Title: A Systematic Review of Central Line-Associated Bloodstream Infection (CLABSI)

Diagnostic Reliability and Error

Emily Larsen^{1,2} GDip(HlthRes), Email: e.larsen@griffith.edu.au [Corresponding Author]

Nicole Gavin^{1,2,3,4,5} PhD Email: nicole.gavin@health.qld.gov.au

Nicole Marsh^{1,2,5} PhD, Email: nicole.marsh@health.qld.gov.au

Claire M Rickard^{1,2,5} PhD, Email: c.rickard@griffith.edu.au

Naomi Runnegar^{1,6,7} FRACP, Email: naomi.Runnegar@health.qld.gov.au

Joan Webster^{1,2,5} BA, Email: joan.webster@health.qld.gov.au

¹Alliance for Vascular Access Teaching and Research Group, Menzies Health Institute, Brisbane, Queensland, Australia;

²Nursing & Midwifery Research Centre, Royal Brisbane and Women's Hospital, Brisbane, Queensland, Australia;

³Cancer Care Services, Royal Brisbane and Women's Hospital, Brisbane, Queensland, Australia;

⁴School of Nursing and Institute of Health and Biomedical Innovation, University of Technology, Brisbane, Queensland, Australia;

⁵School of Nursing and Midwifery, Griffith University, Brisbane, Queensland, Australia;

⁶Southside Clinical Unit, Faculty of Medicine, University of Queensland, Brisbane, Queensland, Australia;

⁷Department of Infectious Diseases, Princess Alexandra Hospital, Brisbane, Queensland, Australia.

Corresponding author:

Ms Emily Larsen

Level 2 (Nursing and Midwifery Research Centre), Bldg. 34, Royal Brisbane and Women's
Hospital, Cnr. Bowen Bridge Rd and Butterfield St, Herston QLD 4029
Australia

Phone: +61438343821

Fax: +617364658332

Email: e.larsen@griffith.edu.au

Abbreviated Title: Systematic Review of CLABSI Diagnostic Error

Word count (excluding the abstract and references): 2762

ABSTRACT:

Objective: To establish the reliability of the application of National Health and Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) criteria within established reporting systems internationally.

Design: Diagnostic-test accuracy systematic review.

Methods: A search of Medline, Scopus, the Cochrane Library and CINAHL (EbscoHost), and PubMed (NCBI), was conducted. Cohort studies were eligible for inclusion if they compared publicly reported CLABSI rates with an independent and expertly trained reviewer/s, using NHSN/Centers for Disease Control (or equivalent) criteria. Two independent reviewers, screened, extracted data and assessed risk of bias with the QUADAS 2 tool. Sensitivity, specificity, negative and positive predictive values were analysed.

Results: A systematic search identified 1259 publications; nine studies were eligible for inclusion (n=7160). Publicly reported CLABSI rates were more likely to be under-estimated (7 studies), than over-estimated (2 studies). Specificity and sensitivity ranged from 0.70 [0.58;0.81]-0.99 [0.99;1.00] and 0.42 [0.15;0.72]-0.88 [0.77;0.95], respectively. Four studies which included a consecutive series of patients (whole cohort), reported CLABSI incidence between 9.8% and 20.9%, with absolute CLABSI rates underestimated by 3.3-4.4%. Risk of bias was low-moderate in most included studies.

Conclusions:

Findings suggest there is consistent underestimation of true CLABSI incidence within publicly reported rates, weakening the validity and reliability of surveillance measures.

Auditing, education and adequate resource allocation is necessary to ensure surveillance data is accurate and suitable for benchmarking and quality improvement measures over time.

