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## Major Article

## Reaching consensus on a home infusion central line-associated bloodstream infection surveillance definition via a modified Delphi approach



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## Key Words:

CLABSI

Central line associated bloodstream infection

Home infusion therapy

**Background:** A consensus on a central line-associated bloodstream infection (CLABSI) surveillance definition in home infusion is needed to standardize measurement and benchmark CLABSI to provide data to drive improvement initiatives

**Methods:** Experts across fields including home infusion therapy, infectious diseases, and healthcare epidemiology convened to perform a 3-step modified Delphi approach to obtain input and achieve consensus on a candidate home infusion CLABSI definition.

**Results:** The numerator criterion was identified by participants as involving one of the 2 following: (1) recognized pathogen isolated from blood culture and pathogen is not related to infection at another site, or (2) one of the following signs or symptoms: fever of 38°C (100.4°F), chills, or hypotension (systolic blood pressure ≤90 mm Hg), and one of the 2 following: (A) common skin contaminant isolated from 2 blood cultures drawn on separate occasions and organism is not related to infection at another site, or (B) common skin contaminant isolated from blood culture from patient with intravascular access device and provider institutes appropriate antimicrobial therapy. The criteria for a denominator included days from the day of admission with a central venous catheter to day of removal of central venous catheter. In addition, 11 inclusion criteria and 4 exclusion criteria were included.

**Discussion:** Home infusion therapy and healthcare epidemiology experts developed candidate criteria for a home infusion CLABSI surveillance definition.

**Conclusions:** Home care and home infusion agencies can use this definition to monitor their own CLABSI rates and implement preventative strategies.

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Annually, 1.2 million use long-term central venous catheters (CVCs) at home for chemotherapy, total parenteral nutrition, outpatient parenteral antimicrobial therapy, and other indications.<sup>1</sup> Unlike in hospitals, patients receiving these therapies through home care, home infusion, or home hospice agencies, and their caregivers (eg, family, friends, neighbors, and coworkers) perform day-to-day CVC care and initiate infusion therapy after being trained and deemed

competent by home care nurses. Patients maintaining CVCs at home are at risk for developing central line-associated bloodstream infections (CLABSIs). CLABSIs developing outside of acute care hospitals can outnumber acute care CLABSIs.<sup>2</sup>

National policies have led to widely-accepted acute care CLABSI surveillance definitions<sup>3–7</sup> reportable through the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN).<sup>4,8,9</sup> With uniform CLABSI surveillance definitions, benchmarked rates, and mandated reporting, quality improvement initiatives using evidence-based intervention bundles have contributed to a 50% drop in acute care CLABSI rates.<sup>10–13</sup>

In order to benchmark home infusion CLABSI data in home infusion patients and to similarly allow for large-scale quality improvement initiatives, there is an urgent need for an improved home infusion CLABSI definition. The Association of Professionals in Infection Control (APIC) developed a definition of home healthcare-associated bloodstream infections<sup>14</sup> relying on NHSN acute care CLABSI criteria available in 2008, but this definition has not been widely adopted.<sup>4,15</sup> We recently showed that significant variation exists nationwide in home infusion CLABSI reporting.<sup>16</sup> In particular, it is unclear how to define, collect, and record denominator data.<sup>17</sup> Determining attribution is also difficult, especially if the CVC is accessed both in the home and in an outpatient clinic, or if a home infusion agency provides product to a patient but a noncontracted home nursing agency provides education.<sup>17</sup> Other challenges with surveillance include accessing inpatient records to access laboratory test results when a blood culture is drawn in an acute care setting, and lack of trained infection preventionists in most home infusion agencies.<sup>16,17</sup>

To address the need for a CLABSI definition in the home, we gathered stakeholders in healthcare epidemiology, infection prevention, measure development, infusion nursing, and home infusion therapy to acquire input and achieve consensus around a home infusion CLABSI surveillance definition.

## METHODS

We performed a modified 3-stage Delphi approach to identify components of a definition of CLABSI for home infusion therapy, consisting of a ranking evaluation, consensus meeting, and final ranking evaluation<sup>18–20</sup> (Fig 1).

### Systematic literature review

A systematic literature review was conducted to inform the components of a definition of CLABSI in home infusion therapy, focusing on the elements used in the NHSN acute care CLABSI definition.<sup>7</sup> These were numerator criteria (or what would be considered a CLABSI), denominator criteria (how to measure CVC days), inclusion criteria (the population eligible to develop a CLABSI), and exclusion criteria (the population excluded from eligibility criteria from CLABSI surveillance).<sup>16,21</sup> We focused on criteria used by researchers studying CLABSI or other bloodstream infections in home infusion therapy, as well as reports of what may be used nationally in monitoring or reporting for patients.

