CMS HOSPITAL CONDITIONS OF PARTICIPATION (COPS) 2022
Part 3 of 5

Nursing and Pharmacy

Speaker

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Recent Changes to the CoPs Affecting Nursing

Changes to Nursing

- Clarified
  - Need a nursing supervisor or sufficient staff

  -PLUS-

  - Immediate availability of RN at the bedside to respond when needed
- Must have current nursing care plan
  - Must have evidence of reassessment and include patient goals

Changes to Nursing – continued

- All nurses, including agency nurses, must follow P&Ps
- CNO must
  - Evaluate all clinical activities of nurses including agency nurses and other staff
  - Must make sure annual evaluation done of all nurses including agency or traveling nurses
- Need an order for drugs

Changes to Nursing – continued

- Have a policy that lists all the outpatient areas and which ones must have a RN
  - Must be approved by the CNO
  - Must be reviewed every three years
  - Must establish the criteria the outpatient area must met such as what types of services are provided (chemo, dressing changes, IV hydration etc.)

Discrimination, Vaccines, Verbal Orders

- Must have P&P prohibiting discrimination
  - Cannot discriminate against race, color, national origin, disability, etc. (not in CoP but OCR 1557 requirement)
  - Must inform the patient in writing, and in a language, they can understand, of their right to be free from discrimination
- Need an order for all medications except flu and pneumovax when you have a protocol
- Standing orders are acceptable in certain circumstances
- Verbal orders are to be used infrequently: P&P

CMS Nursing CoPs

Deficiency Reports February 2022

Name	Tag Number	Number of Deficiencies
Nursing Services	A385	1006
Organization of Nursing Services	A386	243
Staffing and Delivery of Care	A392	632
RN/LPN Staffing	A393	18
Licensure of Nursing Staff	A394	24
RN Supervision of Nursing Care	**A395**	**2,402**

Deficiency Reports

Name	Tag Number	Number
Nursing Care Plan	A396	1033
Patient Care Assignments	A397	331
Supervision of Contract Staff	A398	152
Administration of Drugs, Opioid Administration	A405	927
Standing Orders for Drugs	A406	42
Verbal Orders for Drugs	A407	50

Deficiency Reports

Name	Tag Number	Deficiencies
Accepting Verbal Orders for Drugs	A408	15
Sign-Off for Drugs/Biologicals	A409	156
Blood Transfusions/IV Medication Administration/Reporting Errors	A410/411	37/2
Medication Self Administration	A412/413	10
Total 7,081		

Nursing Services A385 A393

- Must have:
  - An organized nursing service that provides 24-hour nursing services
  - At least one RN furnishing or supervising 24 hours
    - Exception – small rural hospital under a waiver
- Survey procedures –
  - Will determine nursing services are integrated into hospital QAPI
  - Make sure there is adequate staffing: staffing plan
  - Will look for job descriptions including director of nursing

Director of Nursing Service CNO 386

- DON/CNO must be a RN
  - All nurses performing nursing duties must report to nursing leader (not direct report)
- CNO responsible for:
  - Determining types and numbers of nursing personnel
  - Operation of nursing service
- Surveyor
  - May read job description of CNO – ensure it provides for this responsibility
  - May verify CNO approves patient care P&P's

Nurse Staffing A392 (2020)

- Nursing service must
  - Have adequate number of nurses and personnel to care for patients
  - Have nursing supervisor
- Every department or unit must have a RN present
  - Are not available if working on two units at same time
- Survey procedure – will look at staffing schedules that correlate number and acuity of patients nursing plan, nursing schedule, nursing assignments corrolate

Nurse Staffing A392

- There are 3 recent evidenced based studies that show the importance of having adequate staffing which results in better outcomes
- Study said patients who want to survive their new hospital visit should look for low nurse-patient ratio
- Nurse Staffing and Quality of Patient Care, AHRQ, Evidence Report/Technology Report Number 151, March 2007, AHRQ Publication No. 07-E005[1]

[1]http://www.ahrq.gov/downloads/pub/ evidence/pdf/nursestaff/nursestaff.pdf

Nursing Linked to Safety

- **IOM** study also linked adequate staffing levels to patient outcomes
- Limits to number of hours worked to prevent fatigue
- Suggests no mandatory overtime for nurses
- Never work a nurse over 12 hours or 60 hours in one week (or will have 3 times the error)

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Verify Licensure A394

- Must have procedure to ensure nursing personnel have valid and current license
- Licensure verification –primary source-procedure
- Can verify licensure on-line by most state boards of nursing online
  - Can print out information for employee file or electronic evidence
- Include a check of the OIG and document it in the HR file for nurses

RN for Every Patient A395

- A RN must supervise and evaluate the nursing care for every patient
  - Must do admission assessment
    - Plus – ongoing assessment when appropriate per standards and hospital policy
    - RN must do assessment, others gather data and monitor
  - Must use acceptable standard of care
- Evaluation would include assessing each patient's needs, health status and response to interventions

Nursing Care Plan A396 (2020)

- Hospital must ensure that nursing staff develop and keeps a current, nursing care plan for each patient
- Care plan based on assessment and reflects the patient's goals.
- Interventions
- Reassessment
- If nursing participates in interdisciplinary care plan – must still have nursing plan of care

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Care Plan Starts at Admission

- Nursing care plan starts upon admission, includes assessment of discharge planning, physiological and psychosocial factors
  - Based on assessing the patient's needs
  - Is part of the patient's medical records and must be initiated soon after admission, revised and implemented
- Example: multiple trauma patient's goal is to return to running (Discharge planner?)
  - Wants to go to a rehab facility post-discharge for a few weeks
    - In an area near her sister's houses
    - Plans to finish rehab staying at her sister's house

Patient Care Assignments A397

- RN must assign nursing care of each patient to the nursing personnel
  - Per patient's needs
  - Specialized qualifications and competency of staff available
- DNO/CNO and hospital must ensure personnel have appropriate
  - Education >Experience >Licensure
  - Competence >Specialized qualifications
  - Are assigned to provide care to patients according to patient's need

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Agency Nurses A398 (2020)

- Clarified ***all*** nurses providing services must adhere to P&P
  - Employed, contract, or volunteer
- CNO must ensure there is adequate supervision evaluation of clinical activities
  - Evaluate at least annually
  - Includes agency, volunteers
- Orientation must include to the hospital, specific unit, emergency procedures, nursing P&P, and safety P&P's

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Outpatient P&Ps A399 (2020)

- Need P&P establishing which OP departments require a RN
  - Reviewed every 3 years
  - Approved by the CNO
  - Establish alternative staffing plans
- Must establish criteria departments to meet given:
  - Type of services delivered
  - Acuity of patients served
  - Standards of practice
  - For example – Chemo infusion department

Preparation & Administration of Drugs

Safe Opioid Use, Compounding, Safe Injection Practices

Preparation/Admin of Drugs A405

- Drugs must be prepared and administered according to state and federal law
- Need a practitioner's **order**
  - Or by one responsible for patient's care
  - And accepted standards of practice
  - Changes allow other practitioners who can order, sign off orders
    - Such as PharmD – as per P&P, state scope of practice and **MS bylaws/RR**

Administration

- All drugs/biologicals must be administered by or under supervision
  - Nursing or other qualified personnel e.g., RT, PT etc.
  - Per Federal and state laws
  - Per regulations – including licensure requirements
- Per approved medical staff P&P

Federal and State Law

- IGs provide some explanations
- Federal – regulate approval and classification of drugs and biologicals
- States establish laws and regulations which specify scope of practice
  - Prescribing
  - Administering

Accepted Standards of Practice

- P&P must be consistent with accepted SOP
- Based on guidelines or recommendations
- Evidence based guidelines e.g., antibiotics, opioids, anticoagulants)
  - Nationally recognized organizations
  - With expertise in medication preparation and administration
- Must have an **order** or basis of **standing order**
  - Compliant with state, federal laws & SOP

Standing Order

A prewritten order set approved by the medical staff to administer Medications, obtain a diagnostic test or implement a treatment Based on a specific symptom or set of circumstances.
Generally in an emergency situation where delay in treatment would put patient at significant risk

Standing orders are initiated when the patient meets the specific Circumstances outlined in the order. e.g., chest pain, SOB, anaphylaxis reaction during allergy testing

- Clear criteria
- Complete order
- Practitioner notified as soon as possible
- Order placed in order section as standing order initiated
- Approved by MS, nursing, pharm
- Reviewed annually for continued applicability

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Order Must Include

- Patient name
- Age and weight – facilitate dose calculation must be available does not need to be part of order unless weight based order
- Date and time of order
- Dose, frequency and route
- Dose calculation and exact strength or concentration – when applicable
- Quantity and duration
- Specific instructions for use – when applicable
- Prescriber name

Policies and Procedures

- Personnel authorized to administer medications
- Basic safe practice for administration – 5 Rights
  - Or 9 rights
- Timing of medications
- Missed or late administration
- Evaluation of medication administration timing policies
- Assessment/Monitoring of patients
- Documentation

Personnel Authorized to Administer Meds

- P&P identify categories of licensed personnel
  - Types of medications permitted to administer
  - E.g., RT can administer inhalation resiratory medications
- Education must include:
  - Safe handling/preparation
  - Knowledge of indications, side effects, interactions compatibility, dose limits
  - Devices, procedures, techniques for administration

Basic Safe Practice for Administration

- Covers the “5 Rights” (right patient, right drug, right dose, right route, right time)
- Medication “process” procedures
  - Transcribing
  - Verifying
  - Dispensing
  - Delivering
  - Administering
  - Monitoring/Reporting

"9 Rights"?

- Blue Box discussed recent literature identifying 9 rights

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.

Promote Culture of Safety

- References hospitals encouraged to promote a safe culture
  - For staff to **question** when have concerns regarding orders
  - Questions expected to be resolved promptly

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Other Issues Covered

- Must ensure staff adhere to standards to prevent HAI related to preparation
  - Added in compounded sterile preparations
  - Assessed under Infection Prevention
- Expiration dates – set by manufacturer
- Beyond-use-date (BUD) – may be before but never later than expiration date
  - Considers conditions that may occur after opened

Timing of Administration

- IG discusses the importance of timing for medication administration
  - Therapeutic goals require administration at an exact time
  - Now three blocks of time to give medications
  - Thanks to efforts of the ISMP

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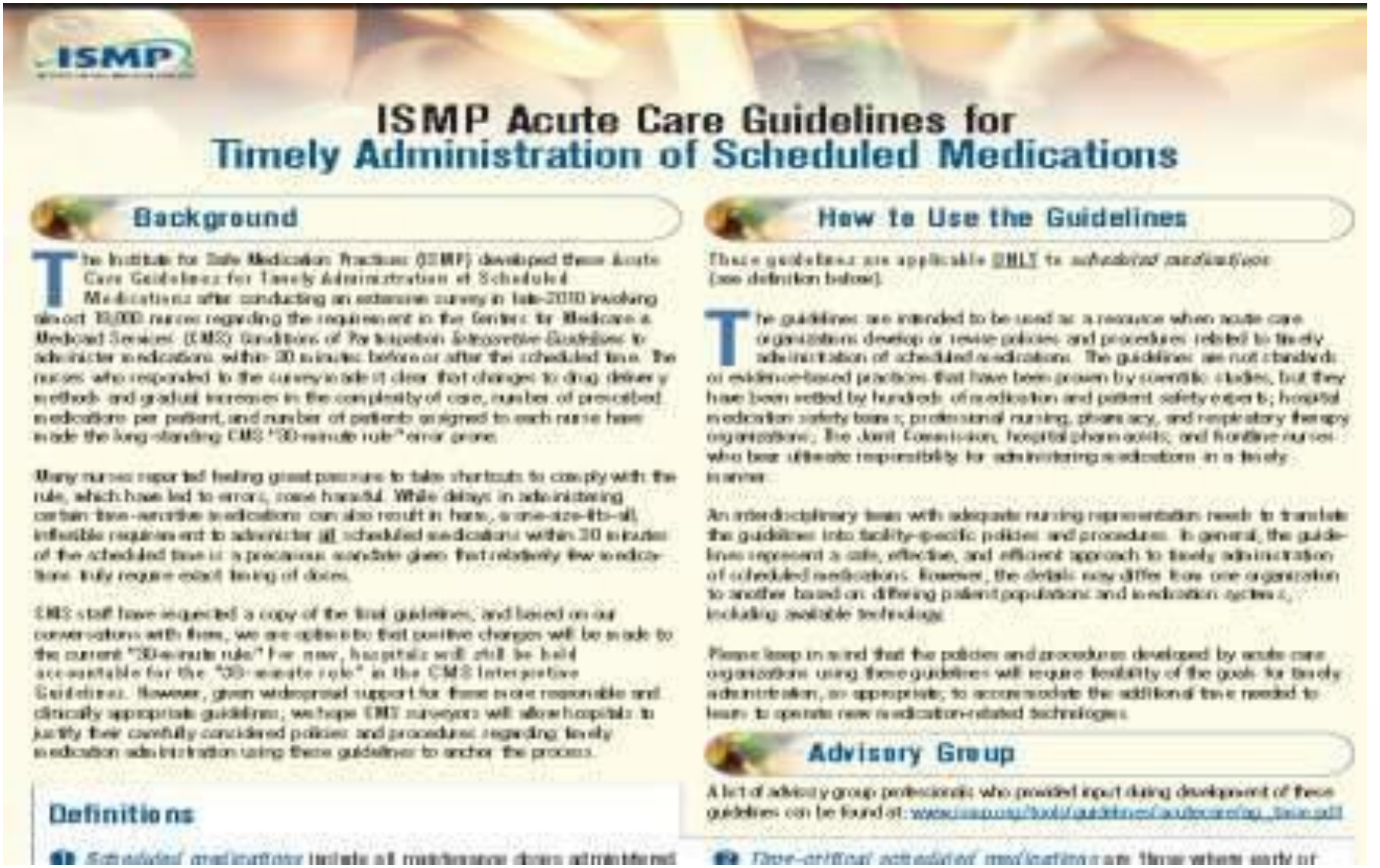
ISMP New Guideline www.ismp.org



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 approach 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

1. *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 boards, 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/tag_team.pdf

2. *Time-critical scheduled medications* are those where early or

Standards of Care and P&P

- National organizations recognized in the field issue written statements and policies that direct patient care
- Hospital's P&Ps must be consistent with Standards of Care (evidenced based guidelines
- 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.

