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ON SAFETY AND QUALITY IN HEALTH CARE**

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Sepsis Medical Record Review: Pilot study

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Level 5, 255 Elizabeth Street, Sydney NSW 2000

Phone: (02) 9126 3600

Fax: (02) 9126 3613

Email: mail@safetyandquality.gov.au

Website: www.safetyandquality.gov.au

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Preface

Context

Sepsis is a time-critical medical emergency that arises when the body's response to an infection damages its own tissues and organs leading to failure of multiple organs, and death if not recognised and treated promptly.¹ Sepsis can occur in response to bacterial, viral or fungal infections which can be acquired in both the community and healthcare settings.

National inpatient data shows that sepsis cases are increasing in Australia. An estimated 55,000 Australians suffer sepsis annually, of which 8,700 die.² In recognition of this, the Australian Commission on Safety and Quality in Health Care (the Commission) has been engaged by the Australian Government Department of Health (the Department), in collaboration with The George Institute for Global Health, to lead and coordinate the National Sepsis Program. The program aims to improve outcomes for people with sepsis in Australia by:

- Improving the recognition of sepsis in all settings (primary, sub-acute, acute)
- Providing clinicians with nationally agreed sepsis clinical guidance materials
- Strengthening the comprehensive care planning process for sepsis survivors.

As part of the program, the Commission conducted a pilot study for a national retrospective medical record review during the period from 20 September 2021 to 7 February 2022 to assess the clinical documentation of patients with sepsis and suspected sepsis across hospital and pre-hospital settings to examine three questions:

1. To what extent are cases of sepsis recognised?
2. Are there cases of gold standard sepsis management?
3. What factors influence deviation from local sepsis guidelines and pathways?

Study design and methodology

Six sites participated in the pilot study: five hospitals, and one pre-hospital (ambulance) setting. Study site selection aimed to ensure representation from different Australian jurisdictions, and took into consideration factors such as geographical isolation, demographic profile and service level. Medical records were included in the sample if they met the following criteria at the participating study sites: records where the date of separation was within the last three financial years; and records with ICD-10 AM codes for sepsis (explicit codes), or a pre-determined set of infection codes and a code for organ dysfunction (implicit codes). Records were excluded from the sample if they were for chemotherapy or dialysis only, under three months of age, or on an end-of-life care pathway.

Using these inclusion and exclusion criteria, and in light of reviewer capacity at participating sites, a sample was generated which included 270 medical records from the hospital sites (based loosely on the assumption that there were 104,912 cases of sepsis in Australia each year, and to get a 90% confidence level with a 5% error margin to detect a proportion of cases with sepsis guideline compliance of 50%), and 100 case files from the ambulance service. Each hospital medical record was reviewed twice – one review was undertaken by a clinical reviewer and one review by a coding reviewer. Ambulance records were reviewed once as the Final Primary Assessment (FPA) is normally determined by the paramedic completing the case record, and hence, to follow the same process the case records were reviewed once by a clinical reviewer. Reviewers considered any clinical documentation available for the medical record, and submitted data through responding to a series of questions in a secure online data collection tool.

The original study design consisted of two phases: a pilot study followed by a main review. The intent of the pilot study was to test the study methodology, followed by a larger and more comprehensive review informed by the findings and recommendations from the pilot study.

Due to the Omicron outbreak of COVID-19, the Commission decided to limit data collection to those collected during the pilot in order to minimise the time and resourcing imposed on local reviewers at a time when there was a heavy service demand on hospitals across the country. As such, there was only one data collection (the pilot study data collection) conducted to form the basis of the analysis in this study. In turn, the findings and recommendations from the pilot study are largely descriptive in nature, and there are a range of limitations associated with the study due to the nature and size of the sample.

Key concepts used in this study

For this study, a number of key concepts underpinned decisions about the data to be collected, and the analysis undertaken. These were:

1. Reviewers determined whether the patient did or did not have sepsis based on their clinical expertise and using the medical records that were available to them at the time of review. The clinical reviewers recruited for the project had substantial knowledge of sepsis identification and management, with experience in emergency or critical care settings, or infectious diseases (noting limitations in their diagnostic judgement due to the need to rely on the information available in the medical record).
2. In order to assess recognition of sepsis, cases needed to be found that were both cases of sepsis that were coded for sepsis and cases of sepsis that were not coded for sepsis. To this end, this study considered both explicit and implicit cases of sepsis, where explicit sepsis describes cases that were coded for sepsis, and implicit sepsis describes cases which might have been cases of sepsis but were not coded as sepsis. In line with previous studies, implicit sepsis included cases that were coded with an infection code as well as a code for organ dysfunction.^{3,4,5}
3. Data were collected about whether or not there was evidence that adult patients met the criteria of the Quick Sequential Organ Failure Assessment (qSOFA), or paediatric patients met the criteria of the paediatric Sequential Organ Failure Assessment (pSOFA). These are both screening tools for sepsis and were selected for this review because they could be applied in multiple health care settings (including pre-hospital settings for adults) as well as in rural and remote communities.^{6,7} The review also collected data on lactate measurements. Subsequently, a modified analysis of lactate + qSOFA was conducted using data regarding whether or not patients met the criteria of qSOFA, whether the patients' lactate measurements were greater than 2mmol/L, as well as, a combination of both parameters (qSOFA + lactate measurement greater than 2mmol/L). Modified criteria were examined for paediatric sepsis in the pre-hospital setting, informed by literature⁸ and advice from ambulance and ICU teams.

Findings

Adult sepsis recognition in Australian hospitals

One of the key aims of this study was to assess the extent to which sepsis is recognised through considering: whether or not the coding reviewer assigned an explicit or implicit sepsis-related diagnosis code to the medical record, whether the medical records indicated the patient met two of the three qSOFA criteria, whether "sepsis" or "septic" appeared in the clinical notes made by the treating team, and finally, whether the clinical reviewer judged the

episode to be sepsis based on all the information available to them. Key insights inferred by the data included:

- For all patients in the sample who were explicitly coded as sepsis, approximately one-quarter of the reviewed episodes were judged not to be sepsis by the clinical reviewer, suggesting that there may be cases that are not sepsis, that are coded as such.
- For all patients in the sample who were explicitly coded as sepsis, approximately one-third were not coded with a sepsis code by the coding reviewer, suggesting a variation in clinical coding practice.
- Records with explicit sepsis codes were more likely to be judged as sepsis by the clinical reviewer compared to those without explicit codes.
- There is a significant discrepancy between cases that met qSOFA criteria and those cases judged as sepsis by the clinical reviewer – a larger discrepancy was observed when assessing for lactate + qSOFA.
- Most cases in the study where the treating clinical team had documented “sepsis” or “septic” were also judged as sepsis by the clinical reviewer.
- Most cases in the study where the treating clinical team had documented “sepsis” or “septic” were also assigned explicit sepsis codes by the coding reviewer.

Adult sepsis management in Australian hospitals

Data about the management of sepsis was only collected where the clinical reviewer believed the patient had sepsis. Data collected on investigations, management and the discharge process of sepsis patients were analysed for these patients. Key insights inferred from the data were:

- There is no clear association between documentation of “sepsis” or “septic” appearing in the medical record and the escalation of care to a senior clinician for majority of cases.
- Patients in the care of, or who had their care escalated to, a senior clinician were more likely to have higher blood lactate levels.
- Most cases (87.1%) had blood cultures taken.
- Most patients (70%) had IV fluids administered, with more than half (53.6%) receiving a second bolus.
- The vast majority of patients (90.7%) who were desaturating (defined as SpO₂ <95% except for patients with Chronic Obstructive Pulmonary Disease (COPD) where it is defined as SpO₂ <88%), received supplemental oxygen.
- Most cases of suspected sepsis (84.9%) received adequate antimicrobial coverage for a provisional diagnosis. However, in the Emergency Department, the majority (74%) of cases with suspected sepsis did not receive antimicrobials within 60 minutes of triage.
- Where there was a documented plan in the medical record to review and / or modify antimicrobials after the blood culture results were reviewed, the majority (95.8%) had evidence that this review occurred.
- Sepsis was mentioned in the discharge summary in just over half of the cases of suspected sepsis, and very few cases had evidence of follow-up for sepsis-related issues in the discharge summary.

Paediatric sepsis recognition and management in Australian hospitals

In this study, a total of nine medical record reviews were for paediatric cases and the clinical reviewer judged all nine patients to not have sepsis. As part of the study protocol, where clinical reviewers judged cases not to be sepsis in their opinion, data collection was limited

to a small amount of information. As such, there was insufficient data to derive insights about the recognition or management of sepsis in Australian hospitals for paediatric patients.

