Parenteral Nutrition Safety: Everyone's Responsibility

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Objectives
Upon completion of this session, the participant will be able to:

• Describe safety issues associated with the parenteral nutrition (PN)-use process.
• Discuss current safe practice clinical guidelines and recommendations for PN.
• Describe some approaches to implementing safety recommendations in your facility.

Outline

• Introduction to PN Safety
• Guidance for Safe PN Practices
• Making Improvements in PN Safety
• Conclusions

Introduction to PN Safety

Parenteral Nutrition (PN)

• Complex prescription drug preparation
• A high-alert medication
• A valuable nutrition support intervention

Types of PN Preparations

- Compounded
  - Customized
    - [patient-specific]
  - Standardized
    - [institutionally-defined]
- Manufactured
  - Standardized
    - [commercially-available]
Types of PN Formulations

- 2-in-1
- 3-in-1

Is Parenteral Nutrition Safe?

- Yes
- No

Do PN Benefits Outweigh Risks?

Therapeutic Complications
- Mechanical
  - Pneumothorax, hemothorax, air embolus, thrombosis, malposition, catheter occlusion
- Infectious
  - Product contamination, line-related bacteremia
- Metabolic
  - Poor glycemic control, hypertriglyceridemia, abnormal electrolytes, abnormal LFTs, metabolic bone disease, GI complications

Process-Related Complications
- But more than just the PN preparation itself
- Hazards exist with some of the current practices in the PN-use process
- These can then lead to PN medication errors
  - For example, …
    - … no standardized PN order templates
    - … no dose warning limits in compounding
    - … poor matching of PN label to PN order
    - … no independent double checks of calculations or of pump programming

PN Medication Errors
- Medication Error
  - Any preventable event that may lead to inappropriate medication use or patient harm
  - “Close call” or “near hit” is a medication error that does not reach the patient
- Can occur at any point in the PN-use process
  - Over 100 errors have been reported to ISMP
  - Most are preventable
  - But only one study ever published so far
A prospective observational study reviewed 4730 PN orders and found 15.6 PN-related medication errors per 1000 compounded orders.
PN-Use Process

• Institutional oversight of PN
  “There can be no expectation of PN safety without a strong integrated PN process based on accepted standards, recommendations, and guidelines”

Safe Practice Issue 2003 (n=651) 2011 (n=895)

Organizational Systems
• ≤5 PN admixtures daily 33% 50-82%
• Outsourcing of PN compounding 15% 21%
• Exclusive use of premixed PN products - - 21%
• Administer outside PN preparations 43% 25%

Order Communication
• Standardized PN order form 88% 90%
• CPOE for PN 31% 33%
• Electronic interface available - - 7%
• Transcription required - - 81%
• Ordered in amount/day (or amount/kg/day)
  • Macronutrient <19% 21-26%
  • Electrolytes 39% 11-35%

Order Review & Clarification
• Dedicated pharmacist time = 0 FTEs - - 23%
• ≥10% of orders requiring clarification 61% 69%

PN Compounding
• ACD in use for PN preparations 22% 64%
• Order transcription to ACD required 84% 82%
• ACD active dose limits in place - - 65%
• PN admixture kept refrigerated/out of light - - 36%

Administration
• Nurse has access to full PN order for review - - 83%
• Policy & procedure for IVFE administration 84% 65%

Medication Errors & Documentation
• Performance improvement process 54% 40%
• Oversight of PN-use process - - 96%
• Aware of PN-related medication errors - - 34-42%
• Document PN order review process in MR - - 27-39%

Guidance for Safe PN Practices

USP and ASHP Sterility Guidance

1960s – 1980s
- Emphasis on patient safety s/p M&M r/t sterile compounding
- USP: National Coordinating Committee on Large Volume Parenterals (NCCLVP)
  1975: Recs for compounding IV admixtures
  1975: Recs for reporting problems
  1978: Recs for transcribing for compounded LVPs
  1980: Recs for IV admix services
  1980: Recs for GSP/P for IV therapy

1990s
- USP 1992: Dispensing products for sterile products
- USP 1995: USP chapter <797> on sterile products
- ASHP 1993: TAB QA for pharmacy-prepared sterile products
- ASHP 1996: National survey for pharmacy-prepared sterile products
- ASHP 1997: Accuracy in hospital IV admixture compounding

2000s
- USP 2004: USP-NF chapter <797> on compounding sterile preparations
- ASHP 2003: Guideline for pharmacy-prepared sterile products
- ASHP 2004: USP-NF chapter <797> on compounding sterile preparations, revision
### Standardization

- Refers to development and implementation of technical and practice standards into a process so that all health care providers deliver the same level of safe care.
- Opportunities for standardization exist at each step in the PN-use process.
- Does **NOT** refer to — and should not lead to — a one-size-fits-all strategy.