Registration: Prospectively registered with International prospective register of systematic reviews (PROSPERO) ID CRD42015021989 (07 June 2015).

http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42015021989

BACKGROUND:

Central Line Associated Blood-stream Infections (CLABSI) are a bloodstream infection associated with a present (or recently present) Central Venous Access Device (CVAD), in the absence of infection at another site.¹ This type of Hospital-Acquired Infection (HAI) carries significant financial burden for health services (i.e. staff time; treatment costs) and often disincentive penalties.² In the United States of America alone, CLABSI is estimated to cost 1.9 billion dollars annually.³ Mortality among patients diagnosed with CLABSI is also high, with extra attributable mortality estimated between 14% and 16%.^{4, 5} A large proportion of these infections are considered preventable (65-70%)⁶ and, as a result, quality improvement activities and implementation of national guidelines aimed at prevention have become core business for health care institutions.⁷ Continuous and reliable surveillance of CLABSI is essential; any underestimation (false-negatives) or overestimation (false-positives) of CLABSI are problematic as it impairs health-care facilities ability to: set targets and benchmark health-care quality between similar facilities; monitor efficacy of quality improvement strategies; measure trends over time; and quickly identify outbreaks.^{8, 9}

The National Healthcare Surveillance Network (NHSN), in partnership with the Centers for Disease Control (CDC), have established definitions which are used to classify CLABSI.¹ These definitions are considered Gold Standard and have been adopted in whole (eg. Australia¹⁰) or in part (eg. European CDC¹¹) by central reporting agencies worldwide. CLABSI classification with this definition is the responsibility of a variety of health care professionals including infection preventionists; infectious disease physicians; or specialist nurses.¹² The number of staff, facility resources and time allocated for this duty is often dependent upon the size, budget and structure of their health-care facilities.⁹ Validity and reliability of this data is essential. However, despite standardised methods and definitions for

reporting, application in practice is not consistent.¹² This may be as a result of subjective clinician selective reporting (ie. ‘over-ruling’) a practice widely discouraged;¹³ uncertainty; inadequate education or unfamiliarity with the NHSN/CDC criteria;¹⁴ insufficient resources; and lack of external validation.^{12, 15}

One of the first retrospective cohort studies to explore the reliability of HAI reporting was conducted by Emori et al (1998).¹⁶ Their findings highlighted inconsistencies of reported bloodstream; surgical; urinary catheter; and respiratory infections.¹⁶ This seminal work prompted other researchers and clinicians to report on inconsistencies, specifically related to CLABSI, within their own institutions.^{17, 18} The aim of this systematic review is to evaluate how application of the NHSN/CDC CLABSI definitions varies between hospital infection control teams/preventionists, compared with expert adjudicators with advanced knowledge of the definitions and their application. The findings of this review will synthesise known levels of specificity and sensitivity for the NHSN/CDC CLABSI criterion and provide an estimated margin of error in CLABSI reporting for institutions not actively validating local data.

METHODS:

We conducted a diagnostic-test accuracy systematic review to explore previously published literature exploring reliability of CLABSI reporting. Methods and outcomes of interest were prospectively registered (07 June 2015), with the International Prospective Register of Systematic Reviews (PROSPERO); ID CRD42015021989.

Search Strategy

A systematic search of literature was conducted 17 April 2018 using the Cochrane Library; MEDLINE (Ovid), CINAHL (EbscoHost), PubMed (NCBI), and Scopus (Elsevier). MESH Terms. Key search terms included: ‘Catheterisation, Central Venous’ (MESH); ‘central line’; ‘central venous access device’; ‘vascular access’; ‘Bacteremia’ (MESH);

‘Catheter-Related Infections’ (MESH); ‘Sepsis’ (MESH); ‘central line- associated bloodstream infections’; ‘Diagnostic Errors’ (MESH); ‘Reproducibility of Results’ (MESH); ‘Validation Studies’ (MESH); ‘interrater’; ‘variation’; ‘reliability’; ‘test-retest’; ‘Centers for Disease Control and Prevention’ (MESH); ‘National Health and Safety Network’; ‘surveillance system’; ‘infection surveillance’.

