Technology and Practice: Collaboration for successful positive patient outcomes

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BACKGROUND: In the healthcare industry today, over five million central venous catheters (CVC) are placed yearly. Central venous access has moved from the periphery of health care to the center of patient care. According to the FDA, major complications occur in approximately 10% of all patients with a CVC. As many as 10% to 25% of hospital admissions are related to CVC complications (Haire, 2000). Furthermore, the correlation between patients with vascular access devices who also become infected by a primary bacteremia is well documented. Ninety-six percent of bloodstream infections are primary bacteremias. Eighty-seven percent of primary bacteremias are catheter related (CRBSI) (Jarvis 2006). CRBSI patient morbidity has been reported to range from 2% - 35% with the highest rates occurring in intensive care (ICU). Based on a nosocomial infection rate of 5%, of which 10% are bloodstream infections, and an attributable mortality rate of 15%, bloodstream infections would represent the eighth leading cause of death in the United States. (Wenzel 2001). The annual cost for CRBSI exceeds 11 billion dollars (Maki 2005). However, hospital reimbursement for CRBSI is much lower and will continue to deteriorate when the Medicare reimbursement for preventable hospital infections is readjusted in 2008 as part of the Federal Deficit Reduction act of 2005.

The Centers for Disease Control and Prevention (CDC) has set a goal of decreasing catheter-associated adverse events by 50% as one of its top patient safety challenges. While developing strategies to reduce CRBSI, it is important to remember that each patient has a set of risk factors that impact outcome. In addition, the nursing shortage, the increasing nurse/patient ratio, the lack of vascular access education in nursing schools, and the shrinking availability of IV experts means that there is greater potential for inconsistent CVC care and maintenance. To achieve sustained low CRBSI outcomes in today’s complex and dynamic healthcare environment, product innovation must not only impact infection processes but also support successful clinician CVC care and maintenance.

The purpose of this paper is to review the causes of CRBSI and identify behavior based practices and technology innovations that when combined will achieve significantly reduced CRBSI.

CRBSI OVERVIEW

CRBSI are caused by the migration of organisms through the cutaneous insertion site and down the catheter track (extraluminal) and/or, through the fluid pathway (intraluminal) into the venous bloodstream. Previous studies indicate that approximately 50% of infections are extraluminal, whereas the remaining 50% are intraluminal. (Ryder, 2006) Once organisms gain access to the CVC, infection
occurs as a result of the bacteria’s ability to adhere to the catheter surface, colonize, and develop biofilm. (Ryder 2006, Moureau 2002, Harbash 2003). While extraluminal colonization is documented to occur around 10 days, the intraluminal colonization occurs as early as 3 days. (De Cicco 2003) Over the past 15 years length of stay has continued to decline less than 5 days today. CVC femoral and jugular insertion sites have also proven to be associated with high CRBSI rates and may be colonized early. Hospital acquired infections by definition occur within the first five (5) days after admission. With this in mind intraluminal contamination must be considered a primary CRBSI nidus.

**Average Length of Hospital* Stay, by Diagnostic Category† — United States, 2003**

<table>
<thead>
<tr>
<th>Category</th>
<th>Days</th>
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<tbody>
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<td>Psychos</td>
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**Intraluminal Fluid Pathway**

Since the introduction of needle-free IV connectors to the market in the early 1990’s, increases in CRBSI have been reported in the literature. Septum design includes problems with septum disinfectant. Research has demonstrated that complete eradication of septum surface contamination is difficult and that in fact, may not be achievable at high rates in the clinical setting. (Seymour 2000, Cmich, 2002) It is known that bacteria enter the intraluminal fluid pathway through the septum. This can happen passively or by being pushed by the syringe luer tip during access. Fibrin is the building block for bacterial adhesion. Normal CVC usage provides multiple opportunities for fibrin buildup. Withdrawing blood prior to infusion to check for catheter position and patency is done with each access. Routine blood sampling is a primary purpose for CVC placement. In addition repetitive blood reflux episodes occur with syringe or IV set removal from split septum or non positive pressure connectors; or with connection to a positive pressure IV connector. As needle-free IV connectors evolved over the past 15 years, the fluid pathway design has become more tortuous, and the associated dead space within the fluid pathway increased. The fibrin deposited in dead space can not be removed with flushing. Research has shown that there has been a significant rise in CRBSI rates especially over the past 6 years with the advent of positive pressure IV connectors in the late 1990’s. (Jarvis, 2005 Maragakis, 2006) The positive pressure connectors have the most tortuous fluid pathway design and associated dead space. The fluid infusing and the heparin lock left in the fluid pathway provide the food source for bacterial colonization.

