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Approximately every 5 years, the Infusion Nurses Society publishes evidence-based practice standards. This article provides an overview of the process used in standards development, describes the format of the standards, and provides a short summary of selected standards as applied to home care. The Standards are an important document that should be available to every home care organization that provides home infusion therapy.

The 2016 INFUSION THERAPY STANDARDS

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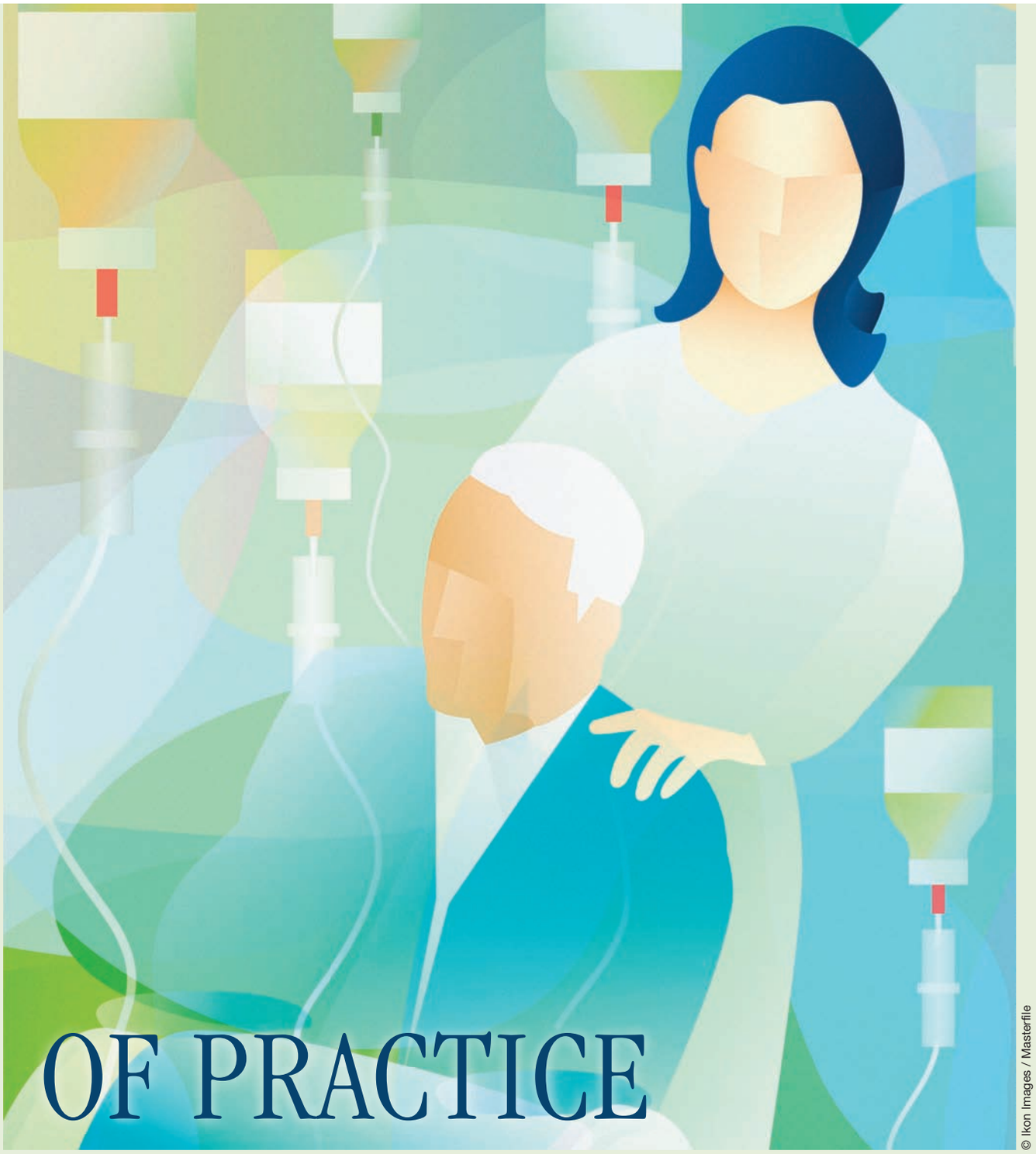
The Infusion Nurses Society (INS) publishes evidence-based practice standards approximately every 5 years. The Infusion Therapy Standards of Practice (the Standards) are widely cited and used to develop and support clinical procedures in many published procedure manuals. As the Committee Chairperson for both the 2011 and the recently published 2016 Standards (Gorski et al., 2016b), I have had many opportunities to share the Standards at meetings within the United States and abroad. There is a high level of global interest in the Standards as I have traveled over the past year providing presentations to nurses in China, Argentina, Chile, Mexico, and Colombia. Although a "formal" home care system is less developed in these countries, in a recent trip to China I was asked a number of questions about home care, for example, how are patients at home managed with a peripherally inserted central catheter?

