Disclosures

• Speaker and/or consultant for:
  – 3M
  – Atrion Corporation
  – B Braun
  – Bard Access Systems
  – Baxter
  – BD Medical
  – Covidien/Medtronic
  – Fresinius Kabi
  – Gayco Healthcare

  – LineGard Medical
  – Lippincott Williams Wilkins
  – Terumo
  – VATA
  – Velano Vascular
• “Whether the purpose lies in informing patient care, legal proceedings, or personal edification and growth, no document is more versatile, time-tested, or valuable in the field of infusion practice.”

• Vineet Chopra, MD, MSC
  Ann Arbor VA Medical Center and the University of Michigan Health System
Learning Objectives

• Describe the methods for revising the 2016 Infusion Therapy Standards of Practice.
• Discuss the ranking of levels of evidence.
• Identify new standards and major changes applicable to vascular access devices.
Committee Members

• Chair - Lisa Gorski, MS, RN, HHCNS-BC, CRNI, FAAN
  – Home care, 3rd edition of the standards
• Lynn Hadaway, Med, RN-BC, CRNI
  – Acute care IV Teams, educator, consultant, 3rd edition of the standards
• Mary E. Hagle, PhD, RN-BC, FAAN
  – Nurse scientist, 2nd edition of the standards
• Mary McGoldrick, MS, RN, CRNI
  – Home care, hospice, infection control & prevention
• Marsha Orr, MS, RN
  – Parenteral nutrition, educator, 2nd edition of the standards
• Darcy Doellman, MSN, RN, CRNI, VA-BC
  – Pediatrics
Revision Process

• Literature searches
  – Identified keywords, phrases for each standard
  – Search English language publications, 2009 through July 2015
    • Classic publications also used
  – Databases used:
    • Cochrane Library
    • CINAHL
    • MEDLINE, PubMed
    • Web of Science

– Other resources
  • United States Pharmacopeia (USP)
  • US Department of Health and Human Services
    – Agency for Healthcare Research and Quality
    – Centers for Disease Control and Prevention
  • US Food and Drug Administration
  • US Department of Labor - OSHA
Revision Process

• Interprofessional External Review
  – Draft sent to INS members, nurses in other specialties, physicians, pharmacists, lawyers, other types of clinicians, industry partners
  – ~800 comments received from 60 reviewers
  – Committee read and evaluated each comment
  – Revised the applicable standard, additional literature searches if required
  – Finalized content for internal editors review
  – Review by editors from publisher, Wolters Kluwer
Review Process

• Revised the *Policies and Procedures for Infusion Therapy*

• Two separate resources
  – Policies and procedures are NOT the same as Standards
Strength of the Body of Evidence

- **I** = Meta-analysis, systematic literature review, guideline based on randomized controlled trials (RCTs), or at least 3 well-designed RCTs.

- **I A/P** = Evidence from anatomy, physiology, and pathophysiology references as understood at the time of writing.

- **II** = Two well-designed RCTs, 2 or more multicenter, well-designed clinical trials without randomization, or systematic literature review of varied prospective study designs.

- **III** = One well-designed RCT, several well-designed clinical trials without randomization, or several studies with quasi-experimental designs focused on the same question. Includes 2 or more well-designed laboratory studies.
Strength of the Body of Evidence

- IV = well-designed quasi-experimental study, case control study, cohort study, correlational study, time series study, systematic literature review of descriptive and qualitative studies, or narrative literature review, psychometric study. Includes 1 well-designed laboratory study.

- V = Clinical article, clinical/professional book, consensus report, case report, guideline based on consensus, descriptive study, well-designed quality improvement project, theoretical basis, recommendations by accrediting bodies and professional organizations, or manufacturer directions for use for products or services. Includes standard of practice that is generally accepted but does not have a research basis (for example, patient identification). May also be noted as Committee Consensus, although rarely used.

