

MSOS Member Briefing

July 2021

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July 2021

Moderated by: E. Robert Feroli, PharmD, FASHP



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Physical Kitting for Continuous Infusion IVPBs

Joel W Daniel, PharmD, MS, CPPS



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Staff:

- 12,583 employees
- 552 physicians
- 1,200 volunteers are members of Cox Auxiliaries

Facilities:

- 6 Hospitals across region
- 87 clinics
- 26 county service area
- 1,014 Licensed Beds – DNV GL Hospitals

Patient Services:

- 208,843 days of care
- 267,780 emergency, urgent care & trauma visits
- 34,699 surgeries
- 4,137 babies born
- 37,731 ambulance services

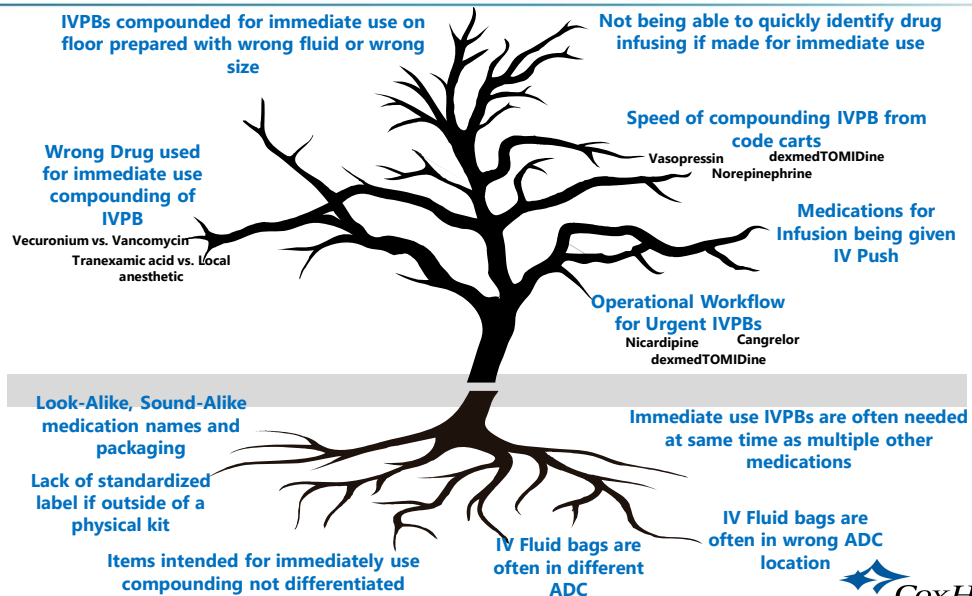
TCD Designations:

- Level I Trauma Center (MO & AR)
- Level I Stroke Center
- Level I STEMI Center



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Problems and Root Causes



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Increase visibility of the root causes

Increase reliability of overall medication management process

PHYSICAL KITTING



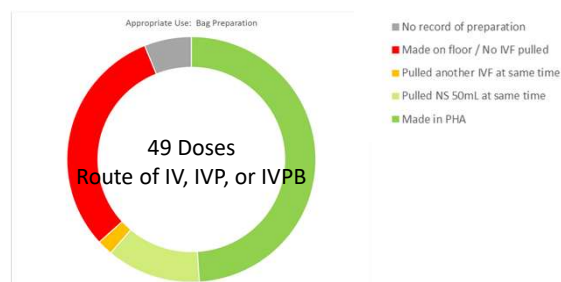
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So why not just use electronic kits for everything?

A safety MUE was performed on a medication that was being compounded on the floor.

1-week chart review was performed on documented doses.

- About half were requested from the Pharmacy IV Room
- About a quarter of doses either had the wrong IV Fluid bag pulled or no bag



