PCA, tubing, etc.)

P&P Requirements

- What must be included in the training during orientation or CNE to demonstrate competence
- Training content and documentation of **competence**
- P&P must include basic safe practices for medication administration such as the following required elements
  - Patient's identity
    - To make sure it is the right patient and identifiers might include name, MR number, id number, DOB
    - Confirmed by wrist band, patient identification card, patient statement or other things included in the hospital policy

P&P Requirements 2014

- There must be agreement between the patient's MAR (medication administration record) and the medication's label
- Need to have culture of safety in which staff feel comfortable to ask questions
- Confirm before medication is given the following on the five rights:
  - Right medication, right patient, right dose
  - Right route (IM, PO, IV, IO, intrathecally, etc)
  - Right time to adhere to the prescribed frequency and time of administration

Medication Process 405 2014

- Medication process has five stages
  - Ordering/prescribing
  - Transcribing and verifying
  - Dispensing and delivering
  - Administering
  - And monitoring/reporting
- CMS also mentions the recent literature mentions the nine rights of medication administration

9 Rights of Medication Administration

For Information – Not Required/Not to be Cited

Recent literature identifies up to nine "rights" of medication administration including:*

- ☐ *Right patient*
- ☐ *Right drug*
- ☐ *Right route*
- ☐ *Right time*
- ☐ *Right dose*
- ☐ *Right documentation*
- ☐ *Right action (appropriate reason)*
- ☐ *Right form*
- ☐ *Right response*

However, other sources refer to 8 or 10 "rights, and some of these topics, such as right action, appear to involve prescribing and/or dispensing. Accordingly, there does not (yet) appear to be consensus about expanding beyond the 5 "rights."

**Reference: Elliott, M. and Lis, Y. (2010). The Nine Rights of Medication Administration: An Overview. British Journal of Nursing, Vol. 19, 5, 300-305.*

Timing of Medication 405

- P&P needs to include the timing of medication based on the nature of the medication and the clinical application to include:
  - Medications or categories of medications **not eligible** for scheduled dosing times
    - These are ones that require exact time based on diagnosis type, treatment requirements or therapeutic goals
    - Include definition in your P&P
    - Also looks at patient risk factors
    - Such as stat drugs, loading dose, one time dose for scheduled procedure, doses timed for serum drug level, PRN, or investigational drugs

3 Time Frames for Administering Medication

Time Critical Medicine

1 hour before or after

2 hours before or after

Timing of Medication P&P

- Medications that are **eligible** for scheduled dosing times
  - These are those prescribed on a repeated cycle of frequency, such as once a day, BID (twice a day), TID (three times a day), hourly intervals (every 1, 2, 3 or more hours), etc.
  - Goal is to achieve a therapeutic blood level
  - BID meds might be given at 9am/9 pm or 8am/8pm
  - Policy has the standardized times so pharmacy knows when to send to unit and nurse can assess VS if needed (such as pulse rate if dig) or review blood work (like a serum K level, INR, or dig level)

Timing of Medication P&P

- Medications that are **eligible** for scheduled dosing times (continued)
  - P&P on first dose of medication, using judgment regarding next dose, retiming of missed or omitted doses
- Medications that can be given outside of their scheduled dosing time
- Evaluation of the medication timing policy and including adherence rate
  - Must track medication errors related to timing of medications and include in the PI process

Timing of Medication P&P

- Time-critical scheduled medications (30 minute or 1 hour total window)
  - These are ones in which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect
  - P&P must include whether these drugs are always time critical
  - Examples include: Antibiotics, Anticoagulants, Insulin, Anticonvulsants, Immunosuppressive agents, Non-IV Pain medication, medication more frequently than every 4 hours, and administered within a specified period of time in the order

Timing of Medication P&P

- Non-time-critical scheduled medications
  - These are medications for which a longer or shorter interval of time since the prior dose does not significantly change the medication's therapeutic effect or otherwise cause harm
  - Greater flexibility is given
  - Medications given once daily, weekly, or monthly
  - May be given within **2 hours** before or after but can not exceed a total window of 4 hours (such as Allegra once a day)
  - Med scheduled more frequently than daily but less than every 4 hours (such as bid or tid) can be given **1 hour** before or after for window not to exceed 2 hours

Timing of Medication P&P

- Missed or late administration of medications
  - Policy must include what action to take if missed or not given in permitted window of time
  - Missed dose may be due from patient who is out of the department, patient refusal, problems related to medication being available or other reasons
  - Policy needs to include parameters of when nursing staff are allowed to use their own judgment on the rescheduling of late or missed dosed
  - Missed or late doses must be reported to the attending physician

Assessment & Monitoring of Patients 2014

- Patients on medications needed to be carefully monitored (all new section)
  - 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

Assessment/Monitoring of Patients Receiving Medications

Observing the effects medications have on the patient is part of the multi-faceted medication administration process. Patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit, and to allow for early identification of adverse effects and timely initiation of appropriate corrective action. Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- *Clinical and laboratory data to evaluate the efficacy of medication therapy, to anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels;*

- *Physical signs and clinical symptoms relevant to the patient's medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc.*

Certain types of medications are considered inherently high risk for adverse drug events. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients. (See also the discussion of high-risk medications (typically referred to as "high-alert" medications) in the guidance for §482.25(b))

For Information – Not Required/Not to be Cited

The Institute for Safe Medication Practices (ISMP) makes available a list of high alert medications, which it defines as those medications that bear a heightened risk of causing significant patient harm when they are used in error. The current list may be found at: http://www.ismp.org/Tools/highAlertMedicationLists.asp

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., **EPINEPH**rine, 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: ■ anticoagulants (e.g., warfarin, low-molecular-weight heparin, IV unfractionated heparin) ■ Factor Xa inhibitors (e.g., fondaparinux) ■ direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran etexilate, lepirudin)	oxytocin, IV nitroprusside sodium for injection potassium chloride for injection concentrate potassium phosphates injection promethazine, IV vasopressin, IV or intraosseous

High Alert How to Guide IHI

v03
10/01/2008

PROTECTING 5 Million lives FROM HARM IHI.org

Getting Started Kit:
Prevent Harm from High-Alert Medications

How-to Guide

A national initiative led by IHI, the 5 Million Lives Campaign aims to dramatically improve the quality of American health care by protecting patients from five million incidents of medical harm between December 2006 and December 2008. The How-to

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

So What's In Your Policy?

WISCONSIN PATIENT SAFETY INSTITUTE

330 E Lakeside St
PO Box 1551
Madison, WI 53701
Voice: 608.442.3789
800.762.8976
Fax: 608.283.5402
www.WPSI.org

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.[i]

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)

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.

Assessment & Monitoring of Patients

- ADE, such as anaphylaxis or opioid-induced respiratory depression may require timely and appropriate
- 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

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.

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)	
-3	Moderate sedation	Movement or eye opening to *voice* **(but no eye contact)**	
-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	

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.

Comparison of Sedation Scales Medscape

Pain Management Nursing

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

Allison Theresa Nisbet, MSN, CPN, AOCNS, RN-BC, Florence Mooney-Cotter, MSN, CNS-BC, RN-BC | Disclosures

Pain Manag Nurs. 2009;10(3):154-164.

Comment Print

Study Aims and Methods

The present research study was designed to report measures of reliability and validity of three sedation scales currently used to measure sedation as an outcome of opioid administration for pain management in non-critical care settings: the Inova Health System Acute Care Sedation Scale (ISS), the RASS, and the POSS. Reliability and validity had not been previously established for any of these scales in the non-critical care setting. The following research questions were addressed by the study:

Research question 1: Is there a significant difference in validity or reliability between three commonly used sedation scales when used by non-critical care nurses for the measurement of postopioid sedation?