Timing of Medication

- P&P needs to include the timing of medication based on the
  - Nature of the medication
  - Clinical application – why used
  - Frequency of administration
- Separated into eligible and not eligible scheduled drugs

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Medications NOT Eligible Scheduled Dosing

- Those that are generally non eligible for scheduled times
  - Stat drugs
  - Loading dose
  - One time dose for scheduled procedure
  - Time sequenced doses for serum drug level
  - PRN
  - Investigational drugs

Medications ELIGIBLE for Scheduled Dosing

- Those prescribed on a repeated cycle of frequency
  - Goal is to achieve a therapeutic blood level
    - Daily
    - BID
    - TID, etc.
- Policy has standardized times so pharmacy knows when to send to unit or nurse can assess VS or review blood work

Eligible Medications P&P

- P&P:
  - 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

3 Time Frames for Administering Medication

Time Critical Medicine

1 hour before or after

2 hours before or after

Time Critical Scheduled Medications

- 30 minute or 1-hour total window
  - Medications where 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: 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

Non-Critical Scheduled Medications

- Non-time-critical scheduled medications
  - 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
  - Medications given once daily, weekly, or monthly
    - May be given within **2 hours** before/after not to exceed 4 hours (such as Allegra once a day)
  - Medications scheduled more frequently than daily but less than every 4 hours – bid, tid
    - May be given **1 hour** before/after for window not to exceed 2 hours

Missed or Late Administration

- Policy must include:
  - Action to take if missed or not given in permitted window of time
    - Missed dose may be due to
      - Patient out of the department
      - Patient refusal
      - Medication not available or other reasons
  - Parameters of when nursing staff may use own judgment on the rescheduling of late or missed dosed
- Missed/late doses must be reported to the attending physician

Question 1

- We have instituted specific policies and procedures regarding monitoring of patients receiving IV opioids
  - Yes
  - No
  - Prefer not to answer

Assessment & Monitoring of Patients

- Patients on opioid medications need to be carefully monitored
  - May need clinical and lab data to evaluate medication
  - Monitor respiratory status, pulse ox, BP, end tidal CO2 with patients on certain **opioids** e.g., IV, post op, self administered
  - Evaluate clinical signs: confusion, agitation, unsteady gait, itching, low pulse, slow respiration etc.
  - Know high risk medications policy and safe practices
  - Know risk factors for adverse drug event: liver or kidney failure, history of sleep apnea, obesity, smoking, drug-drug interaction and first-time medication use

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
  - Richmond agitation sedation scale (RASS)
  - Pasero Opioid-Induced sedation scale (POSS)
  - Inova Sedation Scale (ISS)
  - Aldrete Scoring system

Staff and Patients

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

Survey Procedures

- Verify
  - Method for administration of drugs
  - P&P are approved by medical staff
  - P&P identifies who is authorized to administer medications
  - Nursing practicing within scope of practice
  - If others administering – are they within Federal, State laws scope of practice bylaws, R&R

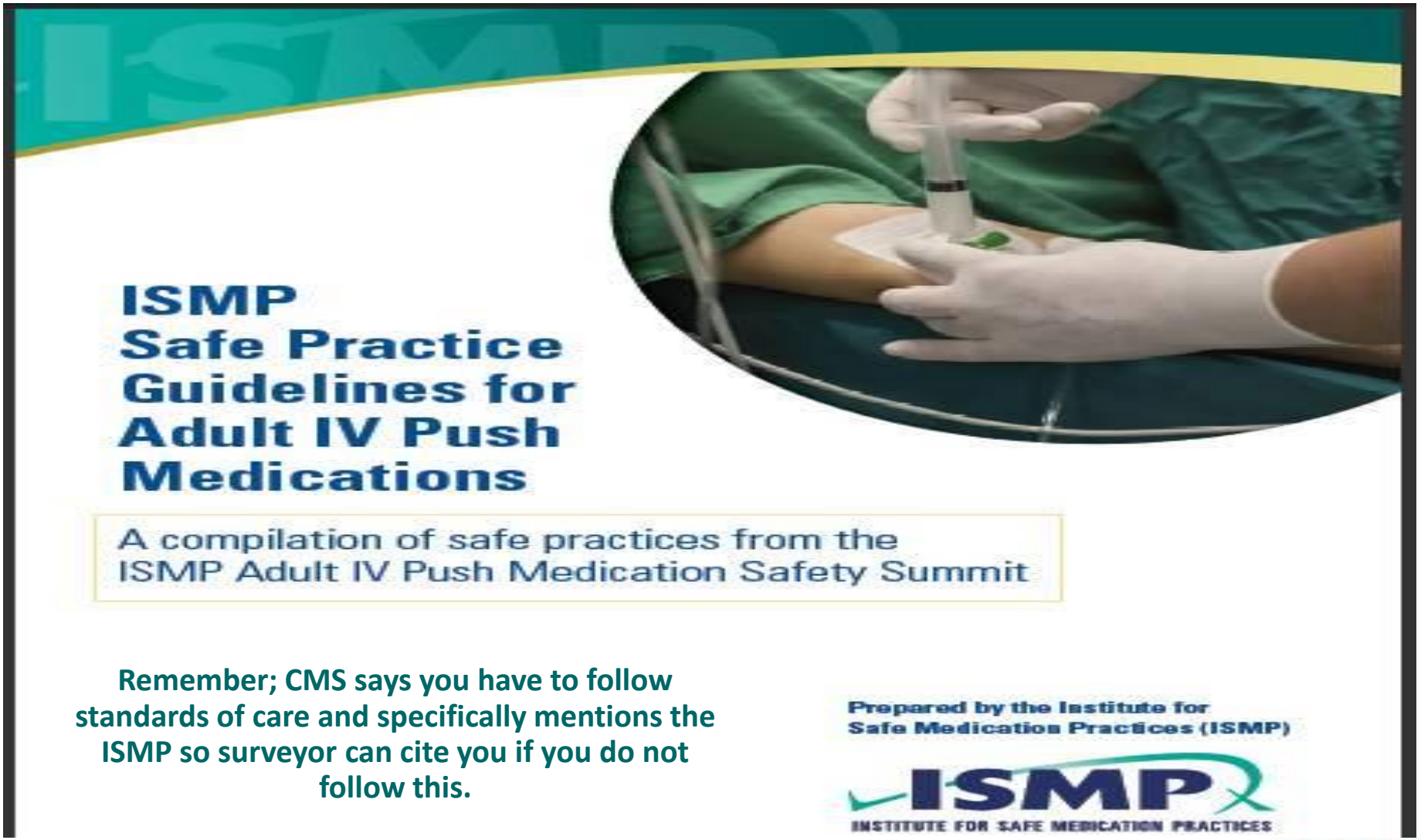
Survey – continued

- Verify if P&P address
  - Timing of administration
  - Medications eligible/not eligible for dosing times
  - Established total windows of time for administration
- Review records – per orders
- Observe preparation and administration
  - Confirm 5 Rights
  - Patients addressed and monitored
  - Staff aware of what to do with ADEs

Survey – continued

- Will interview staff
  - Understanding of policies on timeliness of administration
  - If able to identify time-critical and non-time critical
  - Identify medications not eligible for scheduled dosing times
  - Describe requirement for timing of time-critical and non-time critical

Don’t Forget IV Push Medicine Guidelines



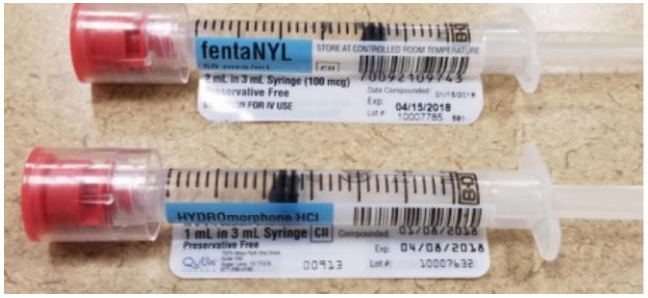
Remember; CMS says you have to follow standards of care and specifically mentions the ISMP so surveyor can cite you if you do not follow this.

Safe Injection Practices

- Must ensure staff follow SOP to prevent HAI related to medication preparation including CSP
  - Assessed under infection control section
- Compounded sterile preparations (CSP) can cause HAI if proper precautions not followed such as USP 797, USP 800 standards
  - Nurses may prepare sterile medication for immediate use
    - Need competency, P&P.

Compounding – Labeling

- Must label unless – prepare and immediately administer
- Label must include:
  - Patient identification
  - Name and amount of ingredients
  - Name or initial of person who prepared it
  - Exact one hour BUD



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Physician Order A406

- Orders must be documented and signed
  - By practitioner authorized to write orders
    - Per State law
    - Hospital policy
    - And is responsible for care of patient
- Can be documented signed by other practitioners if:
  - Acting in scope of practice
  - State law
  - P&P
  - MS bylaws/ R/R

Preprinted Order Sets

- Must date and time when the order set is signed
- Must indicate on last page the total number of pages in the order set – “page 3 of 3”
- To strike out something, delete or add order on blank line – physician needs to initial each place
  - Add this to the MR audit sheet to make sure there is compliance
- Standing orders must address well-defined clinical scenarios involving medication
- Refers to tag 457 and 450 for more information

Verbal Orders A407

- If used – are to be used infrequently
  - Patient safety issue – pose increased risk of miscommunication → medication error
- Only used
  - Meet care needs of patient
  - When impossible or impractical for ordering practitioner to write to order or enter it electronically
    - Surgeon scrubbed into surgery
    - Practitioner with a patient or driving into hospital
  - Never for practitioner convenience

Policies and Procedures

- Requirements:
  - Describe situations in which they can be used and limitations
    - Not for chemotherapy
  - Establish the identity and author of all orders
    - Regulation broadens category of practitioners who can sign orders off such as PA or NP
  - List the elements for a complete VO
    - Patient name – drug – dose – frequency – person giving and person taking order, etc.
  - Protocols for clear and effective communications and verification of verbal orders

Signing Off

- Follow any state law for time period to sign off such as 24 or 48 hours
  - Many hospitals **without** a state law can choose to have signed off but must be less than 30 days
  - Aim for **ASAP**
- Still sign name and date and time the order

Who Can Accept Verbal Orders A408

- Verbal orders must only be accepted
  - Persons authorized per policy
  - Consistent with Federal and State law
- Person taking VO must document it
  - Write it down and repeat it back
  - Any physician on the case can sign off any VO
  - Practice must be addressed in the hospital's P&P

Signing Off Verbal Orders A409

- Orders may be documented and signed off by other practitioners if:
  - Acting within State law
  - Scope of practice
  - Hospital policies
  - Medical staff bylaws, rules and regulations
- Exception – influenza and pneumococcal
- Same information as in Tag 406

Blood Transfusions and IVs 410 (2020)

- Standard: Blood transfusions and IV medications must be administered per state law and MS P&P
  - Previously - required special training and long list of items nurses had to be trained on
  - CMS eliminated mandating training for non-physicians who administer IV medication and blood and blood products
  - Training already standard practice – but must still be competent in those areas

Blood Transfusions

- Confirm correct patient
- Verify correct blood product
- Standard calls for two qualified persons, one who is administering the transfusion
  - TJC allows for 1 person with bar coding
- Document monitoring
- P&P – how frequent you monitor the patient and do vital signs
  - How to identify and treat and report any adverse transfusion reaction

Staff Competency - Evidence

- Blood transfusion:
  - Blood components
  - Administration policy
  - National standards of practice
  - Patient monitoring requirements including frequency
  - Documentation
  - Verifying correct blood and patient

Post-Operative Opioids

- Must be monitored vigilantly via serial assessments
- Must have P&P:
  - Process for assessment
  - Results of assessment
  - Monitoring frequency and duration
  - What monitored
  - Methods used to monitor

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Risk Factors in Patients Receiving Opioids

- Snoring
- History of sleep apnea
- No recent opioid use or first-time use of IV opioids
- Increased opioid dose requirement or opioid habituation
- Pre-existing pulmonary or cardiac disease
- Thoracic/ surgical incisions that may impair breathing
- Longer length of time receiving general anesthesia during surgery
- Receiving other sedating drugs:
  - Benzodiazepines
  - Antihistamines
  - Sedatives
  - Other CNS depressants

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*

Survey Procedures

- Will interview nursing staff who administer IV medications and blood
  - Venipuncture techniques
  - Safe medication practices
  - Maintaining fluid and electrolyte balance
  - Patient assessment, monitoring and intervention
  - Safe blood administration
  - Will compare P&P to observations of care delivery

Reporting Reactions and Errors 411 (2020)

- Must be procedure for reporting transfusion reactions, adverse drug reactions and errors in administration of drugs
- Survey procedure - request procedure for reporting
  - May review the incident reports or other documentation through QAPI program
  - Must have a hospital P&P for reporting transfusion reactions – such as an incident reporting system
  - See tag number 508 in pharmacy

ADE and Drug Administration 2020

- Mentions similar standard in pharmacy – tag A508
- Ensure all drug errors and ADE are reported
- Includes any blood transfusions AE
- Discusses symptoms of a transfusion reaction
- Need P&P for internal reporting of transfusion reactions – could be life threatening
- Must be immediately reported to the practitioner responsible for the patient's care and documented in the medical record and report to QAPI

BREAK

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Question 2

- We allow self-administration of medications with the following requirements – select all that apply
  - Only medications the patient has brought in
  - After assessment by nurses as to patient's ability to safely self-administer
  - Only under direct observation of a nurse
  - After education on use and required notice to the nurse after self-administration
  - We do not allow self-administration of medications

Self Administration of Medication A412

- Standard: Hospital may allow a patient or caregiver to self administer both hospital-issued medication and the medication the patient brought from home
  - As specified in the hospital P&P
  - PCA is considered a self-administered medication
- Add to the education of your nursing and pharmacy staff

Self Administration of Medication A412

- Must have an order
  - Must make sure patient is competent to do
  - Must educate the patient / care giver
- P&P must address security of medication for each patient
- Must document in the MR – patient must let nurse know when self-administered
- Visually inspect medication for integrity

OIG Report June 2019 Compounding and Outsourcing Facilities

Previous OIG Report – 2015

- Surveyor may review the contracts of the stand-alone compounding pharmacy
  - Includes surveyors from accrediting organizations
    - TJC, DNV, AOA (AAHHS) HFAP, and CIHQ
- Surveyors will likely be more aware of standards with additional training and more likely to discover if hospital is not doing safe compounding practices
  - Discussed the 64 deaths from the fungal meningitis case from NECC 2012
  - Made 55 recommendations on overseeing CSPs in hospitals

Pharmaceutical Services

Antibiotic Stewardship Program (ASP)

CMS Antimicrobial Stewardship Program

- Hospital required to develop and maintain ASP to improve prescribing and to reduce C-diff risk
- ASP must be active and hospital wide to prevent and control HAI and to optimize antibiotic use
- Program must demonstrate and adhere to nationally recognized standards to decrease antibiotic resistance
- Must use best practices related to antibiotic use
  - Specifically mentions SHEA, IDSA and CDC guidelines (APIC also important)

TJC Antibiotic Stewardship Program

- Standards effective January 1, 2017*
- Added new Medication Management standard
- MM.09.01.01
- TJC shows a commitment to
  - Slow the emergence of antibiotic resistance bacteria
  - Detect resistant strains
  - Prevent the spread of resistant infections
    - CDC says 20-50% of all antibiotics in the US are unnecessary

CDC Core Elements of an ASP

- Updated November 2019
- Provides examples of leadership commitment to the ASP
- Highlights the priority interventions and process measures
- Emphasizes the key role of the pharmacists and nurse in improving antibiotic use
- 85% of hospitals reported compliance with all 7 of the core elements in 2018
  - This was up 41% from 2014

Introduction

Antibiotics have transformed the practice of medicine, making once lethal infections readily treatable and making other medical advances, like cancer chemotherapy and organ transplants, possible. Prompt initiation of antibiotics to treat infections reduces morbidity and save lives, for example, in cases of sepsis (1). However, about 30% of all antibiotics prescribed in U.S. acute care hospitals are either unnecessary or suboptimal (2, 3).

www.cdc.gov/antibiotic-use/core-elements/hospital.html

The Core Elements of Hospital Antibiotic Stewardship Programs, 2019 [PDF – 40 pages]

Antibiotic Stewardship Program Assessment Tool (Print Only) [PDF – 8 pages]

What's New in the *Core Elements of Hospital Antibiotic Stewardship Programs, 2019* [Video – 5:24]

Hospital Pharmacy CoPs

References to USP

- USP 747 changes were to be implemented December 2019 but delayed
  - Also because of changes and additions such as USP 800 on hazardous medications
- CMS decided NOT to include in the manuals detailed requirements of the USP requirements

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References to USP

- Instead: requires compliance with
  - Federal and state law
  - Generally accepted standards of practice
  - Guidelines issued by nationally recognized professional organizations
- Avoids having to go back and change the manual every time there are USP changes

Pharmaceutical Services A489

- **Standard**: Hospital must have a pharmacy to meet the patient's needs and need to promote safe medication use process
- Must be directed by registered pharmacist or drug storage area under competent supervision
- Medical Staff (such as the MEC) is responsible for developing P&P to minimize drug error
- Function may be delegated to the pharmacy service

Meet Needs of the Patients A490

- **Standard:** The hospital must have pharmacy services that meet the needs of the patients
  - Includes providing medication related information to staff
- Scope and complexity of services is consistent with volume and types of patients served
- If reports of frequent delays – surveyor will talk further with the pharmacy director
- Surveyor will ask how hospital has determined that the services meet the needs of patients

P&P and Drug Storage A491

- **Standard:** The MS is responsible for developing P&P that minimize drug errors
  - This function can be delegated to the pharmacy
  - Many P&Ps required
- **Standard**: The pharmacy or drug storage area must be administered in accordance with accepted professional principles
  - TJC MM 03.01.01
  - A problematic CMS standard

Pharmacy Management A491

- Must ensure safe and appropriate
  - Procurement
  - Storage
  - Preparation
  - Dispensing
  - Use
  - Tracking
  - Control
  - Disposal of medications
    - Includes medication devices

Pharmacy Principles

- Includes compliance with
  - State laws – pharmacy laws
  - Federal regulations – USP 797, 795, USP 800 hazardous drugs, DEA
  - Standards by nationally recognized organizations
    - ASHP, FDA, NIH, USP, ISMP, etc.

