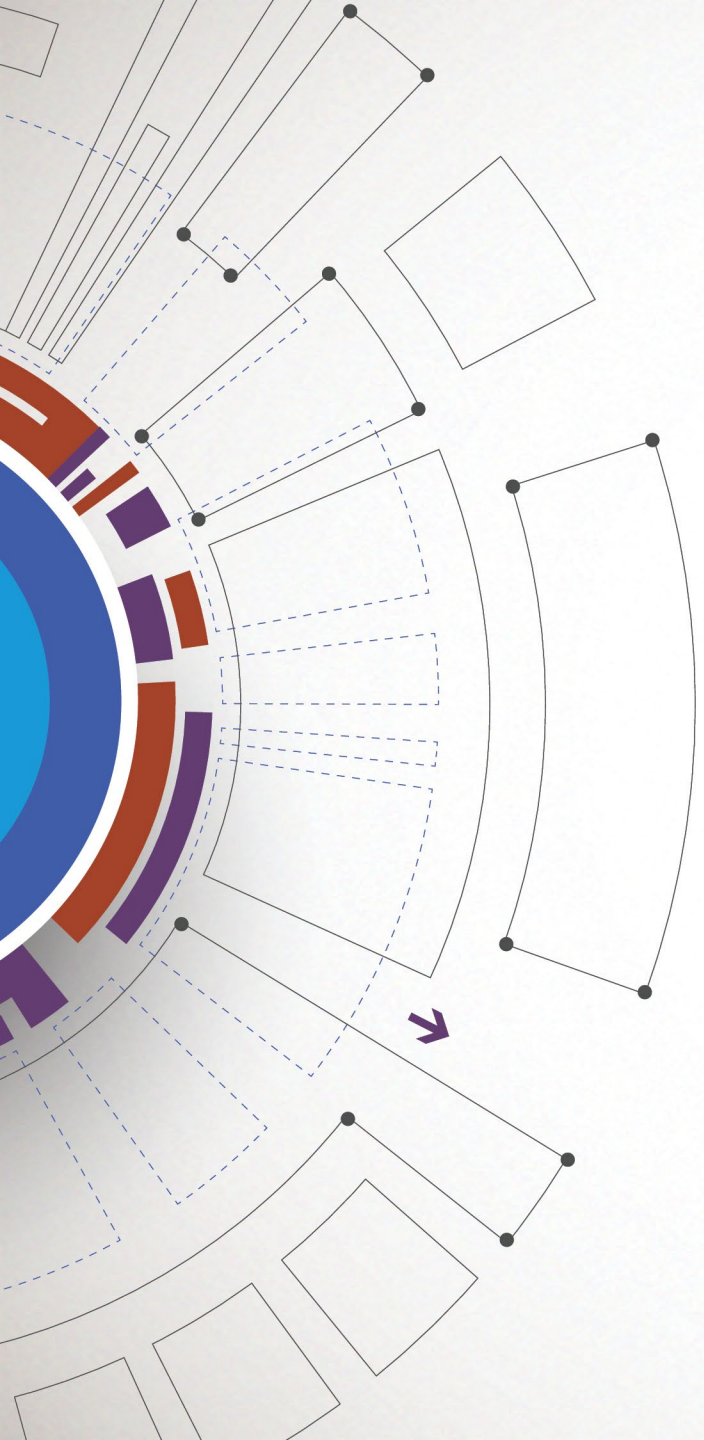




Needleless Connector Design: The impact on intraluminal occlusion and associated infection risk

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Objectives

- **Understand the importance of needle-free connector (NFC) design and its evidence-based effect on vascular catheter related complications**
- **Review evidence from a study which compared the incidence rates of central catheter intraluminal blood occlusions (CVC-IBO) in conjunction with CLABSI in 16 California, USA hospitals, and correlate them with differently designed NFC's.**

Impact of Vascular Catheters

Use of vascular catheters is common in both inpatient and outpatient care.

- In the United States, it is estimated that almost 300 million catheters are utilized each year; nearly 3 million of these are central venous catheters (CVCs).¹
- In the United Kingdom, approximately 250,000 CVCs are utilized annually.²

CVCs play an integral role – with the administration of IV fluids, blood products, medications, parenteral nutrition, as well as providing hemodialysis access, monitoring ,etc.