The search strategy was developed with the assistance of a medical librarian using variations of key MeSH terms associated with

home infusion therapy and CLABSI or bloodstream infection (Appendix 1). The search strategy was applied for the period of January 1, 1980 through January 7, 2019. This search strategy was applied to PubMed, Cochrane Library, and Embase databases. Hand searches were conducted of the reference lists of retrieved articles, and additional literature identified through knowledge of the researchers. We also included bloodstream infection surveillance definitions used in other healthcare settings, particularly the acute care NHSN CLABSI criteria and the NHSN dialysis event surveillance.

Studies were considered for review if they described numerator, denominator, inclusion, or exclusion criteria for CLABSI or bloodstream infection in home infusion therapy, descriptions of CLABSI surveillance activities in home infusion therapy, or guidelines for CLABSI definitions in other healthcare settings. These descriptions of components of CLABSI definitions could have been in descriptions of an intervention, guideline, description of expert opinion, survey of common practices, or description of a cohort. Studies including adult or pediatric patients were eligible. Numerator, denominator, inclusion, and exclusion criteria were abstracted for each paper (Appendix 2).

### Formation of the expert panel

We sought expertise from a United States-based multidisciplinary panel of experts in home infusion therapy, healthcare epidemiology, infectious diseases, infection prevention, home parenteral nutrition (HPN), and home infusion nursing. We reached out to authors of studies identified in the systematic review and experts who have been involved in home health quality collaborations. In addition, we reached out to those who had responded to a prior survey of members of the Infusion Nurses Society, Society for Healthcare Epidemiology of America Research Network, and the National Home Infusion Association<sup>16</sup> as well as leadership of the Society for Healthcare Epidemiology of America Research Network, the Infusion Nurses Society, the Pediatrics at Home Collaborative, the National Home Infusion Association, and the American Society for Parenteral and Enteral Nutrition. Experts were asked if they had experience with CLABSI surveillance in home infusion therapy.

### First stage of Delphi: Ranking evaluation

The expert panel completed an electronic survey listing numerator, denominator, inclusion, and exclusion criteria identified in the literature review, with separate categories for pediatric criteria (Appendix 3). Experts were asked to rate each criteria for importance of the criteria and for feasibility of implementation of the criteria in home infusion therapy on a range of 1–9, where 9 was very important or very feasible. Respondents could also propose additional criteria. The survey was piloted with 3 members of the expert panel and clarifications were made to the instructions based on their comments. This first survey was distributed March through April 2019. Respondents were given 4 weekly reminder emails to complete the survey.

Descriptive statistics were used to summarize survey results. Mean scores of 7–9 on importance were considered high scores, 5–6 were considered moderate scores, and <5 were considered low scores and were excluded in later rounds of the Delphi approach.

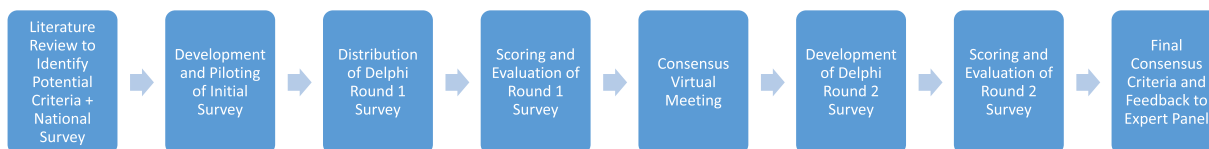


Fig 1. Performance of a 3-stage modified Delphi approach.

### Second stage of Delphi: Consensus meeting

Members of the expert panel were then invited to a 2-hour meeting on June 6, 2019 over a remote web-based platform to discuss the results of the first survey. Participants in the expert panel meeting reviewed summary data prior to the meeting. Participants in the expert panel meeting discussed each criterion with a mean importance rating  $\geq 5$ , as well as additional suggestions proposed by the expert panel. Criteria that were determined unimportant or infeasible by the expert panel meeting participants were considered for removal from the final survey. Participants in the expert panel meeting also proposed additional criteria and modifications of existing criteria. The discussion was recorded and transcribed to ensure no comments were missed.

### Third stage of Delphi: Ranking evaluation

A second survey was distributed to the entire expert panel, including those who did not participate in the meeting. Criteria included on this survey were those ranked with an importance score of  $\geq 5$  on the first survey that were viewed positively by the expert panel, criteria proposed by respondents to the first survey that were viewed positively by the expert panel, modifications of existing criteria as proposed by the expert panel, and new criteria proposed in by the expert panel.