USP 800 Hazardous Drugs in Hospitals

- Effective for hospitals effective December 2019
- Hospitals that handle drugs identified as hazardous or potentially hazardous by NIOSH
- Done to help protect healthcare workers
  - For more information: to www.usp.org/news/usp-publishes-standard-handling-hazardous-drugs-healthcare-settings
  - FAQ at www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings

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NIOSH Hazardous Drugs

- NIOSH reviewed 180 drugs that received new special warnings (usually black box warnings)
  - Found 26 added to the list
  - Removed 15 drugs that are no longer available in the ED
  - Published proposed list in 2018 but still waiting with 5 category system
- Updated in 2016
- 2020 proposed changes added 7 medications

P&P and Drug Storage

- May use unit dose, floor stock, individual prescriptions or a combination
- Hospitals with drug storage areas only must use pre-packaged drugs that require no further preparation
- MS (Medical Executive Committee) is responsible for P&Ps but can delegate it to pharmacy
- Hospital must review P&P periodically and revise
  - Date policy to show last review and
  - Include sources – CMS CoP – TJC standard

P&P and Drug Storage Requirements

- Must train staff on P&Ps
- Must monitor to ensure P&Ps are being followed
- P&Ps for Minimizing Drug Errors
  - Need to take steps to prevent, identify, and minimize drug errors
  - This includes ensuring that the pharmacy process conforms to accepted standards of pharmacy practice
  - Proactively identify and review Adverse Drug Events
  - Be aware of external alerts to real/potential pharmacy-related problems in the hospital

P&Ps for Minimizing Drug Errors

- Many organization issues sentinel event alerts or alerts
  - Such as Joint Commission, ISMP, FDA, IHI, AHRQ, Med Watch, NCCMER, PaPSA, etc.
  - If medication management committee can assign each to one of the members to report at monthly meeting
- Has a list of policies that are expected to be addressed

High Alert Medications

- LASA meds
- Meds with narrow therapeutic range (Warfarin)
- Psychotherapeutic medications
- Ways to minimize errors
  - Dosing limits
  - Packaging
  - Guidelines
  - Labeling and storage (TJC MM.01.01.03)
  - ISMP/USP have lists

High Alert How to Guide IHI

v03
10/01/2008

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

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Required Policies and Procedures

- Must follow standards of practice for all compounding, packaging, dispensing, and drug disposal
  - ASHP has sterile compounding resource center*
- P&P to ensure investigational meds are safely controlled and administered
  - Written process to approve, review, supervise, and monitor investigational drugs
  - Pharmacy must control storage, dispensing, and labeling

Required Policies and Procedures – continued

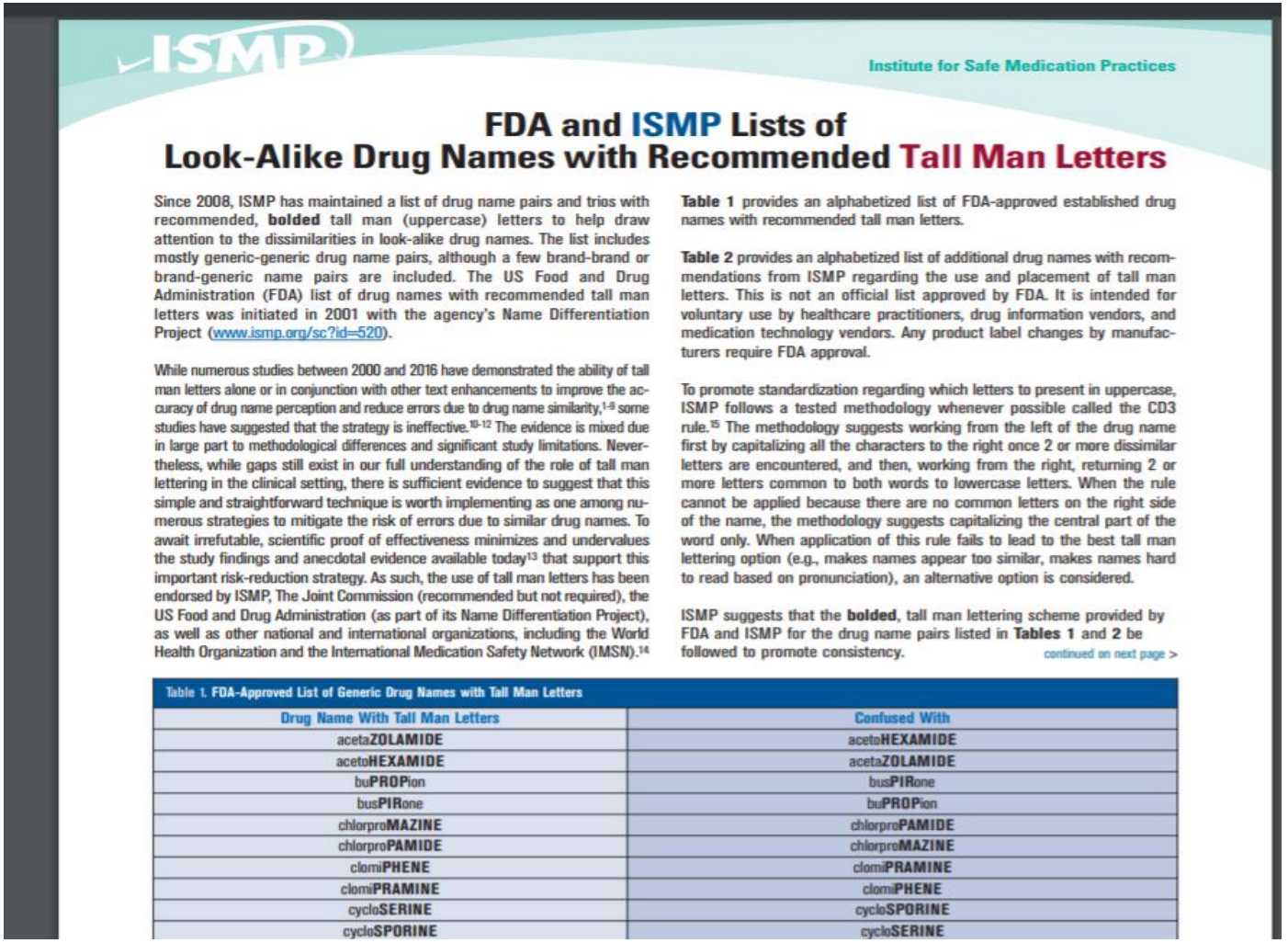
- Standardize equipment and medication related devices
  - Limit general-purpose infusion pumps to one or two
- Availability of up-to-date medication information
- Pharmacist on call if not open 24 hours
- “Resume previous orders” prohibited
- Patient specific information that should be readily available
  - TJC specifies

Standardize Rx & Communication Practices 491

- Avoid dangerous abbreviations (TJC IM.02.02.01)
- All elements of order: dose, strength, route, units, rate, frequency
- Alert system for sound alike/look alike
  - TJC standard MM.04.01.01 and NPSG.03.03.01
  - USP has website to check LASA drugs
- Use of facility approved pre-printed order sheets whenever possible

FDA and ISMP List Look-Alike Drug Names

- https://www.ismp.org/sites/default/files/attachments/2017-11/tallmanletters.pdf



ISMP

Institute for Safe Medication Practices

FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man Letters

Since 2008, ISMP has maintained a list of drug name pairs and trios with recommended, **bolded** tall man (uppercase) letters to help draw attention to the dissimilarities in look-alike drug names. The list includes mostly generic-generic drug name pairs, although a few brand-brand or brand-generic name pairs are included. The US Food and Drug Administration (FDA) list of drug names with recommended tall man letters was initiated in 2001 with the agency's Name Differentiation Project (www.ismp.org/sc?id=520).

While numerous studies between 2000 and 2016 have demonstrated the ability of tall man letters alone or in conjunction with other text enhancements to improve the accuracy of drug name perception and reduce errors due to drug name similarity,[1-9] some studies have suggested that the strategy is ineffective.[10-12] The evidence is mixed due in large part to methodological differences and significant study limitations. Nevertheless, while gaps still exist in our full understanding of the role of tall man lettering in the clinical setting, there is sufficient evidence to suggest that this simple and straightforward technique is worth implementing as one among numerous strategies to mitigate the risk of errors due to similar drug names. To await irrefutable, scientific proof of effectiveness minimizes and undervalues the study findings and anecdotal evidence available today[13] that support this important risk-reduction strategy. As such, the use of tall man letters has been endorsed by ISMP, The Joint Commission (recommended but not required), the US Food and Drug Administration (as part of its Name Differentiation Project), as well as other national and international organizations, including the World Health Organization and the International Medication Safety Network (IMSN).[14]

Table 1 provides an alphabetized list of FDA-approved established drug names with recommended tall man letters.

Table 2 provides an alphabetized list of additional drug names with recommendations from ISMP regarding the use and placement of tall man letters. This is not an official list approved by FDA. It is intended for voluntary use by healthcare practitioners, drug information vendors, and medication technology vendors. Any product label changes by manufacturers require FDA approval.

To promote standardization regarding which letters to present in uppercase, ISMP follows a tested methodology whenever possible called the CD3 rule.[15] The methodology suggests working from the left of the drug name first by capitalizing all the characters to the right once 2 or more dissimilar letters are encountered, and then, working from the right, returning 2 or more letters common to both words to lowercase letters. When the rule cannot be applied because there are no common letters on the right side of the name, the methodology suggests capitalizing the central part of the word only. When application of this rule fails to lead to the best tall man lettering option (e.g., makes names appear too similar, makes names hard to read based on pronunciation), an alternative option is considered.

ISMP suggests that the **bolded**, tall man lettering scheme provided by FDA and ISMP for the drug name pairs listed in **Tables 1** and **2** be followed to promote consistency.

continued on next page >

Table 1. FDA-Approved List of Generic Drug Names with Tall Man Letters

Drug Name With Tall Man Letters	Confused With
aceta**ZOLAMIDE**	aceto**HEXAMIDE**
aceto**HEXAMIDE**	aceta**ZOLAMIDE**
bu**PROP**ion	bus**PIR**one
bus**PIR**one	bu**PROP**ion
chlorpro**MAZINE**	chlorpro**PAMIDE**
chlorpro**PAMIDE**	chlorpro**MAZINE**
clomi**PHENE**	clomi**PRAMINE**
clomi**PRAMINE**	clomi**PHENE**
cyclo**SERINE**	cyclo**SPORINE**
cyclo**SPORINE**	cyclo**SERINE**

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ISMP's List of *Confused* Drug Names

This list of confused drug names, which includes look-alike and sound-alike name pairs, consists of those name pairs that have been published in the *ISMP Medication Safety Alert!*® and the *ISMP Medication Safety Alert!*® Community/Ambulatory Care Edition. Events involving these medications were reported to ISMP through either the ISMP National Medication Errors Reporting Program (ISMP MERP) or ISMP National Vaccine Errors Reporting Program (ISMP VERP). We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as: using both the brand and generic names on prescriptions and labels; including the purpose of the medication on prescriptions; configuring computer selection screens to prevent look-alike names from appearing consecutively; and changing the appearance of look-alike product names to draw attention to their dissimilarities. Both the FDA-approved and the ISMP-recommended tall man (mixed case) letters have been included in the list below.

Updated February 2015

Drug Name	Confused Drug Name
Abelcet	amphotericin B
Accupril	Aciphex
aceta**ZOLAMIDE**	aceto**HEXAMIDE**
acetic acid for irrigation	glacial acetic acid
aceto**HEXAMIDE**	aceta**ZOLAMIDE**
Aciphex	Accupril
Aciphex	Aricept
Activase	Cathflo Activase
Activase	TNKase
Actonel	Actos
Actos	Actonel
Adacel (Tdap)	Daptacel (DTaP)
Adderall	Inderal
Adderall	Adderall XR
Adderall XR	Adderall
ado-trastuzumab emtansine	trastuzumab
Advair	Advicor
Advicor	Advair
Advicor	Altocor
Afrin (oxymetazoline)	Afrin (saline)
Afrin (saline)	Afrin (oxymetazoline)
Aggrastat	argatroban
Aldara	Alora
Alkeran	Leukeran
Alkeran	Myleran
Allegra (fexofenadine)	Allegra Anti-Itch Cream (diphenhydr**AMINE**/allantoin)
Allegra	Viagra

Drug Name	Confused Drug Name
Amikin	Kineret
a**MIL**oride	am**LODIP**ine
amiodarone	amantadine
am**LODIP**ine	a**MIL**oride
amphotericin B	Abelcet
amphotericin B	Ambisome
Anacin	Anacin-3
Anacin-3	Anacin
antacid	Atacand
Anticoagulant Citrate Dextrose Solution Formula A	Anticoagulant Sodium Citrate Solution
Anticoagulant Sodium Citrate Solution	Anticoagulant Citrate Dextrose Solution Formula A
Antivert	Axert
Anzemet	Avandamet
Apidra	Spiriva
Apresoline	Priscoline
argatroban	Aggrastat
argatroban	Orgaran
Aricept	Aciphex
Aricept	Azilect
ARIPiprazole	proton pump inhibitors
ARIPiprazole	**RABE**prazole
Arista AH (absorbable hemostatic agent)	Arixtra
Arixtra	Arista AH (absorbable hemostatic agent)
Asacol	Os-Cal
Atacand	antacid
atomoxetine	atorvastatin
atorvastatin	atomoxetine

QAPI and Reporting of Events

- Integrated into the hospital wide QAPI
  - Flag new types of mistakes and
  - Continue to improve P&Ps as well as analyze errors and ADEs
    - RCA (systematic analysis) and FMEA are two tools
- Voluntary, non-punitive reporting system to monitor and report adverse drug events
  - System analysis theory – most errors are a system problem and not due to bad practitioner
  - Many hospitals balance with Just Culture
  - TJC has the same standard

Alerts and Recalls

- Monitor drug alerts and recalls
- Incorporate external alerts and recommendations from national associations and governmental agencies
  - Need to revise policies
  - CMS says hospital should consider ISMP, NCCMERP, FDA, and MedWatch Program
- FDA – list of drug recalls and can sign up to receive alerts
- ASHP – resources on drug shortages and guidelines

Weight-Based Dosing

- Identification of weight-based dosing for pediatric populations
  - May also require weights for elderly patients in renal failure on antibiotics
  - Weigh babies in grams
  - Weigh children in kg and not pounds or both
  - Weight based charts may help prevent medication errors in high-risk medications

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

Pharmacist A492

- **Standard:** Must have pharmacy directed by a registered pharmacist or a drug storage under competent supervision
  - If has drug storage area instead of pharmacy still need to be under the direction of the pharmacist
- **Standard**: Must have pharmacist to develop, supervise, and coordinate activities of pharmacy
  - Can be part time, full time or consulting
  - Must have documented training or expertise in hospital pharmacy practice and management

Pharmacy Director

- Need written criteria for qualifications of the pharmacy director in accordance with scope of service
  - Include responsible for supervision and coordination of all pharmacy services
  - Can be via regular visits or telecommunications
  - Include active leadership of committees responsible for medication P&Ps
- Some small hospitals may not have a pharmacy
  - Use a drug storage area for dispensing pre-packaged drugs

Pharmacy Staff A493

- **Standard:** Must have adequate number of pharmacy staff to ensure quality pharmaceutical services
  - Include emergency services
- Enough to meet the needs of the patient
- Must have sufficient staff in types, numbers, and training 24/7
- Must have enough staff based on the scope and complexity of the hospital's pharmaceutical services
- Must participate in QAPI program

Question 3

- Our internal controls provide thorough tracking of all medications including controlled/scheduled medications.
  - Yes
  - No
  - Prefer not to answer

Pharmacy Records A494

- **Standard:** Keep accurate records of receipt and disposition of all scheduled drugs
  - Records must be current and accurate
  - Must trace movement of scheduled drugs throughout the service
  - Pharmacist must make sure records are reconciled
  - Need policy to minimize drug diversion

Pharmacy Delivery of Service A500 2020

- **Standard:** Drugs and biologicals must be controlled and distributed in accordance with federal and state law and standards of practice
  - To prevent unauthorized use and distribution of medications
- To provide for an accounting of the receipt and distribution of drugs
  - Drugs subject to the Comprehensive Drug Abuse and Control Act of 1970
  - Law requires physical security of medications and strict record keeping for certain types of drugs such as controlled substances

First Dose Rule

- All medication orders must be reviewed by a pharmacist before the **first dose** is dispensed
  - Review of therapeutic appropriateness of medication regime
  - Therapeutic duplication
  - Appropriateness of drug, dose, frequency, route and method of administration
  - Real or potential med-med, med-food, med-lab test, and med-disease interactions
  - Allergies or sensitivities and variation from organizational criteria for use

Monitoring Effects of Medication

- Must monitor medication effects as per policy to minimize ADE
  - Usually with anticoagulants and antibiotics
- May request a pharmacy to dose order
- Monitoring may include:
  - Clinical or lab data to evaluate dose, toxicity, or ADE
  - Physical signs and clinical symptoms
  - Assess patient's own perceptions about side effects
  - References nursing standards on monitoring of patients

Compounding of Drugs A501 (2020)

- **Standard:** All compounding, packaging, and disposal of drugs and biologicals must be under the supervision of pharmacist
  - Must be performed as required by state or federal law
- Must have P&P to ensure all drugs are prepared by authorized staff
- Medications that need to be reconstituted or mixed are considered compounded preparations

