Catheter Care Bundle and Low Catheter Related Bloodstream Infection Rates in a Home Parenteral Nutrition Population; a 4 Year Observational Study

Mark DeLegge (drmark@deleggemedical.com)
Coram CVS Specialty Infusion Services https://orcid.org/0000-0003-3960-9326
Karen Sexton Hamilton
Coram CVS Specialty Infusion Services
Melissa Leone
Coram CVS Specialty Infusion Services
L. Allyson Checkley
Coram CVS Specialty Infusion Services

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Abstract

Home Parenteral Nutrition (HPN) is often a life-saving therapy for patients. One of the most common complications for HPN is catheter-related blood stream infections (CRBSI). In the home setting there is no single defined “care bundle” for the on-going maintenance of central venous catheters (CVC) for the prevention of CRBSI. We evaluated the impact of a standardized catheter care bundle in patients receiving HPN on the incidence of CRBSI. **Methods:** Data collection included use of standardized tools and processes to capture patient demographics, catheter complications including CRBSI and some associated risk factors. Reported data was collected and analyzed annually and compared year-to-year from the years 2014-2017 from one national home infusion company. CRBSI reported as number of infections/1000 catheter days

Results: The CRBSI rate/1000 days was reported as 0.43, 0.31, 0.30 and 0.23 (2014, 2015, 2016, 2017 respectively) statistically significant difference ($p < .05$) between the years 2014 and 2017. CRBSI.

Conclusion: The use of a catheter care bundle in an HPN population may have contributed to a 4- year reported outcomes of low and continuously declining CRBSI in a large, diverse United States-based HPN population.

Clinical Relevancy Statement

Catheter-related blood stream infections are a common complication of HPN therapy. There is no consensus on the clinical approach to prevention of CRBSI in the home setting. This study evaluated a catheter care bundle approach for the prevention of CRBSI in a large number of HPN patients.

Background

Home parenteral nutrition (HPN) is a treatment for patients with an inability to receive nutrients into and/or absorb nutrients from the small intestine. In general, patients receiving HPN are stable from a medical perspective and do not require hospitalization or care in a supervised medical facility.

Patients require a central venous catheter (CVC) for infusing PN (parenteral nutrition) solutions and sometimes other medical therapy. Because of the presence of a CVC, HPN patients are at risk for the development of catheter-related bloodstream infections (CRBSI). Of the reported complications of HPN therapy related to the CVC, CRBSI is the most common and is associated with significant morbidity and sometimes, mortality. **(1)**

In addition to PN preparation and infusion, a patient and/or caregiver often must provide ongoing care for the CVC. Sometimes, a homecare nurse provides this care during weekly visits. Maintenance care includes activities such as catheter dressing, injection cap changes and flushing of the CVC lumen(s).

The majority of CRBSI stem from the flora found on the patient's skin. It is of utmost importance that the skin around the catheter insertion site be properly cleansed.(2) Overwhelming evidence has shown that using a 2% chlorhexidine antiseptic cleansing solution reduces the rate of CRBSI by up to 50%.(3) There are published reports on the importance of additional interventions to prevent CVC infection in the home setting including the use of disinfecting catheter injection caps, PICC stabilization devices, specialized dressings to prevent microbial growth, and dressing protection from water during bathing. (4-6) Patient and caregiver education are also important. Very few consensus professional society guidelines for care and maintenance of CVC in the HPN population exist.(7)

Assessments have been made to understand the risk factors that a patient, caregiver or home setting may possess that would increase a patient's likelihood of developing CRBSI.(8-10) This can include, but is not limited to, shorter lengths of small bowel remaining after small bowel resection, patient history of alcohol, opioid or anti-anxiolytic drug dependence, lower socioeconomic status and a higher number of family dependents living in the home. Not all home settings are similar with regards to cleanliness and organization. There also is variation in a patient or caregiver's ability to follow instructions.(11)

Vast improvements have been made in the reduction of CRBSI in the hospital setting attributed to standardization of the CVC insertion procedure. The groundbreaking Keystone Project demonstrated the effect of five measures (a bundle) on the improvement of outcomes during insertion of central venous catheters.(12) Those components included hand washing prior to CVC placement, chlorhexidine skin preparation, full barrier precautions, use of the subclavian vein as the preferred access site and early removal of all unnecessary CVC. However, even in institutions where full compliance with the bundle exists, CRBSI are still occurring.(13) Of note, the Keystone Project central line bundle does not include any of the post-insertion aspects of CVC care and management which have been shown to prevent CVC infection.(14)