- However, inherent risks are evident, including bloodstream infections caused by microorganisms. Microorganisms are known of colonizing the external surface of the device, or of the fluid pathway, when the device is inserted, or in the course of its use.³
- CVCs are the most frequent cause of healthcare associated bloodstream infections (HAIs).⁴

Vascular Catheter - Infection Risks

Based on route of entry of bacteria:

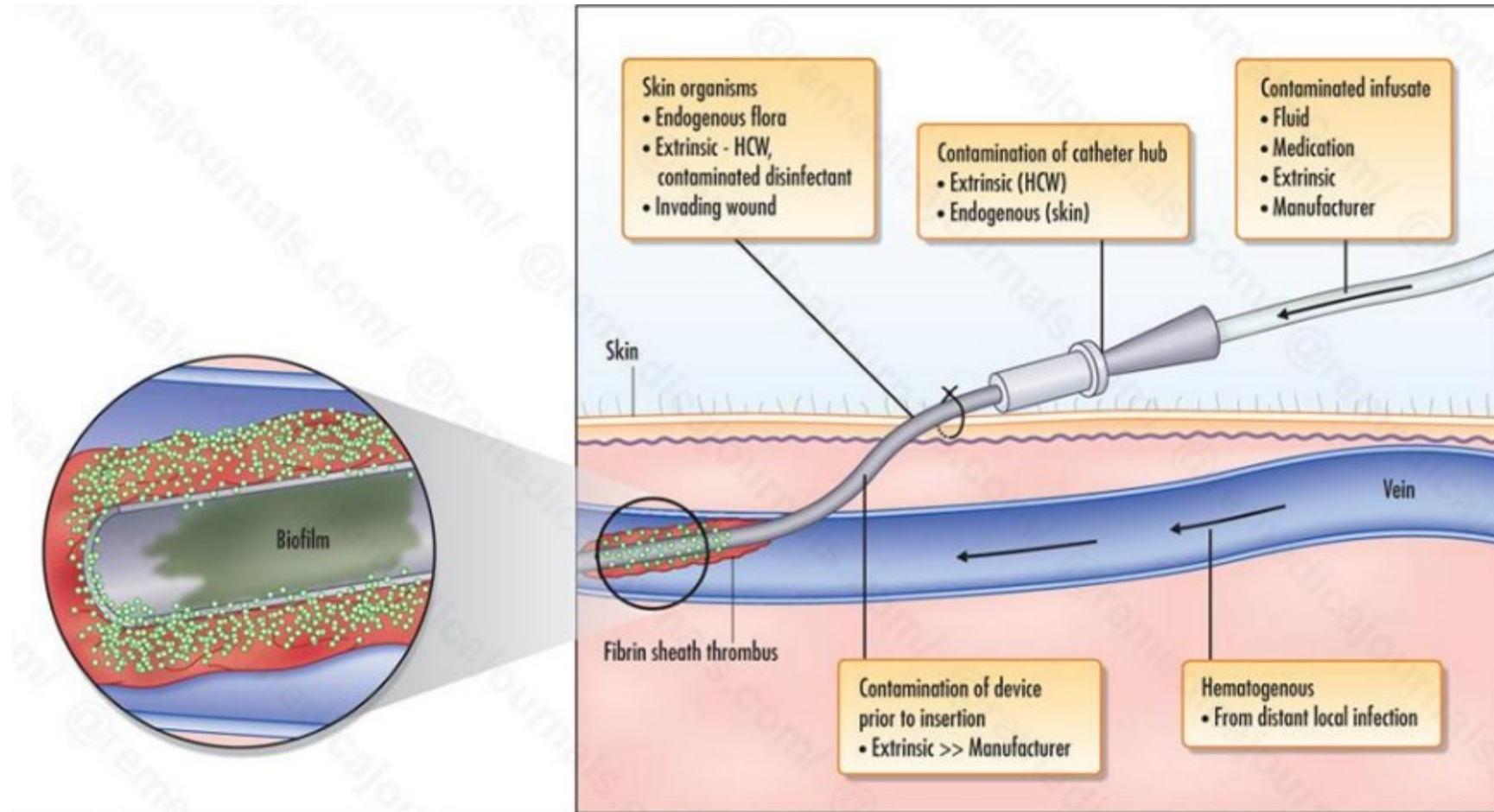
Extraluminal: pathogens migrate along external surface of catheter from skin entry site. Often occurs within 7 days of insertion.

Intraluminal: hub contamination, migration along internal surface of catheter. More commonly occurs >7 days, intraluminal colonization.

Secondary BSI: bacteria from another source in the body infects the blood.

Infusate Contamination: introduction of pathogens from fluids infused through the catheter system.

