

A Look at 2021 Infusion Therapy Standards of Practice

The Infusion Therapy Standards of Practice provide evidence-based recommendations as published by the Infusion Nurses Society every 5 years. This article provides a brief overview of the development process and short summaries of selected standards with attention to highlighting the relevance to home care agencies and nurses. The Standards should be reviewed by any home care organization that provides home infusion therapy.

Every 5 years the Infusion Nurses Society (INS) publishes the *Infusion Therapy Standards of Practice (Standards)*, an evidence-based practice document with each revision widely anticipated. Even if you are not aware of the INS, the *Standards* are used to develop and support clinical procedures in published procedure manuals and are widely cited. The *Standards* are used globally with the 2016 Standards translated into Spanish, Portuguese, Chinese, and Turkish languages. Having served as the Committee Chairperson for the *Standards* since 2011, I have had many opportunities to deliver presentations about the *Standards* and interact with nurses and physicians in the United States as well as numerous Middle Eastern countries, Turkey, Kenya, South Africa, China, and Latin America. As patient advocates, the interest and desire to improve practice and patient outcomes are universal across our cultures. Although formal home care, including home infusion therapy, is available in some countries (e.g., United Kingdom, Australia, Canada), it is less developed or not present in many others, though interest in home infusion therapy is emerging.

The scope of infusion practice addressed in the 2021 *Standards* includes intravenous (IV) as well

as subcutaneous, intraosseous, and intraspinal access devices and infusions. The *Standards* are intended for use by clinicians in any setting where infusion therapy is administered, including acute care, outpatient/ambulatory care, long-term care, and of course, home healthcare. In the United States, home infusion therapy is a common practice.

Consider the advantages of home care during the COVID-19 pandemic. Avoiding the hospital environment to allow patients to self-isolate has increased the need to rapidly evaluate the home setting for delivering ongoing medical treatment. Home antimicrobial infusion is considered the safest option when compared with hospitals, outpatient facilities, and skilled nursing facilities (Mansour et al., 2020).

This article provides a brief 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 full table of contents for the *Standards* is found in Box 1. The *Infusion Therapy Standards of Practice* can be obtained from the Infusion Nurses Society at www.ins1.org.

Development Process

A committee of 11 nurses representing the United States, the United Kingdom, Canada, and Australia, with expertise in research, critical care, neonatal/pediatrics, outpatient, and home care, wrote the initial drafts over approximately 2 years. The committee met initially in person and then via virtual technology. Literature searches for each of the standards were performed using related key

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words and subject headings. Each committee member was assigned specific standards to draft, which were then reviewed and revised based on input from the entire committee. A final draft was created by the committee and reviewed by 120 peer reviewers including nurses, pharmacists, physicians, and an attorney. Given the focus on global practice, 30 reviewers were from outside the United States. The committee reviewed all comments and recommendations and made final revisions. The final document with nine sections includes 66 standards with more than 2,500 references cited to support recommendations. The large number of references speaks to the growing science and advancements in infusion and vascular access care. The reader is referred to the *Standards* for a detailed discussion of the methodology (Gorski et al., 2021).

Format of the Standards

Each standard consists of two components: Standards and Practice Recommendations. The Standards are declarative statements, an expectation by which quality of practice, service, or education can be judged (Gorski et al, 2021). The Standard statements are written to be applicable to infusion therapy across all practice settings and countries.

The Practice Recommendations provide specific evidence-based guidance in the implementation of the corresponding standard. Each Practice Recommendation is supported by evidence, is rated as reflecting the strength of the body of evidence, and all references to support the criteria are cited. The rating scale ranges from the highest ranking of “I” that represents a Practice Recommendation based upon a meta-analysis and other “research on research” (e.g., systematic review of randomized controlled trials) to the lowest level of “V” that includes evidence such as clinical articles, case reports, and quality improvement stud-

ies. There is also a level “A/P” which is evidence from anatomy, physiology, and pathophysiology. “Committee Consensus” was used in some cases when there was a lack of, or very low levels of, evidence, and when the committee decided that a recommendation was warranted.