Research question 2: Is there a significant difference in means observed between scales in the total correct score obtained by the nurses (sedation score and nursing actions chosen)?

Research question 3: Is there a significant difference in means observed between scales in the nurses' total combined rating of each scale's performance regarding ease of use, information provided to inform clinical decision making, and confidence (in

score obtained and actions chosen)?

The study aims had immediate organizational Significance, because the scale (the ISS) used to assess opioid-induced sedation at the facility in which the research was conducted had not previously been tested for

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

MOST POPULAR ARTICLES

According to PHYSICIANS

1. No Amount of Alcohol Is Safe
2. Alcohol and CVD: The Tippling Point
3. 10 Cool, Amazing Gadgets and Trends to Help Your Practice
4. More Evidence Musical Training May Boost Executive Function
5. Utility of a Single Early Warning Score in Patients With Sepsis in the Emergency Department

›› View More

www.medscape.com/viewarticle/708387_3

Assessment & Monitoring of Patients

- Staff are expected to include patient reports of his experience with medication's effect
- Patient should be instructed to notify nurse if there is difficulty breathing or a reaction to the medication
- Hospital needs P&P to address the manner and frequency of monitoring
- P&P should include information to be communicated at shift change
- Should include patient's risk factors
- **Document** after medication administered

Surveyor Procedure Tag 405

- Surveyor to verify the established time requirements do not exceed the following:
  - 1 hour for time-critical scheduled medications
  - 2 hours for medications prescribed more frequently than daily, but no more frequently than every 4 hours and
  - 4 hours for medications prescribed for daily or longer administration intervals

Survey Procedures

- Surveyor to verify nurses are administering medications within their scope of practice
- That the MS has approved the P&P which include the timing of medications
- Verify the hospital has P&P that identify which medications are:
  - Not eligible for scheduled dosing times
  - Eligible for scheduled dosing times and are time-critical and
  - Eligible for scheduled dosing times and are not time-critical.

Survey Procedures

- Surveyor to watch a nurse pass meds and make sure patient is identified
- Make sure nurse follows policy when administering medications
- Surveyor to interview nurses and make sure they understand the hospital policy and timing of medications
- Can the nurses identify time-critical and non-time critical medications?
- Will look at standing orders to make sure they comply with these requirements

Survey Procedures 2014

- Are patients assessed by nursing and/or other staff, per hospital policy, for their risk to their prescribed medications?
- Are patients who are at higher risk and/or receiving high-alert medications monitored for adverse effects?
- Are staff knowledgeable about intervention protocols when patients experience adverse medication-related events?

Blood Transfusions and IVs 409 2013 & 2014

- Standard: Blood transfusions and IV medications must be administered with state law and MS P&P
  - CMS previously issued a memo on May 13, 2011 and updated June 6, 2014
- Use to require special training for this and there was a long list of things that nurses had to be trained on
- 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 but must still be **competent** in those areas
  - Must follow your P&P and state scope of practice

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

Blood Transfusions and IVs 2014

- Hospital P&P for blood and IV medication must be based on state law and MS P&P and must address the following: (all new section)
  - 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

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 §482.25(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.

Blood Transfusions and IVs 2014

- Patient Monitoring
  - 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
- 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

Blood Transfusions and IVs 2014

- 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

Blood Transfusions and IVs 409 2014

- Hospital P&P is expected to address:
  - Monitoring for fluid and electrolyte balance
  - Monitoring patients for high alert medications including IV opioids
  - 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

Assess and Monitor Patients 2014

- 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

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 ETCO2
- Also mentions APSF monitoring of opioids including ETCO2