Sepsis recognition and management in an Australian pre-hospital service

In this medical record review, there were data from a total of 100 reviews available from ambulance cases. In the opinion of the clinical reviewer, 35 of the 100 cases were sepsis, 10 were not considered to be sepsis, and over half (55) were unable to be determined. There was no data provided by the pre-hospital setting regarding investigations. As such, more than half of the cases contained insufficient information for the clinical reviewer to determine sepsis status, despite “sepsis” or “septic” appearing in the medical record.

Sepsis guidelines and pathways in Australian hospitals

The study’s original intent was to examine information captured at the organisational level regarding sepsis management protocols at each participating acute care facility and to consider this question through two lenses:

1. Whether or not health services had sepsis guidelines and pathways
2. The influence of a range of factors on the recognition and management of sepsis (such as care setting, state / territory, remoteness, time of day, day of week, time of year, and patient characteristics / risk factors).

The sample size was limited due to the impacts of COVID-19. As a result, there were insufficient data to conduct the analysis planned to examine the influence of various factors on sepsis care. As such, the analysis related to this part of the study is limited to whether or not health services had sepsis guidelines and pathways. Two key insights inferred from the data collected were:

- Most acute care facilities selected for this study had a dedicated sepsis education package for staff, and a dedicated sepsis pathway.
- However, no sites had a policy to guide sepsis management for patients on an end-of-life care pathway.

Recommendations

Based on the findings presented in this pilot study and stakeholder consultation, the following recommendations are proposed as potential actions for future investigation to support improvement in the recognition and management of sepsis across different health settings in Australia:

- Explore causes of variation between coders with respect to the method of coding sepsis and identify strategies to ensure more consistency.
- Identify strategies to improve clinical documentation of sepsis or suspected sepsis in the medical records.
- Identify strategies to improve documentation of sepsis-related issues in the discharge summary.
- Consider further investigation of sepsis recognition and management:
 - For high-risk populations, including Paediatric, Aboriginal and Torres Strait Islander, Pregnant and postpartum
 - In pre-hospital settings.
- Consider developing a medical record audit tool to support clinicians and health service organisations to improve in sepsis recognition and management.

- Consult with the states and territories, associated peak bodies and professional colleges on:
 - Approaches to develop and implement policies to guide sepsis management for patients on an end-of-life care pathway
 - Approaches to improve practice in relation to the documentation of sepsis within discharge summaries
 - Approaches to improving the follow up of patients with sepsis when they are discharged from hospital
 - Approaches to improving the escalation of care to clinicians with experience in managing sepsis
 - Approaches to improve practices in relation to antimicrobial choice and timing of administration
 - Approaches to improve clinical documentation and coding practices related to sepsis.
- If a larger review was to occur, consider the following in its conduct:
 - Consider expanding the data set questions to collect individual components of the qSOFA criterion to allow expansion of analysis to include LqSOFA.
 - Consider expanding the sample size to include early and late onset of neonatal sepsis as they are more vulnerable when diagnosed with sepsis.

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Glossary

Term	Description
Coding reviewer	The coding reviewer who performed the medical record review. This coder could not see the original codes allocated to the medical record.
Clinical reviewer	Clinician who performed the medical record review
Explicit code	ICD-10-AM codes which include codes with a description containing 'sepsis', or 'septic' or 'coronavirus'
HREC	Human Research Ethics Committee
Implicit code	ICD-10-AM codes which include an infection code plus a code for organ dysfunction
Investigation team	The central team that will be responsible for designing data collection tools, training review teams, analysing and reporting data
Lactate + qSOFA	Positive Quick Sequential Organ Failure Assessment with a lactate measurement >2mmol/L
LqSOFA	Lactate-enhanced Quick Sequential Organ Failure Assessment
Medical record	All the clinical documentation associated with a given case including progress notes, clinical observation charts and medication charts
Participant	Individual patient whose de-identified data will be included in the research sample
Principal Investigator	<p>The Principal Investigator is the person responsible for the submission of essential and other study related documents for consideration by the HREC.⁹</p> <p>The Principal Investigator(s)/institution(s) will permit study-related monitoring, audits, HREC review, and regulatory inspection(s). The Principal Investigator will also provide direct access to source data/documents on request, only where such requests are consistent with the privacy and confidentiality principles described in the Ethical Considerations section.</p>
pSOFA	Paediatric Sequential Organ Failure Assessment
qSOFA	Quick Sequential Organ Failure Assessment
Review team	The review team based at a given site that reviewed each participant's medical record to extract the relevant data. Each review team consisted, at a minimum, of a clinical reviewer and a clinical coding reviewer.

Senior clinician	For the purpose of this study, a senior clinician is someone experienced in recognising and managing sepsis
Senior clinician review	For the purpose of this study, a senior clinician review occurs when a patient with suspected sepsis is seen by, or otherwise escalated to, an appropriate clinician with experience in recognising and managing sepsis.
Sepsis	Life-threatening organ dysfunction caused by a dysregulated host response to infection. ⁶ There is a continuum of severity. This does not differentiate patients with and without 'septic shock'.
Suspected sepsis	For the purpose of this study, suspected sepsis included patients who had 'sepsis' or 'septic' documented in their medical record.

Executive Summary

Context and study design

Sepsis is a time-critical medical emergency that arises when the body's response to an infection damages its own tissues and organs leading to failure of multiple organs, and death if not recognised and treated promptly.¹ National inpatient data indicates that sepsis cases are increasing in Australia. In recognition of this, the Commission has been engaged by the Commonwealth Department of Health to lead and coordinate the National Sepsis Program.

The Commission conducted a pilot for a national retrospective medical record review during the period from 20 September 2021 to 7 February 2022 to assess the clinical documentation of patients with sepsis and suspected sepsis across hospital and pre-hospital settings. The pilot examined three questions: 1) To what extent are cases of sepsis recognised (by the hospital coder and clinical treating team)? 2) Are there cases of gold standard sepsis management? and 3) What factors influence deviation from local sepsis guidelines and pathways?

The original intent was to conduct a pilot study to test the study methodology, followed by a larger and more comprehensive review informed by the findings and recommendations from the pilot study. However, the main review was not able to be progressed due to the impact of the COVID-19 Omicron outbreak on staff availability in the participating sites.

Six study sites participated in the pilot study: five hospitals, and one ambulance service, with the selection aiming to ensure representation from different Australian jurisdictions, taking factors such as geographical isolation, demographic profile and service level into account. Medical records were included in the sample if the date of separation was within the last three financial years and they were coded with ICD-10 AM codes for sepsis (explicit codes), or a pre-determined set of infection codes and a code for organ dysfunction (implicit codes).

A sample was generated which included 270 medical records from the hospital sites, and 100 case files from the ambulance service. Clinical and coding reviewers considered any clinical documentation available for the record and submitted data through responding to a series of questions in a secure online data collection tool.

A number of key concepts underpinned decisions about the data to be collected, and the analysis undertaken. First, clinical reviewers of medical records were asked whether, in their judgement, the patient had sepsis. The investigation team have presumed that the clinical reviewer was able to make the most accurate diagnosis as to whether the patient actually had sepsis based on their clinical expertise and using the medical records that were available to them at the time of review. Second, to assess recognition of sepsis, this study considered both cases that were coded for sepsis, and as well as cases which might have been cases of sepsis but were not coded as sepsis. In addition, data were collected about whether or not there was evidence that adult patients met the criteria of the Quick Sequential Organ Failure Assessment (qSOFA), or paediatric patients met the criteria of the paediatric Sequential Organ Failure Assessment (pSOFA). These are both screening tools for sepsis, and were selected for this review because they could be applied in multiple health care settings (including pre-hospital settings for adults) as well as in rural and remote communities.^{6,7} The use of the sepsis screening tools qSOFA and pSOFA was supported in the literature.⁶ The George Institute of Global Health also found LqSOFA to be a pragmatic screening tool for use across multiple care settings.⁶ As the individual criterion of LqSOFA was not collected in this medical record review, this analysis instead examines a modified criterion (lactate + qSOFA) comprised of a lactate measurement greater than 2mmol/L and a positive qSOFA. Modified criteria were examined for paediatric sepsis in the pre-hospital setting, informed by literature¹⁰ and advice from ambulance and ICU teams.

There are a number of limitations and sources of bias associated with this study which are detailed within Section 1.5. The findings outlined below should be viewed in light of these.