Compounding of Drugs

- Compounded by pharmacy
- By manufacturer, registered outsourcing facility or compounding pharmacies
- Must meet standards for safe compounding to prevent contamination
- Drug Quality and Security Act (DQSA) has sections related to compounding
  - Provides for oversight of compounding of drugs
- Under Section 503B a compounder can become an outsourcing facility

Compounding and Federal Law

- Outsourcing facility is at one location or address and is engaged in the compounding of human drugs
- Must register as one and
  - Comply with requirements
  - Be inspected by the FDA
  - Provide adverse event information

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Non-Registered Outsourcing Facilities

- Compounding pharmacies not registered as outsourcing facilities are called 503A pharmacies
  - These pharmacies are generally subject to oversight by the State Pharmacy board
- If hospital gets compounded medications from compounding pharmacy and not the manufacturer or a registered compounding pharmacy
  - Hospital must demonstrate that compounded medicines have been prepared in accordance with SOC

Medication Compounded by Hospital

- Only the pharmacy compounds or mixes all sterile medications, IV mixtures or other drugs
  - Except in an emergency or immediate administration
- Must be performed consistent with standards of safe practice
  - Sterile and non-sterile compounding

Compounded by Hospital

- Compounded medication can result in contamination and unintended variations in strength
- Microbial contamination and bacterial endotoxins can be hazardous to patients
  - CMS removed much of this section regarding compounding
- CMS does not mention USP – hospitals need to follow standards of care and practice which include USP

Locked Storage Areas A502 & A503

- **Standard:** Drugs and biologicals must be kept in a secure and locked area (502)
- **Standard:** Schedule II-V drugs must be kept locked in secure area (503)
  - Considered a secure area if staff actively providing care
  - Only authorized person can get access to locked areas
- P&P address self administration of drugs
  - See tag 406 (drugs and biologicals) and 412 and 413 also (self administered drugs) in nursing section

Locked Storage Areas

- If medication cart is in use and unlocked
  - Someone with legal access must be close by
  - Direct monitoring of the cart
    - Nurse is passing meds otherwise locked and in secure area
- Need policy for safeguarding, transferring and availability of keys

Outdated or Mislabeled Drugs A505 (2020)

- **Standard**: Outdated, mislabeled or otherwise unusable drugs and biologicals must not be available for patient use
- Hospital has a system to prevent outdated or mislabeled drugs being available for use
  - Include drugs subject of a recall
- Drug can become unusable prior to expiration date
  - If subject to conditions inconsistent with manufacturer's labeling

No Pharmacist on Duty A506

- If no pharmacist on duty
  - Drugs must be removed from storage area
  - Only by personnel designated in policies of MS and pharmacy service
  - Per state and federal law

Minimized and Eliminated Access

- Routine access to pharmacy by non-pharmacist for access should be minimized and eliminated as much as possible
  - E.g., night cabinet for use by nurse supervisor
  - Need process to get meds to patient if urgent or emergent need
  - TJC does not allow nurse supervisor in pharmacy so would need to call the on-call pharmacist

Automatic Stop Orders A507

- Standard: Drugs not specifically prescribed as to time and number must automatically be stopped
  - After a reasonable time
  - Commonly known as automatic stop orders
- Requirements:
  - Must follow acceptable SOP
  - MS & pharmacy services determine automatic stop orders
  - Hospital must monitor and enforce
  - EHR can have dose time parameters built into CPOE screens

Errors, Reactions & Incompatibilites A508

- **Standard:** Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending/designee physician
  - If appropriate also to the QAPI program
- Hospitals are required to ensure attending/designee made immediately aware:
  - Medication errors or drug errors
  - Adverse drug reactions (ADRs)
  - Drug incompatibilities (DI)

Errors, ADRs, Incompatibilities

- Hospital staff are expected to use their best clinical judgment in determining whether immediate reporting is required
  - Based on patient's presentation and assessment
  - Must be done in accordance with the hospital P&P
- QAPI program must track and report medication errors and near misses
  - Must also track suspected ADRs
  - To determine system errors and prevent future errors

Hospital Policies & Procedures

- Hospital must establish P&P
  - Reporting medication errors, ADRs, and incompatibilities
- Hospital:
  - Must ensure staff aware of the reporting requirements
  - Should add this information to orientation for new employees
  - Hospital should consider periodic education

Medication Error Reporting

- Reporting is not limited to
  - The Food and Drug Administration's (FDA) MedWatch program
    - http://www.fda.gov/Safety/MedWatch/default.htm
  - The Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program (USP-ISMP MERP)
    - https://www.ismp.org/orderforms/reporterrortoismp.asp
  - Any reports required by any specific state law requirement

Question 4

- Our policies and procedures include steps to be taken when there is a question or concern with diversion.
  - Yes
  - No
  - Not sure

Abuses and Losses A509

- **Standard:** Abuses and losses of controlled substances must be reported pharmacist and CEO and in accordance with any state or federal laws
- Surveyor
  - Interview pharmacist to determine their understanding of controlled substances policies
  - The procedure for discovering drug discrepancies
- Remember state board of pharmacy rules on abuses and losses

Information Available to Staff A510

- **Standard:** Information must be available to staff
  - Drug interaction, side effects, toxicology, doses, indication for use and routes of administration
- Pharmacy
  - Must be a resource for medication related information to optimize outcomes
  - May assist staff with following medication related functions
    - Collect specific information such as allergies, height, and weight
    - Pharmacy therapeutic goals

Pharmacy Can Help Staff

- Identify any problems such as drug-drug interactions or excessive doses
- Monitor and adjust dose based on lab values such as Warfarin dosing
- Monitor the plan as needed
- Practitioner may write pharmacy to dose and would calculate dose required
- CPOE may have build in functions for dosing & interactions
  - Pharmacy responsible for accurate up to date information

Information Available to Staff

- Have current resources – electronic or hard copy
- Pharmacist needs to be readily available by phone
  - Respond to questions from nursing and other practitioners
- Surveyors will:
  - Ask staff if needed reference material is available to them
  - Ask nursing staff if reference material available when monitoring patients for medication therapies

Formulary A511

- **Standard:** Formulary system must be established by the MS to ensure quality pharmaceuticals at reasonable cost
- Formulary lists the drugs available
- Processes
  - To monitor patient responses to newly added medication
  - To approve and procure meds not on the list
  - To address shortages and outages including
    - Communication with staff
    - Approving substitution and educating everyone
    - How to obtain medications in a disaster

Discussion

- Hospital C's director of pharmacy noticed irregular – multiple – wastage of Morphine in the CCU. The waste usually occurs on the 6pm – 6am shift and involves one nurse per the medication log. The pharmacist shared her concerns with the unit charge nurse and hospital risk manager. Morphine is stored in a double-locked system and 2 persons are required when controlled substances need "wasting". There is no video monitoring of the narcotic drawer. The nurse in question had been observed sleeping during work hours.
- What should or needs to be the next step.

Speaker

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- MPH, BSN, RN
- Senior Consultant
- 978-880-0095

- Email questions to CMS:
- Critical Access Hospitals:
  - qsog_CAH@cms.hhs.gov
- Acute hospitals:
  - qsog_hospital@cms.hhs.gov

Email: Nashhealthcareconsulting.com/contact-us

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APPENDIX

Resources and Internet Links

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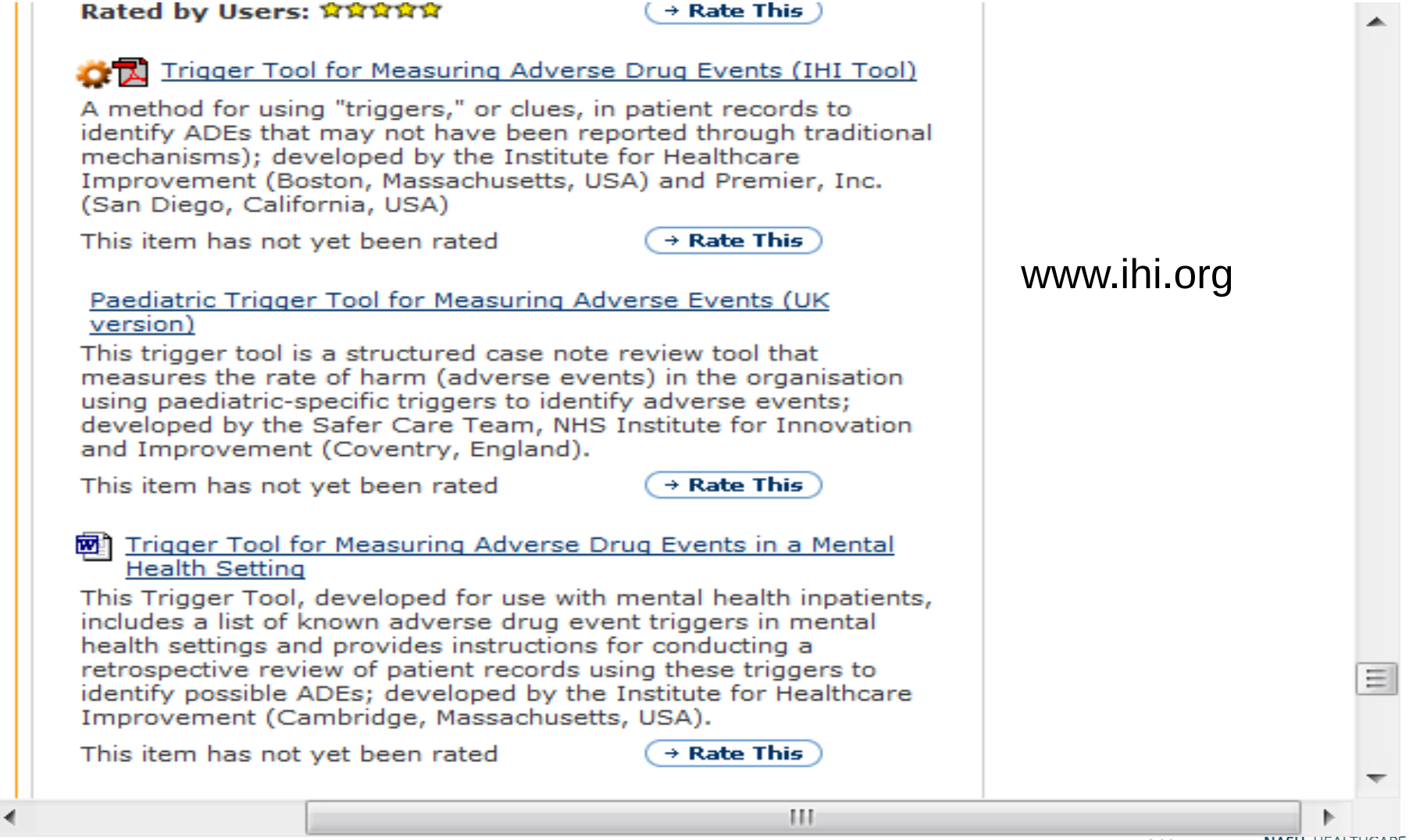
Worksheet Links

- Infection Control:
- https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-15-12-attachment-1.pdf.
- Discharge Planning:
- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-3.pdf.
- QAPI:
- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-2.pdf.

IHI Has Three Trigger Tools for ADEs



www.ihi.org

New Tag Numbers

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/Quality, Safety & Oversight Group

Ref: QSO-20-07-ALL

DATE: **December 20, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Burden Reduction and Discharge Planning Final Rules Guidance and Process

Site: shorturl.at/ryV78

Memorandum Summary

- On September 30, 2019, the Centers for Medicare & Medicaid Services (CMS) published the *Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction* Final Rule, as well as the *Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies* Final Rule.
- This policy memorandum provides guidance to the CMS Regional Offices (ROs), the State Survey Agencies (SAs) and the Accrediting Organizations (AOs) regarding the changes to the regulations and our approach for updating the State Operations Manual (SOM) and applicable surveyor systems.

Background

On September 30, 2019, CMS published two final rules which revised regulatory requirements for the various certified provider and supplier types.

The two final rules are as follows:

NASH HEALTHCARE CONSULTING

Hospital Improvement New Law 393 Pages

This document is scheduled to be published in the Federal Register on 09/30/2019 and available online at **https://federalregister.gov/d/2019-20736**, and on **govinfo.gov**

https://federalregister.gov/d/2019-20736,

[Billing Code: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 488, 491, and 494

[CMS-3346-F; CMS-3334-F; CMS-3295-F]

RIN 0938-AT23

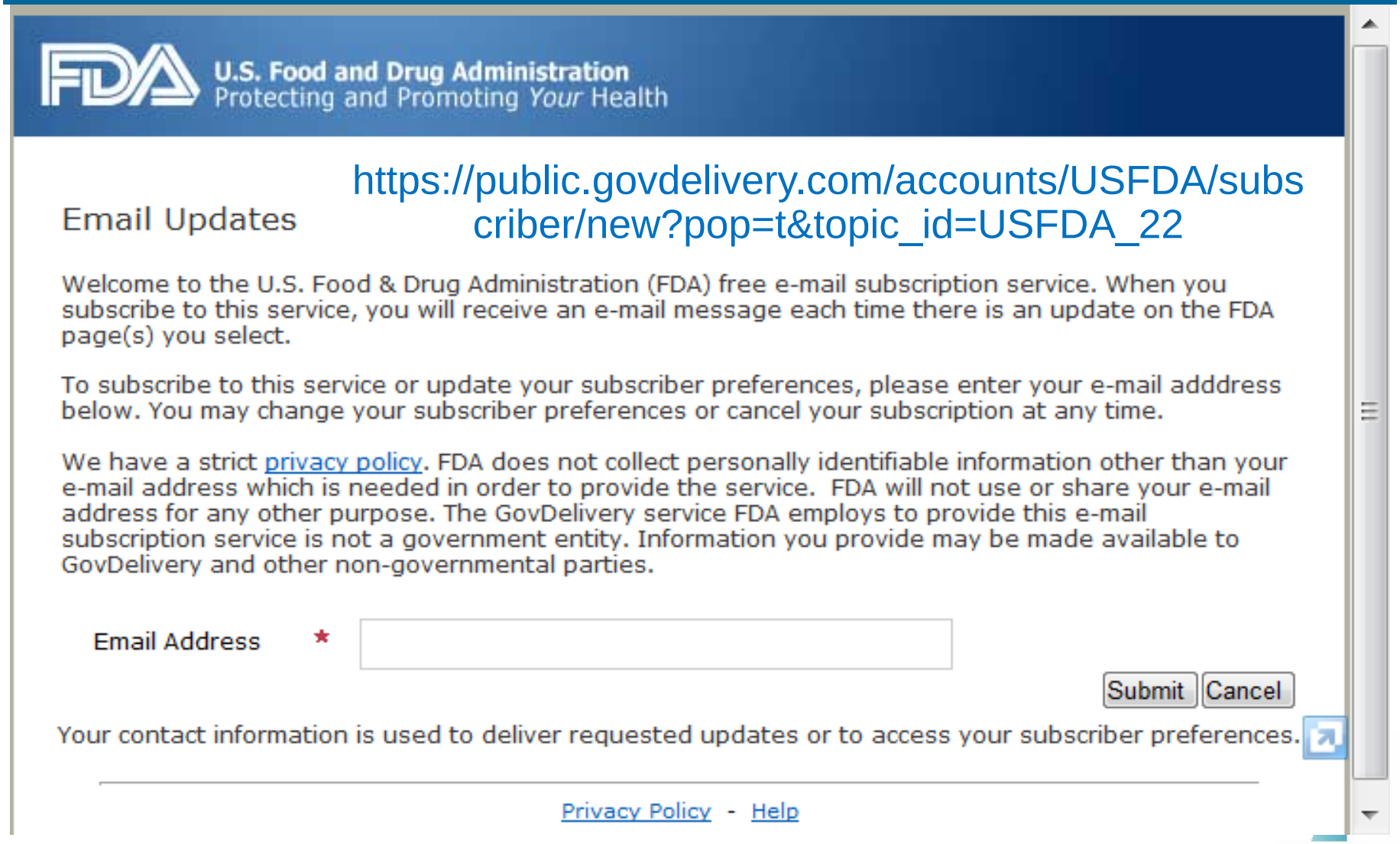
Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule reforms Medicare regulations that are identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. This final rule also

Sign Up To Get Drug Shortage Information



Standards of Practice

Accepted Standards of Practice

Hospital policies and procedures for the preparation and administration of all drugs and biologicals must not only comply with all applicable Federal and State laws, but also must be consistent with accepted standards of practice based on guidelines or recommendations issued by nationally recognized organizations with expertise in medication preparation and administration. Examples of such organizations include, but are not limited to:

- American Society of Health-System Pharmacists (http://www.ashp.org/default.aspx)
- Infusion Nurses Society (http://www.ins1.org)
- Institute for Safe Medication Practices (www.ismp.org)
- National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org)
- U.S Pharmacopeia (www.usp.org)

ISMP Institute for Safe Medication Practices

/www.ismp.org

Upcoming Events

ISMP Medication Safety Guidelines cover a variety of topics, including the safe use of technology, specific high-alert medications, and treating high-risk patient populations.