Pathogenesis of CLABSI



Source: <http://www.remedicajournals.com/The-Journal-of-Invasive-Fungal-Infections/BrowseIssues/Volume-5-Issue-2/Article-The-Story-of-Biofilms>

Needle-Free Connectors

Device Characteristics

- Initially designed to improve patient safety
- Not all designs have evidence-based studies on outcomes
- Numerous connectors utilized in hospitals throughout the world. For example:
 - Negative Displacement
 - Positive Displacement
 - Neutral Displacement



Source: Becton Dickinson

Needle-Free Connector Designs

- Needle-Free Connector (NFC) designs range from simple split-septum devices to more complex constructions containing multiple internal moving components (e.g., mechanical valves), each permitting needleless catheter access.⁵
- NFCs should minimize catheter occlusion risk and allow for easy effective decontamination of the access surface, enabling healthcare workers to reduce needlestick injury and risk to patients.⁶
- The inherent design characteristics of the NFC determine its use and operation.^{6,7}



Source: Becton Dickinson

Needle-Free Connector Designs

- NFCs are accessed by applying pressure from a syringe or tubing by using a blunt plastic cannula or a male luer.⁷
- This applied pressure allows the cannula or male luer to open or depress the NFC septum. Once the cannula or male luer enters the NFC, the fluid flows through a pathway determined by the NFC.⁷
- Fluid paths through NFCs should minimize dead space, areas where fluid can be trapped and cannot be flushed or disinfected and be visibly clear so that clinicians can assess their flush technique.^{5,7}
- Once the fluid is flushed through the NFC, the male luer (or cannula) is removed, and the subsequent fluid displacement at the tip of the catheter can be positive, negative or neutral, depending on the NFC design (**Fig. 1**)

Needle-Free Connector Designs

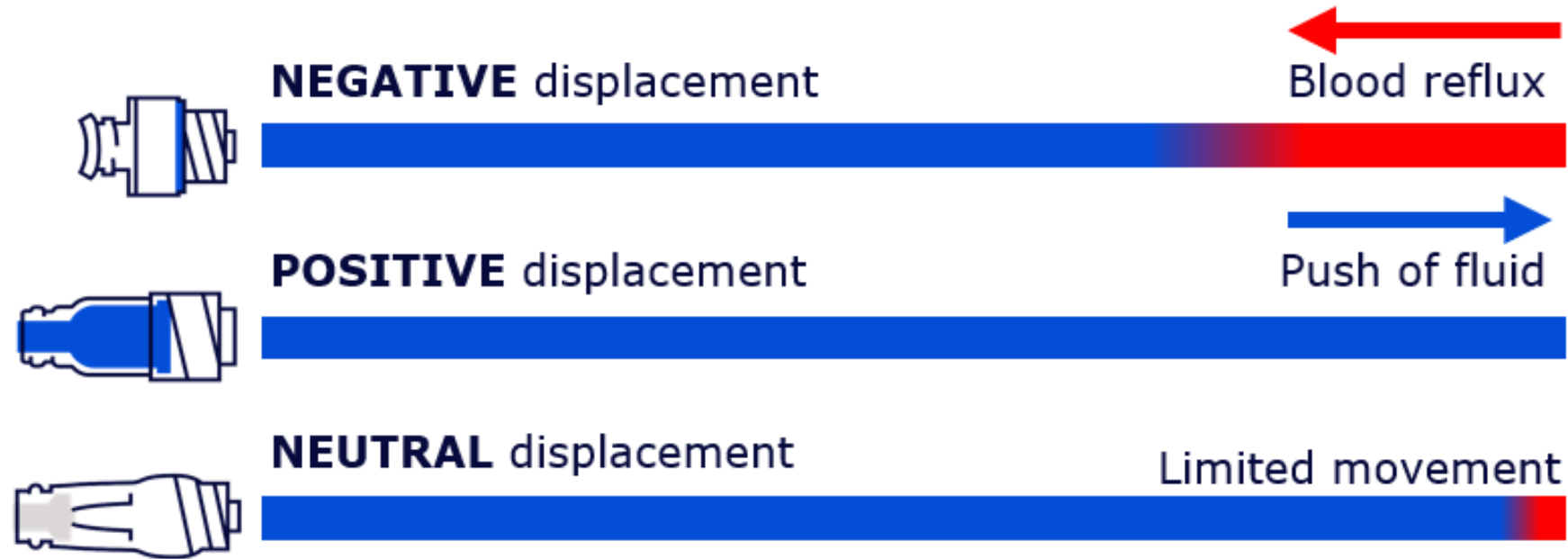


Fig. 1 Fluid flow in NFCs of various displacement types

Needle-Free Connector Design – CLABSI risk

- Prior studies have shown an increased risk of central line-associated bloodstream infections (CLABSIs) when using the NFCs that have positive or negative displacement when compared to split-septum connectors.⁸
- However, other studies have shown that positive-displacement connectors may not increase CLABSI risk.^{9,10}
- It has also been suggested that CLABSI risk does not depend on displacement type but could be device specific and may depend more on the access-surface topography or the device technology.¹¹

