*Infection Control & Hospital Epidemiology* (2019), **40**, 1100–1106
doi:10.1017/ice.2019.205

## Original Article

# A systematic review of central-line–associated bloodstream infection (CLABSI) diagnostic reliability and error

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### 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: We conducted a search of Medline, SCOPUS, the Cochrane Library, CINAHL (EbscoHost), and PubMed (NCBI). Cohort studies were eligible for inclusion if they compared publicly reported CLABSI rates and were conducted by independent and expertly trained reviewers using NHSN/Centers for Disease Control (or equivalent) criteria. Two independent reviewers screened, extracted data, and assessed risk of bias using the QUADAS 2 tool. Sensitivity, specificity, negative and positive predictive values were analyzed.

Results: A systematic search identified 1,259 publications; 9 studies were eligible for inclusion (n = 7,160 central lines). Publicly reported CLABSI rates were more likely to be underestimated (7 studies) than overestimated (2 studies). Specificity ranged from 0.70 (95% confidence interval [CI], 0.58–0.81) to 0.99 (95% CI, 0.99–1.00) and sensitivity ranged from 0.42 (95% CI, 0.15–0.72) to 0.88 (95% CI, 0.77–0.95). Four studies, which included a consecutive series of patients (whole cohort), reported CLABSI incidence between 9.8% and 20.9%, and absolute CLABSI rates were underestimated by 3.3%–4.4%. The risk of bias was low to moderate in most included studies.

Conclusions: Our findings suggest 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 that surveillance data are accurate and suitable for benchmarking and quality improvement measures over time.

Registration: Prospectively registered with International prospective register of systematic reviews (PROSPERO ID CRD42015021989; June 7, 2015). http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42015021989

(Received 11 April 2019; accepted 24 June 2019; electronically published 31 July 2019)

Central-line–associated bloodstream infections (CLABSIs) are bloodstream infections 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 (ie, staff time and treatment costs) and often disincentive penalties.[2] In the United States of America alone, CLABSI is estimated to cost $1.9 billion 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 healthcare institutions.[7] Continuous and reliable surveillance of CLABSI is essential; any underestimation (false negatives) or overestimation (false positives) of CLABSI are problematic because they impair the ability of the healthcare facility to set targets and benchmark healthcare quality between similar facilities; to monitor the efficacy of quality improvement strategies; to measure trends over time; and/or to quickly identify outbreaks.[8,9]

The National Healthcare Surveillance Network (NHSN), in partnership with the Centers for Disease Control (CDC), have established definitions that are used to classify CLABSI.[1] These definitions are considered gold standard and have been adopted in whole (eg, Australia[10]) or in part (eg, European CDC[11]) by central reporting agencies worldwide. CLABSI classification with this

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**Cite this article:** Larsen EN, *et al.* (2019). A systematic review of central-line–associated bloodstream infection (CLABSI) diagnostic reliability and error. *Infection Control & Hospital Epidemiology*, 40: 1100–1106, https://doi.org/10.1017/ice.2019.205

definition is the responsibility of a variety of healthcare professionals including infection preventionists, infectious disease physicians, or specialist nurses.[12] The number of staff, facility resources, and time allocated for this duty often depend upon the size, budget, and structure of the healthcare facilities.[9] Validity and reliability of these data is essential. However, despite standardized methods and definitions for reporting, application in practice is not consistent.[12] This inconsistency may be a result of subjective clinician selective reporting (ie, 'overruling'), which is widely discouraged;[13] uncertainty; inadequate education or unfamiliarity with the NHSN/CDC criteria;[14] insufficient resources; and/or 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[16] in 1998. 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] In this systematic review, we evaluated how the application of the NHSN/CDC CLABSI definitions varies between hospital infection control teams and/or preventionists, compared with expert adjudicators with advanced knowledge of the definitions and their application. The findings of this review synthesize 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 (June 7, 2015), with the International Prospective Register of Systematic Reviews (PROSPERO; ID CRD42015021989).

