CBE ID

1460

Title

Bloodstream Infection in Hemodialysis Outpatients

Project

Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health

Endorsement Status

Endorsed with Conditions

E&M Committee Rationale/Justification

When the measure returns for maintenance, the committee would like to see:

- Update the BSI rate baseline year (2014 in current submission) by measure maintenance.

Is Under Review

No

Next Maintenance Cycle

Fall 2029

Previous Endorsement Cycle

Spring 2024

Steward

Centers for Disease Control and Prevention, National Healthcare Safety Network

1.0 New or Maintenance

Maintenance

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

Annual standardized infection ratio (SIR) of bloodstream infections (BSIs) among children and adults receiving maintenance hemodialysis at outpatient hemodialysis facilities. BSIs are defined as positive blood cultures for hemodialysis patients which are reported monthly by participating facilities. The SIR is reported for a yearly period (calendar year) and is calculated by dividing the number of observed BSIs by the number of predicted BSIs during the year.

1.7 Composite Measure

No

1.7 Measure Type

Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Other

1.9b Other Care Setting

Dialysis Facility

1.10 Measure Rationale

The use of this measure will promote blood stream infection (BSI) prevention activities in the outpatient hemodialysis setting, which will lead to improved patient outcomes including reduction of avoidable medical costs, patient morbidity and mortality through reduced need for antimicrobials, and hospital admissions.

1.11 Measure Webpage

https://www.cdc.gov/nhsn/dialysis/event/index.html

1.13 Data Dictionary

Attached

1.14 Numerator

Number of annual observed new dialysis bloodstream infection events in outpatient hemodialysis facilities.

1.14a Numerator Details

1. Determine the patients who receive outpatient hemodialysis treatment during the month.
2. Determine the patients who developed a positive blood culture.
3. Report all positive blood cultures from specimens collected as an outpatient or collected within one calendar day after a hospital admission.
    a. A positive blood culture is defined as a blood culture that results in growth or of one or more organisms (https://www.cdc.gov/nhsn/xls/master-organism-com-commensals-lists.xlsx).
    b. A second positive blood culture should not be reported if it occurs less than or equal to 21 days after the first positive blood cultures is reported in the same patient. If a subsequent positive blood culture is collected after 21 days of the first blood culture, a new BSI event must be reported.
4. Report the types of vascular access present for the patient at the time of the event.
    - Non-tunneled central line: a central venous catheter that travels directly from the skin entry site to a vein and terminates close at or close to the heart or in one of the

great vessels. These catheters are for short term use.

- Tunneled central line: a central venous catheter that travels a distance under the skin from the point of insertion and terminates at or close to the heart or in one of the great vessels. Tunneled central lines are used for long term hemodialysis.
- Graft: a surgically created connection between an artery and a vein using implanted material (typically synthetic) to provide vascular access for hemodialysis.
- Fistula: a surgically created direct connection between an artery and a vein to provide vascular access for hemodialysis
- Other access device: these devices include hybrid access devices (e.g., HeRO vascular access device), ports, and any other central vascular access devices that do not meet the above definitions.

  - If a patient has more than one vascular access type at the time of the event, the access type with the highest risk for infection is documented, even if that access is not used for dialysis or has been abandoned. The access device reported may not be the one currently used for dialysis. The risk levels for each access type are as follows Highest Infection Risk to Lowest Infection Risk: Nontunneled Central Lines, Tunneled Central Lines, Other Vascular Access Devices, Grafts, Fistulas.

1.15 Denominator

Number of annual predicted new blood stream infections (BSIs) in outpatient hemodialysis facilities.

1.15a Denominator Details

To calculate the number of predicted infections, sum the patient-months per calendar year (number of patients who received hemodialysis at the facility on the first two working days of the month) by vascular access type. Multiply each of the patient-months by vascular access type by the corresponding 2014 NHSN national aggregate BSI rate. The 4 numbers are then added together to produce the facility's total predicted number of BSIs.

Bloodstream Infection (BSI) Rate Stratified by Vascular Access Type-NHSN Dialysis Event Data, 2014

Vascular Access Type	Rate (per 100 patient-months)
Arteriovenous (AV) Fistula	0.26
AV Graft	0.39
Other Vascular Access Type[1]	0.67
Central Venous Catheter[2]	2.16

(1): other vascular access type such as catheter-graft hybrid (2): includes tunneled and non-tunneled catheters (3): the national access type-specific rates are used to calculate the predicted number of BSIs for each access type in a given facility. This is done by multiplying each facility's access type-specific denominator by the corresponding national rate for that access type. A facility's SIR (standardized infection ratio) is the total observed BSI count divided by the total predicted number of BSIs across all access type categories (SIR=number of observed BSI/number of predicted BSI).

1.15b Denominator Exclusions

There are no denominator exclusions.

1.15c Denominator Exclusions Details

There are no denominator exclusions.

1.16 Type of Score

Other

1.16a Other Scoring Method

Ratio

1.17 Measure Score Interpretation

Better performance = Lower score

1.18 Calculation of Measure Score

The Standardized Infection Ratio (SIR) is calculated as follows:

1. Identify the number of BSIs in each vascular access category

2. Total these numbers for an observed number of BSIs

3. Obtain the predicted number of BSIs in the same category by multiplying the observed patient-months by the corresponding BSI rates in specific category from a standard population

4. Sum the number of predicted BSIs from all categories in the annual period

5. Divide the total number of observed BSI events (#2 above) by the predicted number of BSIs (#4 above)

6. Result = SIR

SIR =Observed (O) BSIs/Predicted (P) BSIs

1.18a Attach measure score calculation diagram

1.18a Example Dialysis Event Bloodstream Infection.pdf

1.19 Measure Stratification Details

Both the numerator and denominator are stratified by the type of vascular access. The Number of Observed BSIs equal the total number of positive blood cultures that the facility reported to NHSN during a specific timeframe.
The Number of Predicted BSIs are calculated summing the patient-months per calendar year (number of patients who received hemodialysis at the facility on the first two working days of the month) by vascular access type. Multiply each of the patient-months by vascular access type by the corresponding 2014 NHSN national aggregate BSI rate. The 4 numbers are then added together to produce the facility's total predicted number of BSIs.

