

The role of IV needleless Connectors and IV Complication management and prevention

ABSTRACT

The most common complications associated with vascular access devices are catheter related bloodstream infections (CR-BSI), which occur in acute care patients every minute, and occlusions. This review will address major issues associated with patient care and research associated with vascular access and intravenous (IV) needleless connectors including descriptions of different types of connectors, care and maintenance issues such as septum disinfection and flushing, education of students and practitioners, a new framework for research, and relevant questions for healthcare practitioners to ask during patient assessment. Two overall strategies to prevent CR-BSI's and occlusions; 1) prevent the active and passive migration of microorganisms into the fluid pathway and 2) prevent microorganism adhesion to the catheter surface will be discussed. The IV needleless connector, which is placed on the catheter hub, is the gatekeeper to the intraluminal fluid pathway and its design directly impacts the success of strategies to prevent complications. Best practice requires that practitioners have specific knowledge of connector technology as well as patient factors for caring for vascular access devices. There is a large gap in the scientific literature and in policies and procedures related to evidenced based decision making associated with care and maintenance of needleless intravenous connectors. Understanding IV needleless IV connectors is necessary to meld research and practice together for best patient practices, so the occurrences of CR-BSI's and occlusions can be mitigated and eliminated.

Key words: CRBSI, sepsis, IV needleless connector, nursing care, vascular access, occlusion

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INTRODUCTION

Patients with a vascular access device (VAD) experience two major complications – catheter related blood stream infections (CR-BSI) and occlusion either partial or total. This paper discusses how these

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28 common intravenous therapy complications are impacted by IV needleless connector design. Methods
29 for article preparation included review of CINAHL and MEDLINE using the key words CR-BSI, occlusion,
30 connector, and IV technology. Exclusions included studies not IRB approved. Connector technology
31 included in the paper had to have some published related research. CR-BSI is defined by the Centers for
32 disease control (CDC) as bacteremia/fungemia in a patient with an intravascular catheter with at least one
33 positive blood culture obtained from a peripheral vein, clinical manifestations of infection (i.e., fever, chills,
34 and/or hypotension), and no apparent source for the bloodstream infection except the catheter.¹ A patient
35 obtains a CR-BSI every minute.² This can lead to a diagnosis of sepsis which is the most costly hospital
36 acquired infection with up to a 25% mortality rate² and higher depending on the causative micro-
37 organism. The second complication is catheter occlusions which can result in loss of vascular access, loss
38 of time for treatments and increased length of stay. Either of these complications causes a poorer quality
39 of life for the patient and can result in death.

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40 The intravenous catheter, whether centrally or peripherally placed, is an extension of the venous system
41 to the outside environment. As a result, a hole in the skin referred to as the insertion site (extraluminal)
42 and the hole in the catheter (intraluminal fluid pathway) are entry points for bacteria, and fungus. Best
43 practices for extraluminal care^{3,4} are reported to only prevent 40% of bloodstream infections⁵. Therefore,
44 60% of CR-BSIs have causes that are intraluminal in nature. It is now well known and accepted that CR-
45 BSIs occur when organisms, in particular bacteria, migrate into either the extraluminal or intraluminal fluid
46 pathway and adhere to the pathway wall. Once attached, the bacteria form a colony and develop a
47 protective cover referred to as biofilm. When biofilm is formed it is difficult to eradicate and the colony can
48 proliferate. Over time bacteria shed into the venous system and can cause an infection. Four major
49 pathogens (*Staphylococcus epidermidis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia*
50 *coli*) are responsible for 60% of CR-BSIs at a total cost of \$225 (£ 143) million per year and 200,000
51 intensive care unit days/year⁶. The cost of CR-BSIs has been calculated to be approximately \$33,000-
52 \$35,000 (£20,915-22,183) per episode making it a relevant cost issue^{7,8,9}.

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54 Occlusions are common¹⁰ and under reported with about half directly related to thrombus
55 formation¹¹. Intraluminal reflux related thrombi rates are reported as 5%-25%¹² of occlusions. Fibrin

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56 deposition on the intraluminal surfaces of the intravenous (IV) connector fluid pathway and catheter has
57 been shown to also increase the risk of coagulase-negative staphylococci infection¹¹. Therefore, through
58 several mechanisms thrombosis has been shown to enhance the risk of infection¹³. Interestingly,
59 prevention of occlusions may rely heavily on patient assessment and this has not been recognized by
60 healthcare practitioners. The importance of understanding current connectors research and its association
61 with their care, maintenance and educational needs is imperative to professional best care practices.