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

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*

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

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

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

Anesthesia Patient Safety Foundation

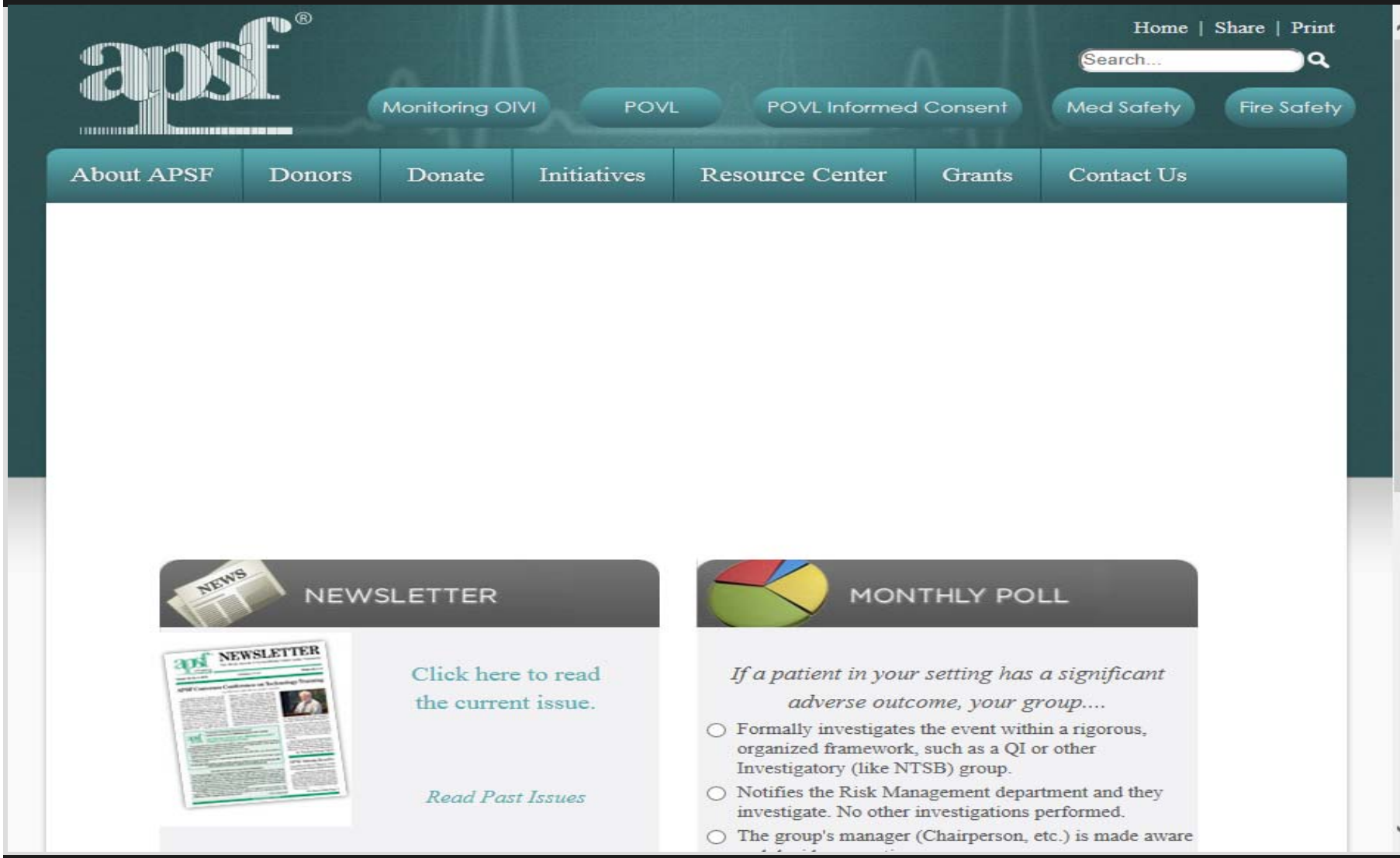
Anesthesia Patient Safety Foundation

- *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.*

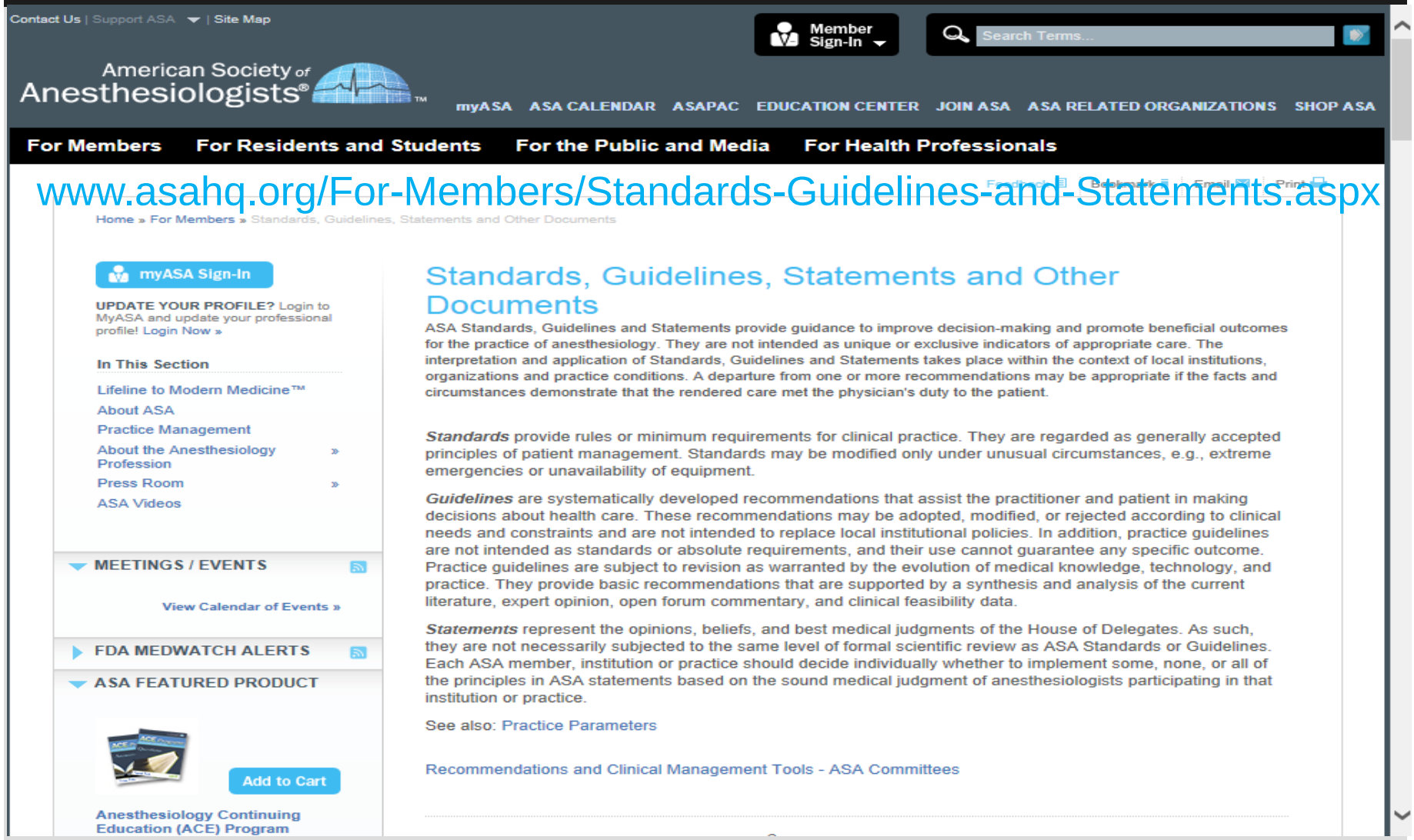
When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations. Continuous monitoring is most important for the highest risk patients, but depending on clinical judgment, should be applied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

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

APSF Website www.apsf.org



ASA Standards and Guidelines



Blood Transfusions 2014

- 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

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 2014

- 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

Survey Procedure 2014

- 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

Survey Procedure 2014

- 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?

Self Administered Medication 409

- **Standard**: The hospital may allow a patient, or his or her caregiver/support person where appropriate,
- To self –administer medication
- This includes both hospital-issued medications and the patient's own medications brought into the hospital
- Must be defined and specified in the hospital's policies and procedures
- CMS only made one change in 409 and that is to include PCA as a self administered medication

Only Change in Tag 409 in 2014

- PCA pumps allow for the self-administration of intravenous (IV) medications to patients
- References the section in Tag 409 just discussed concerning assessment and monitoring requirements for post-surgical patients receiving IV opioids
- Including via patient-controlled analgesia (PCA) pumps, in and out of the post-anesthesia care (PACU) and intensive care units (ICU)
- Information provided in 412 as reference and will not be discussed

CMS Adds New Tag Numbers 412 & 413

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.

(i) If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.
(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).
(C) Instruct the patient (or the patient's support person where appropriate) in the safe and accurate administration of the specified medication(s).
(D) Address the security of the medication(s) for each patient.
(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

Self-Administer Medications 2013 & 2014

- CMS added new tag numbers 412 and 413 in 2013 and revision June 6, 2014
- Previously, the only section on self administered medications was in the pharmacy standard under tag **502**
- Standard: The hospital may allow a patient or caregiver/support person to self administer medications in accordance with hospital P&P
  - This includes hospital issued medication and patient's own medication brought in
- These are very long sections so need to read

Self-Administer P&P Must Include

- Self administer P&P **must** include:
  - Need an order
  - Make sure assess capacity and document
    - Is the patient competent and not confused
  - Instruct the person on how to give safely
  - Address the security of the medication
  - Document when given in the medical record
  - Assess if receiving opioids including PCA

Self-Administer Medications

- Not required to do
  - Could be beneficial to some patients
- Generally applies to inpatients but may find appropriate situations for outpatients
  - Hospital does for observation patients on Medicare since does not pay for oral medications
  - Asthma patient has inhaler at bedside or patient has hemorrhoid cream or patient learns to give subq Heparin
- Teaching patient to use their medications could avoid readmissions or returns to the ED

Self-Administer Medications

- Some cases nurse may need to supervise
- May want to include in the P&P when supervision by the nurse is needed
- May exclude certain medications from self administration
- Medical staff, nursing and pharmacy departments must collaborate in developing P&P
- Surveyor will assess carefully to ensure these standards and policy requirements are met

CMS Hospital CoPs Section on PACU

PACU 957 2014

- Standard: Must be adequate provisions for immediate post-op care
- Must be in accordance with acceptable standards of care, for all patients including same day surgery patients
  - Such as following the ASPAN standards of care and practice
- Separate room with limited access
- P&P specify transfer requirements to and from PACU

PACU 957 2014 Advanced Notice of Changes

- The CMS June 6, 2014 manual has a change to a PACU standard
  - Besides nursing tag numbers 405, 409, and 412
- Emphasizes need for post-operative monitoring of patients receiving IV opioids
- Want to be sure all patients on opioids, including PCA, are monitored carefully
- P&P required which includes how often patient has to be monitored, training of staff, equipment etc.

2014 Changes to PACU Section

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

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal **(Advance Copy)** **Date:**

SUBJECT: Revised Appendix A, 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: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

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/ A-0405, §482.23(c)Standard: Preparation and Administration of Drugs /§482.23(c)(1), (c)(1)(i) & (c)(2)
R	Appendix A/ A-0409, §482.23 Standard: Preparation and Administration of Drugs/§482.23(c)(4)
R	Appendix A/ A-0412, §482.23 Standard: Preparation and Administration of Drugs/§482.23(c)(6)
R	Appendix A/ A-0957, §482.51(b) Standard: Delivery of Services/Immediate Post-operative Care/§482.51(b)(4)

June 6, 2014 Final Changes

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

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 116 | **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-0957/§482.51(b)(4)/There must be adequate provisions for immediate post-operative care.