Most guidelines are driven by multi-disciplinary summits that include a review of the literature, assessment of reported errors, and input from experts. Final statements are developed by consensus decision making.

Best Practices for Hospitals

Guidelines for Safe Insulin Use

Infusion Nurses Society INS

www.ins1.org

Common Sources for Determining BUD

https://pharmlabs.unc.edu/labs/prescriptions/beyond.htm

Step 3. If the manufacturer cannot assist in assigning a beyond use date, the next step is to obtain published stability information from reference books or the primary literature. Direct extrapolation of the information to the specific compounded formulation requires that the scientific study data utilize the same drug source, the same drug concentration, and the same compounding procedures, stores the formulation in the same container, and has subjected the formulation to the same anticipated environmental variables.

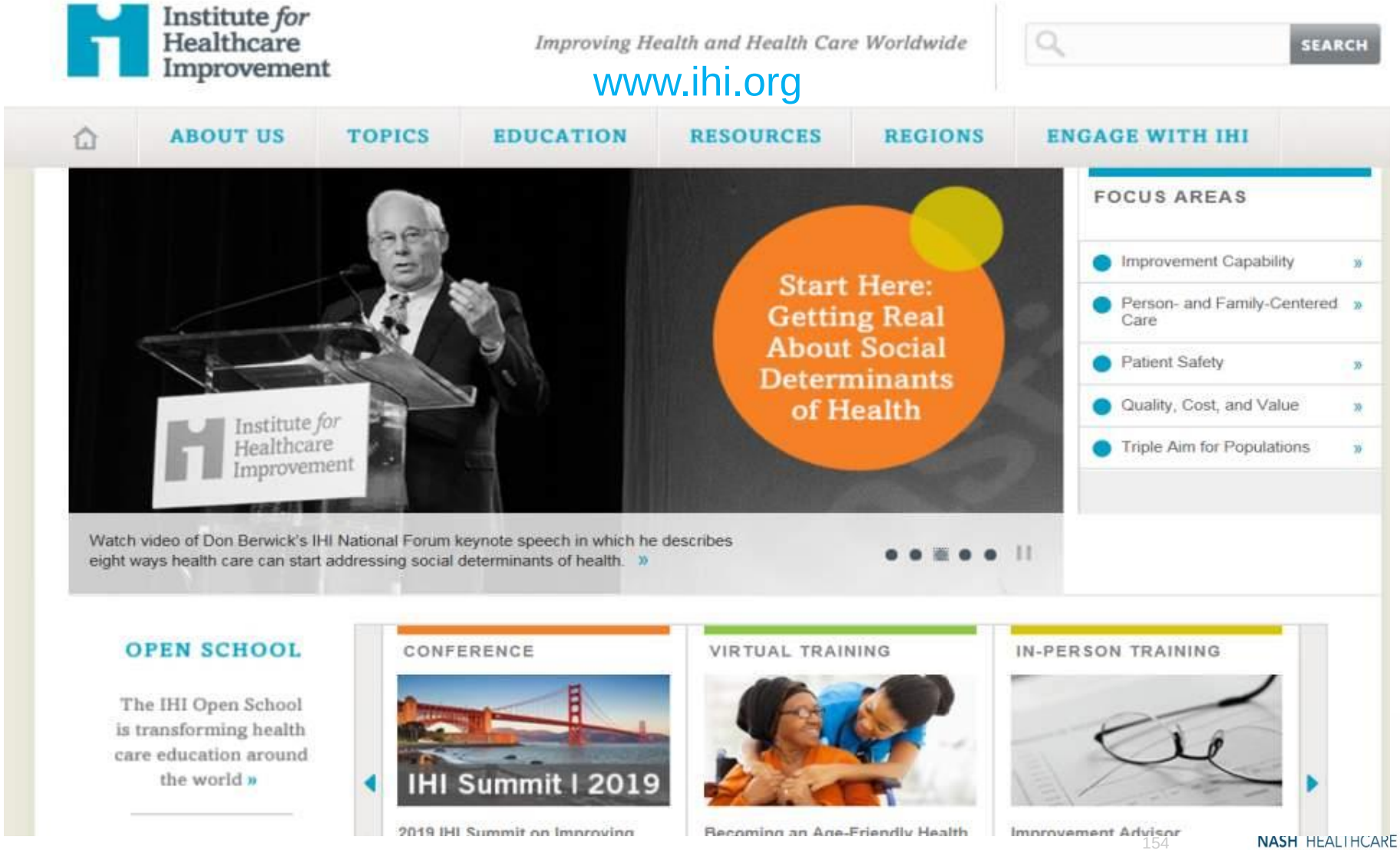
A growing number of reference sources contain stability information, and the pharmacist should have ready access to this material. Some of the more common resources are:

- Trissel's Stability of Compounded Formulations
- Trissel's Handbook of Injectable Drugs
- AHFS Drug Information
- United States Pharmacopeia
- Remington: The Science and Practice of Pharmacy
- USP Dispensing Information
- Journal of Pharmaceutical Sciences
- American Journal of Health-System Pharmacy
- International Journal of Pharmaceutical Compounding

National Coordinating Council

NASH HEALTHCARE CONSULTING

Institute for Healthcare Improvement IHI



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Centers for Disease Control & Prevention CDC

NASH HEALTHCARE CONSULTING

Patient Safety Movement Foundation

Patient Safety MOVEMENT

ACTIONABLE SOLUTIONS | OUR NETWORK | ADVOCACY | NEWS | RESOURCES | EVENTS | LEAD US TO ZERO

https://patientsafetymovement.org

The Problem

Medical Errors

The World's 14th Leading Cause of Death

Medical errors in hospitals are the third leading cause of death in the United States, just behind heart disease and cancer. Globally it is believed that medical errors kill more people than HIV, Malaria, and Tuberculosis, combined.

The Goal

ZERO Preventable Deaths

ZERO is not just a number – it's our mission

The Patient Safety Movement Foundation believes reaching ZERO preventable deaths in hospitals is not only the right goal, but an attainable one with the right people, ideas, and technology.

NASH HEALTHCARE CONSULTING

Patient Safety Challenges

Hospitals are facing the following challenges daily, but there is hope! We have created solutions to address these challenges. When implemented, hospitals can achieve ZERO preventable deaths.

Culture of Safety

Healthcare-associated Infections (HAIs)

Medication Safety

Monitoring for Opioid-induced Respiratory Depression

Patient Blood Management

Hand-off Communications

Neonatal Safety

Airway Safety

OIG Report on Oversight of Hospital Pharmacies

OFFICE OF
INSPECTOR GENERAL

http://oig.hhs.gov/oei/reports/oei-01-13-00400.pdf

MEDICARE'S OVERSIGHT OF COMPOUNDED PHARMACEUTICALS USED IN HOSPITALS

Daniel R. Levinson
Inspector General

Hospital Improvement Rule

This document is scheduled to be published in the Federal Register on 09/30/2019 and available online at **https://federalregister.gov/d/2019-20736**, and on **govinfo.gov**

[Billing Code: 4120-01-P]

https://federalregister.gov/d/2019-20736 and 393 Pages

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 488, 491, and 494

[CMS-3346-F; CMS-3334-F; CMS-3295-F]

RIN 0938-AT23

Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule reforms Medicare regulations that are identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. This final rule also

Viruses or Bacteria
What's got you sick?

Antibiotics only treat bacterial infections. Viral illnesses cannot be treated with antibiotics. When an antibiotic is not prescribed, ask your healthcare professional for tips on how to relieve symptoms and feel better.

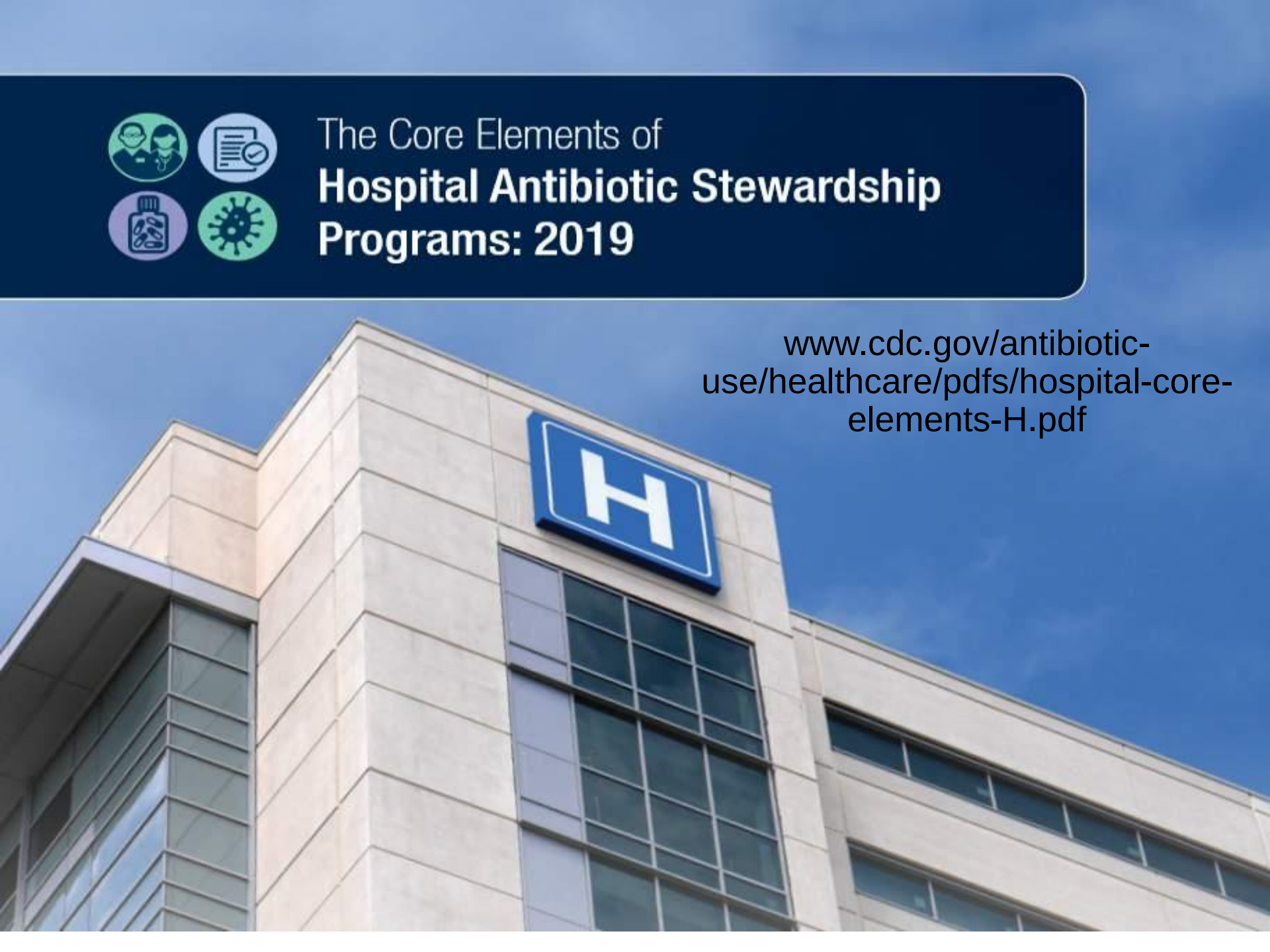
Illness	Usual Cause		Antibiotic Needed
	Viruses	Bacteria	
Cold/Runny Nose	✓		NO
Bronchitis/Chest Cold (in otherwise healthy children and adults)	✓		NO
Whooping Cough		✓	Yes
Flu	✓		NO
Strep Throat		✓	Yes
Sore Throat (except strep)	✓		NO
Fluid in the Middle Ear (otitis media With effusion)	✓		NO
Urinary Tract Infection		✓	Yes

Antibiotics Aren't Always the Answer

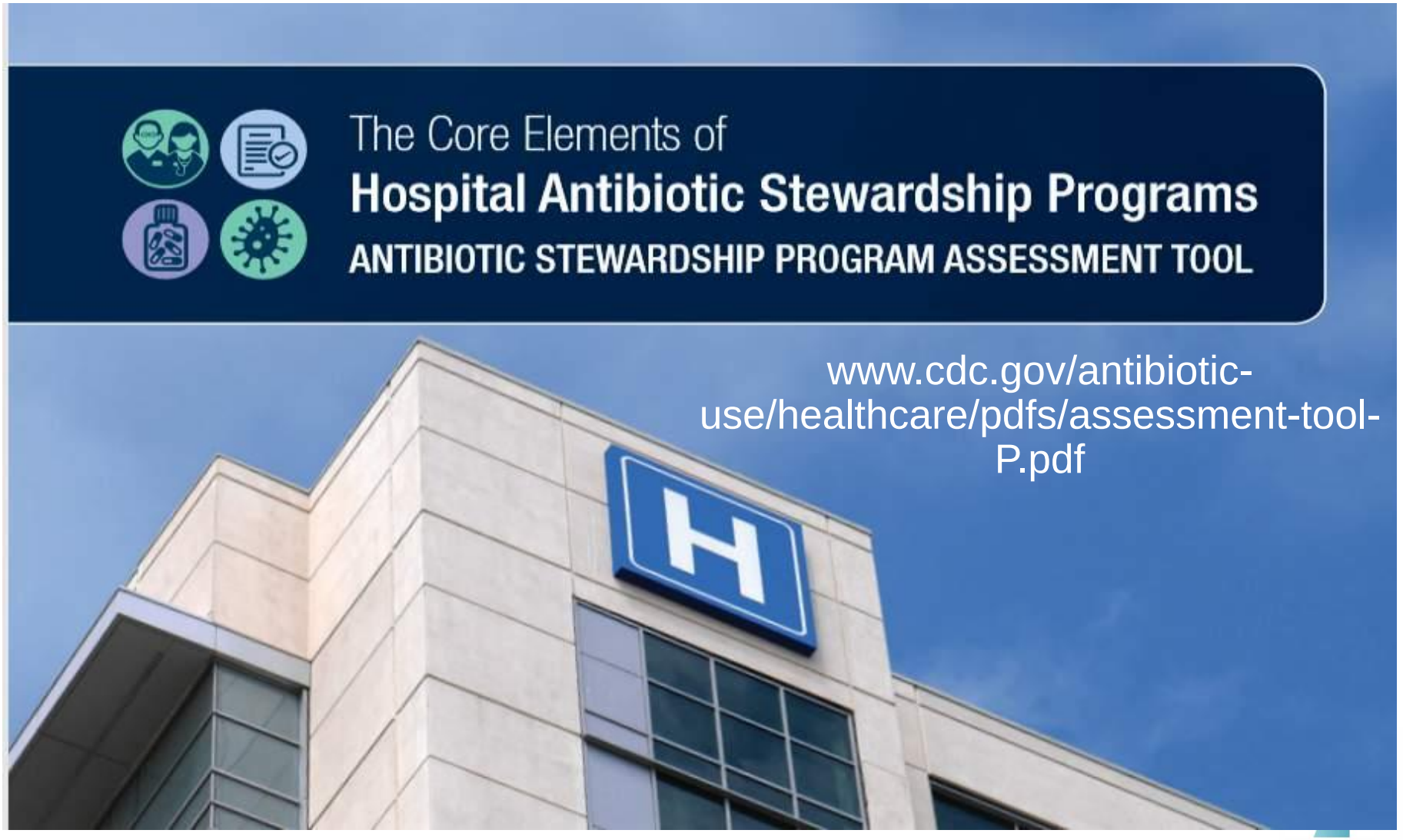
www.cdc.gov/getsmart

GET SMART
Know When Antibiotics Work

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention


The Core Elements of
Hospital Antibiotic Stewardship Programs: 2019
www.cdc.gov/antibiotic-use/healthcare/pdfs/hospital-core-elements-H.pdf