Needle-Free Connector Design – Occlusion risk

- The NFC design may also increase occlusion risk. Some studies have shown that NFCs using mechanical valves decreased catheter occlusion rates vs NFCs using split-septum connectors.¹²
- Other studies have focused on the displacement type contributing to the risk of occlusion. One showed no difference in occlusion rate between positive-displacement connectors and negative-displacement split-septum connectors,¹³ whereas a more recent study associated reduced occlusion risk with the use of a neutral-displacement device.¹⁴
- Conclusive evidence on NFC design and occlusion risk remains unknown given that these studies differed in design, occlusion type measured, patient population, sample size, and catheter care.¹²⁻¹⁴

Study Overview



Study design

- 16 Hospitals in California, USA
- Multicenter voluntary cross-sectional descriptive survey



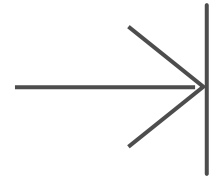
Outcomes

- NFC Type
- CLABSI rate per 1,000 CLDs
- CVC-IBO rate per 1,000 CLDs
- tPA rates



Patient groups

- 88,151 patient days – ICU level of care
- 30,299 CL Days
- 5 various NFC types utilized



Limitations

- Small Sample Size
- Recommend increasing sample size to validate consistency and repeatability of results

Study Methods

- A multicenter voluntary cross-sectional descriptive survey (**Fig. 2**) was conducted by using JotForm® (JotForm Inc.; San Francisco, California).
- Data were collected from Northern and Southern California hospitals that varied in type (eg, acute care), bed size (eg, <50 to >500), and patient population (eg, patient-days).
- Facilities were alike in their desire to reduce CLABSI and CVC-IBO rates and in the interventions introduced.

Study Methods

Central Venous Catheter (CVC) – CLABSI and Occlusion Survey

This survey is intended to learn more about hospital CLABSI rates, as well as occlusion of CVCs. Data included must encompass a complete year of data. We thank you in advance for your time in completing this survey.

What is the geographic location of your hospital/healthcare facility?

- ☐ Central California
- ☐ Northern California
- ☐ Southern California
- ☐ Prefer not to answer
- ☐ Other

How many beds does your hospital have?

- ☐ 0-50
- ☐ 51-200
- ☐ 201-500
- ☐ >500
- ☐ Other

Number of ICU beds

ex. 23

Number of patient-days

ex. 23

Type of needle-free connector used

- ☐ Clave™/MicroClave™
- ☐ CARESITE®
- ☐ InVision-Plus® Clear
- ☐ MaxPlus™/MaxZero™
- ☐ ULTRASITE®
- ☐ Other

Number of central-line days

ex. 23

Number of CLABSIs

ex. 23

Number of occluded CVCs

ex. 23

Number of tPA doses administered

ex. 23

Figure 2: Example of survey questions and interface

Fig 2. Survey – Questions & interface

Study Methods

Hospital bed count and NFC types used

Hospital number	Beds (N)	ICU beds (N)	NFC
1	698	79	Clave/MicroClave
2	641	78	CARESITE
3	574	44	Clave/MicroClave
4	548	72	MaxPlus/MaxZero
5	540	70	MaxPlus/MaxZero
6	453	10	CARESITE
7	272	21	Clave/MicroClave
8	248	25	InVision-Plus Clear
9	228	23	CARESITE
10	168	7	MaxPlus/MaxZero
11	144	6	MaxPlus/MaxZero
12	130	6	Clave/MicroClave
13	113	17	MaxPlus/MaxZero
14	100	5	InVision-Plus Clear
15	98	15	ULTRASITE
16	50	6	MaxPlus/MaxZero

Hospitals are ordered by number of beds (N).

ICU = intensive care unit; NFC = needle-free connector.

Table 1

- 16 hospitals in Northern and Southern California responded to the survey and provided the details listed here (**Table 1**)
- The mean number of beds was 313 (range, 50–698) and of ICU beds was 30 (range, 6–79).
- Each hospital used one of the following five varieties of NFCs: Clave™/MicroClave™ (ICUMedical), CARESITE® (B.Braun Medical Inc.), MaxPlus™/MaxZero™ (BD), InVision-Plus® Clear (RyMed Technologies), or ULTRASITE® (B. Braun Medical Inc.).