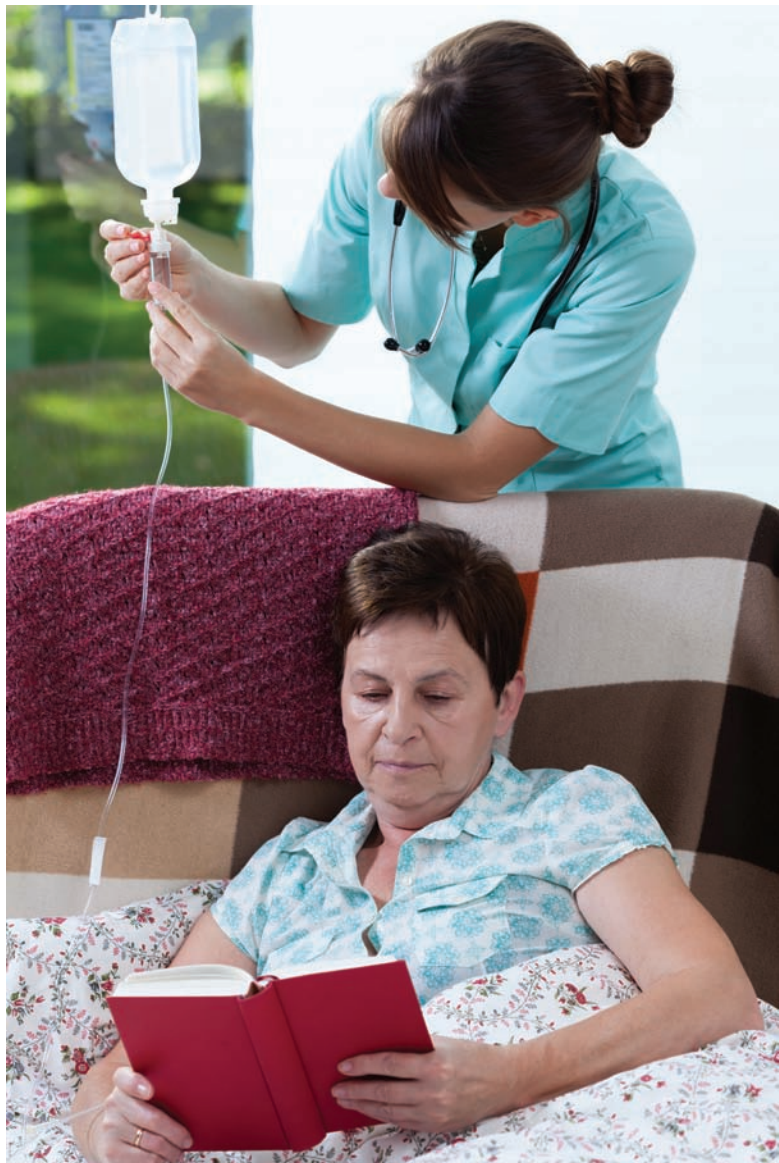
An Overview of Selected Standards

Section One: Infusion Therapy Practice

Standard 2: Special Patient Populations:

Neonatal, Pediatric, Pregnant, and Older Adults

For home care nurses who care for these patient populations, it is important to recognize physiologic and anatomical differences and address



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these needs in the plan of care including vascular access device (VAD) care and management and level of monitoring. Consider, for example, the prevalent older adult home care patient. Vein and skin fragility may make VAD insertion more challenging due to thickening of the inner/middle vein layers (tunica intima/media) and loss of thickness of the dermal skin layer. Physiologic changes associated with the aging process may result in

slower clearance of medications, and polypharmacy increases the potential for adverse events and drug interactions.

Standard 4: Organization of Infusion and Vascular Services

This standard, previously titled *Infusion Teams*, addresses the need for interdisciplinary collaboration and supports the specialty team approach.

