TAKING ACTION TO IMPROVE IV SAFETY IN HEALTH SYSTEMS

Pharmacy Leadership FORUM

A Sunday Symposium conducted at the 2019 ASHP Midyear Clinical Meeting & Exhibition

Sunday, December 8
2:00 – 5:00 p.m.
Las Vegas, Nevada

AGENDA

2:00 p.m.
Introductions and Announcements
Eric S. Kastango, B.S.Pharm., M.B.A., FASHP, Activity Chair

2:10 p.m.
USP Chapter <797>: Examining Revisions and Implications for the Health System
Eric S. Kastango, B.S.Pharm., M.B.A., FASHP

2:40 p.m.
Reflections on Preparing for USP Chapter <797>: Is Your Health System Ready?
Jamie Tharp, Pharm.D.

3:30 p.m.
Refreshment/Stretch Break

3:45 p.m.
IV Push Medication Administration: Overview of Best Practices and Error-Reduction Strategies
Michael Freudiger, Pharm.D., APh, BCPS, BCGP

4:10 p.m.
High Alert Medications: Creating a Culture of Safety in Preparation and Administration
Christina Michalek, B.S.Pharm, FASHP

4:50 p.m.
Faculty Discussion and Audience Questions

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Pharmacy Leadership FORUM

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Angela T. Cassano, Pharm.D., BCPS, FASHP (Planner)
- Baxter Healthcare: consultant

Learning Objectives

- Explain the current status of USP Chapter <797>.
- Describe strategies used by health systems to comply with USP Chapter <797> revisions.
- Apply best practices and corresponding error-reduction strategies for preparation and administration of medications via IV push.
- Recommend best practices for the preparation and administration of high-alert-medications.

USP Chapter <797>: Examining Revisions and Implications for the Health System

Eric S. Kastango, B.S.Pharm., M.B.A., FASHP

Learning Objectives

- **Explain the current status of USP Chapter <797>.**
- Describe strategies used by health systems to comply with USP Chapter <797> revisions.
- Apply best practices and corresponding error-reduction strategies for preparation and administration of medications via IV push.
- Recommend best practices for the preparation and administration of high-alert-medications.

It's Been a Long Ride …

Graphic courtesy of USP

But Wait!

The Appeal!

- Several pharmacy groups filed appeals to USP Chapter <795> and <797>
- Key topics covered in the appeals included:
  - Beyond-Use Date (BUD) provisions in <795> and <797>
  - Removal of Alternative Technology provision from <797>
  - Applicability of <795> and <797> to veterinary practitioners

The Compounding Expert Committee (CMP EC) Appeal decisions!

- Maintain the BUD framework for compounded nonsterile preparations (CNSPs)
- Maintain the BUD provisions for compounded sterile preparations (CSPs) in <797> *with the commitment to develop resources for extending BUDs to include stability, sterility, and monitoring (personnel and environmental) considerations.* (separate chapter?)

https://www.usp.org/sites/default/files/usp/document/health-quality-safety/usp-decision-on-appeals-factsheet.pdf

The Compounding Expert Committee (CMP EC) Appeal decisions!

- Reinstate the Alternative Technology Provision from the 2008 Version of <797>
  - *"The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein."*
- The CMP EC recognized that <797> may not capture all modalities used in pharmacy compounding. However, the CMP EC also intends to publish a Frequently-Asked-Question (FAQ) *to clarify that the reinstatement of the Alternative Technology provision is not intended to permit BUD extension or to extend the time during which single-dose containers may be used.*

https://www.usp.org/sites/default/files/usp/document/health-quality-safety/usp-decision-on-appeals-factsheet.pdf

The Compounding Expert Committee (CMP EC) Appeal decisions!

- Not to Postpone these Chapters and to Maintain Veterinary References
  - <795> and <797> do not state compendial requirements for animal drug compounding under federal law.
  - Section 503A of the Federal Food, Drug and Cosmetic Act, which makes <795> and <797> applicable to pharmacy compounding, applies only to pharmaceuticals for human use.

https://www.usp.org/sites/default/files/usp/document/health-quality-safety/usp-decision-on-appeals-factsheet.pdf

The Compounding Expert Committee (CMP EC) Appeal decisions!

- Not to Postpone these Chapters and to Maintain Veterinary References
  - "<795> and <797> contain provisions that are intended to be relevant and useful for veterinary practitioners. For this reason, it is the CMP EC's view that continued reference to veterinarians in both <795> and <797> may serve value, from a best practice standpoint. The requirements of these chapters are relevant to ensuring quality CSPs for both human and animal patients."

https://www.usp.org/sites/default/files/usp/document/health-quality-safety/usp-decision-on-appeals-factsheet.pdf

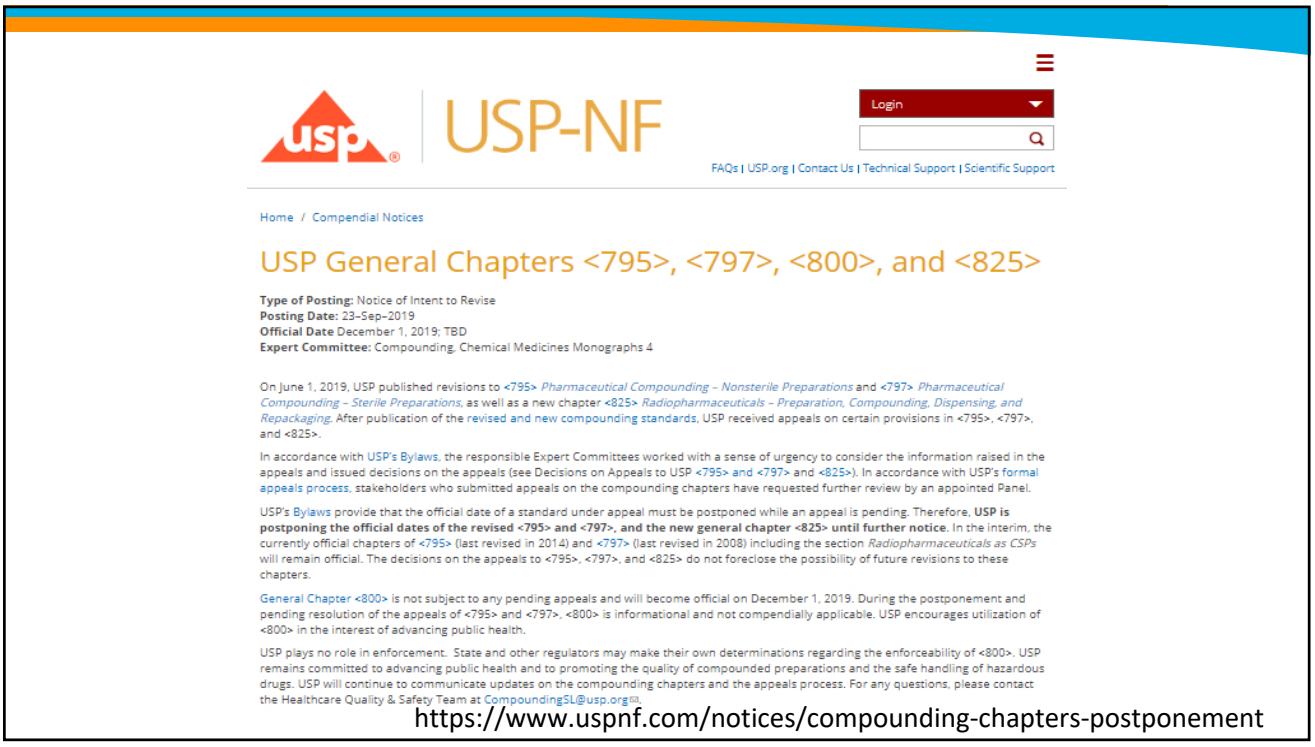
Postponed until further notice!

Note: The current version of General Chapters <795> and <797> published in USP-NF are official.

Graphic courtesy of USP

Which of these describes your organization prior to the USP appeal being announced?

A. We were ready for full compliance with USP <795>, <797>, <800>, and <825> by 12/1
B. We were ready for <800>, but the others were not going to be ready by 12/1
C. We were ready for <797>, but not the others
D. We were ready for all but <800> because we don't work with hazardous drugs
E. We were thrilled to see the pause, we weren't ready for any of them!



USP-NF

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Home / Compendial Notices

USP General Chapters <795>, <797>, <800>, and <825>

Type of Posting: Notice of Intent to Revise
Posting Date: 23-Sep-2019
Official Date December 1, 2019; TBD
Expert Committee: Compounding, Chemical Medicines Monographs 4

On June 1, 2019, USP published revisions to <795> *Pharmaceutical Compounding – Nonsterile Preparations* and <797> *Pharmaceutical Compounding – Sterile Preparations*, as well as a new chapter <825> *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*. After publication of the revised and new compounding standards, USP received appeals on certain provisions in <795>, <797>, and <825>.

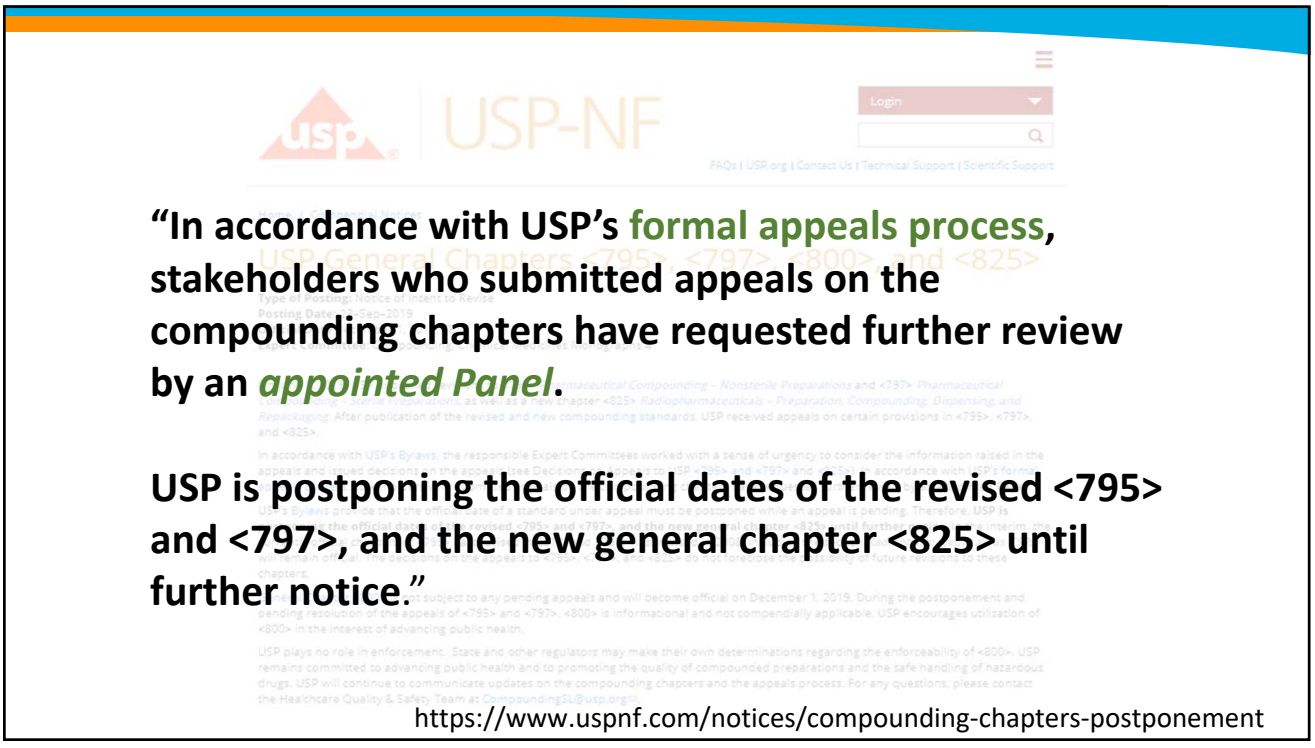
In accordance with USP's Bylaws, the responsible Expert Committees worked with a sense of urgency to consider the information raised in the appeals and issued decisions on the appeals (see Decisions on Appeals to USP <795> and <797> and <825>). In accordance with USP's formal appeals process, stakeholders who submitted appeals on the compounding chapters have requested further review by an appointed Panel.

USP's Bylaws provide that the official date of a standard under appeal must be postponed while an appeal is pending. Therefore, **USP is postponing the official dates of the revised <795> and <797>, and the new general chapter <825> until further notice**. In the interim, the currently official chapters of <795> (last revised in 2014) and <797> (last revised in 2008) including the section *Radiopharmaceuticals as CSPs* will remain official. The decisions on the appeals to <795>, <797>, and <825> do not foreclose the possibility of future revisions to these chapters.

General Chapter <800> is not subject to any pending appeals and will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable. USP encourages utilization of <800> in the interest of advancing public health.

USP plays no role in enforcement. State and other regulators may make their own determinations regarding the enforceability of <800>. USP remains committed to advancing public health and to promoting the quality of compounded preparations and the safe handling of hazardous drugs. USP will continue to communicate updates on the compounding chapters and the appeals process. For any questions, please contact the Healthcare Quality & Safety Team at CompoundingSL@usp.org.

https://www.uspnf.com/notices/compounding-chapters-postponement



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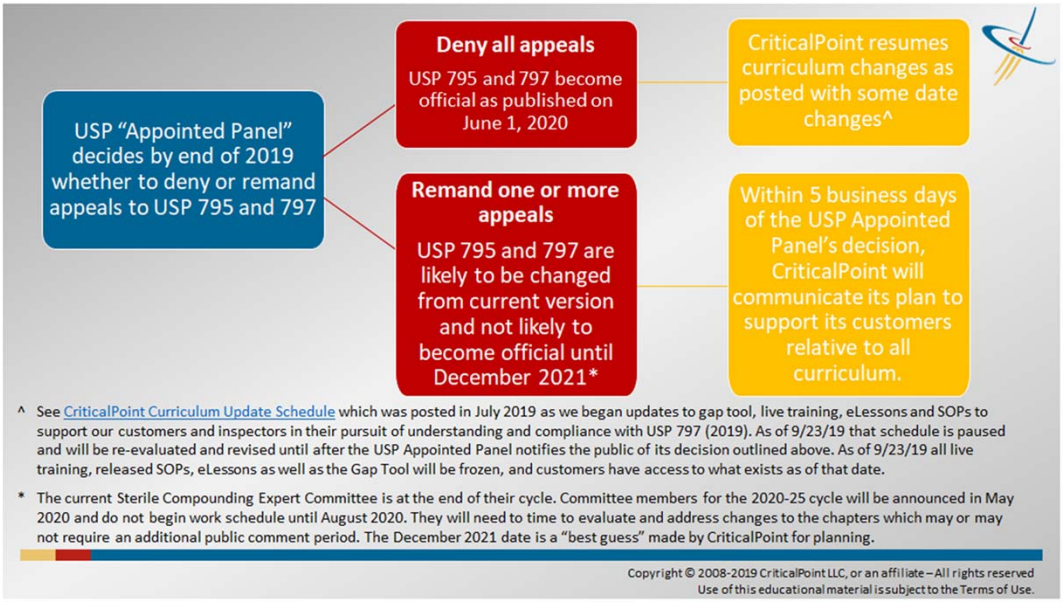
General Chapter <800> is not subject to any pending appeals and will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable. USP encourages utilization of <800> in the interest of advancing public health."

https://www.uspnf.com/notices/compounding-chapters-postponement

Compendial Applicability

- In 2016, USP revised their General Notices
- USP Chapters <797> and <795> are referenced in the General Notices section 3.10.30. as those chapters which apply to compounding. This means that they are required chapters. USP Chapter <800> is not listed.
- The 2019 versions of USP <797> and <795> reference USP <800> and, therefore, when they become official, USP 800 would then have compendial applicability because it is referenced in another applicable "official" general chapter.
- With the announced delay of USP <797> and <795>, USP still intends for USP <800> to become official on December 1, 2019.
- This means that USP <800> will be informational as it is not referenced in an applicable chapter and the current versions of USP <797> (2008) and USP <795> (2014) make no mention of USP 800.
- USP video on the topic:
  - **www.usp.org/sites/default/files/usp/video/hqs/usp-800-applicability-720.mp4**

The seat belt sign is illuminated



The seat belt sign is illuminated

Any anticipated dates offered by third parties are not accurate as the appeals process is currently ongoing. USP is committed to communicate updates on the compounding chapters and appeals process.