In the United States, home infusion therapy is a common practice. Although the safety of home infusion therapy has been established over the past 30-some years, it is important to recognize that infusion therapy is a "high risk" area of practice as these patients have an invasive device and may be receiving high-risk drug infusions such as antineoplastics, opioids, and inotropes. Even home IV antibiotic therapy can result in significant adverse events such as nephrotoxicity or ototoxicity associated with aminoglycoside antibiotics. The Gorski Model for Safe Infusion Therapy (in press) predicts positive patient outcomes, including complication prevention and patient and healthcare provider satisfaction, when careful attention is given to four key areas: appropriate patient selection, effective patient education, meticulous patient care and comprehensive assessment and monitoring, and interprofessional communication and collaboration. These can only occur when evidence-based infusion care is provided by knowledgeable and competent nurses.

In an eloquent foreword to the 2016 Standards, Dr. Vineet Chopra writes that the 2016 edition of the 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" (Gorski et al., 2016b, p. S2).

This article provides an overview of the process used in standards development, describes the format of the standards, and provides a short summary of selected standards as applied to home care. The selection of



OF PRACTICE

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standards is based on the changes in the 2016 Standards and relevance to home care as based upon questions and concerns posed by home care nurses during U.S. presentations.

The scope of infusion practice addressed in the Standards includes intravenous as well as subcutaneous, intraosseous, and intraspinal access devices and infusions. The Standards are intended to be used by clinicians in any setting where infusion therapy is administered including acute care, outpatient/ambulatory care, long-term care, and of course, home healthcare. The full table of contents for the Standards is found in Table 1. Prevention of complications related to infusion therapy is an overarching goal. Although not addressed in this article, the section on Complications provides many important recommendations, and the section on Infection Prevention and Control includes critical recommendations aimed at reduction of infections including hand hygiene, standard and transmission-based precautions, medical waste and sharps safety, and compounding (e.g., mixing) of medications, which may be required in certain home infusion therapies. Most vascular access

device-related complications are preventable or, if they occur, adverse effects can be mitigated through early identification and intervention. The Infusion Therapy Standards of Practice can be obtained from the INS at www.ins1.org.

Development Process

A committee of six nurses from across the country and representing a variety of areas of practice developed and wrote the initial draft of the Standards based upon a review of the literature. The committee members performed literature searches for each of the standards using key words and subject headings related to each standard. The methodology is further described in the Standards document. Initial drafts were reviewed by the committee through frequent and ongoing meetings, email communication, and conference calls. Upon completion of the final draft, it was sent to approximately 90 reviewers, which included healthcare personnel from a variety of settings including nurses, pharmacists, physicians, and an attorney. Fifty-nine reviewers completed this task that yielded approximately 800 substantive comments and suggestions. These were carefully reviewed by the committee and final revisions were made to complete the work.