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63 While the primary responsibility for care and maintenance of a VAD falls on nursing practice, it is
64 extremely important for all healthcare professionals to understand how these complications occur and
65 how they are prevented. It is only when everyone focuses on the two primary prevention strategies;
66 minimize micro-organisms entry into the system, and minimize adhesion that the successful outcome of a
67 VAD remaining safely in place and complication free for the required duration (brief or prolonged) can be
68 accomplished.

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70 This article will focus on the intraluminal fluid pathway and the role needleless IV connector's play in the
71 development of CR-BSIs and occlusions. Best practice requires that practitioners have specific
72 knowledge of connector technology as well as patient factors for caring for VADs in order to provide safe
73 care. There is a large gap in the scientific literature and in policies and procedures related to evidenced
74 based decision making associated with care and maintenance of needleless intravenous connectors. An
75 understanding of needleless IV connectors is necessary to meld research and practice together for best
76 patient practices, so the occurrences of CR-BSI's and occlusions can be mitigated and eliminated.

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77 **NEEDLELESS IV CONNECTOR OVERVIEW**

78 The IV connector is referred to by many different names such as "hep-locks", "male adaptors", "Luer-
79 locks", "split septums", "caps" and "INTs" to name a few. Needleless IV connectors entered the healthcare
80 setting in the 1990's as a means of preventing needle sticks and decreasing the potential for human
81 immunodeficiency virus transmission. During the last decade research findings have questioned the role
82 of IV connectors by category and as contributors to CR-BSI^{14,15}. In 2010, nine design features were
83 outlined as variables that impacted CR-BSI including: septum surface, septum seal, fluid pathway design,

presence of dead space, presence of internal mechanism in the fluid pathway, clamping sequence, visibility, blood reflux and flushing solution¹⁶. All IV connectors available today have four elements in common: an external housing, a septum which is the entry point of the connector, a fluid pathway, and a mechanism for returning the septum to its original closed position with disconnection. Dead space, which exists in most connectors, refers to areas within the fluid pathway that cannot be cleared when flushing. Dead space is often required for the closing mechanism. The designs of IV connectors based on these four elements vary greatly from connector to connector.

There are three major types of needleless IV connectors based on reflux known as negative, positive, and neutral fluid displacement⁷. Connector designs evolved over a decade with changes made to improve usability and to minimize occlusion associated with use. The first type was negative mechanical valves (NMV). Reflux occurs with disconnection. Total or partial occlusion^{11,18} is associated with NMV reflux. In addition NMVs have been associated with CR-BSI¹⁹. The second type is positive pressure mechanical valves (PPMV) and with this type reflux occurs with connection. PPMVs have been associated with increased bloodstream infections^{20,21}. These are under FDA (USA) investigation for possibly causing deaths²². The last and most recent type is neutral. With neutral connectors there is no reflux with either connection or disconnection. Several studies reveal that specific connectors are associated with an increased risk of blood stream infections^{19,20,23,24} including PPMVs^{14,25}, while other studies show a lower rate of CR-BSIs^{26,27,28,29,30}. It is not one design feature that is important in connector design and their associated outcomes, but the combination of all the design features outlined by Dr. Jarvis¹⁶ that will impact complication reductions and eliminations.

CARE & MAINTENANCE OF CONNECTORS

Strategies to prevent intraluminal complications must be two-pronged; 1) prevent the active and passive migration of microorganisms into the intraluminal fluid pathway, and 2) prevent catheter wall adhesion. This approach will block bacterial colonization and biofilm formation. Practice has only two actions for intraluminal care, swabbing the connector septum for disinfection and flushing the fluid pathway to remove residue after use to eliminate the primary building block that enables wall adhesion.