Using the same overall categories of numerator, denominator, inclusion, and exclusion criteria, with subcategories for pediatric patients, we asked participants to rate each proposed criteria on 2 scales focusing on importance and on feasibility. Each scale ranged from 1 to 9, where 9 was highly important or highly feasible.

The electronic survey was distributed to the expert panel members throughout July 2019. Expert panel members were given 4 weekly reminder emails to complete the survey.

### Final definition components

Final survey results including descriptive statistics were returned to the expert panel for final comments and feedback, and no major objections were raised. For the numerator and denominator, the criteria ranked highest on the importance scale were included in the final definition, assuming the feasibility score was  $\geq 6$ . For the

inclusion and exclusion criteria, all with an importance score  $\geq 7$  and a feasibility score  $\geq 6$  were included.

### Ethics

The study was approved by the Johns Hopkins University School of Medicine Institutional Review Board.

### RESULTS

Of an initial 234 potential articles, we excluded 12 duplicate articles and 5 non-English language articles to review 217 abstracts in full (Appendix Fig 1). We excluded 13 articles which did not focus on home infusion and 47 conference abstracts with incomplete methods, then reviewed 157 articles in their entirety. After applying criteria as outlined in the Methods, 49 articles were included in the evidence summary, with an additional 7 articles identified through knowledge of the literature. Data was abstracted and made available to the expert panel (Appendix Table 2).

A total of 46 respondents agreed to participate in the process. Of these, 21 completed the first survey (46%, Table 1). These were primarily home health or home infusion nurses (N = 11, 52%) and infectious diseases physicians (N = 6, 29%). Most worked primarily with adults (N = 14, 67%). Respondents rated the following: 28 numerator criteria with an additional 4 pediatric numerator criteria, 11 denominator criteria, 11 inclusion criteria, and 9 exclusion criteria with an additional pediatric exclusion criteria (Appendix Table 2). In addition, respondents submitted 2 additional denominator criteria and 4 additional inclusion criteria for consideration.

Based on these rankings, we removed from consideration criteria with a rating of importance or of feasibility  $< 5$  (Appendix Table 2). Twenty-two candidate numerator criteria, 3 pediatric-specific numerator criteria, 6 denominator criteria, 8 inclusion criteria, and 7 exclusion criteria, remained, as well as a pediatric-specific exclusion criterion. Each of the pediatric-specific criteria was targeted to neonates and infants  $\leq 1$  year of age, so we also defined pediatric criteria as those  $\leq 1$  year of age.

During the remotely-facilitated live conversation, of the original 46 participants, 18 participated, including 5 infectious diseases physicians, 4 hospital epidemiologists, and 9 home infusion or home health nurses. After this conversation, 9 numerator criteria were

**Table 1**  
Composition of expert panel and participation in elements of the modified Delphi approach to developing a consensus around home infusion central line-associated bloodstream infection

Roles, population and area of expertise	Volunteered to participate N, %	Participated in Delphi survey #1 N, %	Participated in web-based expert panel discussion N, %	Participated in Delphi survey #2 N, %
<i>Role:</i>				
Home care or infusion nursing and quality improvement	27, 59%	11, 52%	9, 53%	11, 52%
Infection preventionist	9, 19.5%	3, 14%	3, 18%	5, 24%
Infectious diseases physician	9, 19.5%	6, 29%	5, 29%	5, 24%
Nutritionist	1, 2%	1, 5%	-	-
Healthcare epidemiologist	5, 11%	3, 14%	4, 24%	4, 19%
Home health/infusion Medical/nursing director	7, 15%	4, 19%	2, 12%	3, 14%
<i>Self-identified population of expertise:</i>				
Primarily sees adults	14, 30%	14, 67%	7, 41%	10, 48%
Primarily sees children	5, 11%	3, 14%	4, 24%	5, 24%
Sees both adults and children	8, 17%	4, 19%	3, 18%	6, 29%
Unspecified/Not asked	19, 41%	-	3, 18%	-
<i>Self-identified area of expertise:</i>				
Home infusion therapy	8, 17%	7, 33%	5, 29%	8, 38%
Healthcare-associated infection surveillance	7, 15%	7, 33%	2, 12%	5, 24%
Both	11, 24%	6, 29%	7, 41%	8, 38%
Unspecified/Not asked	20, 43%	1, 5%	3, 18%	-
<b>Total (N, % of total)</b>	<b>46, 100%</b>	<b>21, 46%</b>	<b>17, 37%</b>	<b>21, 46%</b>

**Table 2**

Candidate criteria for components of numerator definitions, or something that would be used in a definition of a CLABSI in home infusion therapy, after initial rating and web-based discussion. Criteria were rated on their importance and feasibility on a scale of 1–9, where 9 was very important or very feasible