III. FUNDING: No additional funding will be provided by CMS; contractor activities are

A-0957

(Rev.116, Issued: 06-06-14 Effective: 06-06-06-14, Implementation 06- 06-14)

§482.51(b)(4) - There must be adequate provisions for immediate post-operative care.

Interpretive Guidelines §482.51(b)(4)

Adequate provisions for immediate post-operative care means:

- Post-operative care must be *provided to all surgical patients, including same-day surgery patients,* in accordance with acceptable standards of practice.
- *A* post-operative care area, *usually referred to as the post-anesthesia care unit (PACU),* is a separate area of the hospital. Access is limited to authorized personnel.
- Policies and procedures specify transfer requirements to and from the *PACU.* Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the *PACU* include*s, but is not limited to*:
  - Level of activity;
  - Respirations;
  - Blood pressure;
  - Level of consciousness;
  - *Level of pain;*
  - Patient color; and
- If *a* patient *is* not transferred to the *PACU*, determine that provisions are made for close observation until the *patient has* regained consciousness, e.g., direct observation by a qualified RN

PACU 957 2014

- PACU assessment includes level of activity, level of pain, respiration, BP, LOC, patient color, Aldrete
- If not sent to PACU then close observation of patient until has gained consciousness by a qualified RN
- Surveyor is instructed to observe care provided in the PACU to make sure they are monitored and assessed prior to transfer or discharge
- Will look to determine if hospital has system to monitor needs of post-op patient transferred from PACU to other areas of the hospital

Post-Operative Monitoring 2014

- Hospitals are expected to have P&P on the minimum scope and frequency of monitoring in post-PACU setting
- Must be consistent with the standard of care
- Concerned about post-op patients receiving opioids
- Concern about risk for over-sedation and respiratory depression
- Once out of PACU not monitored as frequently
- Need appropriate assessment to prevent these complications (See Tag 405)

ASPAN


Login | My ASPAN | View Cart | Search... Search
ASPAN
American Society of PeriAnesthesia Nurses
www.aspan.org/Home.aspx
Home About Us Members Clinical Practice Education Research Events Resources ASPAN Forums
Serving nurses practicing in all phases of preanesthesia and postanesthesia care, ambulatory surgery, and pain management
ASPAN Highlights
2014-2015 Call for Nominations: Board of Directors and Nominating Committee
Summer/Fall Seminar Registration Now Open
2012-2014 Perianesthesia Nursing Standards, Practice Recommendations and Interpretive Statements
2014-2015 Willingness to Participate Form
ASPAN Webinars: New Modules Now Available
July/August Breathline Online
ASPAN Development
Advance perianesthesia practice, honor your colleagues, and learn about ASPAN's new Legacy for Life program
ABOUT ASPAN
Core Ideology
History
Organization
WTP Form
Contact Us
MEMBERSHIP
Benefits of Membership
Member Get-A-Member
JOIN ASPAN
PUBLICATIONS
Breathline
JOPAN
CLINICAL PRACTICE
Submit Questions
Position Statements
Practice Guidelines
2013 CSP Abstracts
Safety In Practice
RESEARCH
Research Information
Research Grants
2013 Abstracts
Joanna Briggs Institute
DEVELOPMENT
About Development
Hail, Honor, Salute
EDUCATION
ASPAN Seminars
Contact Hours Online
Certification
Education Approver Process
ADVOCACY
Find Your ASPAN Liaison
NIWI
Governmental Affairs Primer
CONFERENCE/EXHIBITS
2014 National Conference
2014 Exhibitor/Sponsor Info
2014 Research/EBP Call for Abstracts
Not a Member?
CAREER CENTER
ASPAN STORE
SPECIALTY PRACTICE GROUPS
PATIENT INFORMATION
abpanc
CERTIFICATION

Perianesthesia Nursing Standards

ASPAN
American Society of PeriAnesthesia Nurses

Home | About Us | Members | Clinical Practice | Education | Research | Events | Resources | ASPAN Forums

Serving nurses practicing in all phases of preanesthesia and postanesthesia care, ambulatory surgery, and pain management

- FAQs
- Submit Questions
- Fatigue Checklist
- Clinical Narratives
- Position Statements
- Practice Resources
- Clinical Guidelines
- ASPAN Standards
- Competency Based Orientation
- Competency Based Orientation (UAP)
- Patient Classification
- Safety in Practice
- CSP Abstracts

2012-2014 Perianesthesia Nursing Standards, Practice Recommendations and Interpretive Statements

Click here to order online.

Or, click here to print an order form to mail or fax:
Mail: ASPAN, 90 Frontage Road, Cherry Hill, NJ 08034-1424
Fax: 856-616-9601

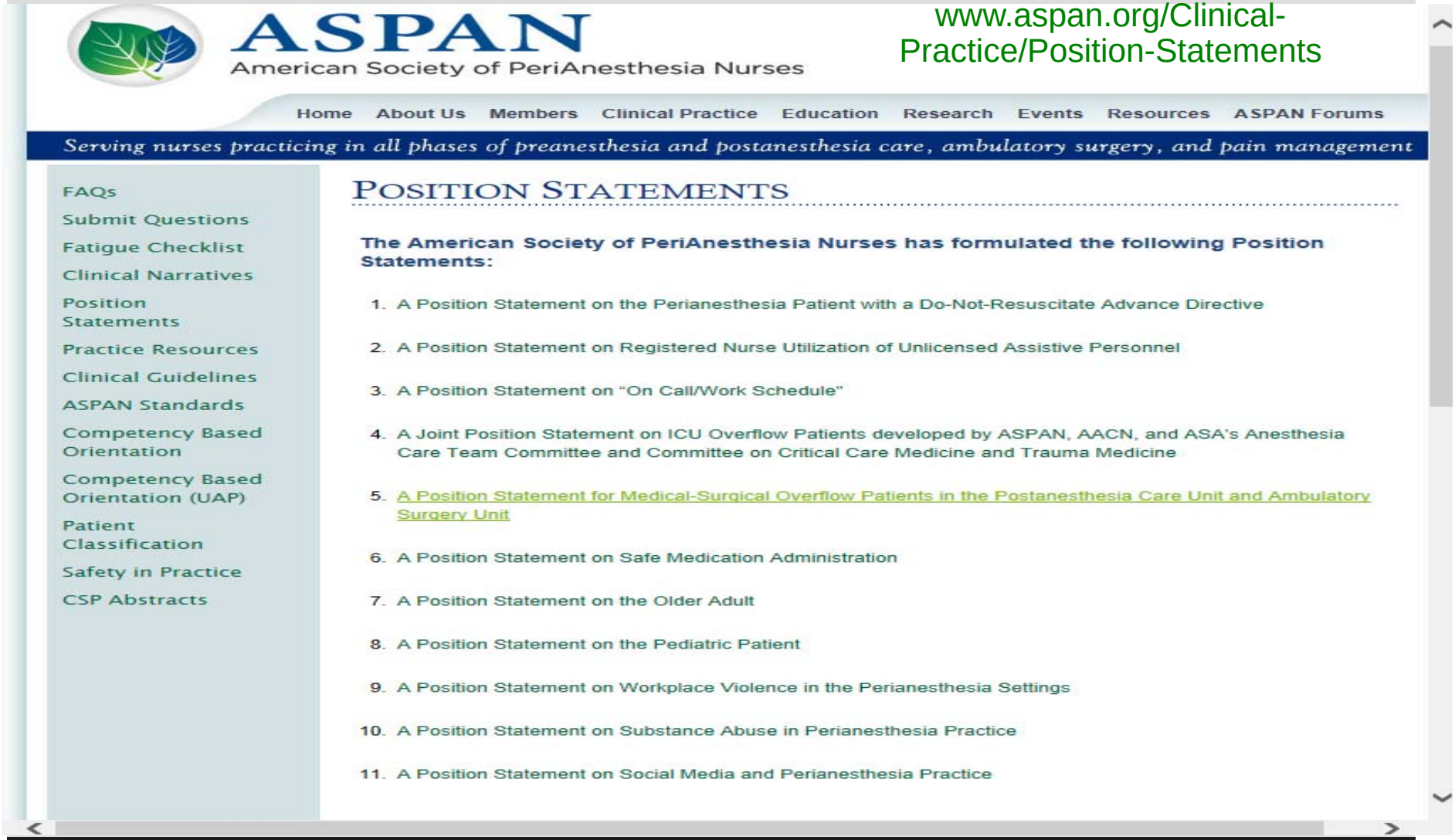
www.aspan.org/Clinical-Practice/ASPAN-Standards

Since its inception in 1984, the American Society of PeriAnesthesia Nurses (ASPAN) *Standards of Perianesthesia Nursing Practice* has provided a framework for the expanding scope of care for a diverse patient population across all perianesthesia settings. The *Standards* are reviewed and updated on an ongoing basis and are republished biennially. Each revised edition incorporates current evidence-based practice, emerging regulatory requirements and reflects changing technology and nursing practice.