The current study was initiated by a specialty pharmacy in the United States providing patient-specific compounded HPN in addition to a variety of specialized medications to a diverse patient population with multiple physician providers. The decision to pursue this study was based on the findings that HPN CRBSI rates were reported in the literature as persistently higher than other home infusion therapies, thus indicating a higher risk level for these patients.(15) Prior to 2014, internal data revealed a persistence of CRBSI in the HPN population of a large, national specialty pharmaceutical provider. It was hypothesized that a dedicated catheter care and maintenance bundle, using best available evidence, would reduce the overall number of CRBSI in an HPN population. A multi-modality catheter care bundle (CCB) including patient education and the use of novel catheter maintenance products was chosen to ensure mitigation of the risks associated with several known contributors to CRBSI, including skin contamination, catheter injection cap antisepsis, catheter pistoning and compromised or wet IV dressings.

Methods

A retrospective, non-randomized analysis was completed on an average of 7385 patients/year receiving HPN from a single national specialty pharmaceutical provider from January 1, 2014 to December 31, 2017. The primary outcome measure was development of CRBSIs which is expressed as the number of CRBSIs per 1,000 catheter days of HPN use by patients in that year. PN use by patients in a given year. This data was compared year over year from 2014 through 2017. Data collected included demographic information, catheter type, number of catheter lumens and organisms responsible for the catheter infections when cultured.

As part of nutrition assessment, the Registered Dietitians completed a catheter history at the start of care, assessed compliance to catheter care as part of the ongoing nutrition assessment, and provided on-going education. The education provided reinforced catheter management techniques. On-going patient interactions with a nurse in the home, clinical support specialist or pharmacist provided additional opportunities for catheter assessment and/or potential to capture a catheter event. All confirmed catheter events were then documented in the pharmacy provider's computer system.

Data was pulled from the pharmacy provider's computer system using a specialized query tool. No individualized chart review was performed. Two or more reported catheter infections occurring in the same patient in a 12-month period were reported to a Clinical Manager or designee to determine alternative care strategies and recommended follow-up education on an as-needed basis based on catheter complication rates, unused supplies and demonstrated non-compliance.

All HPN patients who were not ordered an institution or clinician-specific catheter care protocol were provided with the CCB that consisted of 4 commercially available medical products which included:

1) 70% alcohol impregnated disinfection end cap

2) Foam disc impregnated with polyhexamethylene biguanide hydrochloride

3) Moisture barrier to help protect the intravenous dressing during showering.

4) Securement device for PICC.

All patients received standard CVC catheter maintenance care which included regular catheter flushing, regular timing for injection cap change out, appropriate use of catheter securement devices, appropriate use of extension sets, routine catheter dressing changes and safe catheter clamping techniques.

In conjunction with the CCB, an education program was initiated consisting of:

1. An internal education on the CCB to all home infusion nurses, pharmacists, dietitians and supporting nonclinical staff,

2. A letter outlining the CCB and its associated education program sent to the patients and their physicians

3. Specific patient education tools that addressed both catheter supply use and general guidelines for effective catheter care.

This education was provided in addition to the direct education provided to patients and caregiver(s) on how to effectively use the CCB. Patients were also provided with a laminated mat that was to be used as the location to prepare their prescribed PN. This mat contained instructions for maintaining aseptic technique and provided reminders about CVC maintenance strategies for avoiding CVC complications, including CRBSI. The mat could also be easily cleaned prior to use. Catheter locking of solutions for prevention of CRBSI was not a common practice and was not part of the intervention program.

Catheters were categorized as central catheters non-tunneled (CCNT), central catheters tunneled (CCT), peripherally-inserted catheters (PICC) and PORT. A catheter-related bloodstream infection was defined as when a patient exhibits the following symptoms: fever over 100.6F (38.1C) not attributable to other health issues; catheter exit-site redness, drainage or cord; **and** also has either blood/catheter culture or Gram stain confirmation of bacterial or fungal counts, **or** the prescriber determines that the catheter is the most likely source of infection, thus removing the catheter or treating the patient/catheter with anti-infectives. If the CRBSI symptoms develop less than 48 hours following hospital discharge, this would be considered a nosocomial infection, and not applicable to the home infusion setting. CRBSI symptoms developing 48 hours or more after central line insertion and care in the home infusion setting would be considered a nosohusial infection.**(16)** Patients admitted to the hospital for catheter infections were captured as part of the documentation process.