After much discussion among the committee, a major change in the Standards was made in relation to the name. Previously they were called Infusion *Nursing* Standards and in 2016, the title

Table 1. 2016 Infusion Therapy Standards of Practice: Table of Contents

was changed to Infusion *Therapy* Standards. The committee recognizes that infusion therapy is the responsibility of any clinician involved in the practice, which includes physicians, pharmacists, and also may include technicians and unlicensed assistive personnel. However, in home care practice, nurses are primarily the only direct care providers. Our "patients deserve infusion therapy based on the best available evidence, irrespective of the discipline of the clinician" who provides that care (Gorski et al., 2016b, p. S8).

Upon completion of the Standards, the committee also took on the responsibility of revising the 5th edition of INS' Policies and Procedures for Infusion Therapy (Gorski et al., 2016a). This edition was expanded to include new features for each procedure including key points, key areas for assessment, patient education, and home care/alternative site implications. The intent of this publication is to help clinicians translate the INS Standards into clinical practice.

Format of the Standards

Each standard consists of two components: Standards and Practice Criteria. The Standards are expectations of practice applicable to infusion therapy in all settings. A standard is defined as an authoritative statement enunciated and promulgated by the profession by which the quality of practice, service, or education can be judged (American Nurses Association, 2014; Gorski et al., 2016b). An example from Standard 33: Vascular Access Device (VAD) Site Preparation and Device Placement is: "Skin antisepsis is performed prior to VAD placement" (Gorski et al., 2016b, p. S64). The Practice Criteria provide specific guidance in the implementation of the corresponding Standard. Each Practice Criterion is supported by evidence, is rated as reflecting the strength of the body of evidence, and all references to support the criteria are cited. Practice criteria in Standard 33 related to skin antisepsis include evidence-based recommendations for specific site preparation including the use of >0.5% chlorhexidine in alcohol solution as the preferred skin antiseptic agent (Gorski et al., 2016b, p. S65).

An Overview of Selected Standards

Standard 5: Competency Assessment and Validation

This standard asserts that clinicians are competent in safe delivery of infusion therapy and VAD insertion and management. Competency to perform infusion therapy procedures should never be based upon a nurse's verbal assertion. As a nurse who has served as an expert witness in a number of home infusion therapy cases, I can attest there is sometimes a lack of attention to the education and competency of the nurses who provide infusion care as well as the absence of agency policies and procedures to guide practice. Unfortunately, home care patients have died or suffered significant complications as a result of septic events and infusion drug errors. Such events are highly preventable when competent nurses manage home infusion cases. Home care agencies must have sound competency programs in place. The Standards state that validation of competency is performed initially (e.g., upon hire) and on an ongoing basis. Competency is validated using a variety of techniques. Observation of performance and implementation of knowledge and skills in the work environment are preferred for infusion therapy procedures. Another method of competency validation is written tests to assess knowledge with clinical scenarios integrated to assess critical thinking skills. It is also vitally important to develop qualifications for the "competency assessor" often called the "preceptor." Substandard practice may be passed on to newly hired nurses if the preceptor is not competent with infusion administration. Preceptors should be assessed for expertise and competence and ability to observe and provide critique of nurses' skills (Gorski et al., 2016b, pp. S18–S20).

It is also worth repeating the Professional Practice Standard on "Education" from the American Nurses Association (ANA) Scope and Standards for Home Health Nursing (ANA, 2014). Standard 8 requires each nurse to attain "knowledge and competency that reflect current nursing practice" (ANA, p. 62). This standard requires the home healthcare nurse to be self-directed, self-motivated, and committed in the pursuit of the lifelong learning necessary to practice in home healthcare. As home care nurses, we have a personal responsibility to identify our educational needs.