Has a Program Assessment Tool



CDC Outpatient Core Elements

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 65 / No. 6
November 11, 2016

http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6506.pdf

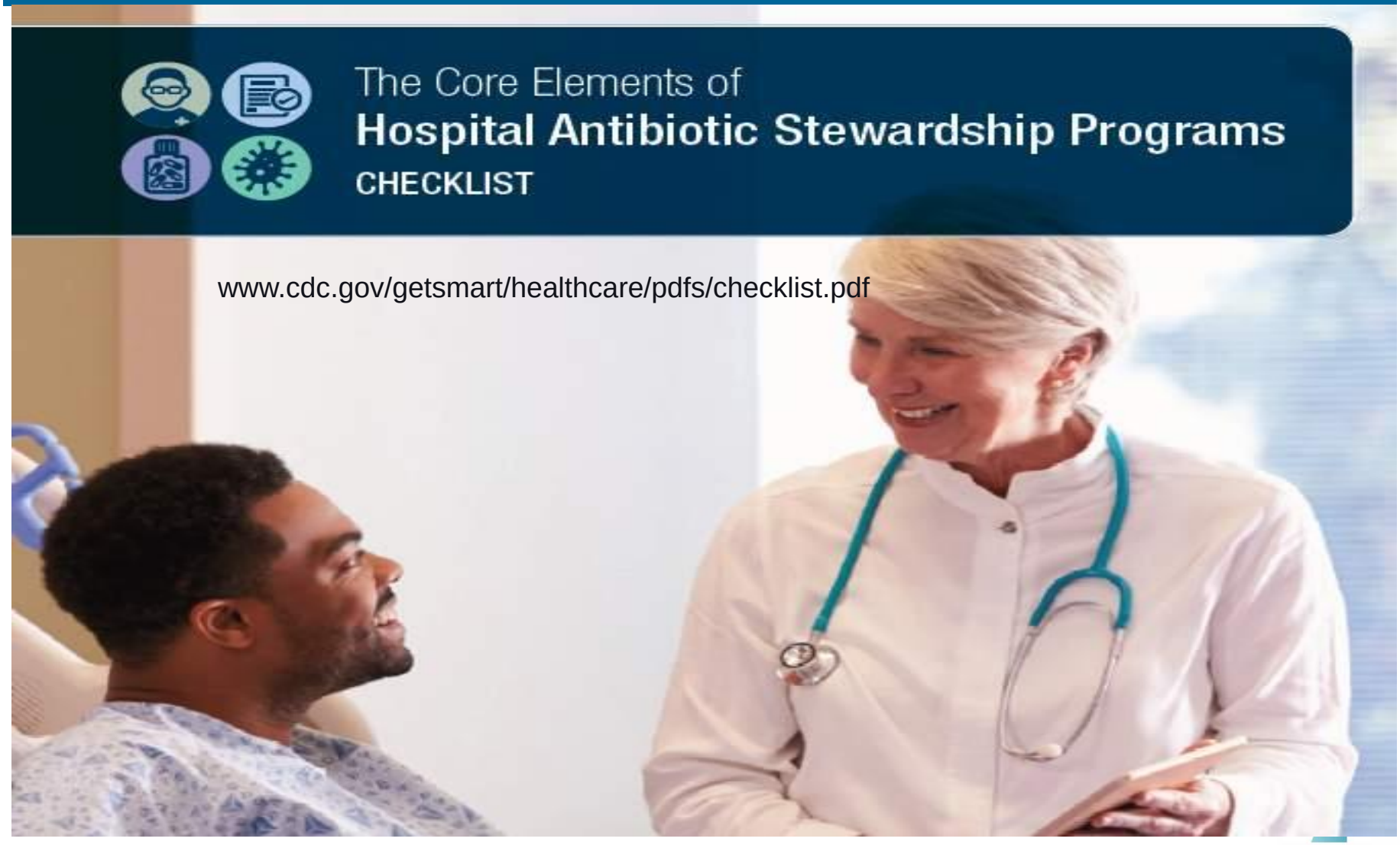
Core Elements of Outpatient Antibiotic Stewardship

The Core Elements of Hospital Antibiotic Stewardship Programs

www.cdc.gov/getsmart/healthcare/pdfs/core-elements.pdf

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion

Check List of Core Elements



Institute for Safe Medication Practices

A Nonprofit Organization Educating the Healthcare Community and Consumers About Safe Medication Practices

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This website is for use by healthcare professionals. Consumers can access our consumer website here.

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February 21-22, 2018

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- Educational Programs
- Let ISMP be your PSO
- Professional Development
- Self Assessments
- ISMP Guidelines
- QuarterWatch

www.ismp.org

Medication Safety Tools & Resources

Featured Tools

- Guide to Building a Smart Infusion System Drug Library
- The Root Cause Analysis Workbook for Community/ Ambulatory Pharmacy
- National Patient Safety Foundation Guidelines on Root Cause Analysis
- Special Error Alerts
- Targeted Medication Safety Best Practices for Hospitals
- ISMP Guidelines
- High-Alert Medications
- Confused Drug Name List

2018-19
Targeted Medication Safety Best Practices for Hospitals
REVIEW DOCUMENTS

ISMP Guidelines on Safe Subcutaneous Insulin Use
VIEW THE DOCUMENT

QuarterWatch
Special Issue on Contraceptive Safety
READ NEW ISSUE

Third in Series
New ISMP Video Newsletter Available
VIEW VIDEO

Join our mailing list and get news, announcements, and event notifications

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Check Out the Medication Best Practices

Targeted Medication Safety Best Practices for Hospitals

The purpose of the Targeted Medication Safety Best Practices for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices for specific medication safety issues that continue to cause fatal and harmful errors in patients, despite repeated warnings in ISMP publications. Hospitals can focus their medication safety efforts over the next 2 years on these best practices, which are realistic and have been successfully adopted by numerous organizations. While targeted for the hospital-based setting, some best practices may be applicable to other healthcare settings. The Targeted Medication Safety Best Practices for Hospitals have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the ISMP Medication Safety Alert! are referenced after each best practice.

DOWNLOAD

www.ismp.org/tools/bestpractices/default.aspx

Resources

TMSBP Main Page

Targeted Medication Safety Best Practices for Hospitals

Educational Programs

- 01-18 Webinar Slides
- 01-18 Webinar Recording

Frequently Asked Questions

Implementation Status Survey Results

NASH HEALTHCARE CONSULTING

ISMP Subq Insulin

www.ismp.org/Tools/guidelines/Insulin-Guideline.pdf

2017

ISMP Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults

USP 800 Hazardous Drugs

BRIEFING

《800》 Hazardous Drugs—Handling in Healthcare Settings. Because there is no existing *USP* chapter for this topic, the Compounding Expert Committee and the Compounding with Hazardous Drugs Expert Panel propose this new general chapter to guide the handling of hazardous drugs in healthcare settings. This new general chapter has been created to identify the requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs to protect the patient, healthcare personnel, and environment. Facility requirements that differ from general chapter 《797》 *Pharmaceutical Compounding—Sterile Preparations* and this chapter will be harmonized. These differences include the following:

1. Elimination of the current allowance in 《797》 for facilities that prepare a low volume of hazardous drugs that permits placement of a BSC or CACI in a non-negative pressure room. All hazardous drug compounding shall be done in a separate area designated for hazardous drug compounding.
2. Allowance for a Containment Segregated Compounding Area (C-SCA), a separate, negative pressure room with at least 12 air changes per hour (ACPH) for use with compounding hazardous drugs. Low- and medium-risk hazardous drug CSP may be prepared in a BSC located in a C-SCA, provided the beyond-use date of the CSP does not exceed 12 hours. A CACI that meets the requirements in 《797》 may be used for hazardous drug compounding if it is placed in a C-SCA.

The proposed chapter is posted online at www.usp.org/usp-nf/notices/compounding-notice with line numbers. To ensure that your comments are received and addressed, please provide the line numbers corresponding to your comments when submitting comments to *CompoundingSL@usp.org*.

www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf

USP 800 Hazardous Drugs

Healthcare Settings

Support

Contact Information

Frequently Asked Questions

- Compliance with the USP–NF
- Compounding
- Dissolution Performance Verification Testing (PVT)
- Elemental Impurities, Rationale for USP's Proposed Standards
- Equipment
- Food Chemicals Codex (FCC)
- <61> Microbial Examination of Nonsterile Products: Microbial

Frequently Asked Questions: <800> Hazardous Drugs—Handling in Healthcare Settings

1. **What is the purpose of General Chapter <800>?**
   The purpose of the chapter is to describe practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection. The new general chapter defines processes intended to minimize the exposure to hazardous drugs in healthcare settings.

   Back to Top

2. **Does General Chapter <800> apply to me?**
   The chapter applies to all healthcare personnel who handle hazardous drug preparations (e.g. pharmacists, pharmacy technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians). The chapter also covers all healthcare entities that store, prepare, transport, or administer hazardous drugs (e.g., pharmacies, hospitals, other healthcare institutions, patient treatment clinics, physicians' practice facilities, and veterinarian offices).

   Back to Top

3. **What is a hazardous drug?**
   A hazardous drug is any drug identified as hazardous or potentially hazardous by the National Institute for Occupational Safety and Health (NIOSH) on the basis of at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals

Hazardous Update List

Leroy A. Richardson,
Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–12808 Filed 5–27–15; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2015–0034; NIOSH 233–A]

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings: Proposed Additions to the NIOSH Hazardous Drug List 2016; Request for Comment

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of draft document available for public comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following draft document for public comment entitled ''NIOSH List of

instructions for submitting comments can be found at *www.regulations.gov*.

This guidance document does not have the force and effect of law.

Table of Contents

DATES: Electronic or written comments must be received by July 27, 2015.

ADDRESSES: You may submit comments, identified by CDC–2015–0034 and Docket Number NIOSH 233–A, by either of the two following methods:

- *Federal eRulemaking Portal: www.regulations.gov* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226.

Instructions: All information received in response to this notice must include the agency name and the docket number (CDC–2015–0034; NIOSH 233–A). All relevant comments received will be posted without change to *www.regulations.gov*, including any personal information provided. All electronic comments should be formatted as Microsoft Word. Please make reference to CDC–2015–0034 and Docket Number NIOSH 233–A. All information received in response to this notice will also be available for public examination and copying at the NIOSH

Applied Research and Technology, Robert A. Taft Laboratories, 1090 Tusculum Avenue, MS C–26, Cincinnati, Ohio 45226. (513) 533–8132 (not a toll free number). Email: *hazardousdrugs@cdc.gov*.

SUPPLEMENTARY INFORMATION: The NIOSH Alert: ''Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings'' was published in September 2004 (*http://www.cdc.gov/niosh/docs/2004-165/*). This Alert contained Appendix A which was a list of drugs that were deemed to be hazardous and may require special handling. This list of hazardous drugs was updated in 2010, 2012 and 2014 and covered all new approved drugs and drugs with new warnings up to December 2011 (*http://www.cdc.gov/niosh/docs/2014-138*). Between January 2012 and December 2013, 60 new drugs received FDA approval and 270 drugs received new warnings based on reported adverse effects in patients. From this list of 330 drugs, 44 drugs were identified by NIOSH as potential hazardous drugs. In addition to these 44 drugs, the panel members were asked to comment on the addition of one drug requested by several stakeholders. Three additional drugs had safe handling recommendations from the manufacturer and NIOSH is following these recommendations. Therefore, these 3 drugs will be listed as hazardous without requiring further review. A panel consisting of peer reviewers and

www.cdc.gov/niosh/docket/review/docket233a/pdfs/233a_2015-12857.pdf

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Additional Guidelines

- Interpretive guidelines specifically mention
  - ISMP
  - ASHP
  - USP
  - American College of Clinical Pharmacy (ACCP)
  - American Pharmacists Association (APA)

NIOSH List of Hazardous Drugs

www.cdc.gov/niosh/docket/review/docket233a/pdfs/2016-161finalpublication.pdf

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016

2020 Updates

January 21,2020

The manufacturers of trabectedin (Yondelis®), inotuzumab ozogamicin (Besponsa™), polatuzumab vedotin (Polivy™), enfortumab vedotin (Padcev™), and trastuzumab deruxtecan (Enhertu®) recommend that they be handled as hazardous drugs. Therefore, NIOSH considers these drugs to be included in Table 1 of the NIOSH list of hazardous drugs. For additional information, see the package inserts for these drugs.

Drug	AHFS Classification	Links	Date Approved
trabectedin (Yondelis®)	10:00 Antineoplastic Agents	DailyMed	October 23, 2015
inotuzumab ozogamicin (Besponsa™)	10:00 Antineoplastic Agents	DailyMed	August 17, 2017
polatuzumab vedotin (Polivy™)	10:00 Antineoplastic Agents	DailyMed	June 10, 2019
enfortumab vedotin (Padcev™)	10:00 Antineoplastic Agents	DailyMed	December 18,2019
trastuzumab deruxtecan (Enhertu®)	10:00 Antineoplastic Agents	DailyMed	December 20, 2019

January 10th, 2019

NIOSH has determined it is unlikely that risperidone (Risperidal®) poses a carcinogenic, reproductive, or developmental hazard to workers in a healthcare setting and is no longer considered a hazardous drug by NIOSH.

January 10th, 2019

NIOSH has determined it is unlikely that paliperidone (Invega®) poses a carcinogenic, reproductive or developmental hazard to workers in a healthcare setting and is no longer considered a hazardous drug by NIOSH.

ISMP High Alert Medications

Institute for Safe Medication Practices (ISMP)

ISMP List of *High-Alert* Medications in Acute Care Settings

www.ismp.org/Tools/institutionalhighAlert.asp

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)	**EPINEPH**rine, subcutaneous
adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)	epoprostenol (Flolan), IV
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)	insulin U-500 (special emphasis)*
antiarrhythmics, IV (e.g., lidocaine, amiodarone)	magnesium sulfate injection
antithrombotic agents, including: ■ anticoagulants (e.g., warfarin, low molecular weight heparin, IV unfractionated heparin)	methotrexate, oral, nononcologic use
	opium tincture
	oxytocin, IV
	nitroprusside sodium for injection
	potassium chloride for injection concentrate

National Coordinating Council

NCCMERP
National Coordinating Council for
Medication Error Reporting and Prevention

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ABOUT | MEDICATION ERRORS | RECOMMENDATIONS / STATEMENTS | FOR CONSUMERS | OPIOIDS RESOURCES

www.nccmerp.org

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) is an independent body composed of 27 national organizations.

NAN ALERT

NASH HEALTHCARE CONSULTING

Many TJC SEAs are Medication Related

Check boxes to select by keyword, content or program

Keywords

- ☐ Medication Errors
- ☐ Pain Management
- ☐ Patient Safety
- ☐ Patient-centered communications
- ☐ Restraints

Web Site Content

- ☐ Blog
- ☐ Content Page
- ☐ News
- ☐ Standards FAQ
- ☑ Topics Library
- ☐ Videos

Accreditation/Certification Programs

- ☐ Ambulatory Health Care
- ☐ Behavioral Health Care
- ☐ Bureau of Primary Health Care
- ☐ Critical Access Hospitals
- ☐ Disease-Specific Care

Sentinel Event Alert/Topics Library Updates

Most Recent

Topics Library

Sentinel Event Alert 55: Preventing falls and fall-related injuries in health care facilities — Read More — 09/28/2015

Falls resulting in injury are a prevalent patient safety problem. Elderly and frail patients with fall risk factors are not the only ones who are vulnerable to falling in health care facilities.

Related Items: Falls , Sentinel Event Alert

Topics Library

Sentinel Event Alert 54: Safe use of health information technology — Read More — 03/31/2015

Health information technology (health IT) is rapidly evolving and its use is growing, presenting new challenges to health care organizations. A Safe Health IT webinar replay and slide presentation from June 11, 2015 are now available. We hope that you find this information helpful and pass it on.

Related Items: Sentinel Event Alert , Safe Health IT

Topics Library

Sentinel Event Alert 53: Managing risk during transition to new ISO tubing connector standards — Read More — 08/20/2014

Tubing misconnections continue to cause severe patient injury and death, since tubes with different functions can easily be connected using luer connectors, or connections can be "rigged" (constructed) using adapters, tubing or catheters. 12/3/14 Webinar replayand slides added.

Related Items: Ambulatory Health Care , Critical Access Hospital , Home Care , Hospital , Nursing Care Center , Sentinel Event , Sentinel Event Alert , Infographic

Topics Library

Sentinel Event Alert Issue 52: Preventing infection from the misuse of vials — Read More — 06/16/2014

Thousands of patients have been adversely affected by the misuse of single-dose/single-use and multiple-dose vials. Webinar replay information added September 2014.

Related Items: Sentinel Event , Sentinel Event Alert , Infection Prevention and HAIs , Sentinel Event Infection

SHARE THIS

So What's In Your Policy?