Findings

In relation to sepsis recognition in adults in the hospital setting, key insights included:

- Approximately one-quarter of reviewed records were judged not to be sepsis by the clinical reviewer and nearly one-third were not coded with a sepsis code by a coding reviewer. There was a discrepancy between cases that met qSOFA criteria and those cases judged as sepsis by the clinical reviewer
- For the cases judged as sepsis by the clinical reviewer, approximately two thirds did not meet lactate + qSOFA
- Most cases in the study where the treating clinical team had documented “sepsis” or “septic” were also assigned explicit sepsis codes by the coding reviewer

In relation to sepsis management in adults in the hospital setting, key insights include:

- The documentation of “sepsis” or “septic” in the medical record was not associated with the escalation of care to a senior clinician
- Patients already in the care of, or whose care was escalated to, a senior clinician, were more likely to have high blood serum lactate concentrations
- Over two thirds (70%) of the patients already in the care of, or whose care was escalated to, a senior clinician, were also judged to be sepsis by the clinical reviewer
- Most records that were judged as sepsis by a clinical reviewer (87.1%) had blood cultures taken
- Most patients (70%) had IV fluids administered, with more than half (53.6%) receiving a second bolus. Of ED patients, 28% received antimicrobials within 60 min of triage
- The vast majority of patients (90.7%) who were desaturating (defined as SpO₂ <95% (patients with COPD defined as SpO₂ <88%) received supplemental oxygen
- Most cases of suspected sepsis (84.9%) received adequate antimicrobial coverage for a provisional diagnosis
- Where there was a documented plan in the medical record to review and / or modify antimicrobials after the blood culture results were reviewed, the majority (95.8%) had evidence that this review occurred
- Sepsis was not mentioned in the discharge summary for nearly half of the cases of suspected sepsis
- Of the 75 cases where the discharge summary included a diagnosis of sepsis, a third (30.6%) had evidence of follow up care
- Of the medical records where there was evidence of follow-up appointments booked for the patient with healthcare specialists in relation to sepsis, 8% had evidence that this had been done.

There was insufficient data to derive insights in relation to paediatric sepsis recognition and management in the hospital setting. In relation to sepsis recognition and management in the pre-hospital setting, the data showed that in the opinion of the clinical reviewer, 35 of the 100 pre-hospital cases were sepsis, 10 were not considered sepsis, and over half were unable to be determined.

Data were also collected on the presence and use of sepsis guidelines and pathways. The data showed that:

- Most acute care facilities selected for this study had a dedicated sepsis education package for staff, and a dedicated sepsis pathway
- No sites had a policy to guide sepsis management for patients on an end-of-life care pathway.

Recommendations

Based on the findings presented in this report and stakeholder consultation, the following recommendations are proposed as potential actions for future investigation to support improvement in recognition and management of sepsis across different health settings in Australia:

- Explore causes of variation between coders with respect to the coding of sepsis and identify strategies to minimise this
- Identify strategies to improve documentation of sepsis and follow up of sepsis-related issues in the discharge summary
- Consider further investigation of sepsis recognition and management for:
 - High risk populations, including Paediatric, Aboriginal and Torres Strait Islander, Pregnant and postpartum
 - In pre-hospital settings.
- Consider developing an audit tool / monitoring tool to support ongoing improvement in sepsis recognition and management, discharge summary documentation, escalation of care to senior clinicians, antimicrobials choices and administration time, as well as, clinical documentation and coding practices
- If a larger review was to occur, consider the following in its conduct:
 - Consider expanding the data set questions to collect individual components of the qSOFA criterion to allow expansion of analysis to include LqSOFA
 - Consider expanding the sample size to include early and late onset of neonatal sepsis as they are more vulnerable when diagnosed with sepsis.
- Consult with the states and territories, associated peak bodies and professional colleges on developing and implementing policies to guide sepsis management for patients on an end-of-life care pathway.

1 Introduction

1.1 Background

Sepsis is a time-critical, medical emergency that arises when the body's response to an infection damages its own tissues and organs leading to failure of multiple organs, and death if not recognised and treated promptly.³ Sepsis can occur in response to bacterial, viral or fungal infections which can be acquired in both the community and healthcare settings.

Inpatient data shows that sepsis cases are increasing in Australia. An estimated 55,000 Australians suffer sepsis annually of which 8,700 die.²

In recognition of this, the Australian Commission on Safety and Quality in Health Care (the Commission) has been engaged by the Australian Government Department of Health (the Department) to lead and coordinate the National Sepsis Program. The program aims to improve outcomes for people with sepsis in Australia by:

- Improving the recognition of sepsis in all settings (primary, subacute, acute)
- Providing clinicians with nationally agreed sepsis clinical guidance materials
- Strengthening the comprehensive care planning process for sepsis survivors.

As part of the program, the Commission undertook a national retrospective medical record review examining clinical records of patients with sepsis and suspected sepsis to assess:

- The relationship between sepsis ICD-10-AM coding practices, and potential under-estimation of sepsis cases in Australia
- Instances of detection, recognition and clinical management of sepsis from the review that could be considered as 'gold-standard'
- The factors that influence, or are most commonly associated with, deviation from local, district or jurisdictional sepsis clinical management guidelines, and the potential reasons for this deviation (including care setting, clinical workforce, geographical location and time).

The use of the sepsis screening tools qSOFA and pSOFA was supported in the literature.⁶ The George Institute of Global Health also found LqSOFA to be a pragmatic screening tool for use across multiple care settings.⁶ As the individual criterion of LqSOFA was not collected in this medical record review, this analysis instead examines a modified criterion (lactate + qSOFA) comprised of a lactate measurement greater than 2mmol/L and a positive qSOFA.

1.2 Purpose of the study

The purpose of this study was to assess the clinical documentation of patients with sepsis and suspected sepsis across hospital and pre-hospital settings to examine three questions:

1. To what extent are cases of sepsis recognised?
2. Are there cases of gold standard sepsis management?
3. What factors influence deviation from local sepsis guidelines and pathways?

1.3 Key concepts utilised in the study

1.3.1 Screening tools

Data were collected about whether or not there was evidence that patients met the criteria of a relevant sepsis screening tool. These included:

- For adult patients, the Quick Sequential Organ Failure Assessment (qSOFA) and lactate + qSOFA
- For paediatric patients
 - In the hospital setting, the paediatric Sequential Organ Failure Assessment (pSOFA)
 - In the pre-hospital setting where the information required for pSOFA is not typically available, some modified criteria, informed by the literature⁸ and advice from ambulance and ICU teams.

These screening tools were selected on the basis that:

- The study needed to choose an approach that was practical, and that used information that would be commonly and consistently available from existing medical records from multiple sites across Australia
- The use of these screening tools was supported in the literature. The George Institute of Global Health also found LqSOFA to be a pragmatic screening tool for use across multiple care settings.⁶ As the individual criterion of LqSOFA was not collected in this medical record review, this analysis instead examines a modified criterion (lactate + qSOFA) comprised of a lactate measurement greater than 2mmol/L and a positive qSOFA.

Further details regarding the use of qSOFA, lactate + qSOFA and pSOFA in this study, and the modified criteria used for paediatric sepsis in the pre-hospital setting, are outlined in Appendix A.

1.3.2 Implicit and explicit sepsis

In order to assess coding of sepsis, cases needed to be found that were both:

1. Cases of sepsis that were coded for sepsis
2. Cases of sepsis that were not coded for sepsis.

In the hospital setting, previous studies have achieved this by finding both 'explicit' cases of sepsis and 'implicit' cases of sepsis.^{10,11,12}

- Explicit sepsis describes cases that were coded for sepsis by coders
- Implicit sepsis describes cases which might have been cases of sepsis but were not coded as sepsis. Typically, implicit sepsis includes cases that were coded with an infection code in addition to a code for organ dysfunction.

The Commission received lists of suggested ICD-10-AM codes through its jurisdictional partners, sepsis experts and other stakeholders with a good understanding of ICD coding regarding the types of infection that are either typically associated with sepsis or that have a high risk of leading to sepsis. The full list of explicit and implicit sepsis codes used for the study is provided in the "ICD-10-AM" section of the Supplementary material. The aggregated list was used for the purpose of the pilot review. The full list will be amended for subsequent use including a formal review by the Independent Hospital Pricing Authority, noting the release of ICD-10- AM 12th edition.

Given that the pre-hospital setting does not use ICD-10-AM codes, a similar approach needed to be defined for this study to capture cases in this setting. In consultation with the study’s participating ambulance service, definitions of implicit and explicit sepsis were agreed:

- Explicit sepsis cases were records where there was either a Final Primary Assessment (FPA) or Case Description containing the term “sepsis”
- Implicit sepsis cases were records that had a Highest Transport Code of “1” AND one of the following FPA: Febrile, Chest Infection, Infection or Urinary Tract Infection.