This was an observational study without patient randomization. Descriptive statistical reporting was performed on all collected data. Comparisons were made between independent variables using the Chi square $(x)^2$. A $p < .05$ was considered statistically significant

All patient data was deidentified. CORAM/CVS internal clinical/ethics research committee reviewed the study and determined that it meets the criteria of 45 CFR 46101(b). Our research involved the “collection of existing data, documents, records” and “information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects”.

Results

There was patient PN exposure data available for the years between 2016-2018. On average for these three years, 68% of the HPN patients were on PN > 90 days with an average of 657 days (range 647-670 days). Thirty-two percent of the patients were on PN < 90 days with an average of 43 days (range 42-45 days).

For the four years of data evaluated, patient demographics remained stable with the mean patient age of 46 years (1.17 SD), with 18% <16 years of age; 82% 17 years of age or older. Of the prescribers who managed this patient population, 86% manage 1-2 TPN patients per year and 14% managed >2 TPN patients/year.

A total of 6933, 7576, 7389 and 7642 patients were followed in 2014, 2015, 2016 and 2017 respectively. The top 5 ICD 10 codes for diagnosis were malnutrition (23%), post-surgical malabsorption (15%), malabsorption (6%), reginal enteritis (5%) and small bowel obstruction (4%). Eighteen percent of the population was pediatric with the 2 largest representative populations of 30-49 (21%) and 50-64 (31%). The CRBSI rates for patients receiving HPN from 2014 to 2017 is shown in **Table 1**. There was a downward trend in CRBSI/1000 catheter days from 2014 to 2017. The reduction in the number of CRBSI/1000 catheter days between years 2014 and 2017 was statistically significant ($p < .05$)

Table 2 notes the specific number and the type of central venous catheters utilized/year and the dwell time of these catheters in days**.** Central tunneled catheters represented the largest overall number of CVC and had the longest overall dwell time in days. Central nontunneled catheters represented the least number of CVC in the study with the least number of overall dwell days. Triple lumen catheters (TLC) had the lowest CRBSI/1000 days numerically**. (Table 3)** However, TLC accounted for 5% or less of the total catheters used on a year to year basis. Because of this very low number, TLC were not included in any further statistical comparison. In the year 2014, single lumen catheters (SLC) had significantly fewer CRBSI as compared to double lumen catheter (DLC) ($p < .05$). In the years 2015 and 2106 single lumen catheters had numerically fewer CRBSI as opposed to double lumen catheters although these values did not reach statistical significance.

On average for the four years studied, seventy-nine percent of reported CRBSI had an associated documented organism(s) (2014-76%, 2015-76%, 2016-86% 2017 -78%). For those CRBSI where blood culture results were available, we divided the organisms into 3 distinct groups based on the categorization of fungal (i.e. Candida), skin-based bacterial organisms (ie. Staphylococcus) or gastrointestinal/respiratory-based bacterial organisms (i.e. Enteroccous) **(Figure 1**). This distinction was made because of our desire to understand the initial location of the catheter-infecting organisms (fungal, skin-based or gastrointestinal/respiratory secretions). Table 4 provides an example of the taxonomy crosstalk that was used to create the 3 reported groups. Based on this categorization, fungal organisms were the least likely cause of CRBSI when evaluated by percentage of the total available documented organisms. Fungal infections were responsible for significantly less percentage of overall infections ($p<.05$) CRBSI as compared to skin-based bacterial organisms for the years 2014, 2016 and 2017 ($p<.05$). For the year 2014 ($p<.05$), fungal infections were responsible for significantly lower percentage of CRBSI as compared to gastroenterology/respiratory-based bacterial organisms. There were no significant differences in percentages of CRBSI between skin- and gastroenterology/respiratory-based bacterial organisms for any of the reported years.