Study Methods

- Clinical outcomes assessed with the survey included the number of CLDs and patient-days, NFC type, the number of CLABSI and CVC-IBOs, and the number of tPA doses administered in a year.
- Central venous catheter (CVC) occlusion is a complication in which blood cannot be aspirated, but infusion through the catheter is possible or complete, or neither aspiration nor infusion is possible.¹⁵
- CLABSI was tracked by all facilities, as defined by the NHSN (National Healthcare Safety Network).
- The CLABSI rate was calculated as the number of CLABSI per 1,000 CLDs.
- The CVC-IBO rate was calculated as the number of CVC-IBOs per 1,000 CLDs.
- The tPA utilization rate was calculated as the number of tPA doses per 100 patient-days.
- Cost per 100 patient-days was calculated by multiplying tPA utilization rate by \$110.¹⁶ Annual cost was estimated by multiplying the total number of annual tPA doses per hospital by \$110 (the estimated cost per tPA dose).

NFCs Evaluated

	Displacement type	Design
CARESITE	Positive	Nonsolid access surface; split septum; luer access
Clave/MicroClave	Neutral	Nonsolid access surface; split septum; luer access; internal blunt cannula
MaxPlus/MaxZero	Positive	Solid access surface; luer access
InVision-Plus Clear	Neutral	Nonsolid access surface; luer access; septum; internal cannula
ULTRASITE	Positive	Nonsolid access surface; luer access; mechanical valve with internal spring

Features and characteristics of NFCs used by the surveyed hospitals⁸

NA = not available; NFC = needle-free connector.

Table 2. The table above describes the features and characteristics of the five NFC varieties used by the hospitals⁷. NFCs differed in design (eg, smooth, flat, tightly sealed surface vs irregular) and characteristics of displacement type. Seven hospitals used NFCs with a solid, flat, sealed top surface, while nine used NFCs with irregular top surfaces (eg, with space between the seal and inner NFC diameter).

Results

- The survey captured 88, 151 patient-days and included 30,299 CLDs from 16 hospitals (**Table 3**)
- The mean CLABSI rate of the 16 hospitals was 2.34 per 1,000 CLDs, while the mean CVC-IBO rate was 3.09.

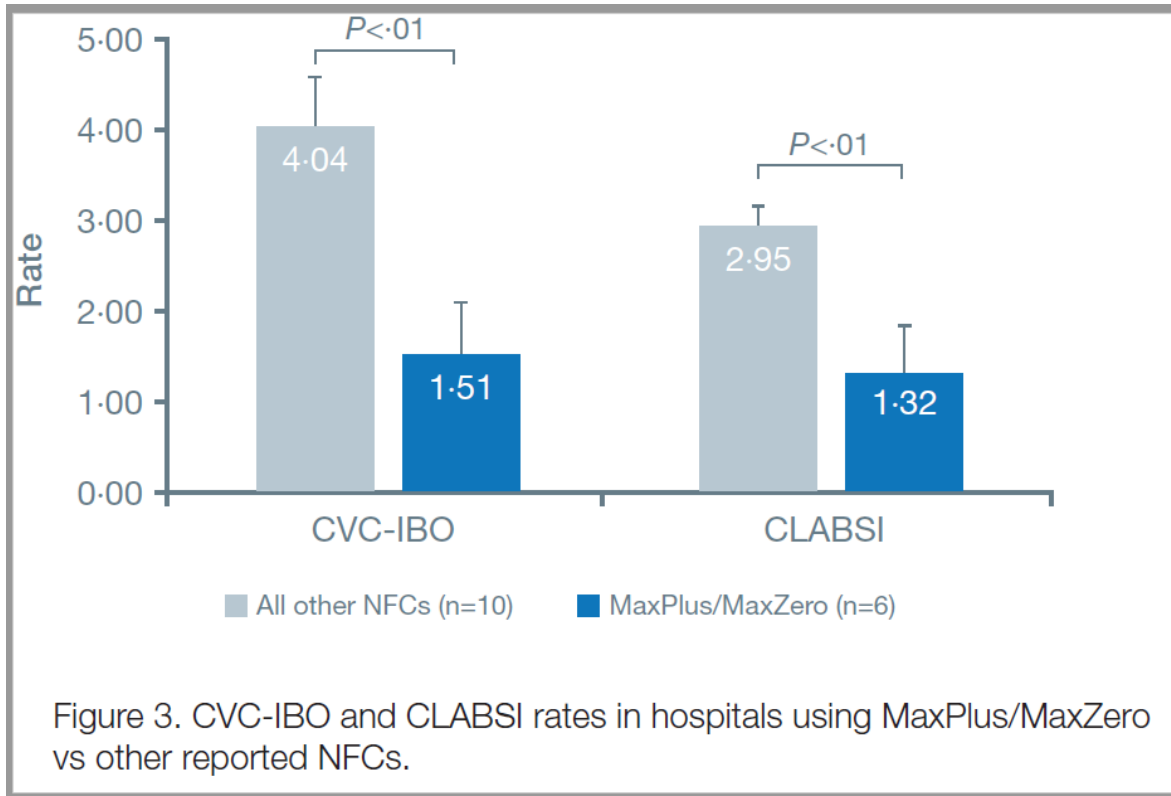
Reported patient-days, CLDs, CLABSIs, CVC-IBOs, and CVC-IBO/CLABSI rates for each hospital and NFC