Numerator criteria	Importance rating mean (standard deviation, N)	Feasibility rating mean (standard deviation, N)
<p>NNIS criteria: ONE of the two following: (1) recognized pathogen isolated from blood culture AND pathogen is not related to infection at another site, OR (2) one of the following signs or symptoms: fever of 38°C (100.4°F), chills, or hypotension (systolic blood pressure ≤90 mm Hg), AND one of the two following: (A) common skin contaminant isolated from two blood cultures drawn on separate occasions AND organism is not related to infection at another site, OR (B) common skin contaminant isolated from blood culture from patient with intravascular access device AND provider institutes appropriate antimicrobial therapy.<sup>27,2,3,31,36,38,42,52</sup></p> <p>APIC/HICPAC criteria: ONE of the three following: (1) patient has a recognized pathogen from one or more blood cultures AND organism cultured from blood is not related to an infection at another site, OR (2) patient has fever, chills or hypotension AND signs or symptoms not related to an infection at another site AND common skin contaminant in ≥2 cultures drawn on two separate occasions.<sup>18</sup></p> <p>NHSN Criteria: LCBI 1: Patient has a recognized bacterial or fungal pathogen not on the common commensal list, identified from one or more blood specimens obtained by a culture or nonculture based microbiologic testing methods AND organism is not related to an infection at another site. OR LCBI 2: Patient has at least one of the three following signs or symptoms: fever (&gt;38°C), chills, or hypotension, AND organism identified in blood is not related to an infection at another site AND the same common commensal is identified by a culture or non-culture based microbiological testing method from two or more blood specimens collected on separate occasions.<sup>6,36,38,42,46,51,52</sup></p>	7.81 (1.76, 21)	6.81 (2.40, 21)
Pediatric numerator criteria	Importance rating mean (standard deviation, N)	Feasibility rating mean (standard deviation, N)
<p>Patient up to one year of age has at least one of the following: fever (≥38°C), hypothermia (&lt;36°C), apnea, or bradycardia, AND organism identified in blood is not related to an infection at another site AND the same common commensal is identified by a culture or non-culture based microbiological testing method from two or more blood specimens collected on separate occasions.<sup>6</sup></p> <p>Patient ≤1 year of age has at least one of the following signs or symptoms: fever (&gt;38°C, rectal), hypothermia (&lt;37°C, rectal), apnea, or bradycardia and positive laboratory results are not related to an infection at another site, AND at least one of the following: (1) common skin contaminant is cultured from two or more blood cultures drawn on separate occasions, OR (2) common skin contaminant is cultured from at least one blood culture from a patient with a CVC, and provider institutes appropriate antimicrobial therapy, OR (3) positive antigen test on blood or urine.<sup>(2)</sup></p> <p>Variant: Patient ≤1 year of age with a CVC has at least one of the following signs or symptoms: fever (&gt;38°C, rectal), hypothermia (&lt;36°C, rectal), apnea, or bradycardia and positive laboratory results are not related to an infection at another site, AND at least one of the following: (1) common skin contaminant is cultured from two or more blood cultures drawn on separate occasions, OR (2) organism not considered a common skin contaminant is cultured in one culture, OR (3) positive antigen test on blood or urine.<sup>(2)</sup></p>	7.68 (1.81, 19)	6.89 (2.49, 18)
	7.11 (2.25, 19)	5.82 (2.75, 18)
	7.00 (2.18, 19)	6.28 (2.76, 17)

ANC, absolute neutrophil count; APIC, Association for Professionals in Infection Control and Epidemiology; BSI, bloodstream infection; CLABSI, central line-associated bloodstream infection; CVC, central venous catheter; HPN, home parenteral nutrition; HICPAC, Healthcare Infection Control Practices Advisory Committee; LCBI, laboratory-confirmed bloodstream infection; NHSN, National Healthcare Safety Network; NNIS, National Nosocomial Infections Surveillance; PICC, peripherally inserted central catheter; WBC, white blood cell.

maintained, and 4 additional criteria proposed.<sup>22</sup> In addition, 2 pediatric-specific numerator criteria were maintained, with one additional pediatric-specific numerator criterion suggested. Four denominator criteria were maintained, with an additional 4 denominator criteria suggested; 16 inclusion criteria were maintained, with an additional 4 inclusion criteria suggested; and 7 exclusion criteria were maintained, with an additional 6 suggested (Appendix Table 3).