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Physical Kits: Components

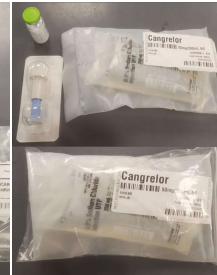
Components

- Medication
- Correct IV Fluid bag
- Adapter (if needed)
- Label
- Heat Sealed

Nicardipine



Cangrelor

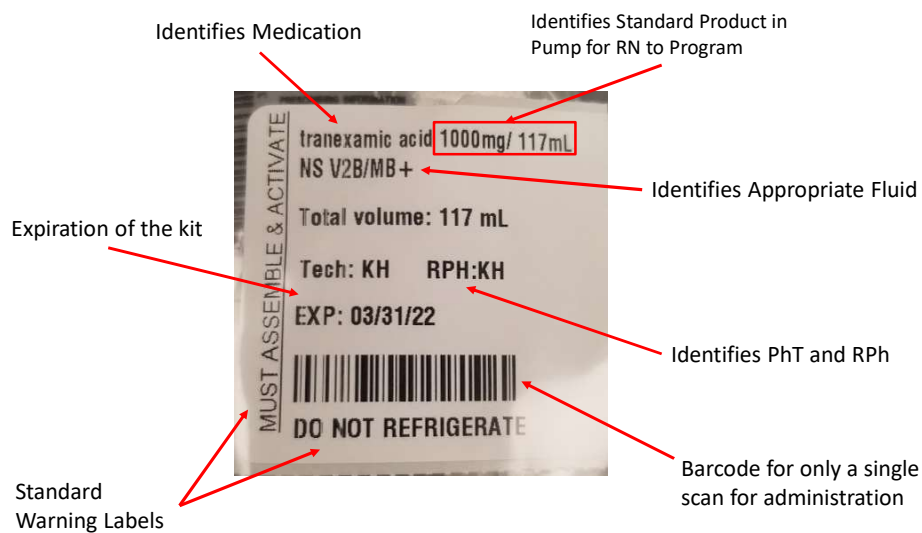


Tranexamic Acid



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Physical Kit: Label



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Physical Kit: Benefits Observed

Risk/Gap/OFI

- Wrong medication infusing
- Wrong fluid used
- Giving IVP



Component/Benefit

- Visually differentiated into what is given IVPB and other routes
- Assembled within Pharmacy
- Physically separated from other medications pulled at the same time

- Titrating wrong med
- Not immediately recognizing medication infusing



- Label hardwired

- Operational inefficiencies with compounding medications for immediate use



- Able to store in kits within ADCs and Crash Carts
- Safely increases speed of preparation of IVPBs during codes



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Lessons Learned: Balancing Positive and Negative Effects

- Increases safety and operational efficiency for medication management **overall** at expense of workflow in Pharmacy
 - Opportunity for buy-in from hospital leadership for allocation of resources
- Balance which kits can be safely made electronically vs. physical kits based upon safety
- Examine vial sizes, as smaller vial openings do not have available adapters



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Specialty Pharmacy Medication Safety Challenges

Jill Paslier, PharmD, CSP, FISMP

Pharmacy Consultant

Former ISMP International Safe Medication Management Fellow

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Specialty Medications

- High cost
 - High complexity
 - Biologics
 - High touch
 - Special storage and handling
 - Special administration
 - Close clinical monitoring
- Treat specialty conditions
 - HIV
 - Hepatitis C
 - Oncology
 - Multiple sclerosis
 - Transplant
 - Cystic fibrosis
 - Autoimmune conditions (e.g., rheumatoid arthritis)



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Specialty Pharmacy Services

- Free medication delivery
- Free supplies
- Proactive refill reminders
- Financial assistance / benefit investigation
- 24-hour access to a pharmacist via phone



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Clinical Therapy Management Services

- Clinical pharmacist reviews medications for:
 - Indication
 - Efficacy
 - Safety
 - Adherence
- Medication reconciliation
- Review charts and labs for appropriate therapy
- Similar to the Medication Therapy Management (MTM) model



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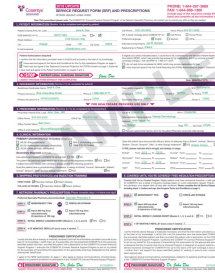
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Prescription Receipt

- Referral sources
 - Specialty providers
 - Primary Care Providers
 - Emergency department (HIV post-exposure prophylaxis)
- Prescription sources
 - Electronic
 - Verbal
 - Transfer
 - Fax
 - Hard copy

— Risk for error and harm

- Prescribing errors
- Hard to read prescriptions
 - Enrollment forms
- Verbal or transfer transcription errors



Cosentyxhcp.com. 2020. [online] Available at: <https://www.cosentyxhcp.com/pdf/T-COS-1371669_COSENTYX_SRF-Annotated_Version-Digital_Q4_2018_Update.pdf> [Accessed 13 August 2020].

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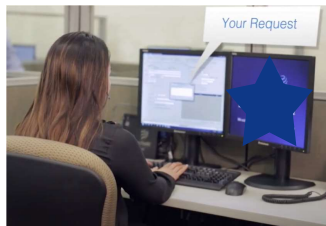
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Data Entry

- Electronic prescriptions
 - May auto populate most fields
- All other prescriptions
 - Technician manually types all data points

— Risk for error and harm

- Patient
- Allergies
- Prescriber
- Drug Name
- Drug Strength
- Drug Dosage Form
- Sig
- Written date
- Quantity (written or dispensed)
- Refills
- Day supply
- Origin code
- DAW
- Copay



Banner Health, 2016. *Banner Family Pharmacy: Specialty Medications*. [video] Available at: <<https://www.youtube.com/watch?v=SB4vgurACCs>> [Accessed 14 August 2020].