	NFC	Patient-days (N)	CLDs (N)	CLABSIs (N)	CLABSI rate	CVC-IBO (N)	CVC-IBO rate
1	Clave/MicroClave	11 296	4 253	17	4.00	23	5.41
5	MaxPlus/MaxZero	11 563	3 475	3	0.86	6	1.72
3	Clave/MicroClave	8 522	3 301	11	3.33	7	2.12
4	MaxPlus/MaxZero	5 825	2 937	0	0	4	1.36
2	CARESITE	19 272	2 425	6	2.47	4	1.65
7	Clave/MicroClave	5 221	2 207	9	4.08	15	6.72
9	CARESITE	5 094	2 108	4	1.90	11	5.39
8	InVision-Plus Clear	6 039	2 066	6	2.90	8	3.72
6	CARESITE	2 415	1 496	3	2.01	5	3.34
10	MaxPlus/MaxZero	2 689	1 147	3	2.62	4	3.91
13	MaxPlus/MaxZero	3 449	1 081	3	2.78	2	2.04
12	Clave/MicroClave	1 648	992	3	3.02	2	2.01
11	MaxPlus/MaxZero	1 748	804	0	0	0	0
14	InVision-Plus Clear	1 167	804	2	2.49	4	4.97
15	ULTRASITE	781	609	2	3.28	3	5.09
16	MaxPlus/MaxZero	1 422	594	1	1.68	0	0
	Mean	..	..	..	2.34	..	3.09

CLD = central-line day; CLABSI = central line–associated bloodstream infection; CVC-IBO = central venous catheter intraluminal blood occlusion; N = number; NFC = needle-free connector.

Table 3

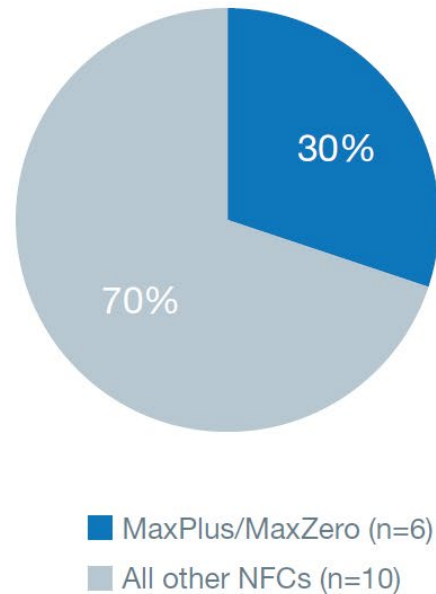
Results



- The average CVC-IBO rate in hospitals using a solid-access-surface NFC (MaxPlus™/MaxZero™) was 1.51 per 1,000 CLDs, whereas the average rate in hospitals using nonsolid-access-surface NFCs was 4.04 per 1,000 CLDs.
- The rate was significantly lower in hospitals using solid-access-surface NFCs vs those using nonsolid-access-surface NFCs ($P=.0065$).
- The average CLABSI rate in hospitals using a solid-access-surface NFC was significantly lower than that in hospitals using a nonsolid-access-surface NFC (1.32 vs 2.95 per 1,000 CLDs; $P=.0052$).