The 2012-2014 edition of the ASPAN *Standards* sports a new title: ***Perianesthesia Nursing Standards, Practice Recommendations and Interpretive Statements***. This updated text contains principles of perianesthesia practice, perianesthesia practice standards, evidence-based clinical practice guidelines, position statements, practice recommendations, resources from partnering organizations and interpretive statements which provide clarity and definition to key elements of the standards.

New content in this publication includes principles of safe perianesthesia practice, a practice recommendation for care of the adult patient with obstructive sleep apnea, a revised practice recommendation for family visitation in perianesthesia care unit and a position statement on substance abuse in the perianesthesia setting.

ASPAN Position Statements



The End Questions????

Sue Dill Calloway RN, Esq.
CPHRM, CCMSCP
AD, BA, BSN, MSN, JD
President
Patient Safety and Healthcare Education
5447 Fawnbrook Lane
Dublin, Ohio 43017
614 791-1468
sdill1@columbus.rr.com
(no email question, call)

- Additional resources on CMS Memos related in infection control and safe injection practices

CMS Memo May 30, 2014

- CMS publishes 4 page memo on infection control breaches and when they warrant referral to the public health authorities
- This includes a finding by the state agency (SA), like the Department of Health, or an accreditation organization
  - TJC, DNV Healthcare, CIHQ, or AOA HFAP
- CMS has a list and any breaches should be referred
- Referral is to the state authority such as the state epidemiologist or State HAI Prevention Coordinator

Infection Control Breaches

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: 14-36-All

DATE: **May 30, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Infection Control Breaches Which Warrant Referral to Public Health Authorities

Memorandum Summary

- ***Infection Control Breaches Warranting Referral to Public Health Authorities:*** If State Survey Agencies (SAs) or Accrediting Organizations (AOs) identify any of the breaches of generally accepted infection control standards listed in this memorandum, they should refer them to appropriate State authorities for public health assessment and management.

- ***Identification of Public Health Contact:*** SAs should consult with their State's Healthcare Associated Infections (HAI) Prevention Coordinator or State Epidemiologist on the preferred referral process. Since AOs operate in multiple States, they do not have to confer with State public health officials to set up referral processes, but are expected to refer identified breaches to the appropriate State public health contact identified at: http://www.cdc.gov/HAI/state-based/index.html

CMS Memo Infection Control Breaches

- If any of the listed breaches are observed, then will take appropriate enforcement action
- And will make the public health authority aware
  - Includes LTC, ASCs, hospice, hospitals, home health agencies, CAH, rural health clinics and dialysis facilities
- CDC is working closely with SA on HAI prevention
- List of breaches to be referred include:
- Using the same needle for more than one individual;

CMS Memo Infection Control Breaches

- Using the same (pre-filled/manufactured/insulin or any other) syringe, pen or injection device for more than one individual
- Re-using a needle or syringe which has already been used to administer medication to an individual to subsequently enter a medication container (e.g., vial, bag), and then using contents from that medication container for another individual
- Using the same lancing/finger stick device for more than one individual, even if the lancet is changed

Finger stick Devices & Glucose Meters

- Part of the 10 CDC Safe Practices for Injection Safety
  - Glucose meters must be cleaned and disinfected between each patient use
  - Do hand hygiene and wear gloves during finger stick blood glucose monitoring and other procedures involving potential exposure to blood or body fluids
  - Finger stick devices (including the lancing device or the lancet itself) should never be used on more than person
  - Items contaminated with blood may not be immediately visible

CDC on Finger stick Devices

- Information for Patients
- Preventing Unsafe Injection Practices
- Infection Prevention during Blood Glucose Monitoring and Insulin Administration
- FAQs regarding Assisted Blood Glucose Monitoring and Insulin Administration
- ▶ **CDC Clinical Reminder: Fingerstick Devices**
- Clinical Reminder: Insulin Pens
- Recent Publications
- Recent Meetings
- The One & Only Campaign

Related Links

- One & Only Campaign
- HICPAC
- 2007 Guideline for Isolation Precautions
- HHS Action Plan to Prevent HAIs

Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens

Available for download Clinical Reminder [PDF - 187 KB]

Summary

The Centers for Disease Control and Prevention (CDC) has become increasingly concerned about the risks for transmitting hepatitis B virus (HBV) and other bloodborne pathogens to persons undergoing fingerstick procedures for blood sampling -- for instance, persons with diabetes who require assistance monitoring their blood glucose levels. Reports of HBV infection outbreaks linked to diabetes care have been increasing [1, 2, 3]. This notice serves as a reminder that fingerstick devices should never be used for more than one person.

Background

Fingerstick devices are devices that are used to prick the skin and obtain drops of blood for testing. There are two main types of fingerstick devices: those that are designed for reuse on a single person and those that are disposable and for single-use.

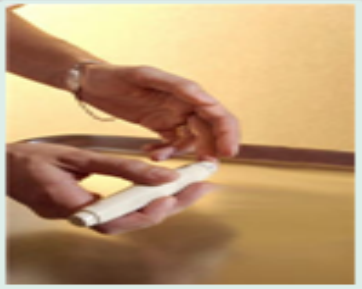


Figure 1: Reusable fingerstick device*

- **Reusable Devices:** These devices often resemble a pen and have the means to remove and replace the lancet after each use, allowing the device to be used more than once (see **Figure 1**). Due to difficulties with cleaning and disinfection after use and their link to numerous outbreaks, CDC recommends that these devices never be used for more than one person. If these devices are used, it should only be by individual

Finger stick Devices

- Anyone performing finger stick procedures should ensure that a device is not used on more than one patient
- Use auto-disabling single-use disposable finger stick devices
- Pen like devices should not be used on multiple patients due to difficulty with cleaning and disinfection (one patient use)

CMS Memo on Safe Injection Practices

- June 15, 2012 CMS issues a 7 page memo on safe injection practices
- Discusses the safe use of single dose medication to prevent healthcare associated infections (HAI)
- Notes new exception which is important especially in medications shortages
- General rule is that single dose vial (SDV)can only be used on one patient
- Will allow SDV to be used on multiple patients if prepared by pharmacist under laminar hood following USP 797 guidelines

Single Dose Medication June 18, 2012

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 Medications to Prevent Healthcare-associated Infections

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.
- ***Administering drugs from one SDV to multiple patients without adhering to USP <797>***

CMS Memo on Safe Injection Practices

- All entries into a SDV for purposes of repackaging must be completed with 6 hours of the initial puncture in pharmacy following USP guidelines
- Only exception of when SDV can be used on multiple patients
- Otherwise using a single dose vial on multiple patients is a violation of CDC standards
- CMS will cite hospital under the hospital CoP infection control standards since must provide sanitary environment
  - Also includes ASCs, hospice, LTC, home health, CAH, dialysis, etc.