### Search strategy

A systematic search of literature was conducted April 17, 2018, using the Cochrane Library; MEDLINE (Ovid), CINAHL (EbscoHost), PubMed (NCBI), and SCOPUS (Elsevier) with MESH terms. We used the following key search terms: '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'; and 'infection surveillance.'

### Inclusion and exclusion criteria

Cohort studies from January 2008 that 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 (ie, the current version at the time of the study) were also eligible for inclusion. There were no age limits or facility- or discipline-related exclusions. Studies were eligible if they had selected a whole cohort or randomly selected cohort of patients over a pre-established period with CVADs. Grey literature and studies reported in a language other than English were excluded. Furthermore, studies that 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 2 independent reviewers using a purpose-built data extraction instrument established by the investigators (E.L. and N.G.). Disagreements and/or discrepancies identified between the 2 independent investigators were resolved by a third adjudicator (J.W.), who informed the final decision. True positives, true negatives, false positives and false negatives, both (1) publicly reported (reference test) and (2) classified by the independent reviewer team (index test, ie, 'gold standard') were extracted and compared for congruence. Sensitivity, specificity, positive predictive values (PPVs) and/or negative predictive values (NPVs) with 95% confidence intervals (CIs) were calculated using SPSS software (IBM, Armonk, NY) if the authors did not report these values. Accuracy and incidence of positive and negative cases were extracted; however, because 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 (E.L. and N.G.) 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 disagreements, a third adjudicator (J.W.) 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 1,259 titles and abstracts. References lists were hand-searched for titles missing from the original search. Duplicates were removed, and studies were initially excluded by title, followed by an assessment of the remaining abstracts and (if indicated) full texts (Fig. 1).

In total, 9 studies, including 7,093 participants (with 7,160 central lines), met the inclusion criteria and were included in the review. All studies included data from adult intensive care units (ICUs), and 3 reports included additional data from pediatric ICUs.[17,21,22] A single study also included data from a long-stay acute-care unit.[22] Most studies (n = 5) were conducted in the United States 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 and/or unclear.[23,24] Table 1 outlines characteristics of each included study, as well as sensitivity, specificity, PPV and NPV, incidence and accuracy results.

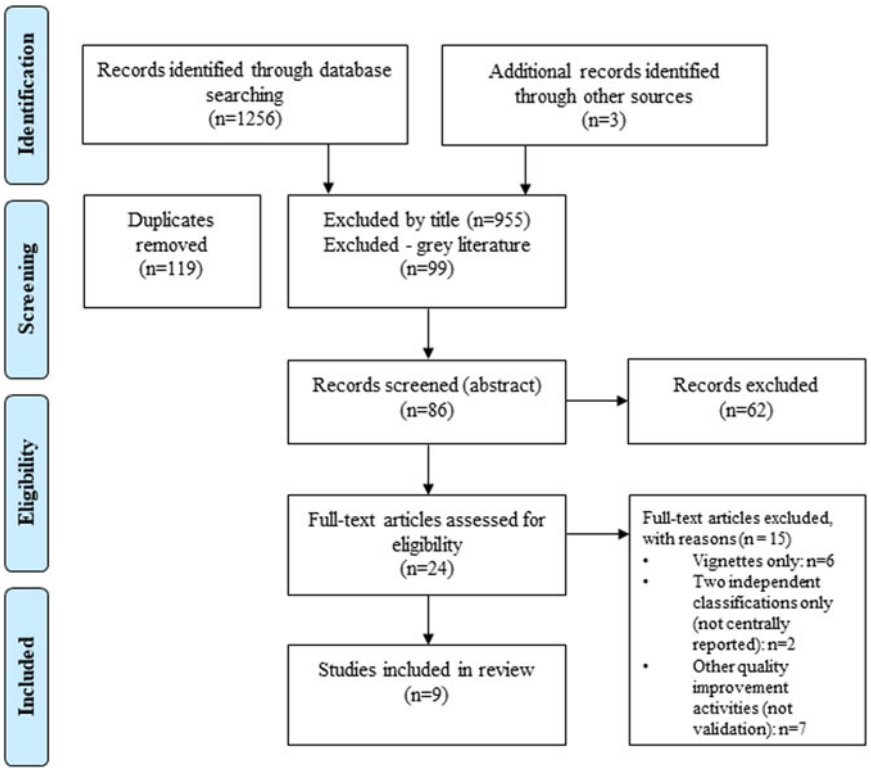


**Fig. 1.** PRISMA flow diagram.

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 (Fig. 2). The SROC curve (Fig. 3) demonstrates overall accuracy of CLABSI classification.