Standard 8: Patient Education

Effective patient and caregiver education is one of the four key areas of practice essential to positive patient outcomes according to the Gorski Model for Safe Infusion Therapy (in press). The home care nurse's skill in patient education is just as

important as the skill and competency in performing infusion procedures, as this will impact patient outcomes related to safety and adherence with infusion administration. In most cases, patients and/or their caregivers are expected to learn how to self-administer their infusions and all must safely live with a VAD in place. In conjunction with home infusion therapy procedures, education must also address safe storage, maintenance, and disposal of solutions, supplies, and equipment; use and troubleshooting of the electronic infusion device; recognition of signs and symptoms of adverse effects; and prevention of complications such air embolism, infection, catheter damage (Gorski et al. 2016b, p. S25). The U.S. Food and Drug Administration (FDA, 2015) provides guidance to both clinicians and patients related to safe infusion pump use. Nurses can refer patients to the FDA Web site or print out helpful teaching information entitled "*Infusion Pump Risk Reduction Strategies for Patients Using Infusion Pumps at Home.*"

It is necessary to teach patients about how to safely live and perform activities of daily living with the VAD, such as how to dress/undress and bathe while protecting the catheter and any infusion tubing. This teaching is often missed in the midst of technical pump teaching. It is not adequate to just "check off" a patient as independent with infusion administration at the beginning of therapy. Performance should be evaluated periodically thereafter (Gorski et al., 2016b, p. S26) to ensure that infusion technique is still sound with continued adherence to aseptic technique.

Teaching methods are based on an assessment that includes a number of factors including age, developmental/cognitive level, health literacy, and cultural influences. With the increasing use of Web sites and social media for health advice and support, the 2016 Standards recommend that patients and caregivers are advised about the benefits and challenges of such sources of information (Gorski et al., 2016b, p. S25).

Learning is evaluated by demonstration and return demonstrations for psychomotor skills. Strategies such as "teach-back" are appropriate for evaluation of "cognitive" knowledge such as naming sign/symptoms to promptly report to the home care nurse or pharmacy.

Standard 22: Vascular Visualization

This new standard addresses the use of technology including visible light devices that provide transillumination, near infrared (nIR), and ultrasound. Especially for patients with difficult venous access, such technology can contribute to success in peripheral catheter placement. In the home setting, the use of nIR technology is now being used by some home care organizations to aid in identification of peripheral venous sites. The Standards state that more informed decisions about vein selection such as bifurcation, tortuosity, and palpable but not visible veins is possible with nIR (Gorski et al., 2016b, p. S45). Research regarding the efficacy and success of nIR in a variety of settings is ongoing.

Standard 26: Vascular Access Device Planning

Most often, patients are referred and admitted to home care with a VAD already in place. The most common VADs among home care patients include peripherally inserted central catheters (PICC), implanted vascular access ports, and more recently, a trend toward use of midline catheters. Midlines are peripheral catheters that are inserted into the upper arm via the cephalic, basilic, or brachial vein and the catheter tip is located at or near the level of the axilla. Advantages to midline catheters include longer dwell time compared to a traditional "short" peripheral catheter. The catheter tip lies in a larger diameter vein allowing better hemodilution of the infusate, most often antibiotics. Although there is no known optimal dwell time and any VAD should not be removed solely based on dwell time, midline catheters are generally placed for infusion therapies intended to last between 1 and 4 weeks. With the increased use of midline catheters, home care nurses must be very careful to appropriately identify and document the presence of a midline catheter versus a PICC as they are usually placed in the same area and via the same veins. Anecdotally, organizations are reporting inappropriate administration of infusates via a midline catheter that should be administered through a central VAD when clinicians do not recognize or confirm the type of VAD. For example, parenteral nutrition or vesicant infusions (e.g., dobutamine) are not appropriate for administration via a midline catheter.

When making a decision for the best VAD for the patient, factors to be considered include the prescribed therapy or treatment regimen; anticipated duration of therapy; vascular characteristics; and patient's age, comorbidities, history of infusion therapy, preference for VAD location, and ability and resources available to care for the device (Gorski et al., 2016b, p. S51).

