Sensitivity and Specificity of a quick Sequential [Sepsis-Related] Organ Failure Assessment Sepsis Screening Tool

Running title: Accuracy of qSOFA sepsis screening

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AUTHOR CONTRIBUTIONS

LA had full access to all the data in the study and takes responsibility for integrity of the data and the accuracy of the analysis. LA, APM, RMW and LMA contributed to the concept and study design. LA and FP collected data. LA, AM and FP provided administrative, technical and material support. LA conducted the statistical analysis. All authors provided further input to the analysis and interpretation of data, revised the manuscript for important intellectual content and approved the final manuscript. AM, RMW, FP and LMA supervised the study process.

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DISCLOSURES

The authors declare that there is no conflict of interest related to this work.

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Abstract

Aim: There is limited evidence on the diagnostic accuracy of a quick Sequential [Sepsis-Related] Organ Failure Assessment (qSOFA) sepsis screening (SS) tool in developing nation health settings. The aim of this study was to test the diagnostic accuracy of a qSOFA-based SS tool, and the predictive validity of the qSOFA score in hospital ward patients from Argentina.

Methods: Prospective observational study. Patients (≥18 years, without sepsis) were recruited within 24-48 hours of admission to a 169-bed tertiary referral private hospital in Buenos Aires. The index test was the qSOFA-based SS tool, and the reference standard sepsis diagnosed at discharge blindly evaluated with reference to the Sepsis-3.

Results: In 1151 patients (median age 69.9 [IQR, 29.0]); 47 (4.1%) had sepsis, 413 (35.9%) had infection and 691 (60.0%) other diagnoses at discharge. The qSOFA-based SS tool (index test) had moderate sensitivity (60%), good specificity (89%), a very low positive (19%) and very high negative (98%) predictive value for sepsis diagnosed at discharge according to the Sepsis-3 criteria (reference standard). For the same outcome, the qSOFA score in isolation had a reasonable predictive validity area under receiver operating characteristics curve 0.77 (95% CI 0.70-0.83) $p < 0.001$.

Conclusion: The qSOFA score could reasonably discriminate patients at risk of developing sepsis; qSOFA-based screening may be valuable where no screening criteria are in place.

Kew words: qSOFA, sensitivity, specificity, sepsis, screening, hospital ward, developing nation

What's already known about this topic?

- Sepsis is a major cause of morbidity and mortality, and a World Health Organization recognized global concern.
- Screening tools for the early recognition of sepsis has been predominantly tested in developed nations. Prospective studies reporting screening tools validated in hospital ward populations in developing nation health settings are scarce.

What does this article add?

- The quick Sequential [Sepsis-Related] Organ Failure Assessment (qSOFA) sepsis screening tool had moderate sensitivity and may be valuable where no screening criteria are in place.
- The qSOFA score could identify patients at risk of developing sepsis during their hospitalisation.
- Patients with suspected infection that score 1 qSOFA point should be assessed for indicators of organ dysfunction and should be closely monitored and treated according to clinical judgment.

INTRODUCTION

Sepsis is an unresolved health issue, a major cause of morbidity and mortality world-wide. Sepsis affects almost 50 million people annually and, based on recent data 11 million will die.[1] In developing nations sepsis remains an under-investigated condition,[2-4] sepsis-related mortality is likely to be higher than in the developed world[5,6] although the true prevalence and consequences of sepsis remains unknown. Despite the impact of sepsis, effective screening methods in hospitalized patients are unclear, particularly in the developing world. This was confirmed by a recent systematic review that reported the majority of screening tools for sepsis were validated in the USA, with wide variation in their sensitivity and specificity.[7]

The clinical criteria to recognise sepsis has evolved. In 2016, the quick Sequential [Sepsis-related] Organ Failure Assessment (qSOFA) was introduced to prompt recognition of organ failure, in patients with suspected infection, and initiate treatment outside the intensive care.[8,9] Recently, a retrospective study reporting secondary analysis of data from nine developing nations found qSOFA could effectively discriminate infected patients at risk of death.[10] In contrast, based on studies predominantly from the developed world, reviewers found qSOFA had poor sensitivity for short term mortality;[11] and Sepsis-3 developers explained qSOFA is not a screening tool for sepsis as it was derived from data on symptomatic patients, and that screening intended to detect preclinical signs of disease.[12] In ward populations that develop sepsis in hospital, sepsis is more difficult to recognise, mortality is high, the use of hospital care is more intense[13,14] and is rarely investigated in developing settings. A tool based on the qSOFA could help screen early signs of sepsis. Therefore, the aim of this study was to test the diagnostic accuracy of a qSOFA-based sepsis screening (SS) tool within hospital ward patient population in a

developing nation. The predictive validity of the qSOFA score in the same population was also tested.

METHODS

Prospective observational study conducted from April to November 2017, in five medical-surgical hospital wards of a 169-bed referral private hospital in Buenos Aires, Argentina. Ethics approval was gained from Griffith University Human Research Ethics; the Ethics Committee of Bio-Ethics Institute, Pontifical Argentine Catholic University; and the study site's Institutional Review Board. Patient informed consent was waived because the information collected was part of routine care. This study was designed and reported following the Standards for Reporting of Diagnostic Accuracy Studies.[15]

Setting

The study wards comprised all general medical-surgical beds representing 55% (n = 94) of hospital beds. The remaining beds were dedicated to patients in paediatric, neonatal, obstetric, emergency department, coronary care and intensive care areas and not included in this study. Patients' health records were a combination of paper (vital signs, medication/fluid orders and medication administered registries) and electronic sources (routine physician/nursing reviews, plan/treatment provided, pathology reports).

Population, sample and recruitment

Study participants were general hospitalized adults (≥ 18 years). Patients were excluded if they were: admitted to and stayed in intensive, coronary, emergency or paediatric units; pregnant and/or receiving obstetrics care; receiving chemotherapy treatment, or bone marrow transplant; patients with acquired immune deficiency syndrome; or, receiving immunosuppressive therapy. Finally, patients who were being

palliated or who were not for resuscitation or had a sepsis diagnosis at the time of hospital admission were also ineligible.