During the conversation stage of the Delphi, participants agreed that a focus should be placed on meaningful and feasible measures over highly sensitive or specific measures. While there was debate around the predictive value of a clinician ordering an antimicrobial agent in response to a single positive culture and around the challenges accessing these data, it was thought that the NNIS definition got at the intent of the patient having a CLABSI. Participants described challenges applying these criteria such as not having the ability to monitor patient signs and symptoms easily, not acquiring blood culture results in a timely fashion, differences in blood culturing techniques, difficulties accounting for new technologies for diagnosing bacteremia that do not rely on cultures, trouble accessing inpatient chart data, and trouble identifying the time between when different cultures were drawn when a home health nurse may drive several miles to drop off the tests. In addition, very lengthy criteria were thought to be difficult to implement in home infusion therapy.

Twenty-eight participants completed the final survey, including 11 home health or home infusion nurses (39%), 7 healthcare epidemiologists (25%), 5 infectious diseases physicians (18%), and 5 infection prevention nurses (18%). Highly-rated numerator criteria

ratings are described in Table 2 (all numerator criteria ratings are described in Appendix Table 4), while highly-ranked denominator criteria ratings are described in Table 3 (all denominator criteria ratings as well as inclusion, and exclusion criteria are described in Appendix Table 5).

After the final survey, the most highly-rated numerator criteria on importance (those with mean scores of ≥7) included the National Nosocomial Infections Surveillance system acute care surveillance definition<sup>23</sup> (NNIS, score 7.81), the Association for Professionals in Infection Control-Healthcare Infection Control Practices Advisory Committee home care bloodstream infection surveillance definition<sup>14</sup> (APIC-HICPAC, score 7.35), and a modification of the NHSN acute care CLABSI surveillance definition<sup>7</sup> (score 7.35) (Table 2). Of these, the modification of the NNIS and NHSN surveillance definitions were rated ≥7 on feasibility (mean scores 6.81 and 6.95, respectively). For pediatric patient numerator criteria, acute care CLABSI NHSN criteria had the highest importance score<sup>7</sup> (mean 7.68).

For denominator criteria, the most highly-rated criteria on importance (mean scores ≥7) included device days (score 7.95); days from day of admission to home infusion services with a CVC to day of removal of CVC, subtracting time spent in acute care hospitals (score 7.50); and device days standardized to per 1,000 home catheter days (score 7.48) (Table 3).

The final numerator criteria included one of the 2 following: (1) recognized pathogen<sup>7</sup> isolated from blood culture AND pathogen<sup>7</sup> is not related to infection at another site, OR (2) one of the following signs or symptoms: fever of 38°C (100.4°F), chills, or hypotension

**Table 3**  
Highly-ranked candidate denominator criteria for a possible definition of a CLABSI in home infusion therapy, after initial rating and web-based discussion. Criteria were rated on their importance and feasibility on a scale of 1–9, where 9 was very important or very feasible

Denominator criteria	Importance rating mean (standard deviation, N)	Feasibility rating mean (standard deviation, N)
Device (CVC) days. <sup>27</sup>	7.95 (2.10, 21)	7.29 (1.88, 21)
Additional suggestion (device days definition): Day of admission to home infusion services with a CVC to the day of CVC removal, subtracting time spent in acute care hospitals.	7.50 (1.47, 20)	6.50 (1.86, 20)
Per 1,000 home CVC days. <sup>30,31,33–35,37,38,43,44,48,53,59,61,65,70–72,74</sup>	7.48 (2.01, 21)	6.29 (2.27, 21)
CVC placement date OR date of admission to home care agency TO date of discharge from home care. <sup>33</sup>	6.95 (2.17, 21)	7.52 (1.71, 21)

ANC, absolute neutrophil count; APIC, Association for Professionals in Infection Control and Epidemiology; BSI, bloodstream infection; CLABSI, central line-associated bloodstream infection; CVC, central venous catheter; HICPAC, Healthcare Infection Control Practices Advisory Committee; HPN, home parenteral nutrition; NHSN, National Healthcare Safety Network; NNIS, National Nosocomial Infections Surveillance; PICC, peripherally inserted central catheter; WBC, white blood cell.

(systolic blood pressure  $\leq 90$  mm Hg), AND one of the 2 following: (A) common skin contaminant<sup>7</sup> isolated from 2 blood cultures drawn on separate occasions (different venipunctures, a combination of venipuncture and lumen withdrawal, or different lumens of the same central line; or at different times)<sup>7</sup> AND organism is not related to infection at another site, OR (B) common skin contaminant<sup>7</sup> isolated from blood culture from patient with intravascular access device AND provider institutes appropriate antimicrobial therapy (antimicrobial active against the organism initiated between 2 days prior and 2 days after the blood culture, Table 4). For pediatric numerator criteria, the final criteria included patient up to 1 year of age has at least one of the following: fever ( $\geq 38^\circ\text{C}$ ), hypothermia ( $< 36^\circ\text{C}$ ), apnea, or bradycardia (heart rate  $< 100$  beats per minute), AND