A couple of key points to keep in mind now!

- There is nothing prohibiting you from implementing all of the quality related expectations of the revised chapter, except:
  - Dating of single-dose vials
  - BUDs of Low, Medium, and High-risk CSPs

SDVs, MDVs, PBP and Point of Care Activated - 2008

Container Type	Preservatives	BUD
Single Dose Ampule	No	N/A because not stored
Single Dose Vial* (SDV)	No	6 hours if opened in ISO class 5 OR 1 hour if opened in air worse than ISO 5*
Multiple Dose Vial (MDV)	Yes	28 days from initial puncture or per manufacturer's package insert
Pharmacy Bulk Package (PBP)	No	6 hours or shorter if opened in ISO class 5
Point-of-Care Activated Systems	• ADD-Vantage, MINI- BAG PLUS, addEASE • Attaching/activating these not considered compounding • Acceptable for nursing to attach and activate • Use manufacturer's instructions for storage and stability	

The CDC advised on a more conservative approach to further safeguard patients. The CDC stipulates that the remaining contents must be discarded at the end of the procedure/case and must not be stored.

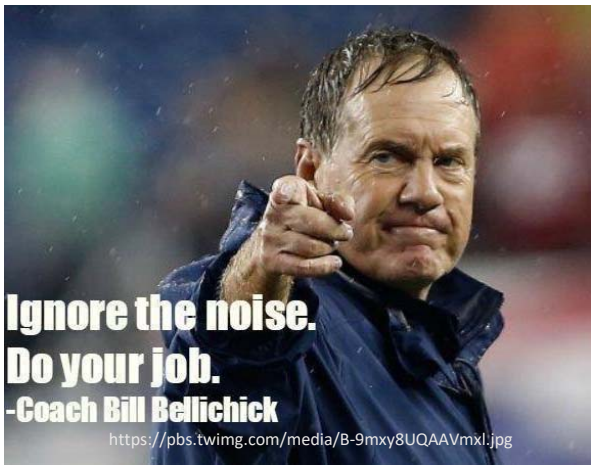
Beyond-Use Dates

- Current definition of BUD: The date (or time) beyond which the drug must not be stored.
  - Sell by/use by dating – does not include infusion time.
- Future definition of BUD: the date or date and hour after which the CSP must not be used, because its required quality characteristics (e.g., sterility, strength, purity) cannot be ensured.

Microbiological Beyond Use Dating - 2008

Beyond-use dating for CSPs according to Risk-Level			
Risk Level	BUD at Room Temperature (20 to 25° C)	BUD under Refrigeration (2° to 8° C)	BUD with Frozen Storage (-25 to -10° C)
Immediate Use	1 hour	N/A	N/A
Low Risk with 12h BUD	12 hours	12 hours	N/A
Low Risk	48 hours	14 days	45 days
Medium Risk	30 hours	9 days	45 days
High Risk	24 hours	3 days	45 days

What comes next?



- Continue your plans to comply with the chapters as if they were going to be official on Dec 1, 2019.
- Learn what your State Board of Pharmacy and Accreditation Organization plans on doing about the postponement.

Summary

- DO NOT STOP IMPLEMENTING YOUR PLAN!
- This temporary delay is the system working according to USP Bylaws
- It's not a matter of if, but when the postponement will be lifted, and compliance will be required within 2 years, if not sooner.

Your Source of Truth

- The USP Compounding Standards Home Page **www.usp.org/compounding**
- The USP Resource Page for Chapter <800> **www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare**
- Your home State Board of Pharmacy rules and regulations

Additional Resources

- CriticalPoint Peer Network: **peernetwork.criticalpoint.info**
- Pharmacy OneSource webinars: **www.pharmacyonesource.com/resources/webinars**
- ASHP. Ensuring Readiness for USP Chapter on Handling Hazardous Drugs: Assessment, Planning and Implementation. 2016. **ashpadvantagemedia.com/800/files/usp800-handout.pdf**
- BBraun. Ready for 800. 2017. Series of videos and other information. **www.readyfor800.com**
- Joint Commission Resources. USP Toolkit. 2016. **hazmedsafety.com/qualify**

Reflections on Preparing for USP Chapter <797>: Is Your Health System Ready?

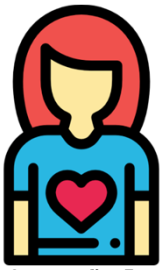
Jamie C. Tharp, Pharm.D.

Outline

1. Consider strategies to assess your current compliance with the revised USP chapter <797> standards
2. Review 2019 Revised USP chapter <797> from a health system response perspective
3. Identify key standards changes that may require the largest effort for health systems to implement

Fandom

- Oxford Dictionary: the state or condition of being a fan of someone or something
- Urban Dictionary: a group of people who willingly have their souls devoured by an obsession


Compounding Fan

Bing Translator of Oxford Dictionary www.bing.com/search; Urban Dictionary www.urbandictionary.com (both accessed 11/2/19)

About Michigan Medicine

- Hospitals: 4
- Licensed Beds: 1000
- Employees: 28,618
- Pharmacy Employees: 635
- Compounding Personnel: 375+ (technicians, pharmacists, supervisors)
- Compounding Locations: 22 sites (11 cleanrooms, 9 segregated compounding areas, 1 clinic, 1 training center)

Courtesy University of Michigan, available under a Creative Commons Attribution-NonCommercial 3.0 license

Michigan Medicine Compounding Compliance

Developed Centralized Team for <797> Compliance in 2018

- Manager, pharmacist, 2 technicians

Expanded in 2019 to encompass <795>, <800> compliance oversight

- Added: 2 pharmacists, 3 technicians

Team Mission: *Ensure and advance Michigan Medicine compounding compliance through policy, education, and oversight*

Team Structure:

Pharmacy Manager	Pharmacist Specialist Lead	Pharmacist Specialist (2)	Pharm Tech Coordinator	Pharm Techs (4)
Planning Oversight Response	Coordinate team Policy lead Rx Liaison	Facility lead Personnel lead	Team Scheduling Reporting Back up tech	Training/Media Fill Viable Sampling Auditing

Which of the following represents the manpower dedicated to sterile compounding oversight at your organization? (Answer all that apply)

A. Frontline staff supervised by director of pharmacy
B. Frontline staff supervised by sterile compounding manager or specialist
C. Additional staff dedicated to environmental monitoring
D. Additional staff dedicated to staff education and training
E. Environmental monitoring is outsourced to a contractor
F. Staff education and training is outsourced to a contractor

Impact of 2019 Revision Appeal cont.

- Regulatory Limbo awaiting guidance
  - States
  - Accreditors

- Michigan Medicine Revised Standards Progress

Implemented Pre-delay	In progress	On hold
Facilities Design Standards <797> Viable Sampling <797>, <800> Staff Education	USP <800>	USP <795>, <797>, <825> (awaiting guidance from state)

Icon made by [Freepik] from www.flaticon.com

USP Guidance on Early Adoption of Revised Standards

- USP Issued FAQs on Compounding Appeals
  - **Q 13. Can facilities early adopt revised (postponed) standards while under appeal?**
  - A 13. "…early adoption of revised standards in advance of the official dates is permitted unless specified otherwise… USP did not prohibit early adoption [under USP General Notices 3.10]"
  - Check with states, regulators, and accreditation bodies for their stance on early adoption

USP. FAQs on the Compounding Appeals. www.usp.org/compounding/compounding-appeals (accessed 11/2/19)

Suggested USP Revision Preparedness Activities

- Read Chapter
- Compare versions & language
- Attend Summary Lectures
- Discuss on List serves
- Form workgroups
- Conduct Gap Analyses
- Revise policies and practices

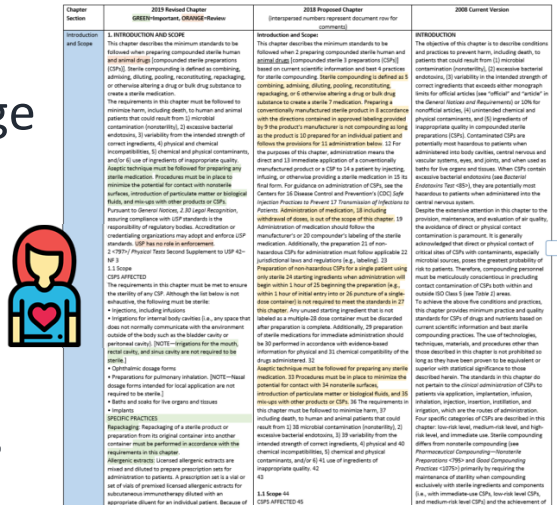


Image: J. Tharp, Michigan Medicine.

Pharmaceutical compounding—sterile preparations (general information chapter 797). Rockville, MD: United States Pharmacopeial Convention; 2019.

Preparing for the (not so) Distant Future

- Today, we'll assume all appeals of the 2019 USP Chapter <797> are overturned
- Health systems should review the following key changes to ensure compliance with revised standards

Be Alert

High Impact Change

Moments of Gratitude

Look for downhill truck to indicate when standards became less stringent

Lessons Learned

Organization's experience or plan

Presentation Scope

Readying your organization for revised <797> from the perspective of a centralized team approach

Readiness & Response	Personnel Education	Compounding Facilities	Resources/ Records
Inspect Report Assess	Develop Conduct Assess/ Evaluate	Design Maintenance Monitoring	Expertise Develop Implement

Readiness and Response

- Key Revised USP <797> standards related to
  - Regulatory readiness
  - General program compliance

At Our Organization:
Compounding readiness oversight and planning falls to the Compounding Compliance Manager

Section 1. Introduction and Scope

Key 2019 Changes	Impact/ Considerations
1. Scope Broadened: includes humans and animals (v2008: patients)	Initially appealed (dropped), possible impact on research hospitals

- Our state law only requires USP compliance for licensed compounding pharmacies
- Currently unclear how USP <797> might be enforced for animal research laboratories

Section 1. Introduction and Scope

Key 2019 Changes	Impact/ Considerations
1.1 Sterile radiopharmaceutical preparation removed from <797> and given new chapter <825>	New chapter introduces stark differences to <797> and requires study
1.1 Designated person introduced	Need to define roles/responsibilities

- USP <825> planning: review of past USP <797> policies and resources that were universally used
- Designated Person: Planning committee oversight with delegation of specific duties to:
  - Compliance/Safety -Supervisors -Pharmacists
  - Created escalation process when responsibility without full authority

Section 1. Introduction and Scope

Key 2019 Changes

1.3 Immediate use definition changed:

- Eliminated emergent need
- Need evidenced-based prep info
- Prep must not involve >3 ingredients
- Unused components must be discarded
- Admin begins w/in 4 hours
- Labeled unless administered by preparer
- Single dose containers may not be used for more than 1 patient

[Cat 1&2 Requirements exempt if above met, all other <797> standards must be followed]

1.4 Preparation Per Approved Labeling if:

- Performed in accordance with directions contained within approved labeling provided by the product's manufacturer
- Single dose for individual patient
- Manufacturer labeling must include diluent, strength, container, and storage

[Outside of chapter scope if above met]

Section 1. Introduction and Scope

Immediate Use and Preparation Per Approved Labeling Considerations

- Areas impacted are primarily outside of pharmacy scope (i.e., nursing, anesthesia, procedural areas)
- Unsure how regulators will enforce for non-pharmacy areas
- Professionals working outside of pharmacy may not be familiar with approved labeling and need to follow to maintain exemption
- Concerned with how to monitor which professionals may need to follow training/assessment and hand hygiene standards
- *Our Planning:*
  - Gap assessments/audits of the following key groups:
    -ICUs - Anesthesia -Surgery -Interventional Radiology
  - Update BUD from 1 hour to 4 hour as default for prep outside of pharmacy

Public Service Announcement: That was only the Introduction

KEEP

CALM

AND

BREATHE

Personnel Education

- Key Revised USP <797> standards related to
  - Education, training, and assessments
    - Initial
    - Ongoing
  - Media Fill and Gloved Fingertip Sampling (GFS)

At Our Organization:

Compounding personnel educational activities and coordination are led by the Personnel Pharmacist on the Compounding Compliance Team

Section 2. Personnel Training and Evaluation

Key 2019 Changes	Impact/ Considerations
2. All personnel involved in the compounding of CSPs must be initially trained and qualified by demonstrating knowledge and proficiency of skills - Training must be completed and documented every 12 months in the core competencies (at least) described on next slide	v2008 - Chapter required initial training: didactic review, written examinations, media fill testing - Routinely undergo evaluation of proper hand hygiene, garbing, & cleaning New standards expand number of observed assessments every 12 months

Section 2. Personnel Training and Evaluation

Key 2019 Changes	Impact/ Considerations
2.1 **Mandatory Competencies** - Hand hygiene$^{+,\wedge}$ - Garbing$^{+,\wedge}$ - Cleaning and disinfection^ - Calculations*, measuring, and mixing - Aseptic Technique - Achieving and/or maintaining sterility and apyrogenicity - Use of Equipment* - Documentation records use* - Principles of HEPA filtered airflow - Principles of materials handling	$^{+}$ Required every 6 months ^ Elements suggested for support staff with regular access to compounding areas (recurrent frequency not mentioned) * Elements more difficult to incorporate into traditional media fill observations

Section 2. Personnel Training and Evaluation

Key 2019 Changes	Impact/ Considerations
2.2 Before independently compounding, all compounders must successfully complete - Initial competency evaluation - Visual observation of hand hygiene and garbing - Initial Gloved fingertip and thumb sampling (GFS) on both hands x 3 - 2.3 Media fill testing (in ISO Class 5)	- New language about independent compounding is less strict than 2008 chapter that states "before beginning to prepare CSPs"

Section 2. Personnel Training and Evaluation

Key 2019 Changes	Impact/ Considerations
2.2 Ongoing assessments must be completed every 6 months for all compounders in - Visual observation of hand hygiene and garbing - Ongoing Gloved fingertip and thumb (GFS) sampling (in ISO class 5) - 2.3 Media fill testing (in ISO class 5)	- New frequency doubles prior v2008 annual frequency - Time and resource intensive to complete - Also applies to Immediate use compounders, who likely don't compound under ISO class 5 conditions

Section 2. Personnel Training and Evaluation

Initial Compounding Personnel Training and Competency Assessment

- Comprehensive didactic learning
  - Requires significant expertise to develop
  - Time and resource intensive to complete
- *Our Program:*
  - Purchased portfolio of eLearning modules (27 hr initial training)
  - Centralized new employee training (3 days for sterile training with 2:1 trainee to trainer ratio during practical instruction)
  - No compounding until: eLearning complete, passed initial assessments, passed media fill and GFS
  - Challenges: Centralizing training for specialized equipment vs. coordinating with supervisors for local training records

Section 2. Personnel Training and Evaluation

Ongoing Compounding Personnel Training and Competency Assessment

Our Program:

- Purchased portfolio of eLearning modules (13 hours annual ongoing)
- Centralized media fill challenges
  - Implemented every 6 month frequency in 2018
  - 6x monthly groups (approx. 60 employees per month)
  - 1 hour each (90 minutes w/equipment assessment included)
  - 3 Different media fill types: Simple, Non-Hazardous, Hazardous
  - Semi-annual assessment includes: Hand hygiene, Garbing, Aseptic assessment, Cleaning assessment, Media Fill, GFS, Surface Sampling
- Challenges: How to identify and incorporate additional immediate use compounders (without primary engineering control (PEC) use experience)