**Current Prevention Strategies**

**Extraluminal**

Extraluminal prevention strategies have been researched and include both behavior based activities and technology. The products support clinical activities as well as interrupt both the movement of bacteria through the insertion site and their successful colonization on the external catheter wall.
**Behavior Based**
- Full barrier precautions for all central venous catheter insertions;
- Routine and PRN dressing changes;
- Education of health-care providers on the prevention of CRBSI;

**Technology Based**
- New antiseptic hand washing formulations;
- New skin antiseptic formulations;
- Impregnated external catheter surface with antibiotics, silver, chlorhexidine gluconate, heparin alone or in combination;
- Chlorhexidine Gluconate impregnated foam disc;
- Stabilization system to minimize catheter movement;

**Intraluminal**
Intraluminal prevention strategies are dependent on behavior practices. There is only on product that is designed to protect the fluid pathway.

**Behavior Based**
- Utilizing aseptic technique when changing tubing and/or IV connectors;
- Minimizing breaks in the complete IV administration system;
- Cleansing the catheter hub with approved antiseptic before attaching tubing or IV connector
- Flushing the catheter after each use to clean the IV connector and catheter lumen;
- Using positive pressure on the syringe plunger when disconnecting from a non positive pressure IV connector;
- Instilling final heparin or normal saline only lock;
- Changing IV administration set components and IV connectors at regular intervals;
- Education of health-care providers on care and maintenance of central venous catheters.

**Technology Based**
- New Patient Fluid Pathway Protected needle-free IV connector;

**CRBSI Bundle**
One approach to improving hospital acquired infections has been the development of practice bundles. The Institute for Healthcare Improvement (IHI) defines a bundle as a structured way of improving the processes of care and patient outcomes: a small, straightforward set of practices that, when performed collectively and reliably, are proven to improve patient outcomes. Developing a successful CVC bundle must combine not only extraluminal and intraluminal clinical behavior practices that prevent contamination, migration, adhesion and colonization, but also includes products that support and enhance these activities. In order for the proposed CVC bundle to be widely acceptable, practices and products must be supported by research, require minimal change in the practice setting, be easy to duplicate consistently and be cost effective. Hospital education must be developed to support the bundle, and ensure compliance.

**Proposed CVC Bundle:**
- Hand washing with approved antiseptic formulations before and after every CVC procedure;
- Chloraprep®, (Medi-Flex Inc. (Enturia, Inc.) Leawood, KS) 2% Chlorhexidine Gluconate or 2% Chlorhexidine Gluconate/70% Isopropyl Alcohol skin prep with every CVC insertion and dressing change;
• Full barrier precautions with every CVC insertion;
• PICC selected as CVC of choice when possible;
• Biopatch® Antimicrobial Dressing with Chlorhexidine Gluconate applied at time of insertion and replaced weekly with dressing change;
• StatLock® Catheter Securement Device placed at time of insertion and changed with dressing changes;
• InVision Plus® Neutral® IV Connector;
• Septum cleansing with approved disinfective before each access;
• Normal Saline flush (manually at least once per shift);

Hand Washing

Health care workers hands have been identified as the primary source of organism transmission from patient to patient. Many studies have shown that traditional soap and water compliance to be low. Research has determined that the use of a alcohol-based waterless product is associated with significantly improved hand hygiene (Kampf 2003) and more importantly compliance (Bischoff 2000). The new CDC hand hygiene guideline recommends using an alcohol-based waterless product.

2% Chlorhexidine Gluconate Formulations

While organisms are transferred to the skin surface by air, hands and clothes, the skin is populated by normal flora as well. The bacteria most likely to produce CRBSI are the coagulase negative staphylocci - Staphyloccous epidermis. Other microorganisms associated with CRBSI are C. albicans, S. aureus, MRSA, P. aeruginosa, E. coli, e. faecalis, and K. pneumonia. Because bacteria are distributed throughout the epidermis layers, the skin can not be sterilized (repopulates in 18 hours). Much research has demonstrated that a combination of 70% isopropyl alcohol and 2% chlorhexidine gluconate (Chloraprep®, Medi-Flex Inc. (Enturia, Inc.) Leawood, KS) enhance skin disinfection. Alcohol is active when wet and dries quickly. Chlorhexidine gluconate (CHG) is chemically active for a least 6 hours and is not affected by blood or other organic material (common with CVCs). In addition CHG is persistent (effectiveness increases over time).

