



## Outbreak of Bloodstream Infection Temporally Associated with the Use of Intravascular Needleless Valve

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### Flaws in the Study:

- A. Data reporting and surveillance of the CRBSI's was not consistent throughout the study period. *"Initially surveillance was conducted every third month; in May 2005, continuous surveillance was instituted."* This change in surveillance began shortly after the institution of the positive pressure luer activated device. The chart in Figure 1 represents a monthly BSI rate of 1000 catheter days which for the baseline period must be a disaggregation of previously reported quarterly data. Comparing actual monthly data to disaggregated quarterly data may limit the value of the comparison.
- B. The positive pressure luer activated device was not used according to the manufacturers' instructions for use. The study reports routinely changing this device at 7-day intervals. The manufacturers' instructions for this particular device suggest changing the device based on number of accesses not the number of days it has been used. As such, the positive pressure luer activated device may have been in use longer than recommended. The Discussion section of this study discusses the increased risk of infection when the connectors are changed less frequently than recommended.
- C. The 6 month period following the discontinuation of the positive pressure luer activated device omits the first two months of CRBSI data due to a "transitional period"; yet there was not an equal "transitional period" between the baseline period and the onset of data collection with the positive pressure device.
- D. Figure 1 Chart B has only two data points represented in the baseline data questioning the significance of the sample size used to determine the baseline rate for this group of inpatient nursing units.
- E. The study involved multiple patients from cooperative care (units where a patient and care partner are housed together in a home like setting) adding a high level of variability to the study groups related catheter maintenance and care. The study does not comment on the homogeneity of the patient populations between study groups.
- F. This reference points out that there was no substantial difference in the proportional of polymicrobial bloodstream infections during the observation periods. This finding is different from the other references that have implicated mechanical valves demonstrating their may have been other factors contributing to the BSI increases in the other studies.
- G. Samples obtained from 9 of the 37 positive displacement luer activated connector's yielded positive results when cultured. All positive samples yielded typical skin flora underlining that proper disinfection of the positive displacement connector did not take place.
- H. The study also reports that in one of the cultured connectors the *"broth was bloody after being flushed through the connector valve."* Once again this demonstrates that the product was not used appropriately. If properly flushed or changes after blood draw there would not have been blood in the connector. The manufacturer of the positive pressure luer activated device used in this study recommends: Replace every 72 hours or 100 activations whichever occurs first. For infusions of blood, blood products or lipid emulsions replace every 24 hours.

### What was studied/reported:

1. Rupp et al. reported an increase in BSI rate with a positive pressure luer activated valve when compared to a split septum device. *"Surveillance for primary bloodstream infection was conducted using standard methods throughout the hospital. Blood culture contamination rates were monitored. Cultures were performed using samples obtained from intravascular catheter connector valves."*

### Conclusions:

2. *"A significant association between primary bloodstream infection and a needleless connector valve was observed. Evaluation of needleless connector valves should include a thorough assessment of infection rates in prospective randomized trials prior to their introduction into the market."*

**Connectors Studied:** Interlink (Before) to Smartsite Plus (After)

### Limitations to Study:

3. *"Limitations of this study must also be emphasized. First, this was not a prospective, randomized trial. These data are retrospective, observational and uncontrolled. In addition, our report details experience at a single institution."*

### Product deficits identified by Author:

4. *"We believe that the design of the connector valve introduced in our hospital in March 2005 may have promoted microbial contamination and colonization. Upon close inspection of the valve, one can observe a shallow depression and a rim between the diaphragm and the plastic housing. It is possible that microbes and debris could collect in this area, which would be relatively resistant to cleansing or disinfection. The internal mechanism of the valve contains moving parts which introduces irregularities in the fluid flow and may promote stagnation and create potential reservoirs for microbial growth. Also, the plastic housing is opaque, which prohibits visual inspection of the connector valve. Therefore, it is possible that blood or infusion products could collect within the valve and because of its opaque nature, go unnoticed by healthcare workers."*

### References Cited:

5. Maragakis et al. *"The device implicated in the outbreak described by Maragakis et al. is the same brand of device temporally associated with the increase in rate of bloodstream infection described in this report."* (Clave to SmartSite Plus)
6. Hall et al. *"In 2004, Hall et al. first reported infection-related concerns regarding the newer devices; reports from other institutions followed."* (Interlink to Ultrasite)