organism identified in blood is not related to an infection at another site AND the same common commensal<sup>7</sup> is identified by a culture or nonculture based microbiological testing method from 2 or more blood specimens collected on separate occasions (different venipunctures, a combination of venipuncture and lumen withdrawal, or different lumens of the same central line; or at different times).<sup>7</sup> The initial denominator criteria included “device days.” In ongoing conversations, the definition of “device days” required further clarification, particularly if a home infusion CLABSI definition were to be used for attribution. Therefore, “device days” were defined as the day of admission to home infusion services with a CVC to the day of removal of the CVC or discharge from home infusion services, subtracting time spent in acute care hospitals.

**Table 4**  
Agreement on candidate criteria for CLABSI in home infusion therapy, including mean ratings on importance to include and feasibility to implement, on a scale of 1–9, where 9 was very important or very feasible

	Importance mean (standard deviation, N)	Feasibility mean (standard deviation, N)
<i>Numerator criteria</i>		
ONE of the two following: (1) recognized pathogen <sup>7</sup> isolated from blood culture AND pathogen is not related to infection at another site, OR (2) one of the following signs or symptoms: fever of $38^\circ\text{C}$ ( $100.4^\circ\text{F}$ ), chills, or hypotension (systolic blood pressure $\leq 90$ mm Hg), AND one of the two following: (A) common skin contaminant <sup>7</sup> isolated from two blood cultures drawn on separate occasions (different venipunctures, a combination of venipuncture and lumen withdrawal, or different lumens of the same central line; or at different times) <sup>7</sup> AND organism is not related to infection at another site, OR (B) common skin contaminant <sup>7</sup> isolated from blood culture from patient with intravascular access device AND provider institutes appropriate antimicrobial therapy (antimicrobial active against the organism initiated between two days prior and two days after the blood culture). <sup>27,2,3,31,36,38,42,52</sup>	7.81 (1.76, 21)	6.81 (2.40, 21)
<i>Pediatric numerator criteria (in those <math>\leq 1</math> year of age)</i>		
Patient up to one year of age has at least one of the following: fever ( $\geq 38^\circ\text{C}$ ), hypothermia ( $< 36^\circ\text{C}$ ), apnea, or bradycardia (heart rate $< 100$ beats per minute), AND organism identified in blood is not related to an infection at another site AND the same common commensal <sup>7</sup> is identified by a culture or nonculture based microbiological testing method from two or more blood specimens collected on separate occasions (different venipunctures, a combination of venipuncture and lumen withdrawal, or different lumens of the same central line, <sup>7</sup> or at different times). <sup>6</sup>	7.68 (1.81, 19)	6.89 (2.49, 18)
<i>Denominator criteria</i>		
Device days defined as: day of admission to home infusion services with a CVC to the day of CVC removal, subtracting time spent in acute care hospitals, per 1,000 home-catheter days.	7.50 (1.47, 20)	6.50 (1.86, 20)
<i>Patients who would be excluded from the home infusion CLABSI criteria.</i>		
Had a CVC within the 48-hour period before the development of the BSI. <sup>51</sup>	8.33 (1.73, 21)	7.90 (1.90, 21)
In home care at least 48 hours. <sup>29,33,35,39</sup>	8.33 (1.39, 21)	8.30 (1.38, 20)
Has a CVC that terminates at or close to the heart, or in one of the great vessels that is used for infusion or withdrawal of blood. <sup>6</sup>	8.19 (1.56, 21)	7.95 (1.73, 21)
Anyone in whom home infusion staff accessed an implanted port or CVC. <sup>35</sup>	7.62 (1.70, 21)	7.76 (1.92, 21)
Include CVC even if it has migrated from the great vessels. <sup>6</sup>	7.42 (2.28, 19)	6.89 (2.49, 19)
Implanted ports accessed within the last 72 hours.	7.38 (1.91, 21)	7.19 (1.82, 21)
A CVC has been in place for at least two consecutive calendar days. <sup>6</sup>	7.33 (1.94, 21)	6.90 (2.02, 21)
Anyone in whom home infusion or home health staff taught the patient or caregivers how to manage the CVC. <sup>35</sup>	7.14 (2.12, 21)	7.33 (2.08, 21)
Anyone in whom home infusion or home health staff performed a CVC dressing or cap change. <sup>35</sup>	6.86 (2.17, 21)	7.00 (2.18, 21)
Anyone in whom staff inserted a PICC. <sup>35</sup>	6.62 (2.90, 21)	7.33 (2.57, 21)
Anyone in whom staff de-accessed an implanted port. <sup>35</sup>	6.43 (2.15, 21)	7.38 (1.91, 21)
<i>Patients who would be excluded from the home infusion CLABSI criteria.</i>		
Hospital readmission within two days of hospital discharge. <sup>58</sup>	8.29 (1.61, 21)	8.10 (1.74, 21)
Midlines or peripheral venous catheters. <sup>6</sup>	8.29 (1.16, 21)	7.85 (1.19, 20)
Patients with Ventricular Assist Device. <sup>6</sup>	7.38 (2.57, 21)	6.67 (2.66, 21)
Munchausen Syndrome (or by proxy, known or suspected). <sup>6</sup>	7.10 (2.58, 21)	5.24 (2.76, 21)