Standard 27: Site Selection: Peripheral Venous Access via Short Peripheral Catheters

Traditional practice has been to initiate short peripheral catheter placement in the hand and move up the arm with subsequent cannulations. The latest evidence-based recommendations now state to use the venous site most likely to last the full duration of the infusion therapy, using the forearm to increase dwell time, decrease pain during dwell time, promote self-care, and prevent accidental removal and occlusions (Gorski et al., 2016b, p. S54). Particularly pertinent for patients in home care, it is important to collaborate with the patient regarding arm preference as use of sites in the nondominant arm is advantageous to an active home care patient.

Certain sites should be avoided due to inherent risks. For example, lower extremities are not recommended in adult patients due to risk of tissue damage, thrombophlebitis, and ulceration. However, for infants who are not walking, veins in the foot are appropriate sites. The ventral surface of the wrist, the cephalic vein at the wrist, and the antecubital sites are associated with a greater risk for nerve injury. Areas of flexion should be avoided due to risks of phlebitis, infiltration, and accidental dislodgment.

Standard 33 VAD Site Preparation and Placement

New recommendations in relation to placement attempts are provided in the Standards. It states that there should be no more than two attempts at short peripheral catheter placement per clinician and total attempts limited to no more than four. This is because multiple unsuccessful attempts cause patient pain, delay treatment, limit future vascular access, increased cost, and increased risk for complications (Gorski et al., 2016b, p. S64). Furthermore, success in cannulation drops with multiple attempts (Hagle & Mikell, 2014). Certainly this is a challenge for home care nurses as it is clearly a burden to send a second nurse out to a home for an additional attempt at placement. Competency again becomes a critical issue with peripheral catheter placement and only nurses who possess this skill and whose competency has been validated should place peripheral catheters. In fact, one of the Practice Criteria under Standard 4 Infusion Team states that VAD insertion and management is assigned only to those with infusion therapy education, training, and validated competency; this is also echoed in guidelines from the Centers for Disease Control and Prevention (Gorski et al., 2016b, p. S17; O'Grady et al., 2011). For patients with difficult vascular access, a careful assessment of the patient's infusion needs and collaboration with the healthcare team are required to discuss alternative and appropriate VAD options (Gorski et al., 2016b, p. S64).

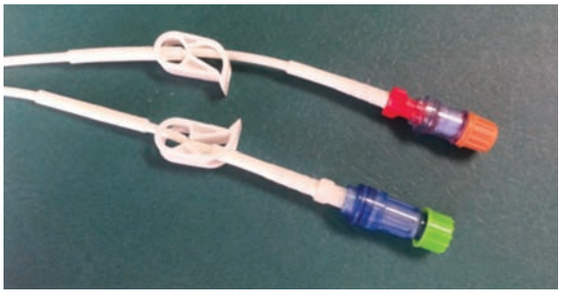

Figure 1. Examples of Disinfection Caps placed on the end of the needleless connector.
Photograph courtesy of Lisa Gorski.

Standard 34: Needleless Connectors

Needleless connectors (NC) are a known, potential site for intraluminal (i.e., via the internal catheter lumen) entry of microbes. Disinfection of the NC prior to entry, whether with a flush syringe, medication syringe, or IV tubing, is a basic standard of practice. A vigorous mechanical scrub using an acceptable disinfectant (e.g., 70% alcohol, povidone iodine, or >0.5% chlorhexidine in alcohol) must be done prior to each access (Gorski et al., 2016b, p. S68). The use of "passive disinfection caps" is addressed in the 2016 Standards; these are small plastic caps that contain alcohol solution, are attached to the NC, and remain in place in-between infusions; they are discarded once removed and replaced after each infusion (Figure 1). The use of passive disinfection caps is growing as evidence in acute care settings has demonstrated reduction in intraluminal contamination and central line-associated bloodstream infection (BSI). There is a need for studies to support the efficacy and impact of their use in the home setting.