The sample size was based on previous published sample sizes for diagnostic studies and administrative information. To achieve a 0.91 sensitivity, taking into consideration a 95% confidence interval (CI) lower limit of 0.88, a sample of 1,127 patients was recommended.[16] Because of the unknown prevalence of sepsis in the study setting, and an estimation of 15% based on an international report,[17] an additional 10% above the recommended sample was computed to ensure an adequate number of sepsis cases. This led to total target recruitment of 1,248 patients. Feasibility was confirmed with the admission of 761 eligible patients per month to the study wards during 2016.

Patients were recruited from the study wards within 24-48 hours of hospital admission. As wards differed in their patient diagnoses and numbers, the order of wards revised for daily recruitment was randomised (from first to fifth) using an online tool to optimise patient variation.[18] The list of admissions and the health records of each ward were reviewed for eligibility every day based on this randomization. Up to eight consecutive, eligible patients were recruited per day.

Data collection

Data collected included: age, gender, medical insurance, hospital and intensive care unit (ICU) length of stay, comorbidities[19] qSOFA variables during all admission, source of confirmed or suspected infection, antibiotics, fluids and vasopressors administered, lactate value, culture reports and diagnosis at discharge. Data for qSOFA variables (Supporting Table 1) were collected from paper-based nursing vital sign charts and electronic nursing notes; where these variables were not documented, the information was collected from physicians' records. Diagnosis at discharge was assessed by an experienced intensivist

who, blinded to the qSOFA score, reviewed the electronic component of patients' health records with reference to the Sepsis-3 criteria,[8,20] and identified patients as having sepsis or septic shock. The Sepsis-3 criteria was preferred because it is the latest criteria for sepsis.[8,20] If during this process, the patient did not meet Sepsis-3 criteria,[8,20] he/she was classified as having infection or other diagnosis according to the information in the health records. All data were prospectively collected and entered into either of two secure forms a Microsoft® Excel (version 2016) file and REDCap 7.0.11© 2018 electronic data capture tools hosted at Griffith University.[21]

Data analysis

Data were cleaned prior to analysis by randomly selecting 10% of participants and independently reviewing entered data against the case report form. The error rate was 0.01%. Continuous non-normally distributed data were analysed descriptively as medians and interquartile ranges (IQR), and categorical data as percentages. Discharge diagnosis groups were compared with Chi-Square and Kruskal-Wallis statistical procedures, where a $p < 0.05$ was considered significant.

The index test was the qSOFA-based SS tool variable defined as a composite of the earliest qSOFA score ≥ 2 and any source of confirmed/suspected infection noted in the health record, or where antibiotics were administered. Previous evidence suggested that patients with suspected infection with qSOFA score ≥ 2 were more likely to have poor outcomes typical of sepsis.[8,9] To determine the earliest ≥ 2 (positive) or ≤ 1 qSOFA (negative) scores among all qSOFA sets during admission, a minimum of two out of three values -either respiratory rate (RR), systolic blood pressure (SBP) or altered mentation (AM)- were present per set. The reference standard was the diagnosis at discharge variable dichotomised; that is patients with sepsis and septic shock were grouped as "sepsis," and

patients with infection and other diagnoses were grouped as "no sepsis." Then, the performance of the qSOFA-based SS tool was assessed against the reference standard using sensitivity, specificity, and predictive values. The predictive validity of the qSOFA score alone for sepsis diagnosis at discharge was examined using the area under the receiver operating characteristic curve (AUROC). All statistical analyses were conducted using IBM SPSS® Statistics for Windows Version 25 (Armonk, NY: IBM Corp).

RESULTS

In 1,151 patients (median, age 69.9 [IQR, 29.0]; female, 619 [53.8%]), 47 (4.1%) had sepsis (including 11 with septic shock), 413 (35.9%) had infection and 691 (60.0%) other diagnoses at discharge (Table 1). Patients' comorbidities are detailed in the Supporting Table 2. The most frequent sources of infection in patients with sepsis were pulmonary (40.4%) or urinary (38.3%) (Table 2). Infections classified at discharge are detailed in the Supporting Table 3. A total of 19,834 qSOFA sets were collected, among them 2,000 sets (10%) had one or more qSOFA individual variables (RR, SBP or AM) not documented (Supporting Figure 1); 213 (18.5%) patients had qSOFA ≥ 2 (Supporting Figure 2) and 145 (12.6%) met the qSOFA-based SS tool criteria (Figure 1). Cross tabulation of the qSOFA-based SS tool by sepsis diagnosed at discharge (Supporting Table 4) resulted in 60% sensitivity, 89% specificity, 19% positive predictive value (PPV) and 98% negative predictive values (NPV). The predictive validity of the qSOFA score in isolation for the same outcome was an AUROC, 0.77; 95% CI, 0.70-0.83; $p < 0.001$ (Figure 2).

DISCUSSION

In this prospective study of over thousand medical-surgical adults from a developing nation, the tested qSOFA-based SS tool demonstrated moderate sensitivity,

high specificity, very low PPV and very high NPV. qSOFA score in isolation adequately discriminated sepsis diagnosis at discharge. The more common infections associated with sepsis were pulmonary and urinary, and the frequency of patients with sepsis was very low.

The diagnostic value of a 4-variable qSOFA-based screening tool (RR, SBP, AM and any confirmed/suspected source of infection) was examined in hospital ward population who developed sepsis in hospital. Screening variables were collected every admission day simulating screening in the real-world setting. This study design differs from others that examined the qSOFA prognostic value for ICU admission and mortality in patients with suspected infection or sepsis at admission,[22,23] although the epidemiological tools used in all studies were similar. The moderate sensitivity (60%) of the qSOFA-based SS tool was similar to that of a more complex sepsis surveillance tool developed by The Centers for Disease Control and Prevention for electronic health record systems use (The Adult Sepsis Event, which uses a simplified Sequential Organ Failure Assessment score named eSOFA).[24] Four of six eSOFA variables are laboratory indicators of organ dysfunction, which may be difficult to assess in settings where electronic resources are unavailable, or laboratory facilities are limited.

Index test positive patients had a very low probability of developing sepsis illustrated by the low PPV (19%). Predictive values have been rarely reported in qSOFA studies. Although for a different outcome, higher PPV (37%) for mortality was found for qSOFA positive patients outside intensive care.[25] Predictive values are highly dependent on the prevalence of the condition they intended to predict,[26] given a very low frequency of sepsis in our data (4.1%) this finding may not be useful.