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66. Therapeutic Phlebotomy

Appendix A. Infusion Teams/Vascular Access Teams in Acute Care Facilities

Appendix B. Aseptic Non Touch Technique (ANTT®) Clinical Practice Framework

Appendix C. CVAD-Associated Skin Impairment (CASI) Algorithm

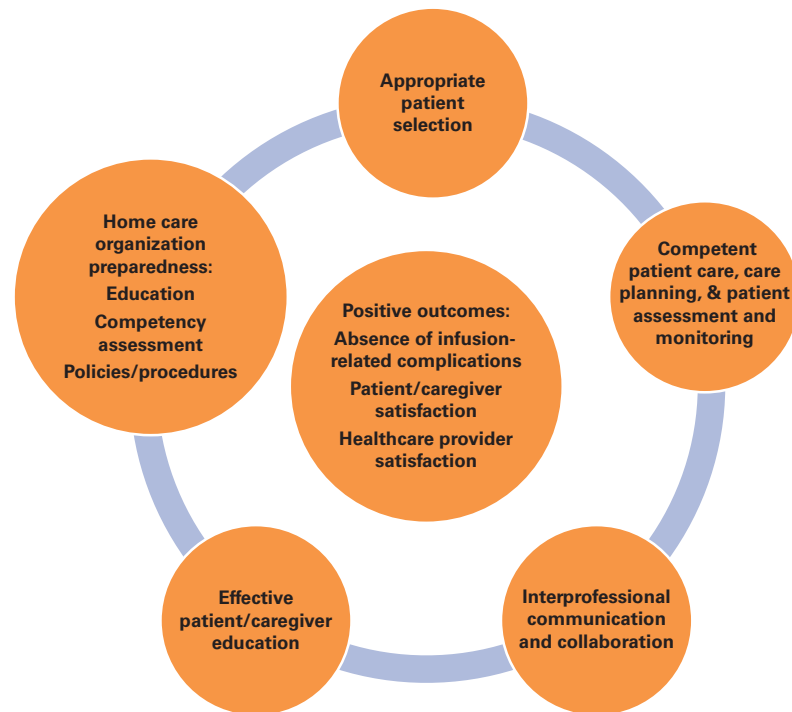
Specialty teams in the acute care setting are associated with improved outcomes such as fewer peripheral IV catheter (PIVC) attempts and lower rates of complications. Although some home care organizations and pharmacies specialize in home infusion, there are also many home healthcare agencies that provide home infusion as a smaller component of their overall program; the concept of an infusion team is not common among such home care agencies. Although specialized infusion teams provide logistical challenges especially when infusion is a low percentage of home care cases, home care organizations must give consideration to clinical specialties and competency as addressed below.

Standard 5: Competency and Competency Assessment

This Standard should be reviewed by every home care provider. It states that clinicians are competent in safe delivery of infusion therapy and VAD insertion and management (Gorski et al., 2021). In accordance with this author's Model for Safe Home Infusion Therapy, home care agencies should not accept patients for home infusion therapy unless they are prepared by having a sound program that includes documented infusion-related competencies (Gorski, 2017; Gorski, 2020) (Box 2). In accordance with the *INS Standards*, competency should be assessed and validated before providing patient care (e.g., upon hire/during the onboarding process) and on a continual basis.

In a recent newsletter article, the lack of competency by a home care nurse who reportedly re-attempted port access with the same needle up to 10 times causing the patient considerable pain and anxiety resulted in a referral to a certified home care nurse (Samarpan, 2020). Competency to perform infusion therapy procedures should not be based on a nurse's verbal assertion of skill, rather it is assessed using a variety of techniques. For psychomotor skills, competency is assessed

Figure 1. The Gorski (Gorski, 2017; Gorski, 2020) Model for Safe Home Infusion Therapy predicts positive patient outcomes, including complication prevention and patient and healthcare provider satisfaction, when careful attention is given to five key areas.



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in four consecutive phases: knowledge acquisition, observation, simulation (e.g., port needle insertion on a chest model), and clinical performance (Gorski et al., 2021). Other methods of competency validation include written tests to assess knowledge, and clinical scenarios that may be used to assess critical thinking skills. It is also critically important to develop qualifications for the competency "assessor" most 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. Also important is that the preceptors not only validate competent performance of the skill but also ensure that the nurse is knowledgeable and understands the rationale for any given step in the observed procedure.

Standard 6: Quality Improvement and Standard 7: Evidence Based Practice & Research

The Quality Improvement Standard speaks to the need for surveillance, analysis, and reporting of

