The Art and Science of Infusion Nursing

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# Accepted but Unacceptable: Peripheral IV Catheter Failure

#### ABSTRACT

Peripheral intravenous (IV) catheter insertion, the most common invasive hospital procedure performed worldwide, is associated with a variety of complications and an unacceptably high overall failure rate of 35% to 50% in even the best of hands. Catheter failure is costly to patients, caregivers, and the health care system. Although advances have been made, analysis of the mechanisms underlying the persistent high rate of peripheral IV failure reveals opportunities for improvement.

**Key words:** bloodstream infection, dislodgment, infiltration, occlusion, peripheral intravenous catheter failure, phlebitis

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ntravenous (IV) catheter therapy has been used for more than 350 years, and it has played a central role in patient care since the first plastic IV catheters were introduced more than 70 years ago by Zimmermann, Meyers, and Massa.<sup>1-6</sup> Necessary for the direct administration of fluids and medications into the bloodstream, IV catheter placement remains the most common invasive hospital procedure performed worldwide. More than 300 million peripheral IV catheters are sold each year in the United States alone, and 60% to 90% of hospitalized patients require an IV catheter during their hospital stay.7-18 Therefore, it's disconcerting that even the most rigorously performed studies indicate that the overall IV catheter failure rate lies between 35% and 50%.7,19-21 Failures take the form of phlebitis, infiltration, occlusion/mechanical failure, dislodgment, and infection, any of which alone or in combination leads to removal of the catheter before the end of its intended dwell time or before the 72- to 96-hour dwell time limit traditionally specified by the Centers for Disease Control and Prevention (CDC) and the Royal College of Nursing.<sup>22-25</sup>

## COSTS OF PERIPHERAL IV CATHETER FAILURE

Peripheral IV catheter failures and related complications are costly to the health care system. The average cost of a short peripheral IV catheter insertion in the United States is between \$28 and \$35 for straightforward "first-stick" insertions.<sup>7,19</sup> However, actual costs can vary considerably, depending on geographic and institutional factors, as well as the type of IV catheter inserted, and the type and extent of supportive technology employed (eg, dressing, needleless connector, extension tubing, dedicated stabilization device).<sup>7,19</sup> The initial insertion cost, as well as the costs of identifying,

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removing, and reinserting the failed IV catheter, is repeated each time a failed catheter is replaced. Unfortunately, the failure of 1 peripheral IV catheter initiates a negative cycle of catheter removal and reinsertion, as the risk of failure of each subsequent catheter is progressively increased.<sup>12</sup> Venous depletion resulting from repeated failed catheters is an increasingly recognized entity and leads to the need for placement of more invasive, risky, and costly venous access devices.<sup>26</sup>

Costs of treating peripheral IV failure-related complications and their sequelae, such as bleeding, hematoma formation, infusate extravasation, thrombophlebitis, and catheter-related bloodstream infection (CR-BSI), are added to the basic costs of catheter removal and reinsertion.<sup>27-30</sup> Caustic medication extravasation from a failed IV catheter can lead to extensive tissue necrosis and the need for repeated surgical debridement and reconstruction.<sup>29,31</sup> It has been estimated that a single case of catheter-related bloodstream infection (CR-BSI) adds 7 to 20 days to hospital length of stay and up to \$56 000 in additional cost, with total costs reaching as much as \$2.3 billion in US intensive care units alone each year.<sup>15,16,32,33</sup> The increase in multi-antibiotic-resistant "superbugs," such as methicillin-resistant Staphylococcus aureus, vancomycinresistant Enterococcus (VRE), and carbapenem-resistant Enterobacteriaceae (CRE), is particularly alarming and has created a real potential for simple peripheral IV catheter surface contamination to have lethal consequences in even otherwise healthy patients.<sup>34-37</sup> Of particular importance is the fact that the widespread use of IV catheters occurs in the places where rapidly emerging superbugs, such as VRE and CRE, are created and exist: hospitals and other health care facilities.<sup>38</sup> The legalmalpractice implications alone are enormous and can be expected to increase as health care system-acquired injury continues to enter the spotlight and ceases to be tolerated from both a cost and societal viewpoint.<sup>28,39-41</sup> Consequently, any potential source of infection or other injury-especially one leading directly to the bloodstream, such as peripheral IV catheters-must be definitively addressed.

Often overlooked, peripheral IV catheter failure is costly to the individual patient as well. Unfortunately, those patient-perspective costs have largely gone unquantified, unstudied, and underemphasized clinically and in the literature.<sup>42</sup> When a peripheral IV catheter fails, caregivers and health care institutions traditionally have accepted it as necessary additional work to be performed. But it is far more than this to the individual patient who is already affected by the illness being treated.<sup>7,43,44</sup> A failed IV catheter means pain, dissatisfaction, prolongation of care, and venous depletion, compounded by the need to treat minor and severe IV catheter failure-related sequelae.<sup>26,28,29</sup> Struggles with obtaining and maintaining peripheral IV access too often adversely affect a patient's overall hospital experience.

## **DWELL TIME**

Central to evaluating peripheral IV catheter failure is the concept of dwell time: the length of time an inserted IV catheter maintains its safe function. Until recently, the dwell time limit for an inserted catheter was restricted to 72 to 96 hours, a limit based on observational data suggesting that the risk of thrombophlebitis and infection increased the longer a catheter was left in place and used.<sup>45,46</sup> IV catheter failure is considered to have occurred when an IV catheter stops safely working before its intended dwell time or before the traditional 72- to 96-hour dwell time limit.