Inclusion/Exclusion Criteria

Cohort studies from January 2008 which compared publicly reported CLABSI rates, using NHSN/CDC criteria (*Reference Test*), with the CLABSI rates determined by blinded, independent, and formally trained expert adjudicators (*Index Test*) were eligible for inclusion. Tertiary facilities using surveillance definitions reproducing NHSN/CDC criteria (as per current version, at time of study) were also eligible for inclusion. There were no age limits or facility/discipline-related exclusions. Studies were eligible if they had selected a whole, or randomly selected, cohort of patients (over a pre-established time period) with CVADs. Grey literature and studies reported in a language other than English were excluded. Furthermore, studies which used either a program or algorithm (electronic) or example scenarios (vignettes) for CLABSI diagnosis were excluded.

Data Extraction

Data from eligible studies were extracted separately by two independent reviewers using a purpose-built data extraction instrument established by the investigators (EL, NG). Disagreements and/or discrepancies identified between the two independent investigators were resolved by a third adjudicator (JW), who informed the final decision. True positives, true negatives, false positives and false negatives, both (i) publically reported (*Reference Test*) and (ii) as classified by the independent reviewer team (*Index Test*; ‘gold standard’),

were extracted and compared for congruence. Sensitivity, specificity, positive predictive values (PPV) and/or negative predictive values (NPV) (with 95% Confidence Intervals (CI)) were calculated using SPSS if the authors did not report these values. Accuracy and incidence of positive and negative cases were extracted, however as these measures should only be used in cases where *all* cases (both positive and negative for CLABSI) were represented in the data,¹⁹ they were excluded for studies including a random sample only.

Two investigators (EL, NG) conducted a risk of bias (quality) assessment of each included study, using the Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS 2) tool.²⁰ The investigators conducted the assessment independently and were blinded to each other's judgments. In the case of any disagreements/discrepancies identified between the two investigators, a third adjudicator (JW) was consulted for a final decision.

Statistical Analysis

Cohort studies eligible for inclusion were presented using descriptive statistics. Forest plots were constructed to display sensitivity and specificity with 95% CI. A Summary Receiver Operating Characteristic (SROC) curve was plotted to demonstrate overall accuracy of CLABSI classification.

RESULTS:

The systematic search yielded 1259 titles and abstracts. References lists were hand-searched for titles missing from the original search. Duplicates were removed; studies were initially excluded by title, followed by an assessment of the remaining abstracts and (if indicated) full-texts (Figure 1. PRISMA Flow Diagram).

A total of nine studies, including n=7093 participants (n=7160 central lines), met the inclusion criteria and were included in the review. All studies included data from adult Intensive Care Units (ICU); three reports included additional data from paediatric ICU;^{17, 21, 22}

a single study also included data from a long-stay acute care unit.²² Most studies were conducted in the United States of America (n=5) using NHSN Reporting;^{17, 18, 21-23} the remaining studies were conducted in Australia,²⁴ Canada,²⁵ Korea,²⁶ and Spain,²⁷ each with their own central reporting systems replicating NHSN/CDC criterion. Four studies included a consecutive series of patients;^{17, 18, 21, 26} the remaining studies included a random sample, either stratified^{22, 25, 27} or unstratified/unclear.^{23, 24}

Table 1 outlines characteristics of each included study, as well as sensitivity, specificity, PPV and NPV, incidence and accuracy results.

(INSERT FIGURE 1. PRISMA Flow Diagram).