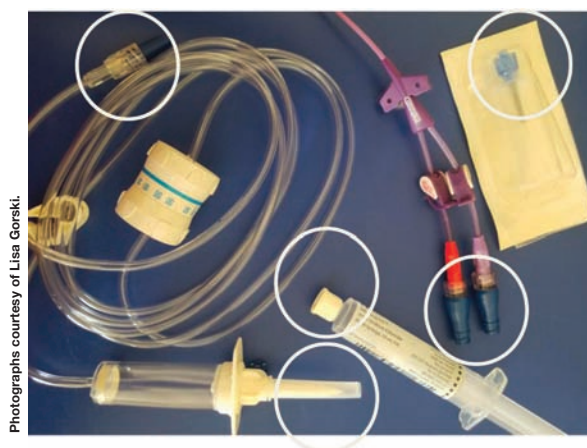
quality indicators and adverse events such as bloodstream infections or occlusions associated with VADs and adverse medication reactions. It is important to establish a structure that encourages reporting. The Evidence-Based Practice and Research Standard addresses the importance of incorporating evidence into practice and involving clinicians in evaluating research findings. It also states that organizational policies and procedures are based on current research findings. Home care organizations are encouraged to compare current procedures against the 2021 *Standards* to identify areas for revision and practice improvement.

Standard 8: Patient Education

Effective patient and caregiver education is one of the five key areas of practice considered essential to positive patient outcomes according to the Gorski Model (Figure 1) and the *Standards*. The home care nurse's skill in patient education is equally important to the skill and competency in performing infusion procedures and impacts patient safety and adherence with infusion administration. In addition to teaching infusion administration, it is also imperative to address how patients can safely live and perform activities of daily living with the VAD to avoid events such as inadvertent VAD removal or exposure to water during bathing for example. Learning is evaluated by demonstration and return demonstrations (i.e., "show me") for psychomotor skills. Strategies such as "teach-back" are appropriate for evaluation of cognitive knowledge such as

Figure 2. Key-Parts for Infusion Administration

The key parts are protected in the photograph; upon removal of the protective cap and disinfection of the needleless connector, the Key-Part cannot be touched except by another Key-Part.



Photographs courtesy of Lisa Gorski.

naming sign/symptoms to promptly report to the home care nurse or pharmacy.

Section Three: Infection Prevention and Control **Standard 18: Aseptic Non Touch Technique**

Recognizing the lack of consistent terminology, education and competency assessment for aseptic technique, a major change in the 2021 *Standards* is the addition of a new standard entitled *Aseptic Non Touch Technique® (ANTT)* and the incorporation of the ANTT concepts throughout the *Standards*. This concept is described in an appendix to the *Standards*. Although a full discussion of this standard is beyond the scope of this article, an introduction to the concept and terminology is presented.

ANTT is a specific and comprehensively defined type of aseptic technique based on an original concept of Key-Part and Key-Site Protection and achieved by integrating Standard Precautions with appropriate aseptic field management, non-touch technique, and sterile supplies (Rowley & Clare, 2019). It is designed for all invasive clinical procedures and management of invasive medical devices. In the context of infusion therapy, this includes VAD placement and management and infusion administration. It is based upon an understanding of:

- **Key-Sites:** the entrance site of the VAD
- **Key-Parts:** those parts of the infusion system that must be protected and cannot be touched (exception: unless sterile gloves are worn) and include items such as the syringe tip, IV tubing spike and male luer end of the tubing, and disinfect needleless connector (Figure 2).

Two approaches to ANTT are described. **Standard-ANTT** requires use of a General Aseptic Field, such as a single use or disinfected surface for placement of all needed supplies to provide a controlled workspace and promote asepsis (Figure 3). Standard-ANTT would be applied to basic infusion administration such as VAD flushing and medication administration. Principles of ANTT can and should be taught to patients and caregivers. When used to teach parents of children requiring parenteral nutrition, a low incidence of catheter-related bloodstream infection was reported (Mutalib et al., 2015).

Surgical ANTT requires a **Critical Aseptic Field** which is a sterile drape or barrier and would be used with more complex procedures such as

central VAD insertion, site care/dressing changes, and implanted vascular access port access. Referring to the earlier example of lack of competency with reattempted port access, the nurse failed to protect both the Key-Site (port site) and Key-Parts due to reuse of a single-use sterile item (port needle).

Section Four: Infusion Equipment

Standard 22: Vascular Visualization

Vascular visualization equipment is included in this section. The research supporting the efficacy for vascular visualization techniques such as near infrared (nIR) light technology and ultrasound continues to grow. Especially for patients with difficult venous access, such technology can contribute to success in peripheral catheter placement. In the home setting, nIR technology is used by some home care organizations to aid in identification of peripheral venous sites providing the ability to visualize veins under the skin surface, identify valves, and increase first time success in PIVC placement.