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Delivery Set Up

- Confirm address, date and time with patient
- Enter in software



- Risk for error and harm
 - Incorrect meds / supplies
 - Old dose
 - Discontinued medication
 - Delivery or shipping method
 - Ship date/time
 - Shipping address
 - Signature or no signature required
 - Payment options
 - Delivery-related notes

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Pre-Verification

- Verifies everything from data entry AND delivery set up
- Calls provider for clarifications and recommendations if needed
- Verifies clinical information
 - Appropriate therapy
 - Dose/directions
 - Allergies
 - Drug interactions
 - May complete patient counseling PRIOR to verification



- Risk for error and harm
 - Any incorrect elements from data entry or delivery set up
 - See previous slides
 - Missing important clinical information
 - Allergies
 - Drug interactions
 - Inappropriate or unsafe therapy

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Fulfillment / Production

- Technicians or automated dispensing machines fill medications
- Tote goes to stations to fill each specific medication



- Risk for error and harm
 - Wrong drug
 - Wrong quantity
 - Expiration date
 - Non-safety cap
 - Medication in wrong tote
 - Order filled twice
 - Hazardous medication and cold chain medication special handling



Banner Health, 2016. *Banner Family Pharmacy: Specialty Medications*. [video] Available at: <<https://www.youtube.com/watch?v=SB4vgurACCs>> [Accessed 14 August 2020].

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Final Verification

- Verifies final product
 - Product Name, strength, dosage form
 - NDC
 - Quantity
 - Expiration date
 - Supplies needed
 - Directions / appropriateness

- Risk for error and harm
 - Any incorrect elements from fulfillment
 - See previous slide



Banner Health, 2016. *Banner Family Pharmacy: Specialty Medications*. [video] Available at: <<https://www.youtube.com/watch?v=SB4vgurACCs>> [Accessed 14 August 2020].

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Packing

- Pack medication into pick up bag
- Pack medication into shipping box with appropriate stability packing
- Risk for error and harm
 - Wrong patient in wrong bag/box
 - Wrong address
 - Incorrect shipping materials (e.g., cold chain box)
 - Signature requirement



Banner Health, 2016. *Banner Family Pharmacy: Specialty Medications*. [video] Available at: <<https://www.youtube.com/watch?v=SB4vgurACCs>> [Accessed 14 August 2020].

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Quality and Safety Considerations



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Questions?

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Parenteral Nutrition Safety: Focus on Administration

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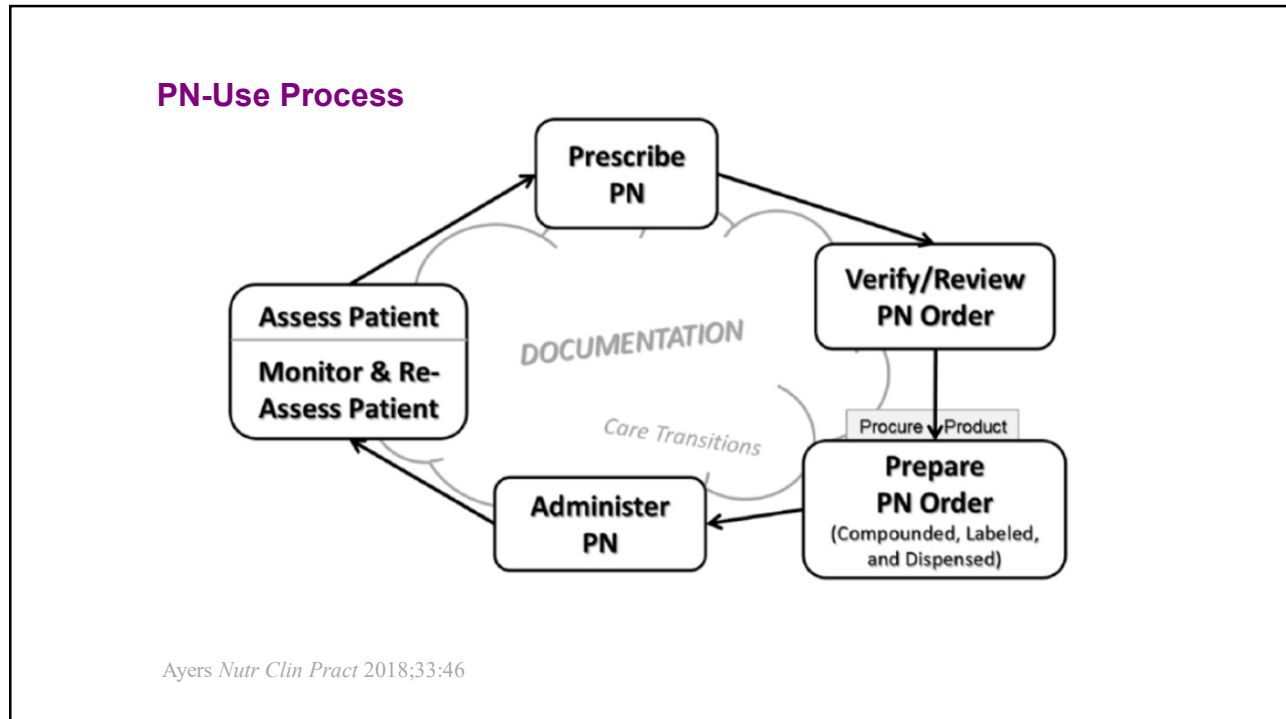
³ University of Mississippi Medical Center, Jackson, MS