- Regulatory = Regulations and other criteria set by agencies with the ability to impose consequences, such as the AABB, Centers for Medicare & Medicaid Services (CMS), Occupational Safety and Health Administration (OSHA), and state Boards of Nursing.
Strength of the Body of Evidence

• Practice Criteria Language
  – Large body of robust evidence = higher ranking of I or II
    • Begins with action verb, use, perform,
  – Robust design, but inconclusive or undetermined findings
    • “Consider use of---”
    • Use identified evidence plus experience and clinical judgment

<table>
<thead>
<tr>
<th></th>
<th>2011</th>
<th>2016</th>
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<tr>
<td>Level I evidence</td>
<td>3.8%</td>
<td>5.8%</td>
</tr>
<tr>
<td>Level V evidence</td>
<td>67%</td>
<td>46%</td>
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Major Changes

• What are the 2 most prominent changes in the 2016 standards document?
  • Title change
    – 2011 Infusion Nursing Standards of Practice
    – 2016 Infusion Therapy Standards of Practice
  • Professional designation broadened
    – 2011 – “nurse”
    – 2016 – “clinician”
Table of Contents

64 Standards – divided into 9 sections

1: Infusion Therapy Practice
2: Patient & Clinician Safety
3: Infection Prevention & Control
4: Infusion Equipment
5: Vascular Access Device (VAD) Selection & Placement
6: VAD Management
7: VAD-Related Complications
8: Other Infusion Devices
9: Infusion Therapies
Section Changes

• New Section Standards for Section 4-9
  – Standard statements that apply to all standards in that section
  – Reduces redundancy of statements
    • “The clinician is competent to ---”
    • “established in organizational policies, procedures, and/or practice guidelines”
  – Don’t overlook this important section!
Standard 1 Patient Care

- Applies to all settings where vascular access are placed, managed, or infusion therapies are administered
- Practices established in organizational policies, procedures, practice guidelines, and/or standardized written protocols/orders
- Attention to patient safety and quality
  - Individualized, collaborative, culturally sensitive, age appropriate
- Ethical principles as foundation for decision-making
- Decisions including device/product selection, are *not* subject to commercial or other conflicts of interest.
Standard 2 - Special Patient Populations

• Includes
  – Neonates
  – Pediatrics
  – Pregnant patients
  – Older adults
Standard 3 Scope of Practice

- Clinicians practice according to applicable regulatory board, clearly defined in organizational policy
- Within boundaries of their legal scope of practice
- Collaboration of the healthcare team members
- Delegation by RNs to unlicensed personnel
  - RN and organization are responsible and accountable for all delegated tasks
- “Recognize the overlap between professional groups and that no single professional can claim exclusive ownership of any skill, activity, or task.”
Standard 3 Scope of Practice

• Nursing personnel
  – RN
  – LPN/LVN
  – Infusion Nurse Specialist, CRNI®
  – Advanced Practice RN

• Unlicensed assistive personnel (UAP)
  – Nursing assistants
  – Medical assistants

• Therapists/Technologists/Technicians
  – Radiologic technologists
  – Respiratory care practitioner
  – Paramedic
Standard 4 Infusion Team

- Scope of service to meet patient and organization needs
- VAD insertion and management assigned to individuals/teams with infusion therapy education, training, and validated competency
- Peripheral catheter insertion by team = increased insertion success, decreased hospital acquired BSI, local infection, occlusions, and accidental removals
- Team managing VADs decrease BSI and related costs, phlebitis and infiltration, and increase patient satisfaction
Standard 5 Competency Assessment and Validation

• Individual clinician responsible and accountable for attaining and maintaining competence within legal scope of practice

• Beyond psychomotor skills, includes knowledge, critical thinking, and decision-making ability

• Competency assessment and validation initially and on an ongoing basis
  – Initially
  – Continuing competency
    • Frequency determined by each organization; known problems, concerns and outcomes

• Standardized, transparent process for assessing and judging competency
  – Imbalance of power when manager is the validator
Standard 5 Competency Assessment and Validation

• Use a variety of evaluation methods to increase outcome reliability

• Clear performance expectations for contracted clinician competencies
  – Documentation, supervision of contractors learning procedures, monitoring outcomes

• “Do NOT perform invasive procedures (eg, venipuncture) on peers due to health risk and the physical and emotional stress created for the volunteer.”