Nineteen patients (40.4%) were index test false negatives (Table 2, Supporting Table 4); among them 18 scored 1 qSOFA point with the remaining scoring 0 (Table 2).

This misclassification was examined by retrospective analysis of qSOFA negative patients that developed sepsis as per Sepsis-2.[27] Researchers found those patients also developed hypothermia, and they hypothesised qSOFA may fail to identify impaired immune responses to infection.[28] Similarly, in a Brazilian study 13% of sepsis non-survivors scored ≤1 qSOFA point.[23] This suggests organ dysfunction must be investigated in patients with suspected/confirmed infection that scored 1 qSOFA point. Perhaps what made our qSOFA-based SS tool a moderate classifier of sepsis may be the tool's inability to capture dysfunctions evident in blood tests or other observations not included in the qSOFA parameters; although, this assumption merits further research.

There is growing evidence examining the predictive role of the qSOFA for sepsis diagnosis and poor outcomes. One Italian report highlighted better prediction performance for sepsis diagnosis (AUROC, 0.83; 95% CI, 0.74–0.89)[29] than ours (AUROC; 0.77; 95% CI, 0.70-0.83) when examined against Sepsis-3,[8] and a Chinese study showed slightly lower AUROC (0.75).[30] During the Coronavirus pandemic 2019 (COVID19), prediction of septic shock in patients represented an AUROC of 0.74.[31] On the other hand, qSOFA discrimination for mortality in various non-ICU settings has been widely examined. The AUROC reports ranged from 0.69 (95% CI, 0.67–0.70) outside ICU population,[22] 0.69 (95% CI, 0.67-0.72) in sub-Saharan Africa,[32] 0.70 (95% CI, 0.68-0.72) in nine developing countries,[10] 0.74 (95% CI, 0.66–0.81) in both emergency department and ward patients,[33] 0.75 in Brazil,[23] and 0.81 (95% CI, 0.80-0.82) in the Sepsis-3 study that used data from the USA and Germany.[9] In COVID19 patients AUROCs reported were 0.73 and 0.77 for in-hospital and 28-day mortality respectively.[31,34] Our findings, together with this evidence, reinforces the ability of the qSOFA score to discriminate either sepsis diagnosis or mortality in non-ICU, hospital ward populations in developed and developing nations, thereby providing further validation of this score.

It has been suggested that including qSOFA in a screening mechanism may lead to deferral of medical treatment and may miss patients at risk.[22,23] However, this assumption may be challenged when tools are implemented in hospital ward patients. A recent interrupted times series study reported a trend towards an improvement in the timing of treatment when qSOFA-based screening was implemented in patients who developed sepsis in hospital wards.[35] While it is known the sensitivity of qSOFA has been questioned, characteristics of a screening tool or scoring system do not always determine what happens in clinical practice. Researchers found that an early warning and response system for sepsis, which had poor sensitivity for a composite outcome (transfer to ICU, rapid response team activation or death) and sepsis diagnosis at discharge (17% and 22%) when implemented resulted in improved provision of treatment.[7,36] This evidence suggests that factors different than the sensitivity of a screening tool may play an important role when tools are introduced in clinical practice. Simplicity and setting characteristics may be important considerations for future research on screening for sepsis, particularly in settings where there are staffing and technology limitations.

Pulmonary, urinary and abdominal were the more common infections associated with a low frequency of sepsis. The types of infection causing sepsis were more like those reported in Brazil, Europe and the USA,[37-39] rather than those common in other developing nations in Africa and South East Asia.[10] The socioeconomic status and access to care of the studied population from a large urban city may explain these differences. However, the low frequency of sepsis (4.1%), measured against the Sepsis-3 criteria,[8] is surprising in the Argentinean setting. A similar percentage (6%) of hospitalizations with sepsis were reported in the USA where researchers used the Sepsis-3 criteria as part of electronic surveillance.[40] Although methodological differences may result in different frequencies,

our study provides an initial understanding of Sepsis-3[8] frequency in hospital wards in Argentina and may serve for future comparisons.

Implications for clinical practice and research

Choosing a screening tool for sepsis is a complex decision for several reasons. There is no reference standard for the diagnosis of sepsis and available screening options are imperfect. Achieving a highly sensitive and specific tool would be ideal. However, identifying the adequate normal-abnormal point is an arbitrary decision, and when testing tools, sensitivity improves at the expense of specificity and vice versa.[41] In hospital ward settings it is difficult to identify subtle and non-specific clinical signs of organ disturbance due to infection. Thus, sensitivity should be prioritised in a screening mechanism, yet specificity should not be overlooked. The qSOFA-based SS tool has moderate sensitivity and high specificity and better represents the current knowledge of sepsis mechanism; importantly it allows the differentiation of patients with infection and inflammation from those presenting dysregulated host response to infection.[42] Clinicians must be reminded that every patient with infection has the potential to develop sepsis and eventually, every hospital ward patient is vulnerable to infection. Therefore, the suspicion of infection may be a valuable screening variable that is relevant for clinical practice. Although robust alerts for sepsis were studied,[22,43] contextual factors and resources available should not be underestimated and should be weighted in the decision making.

There are, however, questions future research should address to improve screening for sepsis. These include whether there is a clinical variable that can improve the qSOFA-based SS tool sensitivity, diverse populations to investigate, different methodological approaches and ways to use qSOFA. Recently, various systematic reviews have highlighted qSOFA strengths and limitations; included studies were largely secondary

analysis, interrogation of retrospective data, and studies predominantly produced in the developed world.[11,44-46] This evidence, while informative, may not be generalizable to the diverse developing settings; sepsis research should be representative of this diversity. In terms of methodological approaches, it has been proposed that in the absence of a reference standard the metrics such as sensitivity and specificity are not useful to evaluate parameters of sepsis; and, instead predictive validity and usefulness should be considered.[47] For example, researchers have evaluated the trajectories of qSOFA, that is repeated measures of the score in patients with infection; they seemed to improve prediction for sepsis.[48] This study, using electronic health records suggested repeated measurements of qSOFA allowed for monitoring of the patient deterioration/improvement, and may be of help where no-electronic resources are available. This study demonstrated a different use of the qSOFA score, considering the dynamic nature of the physiology. This understanding may provide alternatives to identify earlier signs of organ dysfunction and perhaps monitoring recovery. However, this is not a simple task, developing nations have limited or non-existent structures for health research. Thus, future research will require expansion of the current international collaborations, more active involvement of local expertise, governments, funding bodies and other interested stakeholders.