Full Barrier Precautions

The primary event for organism entry into the catheter site is when the catheter is pushed through the skin. Full barrier precautions including head cover, foot cover, and full surgical drape should be used with all CVC insertions including PICC. The CDC recommends that full barrier precautions be used with CVC insertion. When performing bedside insertion, compliance with this recommendation has proven to be inconsistent. Processes that enhance compliance such as checklists should be used.

PICC

The skin has different characterizations depending on body location. The upper chest, neck, and groin are warm, moist, and dark, while the arm is dry and light. The difference in normal skin bacteria counts between the subclavian/jugular location and the anticubital fossa is 1,000 fold (10,000 cfu/cm² vs. 10 cfu/cm²). Research has shown that PICCs have lower infection rates than jugular or subclavian insertion sites. (Safdar. Maki, 2005 O'Grady 2002) Evidence has demonstrated increased success rates and safety for central line insertions performed using ultrasound. This method is recommended by the Agency for healthcare Research and Quality and the American College of Emergency.

Antimicrobial Dressing with Chlorhexidine Gluconate
Current research determined that the use of a 2% Chlorhexidine Gluconate foam sponge (Biopatch®, Johnson & Johnson Wound Management, Cincinnati, OH)) over the insertion site significantly reduces colonization of the insertion site (Hanazaki 1999, Maki 2000, Crawford 2004). The use of the sponge disc allows for dressing changes every 7 days without skin repopulation around the insertion site.

**InVision-Plus® Neutral® IV Connector System**

The *InVision-Plus Neutral I.V. Connector System* (RyMed Technologies, Inc., Franklin, TN) offers the first IV connector specifically developed to prevent CRBSI related to the intraluminal IV connector and catheter fluid pathway. It is designed to support clinician care and maintenance activities as well as offer protection against access to the fluid pathway when not in use.

The *InVision-Plus Neutral* is available in a patented “Touch-Free” package design that assists the clinician in preventing hand and catheter hub contamination. To enhance clinician disinfection the *InVision-Plus® Neutral®* has a uniquely sealed designed surface with no gaps or openings that allows for effective disinfection with current swabbing practices.

To prevent migration into the fluid pathway the *InVision-Plus® Neutral®* has a second internal microbial barrier which covers the fluid pathway when the septum returns to the closed position. The fluid pathway is completely closed when not in use preventing bacterial fluid pathway ingress.

To minimize fibrin adhesion, when a tubing or syringe is connected to the *InVision-Plus® Neutral®*, the two silicone barriers are compressed, opening the straight-through fluid pathway that has a 0.027 priming volume and no dead space. A recent in-vitro study has demonstrated luer-activated needle-free IV connector priming volumes as a predictor of biofilm formation (Cook, Meyer, Luchsinger 2007). In this study, the InVision-Plus Neutral; with a priming volume of 0.027mL was 92% - 99.9% better in reducing the chance for biofilm formation than any other needle-free IV. Connector system tested. This design supports clinician flushing activities developed to “clean” the fluid pathway. In addition, with the *InVision-Plus® Neutral®* connector there is no reflux of blood into the catheter with either connection or disconnection. This neutral fluid displacement feature eliminates repeated reflux episodes associated with either connection or disconnection. With every IV push medication or blood sampling there are at least three accesses (Saline, Med, Saline) or four if a final heparin flush is policy. If a patient has four therapies a day 12-16 reflux episodes are eliminated. Over a 5 day admission 48-64 reflux episodes are eliminated. This connector targets all the identified factors influencing intraluminal CRBSI and thrombocytic occlusion. Research has shown a relationship between occlusion and CRBSI.

The *InVision-Plus® Neutral® I.V. Connector* has been used successfully with a saline flush only protocol, reducing the risk for heparin-induced thrombocytopenia (White 2006). Saline flush only removes a bacterial food source.

**Septum Disinfection**

Cleansing the septum prior to connection is a critical process in preventing bacterial migration into the fluid pathway. The CDC recommends cleaning access ports with 70% alcohol or an iodophor prior to each access. The length of time and the correct technique for swabbing has not been determined. However, research has shown that some connector septum surfaces continue to be contaminated after swabbing (Crinch 2002). Some IV connector surfaces are irregular, many have gaps abetween the septum and the connector housing. Swabbing procedures typically use 3 – 10 second swabbing times. However, in some clinical settings longer times are used. Friction is required. The entire
surface including threads must be cleaned. Any blood residue must be removed. Alcohol and iodophors are active when wet. Once applied these solutions should be allowed to dry completely.

