Infusion Therapy

STANDARDS OF PRACTICE

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The *Journal of Infusion Nursing*, the official publication of the Infusion Nurses Society (INS), seeks to promote excellence in infusion nursing by presenting new research, clinical reviews, case studies, and professional development information relevant to the practice of infusion therapy. Articles selected for publication represent the broad scope of the infusion specialty and draw on the expertise of all health care providers who participate in the delivery of infusion.

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The *Journal of Infusion Nursing* is a member benefit of the Infusion Nurses Society. INS is a professional association dedicated to enhancing infusion practices that will improve patient outcomes. Through its many member benefits, INS offers access to the latest infusion research, technology, and education. For more information about the benefits of INS membership, visit www.ins1.org.

Journal of
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The Art and Science of Infusion Nursing

FOREWORD

These are exciting times in the field of infusion practice. Never before has there been as much interest, technology, evidence, or cross-disciplinary collaboration in the field as there is today. Whether it's research that informs the safety of a particular vascular access device, guidance for when a device may be appropriate for use, or in-depth reviews of how best to prevent complications—the knowledge, data, and wisdom in our specialty are brimming. For infusion and vascular clinicians all over the world, there has never been a better moment to be on the front lines of patient care.

Yet, this progress does not come without a price, for with these times also comes great responsibility. For example, our patients have never been more complex in terms of their vascular access needs. Unlike times past, a dizzying array of devices, designs, and technology to meet nuanced needs (eg, power injection-capable midline catheters) or fill key niches (ultrasound-guided devices for patients with difficult access) are now available. The very health care system within which we all operate has transformed—improving in many ways, but also becoming more fractured and misaligned in others. As patients transition through the labyrinth of outpatient, hospital, and post-acute care settings, the imperative to do what's right in their vascular access voyage has perhaps never been more urgent than it is today.

In this whirlwind of change, clinicians are expected to not only master the insertion, care, and management of vascular access devices but to also inform clinical decisions regarding device choice and venous access route. Although such opportunities present a unique step forward for the field, they also introduce many new and unexpected challenges. For example, what should one do when limited evidence exists to guide clinical decision making? When available data do not support current practice, how should one approach the patient or provider so as to prevent harm? How may one learn, master, and implement the evidence to enact change in her or his facility? And relatedly, what practices are associated with improved outcomes, and which are relics of times past? In the endless quest to improve the care and quality of infusion practice, knowing what we don't know has become more important than ever before.

Highlighting how fortunate we have been to have the *Infusion Therapy Standards of Practice* serve as the bedrock of our field for so many years is not hyperbole. Rather, the *Standards* represents the best of our specialty: a tome within which excellence, expectations, and enigmas are not only defined but also primed and supported by available data and strength of the evidence. 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. As a reviewer and contributor to this 2016 update, I am pleased to say the exulted tradition of the *Standards* continues. With new and improved sections on special patient populations, the definition and role of infusion teams, vascular visualization technologies, and catheter tip location, the 2016 *Standards* incorporates and assimilates the many advances in our field within a single comprehensive document. Not only have new criteria for practice been added but substantial improvements to the key domains of infection prevention, phlebotomy, and device complications have been included.

These significant enhancements reflect the growth in our field and the ever-changing expectations of the public in infusion care. The new *Standards* is thus not merely recommended, but *required* reading for any clinician interested in infusion or vascular therapy.

As a physician researcher dedicated to improving the safety of patients who require vascular access and infusion-based therapies, the *Standards* has informed the work that I do, the questions I ask, and the clinical care I provide. Quite simply put, there is nothing else like it. This edition 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
Ann Arbor VA Medical Center and
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October 2015

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Clinical Nurse Specialist, Wheaton Franciscan Home Health & Hospice, Milwaukee, WI
Ms. Gorski is a former INS president (2007-2008) who served on the INS Standards of Practice Committee in 2006 and chaired the 2011 committee. She is the author of more than 50 journal articles and has authored several books on the topic of infusion therapy. She is a frequent speaker, both nationally and internationally, on standards development, home health care, and infusion therapy.

Lynn Hadaway, MEd, RN-BC, CRNI®
President, Lynn Hadaway Associates, Inc, Atlanta, GA
Ms. Hadaway has more than 40 years of experience as an infusion nurse and is internationally known as a consultant and educator. She is currently serving as the chair for the Infusion Nurses Certification Corporation (INCC) Board of Directors and for the Infusion Team Task Force. She served as a committee member for the revision of the 2006 and 2011 *Standards of Practice*. She has authored more than 75 journal articles and several textbook chapters on infusion therapy. Ms. Hadaway holds board certifications in nursing professional development and infusion nursing.