WISCONSIN PATIENT SAFETY INSTITUTE

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MODEL HIGH-ALERT MEDICATIONS POLICY & PROCEDURES

PURPOSE

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

DEFINITION

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

POLICY

A. The following medications are appropriate for inclusion in a High Alert Medications policy.

- Epidural infusions
- Fentanyl
- Heparin (>100 units, flushes exempt)
- Insulin (including regular, aspart, NPH, and glargine)
- Lidocaine with epinephrine vials
- Neuromuscular blocking agents (atracurium, cisatracurium, mivacurium, pancuronium, rapacuronium, rocuronium, succinylcholine, vecuronium, etc)
- Patient Controlled Analgesia (PCA) infusions of any medication
- Total Parenteral Nutrition (TPN) and Total Nutrient Admixture (TNA) solutions
- Oncologic agents
- Moderate sedation agents (e.g., midazolam)

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.

POLICY

A. The following medications are appropriate for inclusion in a High Alert Medications policy.

- Epidural infusions
- Fentanyl
- Heparin (>100 units, flushes exempt)
- Insulin (including regular, aspart, NPH, and glargine)
- Lidocaine with epinephrine vials
- Neuromuscular blocking agents (atracurium, cisatracurium, mivacurium, pancuronium, rapacuronium, rocuronium, succinylcholine, vecuronium, etc)
- Patient Controlled Analgesia (PCA) infusions of any medication
- Total Parenteral Nutrition (TPN) and Total Nutrient Admixture (TNA) solutions
- Oncologic agents
- Moderate sedation agents (e.g., midazolam)
- Anesthetic agents (e.g., propofol)
- Adrenergic agonists (phenylephrine)

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.

ASHP Sterile Compounding Resources

www.ashp.org/sterilecompounding

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Sterile Compounding Resource Center

Health-system pharmacists routinely compound medications in response to patient needs. This ASHP Resource Center is a compilation of tools and resources to help pharmacists ensure the quality of compounded sterile products.

Contact Us

Topic Areas

- Policies, Best Practices, and Guidelines
- Safety Alerts
- Tools for Sterile Compounding
- Publications and Presentations
- External Resources

News

- FDA Encourages Hospitals, States to Get Sterile Products From Registered Outsourcing Facilities
- Compounding Suppliers Issue Recalls of Products Tested by Front Range Laboratories
- FDA Advises Pharmacies Not To Use Front Range Laboratories

Featured Product

Compounding Sterile Preparations, 3rd Edition

Empower your staff to improve safety, quality and compliance with the help of new guidelines and standards.

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Outsourcing Vendor Assessment Tool

ASHP Foundation
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Outsourcing Sterile Products Preparation: Contractor Assessment Tool

New updated web-based, interactive tool 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/sterileproductstool

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Safety Concerns of Investigational Meds

Institute for Safe Medication Practices
1800 Byberry Road, Suite 810, Huntingdon Valley, PA 19006
www.ismp.org

FOR IMMEDIATE RELEASE
November 7, 2007

CONTACT: **Renee Brehio, Media Relations**
704-831-8822
rbrehio@ismp.org

Product-Related Issues Lead to Potential Errors with Investigational Drugs

Huntingdon Valley, Pa.—Routine practices used to name, label, package, and store investigational drugs raise serious patient safety concerns, warns the Institute for Safe Medication Practices (ISMP). In the most recent issue of the *ISMP Medication Safety Alert!* newsletter, the Institute outlines some of those concerns and provides recommendations for safe use.

www.ismp.org/pressroom/PR20071107_2.pdf

Safety Concerns

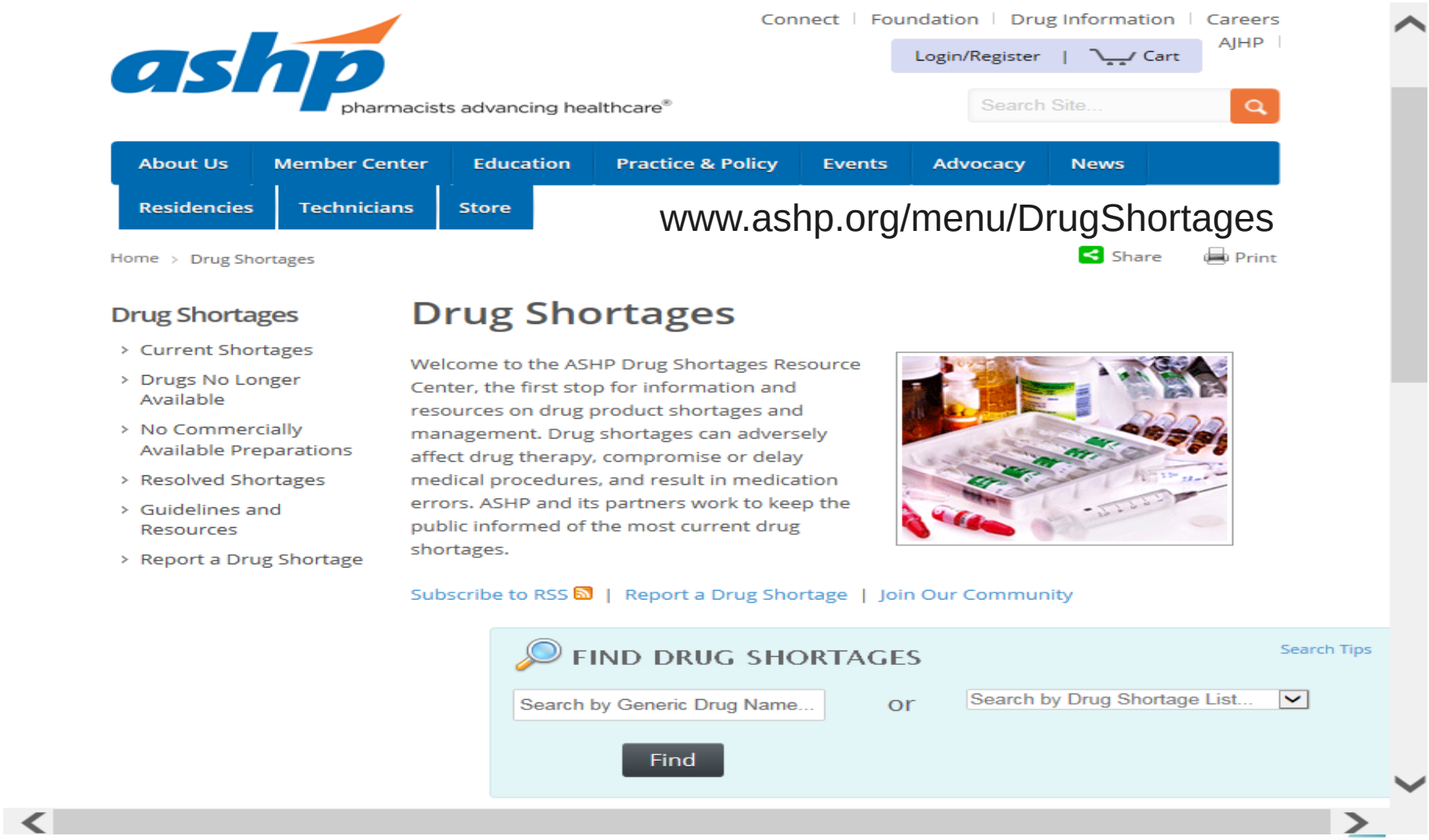
- **Drug names.** Investigational drugs are often identified by a number preceded by an abbreviation of the sponsoring company's name. This may lead to mistakes, including similar names due to participation in multiple studies by same sponsor and truncation of long letter/number designations by pharmacy computer systems. Other mistakes could be due to products receiving a generic or common name during a study that remains on the product label, and changes in code names.

- **Drug labels.** Many investigational drugs are labeled using a very small font size with little use of bold type, color, tall-man letters, or other strategies to help differentiate products. This can lead to confirmation bias when products are selected from the shelf, since the packaging looks so similar.

- **Drug packaging**. Many oral investigational drugs are not supplied in unit-dose packages. Some parenteral drugs may require dozens of vials to prepare a single dose, which sensitizes practitioners to expect to use multiple vials during preparation and makes recognition of overdoses less likely.

- **Tablet markings**. Tablet strengths often look identical and have no markings to help differentiate the strengths. While this may be essential for blinded studies, the same batches of look-alike tablets may be used for open label studies where the tablet strength is known to all participants.

ASHP Website on Shortages



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Sign Up to Get Recall Alerts from FDA

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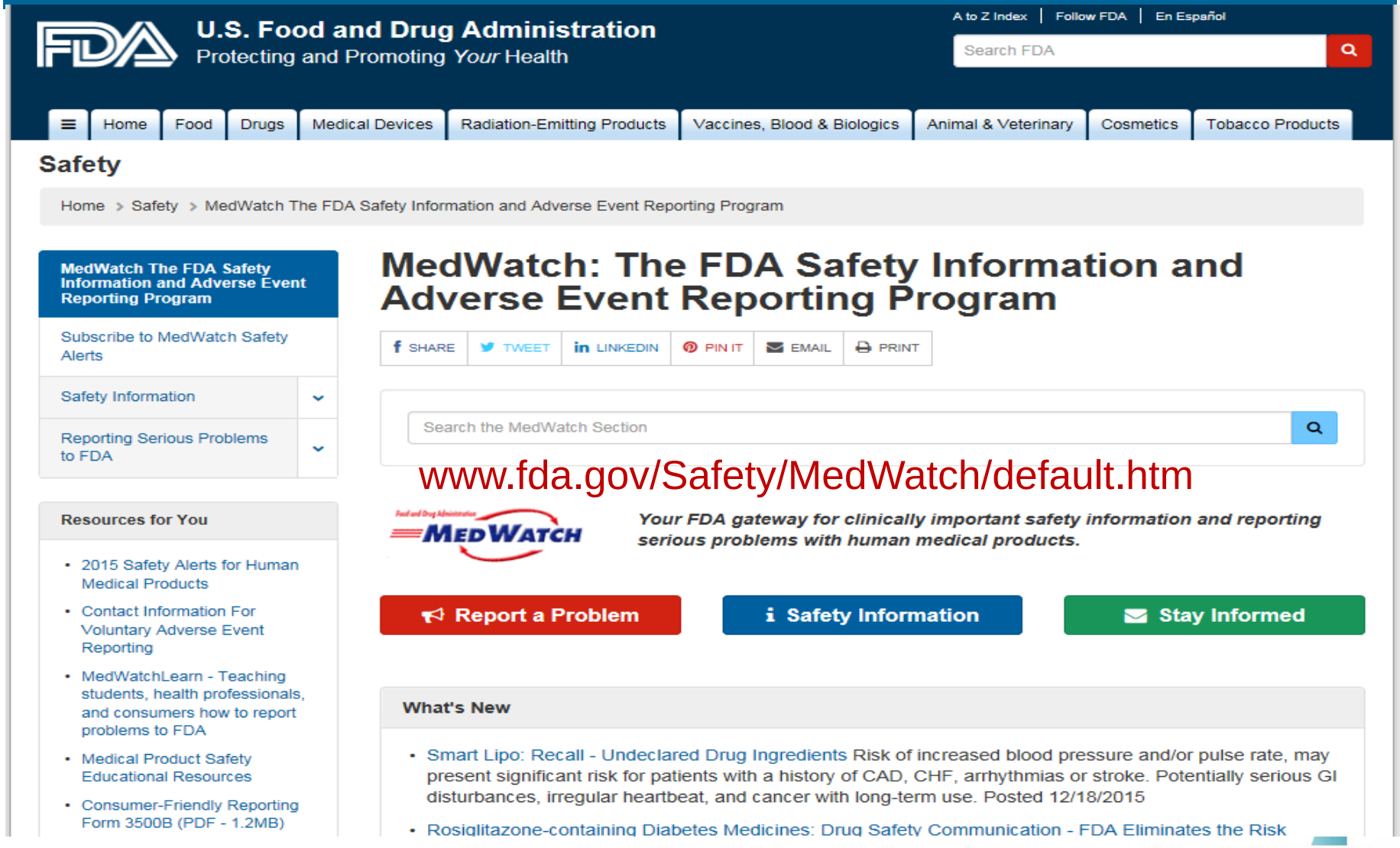
FDA MedWatch Program



Acetaminophen& Ibuprofen Dosing Charts

Fever Medication: Dosage Charts

Acetaminophen Dosage Chart

Dosages may be repeated every four hours, but should not be given more than five times in twenty- four hours. (Note:Milliliter is abbreviated as mL; 5 mL equals 1 teaspoon [tsp]. Don?t use household teaspoons, which can vary in size.) Be sure to read the label to make sure you are using the right product.

Age*	Weight†	Infant Drops 80 mg/0.8 mL	Children's Elixir 160 mg/5 mL	Chewable Tablets 80 mg tabs
0-5 mos.	6-11 lbs. (2.7-5 kg)	0.4 mL	-	-
6-11 mos.	12-17 lbs. (5.5-7.7 kg)	0.8 mL	½ tsp	1 tab
1-2 yrs.	18-23 lbs. (8.2-10.5 kg)	1.2 mL	¾ tsp	1½ tabs
2-3 yrs.	24-35 lbs. (10.9-15.9 kg)	1.6 mL	1 tsp	2 tabs
4-5 yrs.	36-47 lbs. (16.3?21.4 kg)	2.4 mL	1½ tsps	3 tabs

*: Note: Age is provided as a convenience only. Dosing for fever should be based on current weight.

†: Weight given is representative of the age range.

www.healthychildren.org/Documents/tables/Fever-Med-Dosage.

Ibuprofen Dosage Chart

Dosages may be repeated every six to eight hours, but should not be given more than four times in twenty- four hours. (Note: Milliliter is abbreviated as mL; 5 mL equals 1 teaspoon [tsp]. Don?t use household teaspoons, which can vary in size.) Be sure to read the label to make sure you are using the right product.

Age*	Weight†	Infant Drops 50 mg/1.25 mL	Children's Elixir 100 mg/5 mL	Chewable Tablets 50 mg tabs
6-11 mos.	12-17 lbs. (5.5-7.7 kg)	1.25 mL	2.5 mL	-
	18-23 lbs			

CDC Dosing Charts HIV Meds

Peds Dosing Guide 22" x 10" 112706 11/27/06 11:30 AM Page 1

www.cdc.gov/globalaids/docs/program-areas/pmtct/peds-dosing-guide.pdf

Weight range (kg)	Abacavir (Ziagen®, ABC)		Didanosine (Videx®, DDI)			Lamivudine (Epivir®, 3TC)		Stavudine (Zerit®, d4T)		Zidovudine (Retrovir®, ZDV, AZT)		
	8 mg/kg/dose TWICE daily		90-120 mg/m^2/dose TWICE daily	120 mg/m^2/dose TWICE daily	180-240 mg/m^2/dose ONCE daily	4 mg/kg/dose TWICE daily		1 mg/kg/dose TWICE daily		180-240 mg/m^2/dose TWICE daily		
	20 mg/ml solution	300 mg tablets	10 mg/ml suspension	25, 50, 100 mg chewable tablets	125, 200, 250, 400 mg EC capsules	10 mg/ml solution	150 mg tablets	1 mg/ml solution	15, 20, 30 mg capsules	10 mg/ml syrup	100 mg capsules	300 m tablet
5 - 5.9	2 ml		4 ml	25 mg + 25 mg tabs		3 ml		6 ml		6 ml		
6 - 6.9	3 ml		5 ml	25 mg + 25 mg tabs		3 ml		7 ml	10 mg (as 0.5 x 20 mg)	7 ml		
7 - 7.9	4 ml		6 ml	25 mg + 25 mg tabs		4 ml		8 ml	10 mg (as 0.5 x 20 mg)	8 ml		
8 - 8.9	4 ml		6 ml	25 mg + 25 mg tabs		4 ml		9 ml	10 mg (as 0.5 x 20 mg)	9 ml	1 cap	
									10 mg			

So What's In Your High Risk Med Policy?

General Hospital MEDICAL CENTER

HIGH ALERT MEDICATIONS

I. POLICY: To operate a safe medication administration and delivery system that will prevent the misuse medications and prevent misuse of a defined list of high-risk medications that have potential for significant harm.

II. PURPOSE: To reduce the potential for harm to patients by adopting and maintaining measures that specifically target medications with the highest risk of causing injury.