Limitations

The limitations include that the qSOFA-based SS tool was based on clinician documentation of a known or suspected source of infection or administered antibiotics. This resulted in some cases where the infection was ruled-out at the time of the patient's discharge from hospital. However, this is a possible outcome for many screening tools used in clinical settings; patients are assessed for risk that may not be confirmed.[49] The unavailability of some data (RR, SBP, or AM) due to the fragmentation of data sources,

may have prevented some patients from scoring more qSOFA points to meet the screening tool criteria (Supporting Figure 1). Despite the diagnosis at discharge considering the Sepsis-3,[8,20] we did not collect the Sequential [Sepsis-Related] Organ Failure Assessment Score to better inform the reference standard. Given the setting characteristics, this would have contributed to additional data collection burden. Finally, the low frequency of sepsis and deaths, although good for the patients, prevented the evaluation of the qSOFA as a predictor of mortality.

CONCLUSION

In this prospective study in a developing health setting the qSOFA-based SS tool had moderate sensitivity and high specificity for sepsis diagnosis at discharge in a hospital ward population. The qSOFA score demonstrated reasonable predictive validity for the same outcome. The qSOFA base screening might make a valuable contribution to a screening mechanism for sepsis where no screening tools are in place or where clinical resources are limited. Further research is needed to better understand screening for sepsis in developing nations.

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TABLE 1 Patients' characteristics by diagnosis at discharge

Patient's characteristics	Whole cohort (n = 1,151)	Sepsis (n = 47)	Infection (n = 413)	Other (n = 691)	p Value
Age, median (IQR)	69.9 (29.0)	76.4 (21.3)	72.0 (28.8)	68.4 (29.6)	0.004
Gender, n (%)					
Male	532 (46.2)	27 (57.4)	204 (49.4)	301 (43.6)	0.049
Female	619 (53.8)	20 (42.6)	209 (50.6)	390 (56.4)	
Medical insurance, n (%)					
Private-prepaid	755 (65.6)	32 (68.1)	274 (66.3)	449 (65.0)	0.840
Social security	396 (34.4)	15 (31.9)	139 (33.7)	242 (35.0)	
Type of admission, n (%)					
Medical	701 (60.9)	32 (8.1)	285 (69.0)	384 (55.6)	<0.001
Surgical	450 (39.1)	15 (31.9)	128 (31.0)	307 (44.4)	
Condition at discharge, n. (%)					
Alive	1117 (97)	36 (76.6)	407 (98.5)	674 (97.5)	
DNR status, yes	29 (2.5)	9 (19.1)	5 (1.2)	15 (2.2)	
Deaths excluding DNR	7 (0.6)	3 (7.9)	2 (0.5)	2 (0.3)	
CCI, median (IQR)	2.0 (3.0)	3.0 (3.0)	3.0 (3.0)	2.0 (4.0)	<0.001
Hospital LOS, median (IQR), days	4.0 (4.0)	9.0 (11.0)	5.0 (4.0)	4.0 (3.0)	<0.001
Use of higher level of care					
ICU admission, n (%)	114 (9.9)	13 (27.7)	18 (4.4)	83 (12.0)	<0.001
ICU or CCU length of stay, median (IQR), days	1.4 (2.0)	7.8 (7.8)	2.5 (2.2)	1.1 (1.1)	<0.001
No use of OR, n (%)	656 (57)	31 (66.0)	274 (66.3)	351 (50.8)	
1 procedure in OR, n (%)	432 (37.5)	7 (14.9)	111 (26.9)	314 (45.4)	<0.001
≥ 2 procedures in OR, n (%)	63 (5.5)	9 (19.1)	28 (6.8)	26 (3.8)	
Sepsis care					
Antibiotics administered, n (%)					
Antibiotics	559 (48.6)	46 (97.9)	392 (94.9)	121 (17.5)	<0.001
No Antibiotics	592 (54.4)	1 (2.1)	21 (5.1)	570 (82.5)	
Lactate					
Lactate, median (IQR), mmol/L	1.8 (1.0)	1.9 (1.6)	1.7 (1.0)	1.8 (1.0)	0.153
Highest lactate, median (IQR), mmol/L	2.2 (3.1)	3.4 (3.3)	2.1 (1.3)	1.9 (1.5)	0.091
Amount crystalloids, median (IQR), ml	500 (500)	500 (1000)	500 (500)	1000 (500)	0.477
Vasopressors initiated, n (%)	10 (0.9)	8 (80.0)	0 (0)	2 (20.0)	
≥ 1 culture, n (%)	525 (45.6)	45 (95.7)	357 (86.4)	123 (17.8)	

Infective agents, n (%)				
≥ 1 fungi microbe	20 (1.7)	2 (12.8)	12 (2.9)	2 (0.3)
≥ 1 gram-negative bacteria	145 (12.6)	17 (36.2)	110 (26.6)	10 (1.4)
≥ 1 gram-positive bacteria	75 (6.5)	11 (23.4)	46 (11.1)	5 (0.7)
Multiresistant bacteria	35 (3.0)	2 (4.3)	29 (7.0)	4 (0.6)
MRSA	7 (0.6)	0 (0)	7 (1.7)	0 (0)
ESBL producing bacteria	26 (2.3)	2 (4.3)	20 (4.8)	4 (0.6)
KPC producing bacteria	2 (0.2)	0 (0)	2 (0.5)	0 (0)

Abbreviations: IQR, interquartile range; DNR, do not resuscitate; CCI, Charlson Comorbidity Index; LOS, length of stay; ICU, intensive care unit; CCU, coronary care unit; OR, operating room; mmol/L, millimoles per litre; ml, millilitre; MRSA, Meticillin-resistant Staphylococcus Aureus; ESBL, Extended-spectrum β-lactamase; KPC, Klebsiella Pneumoniae Carbapenemase.