Bloodstream Infection (BSI) Rate Stratified by Vascular Access Type-NHSN Dialysis Event Data, 2014

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1.20 Types of Data Sources

Electronic Health Records, Non-Medical Data, Paper Patient Medical Records

1.25 Data Source Details

Data is submitted by dialysis facilities using the National Healthcare Safety Network (NHSN), web-based application (accessed securely via the Secure Access Management Service).

Instructions and protocol for completing dialysis event reporting are available at the following website: https://www.cdc.gov/nhsn/dialysis/event/index.html

Data Collection Forms and Instructions:

- Dialysis event reporting form: https://www.cdc.gov/nhsn/forms/57.502_DIAL_BLANK.pdf
- Instructions for completion of the dialysis event surveillance form (CDC 57.502): https://www.cdc.gov/nhsn/forms/instr/57_502.pdf
- Denominators for dialysis event surveillance (census form – completed once per month; CDC 57.503): https://www.cdc.gov/nhsn/forms/57.503_DenomOutpatDialysis_BLANK.pdf
- Instructions for completion of the denominators for dialysis event surveillance (CDC 57.503): https://www.cdc.gov/nhsn/forms/instr/57_503.pdf

1.26 Minimum Sample Size

N/A

2.1 Attach Logic Model

1460-Bloodstream Infection in Hemodialysis Outpatients Cycle-Spring 2024-Importance- Logic model and description of relationship between structures-processes and outcome.pdf

2.2 Evidence of Measure Importance

Infection is the second leading cause of death among dialysis patients (Mokrzycki, et. al, 2021) (Millson et al., 2019), with most patients who develop a bloodstream infection undergoing hemodialysis (HD) with a central venous catheter (Fisher et al., 2019) (Mokrzycki et al., 2021) (Patel et al., 2013). The U.S. Department of Health and Human Services published The United States Renal Data System 2023 Annual Data Report which reported that the percentage of individuals initiating HD with a catheter, with or without a maturing permanent access, increased by 4.6% from 2018 to 2021, reaching 85.4% (2023). Additionally, the report showed that the percentage of patients initiating HD with a catheter only, which reached a nadir of 60.3% in 2013, grew to 74.0% in 2021 and from 2013 to 2021, the percentage initiating HD with an AV fistula fell from 17.0% to 12.2%, and the percentage starting with catheter and a maturing fistula fell from 18.0% to 10.2%. Patients who undergo HD with a catheter are at significantly increased risk of developing an infection than patients who have an arteriovenous fistulae or graft (Soi, et al., 2016). Measure #1460 Bloodstream Infection (BSI) in Hemodialysis Outpatients allows facilities to track the types of vascular access present in patients who develop a (BSI), so that they can work to improve the type of access a patient has prior to initiating chronic outpatient HD and

thereby reduce infection risk.

Multiple studies provide strong empirical support for the association between the reduction of bloodstream infections (BSI) in HD outpatients and BSI prevention practices. Specifically, chlorhexidine
use for catheter exit-site care, staff training and competency assessments focused on access care and aseptic technique, hand hygiene and vascular access care audits, and feedback of infection and adherence rates to staff have shown to reduce the rates of BSI in outpatient HD patients. Michigan Medicine conducted a recent study in pediatric patients receiving outpatient HD through a central venous catheter (CVC) to determine if BSI rates would decrease with the use of a closed system using needleless connectors and staff audits of dialysis prevention measures. The study began in 2020 and included pediatric patients receiving HD through a central venous catheter (CVC) who had a needless connector added to the end of the atrial and venous blood lines. Monthly surveillance was completed. After one year, the CVC BSI rate decreased from 16.95 per 100 patient-months in 2019 to 5.5 per 100 patient-months in 2020. Hospital admissions associated with BSIs decreased from 14 in 2019 to 5 in 2020 (Yee & Ricchiuti, 2023). The number of BSIs with a loss of vascular access outcome decreased from 5 in 2019 to 3 in 2020 (Yee & Ricchiuti, 2023). The study found that the use of needleless connectors and staff auditing the use of best practices led to a substantial reduction of BSI in pediatric outpatient HD patients.
In 2009, CDC began to work with hemodialysis centers to determine if BSI rates in outpatient hemodialysis centers could be reduced through improved adherence to recommended infection prevention practices. Participants worked with CDC to develop the “Core Interventions for BSI Prevention”, which included bundled prevention activities to decrease BSI rates. The bundle included hand hygiene, reducing the use of catheters and maximizing the use of arteriovenous fistulas and grafts, specific catheter maintenance care practices, staff education and competency assessments, and patient education. Seventeen outpatient hemodialysis centers implemented these bundled interventions and showed a 32% overall reduction of access-related BSI incidence and a 54% reduction in the central venous catheter population following implementation (Patel, et al., 2013). Four years after the interventions were initiated, the facilities continued to see reductions in their access-related BSI incidence rates (Yi, et al., 2016).
In a study published in 2014, a CVC care plan, incorporating use of chlorhexidine with alcohol pads to “scrub the hubs” (consistent w/ CDC recommendations) was implemented in 211 facilities. BSI rates in these facilities were compared to matched facilities practicing usual catheter care. Findings showed that BSI and IVABS rates declined by 20% in facilities that adopted the new catheter care procedure. Further, these declines were sustained over time, and were associated with a lower rate of hospitalizations (Rosenblum et al., 2014).
Another study launched in late 2017 studied safety culture and BSI prevention practices in a large outpatient dialysis program in upstate New York. The study implemented BSI prevention practices including: hand hygiene, station cleaning, fistula/graft and catheter access and access care, exit site care and patient engagement. The programs standardized infection ratio (SIR) decreased from 1.960 in 2017 to 0.985 in 2018 (Millson, et. al., 2019). In addition, the study found that there was a decrease in organisms identified from blood cultures that are associated with poor aseptic technique. The program also observed a decrease their MRSA-related BSI rates by 80% (Millson, et. al., 2019).
This evidence supports a link between BSI prevention practices, such as hand hygiene, appropriate catheter use, aseptic technique for catheter access and maintenance, surveillance, staff education and training, and the reduction of BSIs.