1.3.3 Clinical reviewer judgement

Clinical reviewers of medical records were asked whether, in their judgement, the patient had sepsis. The investigation team have presumed that the clinical reviewer was able to make the most accurate diagnosis as to whether the patient actually had sepsis (noting limitations in their diagnostic judgement due to the need to rely on the information available in the medical record).

1.4 Study design and methodology

This section provides an overview of the study design and methodology.

1.4.1 Study duration

The pilot retrospective review was undertaken during the period from 20 September 2021 to 7 February 2022.

1.4.2 Sample

Study sites

The hospitals and pre-hospital sites were selected and invited to participate in this project by the Commission based on several factors. The selection methodology focused on ensuring that sites from different Australian jurisdictions were part of the sample, and took into consideration factors such as geographical isolation, demographic profile and service level. The sample also included sites whose performance against the National Safety and Quality Health Standards, in particular the requirements outlined in the *Recognising and Responding to Acute Deterioration Standard*, were either met, or met with recommendations.

Six sites were invited to participate in the study. These included five hospitals, and one pre-hospital setting (Table 1). Sites were selected from different peer groups and regional settings in order to cover a wide range of sepsis management scenarios.

Table 1: Sites participating in the study

State	Peer Grouping	n (in-scope sample)
QLD	Large metropolitan hospital	67
TAS	Large regional hospital	39
NSW	Medium regional hospital	29

WA	Small regional hospital	31
QLD	Private metropolitan hospital	44
N/A	Pre-hospital (ambulance)	100

To support participation in the study, and data collection, each site was required to provide the following personnel:

- A project sponsor, clinical lead and data custodian
- Clinical reviewer
- Clinical coding reviewer.

Inclusion criteria

Medical records were included in the sample if they met the following criteria at the participating study sites:

- Records where the date of separation was within the last three financial years (2018/19, 2019/20 and 2020/21)
- Participants with medical records coded with explicit and implicit sepsis codes (see the Supplementary material)
- For the pre-hospital setting, FPA codes with “sepsis” or “infection” as a level one assessment, and records that had a Highest Transport Code of “1” AND an FPA containing one of the following: Febrile, Chest Infection, Infection, or Urinary Tract Infection.

Exclusion criteria

Prior to the generation of the sample for hospital and pre-hospital, the following cases were excluded:

- Chemotherapy-only
- Dialysis-only
- Children under three months of age.

Patients on end-of-life care pathways were also manually excluded from the sample by clinical reviewers. This meant exclusion of:

- Patients on an end-of-life care pathway at the time of diagnosis, or a consultant-led decision was made not to escalate care. For the purpose of this review, the end-of-life pathway means they were not for:
 - Any form of respiratory support or
 - Antibiotics or
 - Vascular access or
 - IV fluids or
 - Inotropes or
 - Pathology.

Sample generation

Using the inclusion and exclusion criteria set out above, the Commission extracted medical records from the five hospital sites from the Admitted Patient Collection (APC) over the in-scope time period. From this, a sample size of 270 patient medical records were generated where the sample size for each site was determined by the proportion of the volume of sepsis-related activity at each site, the capacity of the reviewer’s availability, and capacity at the site.

Table 2 displays the five most common principal codes assigned to the sample of 270 patient records. Of these, not all principal codes were implicit or explicit codes. There were 132 different principal diagnosis codes associated with the sample. The full list of principal codes and their proportion of the sample size is available in the Supplementary material).

Table 2: Top five common conditions with the original principal codes assigned to admitted patient collection data of in-scope reviews and their proportion of the sample size

Primary code assigned	Description	Percentage
A419	Sepsis, unspecified	20.0%
J189	Pneumonia, unspecified	4.8%
A4151	Sepsis due to Escherichia coli [E. Coli]	4.1%
A410	Sepsis due to Staphylococcus aureus	2.6%
O85	Puerperal sepsis	2.2%

From the 270 hospital records, there were only 235 clinical reviews and 237 coding reviews received due to challenges associated with securing experienced staff during the review period. The original intent was to conduct a pilot study to test the study methodology, followed by a larger and more comprehensive review informed by the findings and recommendations from the pilot study. However, the main review was not able to be progressed due to the impact of the COVID-19 Omicron outbreak on staff availability in the participating sites.

Of the 235 clinical reviews conducted, nine were for paediatric patients and the remaining 226 were for adult patients. Of these 226, 16 were on an end-of-life pathway and were excluded. As a result, data from 210 clinical reviews for adult patients in hospital was available for analysis in Section 2 of this report. Coding reviews were available for 207 of these 210 clinical reviews.

Of the 210 medical record reviews, 197 were coded with at least one explicit ICD-10-AM code for sepsis, 21 were coded with at least one implicit code for sepsis, and eight were coded with both an explicit and an implicit code. As shown in Table 3, this meant there were 189 records with explicit sepsis codes but without implicit sepsis codes, and 13 with implicit codes but no explicit codes.

Table 3: Original code in admitted patient collection data of in-scope reviews as either explicit or implicit sepsis

Code type	Number
Explicit sepsis (but no implicit)	189
Implicit sepsis (but no explicit)	13
Explicit and implicit sepsis	8

A summary of the demographic characteristics of the in-scope sample is given in Table 4.

Table 4: Demographic characteristics of the in-scope sample

Characteristic	n	Mean	Standard Deviation
Age group (years)			
18-39	21	-	-
40-59	36	-	-
60-79	96	-	-
80+	57	-	-
Sex			
M	120	n/a	n/a
F	90	n/a	n/a
Not stated	-	n/a	n/a
Indigenous Status			
Aboriginal but Not Torres Strait Islander	23	n/a	n/a
Neither Aboriginal nor Torres Strait Islander	143	n/a	n/a
Not stated	44	n/a	n/a
Average Length of Stay	n/a	8.83 days	9.23 days
Care setting			
Pre-hospital	100*	n/a	n/a
ED	130	n/a	n/a
Acute	80	n/a	n/a

* Demographic information was not available for pre-hospital records

A number of characteristics and risk factors have also been examined across the sample to gather high-level insights on what contributes to sepsis recognition, sepsis management and the impact of sepsis in the adult population.

A summary of the risk factors of the in-scope sample is presented in Table 5.

Table 5: Risk factors of the in-scope sample

Risk factors	Yes	No	Percentage
Aboriginal or Torres Strait Islander	23	143	14%
Allergies to antimicrobials	15	150	9%
Brought in by ambulance	70	95	42%
Burns	0	165	0%
COVID-19	0	165	0%
Fall	5	160	3%
Health care worker concern	3	162	2%
Immunocompromised	46	119	28%
Indwelling medical device, foreign body	25	140	15%
Intravenous drug use	2	163	1%
Neutropaenia or recent chemotherapy	17	148	10%
Pregnancy	2	163	1%
Recent surgery / invasive procedure	21	144	13%
Re-presentation to ED with sepsis	4	161	2%
Re-presentation within 48 hours	8	157	5%
Readmission to hospital within 30 days	29	136	18%
Skin cellulitis, skin graft	4	161	2%
Splenectomy / transplant patients	2	163	1%
Transfer from a residential aged care facility	15	150	9%
Wounds	17	148	10%
Other	35	130	21%

A summary of the inpatient care characteristics of the in-scope sample is given in Table 6.

Table 6: General factors of the in-scope sample

Characteristics	Yes	No	Percentage	Value
Sepsis included in discharge summary	75	84	47%	
Died in hospital	14	143	10%	
If deceased was sepsis on the death certificate	7	7	50%	
Source of infection identified?	123	36	77%	
Number cases that had lactate taken	112	48	70%	
Median lactate scores				2.05

A summary of the Emergency presentation factors of the in-scope sample is given in Table 7.

Table 7: Emergency department factors of the in-scope sample

Characteristics	Yes	No	Value
Number of cases that sepsis or infection was first suspected in ED	130	80	
Arrived via ambulance	53	59	
Triage category			
ATS 1	2		
ATS 2	61		
ATS 3	58		
ATS 4	9		
ATS 5	0		
Referred from			
Home	98		
RACF	12		
Support Accommodation	1		
Transfer from another hospital	13		
Other	6		
Referred by			
Self	82		
GP	14		
Another Hospital	12		
Other	22		
Representation within 48 hours	8	122	
Representation to ED within 30 days for sepsis	31	99	
ED length of stay			Average LoS: 538 minutes

Median LoS: 317 minutes

Discharge destination

Intensive Care Unit (ICU)	16
High Dependency Unit (HDU)	9
Acute medical unit (AMU)	13
Operating theatre	0
Inpatient ward	84
Transferred to another hospital	5
Discharged home	0
Deceased	1
Other	2

A summary of the hospital admission factors of the in-scope sample is given in Table 8.