Recently, however, through the work of Rickard, Webster, Hadaway, O'Grady, and others, the concept of acceptable catheter dwell time has undergone a reevaluation, with a shift toward a strategy of leaving wellfunctioning catheters in place longer, resiting them only when "clinically indicated." Such a change to clinically indicated resiting of peripheral IV catheters is supported by multiple recent observational and prospective randomized controlled studies by those investigators and others.<sup>7,19,47-51</sup> The most recent CDC guidelines carefully reflect this shift, recommending that an IV catheter does not need to be electively resited "more frequently than every 72 to 96 hours," potentially leaving the door open to leaving a well-functioning catheter in for longer than the traditional 72- to 96-hour limit.<sup>22</sup> The Infusion Nurses Society's (INS') 2011 edition of the Infusion Nursing Standards of Practice also reflects the shift toward resiting short peripheral catheters "when clinically indicated."24

### HIGH RATE OF PERIPHERAL IV CATHETER FAILURE

Recent research opens an important window into viewing how long contemporary peripheral IV catheters can last and, just as important, how often and why they fail. Even in major clinical centers with dedicated IV teams performing careful prospective randomized studies, the IV catheter failure rate is as high as 63%, with a mean and median across studies of 46% and 43%, respectively (Table 1).<sup>7,19,20,45,49,52-55</sup> For example, in the 2012 study by Rickard et al<sup>7</sup> at a large tertiary care teaching hospital with dedicated IV teams, the median IV catheter dwell time was only 84 hours (3.5 days) in the clinically indicated resite group, an average of 1.7 catheters were required, indicating that a majority of patients required a second catheter during this average 3.5-day period for reasons related to catheter failure. Furthermore, only 10% to 25% of catheters were able to stay in for more than 5 days; only 3% continued to function adequately after 7 days. Looking at all patients in the study, 40% of catheters failed for reasons that included infiltration,

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C TABLE 1 Peripheral IV Catheter Failure Rate, Assorted Studies, 1990-2014			
Study Type	Incidence of Failure (%)	Median	Mean
Prospective randomized controlled	36, <sup>18</sup> 37, <sup>58</sup> 39, <sup>50</sup> 40, <sup>6</sup> 45, <sup>59</sup> 51, <sup>19</sup> 55, <sup>20</sup> 63 <sup>60</sup>	43%	46%
Prospective observational	$\begin{array}{c} 23.5, {}^{61} \\ 25.5, {}^{62} \\ 32, {}^{63} \\ 36.5, {}^{64} \\ 47.5, {}^{65} \\ 47.6, {}^{51} \\ 65, {}^{66} \\ 66, {}^{54} \\ 69.2, {}^{55} \\ 77^{53} \end{array}$	48%	49%
Retrospective	22.4, <sup>67</sup> 95 <sup>68</sup>	58.7%	59%

occlusion, accidental removal, phlebitis, and infection. A previous randomized study by the same author revealed a peripheral IV catheter failure rate of 39%.<sup>51</sup> A 2008 trial by Webster et al<sup>19</sup> revealed an overall catheter failure rate of 36%.

Studies evaluating other more specific aspects of peripheral IV catheter care also demonstrate the remarkably high failure rate of catheter care even in the most expert and controlled environments. For example, a 2006 study by Smith<sup>54</sup> evaluating the added benefit of dedicated catheter stabilization found that even in the dedicated stabilization device group only half of the IV catheters were able to remain in place for 72 to 96 hours. A second trial revealed that of 302 IV catheters placed, 31% experienced a complication by 48 hours, and 51% experienced complications necessitating catheter removal by 96 hours.<sup>20</sup> A 2012 study evaluating peripheral IV catheter stabilization in 10 164 patients found that 70.7% of catheters needed to be replaced by 72 hours in the nonstabilization device group.<sup>52</sup> A 2008 hospital audit revealed that 69.2% of IV catheters did not last 72 hours.<sup>56</sup> Multiple other studies covering a broad range of peripheral IV catheter-related topics-including insertion technique, securement, phlebitis, and infection-support a minimum overall IV catheter failure rate of 30% to 40%, with one as high as 95%.<sup>7,20,47,52-54,57,58</sup>

#### THE PERIPHERAL IV CATHETER AND THE HUMAN BODY: A COMPLEX INTERACTION

Although it is important to determine the best strategy for minimizing cost and optimizing clinical outcome through such strategies as leaving well-functioning catheters in for longer periods, it is perhaps even more important to determine why current IV catheters fail so

early and frequently. A mean failure rate of nearly 50% would be unacceptable for food processing, automobile driving, or cell phone use, let alone airplane flights, so why has it been accepted for the most commonly performed invasive hospital procedure performed worldwide? In the words of Claire Rickard,<sup>58a</sup> one of the leaders of the clinical resite movement: "Not just in our study but in many published works, the incidence of infiltration, occlusion, and accidental removal is disturbingly high. Up to 90% of catheters fail before therapy is complete. Since routine replacement of catheters is ineffective [at decreasing complication rates], research attention should now focus on other interventions to reduce these complications. Improved dwell time of IV catheters for even small increments of time would further reduce the number of insertions, staff workloads, and costs. Improved insertion, securement, and flushing strategies could be key." Effort can be expended developing guidelines that allow for wellfunctioning catheters to be left in longer, but this effort has marginal value at best, if so few have the capacity for safe long-term function.

The relatively high overall failure rate of IV catheter care is the result of multiple individual failure points in the currently complex and highly variable peripheral IV catheter equipment design, placement, use, and care processes; in individual patient factors such as gender, age, weight, and medical comorbidities; and in the variability and fragility of the upper extremity venous system. Complications of IV catheter therapy are simply the result of 1 complex and highly variable mechanical system-IV catheter equipment design, placement, use and care-being applied to a second complex and highly variable system-the ailing human body. When seeking to understand why IV catheters fail, it is useful to view peripheral IV catheter use and care as having 3 basic component parts: (1) the technology used, such as the catheter, connector, and dressing; (2) the caregiver technique applied, including all aspects of insertion, use, and care; and (3) and the body's response to this technology and technique.

## **MODES OF IV CATHETER FAILURE**

Examination of the failure modes of current IV catheters and IV catheter care sheds light on weaknesses and the potential solutions to the problem of peripheral IV catheter failure. For successfully inserted catheters, 5 basic pathologic processes lead to the majority of peripheral IV catheter failures before completion of their intended dwell time: (1) phlebitis, (2) infiltration, (3) dislodgment, (4) mechanical failure (eg, occlusion, leakage), and (5) site or bloodstream infection (Table 2). Other less frequent failure etiologies, such as pain, are inconsistently reported in the literature.