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### Guidance Documents

- **Clinical Guidelines:** Parenteral Nutrition Safety Consensus Recommendations
  - Authors: Phil Avers, Pharrand, RPh, BCNP, FASN; Stephen Adams, MS, RPh, BCN; et al.
  - Published: JPEN J Parenter Enteral Nutr 2014;38:296

- **Special Report:** Translation Into Practice
  - Authors: Phil Avers, Pharrand, RPh, BCNP, FASN; Stephen Adams, MS, RPh, BCN; et al.
  - Published: Nutr Clin Pract 2014;29:277

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### PN-Use Process

1. **PN Prescribed**
2. **PN Order Verified/Reviewed**
3. **Patient Assessed, Monitored, & Re-assessed**
4. **PN Administered**
5. **PN Order Compounded, Labelled, & Dispensed**

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### PN Safety Focus: Surveys, Summits, Recommendations, and Guidelines

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<th>Year</th>
<th>Description</th>
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### PN Safety Summit

- **ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds**
  - ISMP 2013

- **A.S.P.E.N. Clinical Guideline:** Parenteral Nutrition Safety Consensus Recommendations

- **A.S.P.E.N. Statement on Parenteral Nutrition Standardization**

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PN-Use Process

PN Prescribed

• PN shall be prescribed using a standardized PN order format applicable to patients of every age and disease state within a healthcare organization

Strength of Consensus

- Shall – Recommendation is to be followed strictly
- Should – Among several possibilities one is particularly suitable or preferred but not necessarily recommended

PN should be prescribed using a CPOE system fully integrated with the ACD

- When reordering PN, each PN component should be reordered in its entirety
- The reordering process should be structured to require accountability for reviewing the orders, laboratory findings, and patient’s condition

JPEN J Parenter Enteral Nutr 2014;38:296

Guidance Documents

Standardized Competencies for Parenteral Nutrition
Prescribing: The American Society for Parenteral and Enteral Nutrition Model
PN-Use Process

**Order Verification**
- Confirm presence of IV access if this is the first PN order for the patient (or if aware that the patient has had recent access issues)
- All elements of the order have been completed by the prescriber composing the order
- Received before the cut-off time
- Any transcription has occurred correctly

**Order Review – Clinical**
- The dose of each macronutrient is appropriate for the individual patient
- The dose of each micronutrient is appropriate for the individual patient
- Evaluate clinical dosing especially if an alert is generated against the CNSG note
- Compare dosing with the “Ordering PN” guidelines

**Order Review – Pharmaceutical**
- The ordered components are compatible with each other in the prescribed amounts
- The PN preparation is expected to be sterile from compounding through duration of infusion
- Document all required interventions

PN Order Reviewed

- PN order data should be in a standardized format including standardized sequence of ingredients, standard units, standard formulas
- The review of PN orders should be conducted in an environment free of distractions
- Modifications to the prescriber’s original PN order shall be communicated to the prescriber and documented in the patient’s medical record in a manner that is auditable
- Pharmacists who review PN orders should demonstrate competency at least annually

PN Order Compounded

Healthcare organizations shall:
- Provide a broad orientation with an in-depth training program focusing on compounded sterile preparations
- Provide an ongoing competency assessment program
- Require annual competency evaluations of pharmacists and pharmacy technicians involved in compounding sterile preparations
- Comply with USP <797> standards ... standardized workflow
- (should) Develop a strategic plan for implementing automation and technology
**Types of PN Preparations**

<table>
<thead>
<tr>
<th>Compounded</th>
<th>Manufactured</th>
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<tbody>
<tr>
<td>Custom (patient-specific)</td>
<td>100% 0% 0%</td>
</tr>
<tr>
<td>Standard (institutionally-defined)</td>
<td>60% 30% 10%</td>
</tr>
<tr>
<td>Standard (commercially-available)</td>
<td>20% 60% 20%</td>
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**Manufactured PN Products**
- Product selection/inspection to meet the order
- Activation of multichamber bag in the pharmacy
- Manual additives as needed
- Affix patient-specific label
- Refrigerate / keep out of light until dispensed

**Compounded PN Preparations**
- Proper hygiene and protective garb
- Set up and verification of ACD and ingredients
- Receive recipe, label, and appropriate bag
- Attach bag, scan barcode, pump admixture
- Verify ingredients (volumes and weight)
- Add manually drawn-up ingredients
- Completely affix patient-specific label
- Refrigerate / keep out of light until dispensed

**ACD Environment**
- ACD is an extension of the compounding personnel who retain responsibility for the PN
- Compounding takes place in ISO Class 5 primary engineering control
  - Class 7 secondary engineering control
- Requires protective garb and aseptic technique
- Frequent cleaning