When the disinfection cap is first removed, there is no need to disinfect the NC again. However, the question remains about subsequent entries—is there still risk of contamination? In the absence of any evidence, the Standards Committee made a "Committee Consensus" recommendation to *consider* use of a vigorous scrub with each subsequent entry into the NC (Gorski et al., 2016b, p. S69).

Standard 37: VAD Stabilization

This standard states that VADs are stabilized and secured to prevent VAD complications and unintentional loss of access (Gorski et al., 2016b, p. S72). The intent of VAD stabilization is to reduce movement at the insertion site. When the VAD is not stabilized, consequences can include unintentional dislodgment and other complications including BSI. The use of an engineered stabilization device, defined as a device or system placed subcutaneously or topically that is specifically designed and engineered to control movement at the catheter hub, is recommended. There are a number of specific products that meet this definition. Standard dressings (e.g., nonbordered), tape, or sutures are not considered effective alternatives. Sutures are associated with risk for needle-stick injury and can increase the risk of infection as sutures support the growth of biofilm. The use of roller bandages with or without elastic properties is specifically not recommended. They will not adequately secure the VAD, will obscure the site for assessment, and potentially impair circulation. In this standard, medical adhesive-related skin injury (MARSI) is addressed as a potential risk related to age, joint movement, and presence of edema. The risk of MARSI is associated with the use of adhesive-based engineered stabilization devices. Skin integrity should be assessed with each removal and replacement with the adhesive-based stabilization device. The use of barrier solutions will reduce the risk of MARSI (Gorski et al., 2016b, pp. S73–S74). Another important point addressed in this standard is that a VAD that is dislodged from its original position should never be readvanced back into the vein. Based on the amount of extruded catheter, it could be stabilized at the current location, may require reassessment of VAD tip location via an x-ray, or may require replacement (Gorski et al., 2016b, p. S74).

Standard 40: Flushing and Locking

The purpose of VAD flushing is to assess and maintain patency and prevent precipitation by clearing infused medication/solution from the catheter lumen. The Standard states that VADs are flushed and aspirated for a blood return prior to each infusion to assess catheter function and prevent complications (Gorski et al., 2016b, p. S77). A common question relates to whether patients should be instructed in aspiration of blood prior to each infusion. In the absence of any evidence, this author does not believe in instructing patients (or caregivers) to aspirate with each infusion due to excess manipulation and risk for occlusion. Rather, patients should be clearly instructed in the importance of catheter flushing prior to each infusion and should there be any difficulties (e.g., sluggishness or resistance to the flush), to call the home care agency for further assessment. With every home visit, the home care nurse should aspirate and assess for a blood return in accordance with the Standards. Absence of a blood return should result in an investigation and evaluation of potential causes, such as a thrombotic occlusion (Gorski et al., 2016b, p. S104). One caveat, for patients completely independent in long-term infusion therapy such as parenteral nutrition, teaching patients to check for a blood return is appropriate.

Locking refers to instillation of a solution to maintain patency in-between infusions and/or to reduce the risk of catheter-related BSI. Preferentially, single-dose systems (e.g., prefilled syringes) are used for flushing and locking. In terms of locking central VADs, including implanted ports, either preservative-free 0.9% sodium chloride or low concentration heparin (10 units per mL) may be used as there is insufficient evidence to recommend one solution over the other. Notably, there was one randomized controlled trial done in a home care setting (Lyons & Phalen, 2014). Although there was not a statistically significant difference between two heparin and one saline locking protocol, there was clinical importance in that 10 unit per mL heparin was associated with less PICC sluggishness, alteplase use, and delayed/missed medication doses.

Indications for antimicrobial locking solutions (e.g., antibiotics and antiseptics such as ethanol) are also provided in this standard. Such locking solutions may be used for therapeutic reasons, such as patients with a history of repeated BSI, or for prophylaxis.