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TABLE 2

## The 5 Modes of Peripheral IV Catheter Failure: Prospective Randomized Controlled Studies, 1990-2014<sup>a</sup>

Mode of Peripheral IV Catheter Failure	Range	Mean	Median
	, v		
Catheter-related phlebitis	0.1%-63.3%	15.4%	9.0%
Catheter infiltration	15.7%-33.8%	23.9%	22.2%
Catheter occlusion/mechanical failure	2.5%-32.7%	18.8%	22.8%
Catheter dislodgment	3.7%-9.9%	6.9%	7.0%
Catheter-related infection	0.0%-0.44%	0.2%	0.2%
<sup>a</sup> Summary of data from Tables 4 to 8.			

## TABLE 3 Infusion Nurses Society Phlebitis Scale<sup>24</sup>

Grade	Clinical Criteria	
0	No symptoms	
1	Erythema at access site with or without pain	
2	Pain at access site with erythema and/or edema	
	Pain at access site with erythema	
3	Streak formation	
	Palpable venous cord	
	Pain at access site with erythema	
4 Streak formation Palpable venous cord >1 inch in length		
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#### Phlebitis

*Phlebitis*, or inflammation of the vein, has received the most attention in the IV catheter complication literature and is an important cause of premature catheter failure.<sup>23</sup> Several phlebitis grading scales, such as INS' Phlebitis Scale, have been used clinically (Table 3).<sup>24,61,70,71</sup>

According to INS standards,<sup>24</sup> grade 1 and grade 2 phlebitis are marked by early signs of inflammation, including pain, edema, and erythema. Grade 3 phlebitis consists of migration of the erythema along the skin overlying and proximal to the access site (streak formation), as well as the development of thrombus in the catheter and/or vein, leading to formation of a palpable cord. The most severe form of phlebitis, grade 4 "suppurative" thrombophlebitis, occurs when the thrombophlebitis becomes grossly infected (with purulent drainage), an entity that has been closely linked to CR-BSI.<sup>72,73</sup> The treatment of grades 1 to 4 phlebitis begins with the removal of the IV catheter.<sup>24</sup>

The incidence of phlebitis in the prospective literature ranges from 0.1% to as high as 63.3% (Table 4).<sup>21,57,63,74,75</sup> It's likely that the incidence varies so widely because phlebitis actually encompasses a spectrum of inflammatory and infectious pathology, and because of differences in the definition of phlebitis (eg, whether a standardized phlebitis scale was used), study design, technology and technique applied, study period, patient

selection, and follow-up time.<sup>70</sup> The coexistence or overlapping of multiple catheter failure etiologies—eg, infiltration, occlusion, or early infection that coexists with phlebitis—is also an important factor affecting the reported incidences of phlebitis, because its incidence is directly affected by the choice of failure mode grouping to which any particular catheter failure is assigned.<sup>59</sup> Despite these limitations, even the most rigorously

C TABLE 4 Incidence of Phlebitis			
Study	Incidence of Phlebitis (%)	Mean	Median
Prospective ran- domized control group	${ \begin{array}{c} 1, {}^{19} \ 1.4, {}^{75} \ 3, {}^{18} \ 3.6, {}^{51} \ 4.6, {}^{58} \\ 7, {}^{6} \ 7, {}^{50} \ 9, {}^{76} \ 13, {}^{77} \ 20.4, {}^{78} \\ 24, {}^{20} \ 52.6, {}^{79} \ 63.3 {}^{60} \end{array} } }$	16.1%	7%
Prospective ran- domized inter- vention group	0.1, <sup>76</sup> 0.7, <sup>51</sup> 4, <sup>18</sup> 7, <sup>6</sup> 10, <sup>19</sup> 10, <sup>50</sup> 11, <sup>76</sup> 25, <sup>20</sup> 26.1, <sup>60</sup> 26.2, <sup>79</sup> 41.8 <sup>80</sup>	14.7%	10%
Prospective obser- vational group	$\begin{array}{c} 2.3,^{74} 2.6,^{44} 3.3,^{81} 3.3,^{82} \\ 6.2,^{55} 6.5,^{83} 9.7,^{61} 9.9,^{66} \\ 10.6,^{56} 11.1,^{62} 12.7,^{44} \\ 15,^{84} 21,^{77} 22.7,^{83} 26,^{85} \\ 27,^{86} 29.8,^{87} 30.5,^{88} \\ 30.5,^{88} 31,^{27} 32.0,^{84} \\ 35.2,^{92} 43,^{89} 54.5,^{73} 56,^{90} \\ 56.5,^{90} 59.1^{91} \end{array}$	22.7%	21%

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performed prospective randomized trials, applying standardized phlebitis scales, record mean phlebitis rates between 14.7% and 16.1% across studies.

Phlebitis can be precipitated by mechanical, chemical, and infectious causes, or by any combination of the three.<sup>73,92,93</sup> But as with other forms of catheter failure, it is ultimately the interaction of the catheter, the catheter insertion and care technique used, and the patient's response to the catheter that determines the incidence of phlebitis in any given individual patient.

Mechanical phlebitis is associated with the physicalmechanical properties of the catheter-its gauge, length, stiffness, and material composition-with traumatic movement of the catheter relative to the vessel wall and to the hydrodynamic effects of infused fluids.<sup>88,92,94</sup> Smaller-gauge catheters are associated with a lower phlebitis rate, as presumably the relatively smaller catheter leaves more buffer room around the catheter and catheter tip, allowing for decreased direct traumatic interaction with the vessel wall.<sup>73,95,96</sup> Similarly, longer catheters have shown decreased failure relative to shorter catheters, presumably because the better-stabilized catheter tip lies in the larger-diameter, more proximal veins.<sup>60</sup> The plastic composition and surface characteristics of IV catheters have been shown to affect the rate of mechanical phlebitis.63,81,97 Catheters composed of softer, smoother-surfaced, and less porous plastics, such as polyurethane, have been shown to have improved performance and lower phlebitis and overall failure rates than catheters made of other plastics.96,98 Surface coatings and treatments have been developed that serve to limit fibrin sheath, thrombus, and biofilm buildup, potentially decreasing the incidence of phlebitis and other failure-related complications.<sup>99</sup> The shape and softness of the catheter tip-the main point of vessel wall mechanical interaction-are also important. This was recognized by Massa when designing the original Rochester plastic catheter in the late 1940s; each catheter tip of the original homemade model was specifically treated chemically and then hand shaped with a rotary cloth buffer.<sup>5</sup>