Discussion

This 4-year observational experience with a bundled catheter care program demonstrated a low and declining CRBSI rate as reported per one thousand catheter days. The population of HPN patients was diverse with a multitude of clinicians providing the care for the HPN patient. Most of these physicians

managed 1-2 HPN patients per year. The bundled, standardized approach to catheter care may have contributed to this low incidence of CRBSI.

The incidence of CRBSI remains a topic of reporting from many clinicians and institutions. **Table 5** provides a listing of reference articles for CRBSI infection in the HPN population and the reported CRBSI rates.**(17 - 29)** Only studies that included greater than 100 patients that were published since the year 2000 are listed in this table. These studies report a CRBSI rate between 0.35 – 3.20 per 1000 catheter days. These reports were also observational in nature. Some of the reports were based on surveys. No attempt was made to implement a specific CRBSI practice in these publications other than the practice that was ordered by the responsible clinician or was the standard of practice for the pharmacy compounding the PN or the nursing agency providing care for the HPN patient. The definition of CRBSI varied between the reported studies. There was no bundled approach to catheter care and maintenance. Many of these reports were single center reports and therefore do not represent a diverse patient population where multiple physicians are caring for patients at multiple unique sites. The majority of these studies reported out on only a small fraction of the number of patients included in this study. Specifically evaluating the 3 papers published during the time period of this study **(21, 28, 29)** other than standard patient teaching, only the Vashi publication used one of the products mentioned in the catheter care bundle described in this paper. Interestingly, the Vashi paper also had the lowest reported catheter infection rate/1000 catheter days of these 3 publications.

The use of antimicrobial dressings has been shown to have an impact on CVC infections. The antimicrobial dressing in our bundle contains 0.2% polyhexamethylene biguanide (PHMB). PHMB is an antibacterial polymer and has been shown to inhibit bacterial growth. (**30,31)**

Protective moisture barriers are placed over the CVC site and catheter during times of exposure to water, such as taking a shower. They replace hand-made devices such as a plastic bag placed over the CVC. The use of a protective cover from exposure to tap water contamination during showering and bathing has been shown to have an impact on CVC infections. (**32,33**)

Disinfecting caps are used for needle-free intravascular connections. The cap itself contains 70% isopropyl alcohol on a sponge. A trauma intensive care unit (ICU) study demonstrated that the addition of a disinfecting cap to existing standard central line care bundles resulted in a 40% decrease in CRBSI.(**34)** Another study with a disinfecting cap was performed on adult patients with peripherally inserted central venous catheters (PICC) Compared to the baseline practice of catheter hub scrubbing alone, the use of a disinfecting cap reduced CRBSI.**(35)**

Peripherally inserted central venous catheters can cause vein damage, access site tissue inflammation and CRBSI if the PICC is not secured properly. A poorly secured PICC can “piston” in and out of a vascular access site, resulting in the delivery of skin-based microorganisms into the vein. Vascular access stabilization devices have been shown to reduce complications compared to unsecured CVCs, including CRBSI.**(36)**

Patient education is an important component of the care and management of CVC to prevent complications. The European Society of Parenteral and Enteral Nutrition Guidelines state that education should be provided to HPN patients. The teaching program should include catheter care, pump use, and preventing, recognizing and managing complications. **(37)** No time limits for training should be set; patients should be allowed to make progress at their individual pace.**(38)** It has been reported that patients who receive more detailed written and oral information on the aseptic management of catheters have a lower incidence of catheter sepsis.**(39)** It has also been reported in pediatric HPN patients that one of the factors improving the longevity of a CVC, including a reduction in associated infectious complications, was improved teaching of patients.**(4)** The current study did include educational activites as part of the bundled approach to catheter care.

This study has its limitations. It is a retrospective, observational study. No attempt was made to equalize patient groups with regards to demographics or disease co-morbidities which may have impacted patient outcomes, including catheter related-bloodstream infections. Patient compliance with the CCB was not tracked. We did not collect data on a patient's gastrointestinal anatomy, socioeconomic status, level of education or degree of family support which experts have opined are risk factors for the development of CRBSI. In addition, we did not review each patient's complete medical record as there are limitations in the completeness of the medical record in the home care setting as opposed to the hospital setting. However, the number of patients reported in this study is the largest report of any HPN database; these large patient numbers can often mitigate result errors noted in retrospective clinical study designs. We do acknowledge that studies with large patients also can result in statistically significant findings that are not ultimately clinically significant.