Results

A. tPA utilisation rate



B. Cost per 100 patient-days

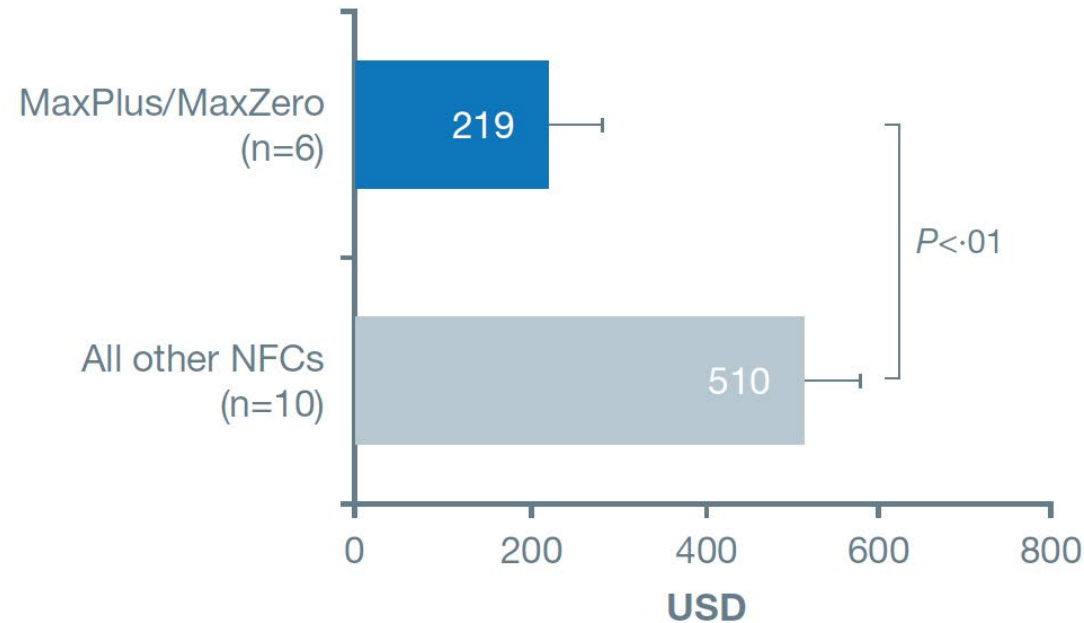


Figure 4. tPA utilization rates were significantly lower in hospitals using the MaxPlus™/MaxZero™ NFC. tPA utilization rate for the 16 hospitals surveyed. B. Cost per 100 patients-days for MaxPlus™/MaxZero™ vs other NFCs.

The number of tPA doses used by hospitals grouped by NFC used varied widely. On average, hospitals using MaxPlus™/MaxZero™ NFCs (solid access surface) used 88 doses in a year, whereas hospitals using other NFCs (nonsolid access surface) used 241 doses. As a result, the tPA utilisation rate was significantly lower in hospitals using MaxPlus™/MaxZero™ NFCs vs other NFCs (1.99 vs 4.63 doses per 100 patient-days; $P = .014$). As shown in the figure above, the tPA utilization rate in hospitals using solid-access-surface NFCs was only 30%.

Results

Reported tPA use by NFC

	NFC	tPA doses (N)	tPA utilisation rate	Cost (per 100 patient-days, USD)	Annual cost (USD)
1	MaxPlus/MaxZero	79	1	149	8 690
2	MaxPlus/MaxZero	199	2	189	21 890
3	MaxPlus/MaxZero	0	0	0	0
4	MaxPlus/MaxZero	24	2	186	2 640
5	MaxPlus/MaxZero	147	4	469	16 170
6	MaxPlus/MaxZero	78	3	319	8 580
Mean		88	1.99	219	9 662
SEM		30	0.59	65	3 350
1	CARESITE	318	2	182	34 980
2	CARESITE	116	5	528	12 760
3	CARESITE	207	4	447	22 770
4	Clave/MicroClave	181	2	234	19 910
5	Clave/MicroClave	52	3	347	5 720
6	Clave/MicroClave	439	8	925	48 290
7	Clave/MicroClave	691	6	673	76 010
8	InVision-Plus Clear	58	5	547	6 380
9	InVision-Plus Clear	295	5	537	32 450
10	ULTRASITE	48	6	676	5 280
Mean		241	5	510	26 455
SEM		65	1	70	7 123

Cost analysis was based on \$110 per dose.

N = number; NFC = needle-free connector; SEM = standard error of the mean; tPA = tissue plasminogen activator; USD = US dollars.

Table 4

Further, cost based on hospital tPA use was analyzed.

- The average cost (per 100 patient-days) with MaxPlus™/MaxZero™ NFCs was \$219, whereas that with other NFCs was significantly higher, \$510 ($P=0.01$) (**Table 4**).
- This resulted in lower annual cost for tPA in hospitals using MaxPlus™/MaxZero™ NFCs.