- Fisher M, Golestaneh L, Allon M, Abreo K, Mokrzycki MH. Prevention of Bloodstream Infections in Patients Undergoing Hemodialysis. Clin J Am Soc Nephrol. 2020 Jan 7;15(1):132-151. doi: 10.2215/CJN.06820619. Epub 2019 Dec 5. Erratum in: Clin J Am Soc Nephrol. 2022 Apr;17(4):568-569. PMID: 31806658; PMCID: PMC6946076.
- Millson T, Hackbarth D, Bernard HL. A demonstration project on the impact of safety culture on infection control practices in hemodialysis. Am J Infect Control. 2019 Sep;47(9):1122-1129.
- Mokrzycki MH, Leigh KA, Kliger AS, Niyyar VD, Bren Asp V, Golestaneh L, Taylor Q, Novosad SA. Implementation of an Electronic Catheter Checklist in Outpatient Hemodialysis Facilities: Results of a Pilot Quality Improvement Project. Kidney360. 2021 Feb 9;2(4):684-694.
- Patel PR, Yi SH, Booth S, Bren V, Downham G, Hess S, Kelley K, Lincoln M, Morrissette K, Lindberg C, Jernigan JA, Kallen AJ. Bloodstream infection rates in outpatient hemodialysis facilities participating in a collaborative prevention effort: a quality improvement report. Am J Kidney Dis. 2013 Aug;62(2):322-30.
- Rosenblum A, Wang W, Ball L, Latham C, Maddux F, Lacson F. Hemodialysis catheter care strategies: a cluster-randomized quality improvement initiative. Am J Kidney Dis. 2014; 63(2):259-267.
- Soi V, Moore CL, Kumbar L, Yee J. Prevention of catheter-related bloodstream infections in patients on hemodialysis: challenges and management strategies. Int J Nephrol Renovasc Dis. 2016 Apr 18;9:95-103.
- United States Renal Data System. 2023 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2023. https://usrds-adr.niddk.nih.gov/2023/introduction. Accessed November 15, 2023.
- Yee, M. & Ricchiuti, S. Preventing Pediatric Outpatient Hemodialysis Morbidity: Implementing the Use of Needleless Connectors and Prevention Process Measures Audits to Reduce Bloodstream Infections. American Journal of Infection Control, Volume 51, Issue 7, Supplement, 2023, Page S35.
- Yi SH, Kallen AJ, Hess S, Bren VR, Lincoln ME, Downham G, Kelley K, Booth SL, Weirich H, Shugart A, Lines C, Melville A, Jernigan JA, Kleinbaum DG, Patel PR. Sustained Infection Reduction in Outpatient Hemodialysis Centers Participating in a Collaborative Bloodstream Infection Prevention Effort. Infect Control Hosp Epidemiol. 2016 Jul;37(7):863-6.

In addition to the studies cited above, the following section describes evidence based-Guidelines for the Prevention of Intravascular Catheter-related Infections 2011.

The following guideline supports the measure and is evidence based-Guidelines for the Prevention of Intravascular Catheter-related Infections 2011.

The guideline recommendations include specific interventions and practices for healthcare personnel who insert intravascular catheters and for persons responsible for surveillance and control of infections in hospital, outpatient, and home healthcare settings to prevent intravascular catheter-related infections. Evidence supports a link between these practices and the reduction of BSIs among outpatient hemodialysis patients, including intravascular catheter-related infection prevention practices, such as aseptic technique for catheter access and maintenance, hand hygiene, and surveillance of implemented bundled prevention strategies and infections to ensure compliance.

- Source: O'Grady NP, Alexander M, Burns LA, Dellinger EP, Garland J, Heard SO, Lipsett PA, Masur H, Mermel LA, Pearson ML, Raad II, Randolph AG, Rupp ME, Saint S; Healthcare Infection Control Practices Advisory Committee (HICPAC). Guidelines for the prevention of intravascular catheter-related infections. Clin Infect Dis. 2011 May;52(9):e162-93.

The system for categorizing recommendations in this guideline is as follows:
Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale; or an accepted practice (e.g., aseptic technique) supported by limited evidence.
Category IC. Required by state or federal regulations, rules, or standards.
Category II. Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.
Unresolved issue. Represents an unresolved issue for which evidence is insufficient or no consensus regarding efficacy exists.

Strategies for Prevention of Catheter-Related Infections in Adult and Pediatric Patients
Education, Training and Staffing
Recommendations
1. Educate healthcare personnel regarding the indications for intravascular catheter use, proper procedures for the insertion and maintenance of intravascular catheters, and appropriate infection control measures to prevent intravascular catheter-related infections. Category IA
2. Periodically assess knowledge of and adherence to guidelines for all personnel involved in the insertion and maintenance of intravascular catheters. Category IA
3. Designate only trained personnel who demonstrate competence for the insertion and maintenance of peripheral and central intravascular catheters. Category IA

Central Venous Catheters Recommendations

1. Weigh the risks and benefits of placing a central venous device at a recommended site to reduce infectious complications against the risk for mechanical complications (e.g., pneumothorax, subclavian artery puncture, subclavian vein laceration, subclavian vein stenosis, hemothorax, thrombosis, air embolism, and catheter misplacement). Category IA
2. Avoid using the femoral vein for central venous access in adult patients. Category 1A
3. Use a subclavian site, rather than a jugular or a femoral site, in adult patients to minimize infection risk for nontunneled CVC placement. Category IB
5. Avoid the subclavian site in hemodialysis patients and patients with advanced kidney disease, to avoid subclavian vein stenosis. Category IA
6. Use a fistula or graft in patients with chronic renal failure instead of a CVC for permanent access for dialysis. Category 1A
8. Use a CVC with the minimum number of ports or lumens essential for the management of the patient. Category IB