• Qualifications for the competency assessor

• Well-designed forms
  – Objective, measurable assessment of actual performance
Standard 9 Informed Consent

- An educational process involving patient in shared decision making
- Process is voluntary without coercion or persuasion
- Includes clinical procedures and research
- Addresses photographs
  - Ability to identify patient falls under HIPAA rules
  - Not able to identify patient may not require informed consent under HIPAA but organization policies should address this issue
Standard 22 Vascular Visualization

- Includes use of
  - Visible light devices for transillumination
    - Cold light source needed
  - Near-infrared light devices
    - More informed decisions about peripheral veins, bifurcation, tortuosity
  - Ultrasound
    - Peripheral sites – requires longer catheters
    - Addresses CVADs
    - Dynamic or “real-time” use is recommended
    - Sterile TSM dressing (peripheral sites), sheath cover and gel
Standard 23 Central Vascular Access Device Tip Location

- Determined prior to initiation of infusion therapy and when clinical signs and symptoms suggest tip malposition
- Documented and made available to all organizations involved in patient’s care
- Location with the greatest safety profile in adults and children is the cavoatrial junction
- Anthropometric measurements to determine desired catheter length
- Avoid suboptimal tip locations
  - Many venous tip location identified for CLABSI data collection and reporting, but these should be used when anatomical or pathophysiological changes prohibit CAJ location
- Post-procedure chest xray or ECG
  - Documented competency for assessment of tip location on both
Standard 26 Vascular Access Device Planning

- Change of focus from selection to planning
  - Collaborative process among interprofessional team, patient and caregiver(s)
  - Smallest outer diameter, fewest number of lumens, least invasive device needed for prescribed therapy
  - Peripheral vein preservation!

- Goal - choose least invasive VAD that has the greatest likelihood of reaching end of planned infusion therapy with fewest number of replacements and lowest rate of complications
Standard 26 Vascular Access
Device Planning

• Consider infusate characteristics and duration of therapy
  – Osmolarity, vesicant nature, pH, stability, compatibility, etc
  – Comprehensive literature review found no evidence to support limiting infusate pH range to <5 to >9 for short peripheral and midline catheters

• Peripheral and midline catheters NOT for continuous vesicant therapy, parenteral nutrition, or infusates with osmolarity greater than 900 mOsm/L

• Midlines – use caution with intermittent vesicant administration due to risk of undetected extravasation
• Short peripheral catheters
  – **Committee Consensus:** Consider increased attention to aseptic technique, including strict attention to skin antisepsis and use of sterile gloves....lack of evidence comparing BSI rates with or without use of sterile gloves, longer dwell times have raised concerns regarding risk for BSI ..furthermore contamination of nonsterile gloves is documented”

• Midline catheters
  – Consider use of maximal sterile barrier precautions with midline catheter insertion

• Short peripheral and midline catheters
  – Skin antiseptic - > 0.5% CHG in alcohol preferred
Standard 33 Vascular Access Site Preparation and Device Placement

- Central line bundle for insertion
- Completion of standardized checklist by someone other than inserter; empowered to stop procedure for identified breach
- Standardized supply cart or kit with all needed supplies
- CVAD insertion on opposite side if pacemaker present, assess pacemaker function before and after CVAD insertion; no practice guidelines available
Standard 34 Needleless Connectors (NC)

- NC between the VAD hub and administration set used for continuous infusions is unknown.
- Avoid use of NCs with rapid flow rates of crystalloid solutions and RBCs as their presence can greatly reduce flow rates.
- No consensus on design or type to prevent or reduce bloodstream infection.
- Device with lowest thrombotic occlusion in VAD is controversial, requires more study.
- Disinfect prior to EACH entry.
- Includes manual and passive disinfection practices.
Standard 34 Needleless Connectors (NC)

- Glossary definitions
- Needleless Connector (NC). A device that allows intermittent access to a vascular access device with an administration set or syringe without the use of needles; types are categorized by description and function upon set or syringe disconnection.
  - Anti-Reflux
  - Complex
  - Negative Displacement
  - Neutral
  - Positive Displacement
  - Simple
Standard 34 Needleless Connectors (NC)

- Use stopcock or manifold with integrated NC rather than a solid cap (III)
- Change NC no more frequently than 96-hour intervals
- Change when
  - NC is removed for any reason
  - Residual blood or debris inside
  - Prior to drawing a blood culture from VAD
  - Upon contamination
  - Required by organizational policy, procedure
  - Required by manufacturer directions
Standard 35 Filtration