CMS Memo on Safe Injection Practices

- Bottom line is you can not use a single dose vial on multiple patients
- CMS requires hospitals to follow nationally recognized standards of care like the CDC guidelines
- SDV typically lack an antimicrobial preservative
- Once the vial is entered the contents can support the growth of microorganisms
- The vials must have a beyond use date (BUD) and storage conditions on the label

CMS Memo on Safe Injection Practices

- Make sure pharmacist has a copy of this memo
- If medication is repackaged under an arrangement with an off site vendor or compounding facility ask for evidence they have adhered to 797 standards
- ASHP Foundation has a tool for assessing contractors who provide sterile products
- Go to www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx
- Click on starting using sterile products outsourcing tool now

ASHP Foundation
FOSTERING SAFE AND EFFECTIVE MEDICATION USE

Contact Us | Donate Now | ASHP.org | SEARCH

HOME | ABOUT US | PROGRAM NEWS | LEADERSHIP | RESEARCH | ADVANCING PRACTICE | AWARDS | EDUCATION | SUPPORT THE ASHP FOUNDATION

→ Print this page → Email this page

Advancing Practice

- Optimizing Antithrombotic Management: An Assessment Tool
- Bar Code Guide
- My Medicine List™
- Outsourcing Sterile Products Preparation: Contractor Assessment Tool
- Pharmacy Practice Model Initiative

Outsourcing Sterile Products Preparation: Contractor Assessment Tool

Developed with support from PharMEDium Services, LLC
Now available!

Preparation of sterile parenteral products is a critical component of health-system pharmacy practice. For departments that choose to outsource the preparation of parenteral medications, this web-based tool can be used to evaluate proposals during the selection of an external organization that would provide parenteral product preparation services.

The assessment tool helps you evaluate each of these areas:

- Regulatory compliance
- Quality and patient safety measures
- Medication administration safety features
- Service excellence

Start using the Sterile Products Outsourcing Tool now!

www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx

ASHP Sterile Compounding Resource Center

www.ashp.org/menu/PracticePolicy/ResourceCenters/Compounding

Not All Vials Are Created Equal

SINGLE-DOSE OR MULTI-DOSE?

NOT ALL VIALS ARE CREATED EQUAL.

Dozens of recent outbreaks have been associated with reuse of single-dose vials and misuse of multiple-dose vials. As a result of these incidents, patients have suffered significant harms, including death. CDC and the One & Only Campaign urge healthcare providers to recognize the differences between single-dose and multiple-dose vials and to understand appropriate use of each container type.

This information can literally save a life.

ONEANDONLYCAMPAIGN.ORG

Safe Injection Practices www.empsf.org

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

Safe Injection Practices Patient Safety Brief
Emergency Medicine Patient Safety Foundation

By: Sue Dill Calloway RN MSN JD CPHRM
Ruth Carrico PhD RN FSHEA CIC

July 2012

ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

About the Campaign | Safe Injection Practices | Healthcare Provider Information | Patient Information | Campaign Resources | News | Contact Us

ONLY ONCE.

Safe injection practices are a set of measures to perform injections in an optimally safe manner for patients, healthcare providers and others.

Learn about **Safe Injection Practices** >

About the Campaign

The One & Only Campaign is a public health campaign, led by the Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC), to raise awareness among patients and healthcare providers about safe injection practices. The campaign aims to eradicate outbreaks resulting from unsafe injection practices.

Injection Safety Toolkits

Featured Content

- Washington Post "Hepatitis & Liver Health" Supplement Raises Awareness – featuring the One & Only Campaign - 9/10/12
- Endorsing the Safe Use of Single-Dose/Single-Use Vials - 5/31/12

Partner States

The SIPC partners with states to promote the messages of the One & Only Campaign.

Read more

Campaign Resources

The SIPC has print materials, videos and more to educate consumers and remind healthcare providers about the basics of injection safety.

Read more

Sign up for email updates: Enter email address SIGN UP | Privacy Policy

INJECTION SAFETY CHECKLIST

The following Injection Safety checklist items are a subset of items that can be found in the *CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care*.

The checklist, which is appropriate for both inpatient and outpatient settings, should be used to systematically assess adherence of healthcare personnel to safe injection practices. (Assessment of adherence should be conducted by direct observation of healthcare personnel during the performance of their duties.)

Injection Safety	Practice Performed?	If answer is No, document plan for remediation
Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids or contaminated equipment.	Yes No	
Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).	Yes No	
The rubber septum on a medication vial is disinfected with alcohol prior to piercing	Yes No	
Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient.	Yes No	
Single dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient.	Yes No	
Medication administration tubing and connectors are used for only one patient.	Yes No	
Multi-dose vials are dated by HCP when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Note: This is different from the expiration date printed on the vial.	Yes No	
Multi-dose vials are dedicated to individual patients whenever possible.	Yes No	
Multi-dose vials to be used for more than one		

www.cdc.gov/HAI/pdfs/guidelines/ambulatory-care-checklist-07-2011.pdf

CMS Memo on Insulin Pens

- CMS issues memo on insulin pens on May 18, 2012
- Insulin pens are intended to be used on one patient only
- CMS notes that some healthcare providers are not aware of this
- Insulin pens were used on more than one patient which is like sharing needles
- Every patient must have their own insulin pen
- Insulin pens must be marked with the patient's name

Insulin Pens

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

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-30-ALL

DATE: **May 18, 2012**

TO: State Survey Agency Directors

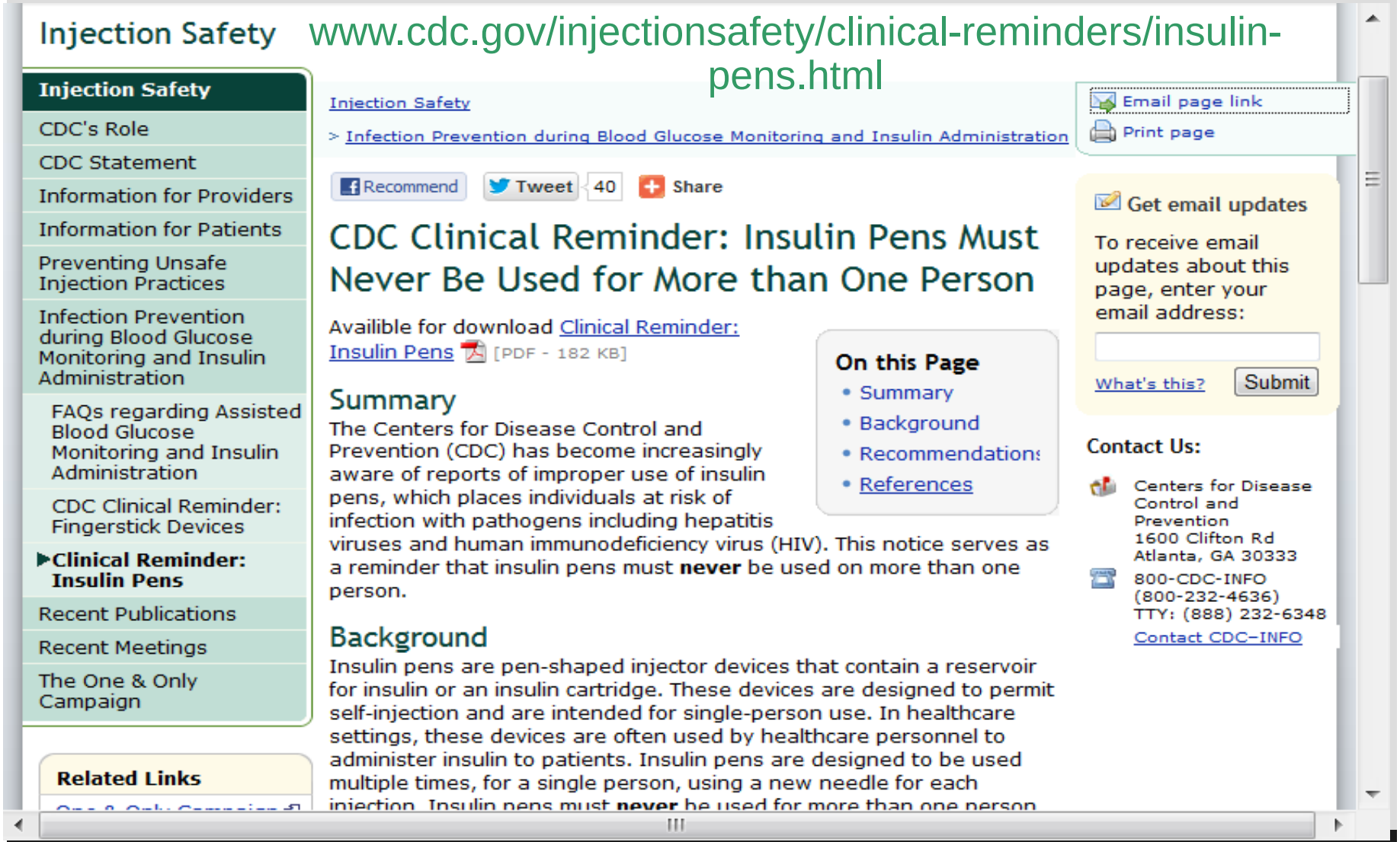
FROM: Director
Survey and Certification Group