BSI, bloodstream infection; CVC, central venous catheter; PICC, peripherally inserted central catheter.

The most highly-rated inclusion criteria based on importance included having a CVC  $\geq 48$  hours before the development of the bloodstream infection (score 8.33), being in home care  $\geq 48$  hours (score 8.33), and having a CVC terminating at or close to the heart per documentation from the acute care hospital or provider placing the CVC (score 8.19) (Table 3). Other highly-rated criteria included anyone in whom home infusion staff accessed an implanted port or CVC (score 7.62), a CVC even if it migrated (score 7.42), an implanted port accessed  $\geq 72$  hours (score 7.38), a CVC that had been in place  $\geq 2$  consecutive calendar days (score 7.33) and anyone in whom contracted or employed staff taught the patient or caregivers how to self-manage the CVC (score 7.14). Additional inclusion criteria rated highly on mean feasibility included anyone in whom the staff performed CVC dressing or cap changes (score 7.00), anyone in whom the staff inserted a peripherally-inserted central catheter (score 7.33), and anyone in whom staff deaccessed an implanted port (score 7.38). All of these were included in the final definition (Table 4).

The most highly-rated exclusion criteria based on importance included those readmitted to the hospital  $\leq 2$  days of hospital discharge (score 8.29), patients with only midlines or peripheral intravenous catheters (score 8.29), patients with ventricular assist devices (score 7.38), and patients with Munchausen Syndrome by proxy, either known or suspected (score 7.10) (Table 3). All of these were included in the final definition (Table 4).

## DISCUSSION

This study gathered experts to rate candidate criteria for home infusion CLABSI surveillance definitions. Our criteria (Table 4) can be used as a starting point for providers of home infusion therapy to perform CLABSI surveillance and quality improvement interventions to reduce CLABSI rates.

We noted substantial variation in definitions used by prior studies and stakeholders for CLABSI definitions in home infusion therapy.<sup>14–16,23–77</sup> Respondents to a survey of home infusion professionals, healthcare epidemiologists, and infusion nurses noted many barriers to home infusion CLABSI reporting, such as difficulty accessing culture data, insufficient or inadequately trained staff to perform CLABSI surveillance, not appreciating the importance of CLABSI surveillance, and not understanding the extent of home infusion CLABSI morbidity and mortality.<sup>16,21</sup> Our consensus candidate definition may reduce variation among home care providers in what is used for a home infusion CLABSI surveillance definition.

The numerator definition sparked much debate. In particular, difficulties with sufficient patient monitoring to record specific signs and symptoms were thought to make the NHSN definition<sup>7</sup> difficult to implement (although wearable monitors may be options in the future). Many respondents noted that the NHSN acute care CLABSI definition would be unwieldy to implement in home infusion therapy.<sup>7</sup> Similarly, although chills were part of the numerator criteria in the definition chosen by the stakeholder panel, this is a subjective symptom. It is very possible that subjective portions of the criteria may be adjusted to be more measurable and replicable, pointing to the need for validation of the definition. Meanwhile, for patients under the age of 1, criteria chosen were the modification of the acute care CLABSI criteria for patients  $\leq 1$  years of age. The numerator criteria agreed upon by the expert panel should be carefully validated and feasibility tested.

Denominator data was considered to be particularly labor intensive in CLABSI surveillance in the home. Staff is not in the homes with patients on a daily basis, and patients may have their CVCs removed or replaced in a radiology suite or acute care hospital without the home infusion agency or home nursing agency being immediately aware. Many home infusion electronic health records are not designed to easily facilitate collection of catheter-day data. While

there was discussion of using a definition similar to a dialysis event denominator (that is, the number of patients receiving services on the first 2 weekdays of a month<sup>22</sup>), there were concerns that this definition would be difficult to compare with hospitals in the same healthcare system. Also, our definition does not adjust for CVC-days in acute care hospitals prior to discharge to home infusion. However, obtaining this data and adjusting for it as a prehome infusion risk factor would be very difficult without doing hand-calculations. In addition, when patients with CVCs at home are admitted to acute care hospitals (for example, a patient on chemotherapy via a CVC placed at another facility admitted for routine chemotherapy), acute care hospitals do not adjust for preadmission CVC days, and our definition is in keeping with this approach. We did not address the fact that many patients may have CVCs indefinitely; for example, those requiring HPN for short bowel syndrome or other conditions. Clearly this impacts the denominator as well as numerator, and the impact of this population of patients on CLABSI rates should be investigated.