Movement of the catheter relative to the vessel wall is of primary importance in the development of phlebitis, as well as in all forms of catheter failure.<sup>94</sup> Movement of the body relative to the secured catheter leads to direct mechanical trauma to the intima and vessel wall; catheters placed in joint/hinge regions (eg, antecubital, wrist) have been shown to have a higher movement-related phlebitis rate.<sup>94</sup> Conversely, movement of the catheter relative to the body also plays a role in the development of mechanical phlebitis. Catheter stabilization, therefore, has become a central means to improve IV catheter outcomes, and several dedicated stabilization products have been clinically introduced. Catheter stabilization with dedicated stabilization devices has shown clear benefit in several prospective trials.<sup>20,54,100,101</sup> In fact, the benefit of catheter stabilization is now reflected in the 2011 edition of the INS standards, which reads: "the use of a catheter stabilization device should be considered the preferred alternative to tape or sutures when feasible."<sup>24</sup>

Chemical phlebitis, which is caused by irritation and inflammatory injury of the vessel wall by infusates, is another important cause of phlebitis.<sup>91</sup> Chemical phlebitis has been shown to be associated with medications including antibiotics, such as levofloxacin, azithromycin, vancomycin,  $\beta$  lactams, and amphotericin; electrolyte replacement therapy solutions, such as potassium; and cancer chemotherapeutic agents.<sup>24,63,81,95,96,102,103</sup> Diluting known chemical irritants to their "no-adverse-effect level" can significantly reduce the incidence of chemical phlebitis.<sup>102</sup>

Infectious phlebitis is a less common but potentially devastating form of phlebitis that occurs in 0.1% to 5% of patients.<sup>15,104</sup> Its occurrence is differentiated from noninfectious phlebitis by the presence of a positive catheter-tip culture, which has been shown to occur in 5% to 25% of catheters that are cultured in the setting of phlebitis.<sup>12,70</sup> It has been postulated, however, that breaks in aseptic technique during insertion, use, and care, as well as colonization of catheters from bacteria residing in the deeper skin layers, cause virtually all catheters to become externally and/or internally contaminated/colonized with bacteria during their clinical life span, even those that are clinically normal and culture-negative.<sup>105,106</sup> Typically, such contamination is linked to biofilm formation, which harbors, nurtures, and protects bacterial growth on the catheter surface. Those bacterial contaminants and their generated biofilm can lead to a primary localized inflammatory infectious phlebitic reaction, or, conversely, preexisting mechanical or chemical phlebitis can interact with bacterial contaminants to form infectious phlebitis. Contamination of the catheter hub has been shown to strongly correlate with catheter infection and CR-BSI.<sup>107</sup> In 1 study, 54% of catheter-related sepsis episodes were preceded by or coincided with contamination of the catheter hub.107 Localized (culturepositive) peripheral IV infectious thrombophlebitis progresses to frank suppurative thrombophlebitis in 0.2% to 2.0% of cases, and suppurative thrombophlebitis can progress to CR-BSI when bacteria emanating from an in-dwelling catheter become blood-borne (relative risk 27.1).<sup>72,108</sup>

Caregiver technique-related factors surrounding IV catheter insertion, use, and care have been shown to play an important role in the development of phlebitis. First-attempt catheter insertion fails in 12% to 26% of adults and 24% to 54% of children, and failed insertion attempts lead to vessel trauma that increases the risk of subsequent catheter failure.<sup>17</sup> It has been shown that caregivers with specific training and experience (eg, the

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"IV team") have a significantly higher first-time insertion success rate, which has been associated with a lower incidence of phlebitis and failure.14,85,109,110 Multiple studies have demonstrated the value of a multimodality approach in improving first-time peripheral IV success as an important route in decreasing the incidence of phlebitis and failure.<sup>111,112</sup> Each time an insertion attempt fails, an access site is lost or compromised, and the risk of subsequent phlebitis and failure is increased.<sup>95</sup> In 1 study, patients experiencing phlebitis with a first catheter were 5.1 times more likely to develop phlebitis in a subsequent IV catheter; in another, 83% of patients with phlebitis developed phlebitis in a subsequent IV catheter.<sup>12,66,113</sup> Repeated failed insertion attempts, phlebitis, and IV catheter failure eventually lead to venous depletion, the incidence of which can also be expected to increase as the population ages.<sup>26,114</sup>

Standardization of catheter use and care *after* insertion, through the use of specially trained IV nurses, is also of proven benefit in reducing the incidence of phlebitis and other complications.<sup>14,19,76,109,115,116</sup> Specific aspects of catheter care that have been shown to affect the incidence of phlebitis and other complications include dressing placement and care, stabilization and securement technique, cap/connector cleaning and use, catheter flush technique, and overall catheter surveillance.<sup>52,76,117,118a</sup> Caregiver education is essential for improving all aspects of catheter care, and initiatives by INS stress the importance of caregiver education in optimizing peripheral catheter outcomes.<sup>118b</sup>

Advances in technology—such as vessel identification devices, integrated Seldinger insertion systems, novel catheter designs, hub cap cleansing/sterilization covers, improved stabilization, integrated catheter dressing systems, and antibiotic-impregnated catheters, dressings, and connectors—offer promise in supporting optimized care algorithms aimed at decreasing the incidence of catheter trauma and contamination-related phlebitis and failure.<sup>20,63,112,119-122</sup>

Finally, patient-specific factors that affect tissue/ vessel fragility, integrity, and accessibility have been shown to affect the rate of catheter phlebitis and loss.<sup>17,57</sup> Patient age, nutritional status, body size, gender, medical history, and clinical status, as well as the venous access site chosen, all have been shown to be important.<sup>24,57,68,81,94,123</sup> In addition, factors such as the exposure to previous or concomitant peripheral IV catheters have been shown to affect the rate of phlebitis.<sup>63</sup> However, findings in the literature have not been consistent, particularly in respect to gender and age.<sup>63</sup> This suggests that extrinsic influences, such as catheter insertion and care technique, might overshadow patientspecific parameters. For example, although age may be important, with older patients having more fragile vessels, poor aseptic technique during insertion and care may be a more powerful driver and determinant of the

incidence of phlebitis. Although it is important to recognize the increased failure risk that patient-specific factors impose, it remains that high-risk patients require IV therapy. Therefore, it is this population that, perhaps more than any, mandates that optimized peripheral IV care systems be developed and applied.