TABLE 2 qSOFA-based Sepsis Screening Tool Variables by Diagnosis at Discharge

Screening tool variables	Whole cohort (n = 1,151)	Sepsis (n = 47)	Infection (n = 413)	Other (n = 691)	p value
Source of confirmed or suspected infection, n (%)					
Pulmonary	178 (15.5)	19 (40.4)	136 (32.9)	23 (3.3)	
Urinary	133 (11.6)	18 (38.3)	103 (24.9)	12 (1.7)	
Skin, soft tissues	120 (10.4)	2 (4.3)	109 926.4)	9 (1.3)	
Abdominal	99 (8.6)	12 (25.5)	69 (16.7)	18 (2.6)	
Wounds	61(5.3)	1 (2.1)	51 (12.3)	9 (5.3)	
Bone, joints	42 (3.6)	0 (0)	36 (8.7)	6 (0.9)	
Bacteraemia	17 (1.5)	7 (63.6)	9 (36.0)	1 (33.3)	
Devices, prosthesis	7 (0.6)	2 (18.2)	4 (16.0)	1 (33.3)	
Central line	6 (0.5)	0 (0)	5 (1.2)	1 (0.5)	
Esophageal, oral candidiasis	4 (0.3)	1 (9.1)	2 (8.0)	1 (33.3)	
Mastoiditis, otitis, parotid, tonsils	4 (0.3)	0 (0)	4 (16.0)	0 (0)	
Pelvis	4 (0.3)	0 (0)	4 (16.0)	0 (0)	
Viral infection	3 (0.3)	1 (9.1)	2 (8.0)	0 (0)	
Meningitis	2 (0.2)	1 (2.1)	1 (0.2)	0 (0)	
Endocarditis	2 (0.2)	0 (0)	2 (0.5)	0 (0)	
Confirmed or suspected infection or antibiotics administered, n (%)	587 (51%)	46 (97.9) †	405 (98.1)	136 (19.7)	
qSOFA scores, n (%)					
Score 0	317 (27.5)	1 (2.1)	84 (20.3)	232 (33.6)	
Score 1	621 (54)	18 (38.3)	235 (56.9)	368 (53.3)	<0.001
Score 2	196 (17)	23 (48.9)	87 (21.1)	86 (12.4)	
Score 3	17 (1.5)	5 (10.6)	7 (1.7)	5 (0.7)	
qSOFA-based sepsis screening tool, n (%)					
Positive	145 (12.6)	28 (59.6)	92 (22.3)	25 (3.6)	<0.001
Negative	1006 (87.4)	19 (40.4)	321 (77.7)	666 (96.4)	

Abbreviations: qSOFA, quick Sequential [Sepsis-Related] Organ Failure Assessment

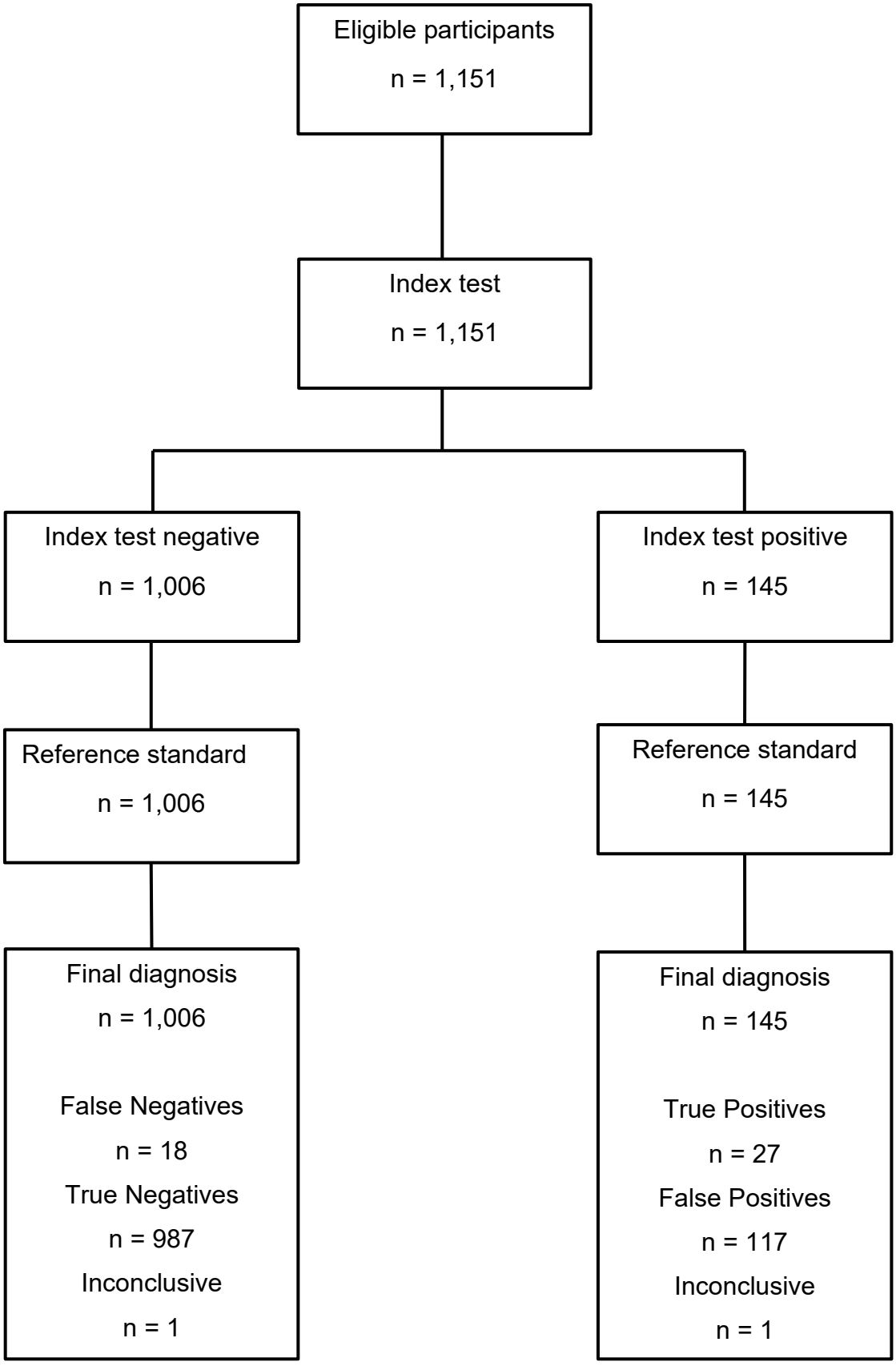
Note: † This cell do not add the total (100%), the remaining patient did not have information related to infection or antibiotics, in the blind diagnosis was found with sepsis.