TABLE 1. Characteristics of included studies and findings

First Author	Year	Country/State	Study Design	Setting	Sample Size	Central Reporting	Sensitivity (95% CI)	Specificity (95% CI)	PPV (%) (95% CI)	NPV (%) (95% CI)	Incidence (Publicly Reported) (%)	Incidence (Independent Team) (%)	Accuracy (%) (95% CI)
Backman ¹⁷	2010	USA/Conneticut	Retrospective cohort	Adult ICU; Paediatric ICU	476^ (410 patients)	NHSN	0.48 [0.33;0.63]	0.99 [0.98;1.00]	85.2 (67.5;94.1)	94.4 (92.8;95.7)	5.7	10.1	93.9 (91.4;95.9)
Fontela ²⁵	2013	Canada/Quebec	Retrospective cohort	Adult ICU	109	SPIN-BACC ^a	0.88 [0.77;0.95]	0.92 [0.80;0.98]	93.0 (83.8;97.2)	86.5 (76.1;92.8)			
Hazamy ²¹	2013	USA/New York State	Retrospective cohort	Adult ICU; Paediatric ICU	3104	NHSN	0.71 [0.68;0.75]	0.97 [0.96;0.98]	86.2 (83.3;88.7)	92.7 (91.9;93.5)	17.3	20.9	91.6 (90.6;92.5)
Kwak ²⁶	2017	Korea	Retrospective cohort	Adult ICU	406	KONIS ^b	0.74 [0.62, 0.84]	0.99 [0.97, 1.00]	94.7 (85.3;98.3)	94.6 (92.2;96.2)	14.0	18.0	94.6 (91.9;96.6)
Lopez-Pueyo ²⁷	2013	Spain	Retrospective cohort	Adult ICU	1486^ (1500 patients; 14 records)	ENVIN-HELICS ^c	0.77 [0.55;0.92]	0.99 [0.99;1.00]	63.0 (46.8;76.7)	99.7 (99.3;99.8)			

					not found)								
McBryde ²⁴	2009	Australia/Victoria	Retrospective cohort	Adult ICU	108	VICNISS ^d	0.61 [0.45;0.76]	0.70 [0.58;0.81]	58.7 (47.7;68.9)	72.6 (63.8;79.9)			
Oh ²³	2012	USA/Oregon	Retrospective cohort	Adult ICU	817	NHSN	0.81 [0.72;0.89]	0.99 [0.98;1.00]	92.1 (83.9;96.3)	97.8 (96.7;98.6)			
Rich ²²	2013	USA/Colorado	Retrospective cohort	Adult ICU; Paediatric ICU; Long-term acute care	531^ (530 patients)	NHSN	0.69 [0.56;0.80]	0.99 [0.98;1.00]	91.5 (80.0;96.7)	96.1 (94.4;97.2)			
Thompson ¹⁸	2013	USA/New Mexico	Retrospective cohort	Adult ICU	123	NHSN	0.42 [0.15;0.72]	0.97 [0.92;0.99]	62.5 (31.2;86.0)	93.9 (90.5;96.1)	6.5	9.8	91.9 (85.6;96.0)

^areported sample and results in devices (not patients)

^aSPIN-BACC: Surveillance Provinciale des Infections Nosocomiales; ^bKONIS: Korean Nosocomial Infections Surveillance System; ^cENVIN-HELICS: Estudio Nacional de Vigilancia de Infección Nosocomial en Uci;

^dVICNISS: Victorian Nosocomial Infection Surveillance System.

(INSERT FIGURE 2. Forest Plot, Sensitivity and Specificity).

Specificity (true negative rate) results were high, ranging from 0.70 [95%CI 0.58;0.81] to 0.99 [95%CI 0.99;1.00]; in most cases publicly reported CLABSI rates did not include patients who experienced a true case of CLABSI. Sensitivity (true positive rate) results trended lower, ranging from 0.42 [95%CI 0.15;0.72] to 0.88 [95%CI 0.77;0.95]; patients were more likely to be *incorrectly* classified as having a non-CLABSI event. In all included studies, sensitivity was lower than specificity. [Figure 2. SROC Plot, Sensitivity and Specificity]. The SROC curve (Figure 3) demonstrates overall accuracy of CLABSI classification.