Conclusion

Home parenteral nutrition is a lifesaving therapy. Catheter–related bloodstream infection remains a common complication of the HPN population. In this study, we successfully achieved a reduction in CRBSI with the use of a bundled CVC care pathway designed to standardize safe maintenance practice after CVC insertion.

Abbreviations

CCB – catheter care bundle

CCT – central catheter tunneled

CCNT – central catheter non-tunneled

CRBSI - catheter-related blood stream infections

CVC – central venous catheter

DLC – double-lumen catheter

HPN – home parenteral nutrition

PICC – peripherally inserted central venous catheter

PHMB – polyhexamethylene biguanide

PN – parenteral nutrition

SLC – single lumen catheter

TLC – triple lumen catheter

Declarations

Ethics Approval and Consent to Participate: This was a retrospective analysis of data in humans. All patient data was deidentified. CORAM/CVS internal clinical/ethics research committee reviewed the study (the Clinical Program Review Committee), and determined that it meets the criteria of 45 CFR 46101(b). Our research involved the “collection of existing data, documents, records” and “information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects”. No consent was required from the de-identified subjects

Consent to Publish: All Authors and CoramCVS have given consent to publish the article

Availability of Data and Materials: Available from KH upon reasonable request

Competing Interests. KH, ML, AC are employees of Coram/CVS. MD is a consultant for Coram/CVS

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Author’s Contribution; KH and MD designed and contributed to the writing of the manuscript. ML and KH analyzed the data and contributed to the writing of the manuscript. AC and MD edited numerous versions of the manuscript and contributed to the writing of the manuscript. All authors read and approved the final manuscript

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Tables

Table 1 – Total Catheter Days Per Year and CRBSI

Year	Total Catheter Days	# CRBSI	CRBSI rate per 1000 catheter Days
*2014	682,590	294	.43
2015	820,232	256	.31
2016	801,271	243	.30
*2017	834,985	196	.23

* P < .05

Table 2 – Number of catheters and catheter days by catheter type per year

Year	Central (non-tunneled) # catheters	Central (tunneled) # catheters	PICC # catheters	Port # catheters
2014	53	1400	4802	1241
2015	60	1374	4396	1168
2016	56	1031	4282	1000
2017	46	1506	7348	1534
	Central (non-tunneled) catheter days	Central (tunneled) catheter days	PICC catheter days	Port catheter days
2014	6826	211603	348121	116040
2015	5725	253197	417064	144246
2016	7859	233665	423997	135751
2017	3959	194636	477020	159370

Table 3 – Catheter Lumens and CRBSI

r	Total Catheter Days	% Single Lumen	# CRBSI	Single Lumen CRBSI/1000 Days	% Double Lumen	# CRBSI	Double Lumen CRBSI/1000 Days	# CRBSI	% Triple Lumen	Triple Lumen CRBSI/1000 days
14	682590	46.6	0	.00*	50.7	118	.17*	13	2.6	.02
15	820323	48.9	111	.14	48.3	140	.17	5	2.6	.01
16	801271	48.9	101	.13	48.3	126	.16	11	2.7	.01
17	836764	42.8	100	.12	52.2	82	.10	6	5.0	.01

** p < .001*

TLC accounted for 5% or less of the total catheters used on a year to year basis. Because of this very low number, TLC were not included in any further statistical comparison.

Table 4 Taxonomy Crosswalk: Examples

Skin organism	GI/Lung organism	Fungal organism
Staphylococcus epidermidis	Escherichia coli	Candida tropicalis
Staphylococcus hominis	Pseudomonas aeruginosa	Candida albicans
Xanthimonas maltophilia	Klebsiella pneumoniae	Mycobacterium
Staphylococcus aureus	Enterococcus faecalis	Candida glabrata
Gram positive cocci		

Table 5 – CRBSI in HPN Patients in Published Reports of Greater than 100 Patients Since the Year 2000