Section Five: Vascular Access Device Selection and Placement

Standard 26: VAD Planning

The VAD Planning Standard is a critically important and fundamental standard because infusion therapy begins with placement of a VAD. The standard states that “the least invasive VAD with the smallest outer diameter and fewest number of lumens needed for the prescribed therapy is selected” (Gorski et al., 2021). Factors considered in choosing a VAD 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. Frequently patients are referred and admitted to home care with a VAD already in place. Common VADs among home care patients include peripherally inserted central catheters (PICCs), implanted vascular access ports, and midline catheters. The Standards of Practice Committee provided new definitions for categories of PIVCs in the 2021 *Standards*.

Short PIVCs are the common over-the-needle catheter inserted into superficial veins. Short PIVCs are now differentiated from “long PIVCs” which are inserted into superficial or deep peripheral veins in the forearm area; these are not common in home

Figure 3. General Aseptic Field used to set up supplies needed for home IV administration



Photographs courtesy of Lisa Gorski.

care, rather used more often in acute care settings. Midline catheters are inserted above the antecubital fossa with the terminal tip located at the level of the axilla in children and adults. Advantages to midline catheters include longer dwell time compared with a short PIVC. The catheter tip lies in a large diameter vein allowing better hemodilution of the infusate, most often antibiotics in the home setting. There are many factors to consider when placing any VAD. Practice Recommendations relative to midline catheters include the following:

- Do not use midline catheters for continuous vesicant infusions, parenteral nutrition, or infusates with extremes of pH or osmolarity.
- Evaluate the risks versus the benefits of intermittently infused vesicants for more than 6 days and increase the frequency of catheter surveillance due to the increased risk for phlebitis and extravasation. It is important to recognize that vancomycin, a vesicant, is sometimes intermittently infused via a midline catheter at home. Careful evaluation of appropriateness and anticipated duration of therapy must occur.
- 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 for 2 or less weeks (Gorski et al., 2021).

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 placed in the same area and via the same veins. I continue

Box 2. Model for Safe Home Infusion Therapy

The Gorski (Gorski, 2017; Gorski, 2020) Model for Safe Home Infusion Therapy predicts positive patient outcomes, including complication prevention and patient and healthcare provider satisfaction, when careful attention is given to five key areas:

1. Home care organization preparedness (e.g., nursing education, competency)
2. Appropriate patient selection
3. Competent patient care (e.g., care planning, assessment, monitoring)
4. Effective patient education
5. Interprofessional communication and collaboration

to hear of 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 in place. Make sure that the home care agency obtains a copy of the VAD placement procedure to verify catheter tip placement.

Standard 27: Site Selection

The Site Selection Standard continues to recommend selection of 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., 2021). Veins in the dorsal hand may be selected for short-term infusions; for example, intermittent biologics given over a few hours (e.g., infliximab). Very pertinent for patients in home care is the importance of collaborating with the patient regarding arm preference as use of sites in the nondominant arm is advantageous for an active home care patient.

Certain sites should be avoided due to known 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/leg are appropriate sites. The ventral surface of the wrist, the cephalic vein at the radial wrist, and the antecubital fossa are associated with a greater risk for nerve injury. Furthermore, areas of flexion should be avoided due to risks of phlebitis, infiltration, and accidental dislodgment.

Standard 28: Implanted Vascular Access Ports

Within the Implanted Vascular Access Port Standard, adherence to ANTT is included as a Practice Recommendation. Questions and concerns from

nurses about appropriate port access are common. Selected Practice Recommendations include:

- In preparation for port access, assess the port site for swelling, pain, erythema, and/or drainage; for presence of collateral veins on the chest wall or other signs indicative of potential catheter-associated deep vein thrombosis.
- Adhere to either Standard-ANTT or Surgical-ANTT based upon the ability to avoid touching Key-Parts and Key-Sites. I reiterate the need for competency assessment with port access and recommend use of a central line kit that includes a sterile drape, mask, sterile gloves, as well as standard skin antisepsis supplies and dressings (Surgical-ANTT). Often the nurse may desire to repalpate the prepped site just prior to needle insertion and sterile gloves are required.
- Recommendations vary regarding the frequency of the solution used to flush and lock the port that is not accessed for current use. At least 10 mL of 0.9% sodium chloride (i.e., normal saline) should be used for flushing before and after each infusion. Some studies suggest saline alone may be as effective as heparin. If heparin is used, 5 mL (10 units or 100 units/mL) is recommended every 4–12 weeks. In adult oncology patients, it was found safe to extend maintenance flushing and locking to every 3 months with 10 mL saline followed by 3 or 5 mL heparin (100 units/mL).
- For long-term infusion patients, consider an annual chest x-ray to assess port position and integrity (Diaz et al., 2017; Gorski et al., 2021; Odabas et al., 2014; Solinas et al., 2017).