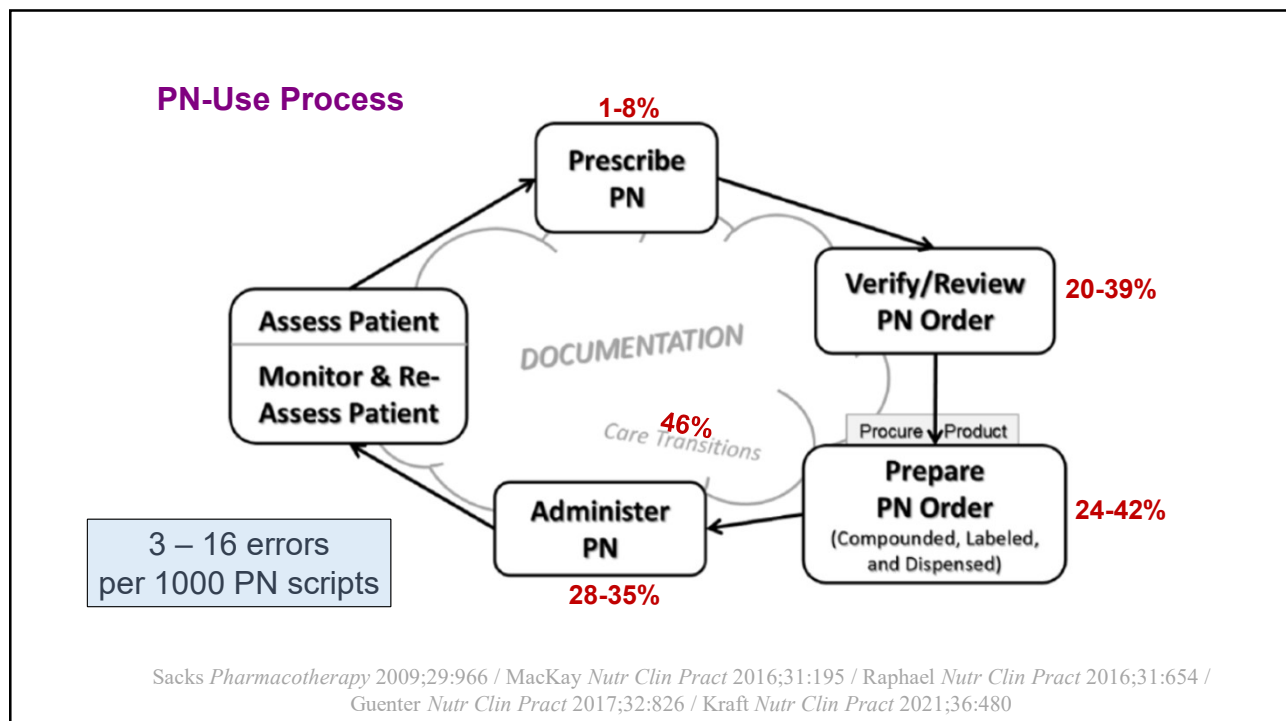
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Focus on ILE Administration

- Survey (n=895) and gap analysis
 - 83% of nurses have access to the full PN order in MAR for verification
 - 33% use bar-code and/or smart pump technology
 - 65% have policy-procedure for separate ILE administration
- Survey (n=670) and gap analysis
 - Separate ILE administered as single container over max of 12 h (72% adult, 41% peds/infant)
 - But infused over >12 h by some (25% adult, 50% peds/infant)

<u>Patients</u>	<u>TNA</u>	<u>Separate ILE</u>
Adults	38%	43%
Pediatrics	18%	57%
Infants	6%	89%


<u>Patients</u>	<u>TNA Filtered</u>	<u>ILE Filtered</u>
Adults	79%	85%
Pediatrics	81%	90%