• Practice Criteria
  – Contraindicated for certain medications due to retention on the filter, consult with pharmacy or literature
  – Avoid filters with very small drug volumes
  – Evolving evidence on effect of
    • particulate matter on capillary endothelium
    • microbubbles on cerebral and pulmonary ischemia
  – Use air-eliminating filters in patients with right-to-left cardiac shunting
  – Consider filtration in critically ill patients; reduction in systemic inflammatory response syndrome in pediatric ICU patients
Standard 35 Filtration

• Practice Criteria
  – 0.2 micron for parenteral nutrition **without** IVFE
  – 1.2 micron for 3-in-1 PN and ALL IVFE infused separately – **new manufacturer directions since SOP published**
    • May require use of both filters
  – Intraspinal infusion requires **surfactant free** 0.2 micron filter
  – Filter needle or straw for glass ampules
Standard 36 Add-on Devices

- Includes single or multiple lumen extension sets, manifold sets, etc
- Avoid use of stopcocks; reduce contamination by using a stopcock with integrated needleless connector
- Change add-ons
  - With new VAD insertion
  - With new administration set
  - Defined by policy and procedures
  - With compromised integrity or suspected of contamination
Standard 37 VAD Stabilization

- Includes adhesive based and subcutaneous devices
- Tape, sutures not effective alternatives
- Standard, nonbordered polyurethane and gauze and tape dressings – insufficient evidence as stabilization devices
- Bordered polyurethane securement dressing alone = more peripheral catheters reaching 72 hours dwell time, more data needed
- Do NOT use rolled bandages
- Medical adhesive related skin injury (MARSI)
  - Apply barrier solutions
- NEVER readvance a dislodged VAD into vein
Standard 38 Joint Stabilization

- Used to facilitate infusion delivery and maintain device patency
- Are NOT considered to be restraints
- Supports area of flexion
- Permits visual inspection/assessment
- Wooden tongue depressors should not be used in preterm infants and immunocompromised patients
Standard 39 Site Protection

- At risk patients - Pediatrics, elderly, cognitive dysfunction
- Consider site protection, ie, clear plastic domes
- Protect from water, other contaminants
- Permits visual inspection of site
Standard 40 Flushing and Locking

• Flush with normal saline, aspirate for blood return, clear medication from lumen, prevent contact between incompatible solutions
  – Minimum volume = twice internal volume of catheter system
  – Larger volume may be needed

• Lock solutions
  – Peripheral catheters – normal saline in adults; heparin 0.5 to 10 units per mL OR normal saline for neonates and pediatrics
  – Midline catheters – insufficient evidence for recommendation
  – CVADs – heparin 10 units per mL OR normal saline
  – Volume = internal volume of catheter system plus 20%
Standard 40 Flushing and Locking

• Antimicrobial lock solutions
  – Therapeutic and prophylactic uses
  – Use standardized formulations
    • Supratherapeutic concentrations of antibiotics
    • Antiseptic solutions
      – Ethanol
      – Citrate
      – Taurolidine
      – Ethylenediaminetetraacetic acid (EDTA)
      – Combinations
    – ASPIRATE all solutions
• CVADs, midlines assess at least daily
• Short peripheral catheters assessed
  – Minimally every 4 hours
  – Critically ill, sedated, or cognitive deficits – every 1-2 hours
  – Neonatal and pediatrics – every hour
  – Vesicant infusion – more often than every hour
• CHG dressing on CVADs when primary source of infection is extraluminal route
• Perform dressing changes on short peripheral catheters if the dressing becomes damp, loosened, and/or visibly soiled and at least every 5 to 7 days.
• 2% CHG bathing for patients more than 2 months of age with CVAD when other strategies not effective
• **Practice Criteria**
  – **General**
    • **Labels**
      – Date of initiation or date of change
      – Sets attached to intraspinal, intraosseous, or subcutaneous devices labeled with medication inside near the connection to the device
    • Trace infusion system from patient to solution container before connecting or reconnecting, at each care transition, during handoff process.
• Primary and secondary continuous infusions
  – Replace no more frequently than every 96 hours
  – Detached secondary sets replace every 24 hours
  – Avoid disconnecting primary continuous sets from VAD hub or access site.
  – Backpriming now addressed in Policy and Procedure Book
Standard 42 Administration
Set Change

- Primary Intermittent Infusions
  - Change sets every 24 hours
  - Aseptically attach new, sterile, compatible covering to male luer after each use. Do not attach to port on the same set (looping).