#### **Catheter Infiltration**

A second well-recognized form of IV catheter failure is infiltration. With a range of 15.7% to 33.8% and a mean incidence of 23.9%, infiltration is the most common form of IV catheter failure (Table 5). Resulting from erosion or penetration of the catheter into or through the venous wall, infiltration leads to infusion of fluids and/or medications into the surrounding soft tissues. Infiltration can also result from loss of surrounding venous wall integrity due to the inflammatory effects of traumatic movement of the catheter within the vessel, caustic or other chemical injury by infusate, needle injury to the vein incurred at the time of initial or previous catheter insertion, or predisposing patient characteristics such as poor vessel integrity.94,124 Extravasation, the infiltration of a known vesicant or caustic agent, is a particular subgroup of infiltration that can lead to extensive soft tissue injury and loss with devastating results.94,125

The body site used for peripheral IV cannulation has particular relevance to the rate of infiltration, this directly related to vessel trauma induced by relative catheter movement.<sup>55</sup> Peripheral IV catheters placed in joint regions (eg, wrist, antecubital fossa) have been shown to have higher rates of infiltration and loss, presumably due to movement of the vessel wall relative to the catheter tip.<sup>94</sup> Similarly, even in nonjoint body regions, inadequate catheter securement can lead to increased catheter tip motion and consequent traumatic injury to the vessel wall, resulting in infiltration through the vein wall or the loss of its integrity.<sup>11</sup> A prospective randomized study of dedicated peripheral catheter securement devices by Bausone-Gazda et al<sup>20</sup> in 2010

TABLE 5 Incidence of Peripheral IV Catheter Infiltration, 1990-2013			
Study Type	Incidence of Infiltration	Mean	Median
Prospective randomized controlled	15.7, <sup>6</sup> 18.3, <sup>20</sup> 22, <sup>19</sup> 22.3, <sup>77</sup> 31.5, <sup>50</sup> 33.8, <sup>18</sup>	23.9%	22.2%
Prospective observational	$5.9,^{62}, 5.2,^{61}, 7,^{89}, 7.4,^{65}, 8.8,^{64}, 13.0,^{66}, 13.2,^{63}, 31.5,^{87}, 36.3^{55}$	14.2%	8.8%

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showed that catheter longevity was increased significantly by improved stabilization. The importance of stabilization has been demonstrated in multiple other clinical studies.<sup>54,56,102</sup> On the basis of those studies, the 2011 edition of INS's *Infusion Nursing Standards of Practice* now recommends the use of a dedicated stabilization device when feasible.<sup>24,103,126</sup>

As with phlebitis, mechanical and compositional characteristics of the IV catheter itself also play a role in infiltration and longevity.<sup>94</sup> Dillon et al<sup>55</sup> found catheter gauge to affect infiltration rates, with larger 18-gauge catheters demonstrating improved IV survival. Other studies found that smaller-gauge catheters have improved survival, suggesting that the relationship between gauge and failure may be complex. The type of catheter material used also has been shown to play a role in infiltration, with smoother, softer catheters leading to a lower incidence of infiltration.<sup>63,127</sup> Catheters constructed of polyurethane, which softens at body temperature, are less erosive toward the vessel wall than stiffer Teflon catheters.<sup>81,128</sup> Newer medical-grade polymers that have the optimal combination of lubricity (intrinsic lubrication), softness, and kink resistance continue to be developed.<sup>129</sup> The microscopic texture and shape of the catheter tip may also play a role in decreasing traumatic infiltration.<sup>129,130</sup> Insertion method and operator insertion experience play an important role in the rate of infiltration and loss.<sup>20,76,110</sup> Whereas all catheter insertion involves 1 vessel wall perforation, often 2 or more perforations can occur (eg, back wall), particularly in the hands of an inexperienced operator or in patients with difficult venous access where multiple access attempts are necessary.<sup>17</sup> While additional perforation sites may seal over and not lead to dysfunction or failure, the sites may remain open or reopen over time, particularly if intravascular pressure is high as a result of increased infusion rate or upstream venous obstruction.94 Concurrent anticoagulation might also be expected to limit occlusive thrombus formation at these perforation sites, increasing the tendency for infiltration to occur.57

Strategies to limit unnecessary additional venous perforation at the time of insertion have been put forward.<sup>111</sup> Foremost among them is the use of specially trained personnel using standardized and optimized technique.<sup>17</sup> The benefits of such an IV team approach are evident, particularly in "difficult stick" patient populations, such as morbidly obese and pediatric populations.<sup>111,131,132</sup> Other techniques found useful in improving peripheral IV catheter insertion success include bevel-down needle insertion in small vessels, the use of local anesthetics and topical visualization agents, the "double tourniquet" technique, and patient reassurance maneuvers.<sup>111,133,134</sup> New technologies are also being developed and applied clinically, such as imaging devices for vein localization and peripheral IV catheters with integrated guidewires directed at decreasing posterior wall perforation.<sup>111,130</sup>

As with all catheter-related complications, patient characteristics that affect tissue/vessel fragility and integrity have been shown to play a role in infiltration and loss.<sup>17,57</sup> Patient age, nutritional status, body size, gender, medical history, and clinical status, as well as the venous access site chosen, all have been shown to be important.<sup>24,57,68,81,94,95,123,135</sup> Steroids and other immune suppressants can lead to loss of tissue integrity and increased vessel wall fragility. Similarly, chemotherapeutic agents and other medications such as vancomycin that cause tissue injury and inflammation also have been associated with infiltration and extravasation.<sup>94</sup> The rate of medication infusion also can lead to infiltration through the effects of localized increase in intravascular pressure. Upstream venous obstruction from concurrent disease of previous catheter-related thrombosis can have similar effects.<sup>94</sup> The use of more than 1 IV catheter in any given patient, either serially or concomitantly, can also affect infiltration rate.94