Boullata *JPEN J Parenter Enteral Nutr* 2013;37:212 / Christensen *Nutr Clin Pract* 2017;32:694

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ILE Administration

ASPEN Guidance (Positions, Recommendations, Standardized Competencies)

- Policies-procedures to standardize nursing practices for each task
 - Order verification, patient access, pump settings, monitoring
 - Verify PN label against original PN order; then independent double-check for infusion pump settings; consider use of bar-coding and smart pump technology
- Administration sets
 - Must be DEHP-free administration sets
 - Change with each new container; attach immediately prior to use
 -  Use in-line filter for all PN, including separate ILE, administration
- Infusion
 - Maintain infusion at the prescribed rate; avoid interruptions
 - Limit separate ILE hang time to max of 12 hours

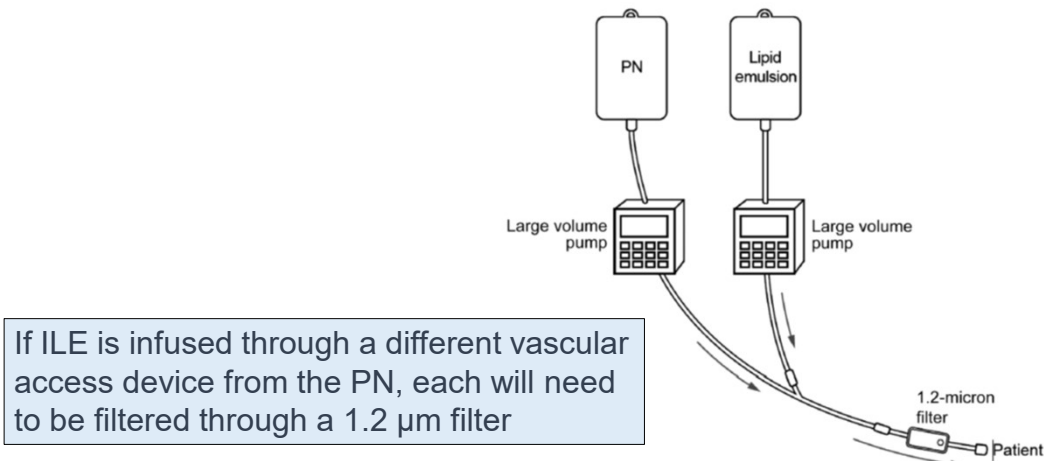
Ayers *JPEN* 2014;38:296 / Boullata *JPEN* 2014;38:334 / Guenter *Nutr Clin Pract* 2018;33:295 / Mirtallo *Nutr Clin Pract* 2020;35:769 / Worthington *Nutr Clin Pract* 2021;36:29 / Cober *Nutr Clin Pract* 2021;36: in review

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ILE Administration – Filtration



Ayers *JPEN* 2014;38:296 / Boullata *JPEN* 2014;38:334 / Guenter *Nutr Clin Pract* 2018;33:295 / Mirtallo *Nutr Clin Pract* 2020;35:769 / Worthington *Nutr Clin Pract* 2021;36:29 / Cober *Nutr Clin Pract* 2021;36: in review

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Summary

- Medication errors around PN administration continue
- Best (safe) practices are available to mitigate risk
- Make sure PN is filtered during infusion (including separate ILE)

Invited Review

Parenteral Nutrition Safety: The Story Continues

Phil Ayers, PharmD, BCNSP, FASHP¹; Joseph Boullata, PharmD, RPh, BCNSP, FASPEN, FACN²; and Gordon Sacks, PharmD, BCNSP, FCCP³

Abstract
Parenteral nutrition (PN) is an important therapeutic modality used for a variety of indications in adults, children, and infants. PN is a complex, high-alert medication that requires appropriate education and ongoing competency assessment to ensure a safe process. PN is not recognized by many organizations as a medication, which leads to underreporting of errors. This article will provide important insight and recommendations to promote a safe PN process. (*Nutr Clin Pract* 2018;33:46-52)

aspen | Learning for patients and providers in clinical practice
Nutrition in Clinical Practice
Volume 33 Number 1
February 2018 46-52
© 2018 American Society for Parenteral and Enteral Nutrition
DOI: 10.1002/ncp.10023
wileyonlinelibrary.com
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Ayers *Nutr Clin Pract* 2018;33:46

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13. Worthington P, Gura KM, Kraft MD, et al. Update on the use of filters for parenteral nutrition: an ASPEN position paper. *Nutr Clin Pract*. 2021;36:29-39.