Author	Patient Number	CRBSI Rate	Year
Bozzetti et al **(18)**	447	.93/1000 catheter days	2002
Colomb et al **(19)**	302	1.20/1000 catheter days	2007
Crispin et al **(20)**	481	0.54/1000 catheter days	2008
Elfassy et al **(21)**	155	2.0/1000 catheter days	2015
*Ireton-Jones et al **(22)**	4540	0.66/1000 catheter days	2005
Lloyd et al **(23)**	188	.85/1000 catheter days	2006
Santarpia et al **(24)**	222	3.20/1000 catheter days	2002
Ugur et al **(25)**	202	1.30/1000 catheter days	2006
Violante et al **(26)**	159	2.89/1000 catheter days	2006
Cotogni et al **(27)**	254	.35/1000 catheter days	2013
Vashi et al **(28)**	241	.54/1000 catheter days	2017
Buchman et al **(17)**	135	.35/1000 catheter days	2013
Dibb et al **(29)**	588	.38/1000 catheter days	2016

*Report was on catheter-related infections (CRI) which included both CRBSI and CVC exit site infections.

Figures

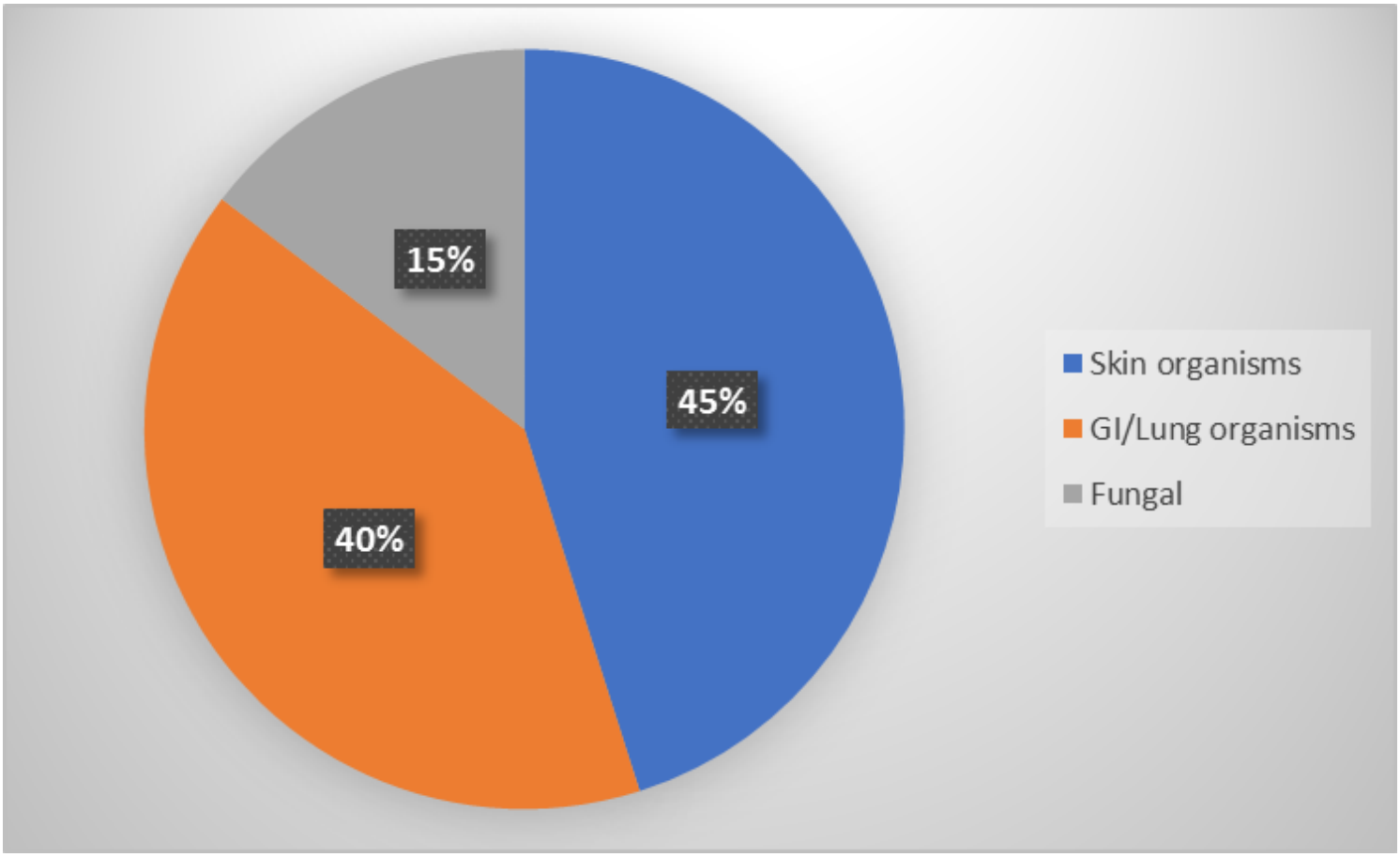
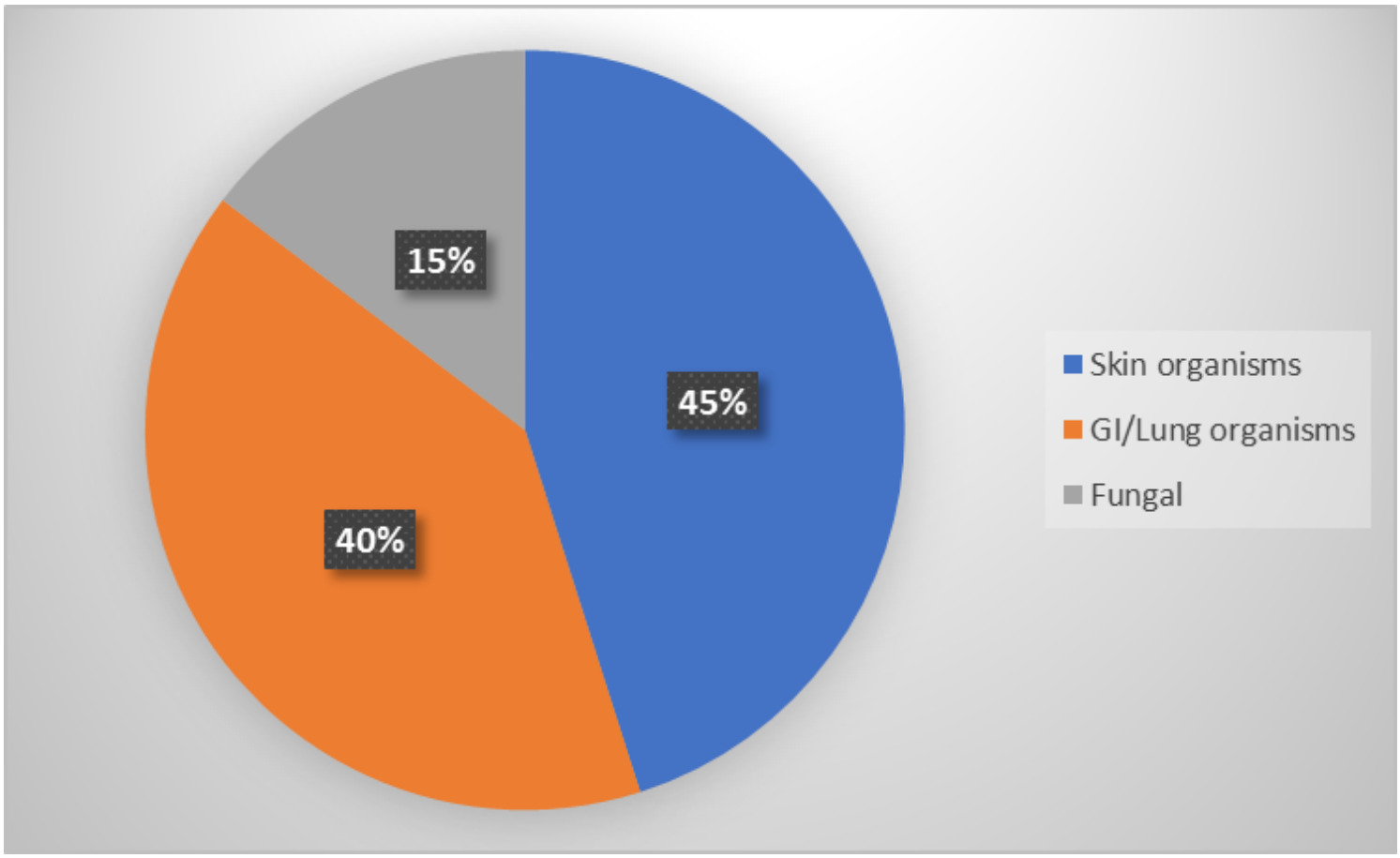


Figure 1

Catheter Related Bloodstream Infection Organism Site of Origin



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