#### **Catheter Occlusion and Mechanical Failure**

Another common cause of premature loss of catheter function necessitating catheter removal is catheter occlusion, which can be defined as the loss of the ability to infuse fluids and/or medications through a previously functioning IV catheter. Occlusion can occur from mechanical obstruction, such as from kinking of the catheter, from catheter migration into a "dead-end" position within the vessel wall or tissue without frank infiltration/extravasation, or from thrombosis of the catheter and/or surrounding vessel. As with infiltration, overlap between catheter loss etiologies can occur (eg, advanced thrombophlebitis or vessel infiltration will lead to catheter occlusion); this likely accounts for the broad range of incidence seen in the catheter literature.<sup>20</sup> Inclusion of related forms of mechanical catheter loss (eg, "leakage") in the category of occlusion can also affect the reported incidence of catheter occlusion in the clinical literature. As with phlebitis and infiltration, useful data regarding catheter occlusion rates can be obtained from recent prospective randomized trials evaluating various aspects of peripheral IV therapy, particularly trials evaluating clinically indicated resiting of catheters (Table 6). Those studies reveal a catheter occlusion rate that ranges from 2.5% to 32.7%, with a mean and median of 18.8% and 22.8%, respectively.

As with infiltration, the incidence of catheter occlusion has been shown to be higher in catheters inserted at hinge points such as the wrist and antecubital fossa. In these positions, catheter movement relative to the vessel wall can lead to tissue injury and occlusive thrombus formation.<sup>20</sup> Direct mechanical bending and kinking of the catheter at these sites can also lead to

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IV an	E 6 cidence of Per Catheter Occ d Mechanical ilure		
Study	Incidence of Occlusion (%)	Mean	Median
Prospective			

Prospective randomized controlled	2.5, <sup>50</sup> 6.6, <sup>18</sup> 21.0, <sup>6</sup> 24.6, <sup>20</sup> 25.6, <sup>58</sup> 32.7 <sup>79</sup>	18.8%	22.8%
Prospective observa- tional	3.0, <sup>62</sup> 3.9, <sup>66</sup> 10.6, <sup>63</sup> 12.4, <sup>65</sup> 16.2 <sup>64</sup>	9.2%	10.6%

temporary or permanent occlusion.94 Inflammation caused by catheter trauma, biofilm formation, and subclinical or overt infection can also lead to thrombosis, and underscore the fact that catheter occlusion is simply the end result of a range of underlying pathologic processes.<sup>108,136</sup> The type of catheter material as well as the catheter diameter can also affect occlusion rates.55,63 Catheter vessel size mismatch has been shown to affect the degree of vessel trauma and the subsequent incidence of occlusion. As with infiltration, patient characteristics such as age, vessel size, vessel location, and tissue integrity (eg, steroid use) also play a role in promoting early catheter occlusion. Also, as with phlebitis and infiltration, catheter stabilization or lack of it plays an important role in catheter occlusion because increased catheter tip movement leads to increased vessel wall trauma and associated thrombosis. Migration of a poorly secured catheter can also lead to the catheter tip pulling back out of the vessel lumen, particularly in cases where the vessel entry site is distant from the skin penetration site.<sup>64</sup> Occlusion can also be directly related to suboptimal care and use technique, such as improper cannula flushing, as well as occlusive problems associated with use of connection devices and other ancillary equipment.137

#### Accidental Catheter Removal/Dislodgment

Accidental dislodgment of catheters is another important cause of premature catheter loss. As with other IV catheter failure modalities, the incidence of accidental IV catheter dislodgment, an easily and clearly defined end point, can be gleaned from the general IV catheter literature, with the rate ranging from 3.7% to 50%, with a mean rate in the prospective controlled literature of 6.9% and 17.5% in the prospective observational literature (Table 7).<sup>20,21,55</sup> A study by Jackson,<sup>69</sup> which looked at 3296 peripheral IV catheter restarts over a

	TABLE 7				
	Incidence of Peripheral				
	IV Catheter				
	Dislodgment/				
Inadvertent Loss					
Periph Studies	eral IV Care s	Rate of Accidental Dislodgment (%)	Mean	Median	
Prospe	ctive		C 00/	7.00/	

Prospective randomized trials	3.7, <sup>20</sup> 6.3, <sup>58</sup> 7, <sup>19</sup> 7.5, <sup>50</sup> 9.9 <sup>6</sup>	6.9%	7.3%
Prospective observational studies	$\begin{array}{c} 4.0, {}^{65} \\ 4.7, {}^{61} \\ 10, {}^{64} \\ 20, {}^{54} \\ 36, {}^{68} \\ 50.1 {}^{69} \end{array}$	17.5%	9.2%

6-month period, found that catheter dislodgment was by far the most common reason for catheter restart and was listed as the reason for restart in 50% of catheter failures. The unintentional removal of a catheter can occur for a multitude of reasons ranging from inadequate securement to catheters inadvertently catching on clothing or surrounding structures.

Without some form of securement-transparent adhesive film dressing, tape, dedicated securement device, or combination of these-all peripheral IV catheters would quickly fall out. For many years, tape (in conjunction with a gauze and/or transparent film dressing) was used as the primary securement means, with operators placing this tape in various patterns to secure the hub and attached IV catheter and/or connector.<sup>138-141</sup> Using tape for hub securement introduces contamination in close proximity to the insertion site and leads to variable success in respect to the actual integrity achieved, and therefore its use for this purpose is no longer encouraged. But because the transparent film adhesive dressing by itself is insufficient to fully stabilize and secure the catheter, as the adhesive contacts only a portion of the round catheter hub, several dedicated securement devices are now clinically available, and their use is encouraged by INS.<sup>24</sup> Catheters with integrated stabilization features, such as wings that serve to expand adhesive dressing contact area, may serve as a viable alternative.<sup>20,69</sup> Another strategy employed to decrease catheter movement is to attach extension tubing to the catheter hub, so that the interaction point is remote from the actual catheter and its insertion site.<sup>21,142</sup> Use of such extension tubing increases overall catheter complex bulk and adhesive surface areaincreasing the tendency for catching on clothing, etc, particularly if located on the hand-and its use is not encouraged by INS.<sup>24,55</sup>

Dedicated securement devices have shown significant benefit in improving catheter longevity with a direct