Hand Hygiene and Aseptic Technique
Recommendations
1. Perform hand hygiene procedures, either by washing hands with conventional soap and water or with alcohol-based hand rubs (ABHR). Hand hygiene should be performed before and after palpating catheter insertion sites as well as before and after inserting, replacing, accessing, repairing, or dressing an intravascular catheter. Palpation of the insertion site should not be performed after the application of antiseptic, unless aseptic technique is maintained. Category IB
2. Maintain aseptic technique for the insertion and care of intravascular catheters. Category IB
4. Sterile gloves should be worn for the insertion of arterial, central, and midline catheters. Category IA
5. Use new sterile gloves before handling the new catheter when guidewire exchanges are performed. Category II
6. Wear either clean or sterile gloves when changing the dressing on intravascular catheters. Category IC

Maximal Sterile Barrier Precautions
Recommendations
1. Use maximal sterile barrier precautions, including the use of a cap, mask, sterile gown, sterile gloves, and a sterile full body drape, for the insertion of CVCs, PICCs, or guidewire exchange. Category IB

Skin Preparation
Recommendations
2. Prepare clean skin with a.0.5% chlorhexidine preparation with alcohol before central venous catheter and peripheral arterial catheter insertion and during dressing changes. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives. Category IA
5. Antiseptics should be allowed to dry according to the manufacturer’s recommendation prior to placing the catheter. Category IB

Catheter Site Dressing Regimens
Recommendations
1. Use either sterile gauze or sterile, transparent, semipermeable dressing to cover the catheter site. Category IA
2. If the patient is diaphoretic or if the site is bleeding or oozing, use gauze dressing until this is resolved.
Category II
3. Replace catheter site dressing if the dressing becomes damp, loosened, or visibly soiled.
Category IB
4. Do not use topical antibiotic ointment or creams on insertion sites, except for dialysis catheters, because of their potential to promote fungal infections and antimicrobial resistance. Category IB
5. Do not submerge the catheter or catheter site in water. Showering should be permitted if precautions can be taken to reduce the likelihood of introducing organisms into the catheter (e.g., if the catheter and connecting device are protected with an impermeable cover during the shower). Category IB
8. Replace transparent dressings used on tunneled or implanted CVC sites no more than once per week (unless the dressing is soiled or loose), until the insertion site has healed. Category II
9. No recommendation can be made regarding the necessity for any dressing on well-healed exit sites of longterm cuffed and tunneled CVCs. Unresolved issue
14. Monitor the catheter sites visually when changing the dressing or by palpation through an intact dressing on a regular basis, depending on the clinical situation of the individual patient. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or bloodstream infection, the dressing should be removed to allow thorough examination of the site. Category IB
15. Encourage patients to report any changes in their catheter site or any new discomfort to their provider. Category II

Catheter Securement Devices
Recommendation
Use a sutureless securement device to reduce the risk of infection for intravascular catheters.
Category II

Antimicrobial/Antiseptic Impregnated Catheters and Cuffs
Recommendation
Use a chlorhexidine/silver sulfadiazine or minocycline/rifampin -impregnated CVC in patients whose catheter is expected to remain in place >5 days if, after successful implementation of a comprehensive strategy to reduce rates of CLABSI, the CLABSI rate is not decreasing. The comprehensive strategy should include at least the following three components: educating persons who insert and maintain catheters, use of maximal sterile barrier precautions, and a .0.5% chlorhexidine preparation with alcohol for skin antisepsis during CVC insertion. Category IA

Systemic Antibiotic Prophylaxis
Recommendation
Do not administer systemic antimicrobial prophylaxis routinely before insertion or during use of an intravascular catheter to prevent catheter colonization or CRBSI.

Category IB

Antibiotic/Antiseptic Ointments
Recommendation
Use povidone iodine antiseptic ointment or bacitracin/gramicidin/polymyxin B ointment at the hemodialysis catheter exit site after catheter insertion and at the end of each dialysis session only if this ointment does not interact with the material of the hemodialysis catheter per manufacturer's recommendation. Category IB

Antibiotic Lock Prophylaxis, Antimicrobial Catheter Flush and Catheter Lock Prophylaxis
Recommendation
Use prophylactic antimicrobial lock solution in patients with long term catheters who have a history of multiple CRBSI despite optimal maximal adherence to aseptic technique. Category II

Replacement of CVCs, Including PICCs and Hemodialysis Catheters
Recommendations
1. Do not routinely replace CVCs, PICCs, hemodialysis catheters, or pulmonary artery catheters to prevent catheter related infections. Category IB
2. Do not remove CVCs or PICCs on the basis of fever alone. Use clinical judgment regarding the appropriateness of removing the catheter if infection is evidenced elsewhere or if a noninfectious cause of fever is suspected. Category II

Performance Improvement
Recommendation
Use hospital-specific or collaborative-based performance improvement initiatives in which multifaceted strategies are ''bundled'' together to improve compliance with evidence-based recommended practices. Category IB

2.4 Performance Gap

The dataset used for testing is the Center for Disease Control's (CDC) National Healthcare Safety Network (NHSN), which collects healthcare infection data from facilities throughout the United States. Data utilized in reliability and validity testing is from 7,240 facilities who reported into NHSN from 1/1/2022 to 12/31/2022. Also shown below are 2021 data from 7,295 facilities.

The below charts provide evidence that a performance gap exists among facilities reporting on the BSI in Hemodialysis Outpatients measure, as there is a widespread between the highest (1.55, 1.57) and lowest (0.0, 0.0) Standardized Infection Ratio (SIR) in 2022 and 2021 respectively.