Table 8: Hospital admissions factors for the in-scope sample

Characteristics	Yes	No
Number of cases that sepsis or infection was first suspected inpatient	80	130
What specialty was the patient admitted under at the time sepsis or infection was suspected?		
Infectious diseases	4	
General medicine	26	
General surgery	12	
Urology	7	
Gastroenterology	1	
Geriatrics	0	
Other	30	
Where was the patient discharged to at the end of this separation?		
Home	31	

Residential Aged Care Facility	4
Rehabilitation Centre	4
Deceased	5
Transferred to another hospital	2
Other	4

Data collected

Data collected by the study included both publicly available data about each site, as well as data from medical records selected in the sample.

Publicly available information about participating sites gathered by the study's investigation team included:

- State or territory
- Remoteness (based on ABS categories)
- Hospital peer group (based on Australian Institute of Health and Welfare (AIHW) classification).

Clinical and coding reviewers then considered all of the clinical documentation associated with that episode of care. This included:

- All inpatient annotations/medical notes
- Case histories
- Discharge summaries
- Fluid balance charts
- Medication charts
- Observation charts
- Pathology (haematology, biochemistry, microbiology) results
- Progress notes
- Pre-hospital patient records.

These data were collected securely via a web-based data collection, analysis and data reporting tool. The data collected was analysed to derive the findings and observations in Section 1.

As outlined in Section 1.4.4 below, this report outlines findings from a data collection that was intended to be a pilot, to be conducted to inform a larger main review. In keeping with this aim, post data collection feedback was gathered from clinical and coding reviewers who participated in the study, in order to understand the utility, appropriateness and effectiveness of the data collection tool and the questions asked. A summary of their feedback is provided in the discussion. If a similar data collection exercise is conducted in the future, this feedback should be considered in its design.

1.4.3 Data collection approach and tool

Clinical and coding reviewers at each site responded to a series of questions about each of the selected medical records from their site within a secure, web-based data collection tool. This meant that each medical record within the sample was reviewed twice: once by a clinical reviewer to collect clinical findings, and once by a coder, for the purposes of assigning a code to the medical record ('blind' to the original code allocated). The data

collected were then analysed by the investigation team to derive the findings and observations outlined in Section 2. Clinical and coding reviewers were provided with a training session as well as written instructions to support their review. Reviewers also had access to the investigation team if they had questions.

The clinical reviewers consisted of a range of disciplines and specialties, including: general surgeons, infectious disease physicians, paediatric nurses, intensive care unit nurses and medical administration registrars.

1.4.4 Impact of COVID-19

The original study design consisted of two phases: a pilot review followed by a main review. The intention was that once the pilot had been conducted, the number of sites and the sample size for the main review would be increased to ensure sufficient statistical power, informed by the findings and insights gathered through the pilot. It was also intended that the study protocol would be updated based on the findings of the pilot.

Unfortunately, the pilot commenced during the Omicron outbreak of COVID-19 in Australia which resulted in several delays and constraints with medical record review completion and data collection across the pilot sites. In turn, the Commission decided to limit data collection to those collected during the pilot in order to minimise the time impost on local reviewers at a time when there was a heavy service demand on hospitals across the country. As such there was only one data collection (the pilot data collection) conducted to form the basis of the analysis in this study.

However, the study protocol as been updated and can be applied to a future study.

1.5 Limitations and sources of bias

There are a number of limitations and sources of bias associated with this study. These include:

- The data for this study were taken from six care settings (five hospital sites and one ambulance service) which may not be representative of the Australian population:
 - The sites which participated were from different regional / remoteness areas but these do not necessarily reflect all regions across the country
 - The sites that participated may not collectively represent all demographics and socioeconomic groups of the broader population
 - Bias may have been introduced into the sample as sites were not sampled such that each site had an equal chance of being selected. This selection bias means that the results may not be representative of the broader population of hospitals or patients.
- The records included in the sample collected may not be representative of the broader population of patients presenting to hospital (for example, only nine paediatrics cases were captured in the hospital sample)
- The sample size for each of the participating sites was constrained by the capacity of the clinical and coding reviewer and, as such, may not be representative of the region and community serviced by the individual hospitals
- As the medical records were reviewed by clinical and coder reviewers across different specialties and with different levels of experience, there may be inter-rater variation in relation to the responses chosen. For example, there is a risk that the questions in the survey tool may have been interpreted differently by each clinical and coding reviewer which may result in inconsistent data being collected
- Given the known unreliability of retrospective reviews, having the records reviewed only once by each of the clinical and coding reviewers may introduce doubt about the findings

- The order in which clinical reviewers answered questions in the survey was not randomised, and there is the possibility that information obtained by asking a given question may influence the answer for a subsequent question, leading to bias in the results
- Reviewers can only assess and collect data based on the documentation they see in the medical records. As such, their ability to capture information that genuinely reflects the nature of care provided was limited to the quality (including, but not limited to, the specificity and timeliness of information) of documentation in the medical record. The clinical reviewer's judgement may also be influenced by the nature medical record documentation, for example but not limited to whether or not the clinical treating team thought the patient had sepsis
- LqSOFA, qSOFA and pSOFA are screening tools and not diagnostic tools. Throughout the study, the investigators have presumed that the clinical reviewer was able to make the most accurate diagnosis as to whether or not the patient had sepsis (noting their diagnostic judgement is limited to the information that was documented in the medical record)
- As the data collection was originally intended to be for a pilot, only a limited number of records were selected. This limited sample size meant that some of the statistical analysis that was originally planned (in particular that related to understanding the factors influencing the recognition and management of sepsis – Review Question 3) was not able to be undertaken. Furthermore, the nature of the design meant that the sample size was not sufficient for inferential statistics, therefore the analysis is mostly descriptive in nature, but should be used to inform the design of future work
- The amount of information collected by the clinical reviewers was limited, as they were instructed to end the survey and not address questions about management or investigations for cases in which they believed the patient did not have sepsis
- There was no assessment of cases with no implicit and/or explicit code assigned i.e. the medical records that were assigned no sepsis code was not reviewed despite the patient possibly having sepsis.

2 Results

The data were collected across hospital and pre-hospital settings for adults and paediatrics. The results are presented in this section and consider three patient cohorts:

- Adult sepsis in hospital
- Paediatric sepsis in hospital
- Sepsis in the pre-hospital setting.

For each of these cohorts, the analysis considers the following, consistent with the study's three lines of enquiry: sepsis recognition (clinical recognition and coding), sepsis management, and factors influencing deviation with sepsis guidelines and pathways.

2.1 Adult sepsis recognition in Australian hospitals

In this study, the investigators have presumed that the clinical reviewer was able to make the most accurate diagnosis as to whether or not the patient had sepsis (noting their diagnostic judgement is limited to the information that was documented in the medical record). Using this as an analytical 'anchor point', other data collected in the survey have been examined against this judgement to consider Study Question 1: 'To what extent are cases of sepsis recognised?' This includes examining the alignment or otherwise of clinical reviewer views on whether or not the patient had sepsis and:

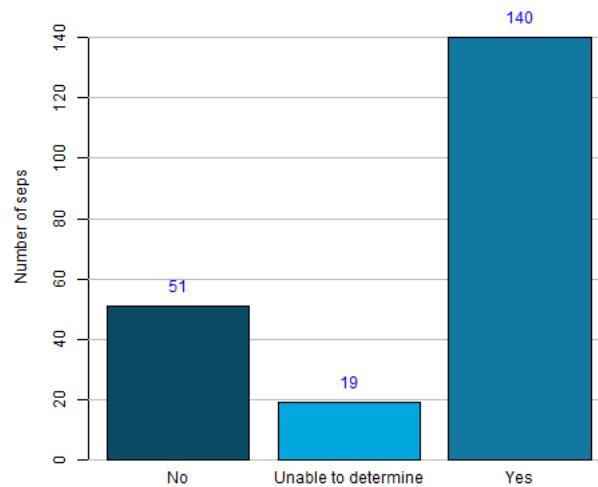
1. Whether or not the original clinical coder at the hospital assigned an explicit or implicit sepsis-related diagnosis code to the medical record. Explicit diagnosis codes for sepsis all include the word "sepsis", "septic" or "coronavirus" in the code description, while implicit codes are those that indicate any type of infection and multiple organ dysfunction (further information on explicit and implicit sepsis is provided in Section 1.3 with specific codes listed in the Supplementary material)
2. Whether or not the patient met the criteria of a relevant sepsis screening tool (qSOFA and, for the purposes of this study, lactate + qSOFA) as described in Section 1.3 and Appendix A, based on the information available in the patient's medical record
3. Whether or not sepsis was identified or suspected by the treating clinical team at the hospital, based on whether the word "sepsis" or "septic" appeared in the clinical notes associated with the hospitalisation for that individual.