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effect on reducing catheter dislodgment. These devices, however, also add bulk to the catheter-dressing complex, extend adhesive surface area, and act to tent the dressing upward, potentially allowing further outside contamination. They also add significant cost and complexity to peripheral IV catheter care, although some studies report a clinical and cost benefit from improved stabilization and securement.<sup>52</sup>

#### **Catheter-Related Infection**

Catheter-related bacterial infection can be divided into (1) CR-BSI and (2) local catheter insertion site infection. Both types of infection are based on the presence of confirmatory positive culture results that can be connected by clinical data to the indwelling catheter. The incidence of CR-BSI attributable to peripheral venous catheters has been well delineated (ranging from 0% to 2.2% in prospective studies), as bloodstream infection is a relatively clear clinical event, especially when it occurs to the degree that it meets the CDC's National Healthcare Safety Network criteria for CR-BSI.<sup>33,143-145</sup> As discussed in the section on phlebitis, the incidence of local culture tip-positive peripheral catheter infection is relatively clinically uncommon, occurring in 0.1% to 5.1% of inserted peripheral IV catheters (Table 8). Although gross clinical peripheral IV catheter infections meeting the accepted criteria for CR-BSI or localized local catheter infection are uncommon, we must remember that the criteria were aimed at delineating catheters that carried enough bacterial load to cause advanced localized infection or frank bacteremia and CR-BSI. Lower levels of localized insertion site catheter bacterial contamination might also be important, leading to early catheter failure through the localized effects of the infectious and inflammatory process, which then result in adverse recorded clinical catheter outcomes such as phlebitis, infiltration, and thrombosis.

TABLE 8 Incidence of Catheter- Related Infection		
Study	Incidence of Infection	
Prospective randomized controlled		
Local (catheter/insertion site) 0, <sup>6</sup> 0, <sup>50</sup> 0.3 <sup>18</sup>		
CR-BSI 0, <sup>50</sup> 0.03, <sup>6</sup> 0.3, <sup>18</sup> . 0.44 <sup>20</sup>		
Prospective observational		
Local (catheter/insertion site)	0.1, <sup>55</sup> 2.7, <sup>82</sup> 4.0, <sup>27</sup> 5.1 <sup>66</sup>	
CR-BSI 2.2 <sup>66</sup>		
Abbreviation: CR-BSI, catheter-related bloodstream infection.		

IV catheter contamination leading to infection can occur on both the extraluminal and intraluminal surfaces of a peripheral IV catheter.<sup>106</sup> Extraluminal and intraluminal contamination have different pathogenic mechanisms and temporal characteristics, with extraluminal colonization and infection occurring early and intraluminal contamination appearing later in the catheter's dwell time.<sup>106,108,146,147</sup>

Extraluminal colonization can result from inadequate skin preparation, break in aseptic technique at the time of initial IV catheter insertion, or attachment of normal skin flora as the insertion needle and catheter are passed through the epidermis and underlying dermal structures.<sup>108,148</sup> Approximately 80% of resident and transient microorganisms inhabit the first 5 layers of the skin's stratum corneum; the remaining 20% exist in biofilms in the underlying epidermal and dermal layers, hair follicles, and sebaceous glands.<sup>149-151</sup> Extraluminal contamination can also occur from inadequate catheter dressing placement and care at the insertion site, allowing organisms to migrate along the external catheter surfaces directly to and through the skin penetration site.<sup>108</sup> One of the basic structural deficiencies of the standard transparent adhesive film dressing is that "tenting up" of the dressing by the catheter hub leaves 2 channels on either side of the hub that lead directly to the skin insertion site.<sup>22,24,25</sup> As the catheter hub moves over time, those channels enlarge, increasing direct access by pathogens.

Intraluminal contamination of IV catheter surfaces can occur at the time of catheter insertion as a result of break points in aseptic technique during the currently complex and highly variable initial catheter-insertion and dressing-placement process (eg, flushing, capping, securing). It should be recognized that the external surfaces of all peripheral IV catheter hubs become contaminated during the insertion process, simply because the hub is grasped with nonsterile gloves that have typically touched multiple nonsterile surfaces. This contaminated surface is then simply covered over by the transparent adhesive film dressing. As might be expected, internal contamination becomes more prevalent as use and dwell time increase, because contamination can occur at any time during use and care of the inserted catheter.<sup>106</sup> Efforts at caregiver needlestick prevention have led to a wide array of needleless connectors, the use of which is now the norm in most health care facilities. Unfortunately, these safety devices have been implicated in the promotion of intraluminal contamination and infection.<sup>152</sup> The type of needleless connector may affect the rate of intraluminal colonization and infection, with the simpler split-septum devices having a reported lower infection rate than devices with more complex internal mechanisms.<sup>106</sup> Inadequate aseptic technique during manipulation of catheter hubs, connectors, and stopcocks is a common source of internal contamination.<sup>119,120</sup> The

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wide array of needleless connectors, with varying pressure and volume displacement characteristics, has only added to complexity of care—and to the compromise that occurs.<sup>152</sup> In 1 study, 31% of caregivers did not disinfect needleless connectors before accessing them.<sup>153</sup> In hospital intensive care units, floors, and operating rooms around the world, failure to clean the access site for the recommended minimum 5-second period (let alone the full 15 seconds) is far too common.<sup>154-157</sup> In response to this, an array of cap disinfection and protection devices have been introduced, with varying degrees of clinical acceptance.