Standard 32: Pain Management for

Venipuncture and Vascular Access Procedures

Improving the patient experience associated with procedures such as PIVC insertion, phlebotomy, and port needle insertion should be a universal goal, yet pain management strategies are underused for VAD-related procedures. Reflecting again on competency, minimizing the number of needlesticks is achieved with highly competent nurses and is one factor in reducing discomfort. Practice Recommendations include a variety of strategies, from behavioral interventions (e.g., distraction, relaxation) to local anesthetics (e.g., vapocoolant spray, topical transdermal agents, jet injection of pressure accelerated lidocaine) (Gorski et al., 2021). The developmental level of children is an

important consideration. There are several citations within this standard that recommend the use of virtual reality with children, using a computer-simulated environment accessed through a head-mounted device. In the home setting, creative use of technology to distract the child is often quite possible even without sophisticated simulation. Distraction methods are found to reduce anxiety as well as perception of pain in school-aged children. Patients and families should be engaged to determine their preferences and needs for pain management. And as nurses, we must understand pain management options and not underestimate the patient's pain.

Standard 33: VAD Site Preparation and Placement

Multiple unsuccessful PIVC insertion attempts cause patient pain, delay treatment, limit future vascular access, increase cost, and increase risk for complications. Based upon Committee Consensus, the Practice Recommendations state that after two unsuccessful attempts, escalate to a clinician with a higher skill level and/or consider alternative routes of medication administration (Gorski et al., 2021). This is a challenge for home care organizations as it is clearly a burden to send a second nurse to a home for an additional attempt at placement. Competency again comes into place with peripheral catheter placement and only nurses who possess this skill and whose competency has been validated should place peripheral catheters. The use of vascular visualization technology such as nIR light technology should be considered by home care organizations as a tool for peripheral access. For patients with difficult IV access, referral to an infusion/vascular specialist should be considered.

Section Six: Vascular Access Device Management

Standard 36: Needleless Connectors

Although needleless connectors (NC) have been used for years, it is important to remember that they are a known, potential site for intraluminal entry of microbes. Disinfection of the NC prior to entry, whether with a flush syringe, medication syringe, or IV tubing, is a fundamental practice. The connection surface and sides of the NC attached to any VAD are disinfected using active or passive disinfection. Active disinfection is achieved by a vigorous mechanical scrub using a flat swab pad containing 70% isopropyl alcohol or



A committee of 11 nurses representing the United States, the United Kingdom, Canada, and Australia, with expertise in research, critical care, neonatal/pediatrics, outpatient, and home care wrote the initial drafts over approximately 2 years.

alcohol-based chlorhexidine suitable for use with medical devices for at least 5–15 seconds; studies show no difference in effectiveness of scrub time between 5 and 15 seconds with 70% isopropyl alcohol and alcohol-based chlorhexidine gluconate (Gorski et al., 2021). In accordance with ANTT, only a sterile syringe tip or sterile male luer end of the IV administration set (i.e., Key-Parts) is attached to the disinfected NC.

Passive disinfection caps, small plastic caps that contain alcohol solution, are attached to the NC, remain in place in between infusions, are discarded once removed, and then replaced after each infusion. When the disinfection cap is removed and has been in place for the time recommended by the manufacturer's directions, there is no need to disinfect the NC prior to the first access (e.g., saline flush). Based upon a Committee Consensus, the Practice Recommendations state the following:

“Although the need for a full disinfection process before subsequent entries is unknown, removal of organic and inorganic debris (e.g., blood-tinged fluid, dried medication, clothing lint, inadvertent touch contamination) with a disinfection pad between each entry may provide additional protection for the intraluminal fluid pathway” (Gorski et al., 2021, p. S105).