Section 3. Personnel Hygiene and Garbing

Key 2019 Changes	Impact/ Considerations
3.2 **Hand Hygiene** Personnel must wash hands - Nail Picks - Closed system soap	- No mention of compounding location = applies to immediate use - May have difficulty accessing sinks & mandated supplies outside of Rx

- Areas impacted are primarily outside of pharmacy scope (nursing, anesthesia, procedural areas)
- Unsure how regulators will enforce for non-pharmacy areas
- *Our Planning:*
  - Await accreditor standards updates on expectations for handwashing outside of pharmacies

Section 3. Personnel Hygiene and Garbing

3.3 **Garbing and Gloving Considerations**

- Garbing and gloving requirements do **not to apply to typical immediate use dose prep**
- Simultaneous doffing/donning garb prohibition
  - New restrictions will impact workflow patterns
  - Anecdotal experience suspecting that garb doffing was cause of ante room viable air failures
  - We prefer doffing (of non-hazardous garb) in general pharmacy (especially in ISO class 7 ante rooms)
- Glove donning location changes
  - New clarification that glove donning can occur in any ISO classified space or within SCA
  - *Our organization:* prefers to don gloves in ante rooms to minimize buffer room bio burden (w/hands-free door activation)

Compounding Facilities

- Key Revised USP <797> standards related to
  - Facilities Design
  - Maintenance
  - Monitoring

At Our Organization:
Compounding personnel educational activities and coordination are led by the Facilities Pharmacist on the Compounding Compliance Team

Section 4. Facilities and Engineering Controls

Key 2019 Changes	Impact/ Considerations

4.2 **Facility Design and Environmental Controls**
- Humidity and Temperature
  - Relative humidity <u>should</u> be <60%
  - Temperature <u>should</u> be 20°C or cooler
  - Should be monitored/recorded on operational days manually or by continuous recording device
	- Are HVAC systems designed/ capable of meeting standards?
	- HVAC common source of project design cost cutting

4.2 **Facility Design and Environmental Controls** - Controls in place to minimize flow of lower-quality air into more controlled areas - Seals and sweeps not recommended - Tacky Mats outside of ISO classified space	- Many of these changes may require redesign of spaces - Pass throughs - Interlocking (minimum)

Section 4. Facilities and Engineering Controls

Key 2019 Changes	Impact/ Considerations

4.2 **Air Exchange Requirements**
- SCAs- No stated requirements
- Restricted access barrier systems (RABS)- documented recovery time to achieve ISO class 5
- Clean Room Suites
  - ISO class 7: 30 air changes per hour (ACPH); minimum 15 from HVAC in room-unchanged
  - ISO class 8: 20 ACPH- previously not regulated
	- Chapter guidance about variable conditions that may require increased ACPH are worth heeding during design phase

Our Experience:
- Our new facilities required significantly higher ACPH to achieve ISO class viable air standards (ISO 7 Ante rooms need 45-60+ ACPH)

Section 4. Facilities and Engineering Controls

Key 2019 Changes	Impact/ Considerations
4.2 **Establishing and Maintaining Pressure Differentials** - Continuous Pressurization Standards	- Continuous is a misnomer, door openings may neutralize pressures
4.2 **Pressure Monitoring** - Continuous pressure differential monitoring device must be used to monitor differentials Daily quantitative results review & documentation daily when compounding	- Interpretation requires technical training and decision making and access

Condition	2008	2019
Positive	0.02-0.05” W.C.	>0.02” W.C.
Negative	<-0.01” W.C.	-0.01 to -0.03” W.C.

W.C. = water column

Section 4. Facilities and Engineering Controls

Our Strategy to Managing Facilities and Engineering Controls:

- Interdisciplinary team (engineers, HVAC, certifiers, pharmacy) established sterile compounding **facility design guidelines**; standardize renovation/construction
- All pass throughs connecting ISO classified & unclassified spaces are HEPA purged
- Centralized compounding compliance team assists area supervisors in more advanced troubleshooting and coordination of service planning

Section 4. Facilities and Engineering Controls

Our Challenges:

- Complex monitoring systems are not easily accessible; difficult to interpret by compounding personnel
- HVAC systems not designed to or capable of maintaining new humidity/ temperature standards in warm months; have prolonged out of range plan
- Insufficient air change rate capabilities to maintain viable air standards
- Pressure fluctuations due to tight construction envelope

Section 4. Facilities and Engineering Controls

Key 2019 Changes	Impact/ Considerations
4.4 **Water Sources** - May now be inside or outside of ante room of cleanroom suite - Must now be outside of perimeter of SCA	- These new options may significantly limit microbial contamination in controlled areas

Our Experience:

- Sinks have been suspected as likely source of viable air sampling failures in ante rooms
- Variable sink locations create confusing staff hand hygiene and garbing sequences
- Debating donning of shoe covers before or after washing

Section 6. Microbial Air & Surface Monitoring

Key 2019 Changes	Impact/ Considerations
6.1. **General Monitoring Requirements** - Microbiological Monitoring (formerly environmental monitoring)	- Impaction Sampling requires expensive sampling equipment, often done by certifiers

Type	2008	2019
Air	• Settling –OR- • Impaction (400-1000 L) • Initial, every 6 months	• Impaction (1000 L) • Dynamic • Initial, every 6 months
Surface	• Contact Plates or Swabs • At end of compounding • Initial, Periodic	• Contact Plates or Swabs • At end of activity or shift • Initial, Monthly*

*Specified in 2019 section 6.3

Section 6. Microbial Air & Surface Monitoring

Key 2019 Changes	Impact/ Considerations
6.2. Data Evaluation and Action Levels Microorganism Identification and Action	- Changes to this section make more frequent sample collection feasible

Requirements	2008	2019
Organism ID (genus level)	• Any colony forming unit (CFU)	• If CFUs exceed action level
Action if Highly Pathogenic Organism (HPO)	• Yes	• No
Investigation	• Yes if action level, any HPO	• Yes if action level exceeded

Our Experience:
- Occasional, below action level recovery of HPOs is not unexpected in ante rooms and more common in warm weather months
- Investigations, time consuming and often don't identify source

Section 6. Microbial Air & Surface Monitoring

Our Strategy for Microbial Monitoring Management:

- Centralized sample collection by trained compounding compliance team
- Send out all samples to pharmacy micro lab for incubation and identification
  - Will continue to identify all CFUs recovered (cheaper by lab)
  - Discontinued identification of HPOs
- Centralized review of results and action planning (Facilities Pharmacist)
- Monthly results review meetings with Compounding Compliance Team, Supervisors, & Infection Prevention

Section 7. Cleaning, Disinfecting [etc.]

Key 2019 Changes	Impact/ Considerations
7. **Cleaning, Disinfecting, and Applying Sporicidal Agents in Compounding Areas** Highlights from Table 8. Minimum Frequency for Cleaning and Disinfecting Surfaces … • If the compounding process takes more than 30 minutes, <u>compounding must not be disrupted</u> and the work surface of the PEC must be disinfected immediately after compounding. • Footnote C: Ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal agent <u>only when visibly soiled and when surface contamination is known or suspected</u>.	- Changes to cleaning/ disinfecting with impact on our operations - Disinfecting work surfaces every 30 minutes has now been clarified as not needing to disrupt processes longer than 30 minutes - SCA Ceilings don't require monthly cleaning if unsoiled

Section 8. Introducing Items into the SEC/PEC

Key 2019 Changes	Impact/ Considerations
8.1 **Introducing Items into secondary engineering control (SEC)** - Chapter continues to allow disinfection of materials with sporicidal agent, EPA registered disinfectant, or sterile Isopropyl Alcohol (sIPA)	*Our Experience* - Internal studies showed spore-former supply contamination. We require sporicidal materials disinfection - Use sporicidal compatible labels
8.3 **Use of sIPA on critical sites within the PEC** - 2019 Chapter removed 2008 language "the surface of the… swab… shall not contact any other object before contacting the surface of the entry point" –AND- 2018 proposed language of unidirectional swiping	- This prior language was the cause of some accreditors requiring <u>1 sIPA swab per critical site</u> - New language requires drying before aseptic manipulations - *Our Plan:* Wait to allow multiple use of swab after The Joint Commission (TJC) updates standard

Resources and Records

- Key Revised USP <797> standards related to
  - Resources
    - Policies and Procedures
    - Master Formulation Records
  - Compounding Records

At Our Organization:
Compounding resources and records oversight is led by the Lead Pharmacist on the Compounding Compliance Team and heavily involves the organization's Medication Use Policy team.

Section 11. Master Formulation & Records

Key 2019 Changes
11.1 Creating Master Formulation Records - Now required for CSPs prepared for >1 patient or from non-sterile ingredients - Box 11-1 lists detailed requirements

11.2 Creating Compounding Records
- A compounding record must be created for all CSPs
  - Rx, Order or Label count as records if capture necessary information
  - Box 11-2 lists detailed requirements

Our Experience:
- Have bulk recipes but lack some required details (i.e., descriptions, supply lists)
- Our inpatient Order and Labels missing: Date/Time of preparation, lot/expiration, compounder identities, assigned BUD, quality control results

Sec 15. Manufactured Products as Components

Key 2019 Changes	Impact/ Considerations

15.1 **Use of Conventionally Manufactured Single Dose Containers**
- Single Dose Vials accessed in ISO class 5 air
  - May be used for <u>up to 12 hours</u> (previously 6 hours)
  - If storage requirements are maintained (i.e., refrigeration)
  - Open ampules may not be stored
	- Benefits of new standards
	  - Additional 6 hours of in-use time
	  - Clarification that vials can be removed from hoods during 12 hours of in-use time

Our Experience:

- Storing single dose containers in PEC during in-use time considered safety risk
- We don't allow containers spiked with adapters that leave hood to be reused

Sec 15. Manufactured Products as Components

Key 2019 Changes	Impact/ Considerations

15.3 **Use of Conventionally Manufactured Pharmacy Bulk Packages**
- Use according to manufacturer's labeling
  - Usually <12 hours allowed for single dose containers
- Must be entered or punctured only in ISO Class 5 PEC
  - Changed from v2018 language "<u>to be used only</u> in ISO Class 5 PEC"
	- Benefits of new standards
	  - Clarification that bulk containers can be removed from hoods during 12 hours of in-use time

Our Experience:

- We don't allow containers spiked with adapters that leave hood to be reused

Section 16. CSPs as Components

Key 2019 Changes	Impact/ Considerations

16. **Use of CSPs as Components** (New)
- BUD of a CSP prepared from compounded components may not exceed shortest BUD
16.2 **Use of Compounded Single-Dose CSPs and CSP stock solutions**
- Original CSP/stock solution must be
  - Entered in ISO class 5
  - Stored in correct conditions (i.e., refrigeration)
  - May be used up to 12 hours or BUD, whichever shorter
	- Benefits of new standards
	  - Clarifies:
	  - CSPs can be used as components
	  - Containers can be removed from hoods during 12 hours of in-use time
	Our Experience:
	- This was a previous gray area for common practice in our children's hospital

Section 17. SOPs

Key 2019 Changes	Impact/ Considerations
17. SOPs - SOPs must have documented review every 12 months - SOP revisions must be communicated to all personnel involved in processes - Personnel should document acknowledgement of communication	Significant Change: - Traditionally SOPs were reviewed at frequency of accreditation/certification (2-3 years) - Documenting acknowledgement by staff complex for large organizations

Our Experience:
- Michigan Medicine has: 21 compounding related policies, 9 centralized work procedures, 34 Forms/Guidelines- Annual review will be time consuming
- We use an electronic survey engine to share compounding SOP updates, quiz, and attestations

Welcome to the Fandom !

Summary and Takeaways

- There are significant changes in the revised USP Chapter <797>
  - some less stringent 
  - some will take considerable planning, resources 
- Readiness activities don't all have to be delayed
- Centralization of oversight and coordination may create standardization and efficiencies

Suggested Readings

- USP Web resources **www.usp.org/compounding/general-chapter-797**
  - USP <797> FAQs
  - USP <797> Commentary
  - Summary of updates of revised (postponed) chapter (published 07/03/2019)
  - Expert Committee Decisions on Appeals General Chapters <795> & <797> (published 08/16/2019)
  - BUD Fact Sheet for revised (postponed) General Chapters <795> & <797> (published 07/03/2019)
- Compare Past Chapters

All Icons in the presentation were made by [Freepik, itim2101, and srip] from www.flaticon.com

IV Push Medication Administration: Overview of Best Practices and Error-Reduction Strategies

Michael J. Freudiger, Pharm.D., APh, BCPS, BCGP

Program Outline

- Summarize Institute for Safe Medication Practices (ISMP) survey results showing the persistence of unsafe practices with IV push medications
- Understand the benefits/risks involved in preparing and administering IV push therapy
- Review best practices and corresponding error-reduction strategies for preparation and administration of medication via IV push

How is your facility currently managing IV push medications that require initial reconstitution?

A. Nursing reconstitutes all medications for IV push immediately before administration.
B. Nursing reconstitutes selected medications; pharmacy reconstitutes the rest.
C. Pharmacy reconstitutes all medications for IV push and delivers as ready to administer syringes.

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ISMP Surveys on IV Push Practices

2010
- **Survey: Impact of the economic crisis/shortages on medication safety**
  - Increase in nurses preparing or manipulating parenteral medications on the clinical unit

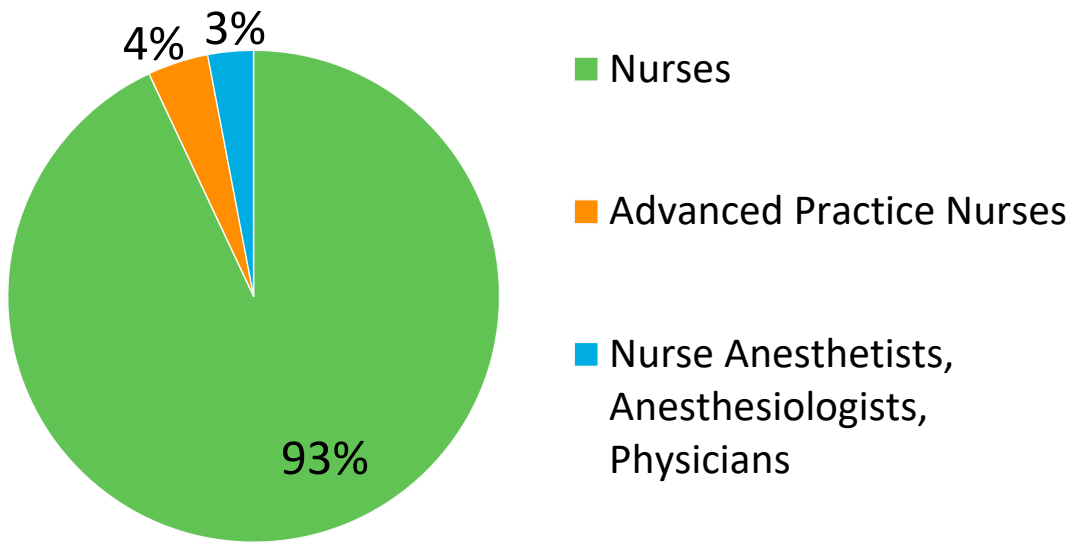
2012
- **Survey: Practices when using prefilled medication syringes**
  - Withdrawing medication from prefilled syringe cartridges