(INSERT FIGURE 3. SROC)

Accuracy measures from the four studies that included data from an entire cohort (n=4109 devices) demonstrated an overall probability of accurate classification between 91.9% (95%CI 85.6;96.0) and 94.6% (95%CI 91.6;96.6). Furthermore, within these four studies, the proportion of patients experiencing true CLABSI was underreported by (+)3.3% - (+)4.4%.^{17, 18, 21, 26} A single study reported this difference per 1000 catheter days (1.97 v. 3.51/1000 catheter days).¹⁷

The overall quality of the included studies was high and applicability concerns were consistently low. The risk of bias was unclear to high in relation to patient selection for two of the nine (22%) included studies;^{21, 22} the index test had an unclear to high risk of bias in three studies;^{21, 26, 27} and a further two studies demonstrated a high risk of bias related to flow/timing.^{22, 27} Figure 2 displays the risk of bias and applicability concerns for each of the n=9 studies using the QUADAS 2 tool.

TABLE 3. Quality Assessment (QUADAS 2)

First Author, Year	Risk of Bias				Applicability Concerns		
	Patient Selection	Index Test	Reference Standard	Flow and Timing	Patient Selection	Index Test	Reference Standard
Backman, 2010	Low	Low	Low	Low	Low	Low	Low
Fontela, 2013	Low	Low	Low	Low	Low	Low	Low
Hazamy, 2013	Unclear	High	Low	Low	Low	Low	Low
Kwak, 2017	Low	Unclear	Low	Low	Low	Low	Low
Lopez-Pueyo, 2013	Low	Unclear	Low	High	Low	Low	Low
McBryde, 2009	Low	Low	Low	Low	Low	Low	Low
Oh, 2012	Low	Low	Low	Low	Low	Low	Low
Rich, 2013	Unclear	Low	Low	High	Low	Low	Low
Thompson, 2013	Low	Low	Low	Low	Low	Low	Low

DISCUSSION:

The findings of this systematic review demonstrate that there is consistent underestimation of the true CLABSI incidence in publicly reported rates. This underestimation may have wide-spread effects as hospital staff; epidemiologists and researchers may be using inaccurate data to inform benchmarking; identification of outbreaks; and prioritisation of resource allocation (such as access to electronic medical records and staff for data collection, and classification).²⁸ The ‘Gold Standard’ NHSN/CDC definitions are intended to enable standardised classification and diagnosis, however despite supplemental CDC educational documents, and available online web-based training,¹⁵ we observed the application of these definitions are sometimes misinterpreted and inappropriately applied. Concern exists underreporting may be intentional so as to (i) avoid financial penalties;²⁹ or (ii) demonstrate ‘zero CLABSI’ to improve the perceived quality and safety of care of the reporting facility.³⁰ Observational studies comparing inter-observer variability between two independent infection preventionists (not against publicly reported rates, as per our approach) found similar classification disparities.^{31, 32} This supports the

argument that variability in classification errors may be related to clinician understanding/application variations rather than deliberate omissions.^{14, 29} Moreover, ongoing changes to NHSN/CDC HAI definitions, most notably the 2013 addition of the mucosal-barrier injury related BSI (MBI-LCBI) classification,³³ while necessary, may instil further confusion. This concern is not only limited to CLABSI however, as comparisons with interobserver agreement of other varieties of HAI (eg. ventilator-associated pneumonia) have similarly found poor concordance of classification.³⁴

It is clear, that validation of CLABSI rates is essential moving forward for accuracy of data. Sexton et al. suggest that cyclic or random audits of facilities reporting either high or low CLABSI (based on local benchmarking) may improve quality of these measures.²⁹ However, validation of large cohort data-sets requires significant time and resources. Consequently, limitations such as these may necessitate the use of prospective surveys/vignettes among clinicians applying CLABSI classifications to explore the variability of definition application. This method has been executed in various facilities applying NHSN/CDC CLABSI definitions, and were able to highlight concordance/disagreement in classification application, as well as the common source of these variations.^{28, 35} While this method is a more feasible a system-wide assessment of CLABSI accuracy, we suggest that a whole or randomly selected cohort of patients should be used to assess accuracy of data reported which is likely to influence changes in clinical practice (eg. trial interventions and quality improvement activities). This more rigorous method of validation is required as randomised controlled trials/other studies often aim to reduce the incidence of primary outcomes such as CLABSI by margins of <5%.³⁶ Small margins such as this may be impacted significantly by misclassification; particularly when this review has identified that CLABSI may be underreported by margins as high as 4.4%.