Both external and internal contamination lead to a cascade of events, central to which is formation of biofilm, a biologically active and bacterial-sustaining coating that forms on the interior and exterior surfaces of all inserted catheters.<sup>42,98,105,108,121,127,158-160</sup> Biofilm has been shown to form in virtually all inserted catheters and provides a matrix for contaminating bacteria to grow and persist, markedly increasing resistance both to natural host defenses and to antimicrobial efforts.<sup>161</sup>

Biofilm formation has been shown to be a 3-step process. The first step is initial adhesion of bacteria to the catheter surface (attachment). The second phase of biofilm formation is proliferation (maturation), during which the attached bacteria multiply in number and secrete polymers that facilitate adhesion and interact to form a stabilizing and nurturing extracellular matrix. Cellular density increases to a steady state within 1 to 2 weeks, depending on species and conditions.<sup>108</sup> The third and final stage of biofilm development is detachment (dissolution), during which the biomass of the biofilm and its contained bacteria begin to shed into the bloodstream. As the biofilm grows and matures, its structure and dimensions are maintained by the sloughing of external layers through several mechanisms, including the actions of secreted peptide surfactants.<sup>158,159</sup> The detachment/dissolution process plays a crucial role in the natural history of catheterrelated infections, as the seeding effects of this sloughing generally concur with systemic symptoms that lead to the diagnosis of CR-BSI, such as fever and hemodynamic changes. CR-BSI is confirmed by standard accepted methodologies.143

Although biofilm generation on catheter surfaces is virtually inevitable in catheters contaminated by bacteria, it does not necessarily lead to overt clinical infection such as CR-BSI, because bacteria contained in biofilms display a range of growth rates and virulence. Although gross clinically evident catheter-related infection as presently defined may not universally result from catheter biofilm contamination, other forms of catheter failure—such as thrombosis, phlebitis, and infiltration—may have the inflammatory, thrombotic, and mass effects of the biofilm process as an underlying central or contributory etiology.<sup>42,136,162</sup>

Once formed, treatment options for catheters affected by bacterial biofilm-beyond catheter removal-are limited. Both antibiotic and nonpharmaceutical antimicrobial treatments have and continue to be evaluated. 42,158 Antimicrobial- and antibiotic-impregnated catheters, connectors, and dressings have been developed. 33,35,121 All add not only complexity and expense but also run directly counter to basic principles of antibiotic stewardship: minimize use of antimicrobial agents to minimize selection of resistant organisms. As with virtually all adverse clinical events, it remains that prevention of bacterial biofilm formation is the best treatment of all. Surface conditioning of catheters with plasma proteins and other blood-borne mediators naturally will occur with all inserted IV catheters, and unless bacteria are prevented from contacting this hybrid synthetic-biologic surface, bacteria-laden biofilm will form, ultimately leading to catheter failure.<sup>108</sup> Prevention of catheter contamination through efforts in education and training, as well as technologic innovation, will be central in efforts to reduce the overall high rate of peripheral catheter failure.

### CONCLUSION

In today's world of multidrug-resistant bacteria and cost and resource efficiency control, the high failure rate of currently applied IV catheter systems, as demonstrated in this paper, mandates that the system be thoroughly questioned. Although advances have been made—such as the prevention of needlesticks through the use of safety needle containment devices and adhesive film dressings, the application of add-on devices to improve securement and decrease vessel trauma, and the use of antimicrobial-impregnated catheter dressings and adjuncts-they largely have been compensatory in nature, trying to make up for the shortcomings of the present system, which in the best of hands yields a failure rate of 35% to 50%. Some compensatory measures, such as the use of antibiotic-impregnated catheters and dressings, actually run counter to accepted infection control dogma, because their widespread use can serve to accelerate the development of multidrug-resistant organisms.

Meaningful change will require that the concept of the peripheral IV catheter as an expendable and replaceable tool be discarded. It will require recognition of the iatrogenic harm that is caused by current IV catheter technology and technique. Penetration of a patient's natural protective skin barrier with a foreign body that directly connects the outside world to the bloodstream for a prolonged period of time is not to be taken lightly. Insertion of an IV catheter is an invasive procedure that introduces multiple risks and potential morbidities, and even mortality, and should be given the respect that it deserves. In a perfect world, an IV catheter would be constructed of the most suitable material and inserted at the best possible site, using optimized simple, reproducible, and fully aseptic technique to minimize trauma to the tissues and eliminate contamination. It should be fully stabilized and secured, and aseptically covered with a dressing that durably protects the uncontaminated catheter over time from outside contamination. The catheter should be used in a manner that preserves its sterility internally and externally—and the stable, fully secured catheter should be left in place until it is no longer needed. It's likely that an IV catheter treated in this way will last significantly longer than the traditional 72- to 96-hour resite interval, making the clinically indicated resite strategy more meaningful.

The problem, however, as demonstrated in this article, is that current IV catheter technology and technique do not always achieve these goals, despite extensive clinical and industrial effort. The relatively complex nature of current IV catheter technology and "notouch" technique precludes insertion without some contamination of the hub, which lies close or adjacent to the skin penetration site. Current transparent adhesive film dressing technology covers over this contamination and can allow additional contamination to occur over time. Breaks in aseptic technique during catheter use and care add to the rate of internal and external contamination. Inadequate securement adds traumatic tissue insult, increasing the likelihood of failure. Bacterial biofilm develops on contaminated catheters, leading to a cascade of events-compounded by patientrelated factors, catheter-related trauma, thrombosis, and mechanical failure-that leads to loss of the IV catheter before its intended time in almost half of patients.

To achieve safe, efficient, and long-term IV therapeutic success, important rational questions will need to be asked and every aspect of vascular catheter technology and technique freshly and carefully analyzed. For example, if external catheter hub contamination occurs universally during insertion, simply because the gloves that are used to grasp the catheter hub have touched one or more nonsterile surfaces during the insertion process, then why isn't catheter insertion performed using maximum barrier precautions (or at least sterile gloves and a localized sterile field)-a shift that has already occurred for central line, midline, and peripherally inserted central catheter (PICC) insertions? Similarly, why doesn't catheter-dressing technology seal and protect the catheter insertion site from outside contamination over time, particularly in the era of multiresistant organisms that increasingly colonize surfaces of health care institutions? And if adequate securement is important for decreasing traumatic catheter movement and loss, why isn't full securement and stabilization used for each and every catheter that is placed? Finally, if guideline-driven education/training is important for achieving optimal use and care outcomes, then why isn't this training requisite?

A catheter failure rate of 35% to 50% in the best of hands is unacceptable to patients, caregivers, and the health care system. The variability and complexity of current state-of-the-art peripheral IV catheter care is simply a confirmation that a truly acceptable solution to the problem set of optimal peripheral IV care has yet to be found. But simple, safe, reproducible, efficient, cost-effective, and long-term peripheral IV catheter care is possible. It is hoped that this article will serve as a stepping-stone toward making acceptable peripheral IV catheter care a reality by bringing the problem of IV catheter failure forward for examination and discussion.

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