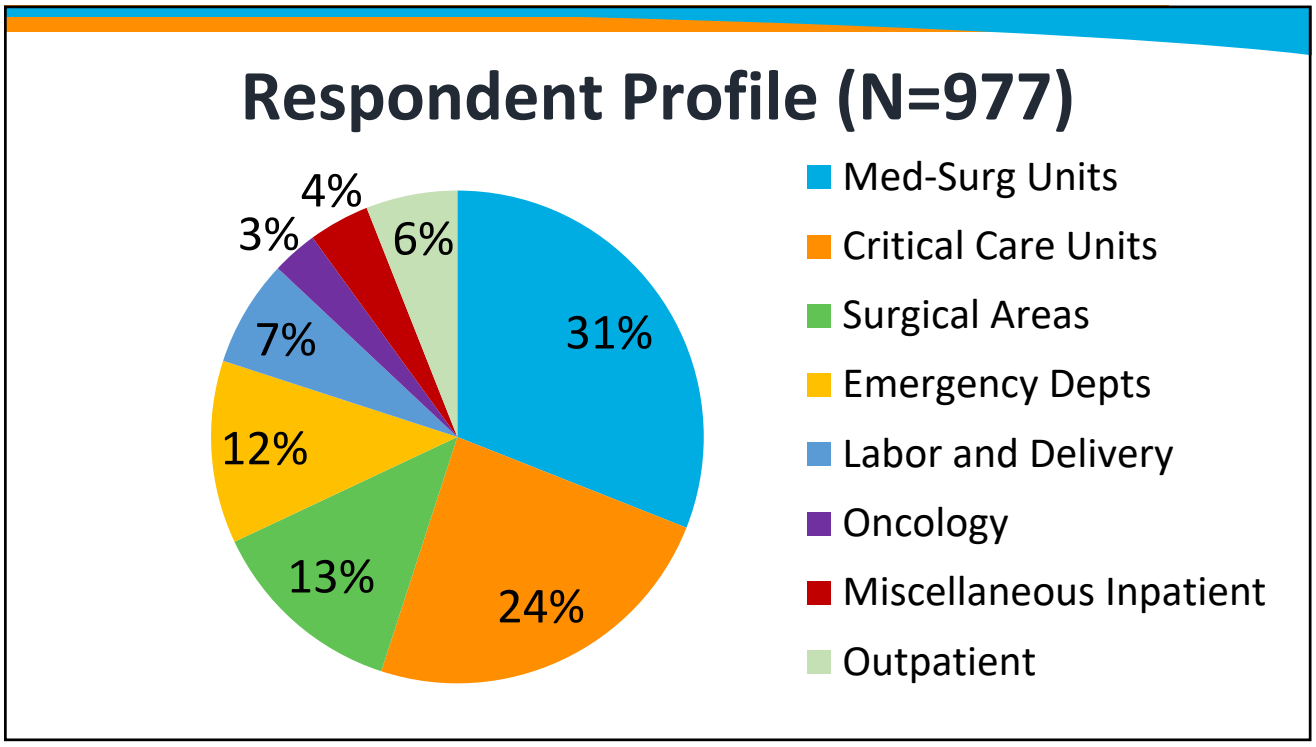
2014
- **Survey: IV push practices**
  - Unnecessary dilution of dispensed ready-to-administer medications
  - Inappropriate use of prefilled saline flush syringes for dilution
- **Summit: ISMP Safe Practice Guidelines for Adult IV Push Medications [2015]**

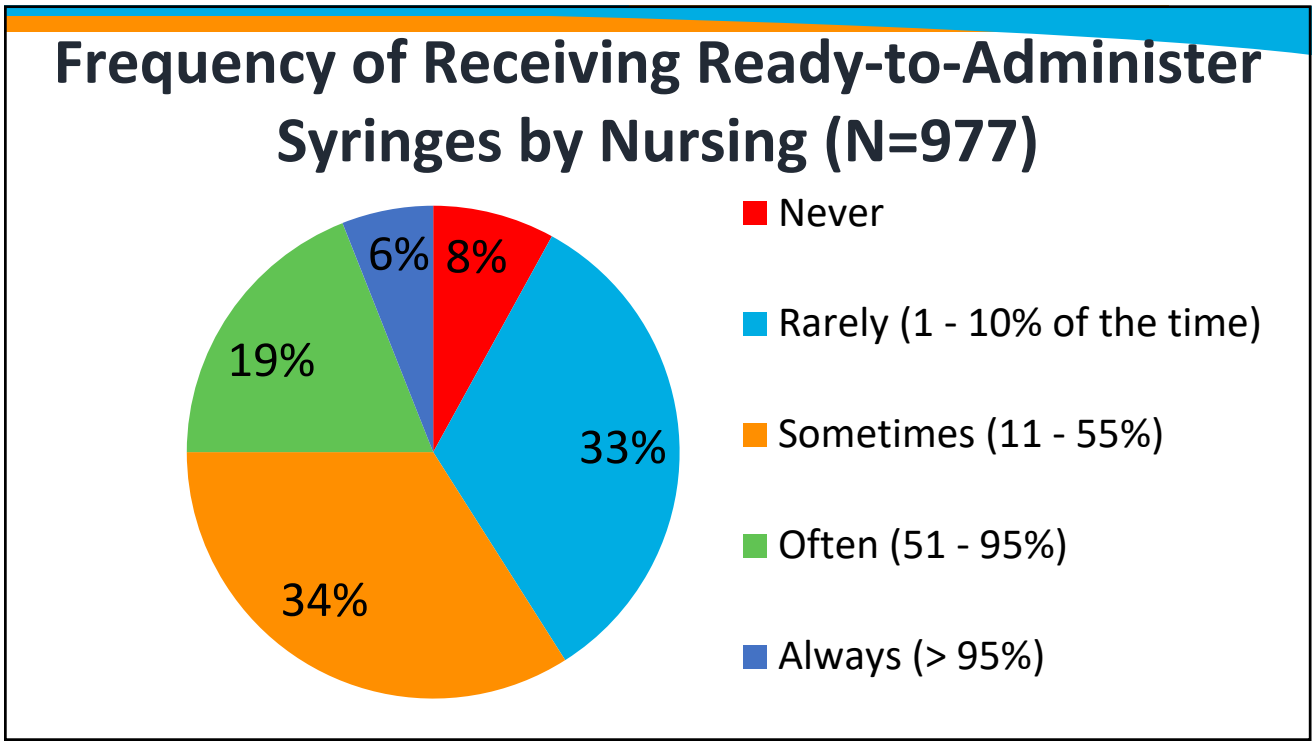
2018
- **Survey: IV push practices (N=977)**
  - Follow up to understand current practices associated with IV push medications
  - Determine if ongoing drug shortages and teaching strategies around this critical skill have impacted current practices

ISMP Survey on IV Push Medication Practices. 2018;16(7):4-5.

Respondent Profile (N=977)







Medications Most Frequently NOT Provided in Ready-to-Administer Syringes

- Antiemetics (e.g., ondansetron, prochlorperazine, promethazine)
- Antipsychotics (e.g., haloperidol)
- Benzodiazepines (e.g., LORazepam, diazePAM)
- Antibiotics with short stability
- Opioids (e.g., fentaNYL, HYDROmorphone, morphine)
- Pantoprazole
- Metoprolol
- Furosemide

SELECTED SURVEY RESULTS: How often are IV push medications provided in pharmacy-prepared or commercially available ready-to-administer syringes?

- 75% reported less than half of the time

  Given the current drug shortage crisis:

  – 31% agree they have **less prefilled, ready-to-use syringes** than before
  – 31% agree they see more IV push drugs provided in **unfamiliar formulations**
  – 34% agree that they are **required to prepare more IV push medications** at bedside
  – 38% agree that they are **giving more medications via IV push** that were previously given as infusions

SELECTED SURVEY RESULTS: How often do you withdraw medications from one syringe (or cartridge) and transfer to another to administer some or all of an IV push medication dose?

- 16% reported more than half of the time (always and often)
- Another 20% reported sometimes

Reason Why?	Percent
Need to dilute the drug	64%
Cannot locate the designated holder	22%
This is how I was taught	15%
Too hard to read dose increments on medication syringe	14%
Syringe has irremovable needle or does not have needleless connector	14%
Other (e.g., must use 10 mL syringe for central lines)	22%

SELECTED SURVEY RESULTS: How often do you dilute medications?

Container	Never/Rarely	Sometimes	Often/Always
Single-dose vial (SDV)	41%	37%	22%
Multiple-dose vial (MDV)	79%	14%	7%
Prefilled syringes	84%	11%	5%
Pharmacy-prepared syringes	95%	4%	2%

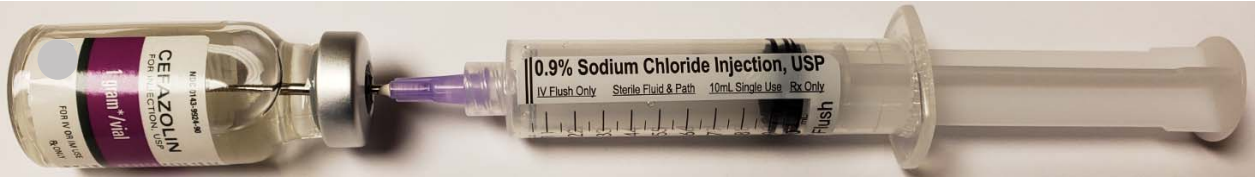
SELECTED SURVEY RESULTS: Why do you dilute IV push medications? (select all that apply)

Reason Why?	Percent
Slow administration; small drug volume	94%
Reduce discomfort at injection site	70%
Afraid of extravasation	33%
Small dose / volume difficult to measure	25%
Other: lorazepam requirements, hospital policy, drug reference recommendation, central lines, how practitioner was taught, drug shortages (especially sodium chloride 0.9%)	13%

SELECTED SURVEY RESULTS: How often do you use prefilled sodium chloride 0.9% (NS) flush syringes to dilute, measure, and administer an IV push medication?

Response	Percent
Sometimes	16%
More than 50% of the time (always and often)	56%
Always	19%

SELECTED SURVEY RESULTS: How often do you use prefilled sodium chloride 0.9% (NS) flush syringes to dilute, measure, and administer an IV push medication?



Three Processes: (syringes most often NOT labeled)

1. Drug drawn directly into NS syringe
2. Drug withdrawn into syringe first, then add to NS syringe
3. Drug and NS (from prefilled syringe) drawn into separate syringe

Photo: Michael Freudiger

SELECTED SURVEY RESULTS: How often do you label IV push syringes that you prepare away from the patient's bedside? 28%: < 10% of the time, and 50%: always

Reason Why?	Percent
Not necessary if preparing just 1 drug	51%
Not necessary if preparing just 1 syringe	45%
Emergency	39%
Too time consuming	20%
No labels	20%
Not an expectation at my facility	12%
Can distinguish by appearance / location	7%

Most labeling is taping of the vial to the syringe.

SELECTED SURVEY RESULTS: How do you distinguish between two or more unlabeled syringe?

Reason Why?	Percent
Know what the syringes contain based on their different volumes	76%
Use different size syringes	40%
Separate syringes in hands or use different clothing pockets	24%
Place syringes on tray or sterile field a certain way	16%
Mark one of the syringes with a marker	12%
Other: visual appearance (color), needle differences, colored tape	36%

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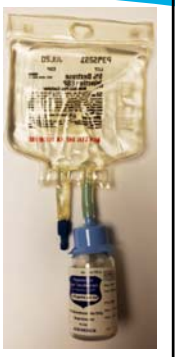
IV Drug Delivery Systems



- Point-of-Care (POC) Activated
- Point-of-Care (POC) Compounded
- Manufacturer Ready-to-Administer (RTA)
- Insourced Ready-to-Administer (RTA) – 503A
  - Manually, IV Workflow, IV Robotics
- Outsourced Ready-to-Administer (RTA) – 503B

Photo: Michael Freudiger

Benefits (Administration)

- Cefazolin IV Push vs. IVPB – no significant difference in rates of phlebitis
- Antibiotics IV Push vs IVPB – 9% lower phlebitis in outpatients and 25% lower in inpatients (N=127)
- Cefepime IV Push in emergency department (ED) had decreased time to administration of vancomycin in sepsis by over 1 hr

Bigger, et al. *J Infus Nurs.* 2012 Nov-Dec; 35(6):384-8
Sherry, et al. *J Vasc Access Networks*. 1993; 3:9, 10, 14-7.
Tran A. *Journal of Pharmacy Practice.* October 2017

Benefits (Administration)

- IV push antibiotics vs. IVPB: no difference in frequency of post-infusion phlebitis (N=155)
- Cost avoidance study found economic benefits when antibiotics were given as IV push in preop as compared to IVPB.

Garrelts, at al. *Clin Pharm.* 1988; 7:760-5.
Garrelts, et al. *PharmacoEconomics.* 1992; 2:1116-23.

Benefits of IV Push Administration

- Cost savings (??) from not using IVPB and infusion lines
- Less limitations on IV drug incompatibilities (e.g., pantoprazole, antibiotics)

Safety Risks with Nurse Compounded IV Push Preparations

- Drug incompatibilities (mixing)
- Drug reconstituted with incorrect volume
- Drug not fully dissolved
- Aseptic technique not followed
- Drug compounded within insanitary area
- Drug vials reconstituted with saline flushes

Risks (Preparation)

- Error rates are lowest (< 1 %) with RTA products
- Error rate increased to 2% with POC devices related to improper activation of the devices
- Errors increase with more preparation steps
  - 5% obtaining the drug, 7% obtaining the diluent, 31% when reconstituting drug and diluent

Flynn EA. *Am J Health Syst Pharm.* 1997; 54:904-12
McDowell SE. et al. *Postgrad Med J.* 2010; 86:734-8

Risks (Administration)

- 30% of errors occur during administration
- Most common error is giving IV push too fast
- Error reported:
  - Labetalol 20 mg (must be given over 2 min)
  - IV push given over 2 seconds = cardiac arrest, death

McDowell SE. et al. *Qual Saf Health Care*. 2010;19(4):341-5.
Taxis K. et al. *BMJ* 2003;326:684
Grissinger M. *PT.* 2007;32:124

Other Unsafe Practices

- Nurses diluting medications without directions
- Dilution practices vary between shifts
- No evaluation of nurse's aseptic technique
- Diluted drug (in saline flush) placed onto syringe pump (no graduations on the syringes)

Other Unsafe Practices

- Nurses diluting medications unnecessarily in attempt to:
  - Reduce drug irritant properties
  - Give the drug more slowly
  - Increase patient comfort
  - Reduce drug viscosity
  - Improve ability to measure the small volume

Grissinger M. *PT*. 2017;42:490-508

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ISMP Safe Practice Guidelines

Factors that Increase the Risk of IV Push Medication Errors in Adults

- Lack of Patient Information
- Lack of Drug Information
- Communication of Drug Information
- Drug Labeling, Packaging, and Nomenclature
- Drug Storage, Stock, Standardization, and Distribution
- Device Use
- Environment, Staffing, and Workflow
- Staff Education and Competency
- Risk Management and Quality Improvement Challenges

Safe Practice Guidelines

- Acquisition and Distribution of Adult IV Push Medications
- Aseptic Technique
- Clinician Preparation
- Labeling
- Clinician Administration
- Drug Information Resources
- Competency Assessment
- Error Reporting

ISMP Revealed 5 Unsafe Practices

1. Using prefilled syringes or cartridges as vials (withdrawing some or all medication from a prefilled syringe or cartridge into another syringe for administration)
2. Diluting adult IV push medications unnecessarily despite their availability in a ready-to-administer form (e.g., manufacturer or pharmacy-prepared syringes, single-dose vials)

ISMP Medication *Safety Alert!®* Nurse Advise*ERR*®. 2018;16(11)

ISMP Revealed 5 Unsafe Practices

3 Diluting or reconstituting an IV push medication in a prefilled 0.9% sodium chloride (saline) flush syringe that is rarely relabeled

4 Failing to properly label syringes of IV push medications prepared away from the patient's bedside

ISMP Medication *Safety Alert!*® Nurse Advise*ERR*®. 2018;16(11)

ISMP Revealed 5 Unsafe Practices

5 Clinicians preparing or manipulating IV push medications on patient care units instead of pharmacy dispensing ready-to-administer syringes of medications