Standard 38: VAD Securement

Vascular access device securement is required to limit movement of the catheter in and out of the insertion site (pistoning) thus preventing complications associated with movement and decreasing the risk for accidental dislodgment. Options for catheter securement include adhesive securement devices, integrated securement devices (securement function built into the dressing), and tissue adhesives. The use of tissue adhesives, a medical grade glue, is increasingly being evaluated to secure PIVCs and PICCs. Further research is ongoing to confirm the safety and efficacy of the various securement methods in all patient populations. Sutures are not recommended as they are associated with needlestick injury, support the growth of biofilm, and increase the risk for catheter-associated bloodstream infection. Another option used for PICC, tunneled cuffed, and nontunneled catheter securement is the subcutaneous anchor securement system (SASS). This device anchors the CVAD in place via feet/posts that are placed underneath the skin, securing the catheter right at the point of insertion. Removal and replacement of the securement device is done at regular intervals according to the manufacturer's recommendations (e.g., with regular site care and dressing changes such as with adhesive securement or integrated securement) or in conjunction with replacement/removal of the CVAD (e.g., SASS) (Gorski et al., 2021).

Section Seven: Vascular Access Device Complications

Standard 55: Catheter-Associated Skin Injury

Notably, and very pertinent for home care nurses, a new Standard "Catheter-Associated Skin Injury" was added. This standard provides guidance in preventing and managing patients who have reactions at/around the VAD insertion site. Patients who have VADs in place for long periods of time may develop skin irritations or sensitivities to antiseptics, dressings, and adhesive products. Practice Recommendations include guidance in identifying the type and severity of skin damage, the potential source of the skin issue, and prevention, such as ensuring that the antiseptic solution is completely dry prior to dressing placement, and other strategies to manage skin health (e.g., use of skin barrier film). An Appendix with an evidence-based algorithm to guide management of skin impairment is included in the *Standards*.

Section Nine: Infusion Therapies

Standard 59: Infusion Medication and Solution Administration

This standard provides important and detailed recommendations related to infusion administration. New to this standard and specific to home and alternate site infusion is guidance on first dose administration. First doses of medications with an appreciable risk of a severe allergic or anaphylactic reactions or other unknown response may be administered in nonacute care settings (e.g., home) **only** if conditions for safe administration are evaluated and verified (Gorski et al., 2021, p. S180). These include an evaluation of patient history (no allergy to medications in same drug class), condition (e.g., alert, oriented, able to respond), geographic location (e.g., access to emergency services), and administration by a competent nurse who is able to respond to immediate reactions with medications (including epinephrine) that are ordered and available in the home. It is important to remember that first exposures may not necessarily result in a reaction and that the risk exists with subsequent exposures. Patient education regarding what to be alert to, what to do, and how to report are imperative. Home care organizations that do administer first doses must have policies, procedures, and education in place.

Another issue pertinent to home care is delivering IV medications via a minibag and a primary administration set (i.e., gravity infusion) often used with IV antibiotics. There can be a significant potential loss of medication in the administration set, especially with small volume minibags (e.g., 50 mL). In the context of antimicrobial stewardship, it is important that patients receive their antibiotics with minimal loss of drug. An additional primary solution to clear the IV tubing is a consideration (p. S182). For example, 25 mL of saline solution after the antibiotic container is empty.

The administration of IV push medications is also addressed in this section. It is important to administer any IV push medications at the recommended rate. This should be listed on the syringe label. If not, contact the pharmacy for guidance. Also, the subsequent saline flush should be administered at the same rate to avoid any inadvertent bolus of drug into the bloodstream.

Conclusion

In this article, I have provided an overview of selected standards. Because there is much more I

have not addressed, I encourage home care organizations to obtain a copy of the *Standards*, to carefully examine how you provide infusion education, both upon hire and on an ongoing basis, assess nursing competency, and ensure that your policies and procedures are in place and up-to-date, and are accessible to nurses. In 1985, this author began her home care career and began the development of a home infusion therapy program. The *Standards* were as essential in ensuring safe practice then as they are today. They are a critical reference that should be available to every home care agency that provides home infusion therapy. Through a discussion of selected standards in relation to home infusion therapy, the importance and relevance of this document to home care has been emphasized. ■

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The author has received speaking honoraria from BD Medical, 3M, Genentech, is on the Vascular Medical Advisory Board for Teleflex, and holds stock in ivWatch. LPD's peer review process has determined that there are no conflicts of interest.

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