Other methods for system-wide CLABSI reporting includes the use of automated electronic surveillance systems; this has been proposed as a means to reduce this risk of unintentional misclassification; and improve efficiency.⁹ These systems are reportedly able to determine the presence of HAI (including CLABSI) using data sourced from microbiological reports, with or without considering patient symptoms and/or other criteria required to fit the NHSN/CDC definitions.⁹ Advantages of this process may include: reduced staff expenditure; surveillance of all admitted patients; early identification of outbreaks; and reduced susceptibility of classification subjectivity, however their use is yet to be perfected.⁹ A systematic review of HAI electronic surveillance identified two studies which assessed the accuracy of CLABSI (NHSN/CDC); which ranged from 94.3-95.2% and 68.0-97.5% for sensitivity and specificity, respectively.³⁷ A further eight studies assessing the accuracy of reporting for BSI (other classification, non-NHSN/CDC) identified sensitivity and specificity ranging from 72.0-100% and 37.3-100%, respectively.³⁷ While this demonstrates a higher sensitivity rate, there was a lower specificity compared with the findings of this systematic review; therefore, in contrast to manually classified rates, these electronic surveillance methods may *overestimate* the incidence of CLABSI. It can be argued that the effects of overestimation may be equal to the those of underestimation, as it would similarly impact upon benchmarking, outbreak identification, and resource allocation.²⁸

Accuracy and reliability of reported CLABSI rates are not only reliant upon objective classification, but also the reported denominator.³⁸ CLABSI incidence is commonly reported against three key denominators: device/central line days; patient days; and (less commonly) neutropenic days.³⁹ Standardisation and validation of these denominators is essential as variation (eg. inclusion/exclusion of admission/discharge days; or differences in accounting for co-existing catheters) may influence a measurable difference in reported rates.³⁹

Accurate CLABSI reporting is essential to facilitate strategic benchmarking between institutions and evaluate the success of interventions aimed at reducing the incidence of HAIs. This systematic review has highlighted the likely underestimation of CLABSI in publicly reported rates, which contrasts to the likely overestimation of electronically classified CLABSI rates previously reported in literature; and further identifies a need to validate local data, particularly that which is likely to lead practice change.

Strengths and Limitations:

Our study has several limitations. The findings of this diagnostic-test accuracy systematic review are limited by the homogeneity of the data presented; most studies were undertaken within the United States of America and 8/9 studies presented data from ICU only. Moreover, the majority (5/9) of studies reported randomly-selected patient sets rather than entire cohorts, and therefore incidence and accuracy measures were only calculated for the remaining four. Additionally, the sensitivity and positive predictive values for most studies reported wide CI margins, compared with the CI margins for specificity and negative predictive values, therefore introducing some uncertainty to the results. Results may also have been impacted by NHSN/CDC CLABSI definitions which continue to change over time (eg. the 2013 inclusion of MBI-LCBI).³³ Although other systematic reviews have compared electronic³⁷ and administrative code data⁴⁰ CLABSI classification accuracy, the strength of this systematic review is that it is the first to explore the concordance of CLABSI classification between experts and clinicians entering publicly reportable data, which more accurately reflects current reporting practices.²¹

Acknowledgements:

The authors would like to acknowledge the support of the Nursing and Midwifery Research Centre, Royal Brisbane and Women's Hospital.

Financial support:

None reported.

Conflicts of interest:

The authors declare no conflicts of interest related to the findings of this systematic review.

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FIGURE 1. PRISMA Flow Diagram

FIGURE 2. Forest Plot, Sensitivity and Specificity

FIGURE 3. SROC