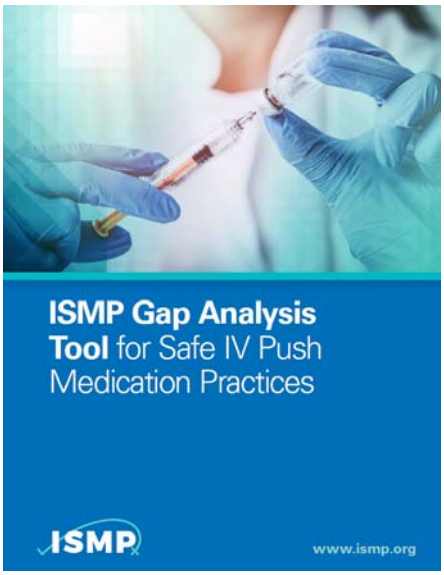
ISMP Medication *Safety Alert!*® Nurse Advise*ERR*®. 2018;16(11)

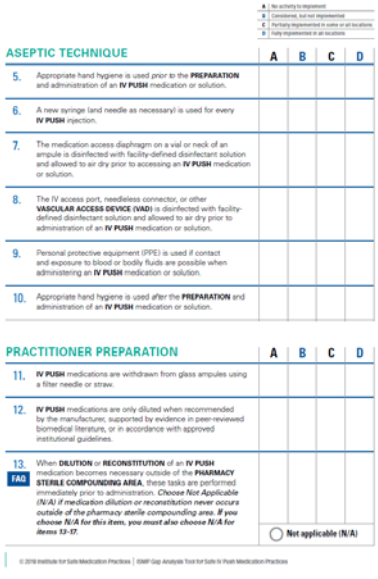
ISMP's Best Recommendations

- Dispense prefilled ready-to-administer syringes when possible.
- Dispense in the correct concentration and volumes for common or patient-specific doses.
- Pharmacy should prepare and dispense syringes if prefilled syringes are not available.
- Review ISMP Gap Analysis Tool

ISMP Medication *Safety Alert!*® Nurse Advise*ERR*®. 2018;16(11)

ISMP Gap Analysis Tool





ASEPTIC TECHNIQUE

	A	B	C	D
5. Appropriate hand hygiene is used *prior* to the **PREPARATION** and administration of an **IV PUSH** medication or solution.				
6. A new syringe (and needle as necessary) is used for every **IV PUSH** injection.				
7. The medication access diaphragm on a vial or neck of an ampule is disinfected with facility-defined disinfectant solution and allowed to air dry prior to accessing an **IV PUSH** medication or solution.				
8. The IV access port, needleless connector, or other **VASCULAR ACCESS DEVICE (VAD)** is disinfected with facility-defined disinfectant solution and allowed to air dry prior to administration of an **IV PUSH** medication or solution.				
9. Personal protective equipment (PPE) is used if contact and exposure to blood or bodily fluids are possible when administering an **IV PUSH** medication or solution.				
10. Appropriate hand hygiene is used *after* the **PREPARATION** and administration of an **IV PUSH** medication or solution.				

PRACTITIONER PREPARATION

	A	B	C	D
11. **IV PUSH** medications are withdrawn from glass ampules using a filter needle or straw.				
12. **IV PUSH** medications are only diluted when recommended by the manufacturer, supported by evidence in peer-reviewed biomedical literature, or in accordance with approved institutional guidelines.				
13. FAQ When **DILUTION** or **RECONSTITUTION** of an **IV PUSH** medication becomes necessary outside of the **PHARMACY STERILE COMPOUNDING AREA**, these tasks are performed immediately prior to administration. *Choose Not Applicable (N/A) if medication dilution or reconstitution never occurs outside of the pharmacy sterile compounding area. If you choose N/A for this item, you must also choose N/A for items 13–17.*				
○ Not applicable (N/A)				

- ❑ Acquisition and distribution of adult IV push medications
- ❑ Aseptic technique
- ❑ Practitioner preparation
- ❑ Labeling
- ❑ Practitioner administration
- ❑ Drug information resources
- ❑ Competency assessment
- ❑ Error reporting

Implementing Safe IV Push Practices

- Ensure IV push rates are programmed into electronic health records (EHRs) for each of the drugs to be given as IV push
- Supply IV push kits when pharmacy cannot prepare
- Provide charts that organize:
  - Drug
  - Diluent
  - IV push rates

Implementing Safe IV Push Practices

- Employee education is important!
  - Dispel the myths: 10 mL is not required, 3 mL is the minimum infusion volume for PICC lines
  - Explain benefits/risks of diluting IV push medications
  - Educate on the 5 unsafe practices identified by ISMP
  - Ensure new staff are not being taught unsafe IV push administration practices

ISMP Medication *Safety Alert!®* Nurse Advise*ERR*®. 2018;16(11)

Supply IV Push Kits for Automated Dispensing Cabinets

EXAMPLE KIT LABEL:

Cefepime 2 Gram Kit
Mixing Instructions:
Dilute Cefepime 2-G vial with Sterile Water 20 mL;
Give IV push over 5 min
Expires 1 hr after mixing

Photo: Michael Freudiger

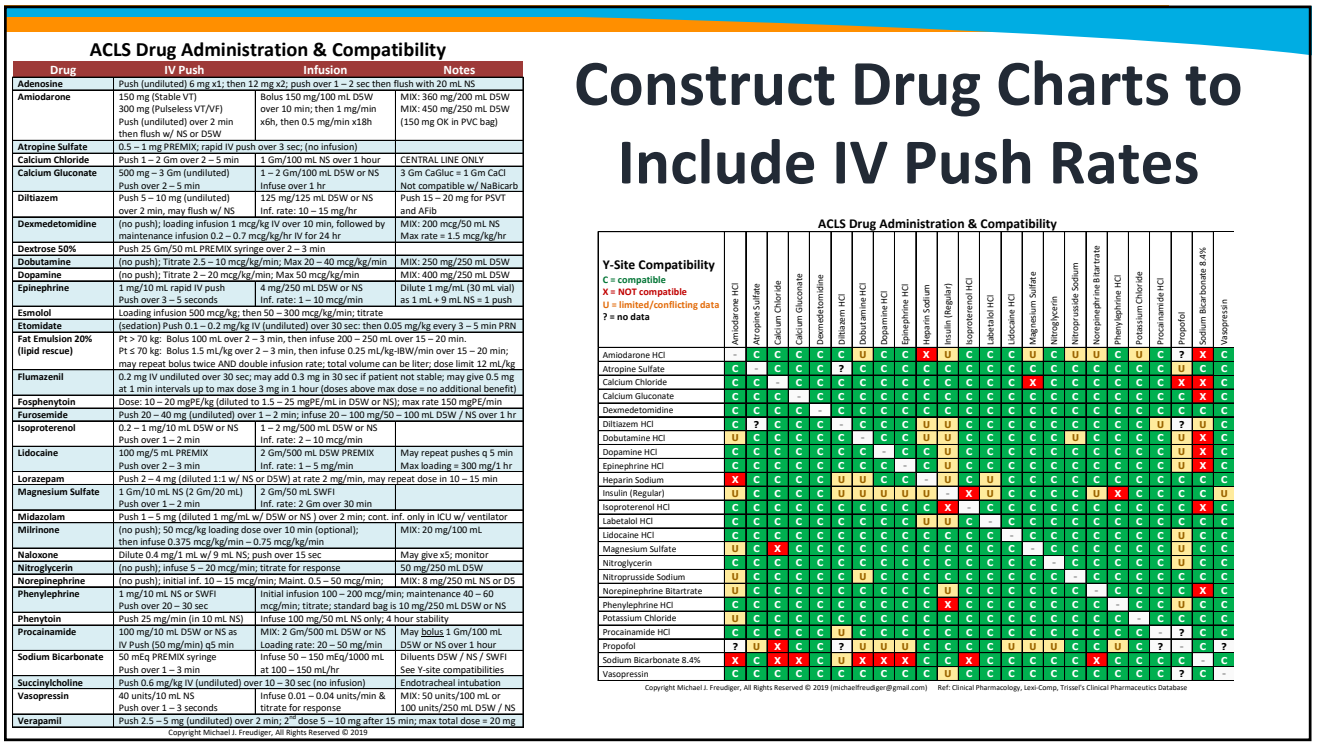
Medications for IV Push (example)

Drug/Dose	Dilution Volume	Compatible Diluents	IV Push Rates	Notes & References
Ampicillin 125 mg	5 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Ampicillin 250 mg	10 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Ampicillin 500 mg	10 mL	SWFI, NS	IV Push over 5 min	References 1 – 6
Ampicillin 1 – 2 g	50 mL	NS, D5W	Infuse over 15 – 30 min IVPB	References 1 – 6
Aztreonam 1 g	10 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Aztreonam 2 g	10 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Cefazolin 1 g	10 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Cefazolin 2 g	10 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Cefepime 1 g	10 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Cefepime 2 g	20 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Cefoxitin 1 g	10 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Cefoxitin 2 g	20 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Ceftaroline 400 mg	20 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Ceftaroline 600 mg	20 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Ceftazidime 1 g	10 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Ceftazidime 2 g	10 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Ceftriaxone 1 g	10 mL	SWFI, NS	IV Push over 2 – 5 min	Not compatible with calcium solutions
Ceftriaxone 2 g	20 mL	SWFI, NS	IV Push over 2 – 5 min	
Cefuroxime 750 mg		SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Cefuroxime 1.5 g	16 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Meropenem 500 mg	10 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Meropenem 1 g	20 mL	SWFI, NS	IV Push over 3 – 5 min	References 1 – 6
Pantoprazole 40 mg	10 mL	NS	IV Push over 2 min; May convert 8 mg/hr continuous infusion to 40 mg every 12hr;[7] Flush IV line with 20 mL NS before and after administration	

SWFI: sterile water for infusion; NS: 0.9% sodium chloride. *DISCLAIMER: this is a standardized chart for ease of reconstitution and administration.*

1. Manufacturer package inserts (all drugs listed, available manufacturer, USA). 2. Lexi-Drugs Internet Database. Hudson (OH): Lexi-Comp, Inc.; 2017. 3. Micromedex 2.0, (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 4. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier. 2018. 5. Trissel LA. Interactive Handbook on Injectable Drugs. Bethesda, MD: ASHP. 19th edition. 6. Gahart BL. Gahart's 2018 Intravenous Medications: A Handbook for Nurses and Healthcare Professionals. St. Louis, MO: Elsevier Inc; 2018. 7. Sachar H et al. *JAMA Intern Med*. 2014 Nov;174(11):1755-62.

See enlargements, p. 86-87



ACLS Drug Administration & Compatibility

Drug	IV Push	Infusion	Notes
Adenosine	Push (undiluted) 6 mg x1; then 12 mg x2; push over 1 – 2 sec then flush with 20 mL NS		
Amiodarone	150 mg (Stable VT) 300 mg (Pulseless VT/VF) Push (undiluted) over 2 min then flush w/ NS or D5W	Bolus 150 mg/100 mL D5W over 10 min; then 1 mg/min x6h, then 0.5 mg/min x18h	MIX: 360 mg/200 mL D5W MIX: 450 mg/250 mL D5W (150 mg OK in PVC bag)
Atropine Sulfate	0.5 – 1 mg PREMIX; rapid IV push over 3 sec; (no infusion)		
Calcium Chloride	Push 1 – 2 Gm over 2 – 5 min	1 Gm/100 mL NS over 1 hour	CENTRAL LINE ONLY
Calcium Gluconate	500 mg – 3 Gm (undiluted) Push over 2 – 5 min	1 – 2 Gm/100 mL D5W or NS Infuse over 1 hr	3 Gm CaGluc = 1 Gm CaCl Not compatible w/ NaBicarb
Diltiazem	Push 5 – 10 mg (undiluted) over 2 min, may flush w/ NS	125 mg/125 mL D5W or NS Inf. rate: 10 – 15 mg/hr	Push 15 – 20 mg for PSVT and AFib
Dexmedetomidine	(no push); loading infusion 1 mcg/kg IV over 10 min, followed by maintenance infusion 0.2 – 0.7 mcg/kg/hr IV for 24 hr		MIX: 200 mcg/50 mL NS Max rate = 1.5 mcg/kg/hr
Dextrose 50%	Push 25 Gm/50 mL PREMIX syringe over 2 – 3 min		
Dobutamine	(no push); Titrate 2.5 – 10 mcg/kg/min; Max 20 – 40 mcg/kg/min		MIX: 250 mg/250 mL D5W
Dopamine	(no push); Titrate 2 – 20 mcg/kg/min; Max 50 mcg/kg/min		MIX: 400 mg/250 mL D5W
Epinephrine	1 mg/10 mL rapid IV push Push over 3 – 5 seconds	4 mg/250 mL D5W or NS Inf. rate: 1 – 10 mcg/min	Dilute 1 mg/mL (30 mL vial) as 1 mL + 9 mL NS = 1 push
Esmolol	Loading infusion 500 mcg/kg; then 50 – 300 mcg/kg/min; titrate		
Etomidate	(sedation) Push 0.1 – 0.2 mg/kg IV (undiluted) over 30 sec: then 0.05 mg/kg every 3 – 5 min PRN		
Fat Emulsion 20% (lipid rescue)	Pt > 70 kg: Bolus 100 mL over 2 – 3 min, then infuse 200 – 250 mL over 15 – 20 min. Pt ≤ 70 kg: Bolus 1.5 mL/kg over 2 – 3 min, then infuse 0.25 mL/kg-IBW/min over 15 – 20 min; may repeat bolus twice AND double infusion rate; total volume can be liter; dose limit 12 mL/kg		
Flumazenil	0.2 mg IV undiluted over 30 sec; may add 0.3 mg in 30 sec if patient not stable; may give 0.5 mg at 1 min intervals up to max dose 3 mg in 1 hour (doses above max dose = no additional benefit)		
Fosphenytoin	Dose: 10 – 20 mgPE/kg (diluted to 1.5 – 25 mgPE/mL in D5W or NS); max rate 150 mgPE/min		
Furosemide	Push 20 – 40 mg (undiluted) over 1 – 2 min; infuse 20 – 100 mg/50 – 100 mL D5W / NS over 1 hr		
Isoproterenol	0.2 – 1 mg/10 mL D5W or NS Push over 1 – 2 min	1 – 2 mg/500 mL D5W or NS Inf. rate: 2 – 10 mcg/min	
Lidocaine	100 mg/5 mL PREMIX Push over 2 – 3 min	2 Gm/500 mL D5W PREMIX Inf. rate: 1 – 5 mg/min	May repeat pushes q 5 min Max loading = 300 mg/1 hr
Lorazepam	Push 2 – 4 mg (diluted 1:1 w/ NS or D5W) at rate 2 mg/min, may repeat dose in 10 – 15 min		
Magnesium Sulfate	1 Gm/10 mL NS (2 Gm/20 mL) Push over 1 – 2 min	2 Gm/50 mL SWFI Inf. rate: 2 Gm over 30 min	
Midazolam	Push 1 – 5 mg (diluted 1 mg/mL w/ D5W or NS) over 2 min; cont. inf. only in ICU w/ ventilator		
Milrinone	(no push); 50 mcg/kg loading dose over 10 min (optional); then infuse 0.375 mcg/kg/min – 0.75 mcg/kg/min		MIX: 20 mg/100 mL
Naloxone	Dilute 0.4 mg/1 mL w/ 9 mL NS; push over 15 sec		May give x5; monitor
Nitroglycerin	(no push); infuse 5 – 20 mcg/min; titrate for response		50 mg/250 mL D5W
Norepinephrine	(no push); initial inf. 10 – 15 mcg/min; Maint. 0.5 – 50 mcg/min;		MIX: 8 mg/250 mL NS or D5
Phenylephrine	1 mg/10 mL NS or SWFI Push over 20 – 30 sec	Initial infusion 100 – 200 mcg/min; maintenance 40 – 60 mcg/min; titrate; standard bag is 10 mg/250 mL D5W or NS	
Phenytoin	Push 25 mg/min (in 10 mL NS)	Infuse 100 mg/50 mL NS only; 4 hour stability	
Procainamide	100 mg/10 mL D5W or NS as IV Push (50 mg/min) q5 min	MIX: 2 Gm/500 mL D5W or NS Loading rate: 20 – 50 mg/min	May bolus 1 Gm/100 mL D5W or NS over 1 hour
Sodium Bicarbonate	50 mEq PREMIX syringe Push over 1 – 3 min	Infuse 50 – 150 mEq/1000 mL at 100 – 150 mL/hr	Diluents D5W / NS / SWFI See Y-site compatibilities
Succinylcholine	Push 0.6 mg/kg IV (undiluted) over 10 – 30 sec (no infusion)		Endotracheal intubation
Vasopressin	40 units/10 mL NS Push over 1 – 3 seconds	Infuse 0.01 – 0.04 units/min & titrate for response	MIX: 50 units/100 mL or 100 units/250 mL D5W / NS
Verapamil	Push 2.5 – 5 mg (undiluted) over 2 min; 2nd dose 5 – 10 mg after 15 min; max total dose = 20 mg		