Mary E. Hagle, PhD, RN-BC, FAAN
Nurse Scientist, Clement J. Zablocki VA Medical Center and University of Wisconsin-Milwaukee College of Nursing, Milwaukee, WI
Dr. Hagle joined the Standards of Practice Committee for the 2011 edition and returned for this updated version, refining the "Strength of the Body of Evidence" document after 5 years' use and serving as a reference point for the quality of evidence. With 15 years' experience as a researcher and more than 20 years as a clinical nurse specialist in academic and community medical centers, she has worked with patients and nurses in acute, ambulatory, and long-term care settings. Focusing on vascular access device management and prevention of adverse events, Dr. Hagle is a mentor for research and quality improvement teams, a leader for translating evidence into practice, and a clinical investigator.

Mary McGoldrick, MS, RN, CRNI®
Home Care and Hospice Consultant, Home Health Systems, Inc, Saint Simons Island, GA
Ms. McGoldrick began her home care career more than 35 years ago, and since that time she has served in a myriad of home care clinical, management, and executive-level positions, including 12 years as a home care and hospice surveyor for The Joint Commission (TJC). She is a frequent speaker on the topic of infection prevention in home care and hospice and has authored several books, articles, chapters, and manuals.

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STANDARDS OF PRACTICE COMMITTEE

CONFLICT OF INTEREST DISCLOSURES

The authors have completed and submitted a form for disclosure of potential conflicts of interest. **Lisa Gorski** reported relationships with ivWatch, BD, 3M, and Covidien; **Lynn Hadaway** reported relationships with 3M, BD, Terumo, Excelsior, Ivera, B Braun, Baxter, Covidien, DEKA, Discrub, SplashCap, Velano Vascular, VATA, West Pharmaceuticals, Elcam, Christie Medical, and Bard Access; **Mary Hagle, Mary McGoldrick,** and **Marsha Orr** reported no relationships; and **Darcy Doellman** reported relationships with Arrow International, Hospira, and Genentech.

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PREFACE

Recognized as the premier organization for the specialty practice of infusion nursing, the Infusion Nurses Society (INS) understands the significance the *Infusion Therapy Standards of Practice (*the *Standards)* holds in relation to the delivery of safe patient care. Developing and disseminating *Standards* is one of the pillars of INS' mission. Infusion therapy is administered to all patient populations in all practice settings, all the more reason to ensure the *Standards* are applied to one's clinical practice. It provides a framework to guide safe practice to ensure the best patient outcomes. There is an expectation that all clinicians are competent in their practice.

With more published research, advances in science, and innovation in technology, it's imperative that the *Standards* is relevant to the clinician's practice. Therefore, INS is committed to revising the document every 5 years. This seventh edition cites 350 more references than the sixth edition of the *Standards* (2011), a testament to the advancing science of infusion therapy. The rankings of the strength of the body of evidence have also shifted in this edition. In 2011, there were 3.8% of Level I rankings, the highest rating. In this revision, that ranking has grown to 5.8%, evidence that there is more robust research with consistent findings in the literature to support the practice. In contrast, the percentage of Level V rankings, the lowest rating, was 67% in 2011 and has decreased to 46% in this document. With more published data and research adding to the science of the practice, the distribution of rankings has changed based on the nature and robustness of the research. As we've seen over time, more strong evidence has provided clinicians with information and data that can justify existing practice or lead to a change in practice.

A major change in this edition of the *Standards* is its title. Infusion therapy does not "belong" to one group of clinicians, but it is the responsibility of any clinician who is involved in the practice. Recognizing infusion care goes beyond nursing, the title has been changed to the *Infusion Therapy Standards of Practice*. This change aligns with the interprofessional approach that is being implemented in health care today.

In this edition, new standards have been added, while other sections have been expanded to offer more guidance to clinicians. The format remains unchanged with practice criteria and relevant references listed after each set of standards.

INS' focus has never changed. We still keep in mind that our patients are the reason we do what we do. We want to ensure we're providing the safe, quality infusion care that our patients deserve. As INS continues to "set the standards for infusion care," the *Infusion Therapy Standards of Practice* is an invaluable guide for *all* clinicians who are responsible for their patients' infusion care.

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A MESSAGE FROM BD MEDICAL

We at BD feel honored to support the *Infusion Therapy Standards of Practice* revision for the fifth time since 1998, as part of our commitment to helping more efficiently deliver health care and improve patient outcomes. With a long history of providing global education and training on best practices, we award grants for education and research to promote innovative solutions in infusion therapy and across the care continuum.

We applaud the Infusion Nurses Society (INS) for striving to keep the *Standards of Practice* current, relevant, and evidence based, helping millions of clinicians provide quality infusion therapy to their patients. We look forward to working with INS in the future while helping improve infusion therapy around the world.