**JPEN J Parenter Enteral Nutr 2014;38:334**
Oversight of PN Compounding

- A.S.P.E.N.
  - PN guidelines, recommendations, competencies, toolkits
- ASHP
  - Guidelines on compounding sterile preparations
  - Guidance on safe use of ACDs
  - Outsourcing
- ISMP
  - Guidelines for safe preparation of sterile compounds
- US Pharmacopeia
  - Chapter <797> (compounding sterile preparations)

PN-Use Process

- Written policies and procedures shall be developed to standardize nursing practices for the administration of PN throughout the organization
  - Healthcare organizations should conduct ongoing validation of competency in PN administration based on
  - changes in practice
  - results of med error monitoring
  - vulnerability of the patient population

PN Administered

- Nurses, caregivers, and patients shall visually inspect the integrity of the PN container and formulation
- The PN label shall be verified against the original prescriber order; no verbal orders shall be accepted
- The administration tubing shall be traced to the point of origin in the body
- An independent double-check process and verification of infusion pump settings should be performed by a second clinician

PN Administered

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Making Improvements in PN Safety

- Examine your PN-use process
  - Map it out, step by step
  - Make sure each step is reflected in P&P
  - Compare with guidance/regulatory documents
- Select an area for improvement
  - Develop target plan
- Identify your oversight system and participants
  - P&T or Med Safety committee
  - Nutrition support, pharmacy, information services, …

Improving PN Safety

- Institutional oversight of PN
  - Develop and maintain policies, procedures, and best practices
    - Clearly written → all roles and responsibilities
    - Assure consistency of policies, procedures, and practices
  - Validate competencies of those involved at each step
    - Meet institutional criteria
  - Perform systematic review of all PN-related medication errors
    - Identify significant deviations from standard of care

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Some Tips – prescribing

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<tr>
<th>Step in the Process</th>
<th>Minimum Criteria</th>
<th>Optional Criteria</th>
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<tbody>
<tr>
<td>Prescribing</td>
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<tr>
<td>Documentation</td>
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<tr>
<td>PN Order Available</td>
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<tr>
<td>PN Order Compounded, Labeled, &amp; Dispensed</td>
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JPEN J Parenter Enteral Nutr 2014;38:378
Some Tips – reviewing

1. Review each PN order (by a pharmacist) to ensure it is compliant with institutional protocols.
2. Identify the individual who reviews each PN order for completeness and accuracy.
3. Clarify any concerns about the PN order.
4. Review the administration of other drugs with PN to ensure safety, stability, and compatibility.

Some Tips – preparing

1. Develop written policies and procedures for preparing PN solutions.
2. Do not allow PN to remain unused for more than 24 hours.
3. Check the sequence of ingredients and the volume on the PN order.
4. Include patient’s weight on the label.

Some Tips – administering

1. Identify a standardized PN start time.
2. Compare the PN label with the original PN order for accuracy.
3. Complete appropriate patient identification before administration.
4. Include an independent double-check system to ensure PN order before administration.

Some Tips – monitoring, documenting

1. Monitor all patients receiving PN.
2. Develop evidence-based practice guidelines to support the assessment and monitoring of patients receiving PN.
3. Document the PN order and any changes in the prescription and administration of the medication.
4. Document any work related to the patient’s PN order.

PN Safety Resources

A.S.P.E.N. PN Safety Checklists:

- PN Safety Preparation
- PN Prescribing and Communicating PN Order
- PN Order Review and Verification
- PN Compounding
- PN Administration

PN Safety Resources

Parenteral Nutrition Safety Toolkit
Parenteral nutrition tools and resources for interdisciplinary clinicians

Advises, educates, and supports professionals involved in PN therapy and patient care. It offers a comprehensive tool for standardizing practice and improving patient outcomes. It includes evidence-based practice guidelines, policies, and procedures to support the assessment, monitoring, and management of patients receiving PN. It also provides educational opportunities and resources for interdisciplinary clinicians involved in PN therapy.
Conclusions

• PN is a high-alert medication
  – Requires safety-focused policies, procedures, practices and systems
  – Benefits from standardization and communication
    – Institutions: …
    – Providers: …

• Institutions:
  – Incorporate appropriate clinical guidelines & consensus recommendations into policies, procedures, and practices
  – Collect and report all errors associated with PN
    • Internally (e.g., medication safety officer) → evaluate and respond
    • Externally (e.g., https://www.ismp.org/orderforms/healthcaremerp.asp)
  – Support a culture of safety

• Providers:
  – Even without a nutrition support department or team:
    • Individuals with nutrition support expertise can enhance patient safety and reduce PN-related hazards by becoming more directly involved in all steps
    • Start with just one area in the PN process to improve
  – Document each step in the PN-use process so that errors can be evaluated and corrective actions taken

References