To further examine recognition of sepsis by hospital coders, the assessment of the hospital coder has also been compared to the assessment of a second, blind coding reviewer, i.e. with an explicit sepsis code.

Records judged as sepsis by the clinical reviewer

Despite the fact that all 210 medical record reviews had at least an explicit or implicit ICD-10-AM diagnosis code for sepsis, in the judgement of the clinical reviewer, only 140 (66.7%) records were sepsis. Fifty-one (24.3%) were considered not to be sepsis, and 19 (9.0%) were "unable to determine", as shown in Figure 1.

Figure 1: Records in the sample that were / were not determined to be sepsis in the judgement of the clinical reviewer (n=210)



When considering only the 197 records that were coded with an explicit code for sepsis, there were 136 (69%) that were considered sepsis by the clinical reviewer, 44 (22.3%) that were not, and 17 (8.6%) were unable to be determined. On the other hand, for the 13 records that were coded with an implicit code for sepsis (and no explicit code), there were four (30.8%) that were considered sepsis, seven (53.8%) that were not, and two (15.4%) that were unable to be determined (Table 9).

Table 9: Count of records that were determined to be sepsis in the judgement of the clinical reviewer and the original code assigned to the admitted patient collection data (n=210)

Clinical reviewer judgement	All	At least an explicit code	Implicit code only
Sepsis	140	136	4
Not sepsis	51	44	7
Unable to determine	19	17	2
Sum	210	197	13

Records that met at least two of the qSOFA criteria

The qSOFA is a simple screening tool that can be used in any healthcare setting. It identifies patients who may have sepsis. In this study, there were 121 patients who did not meet the qSOFA criteria, and 89 who did, as shown in Table 10.

Table 10: Number of patients who met and did not meet two of three qSOFA criteria (n=210)

Did not meet qSOFA	Met qSOFA
121	89

As discussed above, the study also asked for the clinical reviewer’s clinical judgement on whether they believed the patient had sepsis. The clinical reviewers determined whether the

patient did or did not have sepsis based on their clinical expertise and using the medical records that were available to them at the time of review. Of the 140 adult patients where the clinical reviewer believed the patient had sepsis, 84 (60%) met two of the three qSOFA criteria, while 56 records did not (Table 11). These data would suggest that there is a discrepancy between the number of cases that could have been screened as sepsis using the qSOFA tool and those cases judged as sepsis by the clinical reviewer. Interestingly, there were no records where the patient met the qSOFA criteria and the clinical reviewer did not judge that the patient had sepsis. Further investigation revealed that of the 56 records that did not meet qSOFA, but were judged as sepsis, 17 had high lactate (over 2 mM) and 21 did not (with the remaining 18 not having had lactate measurements available).

Table 11: Counts of patients who met and did not meet qSOFA criteria, and whether the clinical reviewer thought they had sepsis (n=210)

Clinical judgement	Did not meet qSOFA criteria	Met qSOFA criteria
Yes	56	84
No	51	0
Unable to determine	14	5

In a literature review undertaken by the George institute, the rapid lactate measurement and qSOFA (LqSOFA) score has been suggested as an effective screening tool for early identification of sepsis in hospital patients.⁶ As the individual criterion of LqSOFA was not collected in this medical record review, this analysis instead examines a modified criterion (lactate + qSOFA) comprised of a lactate measurement greater than 2mmol/L and a positive qSOFA. A total of 112 of the 210 cases for which blood lactate measurements were available. Of these 112 cases, only 38 (20.5%) met lactate + qSOFA (Table 12).

Table 12: Number of patients who met or did not meet lactate + qSOFA criteria, where lactate measurements were available (n=112)

Clinical judgement	Did not meet lactate + qSOFA criteria	Met lactate + qSOFA criteria
Yes	62	35
No	1	0
Unable to determine	11	3

The cases for which the lactate + qSOFA criteria were met were compared to the clinical reviewer's judgement as to whether they believed the patient had sepsis. Of the 97 cases judged as sepsis by the clinical reviewer and where lactate + qSOFA data were collected, 62 (63.9%) did not meet the lactate + qSOFA criteria. These data would suggest that there is a discrepancy between cases judged as sepsis by the clinical reviewer and cases which did not meet lactate + qSOFA. This discrepancy is greater than that observed for qSOFA, since lactate + qSOFA has a higher threshold (both lactate greater than 2mmol/L and positive qSOFA).

Coding of sepsis

Separate from the clinical review, a second “blind” coding reviewer (who had no access to the original ICD-10-AM codes assigned to that episode, referred to as coding reviewer) assessed the records and determined which ICD-10-AM codes they believed were relevant to the file, according to their expert judgement. Of the 210 in-scope clinical reviews, 207 had coding reviews available. Out of the 207 coding reviews, 151 (72.9%) received explicit sepsis codes only by the coding reviewers while seven (3.4%) received implicit sepsis codes only. Table 13 compares the sepsis codes in the original data with the codes assigned by the coding reviewer, showing that of the 189 records originally coded with an explicit sepsis code, 150 were coded with an explicit code by the coding reviewer, while 38 were not coded as sepsis either explicitly or implicitly. Further, of the 13 records coded with only implicit sepsis codes, seven were coded by the coding reviewer with implicit sepsis codes (one episode also with an explicit code) and six were not coded with sepsis. These results suggest there is variation between codes with respect to coding of sepsis.

Table 13: Comparison of original sepsis codes with codes assigned through the coding review (n=207)

Original code in admitted patient collected data	Explicit sepsis code only	Implicit sepsis code only	Both explicit and implicit codes assigned by coding reviewer	No sepsis codes assigned by coding reviewer
Explicit only	150	0	1	35
Implicit only	0	6	1	6
Explicit and implicit	1	1	5	1

Of the 151 records coded as explicit sepsis only by the coding reviewer, 27 (17.9%) were judged as not having sepsis by the clinical reviewer. Assuming the judgement of the clinical reviewer is a reliable indicator, these results would suggest that there may be cases that are not sepsis, that are coded as sepsis by the coding reviewer (Table 14).

Table 14: Patients who were judged as sepsis by the clinical reviewer, and whether they received sepsis codes by the coding reviewer (n=207)

Clinical review judgement	Explicit sepsis code only	Implicit sepsis code only	Both explicit and implicit codes assigned by coding reviewer	No sepsis codes assigned by coding reviewer
Sepsis	111	2	5	22
Not sepsis	27	3	1	17
Unable to determine	13	2	1	3

Records that were identified by the treating clinical team as sepsis

If the word “sepsis” or “septic” was documented in the clinical notes, it is suggestive that the treating clinical team thought the patient may have had sepsis. Of the 140 adult patients who were judged as having sepsis by the clinical reviewer, 121 (86.4%) were also identified by the treating clinical team as potentially having sepsis (Table 15). These results suggest that the criteria for identification of sepsis is likely similar between the treating clinical team to that used by the clinical reviewer.

Table 15: Clinical reviewer judgement and whether or not “sepsis” or “septic” appeared in clinical notes (n=210)

Clinical reviewer judgement	“sepsis” or “septic” appeared in clinical notes	“sepsis” or “septic” did not appear in clinical notes
Sepsis	121	19
Not sepsis	14	37
Unable to determine	15	4

Furthermore, Table 16 shows that when “sepsis” or “septic” appeared in the clinical notes, the coding reviewer usually assigned explicit sepsis codes. However, there were still 22 records in which sepsis codes were not assigned by the coding reviewer, despite “sepsis” or “septic” appearing in the clinical notes.

Table 16: Whether or not “sepsis” or “septic” appeared in clinical notes by coding reviewer (n=207)

“sepsis or “septic” in clinical notes	Explicit sepsis code only	Implicit sepsis code only	Both explicit and implicit codes assigned by coding reviewer	No sepsis code assigned by coding reviewer
Yes	118	4	6	22
No	33	3	1	20

Key insights – Sepsis recognition

- For all the cases included in the study, approximately one-quarter of reviewed records was judged not to be sepsis by the clinical reviewer
- For all the cases included in the study, nearly one-third were not coded with a sepsis code by a coding reviewer
- Records with explicit sepsis codes were more likely to be judged as sepsis by the clinical reviewer compared to those without explicit codes
- Assuming the judgement of the clinical reviewer is a reliable indicator of sepsis, these results would suggest that there may be cases that are not sepsis, that are coded as sepsis
- There is a significant discrepancy between cases that met qSOFA criteria and those cases judged as sepsis by the clinical reviewer. There was a larger discrepancy observed for lactate + qSOFA
- Most cases that were coded with explicit codes for sepsis in the study sample did not meet the qSOFA criteria for sepsis
- Most cases in the study where the treating clinical team had documented “sepsis” or “septic” were also judged as sepsis by the clinical reviewer.