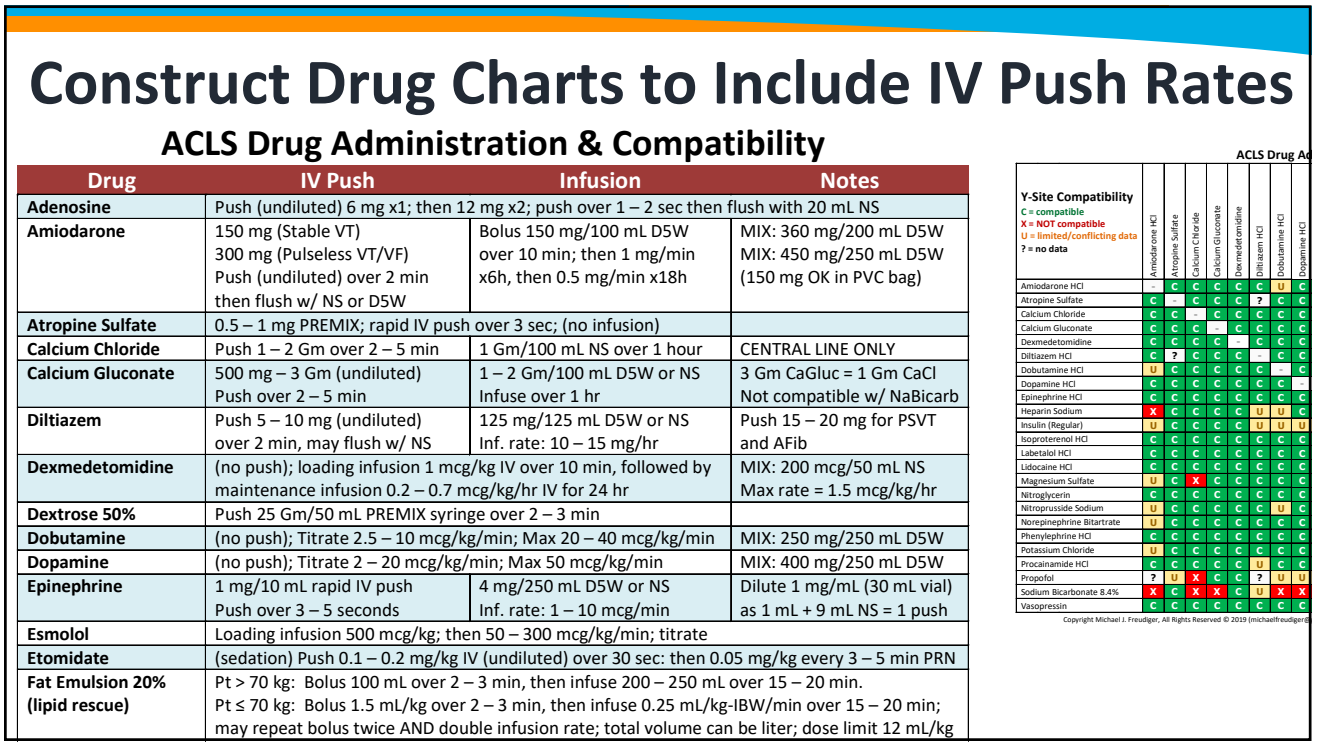
Construct Drug Charts to Include IV Push Rates

ACLS Drug Administration & Compatibility

Y-Site Compatibility
C = compatible
X = NOT compatible
U = limited/conflicting data
? = no data

	Amiodarone HCl	Atropine Sulfate	Calcium Chloride	Calcium Gluconate	Dexmedetomidine	Diltiazem HCl	Dobutamine HCl	Dopamine HCl	Epinephrine HCl	Heparin Sodium	Insulin (Regular)	Isoproterenol HCl	Labetalol HCl	Lidocaine HCl	Magnesium Sulfate	Nitroglycerin	Nitroprusside Sodium	Norepinephrine Bitartrate	Phenylephrine HCl	Potassium Chloride	Procainamide HCl	Propofol	Sodium Bicarbonate 8.4%	Vasopressin
Amiodarone HCl	-	C	C	C	C	C	U	C	C	X	U	C	C	C	U	C	U	U	C	U	C	?	X	C
Atropine Sulfate	C	-	C	C	C	?	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	U	C	C
Calcium Chloride	C	C	-	C	C	C	C	C	C	C	C	C	C	C	X	C	C	C	C	C	C	X	X	C
Calcium Gluconate	C	C	C	-	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	X	C
Dexmedetomidine	C	C	C	C	-	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Diltiazem HCl	C	?	C	C	C	-	C	C	C	U	U	C	C	C	C	C	C	C	C	C	C	U	?	U	C
Dobutamine HCl	U	C	C	C	C	C	-	C	C	U	U	C	C	C	C	C	U	C	C	C	C	C	U	X	C
Dopamine HCl	C	C	C	C	C	C	C	-	C	C	U	C	C	C	C	C	C	C	C	C	C	C	U	X	C
Epinephrine HCl	C	C	C	C	C	C	C	C	-	C	U	C	C	C	C	C	C	C	C	C	C	C	U	X	C
Heparin Sodium	X	C	C	C	C	U	U	C	C	-	U	C	U	C	C	C	C	C	C	C	C	C	C	C	C
Insulin (Regular)	U	C	C	C	C	U	U	U	U	U	-	X	U	C	C	C	C	C	U	X	C	C	C	C	U
Isoproterenol HCl	C	C	C	C	C	C	C	C	C	C	X	-	C	C	C	C	C	C	C	C	C	C	X	C	
Labetalol HCl	C	C	C	C	C	C	C	C	C	U	U	C	-	C	C	C	C	C	C	C	C	C	C	C	
Lidocaine HCl	C	C	C	C	C	C	C	C	C	C	C	C	C	-	C	C	C	C	C	C	C	U	C	C	
Magnesium Sulfate	U	C	X	C	C	C	C	C	C	C	C	C	C	C	-	C	C	C	C	C	C	U	C	C	
Nitroglycerin	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	-	C	C	C	C	C	U	C	C	
Nitroprusside Sodium	U	C	C	C	C	C	U	C	C	C	C	C	C	C	C	C	-	C	C	C	C	C	C	C	
Norepinephrine Bitartrate	U	C	C	C	C	C	C	C	C	C	U	C	C	C	C	C	C	-	C	C	C	C	X	C	
Phenylephrine HCl	C	C	C	C	C	C	C	C	C	C	X	C	C	C	C	C	C	C	-	C	C	C	U	C	
Potassium Chloride	U	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	-	C	C	C	C	
Procainamide HCl	C	C	C	C	C	U	C	C	C	C	C	C	C	C	C	C	C	C	C	C	-	?	C	C	
Propofol	?	U	X	C	C	?	U	U	U	C	C	C	C	U	U	U	C	C	U	C	?	-	C	?	
Sodium Bicarbonate 8.4%	X	C	X	X	C	U	X	X	X	C	C	X	C	C	C	C	C	X	C	C	C	C	-	C	
Vasopressin	C	C	C	C	C	C	C	C	C	C	U	C	C	C	C	C	C	C	C	C	C	?	C	-	

 Ref: Clinical Pharmacology, Lexi-Comp, Trissel's Clinical Pharmaceutics Database



Construct Drug Charts to Include IV Push Rates

ACLS Drug Administration & Compatibility

Drug	IV Push	Infusion	Notes
Adenosine	Push (undiluted) 6 mg x1; then 12 mg x2; push over 1 – 2 sec then flush with 20 mL NS		
Amiodarone	150 mg (Stable VT) 300 mg (Pulseless VT/VF) Push (undiluted) over 2 min then flush w/ NS or D5W	Bolus 150 mg/100 mL D5W over 10 min; then 1 mg/min x6h, then 0.5 mg/min x18h	MIX: 360 mg/200 mL D5W MIX: 450 mg/250 mL D5W (150 mg OK in PVC bag)
Atropine Sulfate	0.5 – 1 mg PREMIX; rapid IV push over 3 sec; (no infusion)		
Calcium Chloride	Push 1 – 2 Gm over 2 – 5 min	1 Gm/100 mL NS over 1 hour	CENTRAL LINE ONLY
Calcium Gluconate	500 mg – 3 Gm (undiluted) Push over 2 – 5 min	1 – 2 Gm/100 mL D5W or NS Infuse over 1 hr	3 Gm CaGluc = 1 Gm CaCl Not compatible w/ NaBicarb
Diltiazem	Push 5 – 10 mg (undiluted) over 2 min, may flush w/ NS	125 mg/125 mL D5W or NS Inf. rate: 10 – 15 mg/hr	Push 15 – 20 mg for PSVT and AFib
Dexmedetomidine	(no push); loading infusion 1 mcg/kg IV over 10 min, followed by maintenance infusion 0.2 – 0.7 mcg/kg/hr IV for 24 hr		MIX: 200 mcg/50 mL NS Max rate = 1.5 mcg/kg/hr
Dextrose 50%	Push 25 Gm/50 mL PREMIX syringe over 2 – 3 min		
Dobutamine	(no push); Titrate 2.5 – 10 mcg/kg/min; Max 20 – 40 mcg/kg/min		MIX: 250 mg/250 mL D5W
Dopamine	(no push); Titrate 2 – 20 mcg/kg/min; Max 50 mcg/kg/min		MIX: 400 mg/250 mL D5W
Epinephrine	1 mg/10 mL rapid IV push Push over 3 – 5 seconds	4 mg/250 mL D5W or NS Inf. rate: 1 – 10 mcg/min	Dilute 1 mg/mL (30 mL vial) as 1 mL + 9 mL NS = 1 push
Esmolol	Loading infusion 500 mcg/kg; then 50 – 300 mcg/kg/min; titrate		
Etomidate	(sedation) Push 0.1 – 0.2 mg/kg IV (undiluted) over 30 sec: then 0.05 mg/kg every 3 – 5 min PRN		
Fat Emulsion 20% (lipid rescue)	Pt > 70 kg: Bolus 100 mL over 2 – 3 min, then infuse 200 – 250 mL over 15 – 20 min. Pt ≤ 70 kg: Bolus 1.5 mL/kg over 2 – 3 min, then infuse 0.25 mL/kg-IBW/min over 15 – 20 min; may repeat bolus twice AND double infusion rate; total volume can be liter; dose limit 12 mL/kg		

ACLS Drug Ad

Y-Site Compatibility
C = compatible
X = NOT compatible
U = limited/conflicting data
? = no data

	Amiodarone HCl	Atropine Sulfate	Calcium Chloride	Calcium Gluconate	Dexmedetomidine	Diltiazem HCl	Dobutamine HCl	Dopamine HCl
Amiodarone HCl	-	C	C	C	C	C	U	C
Atropine Sulfate	C	-	C	C	C	?	C	C
Calcium Chloride	C	C	-	C	C	C	C	C
Calcium Gluconate	C	C	C	-	C	C	C	C
Dexmedetomidine	C	C	C	C	-	C	C	C
Diltiazem HCl	C	?	C	C	C	-	C	C
Dobutamine HCl	U	C	C	C	C	C	-	C
Dopamine HCl	C	C	C	C	C	C	C	-
Epinephrine HCl	C	C	C	C	C	C	C	C
Heparin Sodium	X	C	C	C	C	U	U	C
Insulin (Regular)	U	C	C	C	C	U	U	U
Isoproterenol HCl	C	C	C	C	C	C	C	C
Labetalol HCl	C	C	C	C	C	C	C	C
Lidocaine HCl	C	C	C	C	C	C	C	C
Magnesium Sulfate	U	C	X	C	C	C	C	C
Nitroglycerin	C	C	C	C	C	C	C	C
Nitroprusside Sodium	U	C	C	C	C	C	U	C
Norepinephrine Bitartrate	U	C	C	C	C	C	C	C
Phenylephrine HCl	C	C	C	C	C	C	C	C
Potassium Chloride	U	C	C	C	C	C	C	C
Procainamide HCl	C	C	C	C	C	U	C	C
Propofol	?	U	X	C	C	?	U	U
Sodium Bicarbonate 8.4%	X	C	X	X	C	U	X	X
Vasopressin	C	C	C	C	C	C	C	C

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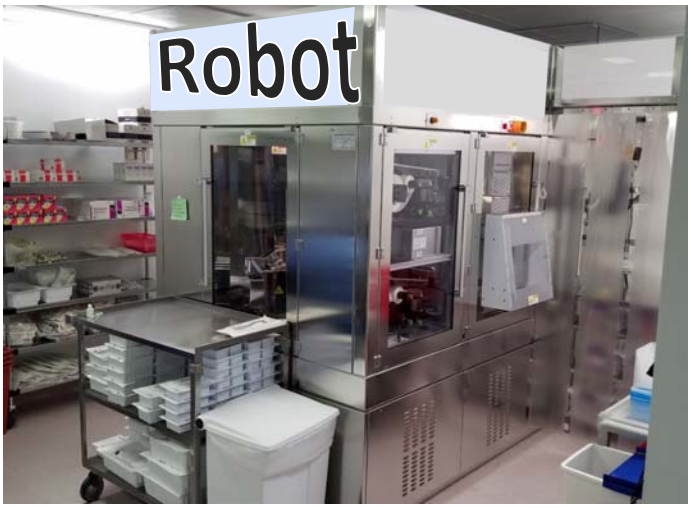
Pharmacy Compounded IV Push Syringes

- Increased workload in the IV room
- May require different handling for short stability reconstituted / compounded preparations
- IV workflow systems
- IV robotics systems

Sterile Compounding Automation



Photos: Michael Freudiger

Program Outline

- Summarize Institute for Safe Medication Practices (ISMP) survey results showing the persistence of unsafe practices with IV push medications
- Understand the benefits/risks involved in preparing and administering IV push therapy
- Review best practices and corresponding error-reduction strategies for preparation and administration of medication via IV push

Key Takeaways

- Key Takeaway #1
  - Educate staff on proper preparation and administration of IV push medications
- Key Takeaway #2
  - Ensure staff know the risks of IV push administration, including incorrect infusion rates, and where to find the correct information
- Key Takeaway #3
  - Review the ISMP Gap Analysis Tool to optimize IV push practices at your facility

Selected Resources

- Institute for Safe Medication Practices (ISMP). ISMP Safe Practice Guidelines for Adult IV Push Medications; 2015. **www.ismp.org/guidelines/iv-push**
- Infusion Nurses Society. Infusion therapy standards of practice (standard 40, flushing and locking, practice criteria D3). *J Infus Nurs.* 2016;39(1S):S1-S159.