Accuracy measures from the 4 studies that included data from an entire cohort (n = 4,109 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 4 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 1,000 catheter days (1.97 vs 3.51 per 1,000 catheter days).[17]

The overall quality of the included studies was high and applicability concerns were consistently low (Table 2). The risk of bias was unclear to high in relation to patient selection for 2 of the 9 (22%) included studies[21,22]; the index test had an unclear to high risk of bias in 3 studies,[21,26,27] and a further 2 studies demonstrated a high risk of bias related to flow and/or timing.[22,27] Table 2 displays the risk of bias and applicability concerns for each of the 9 studies using the QUADAS 2 tool.

## Discussion

The findings of this systematic review demonstrate consistent underestimation of the true CLABSI incidence in publicly reported rates. This underestimation may have widespread effects. Hospital staff, epidemiologists, and researchers may be using inaccurate data to inform benchmarking, to identify outbreaks, and to prioritize resource allocation (eg, access to electronic medical records and staff for data collection, and classification).[28] The 'gold standard' NHSN/CDC definitions are intended to enable standardized classification and diagnosis; however, despite supplemental CDC educational documents and available online web-based training,[15] these definitions are sometimes misinterpreted and/or inappropriately applied. Concern exists that underreporting may be intentional (1) to avoid financial penalties[29] or (2) to demonstrate 'zero CLABSI' to improve the perceived quality and safety of care of the reporting facility.[30] Observational studies comparing interobserver variability between 2 independent infection preventionists (not against publicly reported rates, according to our approach) found similar classification disparities.[31,32] This finding 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 create 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]

Clearly, validation of CLABSI rates is essential moving forward for accuracy of data. Sexton et al[29] suggest that cyclic or random audits of facilities reporting either high or low CLABSI (based on local benchmarking) may improve quality of these measures. However, validation of large cohort datasets requires significant time and resources. Consequently, limitations such as these may necessitate the use of prospective surveys or 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 we were able to highlight concordance/disagreement in classification

**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; pediatric ICU | 476[a](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 | 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; pediatric 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 | 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 | 1,486[a] (1,500 patients[b]) | ENVIN-HELICS | 0.77(0.55–0.92) | 0.99(0.99–1.00) | 63.0(46.8–76.7) | 99.7(99.3–99.8) | . . . | . . . | . . . |
| McBryde[24] | 2009 | Australia/ Victoria | Retrospective cohort | Adult ICU | 108 | VICNISS | 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; pediatric ICU; long-termacute care | 531[a] (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) |

Note. CI, confidence interval; NPV, negative predictive value; PPV, positive predictive value; ICU, intensive care unit; SPIN-BACC, Surveillance Provinciale des Infections Nosocomiales; KONIS, Korean Nosocomial Infections Surveillance System; ENVIN-HELICS, Estudio Nacional de Vigilancia de Infección Nosocomial en Uci; VICNISS: Victorian Nosocomial Infection Surveillance System; NHSN, National Health Safety Network.

[a]Reported sample and results in devices (not patients).

[b]14 records not found.