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ISMP Update

MSOS Briefing July 2021

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP
President, Institute for Safe Medication Practices

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ISMP Medication Safety Self Assessment® for Perioperative Settings

- Launched May 18th.
- Data submission extended to October 1, 2021



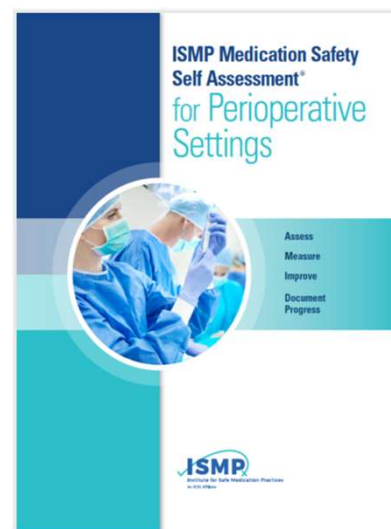
<https://www.ismp.org/node/18027>

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Benefits to Organizations

- Provide a standardized way for organizations to assess the safety of systems and practices associated with medication use in any phase of perioperative care
- Heighten awareness of best practices
- Compare their results with demographically similar organizations
- Create organization-specific, safety focused initiatives



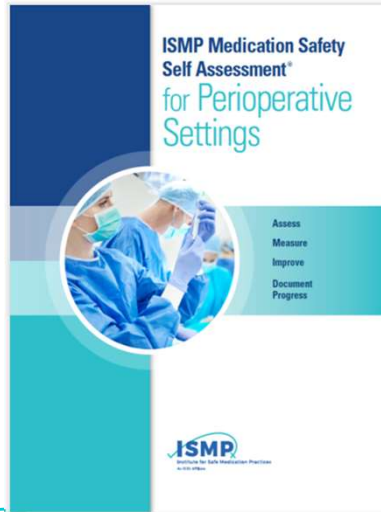
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National Benefits



- Create a baseline of national efforts
- Pinpoint how currently designed systems, staff practices, and emerging challenges may impact perioperative medication safety
- Determine challenges many healthcare providers face in keeping patients safe during all perioperative phases of care
- Develop tools/resources associated with preventing harm from medication use



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July 15, 2021 • Volume 26 Issue 14

Acute Care ISMP Medication Safety Alert!

Educating the Healthcare Community About Safe Medication Practices

Screening for dihydropyrimidine dehydrogenase (DPD) deficiency in fluorouracil patients: Why not?

ISMP is aware of several reports of patients who suffered severe toxicities or even death from the fluoropyrimidine chemotherapy drugs, fluorouracil and capecitabine (XELODA), an oral prodrug that is metabolized to fluorouracil after ingestion. These patients had a genetic condition called dihydropyrimidine dehydrogenase (DPD) deficiency, a diagnosis that neither the patients nor their doctors were aware of until it was too late. The DPD enzyme is critical for the metabolism of fluoropyrimidine drugs. With deficient enzyme function, patients can experience severe toxicities with standard doses of fluoropyrimidine chemotherapy. While the incidence of DPD deficiency is relatively low, ranging from 1 to 7 percent of the population depending on ancestry,¹ the consequences are potentially fatal.

Recent Event

A recently reported case involved a patient with breast cancer who was prescribed capecitabine. Within the first week of treatment, she began to develop mild drug-related symptoms including fatigue, weight loss, loss of appetite, and diarrhea. By the second week, her symptoms worsened, including mucositis, hand foot syndrome (skin reaction caused by leakage of the chemotherapy through capillaries in the palms of the hands and soles of the feet), extreme weight loss, fatigue, diarrhea, and a cough. After completing her first 2 weeks of therapy, she had become so weak that she required hospitalization. After hospitalization, her symptoms continued to worsen, including hand and foot desquamation, severe mucositis, dry eyes requiring artificial tears, delirium, and prolonged leukopenia. Her mouth, lips, throat, and esophagus were covered with lesions and blood. Her hair was falling out. Eventually she became unresponsive. Only later was it found that she had a DPD deficiency, so her body was unable to clear the capecitabine. She died just one month after starting therapy.

ISMP was heartbroken to learn about this preventable death, as a DPD deficiency can be detected through genetic testing prior to starting fluoropyrimidine chemotherapy. Having this information beforehand allows providers to preemptively reduce the dose of the patient's therapy and mitigate potential toxicities, or not give therapy at all if the patient is totally deficient, as no fluorouracil dose has been proven safe for patients with complete absence of DPD activity.

continued on page 2 — DPD deficiency >

SAFETY briefs

Improved safety needed for pediatric pegfilgrastim use. ISMP has received error reports involving pediatric patients who are receiving injectable medications as outpatients and require the removal of "partial doses" from a prefilled syringe. For example, Amgen's NEULASTA (pegfilgrastim), which is used primarily for the prevention of chemotherapy-induced neutropenia, is only available in a 6 mg prefilled syringe, the standard dose for adults. Since Amgen is the product sponsor, the same issue for lasinix-like versions, RUPELA (pegfilgrastim-inject), IDENZA (pegfilgrastim-inject), and NIVEPRA (pegfilgrastim-inject). For the package insert includes a table for dosing pediatric patients under 45 kg that includes volumes less than 0.6 mL (6 mg). Furthermore, despite the weight-based pediatric dosing, confoundingly, the product labeling also states, "Note: The Neulasta prefilled syringe is not designed to allow for direct administration of doses less than 0.6 mL."