Table 1. Performance Scores by Decile

Performance Scores by Decile

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Mean Performance Score	0.40	0	0.0	0.130	0.21	0.28	0.36	0.44	0.55	0.70	0.95	1.57	8.75
N of Entities	7295		2276	557	558	558	558	557	558	558	558	557	
N of Persons / Encounters / Episodes	5,115,103		1,129,324	613,724	488,127	454,064	439,692	430788	412,522	421,758	399,347	325,757	

2.4a Attach Performance Gap Results

2.4a Performance Gap.pdf

2.6 Meaningfulness to Target Population

The below feedback on the measure was obtained from the Patient Safety Action Network.

Fundamentally, this measure is essential to preventing infections. If we do not measure these events in a continuous, standardized way, we cannot truly know or understand when actual progress is made by reducing harm to patients.

Dialysis patients are among the most vulnerable people when it comes to health care acquired infections – they are in a long-term struggle with their health and they require regular interactions for their treatment with health care providers. That is one of the most important reasons to keep this measure. Further, this measure's more global scope makes it more valuable to patients. Because it covers all bloodstream infections and is not parsed by association with specific pathogens, it is a measure that dialysis patients can understand.

Dialysis patients can use this publicly reported information to make choices of where they go for this continuous treatment if they have a choice. If they do not have a choice, this measure can alert them to problems and the need to take the initiative to protect themselves, which may include discussing prevention priorities with their provider. Getting an infection is an unexpected difficulty for them that can be life-threatening. People who are unaware of the measure are generally outraged when a poor record of preventing infections was not widely known in their community. We hear several common responses from patients infected while receiving health care. They understand the importance of being counted and want to know "will my infection be counted?" They understand the purpose of these measures and want to know "how can we prevent it from happening again to someone else?"
Lisa McGiffert
Patient Safety Activist
Patient Safety Action Network
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@ptsafetyaction

The bloodstream infection (BSI) in hemodialysis outpatients Standardized Infection Ratio serves as a broad, objective measure of healthcare-associated infection (HAI) burden within outpatient hemodialysis locations. HAI reduction has been a national priority set by U.S. Government going back to 2008 with the U.S. Health and Human Services (HHS) National Action Plan to Prevent Health Care-associated Infections: Roadmap to Elimination.1 While there has been overall progress in reducing these specific HAIs, there is room for improvement in both the surveillance and prevention of BSIs.

Measuring BSIs has also been a priority for CMS as indicated by using the measure in the CMS End-Stage Renal Disease Quality Incentive Program (ESRD QIP).

1. U.S. Health and Human Services (HHS) National Action Plan to Prevent Health Care-associated Infections: Roadmap to Elimination. Accessed December 11, 2023 at HAI National Action Plan | HHS.gov

3.1 Contributions Towards Closing Care Gaps

N/A. This question is optional.

4.1 Feasibility Assessment

The measure specifications have not been updated since the measures last endorsement. No feasibility challenges were experienced with the use of the measure. All required data elements are routinely generated and used during care delivery.

4.3 Feasibility Informed Final Measure

The measure specifications have not been updated since the measures last endorsement. No feasibility challenges were experienced with the use of the measure. All required data elements are routinely generated and used during care delivery.

4.4 Proprietary Information

Not a proprietary measure and no proprietary components

5.1.1 Data Used for Testing

Reliability Testing:

The dataset used for testing is the Center for Disease Control’s (CDC) National Healthcare Safety Network (NHSN), which collects healthcare infection data from facilities throughout the United States. Data utilized in testing is from 1/1/2022 to 12/31/2022.

Validity Testing:
The dataset used for testing is the Center for Disease Control’s (CDC) National Healthcare Safety

Network (NHSN), which collects healthcare infection data from facilities throughout the United States. Data utilized in testing is from 1/1/2022 to 12/31/2022. In addition to reporting infection events facilities submit an annual survey which collects data about the facilities characteristics, staffing and infection control practices, and the 2022 Annual Survey was used for validity testing.

Risk Adjustment:
The dataset used for risk adjustment is the Center for Disease Control's (CDC) National Healthcare Safety Network (NHSN) data from 01-01-2014 – 12-31-2014.

5.1.2 Differences in Data

Reliability and Validity Testing:
The dataset used for testing is the Center for Disease Control's (CDC) National Healthcare Safety Network (NHSN), which collects healthcare infection data from facilities throughout the United States. Data utilized in testing is from 1/1/2022 to 12/31/2022. Additionally, for validity testing facilities submit an annual survey which collects data about the facilities characteristics, staffing and infection control practices, and the 2022 Annual Survey was used for validity testing.

Risk Adjustment:

The 2014 NHSN Dialysis data is the source for the risk modeling.

5.1.3 Characteristics of Measured Entities

Reliability and Validity Testing:

7240 facilities that reported NHSN data from 1/1/2022 to 12/31/2022 were examined. See table of descriptive characteristics below.

Characteristics of facilities reporting to Dialysis Event Surveillance, National Healthcare Safety Network, 2022

Characteristics	***N***
No. of facilities reporting	7240
Ownership, *n* (%)	
Profit	6,350 (88)

Nonprofit	854 (12)
Government	36 (<1)
Part of a dialysis chain, *n* (%)	6,764 (93)
Location, *n* (%)	
Freestanding clinic	6,759 (93)
Hospital-based clinic	278 (4)
Freestanding clinic owned by hospital	202 (3)
No. of stations, median (IQR)	17 (13–24)
No. of patients treated, median (IQR)	626 (408–901)

Risk Adjustment:

The data set for risk adjustment includes blood stream infections reported to NHSN in 2014.

The level of analysis for risk adjustment is the facility. The Table below shows descriptive characteristics of facilities used in the risk adjustment.

Characteristics of facilities reporting to Dialysis Event Surveillance, National Healthcare Safety Network, 2014

Characteristics	
N	
No. of facilities reporting	6005
Ownership, *n* (%)	
Profit	5142 (86)
Nonprofit	813 (14)
Government	50 (1)
Part of a dialysis chain, *n* (%)	5392 (90)
Location, *n* (%)	

Freestanding clinic	5429 (90)
Hospital-based clinic	356 (6)
Freestanding clinic owned by hospital	220 (4)
No. of stations, median (IQR)	17 (12–23)
No. of patients treated, median (IQR)	59 (34–90)

5.1.4 Characteristics of Units of the Eligible Population

Reliability/Validity Testing and Risk Adjustment: Due to the data collection burden, demographic data on patients is not available for analysis, as it is not required in the NHSN Dialysis Module.