Certain inclusion and exclusion criteria also prompted debate. For example, patients with implanted ports may be intermittently accessing and deaccessing these ports for years at a time. Whether these implanted ports should be considered eligible for CLABSI for the entire length of time that the implanted port is in place once accessed in the home was unclear, so the expert panel elected to focus on those ports accessed within 72 hour of the positive blood cultures. In addition, lack of access to data around quantitative diarrhea volume and recent white blood cell or neutrophil counts, and even blood culture results make mucosal barrier injury criteria difficult to apply. Although mucosal barrier injury criteria were discussed by the members, these were not scored highly, perhaps due to difficulties applying these criteria (particularly volume of stool or recent blood test results) in the home infusion setting. In addition, although several participants suggested that criteria similar to mucosal barrier injury criteria be developed for patients with short bowel syndrome or significantly immunocompromised who are on HPN, these criteria were not ranked highly enough to be included. Although there were conversations around excluding patients who receive products from one home infusion agency and education and evaluation from a nonaffiliated home nursing agency, or receive services from outpatient infusion centers, the participants elected to include all patients in whom there was contact with employed or contracted staff from the home infusion or home nursing agency. It was felt that this may mitigate training variance between agencies. However, there was no consensus reached on these inclusion or exclusion criteria (with the exception of those who received home nursing from an unaffiliated agency; the focus was on CVCs that employed or contracted staff physically touched and patients for whom these staff provided education).

The expert panel discussed difficulties in implementing a home infusion CLABSI definition. Home infusion therapy is under-resourced in both staff time available and in expertise in healthcare-associated infection surveillance. In a recent study, less than 5% of respondents reported that their home infusion therapy agency employed someone with a certification in infection control.<sup>16</sup> Therefore, a CLABSI definition must be relatively simple to implement. It is important to know whether different home infusion therapy agencies may implement this definition in the same way.<sup>78</sup> Further work is needed to determine this definition's feasibility and validity.

In acute care, CLABSI definitions have been used and modified over the years.<sup>4,7,9,79</sup> Our home infusion CLABSI definition may also require modifications based on feedback and experience. Interestingly, the CLABSI candidate criteria included modifications of the NHSN acute care CLABSI definition,<sup>7</sup> the 2008 APIC-HICPAC home infusion bloodstream infection definition,<sup>14</sup> the NHSN dialysis event definition,<sup>22</sup> the NNIS acute care CLABSI definition,<sup>23,24</sup> and that proposed in 2000 as a draft definition for home infusion CLABSI surveillance.<sup>24</sup> Our definition may also need to be modified based on experience.



Having a clear definition for CLABSI in acute care hospitals has allowed for comparisons between acute care hospitals as well as target-setting to drive CLABSI prevention efforts.<sup>80</sup> With a definition of home infusion CLABSI, home infusion, home care, and home hospice agencies can begin the work of benchmarking data and then identifying interventions which may reduce home infusion CLABSI.

This study had limitations. We sought representation from stakeholders involved in home infusion CLABSI surveillance, but several experts were unable to participate. It is also possible we missed certain studies or approaches in our literature search. We tried to identify other sources by searching through references and asking experts. Our identified definition has not yet been validated or tested for feasibility and validation and feasibility testing is needed before the definition is widely implemented. In addition, our final criteria did not contain exclusion criteria for stem cell transplant, bone marrow transplant, neutropenic, or certain patients receiving. Future work may add these or other populations as exclusion criteria. For the denominator criteria, 3 very similar definitions were each rated highly and we chose the most inclusive criteria as the final criterion.

## CONCLUSIONS

We have developed a candidate home infusion CLABSI definition. While work needs to be done to validate, test its feasibility, and benchmark the definition, this serves as an expert-driven basis for beginning work to measure, define, and reduce CLABSI rates in home infusion therapy. This candidate surveillance definition developed by expert consensus is a method by which we can perform surveillance to understand the burden of home infusion CLABSI. We can use this definition to perform internal and industry-wide preventative strategies to drive down CLABSI rates. As Medicare begins to expand payments for home infusion therapy, understanding the incidence of CLABSI in the home infusion setting is essential.

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## SUPPLEMENTARY MATERIALS

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