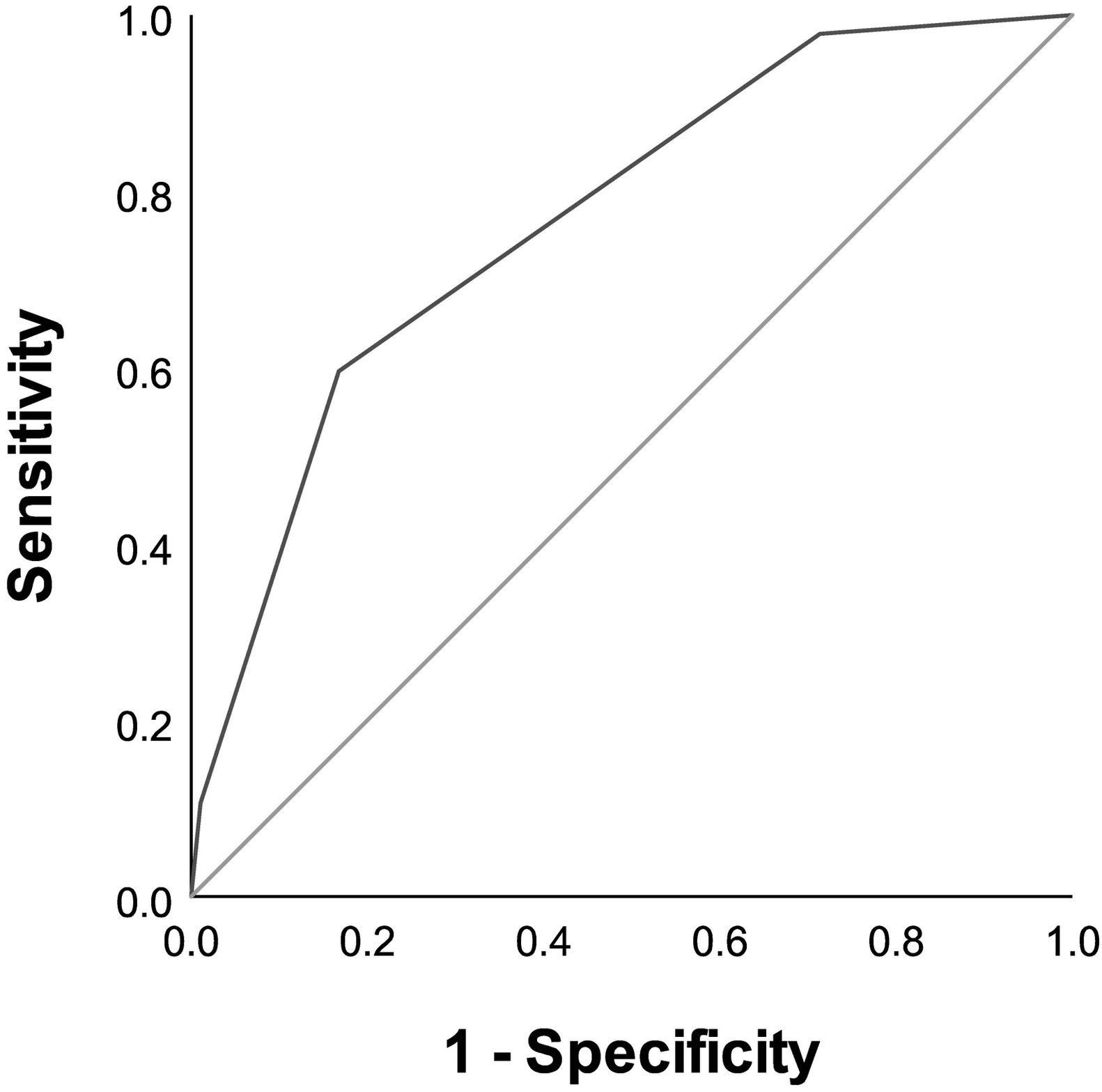
Figure 1 STARD flow diagram

Abbreviation: qSOFA, quick Sequential [Sepsis-Related] Organ Failure Assessment
Note: Index test was the qSOFA-based sepsis screening tool variable. The reference standard was the sepsis diagnosis at discharge blindly defined according to Sepsis-3 criteria.

Figure 2 qSOFA score area under the receiver operating characteristic curve (AUROC) for sepsis diagnosis at discharge

Abbreviation: qSOFA, quick Sequential [Sepsis-Related] Organ Failure Assessment
Note: 2 patients included in the sepsis group were clinically judged with sepsis during the blind diagnosis, although it was inconclusive the organ dysfunction observed in the chart review could have been related to the documented infection.


Eligible participants
n = 1,151
Index test
n = 1,151
Index test negative
n = 1,006
Index test positive
n = 145
Reference standard
n = 1,006
Reference standard
n = 145
Final diagnosis
n = 1,006
False Negatives
n = 18
True Negatives
n = 987
Inconclusive
n = 1
Final diagnosis
n = 145
True Positives
n = 27
False Positives
n = 117
Inconclusive
n = 1


1.0
0.8
0.6
0.4
0.2
0.0
Sensitivity
0.0
0.2
0.4
0.6
0.8
1.0
1 - Specificity

Sensitivity and Specificity of a quick Sequential [Sepsis-Related] Organ Failure Assessment Sepsis Screening Tool

Supporting Table 1. quick Sequential [Sepsis-Related] Organ Failure Assessment scoring

	Score
Respiratory rate: ≥22/min	1
Systolic Blood Pressure: ≤100mmHg	1
Altered mentation was an acute, sudden deterioration in consciousness determined by one of the following [1,2]: - a decrease of 2-points on the Glasgow Coma Scale - or the patient became disorientated to place - or time - or person - or assessed somnolent - or confused - or agitated	1

References

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Sensitivity and Specificity of a quick Sequential [Sepsis-Related] Organ Failure Assessment (qSOFA) Sepsis Screening Tool