Discussion

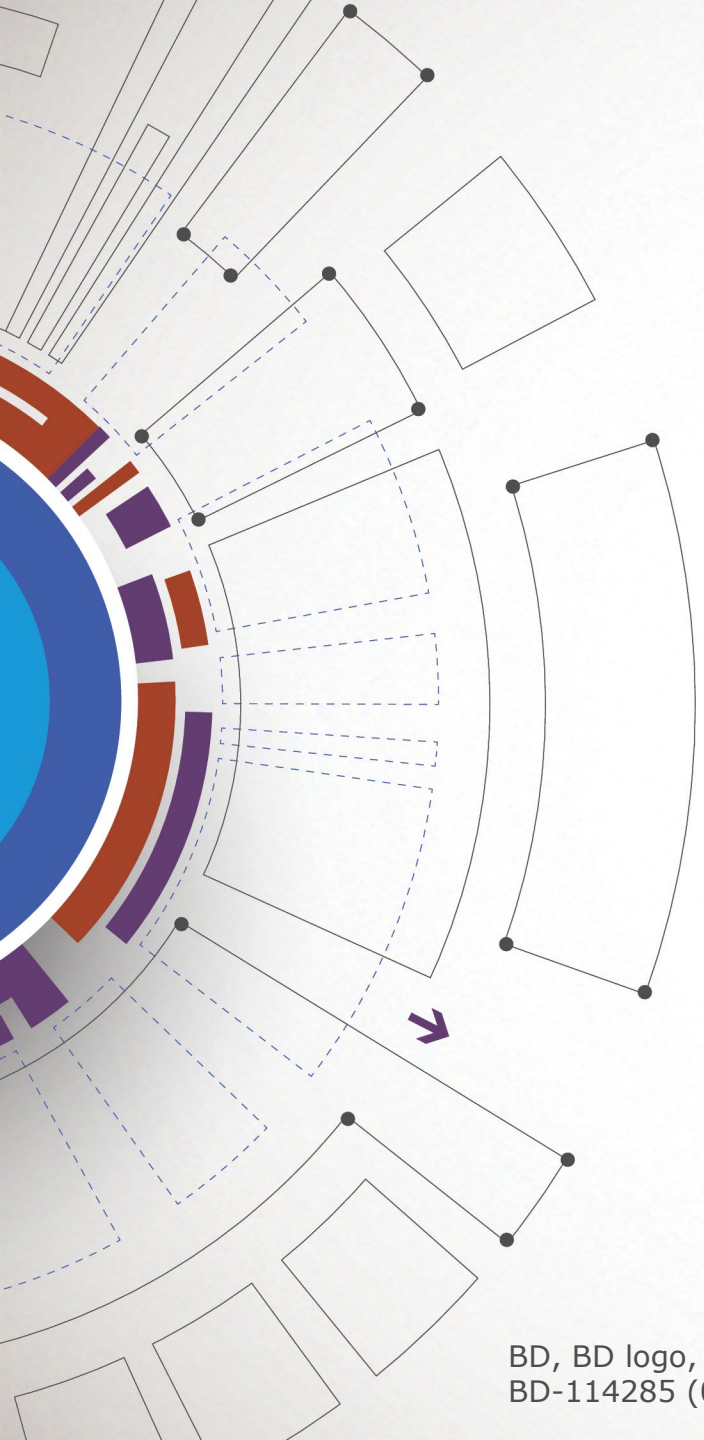
- Unlike data in other published studies that have associated negative- or positive-displacement NFCs with increased infection,⁸ the current study data strongly suggest that external NFC design (access surface) can influence CLABSI rate.
- In the current study, the occlusion rate in hospitals using the BD MaxPlus™/MaxZero™ device was 1.51 per 1,000 CLDs, whereas the rate in hospitals using other nonsolid access NFCs was significantly higher, at 4.04 per 1,000 CLDs.
- Our results agree with those of a previous study that found an association of reduced occlusion rate with use of solid-surface NFCs over split-septum NFCs.¹⁶
- Reducing rates of CLABSI and catheter-related occlusion can result in improved patient safety, along with substantial cost savings to the facility.¹⁶

Conclusion

- New-generation NFCs are specifically designed to improve clinical outcomes and reduce CLABSI risk.
- The current study surveyed 16 hospitals and determined that their mean CLABSI rate was 2.34 per 1,000 CLDs, which was higher than the national average of 0.8 per 1 000 CLDs.¹⁷
- It is interesting that the hospitals that used the MaxPlus™/MaxZero™ devices, the only NFCs in this survey with a solid access surface, had significantly lower CLABSI rates vs those with a nonsolid access surface (CLABSI rate for MaxPlus™/MaxZero™ vs others: 1.32 vs 2.95, respectively. (**Fig. 3**)
- Even in other studies, the MaxPlus™ device has been associated with significantly lower CLABSI rates.¹⁸
- Findings of previous evidence-based reports have suggested that near-zero CLABSI rates could be achieved by using positive-displacement connectors, along with additional interventions.¹⁹

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Thank you!