Septum Disinfection of Connectors

112 Septum disinfection is the first action necessary to prevent bacterial migration. In the US it has been the
113 care giver who has received the attention. The needleless IV connector must be swabbed before each
114 access. 70% alcohol alone or Chlorhexidine (CHG) alcohol are the two most common disinfection agents
115 selected by institutions in the United States. This protocol results in three or four (if using heparin as a final
116 flush) separate swabbing actions with each IV push medication or blood draw. It is common for
117 connectors to be accessed repeatedly during a patient care shift and in many different healthcare areas
118 (e.g. xray, nuclear med, OR). In the US, there has been an increase in swabbing times to 15- 30 seconds
119 in an attempt to improve disinfection. This action has placed the entire burden on the care provider and
120 may not be clinically realistic. Even with conventional disinfection with 70% alcohol one study of NMVs
121 revealed 67% transmit microorganisms ranging from 442 to 25,000 colony-forming units³¹ and it is known
122 that greater than 15 colony-forming units can lead to sepsis³². Another study revealed a range of colony
123 forming units for different connectors, post 70% alcohol swab using downward pressure and 3 rotations,
124 to range from zero to over 13,500 for 4 different bacteria lending data to the knowledge base that
125 connector septum design is a significant variable in the development of infections³³. Connector design
126 has not been considered even though research has confirmed that complete disinfection of some IV
127 connectors septum's surfaces is difficult and in fact may not be achievable at high rates in the clinical
128 setting^{31,34}.

129
130 To increase septum disinfection success, the septum should be made of hydrophobic material and be
131 smooth without irregularities to prevent bacteria from sticking. The septum seal should be tight when not
132 activated so that there are no areas that lie outside disinfectant contact. When relying on research to set
133 the swabbing practice, it is important to remember that generalization of research findings to connectors
134 not included in the study is problematic. Long, complicated swabbing practices are cumbersome and
135 difficult to consistently perform in the healthcare setting. Selecting a connector that can be swabbed
136 simply with > 99% bacterial kill will improve compliance. The new alcohol caps provide a continuous
137 passive disinfection approach. However, the connector needs to be swabbed prior to applying a new
138 cap. This is not widely understood in the clinical setting. A properly designed connector should not
139 require add-ons to enhance practice outcomes. Ask IV connector manufacturers for independent research

140 in this area and if they have none be weary of using the product. If the manufacturer tells you to follow
141 your hospital policy on swabbing do NOT accept this as valid as it is not research based and is actually
142 an admission that the manufacturers have no research on their product. This lack of research and
143 evidence does not support evidence based nursing practice and can be detrimental to patient
144 outcomes. Research on one neutral fluid displacement connector, validated through an *in vitro* study by
145 Nelson laboratories (Salt Lake City, UT), that 3-5 twists of swabbing with 70% alcohol pad, like squeezing
146 an orange, removes 100% of bacteria³⁵. The connector septum provides an environment that supports
147 simple effective practice.

148 **CLEARING THE INTRALUMINAL PATHWAY**

149 Flushing is the only mechanism available in the clinical setting to clear the intraluminal fluid pathway.
150 Blood is routinely withdrawn prior to injection to check for patency and confirm venous placement. With
151 withdrawal the entire fluid pathway is filled with blood. In order for flushing to be successful, the fluid
152 pathway must be straight. This is because fluid follows the path of least resistance therefore anything
153 outside this pathway (dead space) will not come in contact with the flushing solution. These areas
154 outside the pathway continue to have blood and medication residue providing an environment for
155 bacterial growth. Fibrin deposition on the intraluminal surfaces of the fluid pathway increases the risk of
156 coagulase-negative staphylococci infection¹² and occlusions. Thrombosis has been shown to enhance
157 the risk of infection¹³ Edminston³⁶ inoculated connector intraluminal fluid pathways and reported that
158 increased intraluminal fluid pathway volume corresponds to higher organism growth rates. With a larger
159 internal volume there was increased area outside the fluid pathway. A small unobstructed, straight fluid
160 pathway provides an area where 100% of the pathway surface comes into contact with the flush solution.
161 An *in vitro* study showed that a connector designed with a very small priming volume (0.027 mL) and using
162 as little as 1 mL saline flush 99.96% and with 4 mL saline that 100% of microscopic hemoglobin was
163 removed³⁷.