Supporting Table 2. Charlson Comorbidity Index frequency

Index Variables	Whole cohort (n = 1,151)	Sepsis (n = 47)	Infection (n =413)	Other (n = 691
HBP	524 (45.5)	21 (44.7)	187 (45.3)	316 (45.7)
Cancer	221 (19.2)	11 (23.4)	72 (17.4)	138 (20.0)
Metastases	42 (3.6)	3 (6.4)	11 (2.7)	28 (4.1)
COPD	190 (16.5)	4 (8.5)	88 (21.3)	98 (14.2)
Diabetes	159 (13.8)	9 (19.1)	65 (15.7)	85 (12.3)
Dementia	144 (12.5)	8 (17.0)	73 (17.7)	63 (9.1)
Myocardial infarction	129 (11.2)	10 (21.3)	46 (11.1)	73 (10.6)
Moderate to severe renal disease	104 (9.0)	8 (17.0)	47 (11.4)	49 (7.1)
Warfarin	101 (8.8)	7 (14.9)	31 (7.5)	63 (9.1)
Skin ulcer	92 (8.0)	7 (14.9)	57 (13.8)	28 (4.1)
Gastric or peptic ulcer	76 (6.6)	2 (4.3)	29 (7.0)	45 (6.5)
Heart failure	67 (5.8)	3 (6.4)	18 (4.4)	46 (6.7)
Peripheral vascular disease	36 (3.1)	2 (4.3)	14 (3.4)	20 (2.9)
Cerebrovascular accident	54 (4.7)	6 (12.8)	18 (4.4)	30 (4.3)
Depression	53 (4.6)	2 (4.3)	19 (4.6)	53 (4.6)
Hemiplegia	45 (3.9)	1 (2.1)	24 (5.8)	20 (2.9)
End organ damage from diabetes	12 (1.0)	1 (2.1)	5 (1.2)	6 (0.9)
Rheumatic	24 (2.1)	1 (2.1)	9 (2.2)	14 (2.0)
Chronic liver disease	16 (1.4)	0 (0)	6 (1.5)	10 91.4)
HIV	13 (1.1)	1 (2.1)	6 (1.5)	6 (0.9)
Severe liver disease	7 (0.6)	2 (4.3)	0 (0)	5 (0.7)

Abbreviations: HBP, high blood pressure; COPD, chronic obstructive pulmonary disease; HIV, human immunodeficiency virus

Sensitivity and specificity of a quick Sequential [Sepsis-Related] Organ Failure Assessment (qSOFA) Sepsis Screening Tool

Supporting Table 3. Infections classified at discharge

Infections	Whole cohort (n = 1,151)	Sepsis (n = 47)	Infection (n = 413)
Infections at discharge, n (%)			
1 Infection	434 (37.7)	38 (80.9) *	396 (95.9) *
≥ 2 Infections	26 (2.3)	9 (19.1) *	17 (4.1) *
Type of Infections at discharge, n (%)			
Pulmonary or Respiratory Infections	145 (31.6)	16 (34.8)	129 (31.2)
Urinary tract infection	102 (22.2)	15 (32.6)	87 (21.1)
Cellulitis or soft tissues	59 (12.9)	0 (0)	59 (14.3)
Abdominal Infections	51 (11.1)	9 (19.6)	42 (10.2)
Surgical site infection	38 (8.3)	0 (0)	38 (9.2)
Joints, Prosthesis or Osteomyelitis	19 (4.1)	0 (0)	19 (4.6)
Bacteraemia or Catheter-related bloodstream infection	10 (2.2)	3 (6.5)	7 (1.7)
Viral infection	13 (2.8)	1 (2.2)	12 (2.9)
Gastrointestinal infection	12 (2.6)	1 (2.2)	11 (2.7)
HIV or Hepatitis	4 (0.9)	0 (0)	4 (1.0)
Other	6 (1.3)	1 (2.2)	5 (1.2)
Type of concurrent infections in patients with ≥2 Infections at discharge, n (%)			
Bacteraemia or Catheter-related bloodstream infection	7 (26.9)	6 (66.7)	1 (5.9)
Abdominal Infections	6 (23.1)	1 (11.1)	5 (29.4)
Cellulitis or soft tissues	5 (19.2)	0 (0)	5 (29.4)
Pulmonary or Respiratory Infections	4 (15.4)	1 (11.1)	3 (17.6)
Urinary tract infection	2 (7.7)	1 (11.1)	1 (5.9)
Gastrointestinal infection	1 (3.8)	0 (0)	0 (0)
Viral infection	1 (3.8)	0 (0)	1 (5.9)

Abbreviation: HIV, human immunodeficiency virus

Note: * p value < 0.001 (difference between infection and sepsis groups)

Sensitivity and Specificity of a quick Sequential [Sepsis-Related] Organ Failure Assessment (qSOFA) Sepsis Screening Tool

Supporting Table 4. Two by two table: quick Sequential [Sepsis-Related] Organ Failure Assessment Sepsis Screening Tool by Sepsis Diagnosed at Discharge

		Reference Standard		
		Sepsis	No sepsis	Total
Index Test qSOFA-based Sepsis Screening Tool	Positive	28[£]	117	145
	Negative	19[£]	987	1,006
	Total	47	1,104	1,151