SUBJECT: Use of Insulin Pens in Health Care Facilities

Memorandum Summary

Insulin Pen devices: The Centers for Medicare & Medicaid Services (CMS) has recently received reports of use of insulin pens for more than one patient, with at least one 2011 episode resulting in the need for post-exposure patient notification. These reports indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients. **Insulin pens are meant for use by a single patient only.** Each patient/resident must have his/her own. Sharing of insulin pens is essentially the same as sharing needles or syringes, and must be cited, consistent with the applicable provider/supplier specific survey guidance, in the same manner as re-use of needles or syringes.

CDC Reminder on Insulin Pens



CDC Has Flier for Hospitals on Insulin Pens

CDC CLINICAL REMINDER

Insulin Pens
Must Never Be Used for More than One Person

Summary

The Centers for Disease Control and Prevention (CDC) has become increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV). This notice serves as a reminder that insulin pens must **never** be used on more than one person.

Background

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times, for a single person, using a new needle for each injection. Insulin pens must **never** be used for more than one person. Regurgitation of blood into the insulin cartridge can occur after injection [1] creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed.

In 2009, in response to reports of improper use of insulin pens in hospitals, the Food and Drug Administration (FDA) issued an alert for healthcare professionals reminding them that insulin pens are meant for use on a single patient only and are not to be shared between patients [2]. In spite of this alert, there have been continuing reports of patients placed at risk through inappropriate reuse and sharing of insulin pens, including an incident in 2011 that required notification of more than 2,000 potentially exposed patients [3]. These events indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients.

Recommendations

Insulin Pen Posters and Brochures Available

ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.
Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

About the Campaign | Safe Injection Practices | Healthcare Provider Information | Patient Information | Campaign Resources | News | Contact Us

Insulin Pen Safety – One Insulin Pen, One Person

www.oneandonlycampaign.org/content/insulin-pen-safety

The Safe Injection Practices Coalition created an insulin pen poster and brochure for healthcare providers as a reminder that insulin pens and other injectable medications are meant for one person and should never be shared. PDFs of these educational materials are linked below:

Specific Materials for Safe Use of Insulin Pens – for Clinicians and Patients

- Poster
- Brochure

Click here to order free copies of these materials from the Centers for Disease Control and Prevention (CDC) (*publication numbers 22-1501 and 22-1503*).

Additional Resources

- VA Patient Safety Alert: Multi-Dose Pen Injectors (Department of Veterans Affairs, January 2013)

BE AWARE
DON'T SHARE

Insulin pens that contain more than one dose of insulin are only meant for one person.

They ***should never be used for more than one person***, even when the needle is changed.

ONE INSULIN PEN, ONLY ONE PERSON

The One & Only Campaign is a public health campaign aimed at raising awareness among the general public and healthcare providers about safe injection practices.

For more information, please visit:
www.ONEandONLYcampaign.org

Brochure

DON'T DO IT

Sharing Insulin Pens and Other Injection Equipment Jeopardizes Patients

In 2009, in response to reports of improper use of insulin pens in hospitals, the Food and Drug Administration issued an alert for healthcare professionals reminding them that insulin pens are meant for use on a single person only and are not to be shared. Unfortunately, there have been continuing reports of persons placed at risk of bloodborne and bacterial pathogen transmission through sharing of insulin pens.

A SIMPLE RULE

Injection equipment (e.g., insulin pens, needles and syringes) should **never** be used for more than one person.

1 ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

About the Safe Injection Practices Coalition

The Safe Injection Practices Coalition (SIPC) is a partnership of healthcare-related organizations led by the Centers for Disease Control and Prevention that was formed to promote safe injection practices in all U.S. healthcare settings. The SIPC has developed the One & Only Campaign – a public health education and awareness campaign – aimed at both healthcare providers and patients to advance and promote safe injection practices.

For more information, please visit:
www.ONEandONLYcampaign.org

BE AWARE
DON'T SHARE

ONE INSULIN PEN, ONLY ONE PERSON

What Every Healthcare Professional Needs To Know

ONE INSULIN PEN, ONLY ONE PERSON

Recommendations for Safe Insulin Pen Use

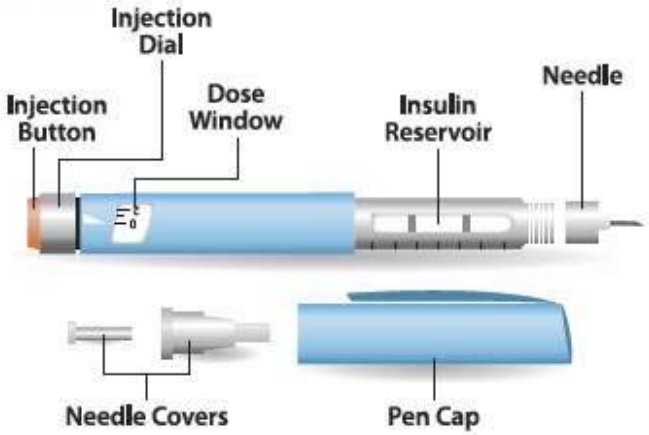
Protection from infection is a basic expectation anywhere healthcare is delivered. Use of insulin pens and other injection equipment for more than one person poses unacceptable risks and should be considered a "never" event.

- Insulin pens and other injection equipment containing multiple doses of medication are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens and other injection equipment should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

These recommendations apply to any setting where insulin pens and other injection equipment are used, including assisted living or residential care facilities, skilled nursing facilities, clinics, health fairs, shelters, detention facilities, senior centers, schools, and camps as well as licensed healthcare facilities.

Insulin Administration

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection. They are intended for single-person use.



In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used for a single person multiple times, using a new needle for each injection.

Back flow of blood into the insulin reservoir can occur during an injection. This creates a risk of bloodborne and bacterial pathogen transmission if the pen is used for more than one person, even when the needle is changed.

The Safe Injection Practices Coalition created an easy to use check list for facilities. Similar to a risk assessment, the list contains the necessary components of injection safety for facilities to quickly assess their practices.