Catheter Securement Device
Catheter stabilization minimizes insertion site and catheter tract trauma. The physiological responses to this trauma are edema, interstitial fluid secretion, inflammation. The edema causes the insertion site to enlarge. Moisture promotes passive bacterial migration down the extraluminal catheter tract. Wall inflammation enhances the physiologic healing response leading to fibrin buildup. Pistoning (moving in and out of the insertion site) of the CVC occurs with patient movement. This movement moves pathogens on the skin into the catheter tract. Sutures were found to be a source of infection and did little to prevent pistoning. StatLock® Catheter Securement Device (Bard Medical Division, Covington, GA) has been shown to minimize catheter movement and significantly reduce CRBSI (Yamamoto, 2002).

Saline Only Flush
Normal saline flushing reduces the potential risk of heparin-induced thrombocytopenia (HIT) along with a significant cost savings to the healthcare provider. The common use of infusion pumps with continuous fluids and piggyback medications had resulted in manual flushing not being routinely done. Catheter clearance is accomplished with continuous fluid infusion. The continuous fluid rate may not be sufficient and lacks turbidity necessary clean the fluid pathway. Manual flushing permits the clinician to use a larger volume and provide a turbulent flushing episode. The clinician is able to assess the fluid pathway for resistance and institute interventions early.

DISCUSSION
Historically, all products and behaviors identified in the proposed bundle have been used alone or in groupings. It is the premise of bundle development that it is the synergy of the strategies when applied together that results in positive results. In conjunction with adding the InVision-Plus Neutral I.V. Connector System to their existing CVC care two hospitals experienced significant reduction in CRBSI. InVision-Plus® Neutral® I.V. Connector implementation.

Hospital A – California (32 ICU beds)
Bundle components in place prior to InVision-Plus Neutral I.V. Connector Conversion
• Waterless Hand Sanitizer;
• Chloraprep skin prep;
• Full Barrier Precautions with all CVC (including PICC) insertions;
• Ultrasound PICC placement;
• 5-10 second swab with each IV connector access;

Bundle components added at time of InVision-Plus Neutral I.V. Connector conversion
• Biopatch,
• Saline flush only
• Manual saline flush once each shift

RESULTS: The CRBSI rate was lowered to “zero” during the first quarter after InVision-Plus Neutral I.V. Connector implementation and continued at “zero” rate for an additional four quarters. At the time of this publication, the CRBSI rate continues at “zero”.
Hospital B – Missouri (12 Medical ICU Beds)

Follows CDC NNIS (National Nosocomial Infections Surveillance) definitions for laboratory confirmed bloodstream infection (LCBI)

Pre-intervention 2005 rate: 8.5 (14 infections/1,648 device days)

Internal medicine and OB/GYN teaching facility; 307 staffed beds

Primarily utilizes non-antimicrobial coated triple lumen central line catheters

Bundle components in place prior to InVision-Plus® Neutral® I.V. Connector Conversion

- MaxPlus (Medegen) IV connector;
- Waterless Hand Sanitizer;
- Chloraprep skin prep;
- Full Barrier Precautions with all CVC (including PICC) insertions;
- Ultrasound PICC placement by a IV Therapy team;
- StatLock;
- 3 second swab with 70% isopropyl alcohol pad prior to each IV connector access;

Bundle components added at time of InVision-Plus Neutral I.V. Connector conversion

- Saline flush only

**RESULTS:** A "zero" triple lumen CRBSI rate out of 374 device days was achieved for the first quarter of InVision-Plus Neutral implementation in the Medical ICU. Biopatch was implemented November 2006 following conversion to the InVision-Plus Neutral in an effort to observe the outcome of each intervention.

When these zero CRBSI results were achieved in two different hospitals, the proposed bundle was developed. It combines products and practices from both settings. Further multi-site bundle implementations need to be trialed to demonstrate both reliability and validity of the bundle.

**Conclusion**

When prevention behavior activities and innovative products are combined, the synergist effect is greater than when the same strategies are used individually. The products identified in the proposed bundle enhance accepted behavior practices related to CVC care and maintenance. They also provide additional design features that interrupt the bacterial migration to colonization cascade. The proposed bundle of behaviors plus products has shown that reducing CRBSI rates to zero is possible. While some of the bundle components have not been widely researched and are instead based on theory or accepted clinical practice, the early proposed CVC outcome provides a basis for additional study and refinement.
REFERENCES


IHI.org What is a Bundle


White K. PICC Occlusion Rates: Prospective Study Comparing Positive Pressure I.V. Connector versus Neutral Displacement I.V. Connector. Poster AVA Indianapolis IN Sept 2006. view at www.rymedtech.com