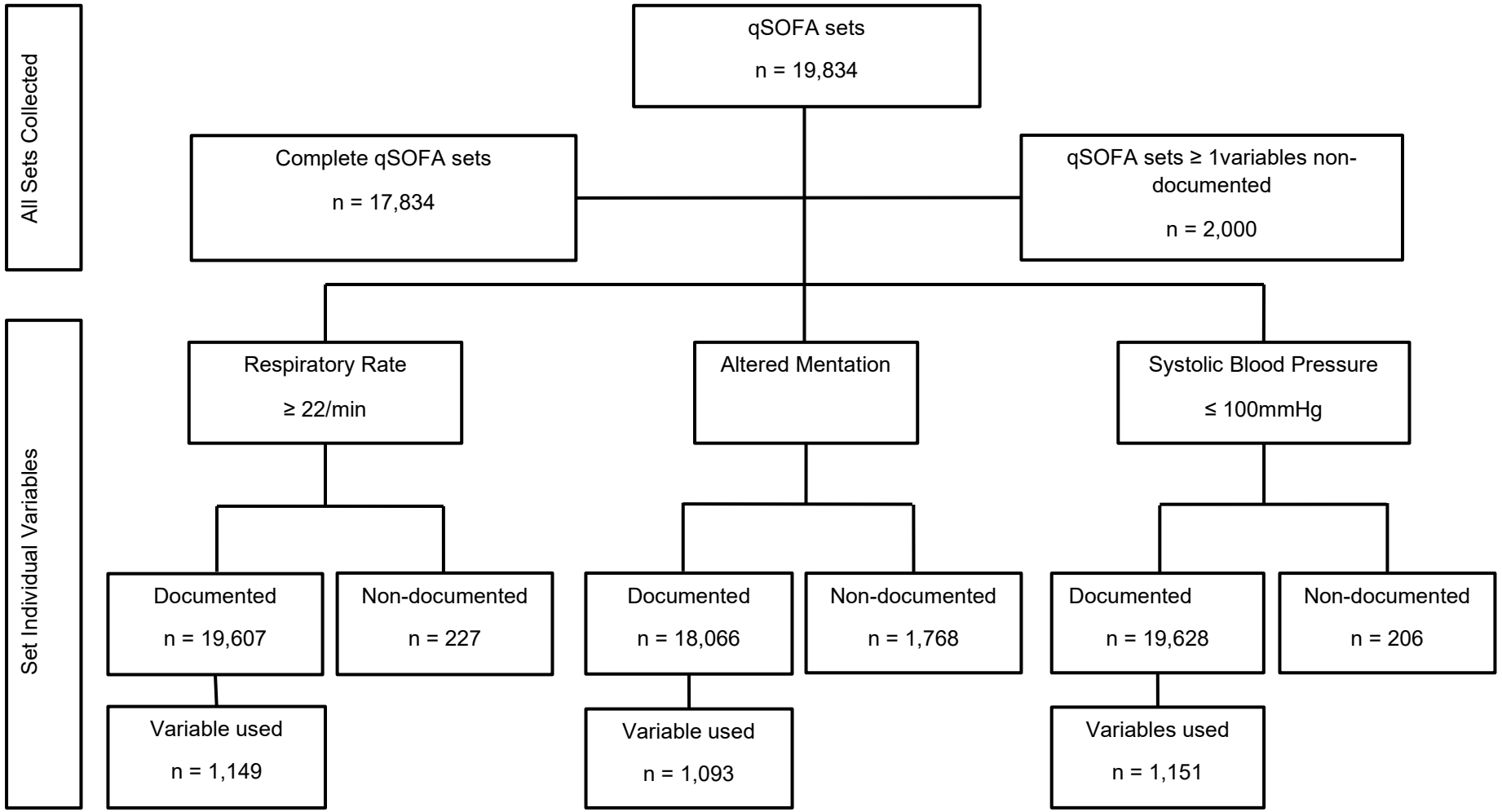
Abbreviation: qSOFA, quick Sequential [Sepsis-Related] Organ Failure Assessment

Note:

[£] 1 patient from this cell group was clinically judged with sepsis during the blind diagnosis, although it was inconclusive the organ dysfunction observed in the chart review could have been related to the documented infection

Sensitivity and Specificity of a quick Sequential [Sepsis-Related] Organ Failure Assessment Sepsis Screening Tool

Supporting Figure 1. qSOFA Flow Diagram of documented versus non-documented respiratory rate, systolic blood pressure and altered mentation variables in all patients

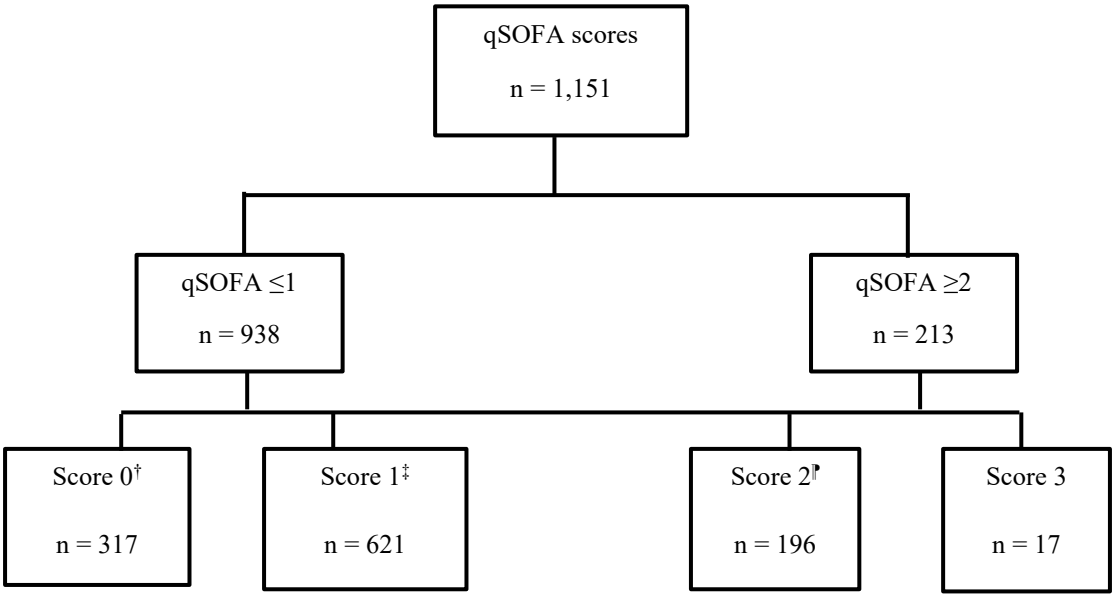


Abbreviation: qSOFA, quick Sequential [Sepsis-Related] Organ Failure Assessment

Note: A qSOFA set consisted of respiratory rate, altered mentation and systolic blood pressure assessed in one nursing observation. Variable used were either respiratory rate, altered mentation or systolic blood pleasure present in the first qSOFA set chosen for the qSOFA-based sepsis screening tool, and they were one per patient.

Sensitivity and Specificity of a quick Sequential [Sepsis-Related] Organ Failure Assessment Sepsis Screening Tool

Supporting Figure 2. Flow diagram of the earliest qSOFA score per patient chosen for the qSOFA-based sepsis screening tool



Abbreviation: qSOFA, quick Sequential [Sepsis-Related] Organ Failure Assessment

Notes:
† 21 patients had altered mentation non-documented
‡ 2 patients had respiratory rate, and 32 had the systolic blood pressure non-documented
⁋ 5 patients had altered mentation non-documented