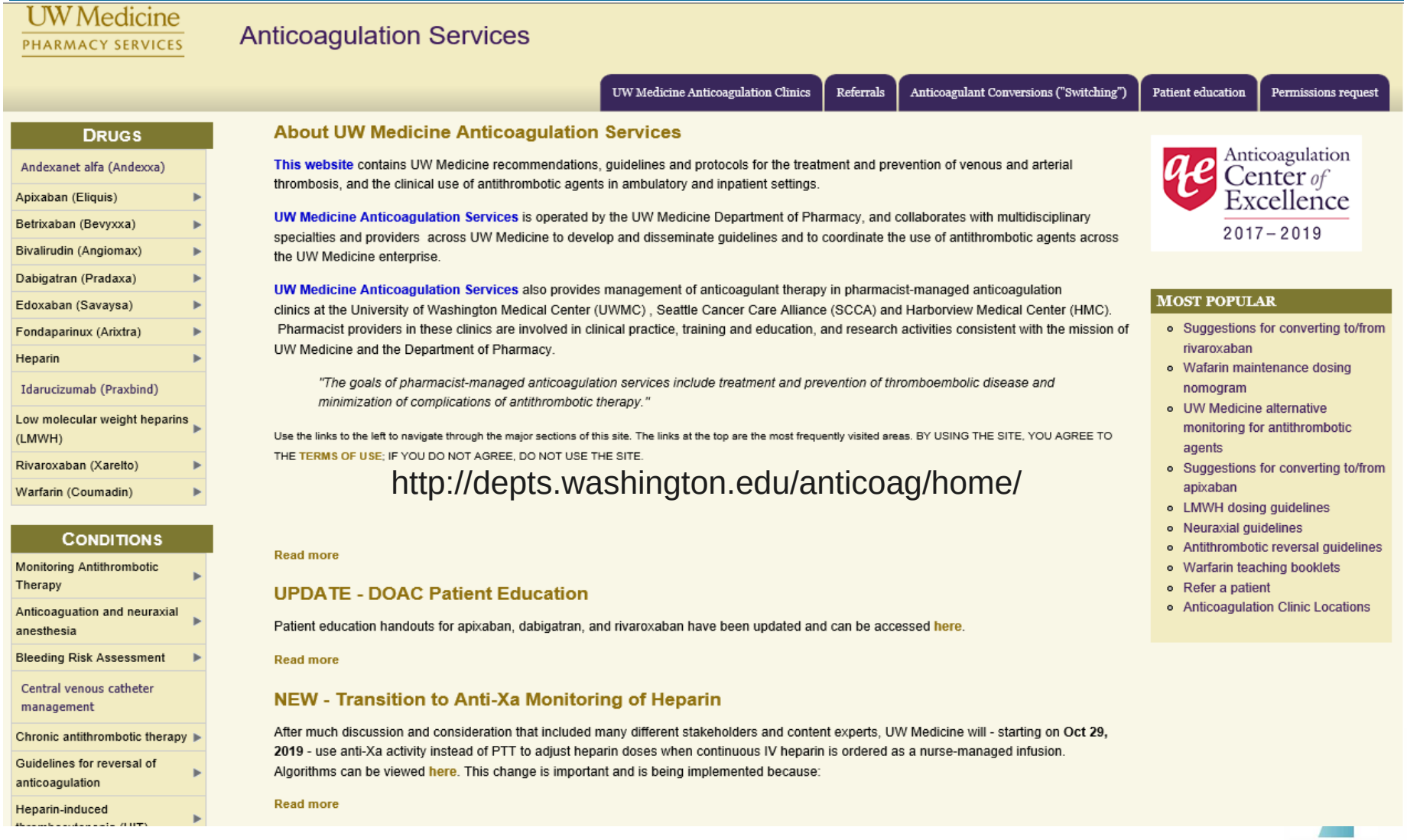
III. EQUIPMENT: A. High Alert Medication List
B. Medication Administration Record

IV. WHO DOES IT: A. Two licensed nurses, one being an RN

V. PROCEDURE: A. The high-alert list includes the medication groups that we determined were our highest risk medications. The list may be altered as necessary.

1. **Insulin, (subcutaneous,IV)**
2. **Heparin (LMWH, subcutaneous, IV)**
3. **Potassium chloride for injection concentrate**

Anticoagulant Resources UM



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Chronic antithrombotic therapy
Guidelines for reversal of anticoagulation
Heparin-induced thrombocytopenia (HIT)
Mechanical Circulatory Support
Peri-procedural anticoagulation
VTE

REVISED GUIDELINES - Management of Antithrombotic Therapy for Neuraxial and Peripheral Nerve Procedures

In February 2018, Harborview Medical Center adopted new internal recommendations for management of antithrombotic therapy for selected lower extremity peripheral nerve procedures. UW Medicine guideline were updated to reflect these internal recommendations.

Read more

REVISED GUIDELINES - Recommendations for Chronic Antithrombotic Therapy

In March 2017, the American Heart Association/American College of Cardiology Task Force on Clinical Practice Guidelines published a focused update to the AHA/ACC guideline for management of patients with valvular heart disease. The UWMedicine ***Recommendations for Chronic Antithrombotic Therapy*** have been revised to reflect this focused update.

Read more

REVISED GUIDELINES - Guidelines for Reversing Coagulopathies in Patients with Symptomatic Spontaneous Intraparenchymal Hemorrhage

In February 2017, UWMedicine Guidelines for Reverse Coagulopathies in Patients with Symptomatic Intraparenchymal Hemorrhage and related algorithms were revised to reflect the availability of idarucizumab for reversal of dabigatran, edoxaban (a new factor Xa inhibitor) and the PATCH trial (Lancet 2016; 387:2605-13) investigating the role of platelet transfusion in IPH patients taking antiplatelet agents.

Read more

REVISED GUIDELINES - Risk Stratification and Recommendations for Bridge Therapy in Patients on Warfarin

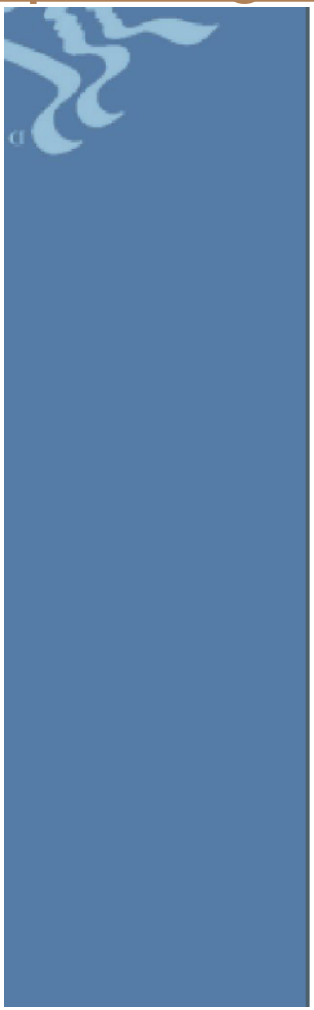
In January 2017, the American College of Cardiology published new recommendations for periprocedural management of anticoagulation in patients with nonvalvular AF. These guidelines use the CHA2DS2-VASc score, rather than the CHADS2 score, to guide decision-making. As a result, UWMedicine's Risk Stratification and Recommendations for Bridge Therapy in Patients on Warfarin has been revised.

Read more

NEW - Patient Information on Bridging

OIG 2019 Report – Compounding

- https://oig.hhs.gov/oei/reports/oei-01-17-00090.pdf.



U.S. Department of Health and Human Services

Office of Inspector General

Most Hospitals Obtain Compounded Drugs From Outsourcing Facilities, Which

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FDA's Compounding Website

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Use a Company that is Registered

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FDA Resources on Drug Diversions

CDC Home

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

SEARCH

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Injection Safety

- Injection Safety
- CDC's Role
- CDC Statement
- Information for Providers
- Information for Patients
- Preventing Unsafe Injection Practices
- ▶Drug Diversion
  - U.S. Outbreaks Associated with Drug Diversion by Healthcare Providers, 1983-2013
- Infection Prevention during Blood Glucose Monitoring and Insulin Administration
- Recent Publications
- Recent Meetings
- The One & Only Campaign
- Patient Notification Toolkit

Related Links

- CDC's HAI site
- 2007 Guideline for Isolation Precautions
- HHS Action Plan to Prevent HAIs
- HICPAC
- One & Only Campaign

Injection Safety

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Risks of Healthcare-associated Infections from Drug Diversion

When prescription medicines are obtained or used illegally, it is called drug diversion. Addiction to prescription narcotics called opioids has reached epidemic proportions and is a major driver of drug diversion. This webpage focuses on diversion involving healthcare providers who steal controlled substances such as opioids for their own use. This can result in several types of patient harm including:

- Substandard care delivered by an impaired healthcare provider,
- Denial of essential pain medication or therapy, or
- Risks of infection (e.g., with hepatitis C virus or bacterial pathogens) if a provider tampers with injectable drugs.

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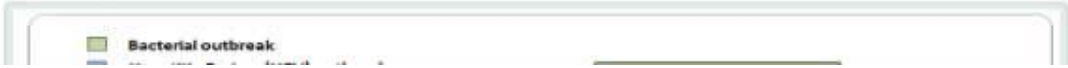
(800-232-4636)
TTY: (888) 232-6348
Contact CDC–INFO

Join the conversation

Outbreaks

CDC and state and local health departments have assisted in the investigation of infection outbreaks stemming from drug diversion activities that involved healthcare providers who tampered with injectable drugs. A summary of recent outbreaks is illustrated in the following timeline.

U.S. Outbreaks Associated with Drug Diversion by Healthcare Providers, 1983-2013



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Prevention Resources:

- National Association of Drug Diversion Investigators
- Minnesota Hospital Association Drug Diversion Prevention Toolkit
- Drug Diversion in Hospitals: A Guide to Preventing and Investigating Diversion Issues [Word - 137 KB]
- CDC Public Health Ethics Case Study, Unsafe Injections: Duty to Warn? [PDF - 264 KB]
- Premier Inc. Drug Diversion Website
- Substance Abuse and Mental Health Services Administration
- National Institute on Drug Abuse (NIDA)

www.cdc.gov/injectionsafety/drugdiversion/index.html

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Enforcement Agencies:

- Drug Enforcement Administration
- FDA Office of Criminal Investigations

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State Health Department Reports:

- Minnesota Controlled Substance Diversion Prevention Coalition [PDF - 391 KB]
- New Hampshire Hepatitis C Outbreak Report [PDF - 3.93 MB]
- Public Health Vulnerability Review: Drug Diversion, Infection Risk [PDF - 1.04 MB]

Medications in the OR ASA Position

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

American Society of Anesthesiologists®

STATEMENT ON SECURITY OF MEDICATIONS IN THE OPERATING ROOM

(Approved by the ASA Executive Committee in October 2003, and last amended by the ASA House of Delegates on October 16, 2013)

Preamble

A secure environment of care is needed for medication safety. Medication safety includes the security of oral, sublingual, parenteral, and inhaled drugs used for elective and emergency patient care. A secure area ensures the integrity of anesthesia machines as well as other equipment and materials. Security of medications in the operating room suite is essential for patient safety.

Recommended Policies

1. Access to operating room suites must be strictly limited to authorized persons.
2. All Schedule 3 and 4 narcotic medications must be kept in locked enclosed areas when not under the direct control of an anesthesia professional.
3. Anesthesia professionals must have immediate access to drugs required for emergency patient care. Procedures designed to prevent unauthorized access to such drugs must be consistent with this imperative for patient safety.
4. Anesthesia carts and anesthesia machines may remain unlocked, and non-controlled* medications may be left in or on top of unlocked anesthesia carts or anesthesia machines immediately prior to, during, and immediately following surgical cases in an operating room, so long as there are authorized operating room personnel in the OR suite.

Rationale

A. Because the operating room suite is a limited-access secure location, it is safe practice for anesthesia professionals to leave non-controlled* medications on the top of their anesthesia carts or anesthesia machines for brief periods (e.g., while going to a nearby holding area to bring a patient into the operating room).

B. At the end of anesthesia cases, when patients are particularly vulnerable, anesthesia

Recommendation on Medications in the OR

The Official Journal of the Anesthesia Patient Safety Foundation

apsf www.apsf.org **NEWSLETTER** Spring 2010

www.apsf.org/newsletters/html/2010/spring/01_conference.htm

In this issue:

Letters to the Editor:

APSF Hosts Medication Safety Conference

Consensus Group Defines Challenges and Opportunities for Improved Practice

by John H. Eichhorn, MD

Overview

On January 26, 2010, the Anesthesia Patient Safety Foundation (APSF) convened a consensus conference of 100 stakeholders from many different backgrounds to develop new strategies for "predictable prompt improvement" of medication safety in the operating room. The proposed new paradigm to reduce medication errors causing harm to patients in the operating room is based on Standardization, Technology, Pharmacy/Prefilled/Premixed, and Culture (STPC). This new paradigm goes far beyond the important but traditional emphasis on medication label format and the admonition to "always read the label." Small group sessions on each of the 4 elements of the new paradigm (STPC) debated and formulated specific recommendations that were organized and prioritized by all the attendees.

The resulting consensus recommendations include:

Standardization

- High alert drugs (such as phenylephrine and epinephrine) should be available in

Table 1:
Consensus Recommendations for Improving Medication Safety in the Operating Room

Standardization

1. High alert drugs (such as phenylephrine and epinephrine) should be available in standardized concentrations/diluents prepared by pharmacy in a ready-to-use (bolus or infusion) form that is appropriate for both adult and pediatric patients. Infusions should be delivered by an electronically-controlled smart device containing a drug library.
2. Ready-to-use syringes and infusions should have standardized fully compliant machine–readable labels.
3. *Additional Ideas:*
   a. Interdisciplinary and uniform curriculum for medication administration safety to be available to all training programs and facilities.
   b. No concentrated versions of any potentially lethal agents in the operating room.
   c. Required read-back in an environment for extremely high alert drugs such as heparin.
   d. Standardized placement of drugs within all anesthesia workstations in an institution.
   e. Convenient required method to save all used syringes and drug containers until case concluded.
   f. Standardized infusion libraries/protocols throughout an institution.
   g. Standardized route-specific connectors for tubing (IV, arterial, epidural, enteral).

Technology

1. Every anesthetizing location should have a mechanism to identify medications before drawing up or administering them (bar code reader) and a mechanism to provide feedback, decision support, and documentation (automated information

Pharmacy/Prefilled/Premixed

1. Routine provider-prepared medications should be discontinued whenever possible.
2. Clinical pharmacists should be part of the perioperative/operating room team.
3. Standardized pre-prepared medication kits by case type should be used whenever possible.
4. *Additional Ideas:*
   a. Interdisciplinary and uniform curriculum for medication administration safety for all anesthesia professionals and pharmacists.
   b. Enhanced training of operating room pharmacists specifically as perioperative consultants.
   c. Deployment of ubiquitous automated dispensing machines in the operating room suite (with communication to central pharmacy and its information management system).

Culture

1. Establish a *"just culture"* for reporting errors (including near misses) and discussion of lessons learned.
2. Establish a culture of education, understanding, and accountability via a required curriculum and CME and dissemination of dramatic stories in the *APSF Newsletter* and educational videos.
2. Establish a culture of cooperation and recognition of the

Joint Commission Requirement

New Antimicrobial Stewardship Standard

www.jointcommission.org/assets/1/6/HAP-CAH_Antimicrobial_Prepub.pdf

APPLICABLE TO HOSPITALS AND CRITICAL ACCESS HOSPITALS

Effective January 1, 2017

Medication Management (MM)

Standard MM.09.01.01

The [critical access] hospital has an antimicrobial stewardship program based on current scientific literature.

Elements of Performance for MM.09.01.01

1. Leaders establish antimicrobial stewardship as an organizational priority. (*See also* LD.01.03.01, EP 5)

   Note: *Examples of leadership commitment to an antimicrobial stewardship program are as follows:*

   - *Accountability documents*
   - *Budget plans*
   - *Infection prevention plans*
   - *Performance improvement plans*
   - *Strategic plans*
   - *Using the electronic health record to collect antimicrobial stewardship data*

2. The [critical access] hospital educates staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and antimicrobial stewardship practices. Education occurs upon hire or granting of initial

   Note: *An example of an educational tool that can be used for patients and families includes the Centers for Disease Control and Prevention's Get Smart document, "Viruses or Bacteria—What's got you sick? at http://www.cdc.gov/getsmart/community/downloads/getsmart-chart.pdf.*

4. The [critical access] hospital has an antimicrobial stewardship multidisciplinary team that includes the following members, when available in the setting:

   - Infectious disease physician
   - Infection preventionist(s)
   - Pharmacist(s)
   - Practitioner

   Note 1: *Part-time or consultant staff are acceptable as members of the antimicrobial stewardship multidisciplinary team.*

   Note 2: *Telehealth staff are acceptable as members of the antimicrobial stewardship multidisciplinary team.*

5. Ⓓ The [critical access] hospital's antimicrobial stewardship program includes the following core elements:

   - Leadership commitment: Dedicating necessary human, financial, and information technology resources.
   - Accountability: Appointing a single leader responsible for program outcomes. Experience with successful programs shows that a physician leader is effective.
   - Drug expertise: Appointing a single pharmacist leader responsible for working to improve antibiotic use.
   - Action: Implementing recommended actions, such as