5.2.1 Level(s) of Reliability Testing Conducted

Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

Signal-to-noise reliability testing was performed to distinguish measure scores between facilities (Adams J.L. 2009). The annual standardized infection ratio (SIR) is defined as the sum of observed (O) events at the facility divided by the sum of predicted (P) events calculated from the risk-adjustment model. Signal-to-noise reliability testing denotes between-facility variance and within-facility variance (Adams J.L. 2009). Each facility SIR represents the between-facility variance; total variance of the data across eligible facilities. The within-facility variance of the SIR for each facility was then calculated as Var(O/P) where P is a constant, a nuisance factor with no random variation. O was assumed to follow a Poisson distribution with rate parameter approximated by P. The result is Var(O/P) = Var(O)/P2 = P/P2 = 1/P. Signal to noise reliability scores can range from 0 to 1. A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real difference in performance.

References:

- Adams, J. L. (2009). The reliability of provider profiling: a tutorial. RAND.

5.2.3 Reliability Testing Results

The median reliability score for outpatient dialysis facilities was 0.52 with the overall reliability from 0.23 in decile 1 to 0.75 in decile 10.

5.2.4 Interpretation of Reliability Results

Signal-to-Noise reliability scores vary across facilities from zero to one, with a score of zero indicating that all variation is attributable to noise (variation across patients within facilities) and a score of one indicating that all variation is caused by real differences in performance across facilities.

The median reliability score for outpatient dialysis facilities was 0.52. The median signal-to-noise reliability score demonstrates moderate agreement. Our interpretation of the results is based on the standards established by Landis and Koch (1977):

- < 0 – Less than chance agreement
- 0 – 0.2 Slight agreement
- 0.21 – 0.39 Fair agreement
- 0.4 – 0.59 Moderate agreement
- 0.6 – 0.79 Substantial agreement
- 0.8 – 0.99 Almost Perfect agreement
- 1 Perfect agreement

Overall reliability for the BSI in Hemodialysis Outpatients measure is tied directly to denominator size (in this case, patient months) and thus the size of the facility. When measuring outpatient dialysis BSI events, to promote accountability for preventing BSIs at all dialysis facilities, all sites are included, regardless of size and exposure, including sites with near zero predicted events. Since sites with low exposure are included, the overall reliability coefficient is reduced. A decreased overall reliability results from the inclusion of every outpatient dialysis clinic which covers the fullest range of exposure volume. The reliability results show that, as expected, as the denominator (patient months) size increases, so does the overall reliability (from .23 in decile 1 to .75 in decile 10).

Reference

- Landis, J. R., & Koch, G. G. (1977). The measurement of observer agreement for categorical data. *biometrics*, 159-174.

Table 2. Accountable Entity Level Reliability Testing Results by Denominator, Target Population Size

Reliability Results by Decile

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Reliability	0.52	<0.01	0.23	0.37	0.43	0.48	0.52	0.55	0.59	0.63	0.67	0.75	0.90
Mean Performance Score	0.36	0	0.43	0.39	0.37	0.35	0.35	0.36	0.37	0.34	o.35	0.36	0.217
N of Entities	7240		722	723	723	722	723	721	724	722	724	723	
N of Persons / Encounters / Episodes	5077078		127123	243541	311005	374483	428492	487548	558691	654498	793668	1098029	

5.3.1 Level(s) of Validity Testing Conducted

Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.3 Method(s) of Validity Testing

To test the Standardized Infection Ratio (SIR) validity, data submitted to NHSN in 2022 by 7,240 outpatient dialysis facilities were analyzed to examine the relationship between the SIR and selected infection control (IC) practices, controlling for facility characteristics. Facility infection control practices and characteristics were obtained from the 2022 CDC NHSN Annual Dialysis Practice Survey.

Facilities that report to NHSN are asked about IC practices in the Annual Dialysis Practices Survey. SIRs were calculated using the number of events observed at a facility divided by expected numbers of events, which was calculated by multiplying the number of patient months by the national BSI rates, stratified by access type. We hypothesized the facilities that reported adopting certain IC practices would have lower SIRs than those that did not.

Analysis explored the relationship between SIRs and selected IC practices and covariates (facility characteristics). Associations between IC practices and the SIR were tested using a series of one-tailed binomial tests with mid-p 95% confidence intervals.

5.3.4 Validity Testing Results

Comparison of SIRs in dialysis facilities that practice specified infection control practices.	**Facility Count**	**SIR**	**Ratio of SIRs (CI)**	**p-value**
Total	7,240	.36	----	----
Practice/Core Intervention*				
Yes ALL (ref)	5,167	.35	----	----
Yes SOME	2,072	.38	1.06(1.03, 1.10)	0.0004
Use Antimicrobial Barrier Caps				
Yes (ref)	3,560	.31	----	----
No	3,679	.40	1.3 (1.26, 1.34)	<.0001

Perform Cath Care Observations				
Yes (ref)	7,109	.35	-----	---
No	130	.67	1.88(1.69, 2.09)	<.0001
Antiseptic used for cleaning site at dressing changes**				
CWA (ref)	512	.33	----	----
Alcohol	368	.361	.10(.99,1.21)	027
Chlorhexidine Only	5,991	.351	.07(1.01,1.47)	.015
SHCWA	153	.58	1.77(1.60,1.97)	<.0001
Other (incl. SHC, PI, Other)	194	.371	.25(1.00,1.26)	.023
All Else Combined	6,109	.36	1.09(1.03, 1.17)	.003

*CDC Recommended Core Interventions include: surveillance and feedback using NHSN, ,hand hygiene observations, catheter/vascular access care observations, staff education and competency, patient education/engagement, catheter reduction, use of chlorhexidine with alcohol as antiseptic for central line insertion and during dressing changes, scrubbing the catheter hub with appropriate antiseptic every time catheter is accessed or disconnected, applying antibiotic or povidone-iodine ointment to catheter exit sites during dressing changes.