Figure 1. Pegfilgrastim-inject (6 mg/0.6 mL) bicolor syringe has no graduated markings.

(6 mg). The syringe does not bear graduation marks, which are necessary to accurately measure doses of Neulasta less than 0.6 mL (6 mg) for direct administration to patients. Thus, the direct administration to patients requiring dosing of less than 0.6 mL (6 mg) is not recommended due to the potential for dosing errors."

The error reports have been indicated that parents are sometimes instructed to withdraw a partial dose from the prefilled syringe using an empty sterile syringe and needle. While this is certainly not a risk-free option, parents of children who need this

continued on page 2 — SAFETY briefs >

Deadline for new assessment extended to October 1, 2021

We have extended the deadline to submit your findings to us for the ISMP Medication Safety Self Assessment® for Perioperative Settings until October 1, 2021. If you are a US hospital that offers perioperative services, a free-standing ambulatory surgery center (ASC), or another facility that offers medical and/or surgical procedures under sedation, we encourage you to take this opportunity to complete the assessment tool. Also, facilities can listen to a FREE recorded webinar (<https://www.ismp.org/medsafety/2021/08/03/20210803>) to learn how to complete the self assessment, submit your findings to ISMP anonymously, promote interdisciplinary staff engagement to complete the assessment, and use the assessment reports to make perioperative medication safety improvements in their organization. Visit our perioperative assessment webpage (<https://www.ismp.org/node/718027>) to download a workbook with instructions, an Excel file to use to conduct the assessment, and to access the online assessment.



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NEWS RELEASE

FOR IMMEDIATE RELEASE
July 20, 2021

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ISMP Calls for Manufacturers to Stop Printing Medication Barcodes Across Round Surfaces

Horsham, Pa.—Despite ongoing advocacy by the Institute for Safe Medication Practices (ISMP), some pharmaceutical manufacturers continue to place barcodes on rounded medication container surfaces, which can lead to scanning failures that can compromise patient safety and create billing issues.

The July 15, 2021, issue of the *ISMP Medication Safety Alert®: Acute Care* newsletter reports on a recent situation where a hospital discovered while auditing their 340B program that they were not receiving the correct contract price for a rabies immune globulin product because it was not being charted to the medication administration record. The barcode was printed horizontally on the curve of the round vial and could not be completely read by the laser scanner.

ISMP recommends that linear barcodes on round ampules, vials, inhaler canisters, and oral liquid bottles only be printed perpendicular to the curve of the container, usually along the edge of the label on one side, rather than horizontally around the curve. Purchasers are advised to avoid products with curved barcodes, when possible. If scanning technology is being used during product selection and administration.

"Placing barcodes on curved medication container surfaces is an ongoing patient safety concern," says ISMP President Michael Cohen, RPh, MS, SCD (hon), DPS (hon), FASHP. "It can result in the medication not being scanned for verification, and the dose may be repeated if another practitioner believes it has not been administered. The healthcare team might also make incorrect decisions about patient care based on an inaccurate medication history."

ISMP is calling for the U.S. Food and Drug Administration (FDA) to consider raising manufacturer awareness of this problem and addressing it in the finalized draft guidance on *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors*.

For more information on this issue, see ISMP's previous newsletter coverage at: <https://www.ismp.org/resources/barcode-related-safety-briefs>

About the Institute for Safe Medication Practices

The Institute for Safe Medication Practices (ISMP) is the nation's first (1) nonprofit organization devoted entirely to preventing medication errors. ISMP is known and respected for its medication safety education. For more than 25 years, it also has served as a vital force for progress. ISMP's advocacy work also has resulted in numerous necessary changes in clinical practice, public policy, and drug labeling and packaging. Among its many initiatives, ISMP runs the only national voluntary practitioner medication error reporting program, publishes newsletters with real-time error information and trends throughout the global healthcare community, and offers a wide range of unique educational programs, tools, and guidelines. In 2020, ISMP formally affiliated with ECRI to create one of the largest healthcare quality and safety entities in the world, and ECRI and the ISMP PPS is a nationally certified patient safety organization by the U.S. Department of Health and Human Services. As an independent watchdog organization, ISMP receives no advertising revenue and depends entirely on charitable donations, educational grants, newsletter subscriptions, and volunteer efforts to pursue its life-saving work. Visit www.ismp.org and follow @ismp_org to learn more.