High Alert Medications: Creating a Culture of Safety in Preparation and Administration

Christina Michalek B.S.Pharm., FASHP

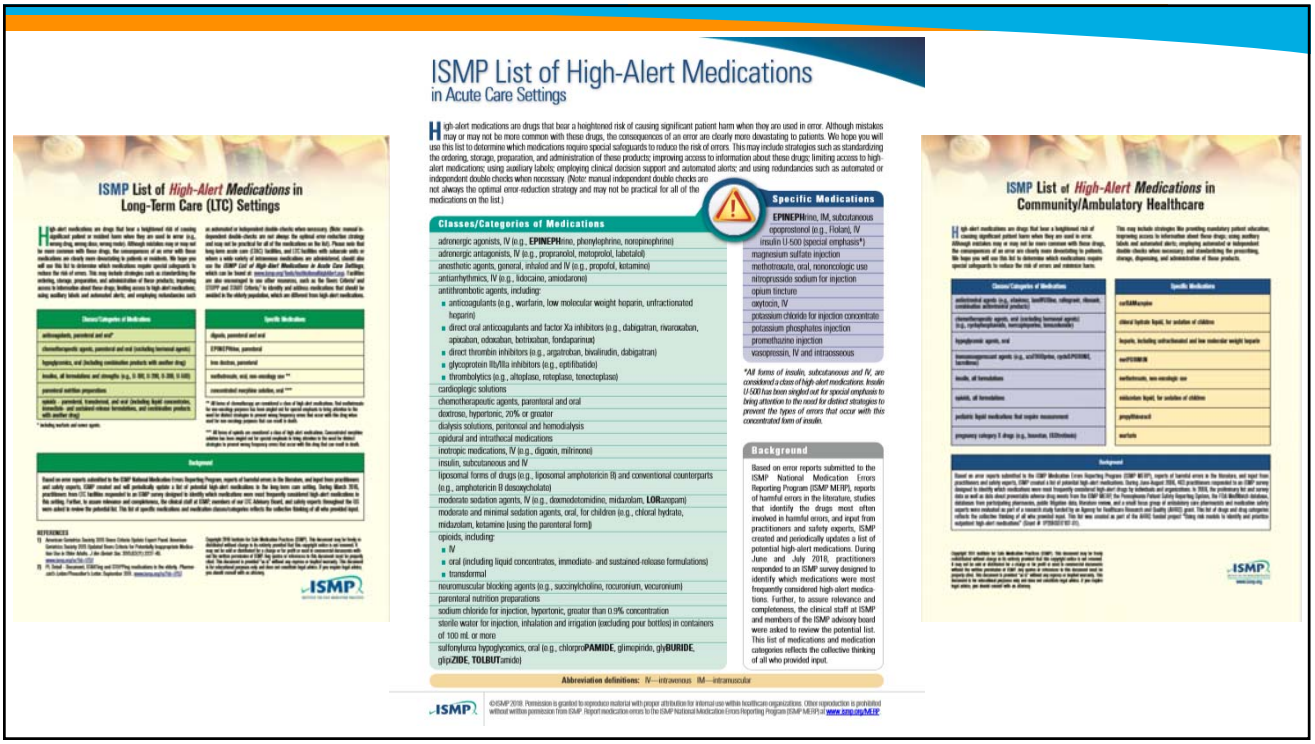
Culture of Safety

What are High-Alert Medications?

- Include hazardous drugs
- Involved in a high percentage of errors
- Cause more harm, more frequently
- Include medications that carry a high risk of abuse
- Include sound- and look-alike medications and similar packaging
- Also referred to as “high-risk”

What are High Alert Medications?

- Drugs that bear a heightened risk of causing significant patient harm when they are used in error
- Mistakes may/may not be more common; consequences are more devastating



ISMP List of High-Alert Medications in Acute Care Settings

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 such as standardizing the ordering, storage, preparation, and administration of these products; improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels; employing clinical decision support and automated alerts; and using redundancies such as automated or independent double checks 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, IM, subcutaneous
adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)	epoprostenol (e.g., 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:	methotrexate, oral, nononcologic use
▪ anticoagulants (e.g., warfarin, low molecular weight heparin, unfractionated heparin)	nitroprusside sodium for injection
▪ direct oral anticoagulants and factor Xa inhibitors (e.g., dabigatran, rivaroxaban, apixaban, edoxaban, betrixaban, fondaparinux)	opium tincture
▪ direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran)	oxytocin, IV
▪ glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)	potassium chloride for injection concentrate
▪ thrombolytics (e.g., alteplase, reteplase, tenecteplase)	potassium phosphates injection
cardioplegic solutions	promethazine injection
chemotherapeutic agents, parenteral and oral	vasopressin, IV and intraosseous
dextrose, hypertonic, 20% or greater	
dialysis solutions, peritoneal and hemodialysis	
epidural and intrathecal medications	
inotropic medications, IV (e.g., digoxin, milrinone)	
insulin, subcutaneous and IV	
liposomal forms of drugs (e.g., liposomal amphotericin B) and conventional counterparts (e.g., amphotericin B deoxycholate)	
moderate sedation agents, IV (e.g., diazemdatomidine, midazolam, **LOR**azepam)	
moderate and minimal sedation agents, oral, for children (e.g., chloral hydrate, midazolam, ketamine [using the parenteral form])	
opioids, including:	
▪ IV	
▪ oral (including liquid concentrates, immediate- and sustained-release formulations)	
▪ transdermal	
neuromuscular blocking agents (e.g., succinylcholine, rocuronium, vecuronium)	
parenteral nutrition preparations	
sodium chloride for injection, hypertonic, greater than 0.9% concentration	
sterile water for injection, inhalation and irrigation (excluding pour bottles) in containers of 100 mL or more	
sulfonylurea hypoglycemics, oral (e.g., chlorpro**PAMIDE**, glimepiride, gly**BURIDE**, glipi**ZIDE**, **TOLBUT**amide)	

*All forms of insulin, subcutaneous and IV, are considered a class of high-alert medications. Insulin U-500 has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with this concentrated form of insulin.

Background

Based on error reports submitted to the ISMP National Medication Errors Reporting Program (ISMP MERP), reports of harmful errors in the literature, studies that identify the drugs most often involved in harmful errors, and input from practitioners and safety experts, ISMP created and periodically updates a list of potential high-alert medications. During June and July 2018, practitioners responded to an ISMP survey designed to identify which medications were most frequently considered high-alert medications. Further, to assure relevance and completeness, the clinical staff at ISMP and members of the ISMP advisory board were asked to review the potential list. This list of medications and medication categories reflects the collective thinking of all who provided input.

Abbreviation definitions: IV—intravenous IM—intramuscular

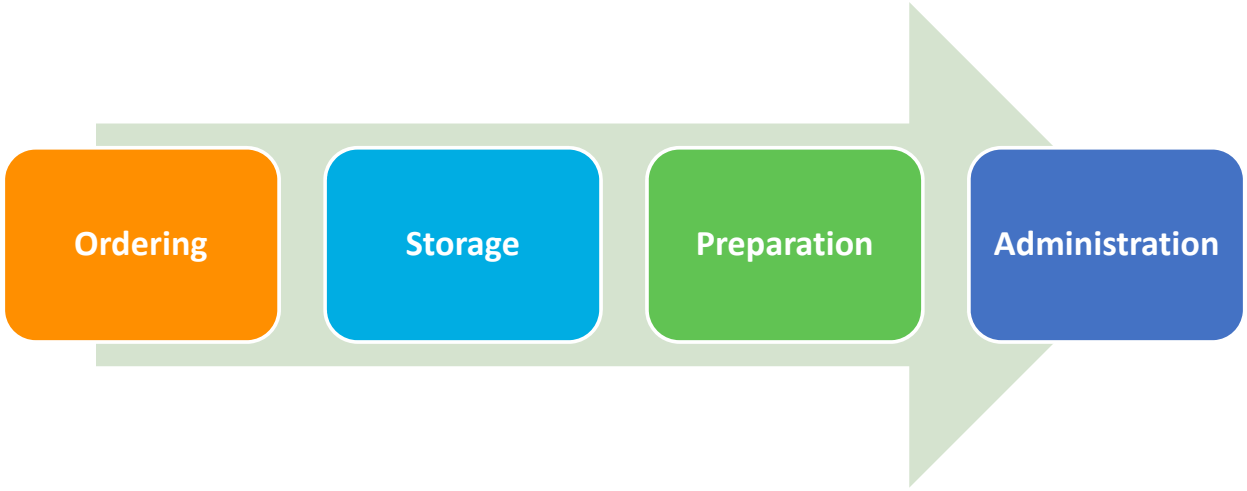
ISMP


ISMP
Educating the healthcare community about safe medication practices
ISMP Medication Safety Alert! Acute Care
June 13, 2013 ■ Volume 18 Issue 12
Independent double checks: undervalued and misused
Selective use of this strategy can play an important role in medication safety
A manual independent double check of high-alert medications is a strategy that has been widely promoted in healthcare to help detect potentially harmful errors before they reach patients.
September 26, 2019 • Volume 24 Issue 19
ISMP
Acute Care
ISMP Medication Safety Alert!
Educating the Healthcare Community About Safe Medication Practices
Published review of independent double checks shouldn't dissuade providers from using them judiciously
A recent systematic review of the effectiveness of double checking to reduce medication administration errors, published by Australian researchers in *BMJ Quality & Safety*, clearly demonstrates an overall lack of high-quality studies on the subject.

What are High-Alert Medications?

- Include hazardous drugs
- Involved in a high percentage of errors
- Cause more harm, more frequently
- Include medications that carry a high risk of abuse
- Include sound- and look-alike medications and similar packaging
- Also referred to as “high-risk”

High Alert Medication Safeguards



Regulatory Agency Expectations

- Safely manages high-alert and hazardous medications
- Policies address high-alert medications
- Implements a process to improve the safety of high-alert medications; manages concentrated electrolytes

Your high-alert medication list–Relatively useless without associated risk-reduction strategies

PROBLEM: Have you ever watched the 1993 movie, **Groundhog Day**? Bill Murray plays Phil Conners, a television news reporter who finds himself reliving the same day over and over again—a much-hated assign-

develop their own list of high-alert medications; to have a process for managing high-alert medications; and to implement that process. While most facilities meet the minimum requirements for The Joint

Image by skeeze from Pixabay

Safety Hierarchy

High Level

- Failure-mode proposed strategies
- Use commercially-available patient-specific doses
- Use automation and technology to assist human decision making

Mid Level

- Limit complexity and access
- Provide decision support or reminders at the right time in the workflow
- Consider the use of redundancies

Low Level

- Create policies and expectations of practice
- Educate practitioners about risk

Best practices for the *preparation* and *administration* of *intravenous* high alert-medications

Intravenous (IV) Medications

- Essential component of patient care
- Clinical advantages
  - Immediate effect/onset of action
  - Can use for bolus dosing or infusion over time
  - Achieve optimal plasma levels
  - Avoids oral intake

High Alert IV Medications

- Neuromuscular blocking agents
- Concentrated electrolytes
- Magnesium sulfate injection
- Moderate sedation
- Intravenous insulin
- Parenteral chemotherapy
- Anticoagulants
- Opioids

Safety Strategies

- General, that are applicable to a variety of medications
- More targeted based on the specific high alert medication

Preparation Errors

- Survey data: in past 5 years one-quarter of all facilities have experienced a patient incident related to a compounding error
- Data indicate that as production increases so do errors
  - 47% when compounding volume over 200 preparations per day

Pharmacy Purchasing & Products State of Pharmacy Compounding 12th Annual National Survey. April 2019;16(4):s1-64.

Preparation Errors

- Study of a newly-implemented workflow software system
  - 15,843 doses prepared
  - 1,126 detected errors (7.1% of total doses)
- Detection of errors:
  - Drug weighing step before injection into final bag (71%)
  - Barcode scanning step (26%)
  - Vial reconstitution step (3%)

Reece KM, et al. *Am J Health-Syst Pharm*. 2016; 73:165-73.

Compounding Considerations

- Manufacturer supplied 

  - Ready to administer; alternatively, ready-to-use
- Pharmacy prepared
  - Technology-assisted
  - Manual preparation methods
- Outsourced

Image by OpenClipart-Vectors from Pixabay

Outsourcing Considerations

- Outsourcing the preparation of compounded sterile preparations (CSPs) is considered as an alternative to in-house compounding when:
  - the frequency of use for certain CSPs is very low
  - the volume of use for certain CSPs is high, and staff resources are limited
  - the organization does not possess the resources to be compliant with USP
  - a commercially-manufactured product is not available, including product shortages

ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations, revised September 2016

Administration Errors

- Observational evaluation
  - Intensive care setting; error-prone medications
  - 851 patients; 187 errors found
  - Most common error: wrong infusion rate (40.1%)
- Deep dive: Medication Safety
  - Most common node: administration (68%)
  - Errors with IV medications most common (36.9%)

Calbrese AD, et al. *Intensive Care Med* 2001; 27:1592-8.
ECRI Institute PSO Deep Dive: Medication Safety. December 2011.
https://www.ecri.org/Resources/In_the_News/Medication_Safety(Deep_Dive).pdf

Administration Considerations

- Barcoding
  - When removing from stock (override; matrix drawer)
  - Prior to administration
- Smart infusion pumps
  - Dose-error reduction software (DERS) system
  - Integrated with electronic record

TMSBP: ISMP Targeted Medication Safety Best Practices for Hospitals

Administration Considerations

- IV push doses
  - Ready-to-administer (to avoid manipulation)
  - Commercially-available flush syringes
  - Label all clinician-prepared syringes; unless at the bedside and immediately administered

Specific High-alert Medications (HAMs)

IV Opioids

- Standardization to a single usual concentration of IV opioid infusions; and a single high concentration
- Concentrated formulations include auxiliary labeling
  - Availability based on appropriate use

IV Opioids

- If multiple choices for pain therapy exist, practitioners are provided with a standard guidance
- IV push doses in commercially-available or pharmacy-prepared syringes are not further diluted
- IV push doses are never diluted by drawing contents into a prefilled flush syringe of 0.9% sodium chloride

IV Opioids

- Monitoring
  - Continuous IV opioids – continuous pulse oximetry
  - With supplemental oxygen - ventilation and airflow assessment
  - Prior to, during, and following administration assessments
- Guidelines exist to rescue patients with unintended advancing sedation and/or respiratory depression

IV Insulin

- Preparation and Administration
  - mL confused with units
  - Amount of volume confused
    - Syringe selection (size)
    - Syringe selection (insulin versus parenteral)
    - Full vial bias

Case Examples

- A nurse accidentally added 50 units of insulin instead of 5 units to an existing infusion bag
- The nurse felt the small length of an insulin needle was not long enough to insert into the IV bag
- A double-check failed to detect the error

Neuromuscular Blocking Agents (NMBAs)

- Pharmacy prepares and dispenses continuous infusions of NMBAs (outside surgical suites)
  - A single, standard concentration is used
- Pharmacy supplies prefilled syringes of NMBAs
  - If prepared by anesthesia staff, label includes drug name, concentration/dose, expiration date and time
- Final container includes a warning: WARNING: PARALYZING AGENT—CAUSES RESPIRATORY ARREST

TMSBP

Neuromuscular Blocking Agents

- Administration
  - Before extubating a patient, IV administration set is flushed (or changed) to prevent inadvertent bolus
  - After discontinuation, infusions are immediately discarded (not left on IV pole or at bedside)

IV Chemotherapy

- Preparation

TMSBP

  - Provided in a form that needs no further manipulation
  - Barcoding and gravimetric analysis are used to confirm the drug and dose volume
  - Volume expressed on label (drug, base, overfill)
  - Tubing flush procedure
  - Only during established time frames

IV Chemotherapy

- Independent double-checks
  - Both Pharmacist and Nurse verify and document:
    - Current cycle and day within the cycle against the protocol
    - Dosing method and calculated dose to the protocol

IV Chemotherapy

- Vinca alkaloids and bortezomib
  - Dispense in a minibag
  - Add warning: FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES
  - Presence of vinca alkaloids is not in the same location as where intrathecal medications are administered
  - Confirm completion of intrathecal administration

IV Anticoagulants

- Only commercially prepared, premixed IV solutions of unfractionated heparin are used
  - Commercially prepared, premixed glycoprotein IIb/IIIa inhibitors and direct thrombin inhibitors, OR pharmacy prepared, OR trained staff using a kit
- Single standard concentration for therapeutic heparin
- Pharmacy preparation of thrombolytic bolus and infusion doses
  - Or trained staff using a disease-specific kit