**CWA=Chlorhexidine with Alcohol, SHCWA=Sodium Hydrochloride with Alcohol, SHC=Sodium Hydrochloride, PI=Povidone Iodine

5.3.5 Interpretation of Validity Results

Overall, these results show that, as expected, the SIR was significantly lower in facilities that reported adopting all vs. some of CDC's core interventions and in facilities that reported practicing the following infection control practices; using antimicrobial barrier caps with catheters, performing observations of catheter care, and using Chlorhexidine with Alcohol (vs. other antiseptics) on the site during dressing changes. Facilities that reported practicing "ALL" of the recommended core interventions had a significantly lower SIR than those reporting to practice "SOME" (.35 vs. .38; SIR ratio=1.06, p=.0004). Facilities reporting use of antimicrobial barrier caps on catheters had a significantly lower SIR than facilities not using them (.31 vs .40; SIR ratio=1.3, p<.0001). Facilities that practiced observations of catheter care had a significantly lower SIR than those saying they did not conduct such observations (.35 vs. .67; SIR ratio=1.88, p<.0001). Facilities reporting that they used Chlorhexidine with alcohol (as recommended by CDC) had lower SIRs than those using other antiseptics, particularly Sodium Hydrochloride with

Alcohol (.33 vs. .58; SIR ratio=1.77, p<.0001) and Chlorhexidine alone (.33 vs. .35; SIR ratio=1.07, p=.015).

5.3.2 Type of Accountable Entity Level Validity Testing Conducted (derived)

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis)

5.4.1 Methods Used to Address Risk Factors

Statistical risk adjustment model with risk factors

5.4.2 Conceptual Model Rationale

The attached conceptual model shows how infection risk increases based on access type as this is the sole risk factor included in the SIR model. The next table shows the beta weights which can be used to calculate the predicted number of events. Finally, we have provided a description of how to calculate the SIR.

The following formula was used to derive the predicted BSI events:

Logit(BSI)={-5.9332 + (.5642*(AccessType="Other")) + (.4279*(AccessType="Graft"))+ (2.1379*(AccessType="CVC"))}

Predicted(BSI)=Exp(Logit(BSI)) * Number of Patient Months

The model was developed using SAS 9.4 with fistula access as the referent group and ln of patient month used as the models offset.

Reference: Nguyen DB, Shugart A, Lines C, Shah AB, Edwards J, Pollock D, Sievert D, Patel PR. National Healthcare Safety Network (NHSN) Dialysis Event Surveillance Report for 2014. Clin J Am Soc Nephrol. 2017 Jul 7;12(7):1139-1146. doi: 10.2215/CJN.11411116. Epub 2017 Jun 29. PMID: 28663227; PMCID: PMC5498356

For calculation of the SIR, risk adjustment is performed based on stratification of rates by vascular access type. This stratification accounts for direct contributions to risk impacted by the access type and may also account for other factors correlated with vascular access type. Within each stratified category of patient-vascular access type, risks of bloodstream infection are more consistent and more dependent upon practices related to vascular access.

The SIR is calculated as the number of observed infections divided by the number of predicted infections.

SIR=Observed (O) BSIs/Predicated (P) BSIs

The number of predicted infections may alternately be calculated using a negative binomial regression model generated from the nationally aggregated 2014 data that produced the stratified rates mentioned above. The model below represents another statistical method for calculating each facility's predicted number of infections.

Note: The access device reported may not be the one currently used for dialysis. The risk levels for each access type are shown below. Data is reported using the vascular access type that is in place with the highest risk of infection. This access type with the highest risk of infection is used for analysis.

5.4.2a Attach Conceptual Model

Q. 4.4.2 Risk Conceptual Model.pdf

5.4.3 Variable Distribution Across Measured Entities

Table : Pooled mean BSI rates by vascular access type (Dialysis Event Surveillance, National Healthcare Safety Network, 2014)

Access Type	# BSI Events	# Patient Months	Pooled Mean
Fistula	7587	2,876,871	0.26
Graft	3262	827,821	0.39
Other	76	15,016	0.51
CVC	18,591	859,119	2.16

The order of access type above reflects the order based on risk in the conceptual model.

5.4.4 Risk/Case-Mix Adjustment Modeling and/or Stratification Results

Variables were eligible for entering the model at p-value=0.25 and retaining in the model at p-value=0.05 significance level. Factors were evaluated using negative binomial regression and entered a multivariate model using forward stage-wise selection, based on the highest Wald Chi-square value and greatest reduction to Akaike Information Criterion (AIC). Goodness of fit was assessed at each modeling step using the Akaike Information Criterion, log likelihood and

deviance statistics. The final model resulting from forward stage-wise selection was validated by bootstrap sampling.

Model validation was performed by bootstrap validation. 1.The BSI model (Full model) was trained on the 2014 national dataset. 2. 1000 bootstrap samples were formed by drawing randomly with replacement from the original sample dataset. 3. A new model was trained on each bootstrap sample, and record of each corresponding model parameters and performance metrics were saved. 4. Repeat steps 1-3 for an intercept only (Null) model. Finally, the 1000 Null and 1000 Full models were compared using several measures for model error and Likelihood ratios.

5.4.4a Attach Risk/Case-mix Adjustment Modeling and/or Stratification Specifications

Q4.4.4a Risk Adjustment Modeling.xlsx

5.4.5 Calibration and Discrimination

Model validation was performed by bootstrap validation. 1.The BSI model (Full model) was trained on the 2014 national dataset. 2. 1000 bootstrap samples were formed by drawing randomly with replacement from the original sample dataset. 3. A new model was trained on each bootstrap sample, and record of each corresponding model parameters and performance metrics were saved. 4. Repeat steps 1-3 for an intercept only (Null) model. Finally, the 1000 Null and 1000 Full models were compared using several measures for model error and Likelihood ratios.