A nonprofit organization



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July 16, 2020 • Volume 25 Issue 14

Acute Care ISMP Medication Safety Alert!

Educating the Healthcare Community About Safe Medication Practices

NRFit: A global "fit" for neuraxial medication safety

Introduction

In an effort to prevent tubing misconnections that could result in harmful, sometimes fatal, wrong route errors, the International Organization for Standardization (ISO) developed the ISO 80369 engineering standards to specify the design of small-bore connectors for various clinical applications that are dissimilar. The new ISO 80369 standards employ forcing functions to ensure that small-bore connectors and tubing used for a specific route of delivery will not fit into small-bore connectors used for different applications, including for intravenous (IV), enteral, and neuraxial medication administration, thus reducing the risk of misconnections. The transition to the new ISO 80369-compliant connectors can improve patient care by greatly minimizing the risk of adverse events.

Implementation of the new ISO standards began in 2016 with enteral connectors (ISO 80369-3), which the Global Enteral Device Supplier Association (GEDSA) named ENFit. More than 80% of California hospitals have transitioned to ENFit because its use is mandated in that state. However, fewer hospitals have adopted ENFit across the rest of the U.S. Many are in the planning stages, realizing that full adoption is a complex process that takes several months. According to GEDSA, approximately 25% of all U.S. hospitals have adopted the ENFit system. GEDSA is a nonprofit trade association comprised of manufacturers, distributors, and suppliers worldwide, which was formed to help introduce the ISO standards in medical device connectors (<http://bit.ly/gedsa-usa>). ISMP joins GEDSA and other supporting organizations listed on its website, including ECRI, The Joint Commission, and the American Society for Parenteral and Enteral Nutrition, in strongly recommending widespread implementation of ENFit, the only ISO-compliant option for enteral administration.

The next phase of implementation of the ISO standards began last year with neuraxial connectors (ISO 80369-6), commonly referred to as NRFit. Does your organization have plans in place to transition to the new neuraxial connectors? The information that follows is intended to help you learn more about NRFit and how to select this life-saving strategy in your organization.

What is NRFit?

Medical device connectors for neuraxial applications are changing from Luer connectors to ISO 80369-6-compliant connectors, which are incompatible with the Luer system, thus preventing misconnections. Similar to ENFit, NRFit is the name selected by GEDSA to use for these ISO-compliant medical connectors. While the ISO 80369 standards only

continued on page 2 — NRFit >

SAFETY briefs

1 Use brand names to help differentiate tacrolimus formulations. An order for oral tacrolimus extended-release (ASTAGRAF XR) 1 mg daily was to be dispensed from a hospital outpatient pharmacy using three 1 mg extended-release capsules for each dose. However, the pharmacist accidentally selected tacrolimus 1 mg immediate-release (PROGRAF) capsules instead of Astagraf XR. All tacrolimus products were in the same drop-down menu because the hospital's computer system displayed all strengths of an active ingredient in a single list. Also, immediate-release and extended-release tacrolimus products are available in similar 65 mg, 1 mg, and 5 mg strengths, which may increase the potential for confusion between the two dosage forms. In this case, the patient noticed a difference in the capsule appearance compared to prior refills and reported it to the pharmacy. The error was then discovered.

ISMP reviewed multifactorial causes of tacrolimus medication errors, including confusion with the various strengths and formulations, look-alike names, preparation errors, and more in our August 10, 2017 newsletter (www.ismp.org/news/180). To prevent errors similar to the one described above, we recommended displaying the brand name of tacrolimus extended-release formulations (i.e., Astagraf XR, BNAVERSUS XR) on medication ordering and verification screens to help differentiate them from immediate-release tacrolimus (i.e., Prograf, generics). As an aside, when prescribing immediate-release tacrolimus, use only the brand or generic name, without modifiers such as "IR" for immediate-release.

⚠️ Name confusion with rapid-acting insulins. Searching by generic name for rapid-acting insulins may result in dispensing the incorrect product. Medication errors have been reported due to mix-ups between continued on page 2 — SAFETY news >



Figure 1. Most ISO 80369-6 compliant devices will incorporate the color yellow and include a NRFit logo.



Figure 2. Luer syringe (left) will not fit into the NRFit syringe (right) to flush with the line.



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MSOS Member Briefing

July 2021

Questions?



- A copy of today's slides will be posted on our website
- Next MSOS Briefing date – September 23, 2021.

Register:

https://ecri.zoom.us/webinar/register/WN_266jVUPfTeOaOXignK2AVA