IV Anticoagulants

- Heparin flush
  - Adults: commercially prepared, unit dose or single-use vials
  - Neonates and pediatric patients: pharmacy prepares a single concentration of diluted heparin flush

IV Anticoagulants

- Administration

  - Smart infusion pumps with dose error reduction functionality to detect and prevent wrong dose and rate errors
  - Nurses independently double-check new bag/bottle changes and rate changes

Concentrated Electrolytes

- Commercially available premixed solutions are used for electrolyte replacement
- Vials of concentrated electrolytes that require dilution are not available in unit stock
- Concentrated potassium chloride for cardioplegic solutions is sequestered in sealed kits or locked storage
  - Return process for unused portions

Concentrated Electrolytes

- 3% sodium chloride is dispensed from pharmacy or approved critical/emergency care units
- 23.4% sodium chloride is never stocked outside pharmacy
  - IV push doses are prepared by pharmacy and labeled with a warning: *CONCENTRATED sodium chloride 23.4%, administer via central line only*

Case Examples

- A nurse accidentally restarted an infusion of magnesium sulfate instead of beginning a new infusion of oxytocin after a mother delivered her baby
- Magnesium sulfate began infusing at 200 mL/hour to deliver a 4 g bolus dose; after 20 minutes the nurse was called away; returned to find patient received 6 g of drug

Magnesium Sulfate

- Loading doses are prepared or supplied by pharmacy
  - Commercially available premixed bags are used for all maintenance infusions
- If administering bolus doses from an infusion bag, this should be done using a smart infusion pump with a loading dose feature
- During administration, the patient is assessed for signs of toxicity

Magnesium Sulfate

- Preeclampsia and eclampsia, fetal neuroprotection
- Preparation: Use only 20 g/500 mL bags
- Administration
  - monitoring includes continuous cardiac monitoring, one-on-one care during 1st hour with every 15-minute assessment; every 30 minutes for the 2nd hour; then every 1 hour
  - Upon discontinuation, the infusion is disconnected and removed

Moderate Sedation

- Only a 1 mg/mL strength of midazolam is provided
- If ketamine 100 mg/mL is used, an auxiliary label warns that it should be diluted for IV use
- If ketamine and propofol are mixed together, do not refer to it as “ketafol”

Key Takeaways

- Key Takeaway #1
  - Providing commercially-prepared products in a ready-to-administer form can help to prevent errors with high-alert medications.
- Key Takeaway #2
  - Promoting and expanding use of smart infusion pumps, infusion pump integration, & barcode medication administration, AND monitoring compliance with use of these technologies can help to prevent administration errors with high-alert medications.
- Key Takeaway #3
  - Medication specific best practices for the preparation and administration of high-alert medications can be found in ISMP's Medication Safety Self Assessment® for High-Alert Medications.

Selected Resources

- Your high alert medication list—Relatively useless with associated risk-reduction strategies. ISMP Medication Safety Alert! April 4, 2013 18(7) **www.ismp.org/resources/your-high-alert-medication-list-relatively-useless-without-associated-risk-reduction**
- Survey results suggest action is needed to improve safety with adult IV push medications. ISMP Medication Safety Alert! November 15, 2018 23(23) **www.ismp.org/resources/part-ii-survey-results-suggest-action-needed-improve-safety-adult-iv-push-medications**
- ISMP Medication Safety Self Assessments®: High Alert Medications, Antithrombotic Therapy, Oncology, and Guidelines for Safe Preparation of Compounded Sterile Preparations **www.ismp.org/assessments/high-alert-medications**
- ASHP: Standardize 4 Safety, Resource Center for Sterile Compounding, Guidelines for Outsourcing Sterile Compounding **www.ashp.org/Pharmacy-Practice/Standardize-4-Safety-Initiative**

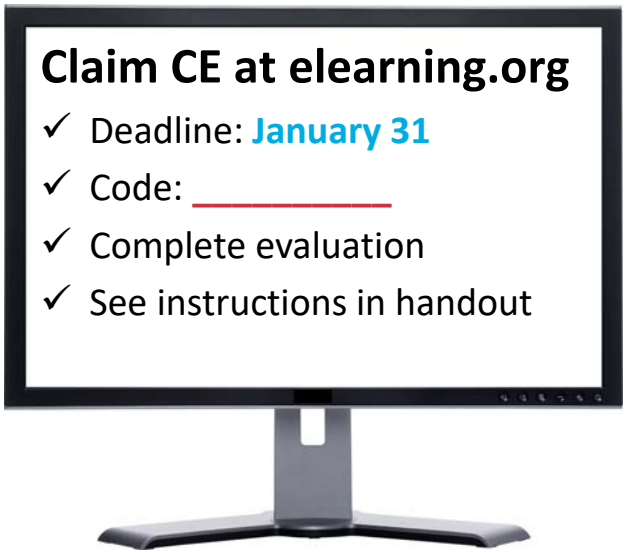
How will you change your practice?

- Discuss implications of revisions in USP Chapter <797> published in June 2019 with my colleagues.
- Implement or update document management process to track increased personnel training and environmental monitoring requirements.
- Create a centralized compounding compliance team
- Perform an ISMP Gap Analysis Tool for Safe IV Push Medication Practices.
- Audit preparation and administration processes for high-risk IV medications compared to organization's standard guidance

Faculty Discussion & Questions

Write your questions on the provided index cards and hand to a staff member

Thank you for joining us!



Coming Soon!

- On-demand archive of today's activity

www.ashpadvantage.com/improveivsafety

ACLS Drug Administration & Compatibility

Drug	IV Push	Infusion	Notes
Adenosine	Push (undiluted) 6 mg x1; then 12 mg x2; push over 1 – 2 sec then flush with 20 mL NS		
Amiodarone	150 mg (Stable VT) 300 mg (Pulseless VT/VF) Push (undiluted) over 2 min then flush w/ NS or D5W	Bolus 150 mg/100 mL D5W over 10 min; then 1 mg/min x6h, then 0.5 mg/min x18h	MIX: 360 mg/200 mL D5W MIX: 450 mg/250 mL D5W (150 mg OK in PVC bag)
Atropine Sulfate	0.5 – 1 mg PREMIX; rapid IV push over 3 sec; (no infusion)		
Calcium Chloride	Push 1 – 2 Gm over 2 – 5 min	1 Gm/100 mL NS over 1 hour	CENTRAL LINE ONLY
Calcium Gluconate	500 mg – 3 Gm (undiluted) Push over 2 – 5 min	1 – 2 Gm/100 mL D5W or NS Infuse over 1 hr	3 Gm CaGluc = 1 Gm CaCl Not compatible w/ NaBicarb
Diltiazem	Push 5 – 10 mg (undiluted) over 2 min, may flush w/ NS	125 mg/125 mL D5W or NS Inf. rate: 10 – 15 mg/hr	Push 15 – 20 mg for PSVT and AFib
Dexmedetomidine	(no push); loading infusion 1 mcg/kg IV over 10 min, followed by maintenance infusion 0.2 – 0.7 mcg/kg/hr IV for 24 hr		MIX: 200 mcg/50 mL NS Max rate = 1.5 mcg/kg/hr
Dextrose 50%	Push 25 Gm/50 mL PREMIX syringe over 2 – 3 min		
Dobutamine	(no push); Titrate 2.5 – 10 mcg/kg/min; Max 20 – 40 mcg/kg/min		MIX: 250 mg/250 mL D5W
Dopamine	(no push); Titrate 2 – 20 mcg/kg/min; Max 50 mcg/kg/min		MIX: 400 mg/250 mL D5W
Epinephrine	1 mg/10 mL rapid IV push Push over 3 – 5 seconds	4 mg/250 mL D5W or NS Inf. rate: 1 – 10 mcg/min	Dilute 1 mg/mL (30 mL vial) as 1 mL + 9 mL NS = 1 push
Esmolol	Loading infusion 500 mcg/kg; then 50 – 300 mcg/kg/min; titrate		
Etomidate	(sedation) Push 0.1 – 0.2 mg/kg IV (undiluted) over 30 sec: then 0.05 mg/kg every 3 – 5 min PRN		
Fat Emulsion 20% (lipid rescue)	Pt > 70 kg: Bolus 100 mL over 2 – 3 min, then infuse 200 – 250 mL over 15 – 20 min. Pt ≤ 70 kg: Bolus 1.5 mL/kg over 2 – 3 min, then infuse 0.25 mL/kg-IBW/min over 15 – 20 min; may repeat bolus twice AND double infusion rate; total volume can be liter; dose limit 12 mL/kg		
Flumazenil	0.2 mg IV undiluted over 30 sec; may add 0.3 mg in 30 sec if patient not stable; may give 0.5 mg at 1 min intervals up to max dose 3 mg in 1 hour (doses above max dose = no additional benefit)		
Fosphenytoin	Dose: 10 – 20 mgPE/kg (diluted to 1.5 – 25 mgPE/mL in D5W or NS); max rate 150 mgPE/min		
Furosemide	Push 20 – 40 mg (undiluted) over 1 – 2 min; infuse 20 – 100 mg/50 – 100 mL D5W / NS over 1 hr		
Isoproterenol	0.2 – 1 mg/10 mL D5W or NS Push over 1 – 2 min	1 – 2 mg/500 mL D5W or NS Inf. rate: 2 – 10 mcg/min	
Lidocaine	100 mg/5 mL PREMIX Push over 2 – 3 min	2 Gm/500 mL D5W PREMIX Inf. rate: 1 – 5 mg/min	May repeat pushes q 5 min Max loading = 300 mg/1 hr
Lorazepam	Push 2 – 4 mg (diluted 1:1 w/ NS or D5W) at rate 2 mg/min, may repeat dose in 10 – 15 min		
Magnesium Sulfate	1 Gm/10 mL NS (2 Gm/20 mL) Push over 1 – 2 min	2 Gm/50 mL SWFI Inf. rate: 2 Gm over 30 min	
Midazolam	Push 1 – 5 mg (diluted 1 mg/mL w/ D5W or NS) over 2 min; cont. inf. only in ICU w/ ventilator		
Milrinone	(no push); 50 mcg/kg loading dose over 10 min (optional); then infuse 0.375 mcg/kg/min – 0.75 mcg/kg/min		MIX: 20 mg/100 mL
Naloxone	Dilute 0.4 mg/1 mL w/ 9 mL NS; push over 15 sec		May give x5; monitor
Nitroglycerin	(no push); infuse 5 – 20 mcg/min; titrate for response		50 mg/250 mL D5W
Norepinephrine	(no push); initial inf. 10 – 15 mcg/min; Maint. 0.5 – 50 mcg/min;		MIX: 8 mg/250 mL NS or D5
Phenylephrine	1 mg/10 mL NS or SWFI Push over 20 – 30 sec	Initial infusion 100 – 200 mcg/min; maintenance 40 – 60 mcg/min; titrate; standard bag is 10 mg/250 mL D5W or NS	
Phenytoin	Push 25 mg/min (in 10 mL NS)	Infuse 100 mg/50 mL NS only; 4 hour stability	
Procainamide	100 mg/10 mL D5W or NS as IV Push (50 mg/min) q5 min	MIX: 2 Gm/500 mL D5W or NS Loading rate: 20 – 50 mg/min	May bolus 1 Gm/100 mL D5W or NS over 1 hour
Sodium Bicarbonate	50 mEq PREMIX syringe Push over 1 – 3 min	Infuse 50 – 150 mEq/1000 mL at 100 – 150 mL/hr	Diluents D5W / NS / SWFI See Y-site compatibilities
Succinylcholine	Push 0.6 mg/kg IV (undiluted) over 10 – 30 sec (no infusion)		Endotracheal intubation
Vasopressin	40 units/10 mL NS Push over 1 – 3 seconds	Infuse 0.01 – 0.04 units/min & titrate for response	MIX: 50 units/100 mL or 100 units/250 mL D5W / NS
Verapamil	Push 2.5 – 5 mg (undiluted) over 2 min; 2nd dose 5 – 10 mg after 15 min; max total dose = 20 mg		

ACLS Drug Administration & Compatibility

Y-Site Compatibility
C = compatible
X = NOT compatible
U = limited/conflicting data
? = no data

	Amiodarone HCl	Atropine Sulfate	Calcium Chloride	Calcium Gluconate	Dexmedetomidine	Diltiazem HCl	Dobutamine HCl	Dopamine HCl	Epinephrine HCl	Heparin Sodium	Insulin (Regular)	Isoproterenol HCl	Labetalol HCl	Lidocaine HCl	Magnesium Sulfate	Nitroglycerin	Nitroprusside Sodium	Norepinephrine Bitartrate	Phenylephrine HCl	Potassium Chloride	Procainamide HCl	Propofol	Sodium Bicarbonate 8.4%	Vasopressin
Amiodarone HCl	-	C	C	C	C	C	U	C	C	X	U	C	C	C	U	C	U	U	C	U	C	?	X	C
Atropine Sulfate	C	-	C	C	C	?	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	U	C	C
Calcium Chloride	C	C	-	C	C	C	C	C	C	C	C	C	C	C	X	C	C	C	C	C	C	X	X	C
Calcium Gluconate	C	C	C	-	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	X	C
Dexmedetomidine	C	C	C	C	-	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Diltiazem HCl	C	?	C	C	C	-	C	C	C	U	U	C	C	C	C	C	C	C	C	C	U	?	U	C
Dobutamine HCl	U	C	C	C	C	C	-	C	C	U	U	C	C	C	C	C	U	C	C	C	C	U	X	C
Dopamine HCl	C	C	C	C	C	C	C	-	C	C	U	C	C	C	C	C	C	C	C	C	C	U	X	C
Epinephrine HCl	C	C	C	C	C	C	C	C	-	C	U	C	C	C	C	C	C	C	C	C	C	U	X	C
Heparin Sodium	X	C	C	C	C	U	U	C	C	-	U	C	U	C	C	C	C	C	C	C	C	C	C	C
Insulin (Regular)	U	C	C	C	C	U	U	U	U	U	-	X	U	C	C	C	C	U	X	C	C	C	C	U
Isoproterenol HCl	C	C	C	C	C	C	C	C	C	C	X	-	C	C	C	C	C	C	C	C	C	C	X	C
Labetalol HCl	C	C	C	C	C	C	C	C	C	U	U	C	-	C	C	C	C	C	C	C	C	C	C	C
Lidocaine HCl	C	C	C	C	C	C	C	C	C	C	C	C	C	-	C	C	C	C	C	C	C	U	C	C
Magnesium Sulfate	U	C	X	C	C	C	C	C	C	C	C	C	C	C	-	C	C	C	C	C	C	U	C	C
Nitroglycerin	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	-	C	C	C	C	C	U	C	C
Nitroprusside Sodium	U	C	C	C	C	C	U	C	C	C	C	C	C	C	C	C	-	C	C	C	C	C	C	C
Norepinephrine Bitartrate	U	C	C	C	C	C	C	C	C	C	U	C	C	C	C	C	C	-	C	C	C	C	X	C
Phenylephrine HCl	C	C	C	C	C	C	C	C	C	C	X	C	C	C	C	C	C	C	-	C	C	U	C	C
Potassium Chloride	U	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	-	C	C	C	C
Procainamide HCl	C	C	C	C	C	U	C	C	C	C	C	C	C	C	C	C	C	C	C	C	-	?	C	C
Propofol	?	U	X	C	C	?	U	U	U	C	C	C	C	U	U	U	C	C	U	C	?	-	C	?
Sodium Bicarbonate 8.4%	X	C	X	X	C	U	X	X	X	C	C	X	C	C	C	C	C	X	C	C	C	C	-	C
Vasopressin	C	C	C	C	C	C	C	C	C	C	U	C	C	C	C	C	C	C	C	C	C	?	C	-

 Ref: Clinical Pharmacology, Lexi-Comp, Trissel's Clinical Pharmaceutics Database

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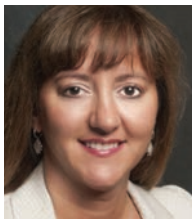

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On-demand activity of today's live symposium coming in February 2020

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