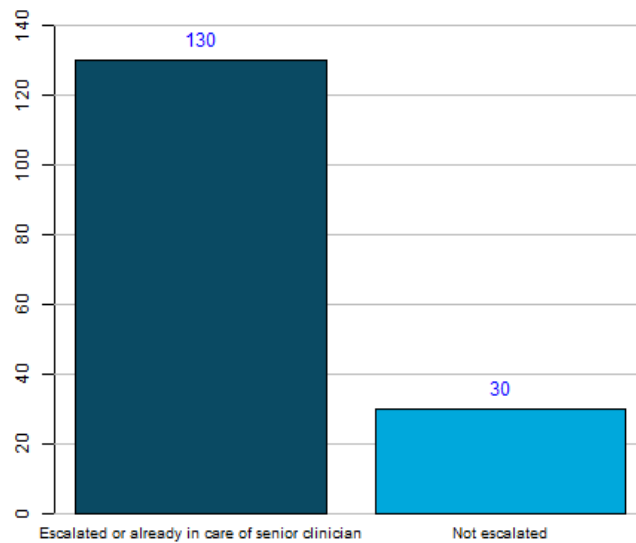
2.2 Adult sepsis management in Australian hospitals

The data used to inform the analysis in this section only includes that from the medical records where the clinical reviewer believed the patient had sepsis. These data were used to explore Review Question 2, ‘Are there cases of gold standard sepsis management?’.

Senior clinician referral

Good practice guidelines suggest that all patients with suspected sepsis are to be seen by, or otherwise escalated to, an appropriate clinician with experience in sepsis.⁶ Data were collected about whether cases were escalated to a senior clinician when the patient first became unwell with suspected sepsis or infection. One hundred thirty (81.25%) of the 160 cases for which data were available showed patients had care escalated or were already in the care of a senior clinician (66 were escalated, and 64 were already in the care of a senior clinician). The remaining 30 (18.7%) patients did not have their care escalated.

Figure 2: Cases that were either escalated or not escalated to a senior clinician (n=160)



Of the 130 cases that were escalated or were already in the care of a senior clinician, 112 (70%) were judged to be sepsis by the clinical reviewer, while of the 30 that were not escalated, 28 were judged as sepsis (with two unable to be determined).

The analysis also examined whether or not there was an association between qSOFA and escalation to a senior clinician. Of the 130 patients who had their care escalated or were already in the care of a senior clinician, 74 (46.2%) met qSOFA criteria, while of the 30 patients who did not have their care escalated, 15 (50%) met qSOFA criteria (Table 17).

Table 17: Number of cases that were escalated (or not) to a senior clinician, and whether or not they met qSOFA criteria (n=130)

Escalation status	Met qSOFA	Did not meet qSOFA
Escalated to / already in care of senior clinician	74	56
Not escalated	15	15

The study also examined whether or not there was an association between there being evidence that the treating clinical team thought the patient had sepsis, and escalation of care to the senior clinician. Of the 130 patients who had their care escalated, 90 (69.2%) patients had evidence of lactate measurements. Of those 90, 49 (54%) had a lactate measurement over 2mmol/L. Additionally, of the 130 patients who had their care escalated, 114 (71.3%) had “sepsis” or “septic” written in the clinical notes, while of the 30 patients who did not have their care escalated, 23 (77%) had “sepsis” or “septic” written in the clinical notes. Assuming the documentation of “sepsis” or “septic” in the medical record is a reliable indicator that the clinical team thought the patient may have sepsis, it would appear that this differential or diagnosis was not associated in the escalation of care to a senior clinician.

Table 18: Number of cases that were escalated (or not) to a senior clinician, and whether (or not) they had “sepsis” or “septic” written in clinical notes (n=160)

Escalation status	Had “sepsis” or “septic” written in clinical notes	Did not have “sepsis” or “septic” written in clinical notes
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Escalated to / already in care of senior clinician	114	16
Not escalated	23	7

The results above show that, where patients are not already in the care of a senior clinician, if “sepsis” or “septic” was written in the clinical notes, most patients’ care was escalated.

2.2.2 Investigations of suspected sepsis

Blood cultures

There were 160 records for which information was available about whether blood cultures were taken. Of the 160 cases, 137 (85.6%) of these had blood cultures taken when they first became unwell with suspected sepsis or infection. The remaining 23 (14.4%) did not have their blood culture taken.

Of the 140 cases that were judged as sepsis by a clinical reviewer, 122 (87.1%) cases had a blood culture taken while 18 (12.9%) cases did not. When the clinical reviewer judged an episode not to be sepsis (51 cases), the clinical reviewer was instructed not to collect further information about blood cultures or other investigations.

Table 19: Number of cases that had blood cultures taken, by clinical reviewer judgement on whether or not the patient had sepsis (n=210)

Blood culture status	Judged as sepsis	Not sepsis	Unable to determine
No blood culture taken	18	0	5
Blood culture taken	122	1*	14
No information on blood culture	0	50	0

*Due to a discrepancy in the data collection process, one case had information about blood cultures collected when the clinical reviewer had judged the patient as not having had sepsis

Of the 89 cases that met qSOFA criteria, 76 (85.4%) cases received a blood culture while 13 (14.6%) cases did not.

Table 20: Number of cases that had blood cultures taken, by whether or not they met qSOFA (n=210)

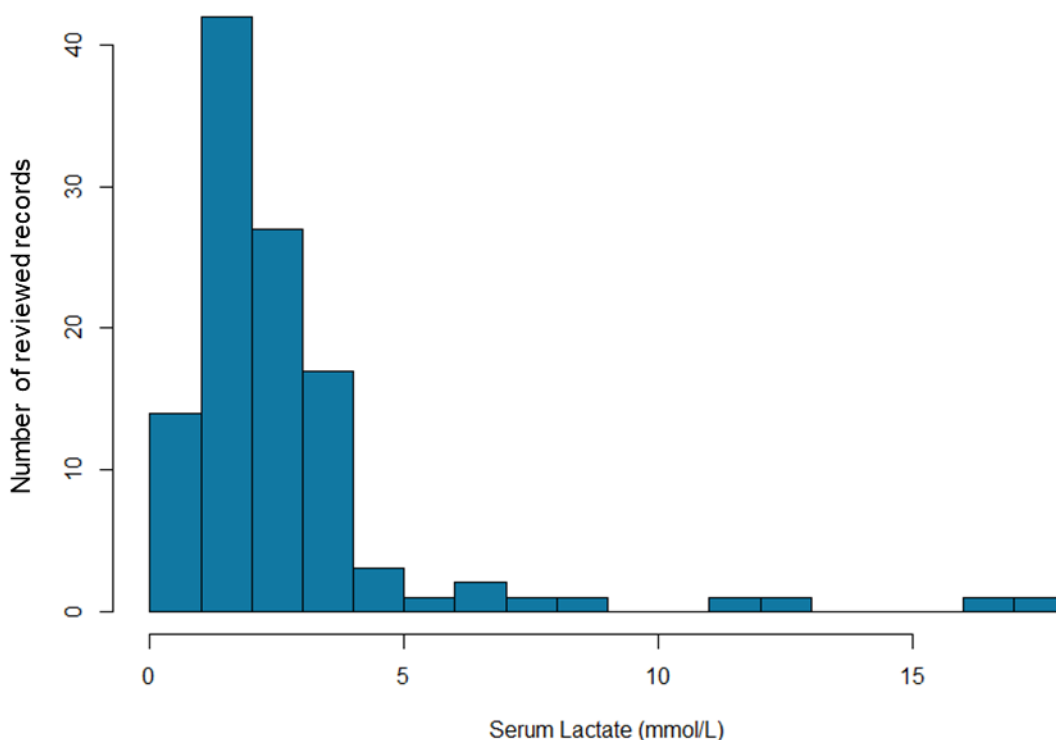
Blood culture status	Met qSOFA	Did not meet qSOFA
No blood culture taken	13	10
Blood culture taken	76	61
No information on blood culture	0	50

Serum lactate

One hundred twelve of 160 (70%) cases had serum lactate measured when they first became unwell with suspected sepsis or infection. There were 61 of these cases (54.5%) for

which the highest serum lactate concentration was over 2 mmol/L. A histogram showing the distribution of maximum lactate concentrations for all 112 cases is shown in Figure 3.