A copy of the checklist can be found at: www.cdc.gov/injectionsafety/Checklist

Luer Misconnections Memo

- CMS issues memo March 8, 2013
- 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
- For example, a patient had the blood pressure cuff connected to the IV and died of an air embolism
- Luer connections easily link many medical components, accessories and delivery devices

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

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.

June 2010 Pa Patient Safety Authority

Tubing Misconnections: Making the Connection to Patient Safety

ABSTRACT

Some patients may have multiple tubing lines connected to them for reasons such as delivery of medication and nutrition therapy. With these multiple lines, the potential for tubing misconnections becomes more prevalent. Tubing misconnections can occur with intravenous catheters, feeding tubes, hemodialysis tubes, and tracheostomy coils, among other devices. One of the main reasons for tubing misconnections is that many types of tubing for different types of medical devices incorporate luer connectors. These connectors contribute to misconnections because they allow functionally dissimilar tubes or catheters to be connected together. Between January 2008 and September 2008, 38 events of tubing misconnections were reported to the Pennsylvania Patient Safety Authority involving various types of misconnections. Methods for reducing the likelihood of tubing misconnections include equipment design solutions and administrative controls (policies and work practices). Equipment design solutions either prevent the user from making a misconnection or prompt the user to make the correct connection. Administrative controls are policies and practices that reduce the risk of misconnections such as tracing lines back to their source. (Pa Patient Saf Advis 2010 Jun;7(2):41-5.)

Introduction

Depending on acuity level, patients may have many tubing lines connecting them to medical devices only or for delivering medication or nutrition therapy. Medical devices connected to patients may also have tubing lines connecting the devices with other medical devices. Under these circumstances, tubing misconnections can occur with potentially fatal results.[1] Misconnections have been recognized as a serious problem for many years. One of the earliest published reports of misconnections was the inadvertent delivery of breast milk via intravenous (IV) administration in 1972.[2] However, misconnections have garnered more attention in recent years, especially in the United States, due in part to the tubing misconnection Sentinel Event Alert issued by the Joint Commission in April 2006.[3]

for IV delivery connected to nasogastric tubes.[4] The Alert offers risk reduction strategies and recommendations, which are included in the overall risk reduction strategies below.

There are many types of misconnections; however, this article will focus on liquid-to-liquid and liquid-to-gas misconnections because these misconnections can pose the most serious harm to patients and are the most frequently reported to the Pennsylvania Patient Safety Authority.[5] Liquid lines are typically those that administer medications or nutrition but can also include solution lines such as flush lines. Medical gas lines are typically used for respiratory support or to power pneumatic medical devices. Liquid-to-liquid misconnections can result in a liquid substance entering the wrong body part or the wrong substance entering the patient. Liquid-to-gas misconnections are luminal connections that can result in gas introduced into patients' blood vessels or liquid entering patients' respiratory tracts.[1]

A common reason for tubing misconnections, whether liquid-to-liquid or liquid-to-gas, is that many types of tubing lines for different medical devices incorporate common luer connectors. The International Organization for Standardization (ISO) characterizes a luer connector as a conical fitting with a 6% (Luer) taper for syringes, needles, and other medical equipment.[6] The luer connection system consists of male and female counterparts that are joined together either by push-thru slip or screw-in threaded (luer lock) fittings. Luer connectors contribute to misconnections because they easily allow functionally dissimilar tubes or catheters to be connected together.[7]

Misconnections in Pennsylvania

Between January 2008 and September 2008, 38 tubing misconnection events were reported to the Authority: 35 liquid-to-liquid events and 3 liquid-to-gas events. (See the Table for a breakdown of the types of misconnections reported.) Examples of the serious events and incidents involving misconnections reported to the Authority include the following:

> The patient is a 4-month-old infant admitted . . . to determine need for surgery. The physician ordered a 22 ml bolus of 50% dextrose saline[8]. A . . . nurse connected the leg of IV set to the patient's lower "Y" on

June 2010 Pa Patient Safety Authority

Tubing Misconnections: Making the Connection to Patient Safety

ABSTRACT

Some patients may have multiple tubing lines connected to them for reasons such as delivery of medication and nutrition therapy. With these multiple lines, the potential for tubing misconnections becomes more prevalent. Tubing misconnections can occur with intravenous catheters, feeding tubes, hemodialysis tubes, and tracheostomy cuffs, among other devices. One of the main reasons for tubing misconnections is that many types of tubing for different types of medical devices incorporate luer connectors. These connectors contribute to misconnections because they allow functionally dissimilar tubes or catheters to be connected together. Between January 2008 and September 2008, 38 events of tubing misconnections were reported to the Pennsylvania Patient Safety Authority involving various types of misconnections. Methods for reducing the likelihood of tubing misconnections include equipment design solutions and administrative controls (policies and work practices). Equipment design solutions either prevent the user from making a misconnection or prompt the user to make the correct connection. Administrative controls are policies and practices that reduce the risk of misconnections such as tracing lines back to their source. (Pa Patient Saf Advis 2010 Jun;7(2):41-5.)

Introduction

Depending on acuity level, patients may have many tubing lines connecting them to medical devices only or for delivering medication or nutrition therapy. Medical devices connected to patients may also have tubing lines connecting the devices with other medical devices. Under these circumstances, tubing misconnections can occur with potentially fatal results.[1] Misconnections have been recognized as a serious problem for many years. One of the earliest published reports of misconnections was the inadvertent delivery of breast milk via intravenous (IV) administration in 1972.[2] However, misconnections have garnered more attention in recent years, especially in the United States, due in part to the tubing misconnection Sentinel Event Alert issued by the Joint Commission in April 2006.[3]

for IV delivery connected to nasogastric tubes.[4] The Alert offers risk reduction strategies and recommendations, which are included in the overall risk reduction strategies below.

There are many types of misconnections; however, this article will focus on liquid-to-liquid and liquid-to-gas misconnections because these misconnections can pose the most serious harm to patients and are the most frequently reported to the Pennsylvania Patient Safety Authority. Liquid lines are typically those that administer medications or nutrition but can also include solution lines such as flush lines. Medical gas lines are typically used for respiratory support or to power pneumatic medical devices. Liquid-to-liquid misconnections can result in a liquid substance entering the wrong body part or the wrong substance entering the patient. Liquid-to-gas misconnections are misconnections that can result in gas introduced into patients' blood vessels or liquid entering patients' respiratory tracts.[1]

A common reason for tubing misconnections, whether liquid-to-liquid or liquid-to-gas, is that many types of tubing lines for different medical devices incorporate common luer connectors. The International Organization for Standardization (ISO) characterizes a luer connector as a conical fitting with a 6% (Luer) taper for syringes, needles, and other medical equipment.[5] The luer connection system consists of male and female counterparts that are joined together either by push-thru slip or screw-in threaded (luer lock) fittings. Luer connectors contribute to misconnections because they easily allow functionally dissimilar tubes or catheters to be connected together.[1]

Misconnections in Pennsylvania

Between January 2008 and September 2008, 38 tubing misconnection events were reported to the Authority: 35 liquid-to-liquid events and 3 liquid-to-gas events. (See the Table for a breakdown of the types of misconnections reported.) Examples of the serious illness and incidents involving misconnections reported to the Authority include the following:

> The patient is a 4-month-old infant admitted . . . to determine need for surgery. The physician ordered a 22 ml bolus of 5% [normal saline]. A . . . nurse connected the bag of NS to the patient's lower "Y" on

ISMP Tubing Misconnections www.ismp.org

ISMP Medication Safety Alert! Acute Care

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 gastrointestin 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. *A 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 a 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 whic 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.

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

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/

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.

Thank you for attending!

- Sue Dill Calloway RN, Esq. CPHRM
- AD, BA, BSN, MSN, JD
- President of Patient Safety and Education Consulting
- Chief Learning Officer of the Emergency Medicine Patient Safety Foundation
- 614 791-1468
- sdill1@columbus.rr.com