Standard 41: VAD Assessment, Care, and Dressing Changes

Ongoing care and maintenance of the VAD is critical to reducing the risk of infection. Site care, including skin antisepsis and dressing changes, is performed every 5 to 7 days when using a transparent semipermeable membrane dressing, every 2 days for gauze dressings, and immediately if the

dressing integrity becomes damp, loosened, or visibly soiled, or if moisture, drainage, or blood is present under the dressing. Assess the catheter-skin junction site and surrounding area by visual inspection, palpate through the intact dressing, and ask the patient about any discomfort including pain, paresthesias, numbness, or tingling. The presence of redness, tenderness, swelling, and/or drainage may be indications of infection, phlebitis, infiltration, or catheter-associated venous thrombosis.

In a recent presentation about the INS Standards, a home care nurse asked if it was appropriate to extend the time of dressing changes beyond 7 days, for example, every 9 or 10 days. In the absence of any studies to support the safety of such practice, the answer is a simple no. Microbes can enter the bloodstream via the extraluminal route, in essence, bacteria residing on the skin reach the bloodstream by traveling along the outside of the catheter. Recognize that microbial growth does occur underneath the transparent dressing (citation) and that routine removal of the dressing for skin antisepsis and replacement with a sterile dressing is an intervention that is aimed at reducing skin colonization and thus the risk of a local site infection or a BSI.

Standard 47: Nerve Injuries

This is a new 2016 standard. Nerves and veins often lie close to each other in the extremities. There are certain sites associated with greater risk of nerve injury. Examples include the superficial radial nerve at the cephalic vein of the radial wrist, inner aspect of the wrist (median nerve), and at or above the antecubital fossa (median, anterior interosseous nerve) (Gorski et al., 2016b, p. S102). Should a patient report any paresthesia-type pain during placement or during dwell time, the VAD should be removed. Consequences of a nerve injury can be severe and include neuroma, compartment syndrome, and complex regional pain syndrome.

Standard 57: Parenteral Medication and Solution Administration

This standard provides important and detailed recommendations related to infusion administration. One of the key standard recommendations addresses the need for the clinician to review the prescribed infusate for indications, dosage, acceptable infusion routes/rate, compatibility, and adverse/side effects. Reviewing a drug reference resource and any drug literature supplied by the home infusion pharmacy is essential and if uncertain about any medication, consultation with the pharmacist is always appropriate. In the practice criteria, medication reconciliation, assessment of VAD patency before administration, and disinfection of NC are addressed. Any solutions and medications are prepared (i.e., spiking the container, priming the IV tubing) just prior to administration (Gorski et al., 2016b, p. S125–S126). Another question recently posed by a home care nurse was the acceptability of spiking and priming a solution in the afternoon for the patient to "hook up" later in the evening, presumably to avoid an evening home visit. This is not considered acceptable practice. The safe administration of IV push medications is also addressed including the need to administer at the recommended rate. A recent paper by the Institute for Safe Medication Practices (ISMP, 2015) is an excellent resource on IV push issues.

The use of roller bandages with or without elastic properties is specifically not recommended. They will not adequately secure the VAD, will obscure the site for assessment, and potentially impair circulation.

Conclusion

Approximately 30 years ago, I began my home care career and was responsible for the development of a home infusion therapy program. The INS Standards were the essential resource and reference in development of the original program and remain so today. They should be available to every home care organization that provides home infusion therapy. Home care nurses who provide home infusion therapy should be educated in the existence and intent of the Standards. Our home care patients deserve highly skilled nurses. Through providing a brief discussion of just a few of the standards in relation to home infusion therapy, the importance and relevance of this document to home care is apparent. The Standards are used as

a foundation for development of agency policies, procedures, and protocols. By providing evidence-based guidance in infusion therapy, our patients are ensured the best possible outcomes.

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