164 It is practice in some institutions in the US to use a push-pause flushing method. This practice became
165 very popular because it was hypothesized that fluid turbulence enhances the "scrubbing" action of the
166 flush. No research is available to support this practice. Donlan³⁸, a leader in biofilm science, reported in
167 2002 that turbulent flow actually enhances bacterial adhesion and that a steady flush minimizes adhesion.

168 No research exists that focuses flushing on patient diagnosis yet many patients are at high risk for
 169 occlusion (Table 1). Performing the identical flushing procedures with all patients may result in uneven
 170 outcomes and research is needed in this area.

171 Table 1: Patients at High Risk For Vascular Access Occlusion

Acute Spinal Cord Injury
Advanced Age
Bone Marrow Transplant
Brain Tumor
Catheters Placed via the Left Subclavian Vein
Catheter Tip Location in Subclavian Vein
Chronic Obstructive Pulmonary Disease
Dehydration
Diabetes
High Platelet Levels
History of Deep Vein Thrombosis
Lung Cancer
Major Trauma Gynecologic Malignancies
Malposition of the Catheter
Oral Contraceptive Use
Pregnancy
Renal Failure
Sickle Cell Anemia
Trauma Patients

172 Negative and positive connectors have reflux associated with usage. Reflux occurs either with
 173 disconnection (NNV) or connection (PPV). Mitigating reflux depends on the practitioner's ability to identify
 174 the connector by type and then apply the correct clamping sequence¹⁷ either clamping before
 175 disconnection (NNV) or disconnecting and then clamping (PPV). There is no clamping sequence with
 176 neutral connectors because there is no reflux with either connection or disconnection. However, when
 177 using the Y-port on any IV administration tubing a clamping sequence cannot be used and reflux cannot
 178 be mitigated. Many institutions use more than one type of connector necessitating the care practitioner to
 179 visually identify the connector type and then select the correct clamping sequence. The package label
 180 usually does not identify the connector type or which clamping sequence to use. This makes the
 181 practitioner's job more difficult. Using the wrong sequence means that occlusion is more prevalent when
 182 using a negative pressure system^{39,40} with reflux occurring with disconnection. Occlusion incidence is less
 183 using one neutral connector⁴¹. Selecting one IV connector to be used exclusively throughout the
 184 institution enhances education and ultimately improves procedure compliance¹⁴. Knowledge about
 185 connector design and associated best flushing practices will help in overcoming CR-BSIs and occlusions.

187 EDUCATION

188 The prevention of CR-BSIs and occlusions are possible but requires education of healthcare providers on
189 complication cause, care and maintenance actions related to the specific IV connector, and continual
190 current research evaluation with associated implementation of policy and practice changes. Research
191 reveals, for example, that 78% of acute care nurses are uninformed about different connector types and
192 their specific, yet opposing, care⁴³. Forty three percent of nurses could not name 2 complications
193 associated with IV connectors (e.g.: infection, occlusion, thrombosis) and 64% are involved with 4 to 5
194 hours of IV therapy care and maintenance per 12 hour nursing shift, making IV therapy an important
195 clinical issue and educational necessity⁴³. There has been no research done looking at similar issues
196 with other care providers who have contact with IVs. However, there are neither courses nor enough
197 lectures in most healthcare provider programs on IV therapy, though information related to science and
198 research has resulted in several books being published in the area of IV therapy.

199

200 The ability of healthcare providers to collect cues related to needless IV connector problems begins with
201 education on information that is basic, understandable, differentiating and complete to aid in clinical
202 reasoning. Patient assessment, knowledge of technology and specific care are required to best protect
203 the intraluminal fluid pathway of VADs^{26,44-47}. Without knowledge and appropriate interventions
204 intraluminal protection becomes compromised and there can be an increase in CR-BSI, occlusions,
205 thrombi and potential associated deaths.

206 RESEARCH FRAMEWORK

207 For nursing and medical research associated with VADs the Healthcare And Technology Synergy (HATS)
208 framework (Figure 1) is appropriate. This framework⁴⁸ represents a synergy between three major
209 variables (patient, product, practice) with each one affecting the others and being affected by the others.
210 This framework adds a more holistic and comprehensive approach to comparative effectiveness and
211 evidence based practice research and when translating findings to bedside care. Using connectors as an
212 example the patient variables to be considered, though not an exhaustive list, include age, diagnosis,
213 comorbidities, therapeutic regimens, projected length of stay, physical assessment, mental health status,
214 transcultural beliefs, finances, and length of treatment including current needs and recurring needs.