5.4.5a Attach Calibration and Discrimination Testing Results

Q 4.4.5a Calibration and Discrimination Testing Results.pdf

5.4.6 Interpretation of Risk/Case-mix Factor Findings

This analysis included the vascular access type by which dialysis was administered (collected monthly) and several additional variables collected from an annual survey for each outpatient dialysis facility. The list of survey variables collected on the annual survey included ownership (i.e., Government, Not for profit, For profit), whether a dialysis facility was part of a group or chain, the location/hospital affiliation (i.e., Freestanding, Hospital based, Freestanding but owned by a hospital) and the number of In-center hemodialysis stations. Vascular access type was the only factor significantly associated with BSI event incidence as determined by negative binomial regression analysis including Wald and Likelihood Ratio chi-square tests and a model fit using Akaike Information Criterion. These results led to a best model that included vascular access type alone. Identification of this single factor is understandable since there was prior literature review that helped direct the monthly collection of dialysis exposures by vascular access type. Furthermore, varying monthly denominator (i.e., exposure) data collected for each vascular access type may have allowed for capturing more granular differences in BSI incidence that led to a significant association. In contrast, survey factors reported annually were done so with very few response levels and certainly not by vascular access type, which may have contributed to their lack of association with BSI incidence.

5.4.7 Final Approach to Address Risk Factors

Statistical risk adjustment model with risk factors, Stratification by risk factor category

6.1.1 Current Status

In use

6.1.3 Current Use(s)

Public Reporting, Public Health/Disease Surveillance, Payment Program, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

6.1.3 Program Details

Name of the program and sponsor
Care Compare
URL of the program
https://www.medicare.gov/care-compare/?providerType=Hospital&redirect=true
Purpose of the program
For people with Medicare or their caregivers who want to choose a Medicare provider, such as a physician, hospital, nursing home, and others, this tool provides a single source search and compare experience. Care Compare lists the quality of care and pat
Geographic area and percentage of accountable entities and patients included
Outpatient hemodialysis facilities across the nation.
Applicable level of analysis and care setting

Facility, Outpatient

,
Name of the program and sponsor
Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN)
URL of the program
http://www.cdc.gov/nhsn/
Purpose of the program
The CDC NHSN healthcare-associated infection tracking system provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections
Applicable level of analysis and care setting

Facility, outpatient

,
Name of the program and sponsor
CMS End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
URL of the program
https://www.cms.gov/medicare/quality/end-stage-renal-disease-esrd-quality-incen…
Purpose of the program
To promote high-quality services in outpatient renal dialysis facilities by linking a portion of CMS payments directly to facilities’ performance on quality-of-care measures.

Geographic area and percentage of accountable entities and patients included
Over 7,000 outpatient hemodialysis facilities across the nation.
Applicable level of analysis and care setting

Facility, Outpatient

6.2.1 Actions of Measured Entities to Improve Performance

Numerous prevention efforts have been identified to reduce the incidence of bloodstream infections in patients receiving hemodialysis at outpatient facilities. These interventions include (i) hand hygiene, (ii) appropriate catheter use: incorporating patient education, employing a vascular access coordinator to reduce catheters by identifying and addressing barriers to permanent vascular access placement and catheter removal, (iii) proper techniques for catheter/vascular access maintenance, (iv) administrative infrastructure and surveillance: training staff on infection control topics, including access care and aseptic technique, competency evaluation of clinical skills such as catheter care and assessing skills every 6-12 months and upon hire, conducting monthly surveillance for BSIs and sharing results with front-line clinical staff.

The difficulty in implementing prevention strategies and achieving decreased outcomes is based on support from the facility leadership and the overall capabilities of the facility. However, for most facilities these infection control practices are routine.

6.2.2 Feedback on Measure Performance

We have not received feedback from facilities, large dialysis organizations (LDOs) and jurisdictions about measure performance and implementation but do receive questions about how to calculate the SIR. To answer these questions, we have multiple resources that describe/demonstrate how the SIR is calculated, including an informational handout, descriptions on the NHSN webpage and individualized responses to clients submitting questions to the NHSN Service Desk.

6.2.3 Consideration of Measure Feedback

The SIR is seen as a better indicator of infection prevention performance because it is inherently risk stratified, unlike crude rates. In response to questions about the SIR, we have developed resource materials (described above) that explain how it is calculated and can be interpreted and used. There are currently plans to modify the SIR in the future to assess the inclusion of risk factors in addition to access type. Otherwise, NHSN has not received any feedback regarding the measure specifications. For any measure revision recommendations received, CDC NHSN will perform a literature review to determine if the recommendation is based on current guidelines and practices. If literature is found to support the revision, we then turn to subject matter experts to advise on further revisions and make updates to the measure specifications as appropriate.

6.2.4 Progress on Improvement

Improvement in infection prevention performance has been demonstrated by a decreasing trend in national SIRs over time. In a 2017 published study by Nguyen et al., the median facility SIR for 2014 data was .84. The table below shows that more recent NHSN data has shown a continued decline. Publications and annual surveillance reports that substantiate this decline and demonstrate improved BSI prevention performance are forthcoming.

Year	# Facilities	Median facility-level SIR	Pooled mean national SIR
2015	6,005	0.84	Not Available
2019	7,117	0.48	0.60
2020	7,183	0.28	0.40
2021	7,295	0.28	0.40
2022	7,240	0.24	0.36

6.2.5 Unexpected Findings

NHSN has not had any unexpected findings during implementation of the measure.

Developer POC email

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Measure Developer POC

Jeneita Bell
CDC NHSN
United States

Measured/accountable entity (reliability and/or validity) methodology and results (if available)

Measured entity (reliability and validity) methodology and results (if available)

The measure developer is different from the measure steward

Yes

Steward Address

United States

Steward Organization

Centers for Disease Control and Prevention, National Healthcare Safety Network

Steward Organization URL

https://www.cdc.gov/nhsn/index.html

Steward POC email

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