Alicia Mares, BSN, RN, CRNI®
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BD Medical

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Vice President, Catheter Solutions
BD Medical

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ACKNOWLEDGMENTS

INS recognizes the significance the *Infusion Therapy Standards of Practice* has to clinical practice and to all clinicians involved in the delivery of safe infusion care. Without the following dedicated individuals and their passion for quality patient care, the seventh edition of the *Standards* would not have been possible.

First, I want to recognize and thank the Standards of Practice Committee: Lisa Gorski, chair; Lynn Hadaway; Mary Hagle; Mary McGoldrick; Marsha Orr; and Darcy Doellman. They spent countless hours researching and critically analyzing the evidence, and writing, reviewing, and revising all the *Standards*. Not only is the depth of their expertise in clinical practice, research, and infusion-related knowledge unsurpassed, but their commitment to this important work is also exceptional.

Thanks go to the reviewers of the *Standards*. From INS members and volunteer leaders, to physicians, pharmacists, legal experts, health care clinicians, and industry partners, their thoughtful reviews and feedback contributed to the global perspective and interprofessional approach of the document.

I want to thank the INS Board of Directors for supporting the efforts of the Standards of Practice Committee during the revision process. I am grateful to the INS staff for the assistance they offered in ensuring that the publication was completed.

I also want to recognize BD Medical for their continuous support over the years of the *Standards of Practice* revisions. INS thanks them for the educational grant that helped fund this project.

Lastly, I want to thank our INS members. It is your passion and commitment to providing quality patient care that motivates us to continue to support the infusion specialty practice.

Mary Alexander, MA, RN, CRNI®, CAE, FAAN
Chief Executive Officer, INS

METHODOLOGY FOR DEVELOPING THE STANDARDS OF PRACTICE

Role of the Standards of Practice Committee

The Standards of Practice Committee brought together a group of professional nurses with a wealth of clinical knowledge and expertise in all the domains of infusion therapy. They initially met to review and agree on the evidence rating scale and to discuss methods and sources of searching for evidence. They also agreed on how to evaluate types of evidence. Throughout the *Standards* review and revision process, the committee met regularly by phone, reviewed each standard in detail, and came to consensus on the final strength of the body of evidence rating for the final draft of the *Infusion Therapy Standards of Practice*. This draft then was sent to over 90 interdisciplinary reviewers who are experts in the field, comprising all aspects of infusion therapy. Sixty reviewers provided in excess of 790 comments, suggestions, references, and questions. The committee addressed each comment and made revisions to the standards, seeking additional evidence as needed. Each standard had a final review by the committee for agreement on the content, evidence, recommendation, and rating.

The standards are written for clinicians of multiple disciplines with various educational backgrounds, training, certification, and licensing, including licensed independent practitioners, because infusion therapy may be provided by any one of these individuals. The premise is that patients deserve infusion therapy based on the best available evidence, irrespective of the discipline of the clinician who provides that therapy while operating within her or his scope of practice.

Searching for Best Evidence

A literature search was conducted for each of the standards of practice using key words and subject headings related to the standard. Searches were limited to English-language, peer-reviewed journals published between 2009 and July 2015. Databases included, but were not limited to, Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, PubMed, and Web of Science. The references of retrieved articles were reviewed for relevant literature.

Additional sources of evidence included, but were not limited to, the Web sites of professional organizations, manufacturers, pharmaceutical organizations, and the United States Pharmacopeia (USP). US sites included the US Department of Health and Human Services for national centers, such as the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and the US Food and Drug Administration (FDA); and the US Department of Labor (eg, Occupational Safety and Health Administration [OSHA]). Classic papers were included as needed. On occasion, textbooks served as sources of evidence when clinical research and scholarship are widely accepted, such as for anatomy and physiology. Because standards of practice are written for all health care settings and all populations, evidence was included for each of these areas as available.

Evaluating Evidence

Each item of evidence is evaluated from many perspectives, and the highest, most robust evidence relating to the standards of practice is used. Research evidence is preferred over nonresearch evidence. For research evidence, the study design is the initial means for ranking. Other aspects of evaluation of quality include sufficient sample size based on a power analysis, appropriate statistical analysis, examination of the negative cases, and consideration of threats to internal and external validity.

Research on research, such as meta-analyses and systematic reviews, is the highest level of evidence. Only specific study designs are acceptable for a meta-analysis, and with its statistical analysis, this is the most robust type of evidence. Single studies with strong research designs, such as randomized controlled trials (RCTs), form the basis for research on research or a strong body of evidence when there are several RCTs with similar findings. Other research designs are needed as well for a developing area of science and often before an RCT can be conducted. A necessary and foundational study for learning about a question or a population is the descriptive research project, but because of its lack of research controls, it is ranked at a low level of evidence for clinical practice.