Product variables may include the following; intravenous connectors categorized on the basis of reflux as well as bacterial and biofilm growth as previously discussed, connector septum design including septum seal tightness, fluid pathway design, type of VAD, insertion site, and number of catheter lumens. Practice variables may include connector septum disinfection practice, dressing management, clamping sequence, flushing practice including solution(s) and time frequency (eg: 10 mL normal saline every 6 hours), the education and skill levels of the nurse specific to vascular access, availability of specialized vascular access teams, and nurse-patient staffing ratios. A multicenter, quasi experimental, 140 month/50,080 catheter days, acute care study comparing central line-associated bloodstream infection rates associated with PPMV and NPMV before and after changing only the connector to a neutral connector. There was a statistically significant higher CR-BSI rate when either NPMV ($P = .001$) or PPMV ($P = .032$) were used.³⁰ Product can be a variable and if not specifically studied should be noted as a limitation. Research in some of these areas have already been implemented, presented and/or published.^{26-29,44,49,50}

PATIENT IV CONNECTOR ASSESSMENT

If proper care of a needless IV connector depends on the type of connector, then it may be helpful to answer questions the following prior any care activities.

What type of connector does my patient have? Is it negative, positive or neutral?

Do I have the materials, skills and knowledge to correctly implement scrubbing the hub and flushing?

Do I have the knowledge to implement appropriate disconnection?

When should I change the connector? This time frame should be specifically stated by the manufacturer as "follow your usual hospital policy" is meaningless to care.

Does the patient have a three way stop cock? The use of open stop cocks increased bloodstream infections when compared to using IV connectors to cover entry hubs⁵⁰.

SUMMARY

- Connector design and category impact occlusion and CR-BSI rates.
- Connector design impacts disinfection and flushing practice success.

- Best practice requires that health care professionals have specific knowledge of connector technology as well as patient factors for caring for vascular access devices.
- The more desirable design features a connector has included in its final product the more user friendly the connector will be and the less complications you will encounter.
- Without specific knowledge regarding connector technology there is an increase in the potential for sepsis, catheter occlusion and death.
- When the connector surface is not properly disinfected, flushed, and/or disconnected then bacteria can enter the intraluminal fluid pathway, adhere to the internal surface, colonize and develop biofilm increasing the risk for patient infection and sepsis.
- Healthcare providers should demand that manufactured connector devices be developed with fail-safe engineering advances aimed at further mitigation of risk of infection in the complex hospital environment and devices that include ease of use by the nurse.
- The addition of alcohol caps is another step to implement and one that should not be necessary with a properly designed connector. Additional steps to care also increase human error.
- Instituting the "Healthcare And Technology Synergy (HATS)" framework that includes "Patient, Practice, Product", into intravenous practice settings and within research is paramount to a better understanding of intraluminal vascular access infections.
- The frequent usage and care of connectors in all healthcare settings makes connectors significant variables for practice and comparative effectiveness and outcomes research.
- There are large gaps in the scientific literature, policies and procedures in regards to unbiased evidenced based decision making, care and maintenance related to needleless connectors.

CONCLUSIONS

An increased understanding of connector design's impact on the intraluminal fluid pathway combined with evidence based practice can prevent CR-BSI's and occlusions through preventing the active and passive migration of microorganisms into the fluid pathway and preventing microorganism adhesion to the catheter surface. The connector, as the gatekeeper to the intraluminal fluid pathway, plays a significant and vital role in the prevention of patient complications, including death. The best designed connector

270 should include^{ALL} design features outlined by Dr. WR Jarvis¹⁶ Best practice requires utilization of
271 research in the development and implementation of policy and procedures associated with needleless
272 intravenous connector care and maintenance. Product should be considered an important variable when
273 designing research. Practice should not be the entire focus for change to improve outcomes. Also, the
274 potential of value enhanced purchasing can best be accomplished through inclusion of evidence. Through
275 a combination of research and education there could be a very significant decrease in 'one every minute'
276 CR-BSI's and vascular access catheter occlusions.

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427 Figure 1: Healthcare And Technology Synergy (HATS) Framework