**Table 2.** Quality Assessment (QUADAS 2)

| | Risk of Bias | | | | Applicability Concerns | | |
|---|---|---|---|---|---|---|---|
| First Author and Year | 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 |

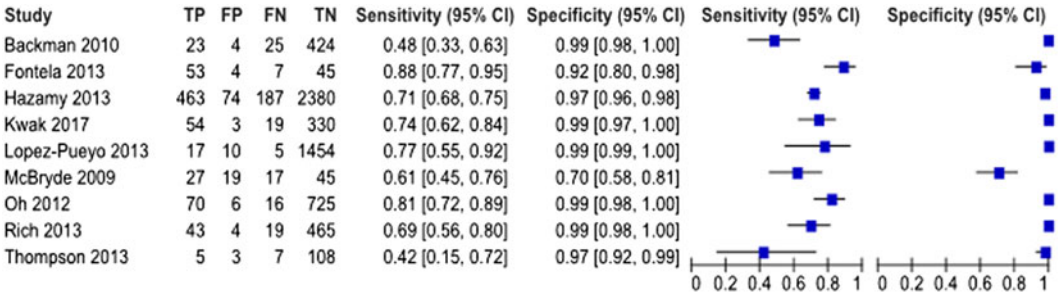


**Fig. 2.** Forest plot, sensitivity and specificity.

application, as well as the common source of these variations.[28,35] Although this method is a more feasible a systemwide assessment of CLABSI accuracy, 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 because randomized controlled trials and/or 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, as we have identified, CLABSI may be underreported by margins as high as 4.4%.

Other methods for systemwide CLABSI reporting include the use of automated electronic surveillance systems, which 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] The 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 has yet to be perfected.[9] A systematic review of HAI electronic surveillance identified 2 studies that assessed the accuracy of CLABSI (NHSN/CDC); which ranged from 94.3% to 95.2% for sensitivity and from 68.0% to 97.5% for specificity.[37] A further 8 studies assessing the accuracy of reporting for BSI (other classification, non-NHSN/CDC) reported sensitivity ranging from 72.0% to 100% and specificity ranging from 37.3% to 100%.[37] Although this finding 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. The effects of overestimation may be equal to the those of underestimation because it would similarly influence benchmarking, outbreak identification, and resource allocation.[28]

Accuracy and reliability of reported CLABSI rates are not only reliant upon objective classification but also on the reported denominator.[38] CLABSI incidence is commonly reported against 3 key denominators: device/central line days; patient days; and (less commonly) neutropenic days.[39] Standardization and validation of these denominators is essential because variation (eg, inclusion/exclusion of admission/discharge days; or differences in accounting for coexisting 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 we have further identified a need to validate local data, particularly that which is likely to lead practice change.

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, and 8 of 9 studies presented data from ICU only. Moreover, most studies (5 of 9) reported randomly selected patient sets rather than entire cohorts; therefore, incidence and accuracy measures were only calculated for the remaining 4 studies.

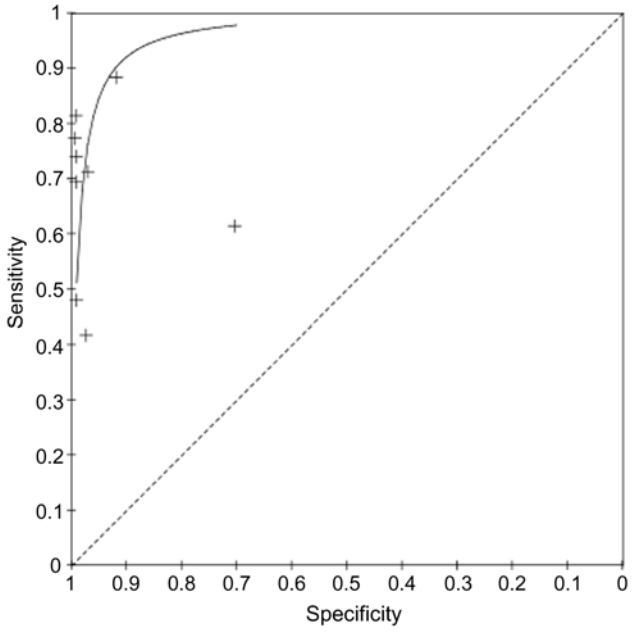


**Fig. 3.** SROC.

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 electronic[37] and administrative code data[40] regarding CLABSI classification accuracy, this systematic review 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]

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

**Financial support.** No financial support was provided relevant to this article.

**Conflicts of interest.** All authors report no conflicts of interest relevant to the findings of this systematic review.

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