- Parenteral Nutrition
  - Replace set at least every 24 hours; also recommendations to change with each PN container
  - Replace IV fat emulsion (IVFE) sets for separate infusion every 12 hours and with each new container
  - DEHP-free sets for all IVFE and 3-in-1 PN solution
    - Toxin found in lipids solutions
    - Risk factor for neonates, pediatrics, and long term home care
Standard 43 Phlebotomy

• Greatly expanded!
• Blood conservation strategies to reduce blood loss and hospital-acquired anemia
• Tourniquet time less than 1 minute
  – Insert peripheral catheter, secure and dress, then draw sample after insertion, NOT during insertion
• Discard and push-pull (mixing) method addressed
• No routine sampling from CVAD infusing parenteral nutrition
Standard 44 VAD Removal

- Peripheral and nontunneled CVAD assessed daily
- Removed for unresolved complications, discontinuation of infusion therapy, no longer necessary for plan of care
- Peripheral catheter – remove if not used for 24 hours
- List of clinical indications for removal of peripheral and midline catheters
- List of criteria for justification of continued use of CVAD
- VAD inserted under suboptimal aseptic conditions – label as such for removal ASAP or with 24 to 48 hr
- CVAD unresolved complications and need for continued infusion therapy requires collaborative decision
Standard 47 Nerve Injuries

- Paresthesia during venipuncture – immediate removal
- Respiratory difficulty, unusual presentations of pain or discomfort – high index of suspicion for nerve injury
- Anatomically, veins and nerves are located close together. Sites with greatest risk listed
- No subcutaneous probing or multiple passes to enter vein
- Neurovascular assessment
  - Neuroma
  - Compartment syndrome
  - Complex regional pain syndrome
Standard 48 CVAD Occlusion

• Previously – Catheter clearance
• Regular patency assessment includes blood return
• Catheter salvage is preferred over removal
• Criteria to
  – Reduce risk of CVAD occlusion
  – Identify signs
  – Investigate potential causes
• Do NOT leave a CVAD or lumen with occlusion untreated
• Collaboration with pharmacists and LIP for appropriate management
Standard 51 Catheter Damage (Emboli sm, Repair, Exchange)

- Merger of 2 old standards
- Risk versus benefit assessment for repair or exchange
- Catheter embolism
  - Pinch-off syndrome for subclavian sites
- Catheter repair
  - Only with manufacturer-specific repair kit
  - Regular assessments of integrity of repair
- Catheter exchange
  - Only if no evidence of infection
  - Maximal barrier precautions
  - Confirm tip location after exchange
Standard 52 CVAD-Associated Thrombosis

- PICCs = greater risk of DVT in critical care and oncology patients
- Measure vein diameter for PICCs
  - Catheter to vein ratio 45% or less
- Majority of CVAD thromboses are clinically silent
- For PICC measure upper arm circumference before insertion and when clinically indicated
  - Measure 10 cm above antecubital fossa
- For CVAD with DVT, do NOT remove when catheter is correctly positioned at CAJ, is functioning with a blood return, and no evidence of infection.
Standard 53 CVAD Malposition

• 4 types
  – Primary malposition – during insertion
  – Secondary malposition – during dwell
  – Intravascular malposition
  – Extravascular malposition

• Growth of infants and children with CVAD results in suboptimal tip locations over time

• Scout scan for power-injectable PICC before contrast injection

• Blood return is critical component of assessment

• Management requires collaborative plan before removal based on where tip is located
Appendices

• Infusion Team definition
• Better illustrations
• Glossary greatly expanded
  – Definitional information from previous document moved to glossary
  – Example
    • Blood return – A component of VAD patency assessment; blood that is the color and consistency of whole blood upon aspiration.
• “This edition (i.e. Standards) continues to provide us with critical answers to the many important questions, conundrums, and challenges we face today. I urge you all to read, evaluate, and adapt the recommendations within this document to your care and decision making. Your patients, practice, and society will thank you for it.”

• Vineet Chopra, MD, MSc

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