Figure 3: Distribution of maximum blood serum lactate across all patients (n=112)



Interestingly, the average maximum lactate blood serum concentration was highest for those judged as sepsis by the clinical reviewer, and who were already in the care of a senior clinician, as shown in Table 21. Of the 61 patients with lactate measurements greater than 2mmol/L, 49 (80%) patients were escalated. For those cases, the average maximum blood lactate was 3.39 mM, while those who were not escalated had an average blood lactate of 2.17 mM. Patients who were escalated had a slightly higher average lactate concentration at 2.81 mM. The likelihood that patients were in the care of, or escalated to, a senior clinician was higher if the patient’s blood lactate was over 4 mM.

Table 21: Average maximum recorded lactate for cases that were escalated (or not) to a senior clinician, by sepsis judgement of the clinical reviewer

Escalation status	Judged as sepsis	Not sepsis	Unable to determine
Escalated to senior clinician	2.81 mM	2.30 mM	1.94 mM
Not escalated	2.17 mM	No data	1.90 mM
Not applicable as already in senior clinician care	3.39 mM	No data	2.48 mM

2.2.3 Sepsis interventions

Intravenous (IV) fluids and supplemental oxygen

Of 159 records for which information was available about IV fluids, 112 (70%) patients had IV fluids administered when the patient was deteriorating. Of the 112 patients who had the first bolus, another 60 (53.6%) had a second bolus administered.

For patients who were admitted through the ED, there were 71 patients who received IV fluids, with an average time to receive a first bolus of 446 minutes. The median time to receive the first bolus was 72 minutes. A further 41 patients received a second bolus of fluid, and the average time between first and second bolus was 122 minutes. The total volume of fluid administered was, on average, 2.3 L for patients who received one bolus, and 3.3 L for patients who received a second bolus.

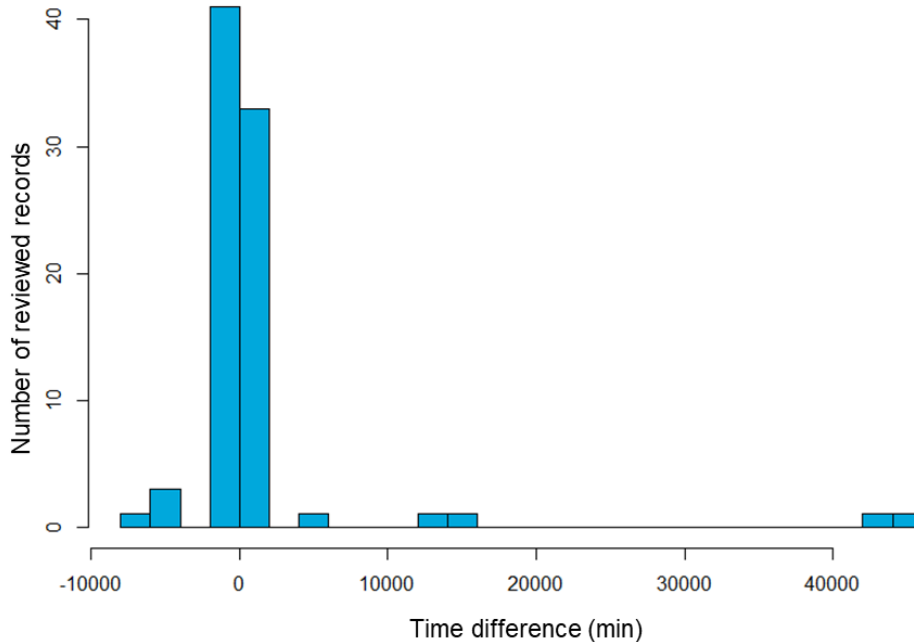
For patients who were suspected to have sepsis, there were 159 cases for which information was available about desaturation. Of the 159 cases, there were 75 (47.2%) desaturating on room air (where desaturating is defined as an SaO₂ <95%, except for patients with chronic obstructive pulmonary disease (COPD) where it is defined as an SaO₂ <88%). Sixty-eight of the 75 (90.7%) patients received supplementary oxygen.

Antimicrobial coverage and timing

For patients who became unwell with suspected sepsis, 147 of the 159 cases for which information was available received antimicrobial agents when they deteriorated. There were 135 of 159 (84.9%) who received adequate antimicrobial coverage for their provisional diagnosis, based on the Australian Therapeutic guidelines. Of these cases, 7.5% were unable to be assessed and another 7.5% did not receive adequate coverage.

The time difference between when the patient received the first dose of antimicrobial agent and when the word “sepsis” or “septic” was first documented in the medical record during this admission was calculated. In the majority of instances, an antimicrobial agent appeared to be administered prior to the first documentation of “sepsis” in the medical record as the time difference was negative (Figure 4). This indicates that, in some cases, the word “sepsis” may have been entered into the clinical notes after antimicrobials were administered.

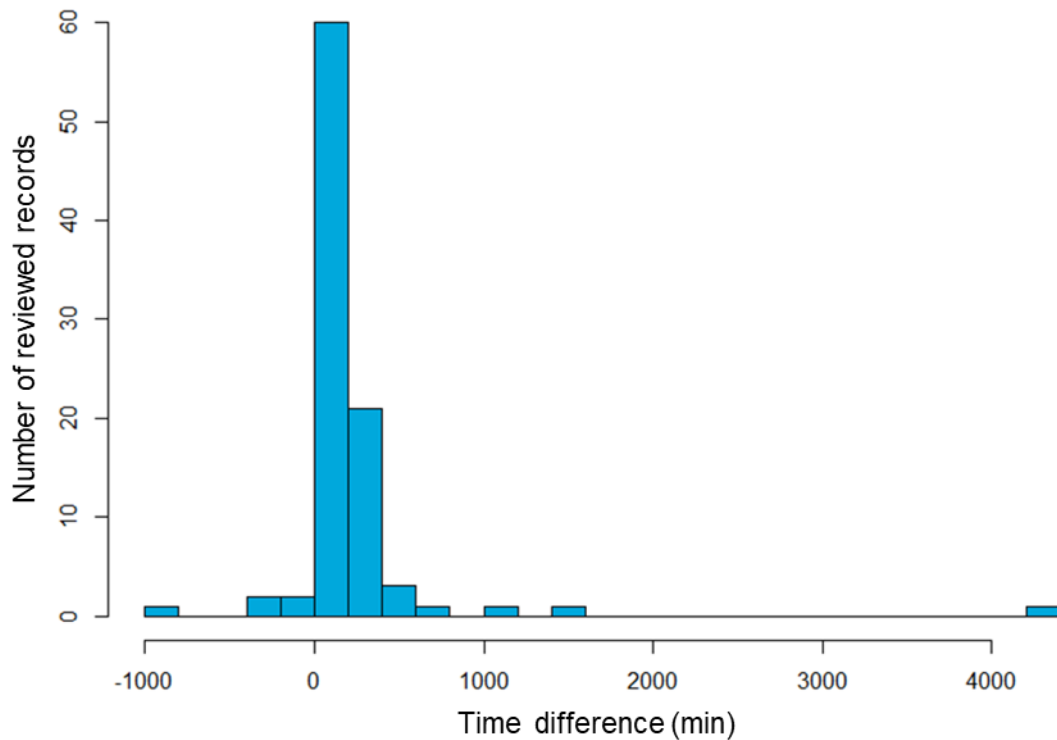
Figure 4: Time difference between when "sepsis" or "septic" first appeared in the medical record and first administration of antimicrobials. A negative value indicated that the patient received antimicrobials prior to the word "sepsis" or "septic" first appearing in the clinical notes (n=84)



It is recommended that, for a patient with suspected sepsis and where signs of infection-related organ dysfunction are present, appropriate antimicrobials are started within 60 minutes.⁷ The time difference between when the patient received the first dose of antimicrobial agent and when the patient was triaged was also measured for cases where the patient deteriorated from sepsis in the ED. Excluding cases where the anti-microbials were administered prior to triage, in a majority of instances, an antimicrobial agent was administered between 0 and 500 minutes after when the patient was triaged, with 28.1% of ED patients receiving antimicrobials within 60 minutes of triage. However, there were some instances when the patient received antimicrobials more than several hours after being triaged (Figure 5).

The average time between triage and administration of antimicrobials was 188 minutes. This was 187 minutes for patients determined to have sepsis by the clinical reviewer, and was 200 minutes for cases in which the clinical reviewer was unable to determine the sepsis status. The median timeframe between triage and administration of antimicrobials was 111 minutes overall. For patients with sepsis the median time between triage and administration of antimicrobials was 91 minutes and 166.5 minutes for patients where sepsis was unable to be determined.

Figure 5: Time difference between triage and first administration of anti-microbials for ED patients (n=92)



For 71 of 102 cases (69.6%) for which information was available, there was a documented plan able to be identified by the clinical reviewer in the medical record to review and / or modify antimicrobials after the blood culture results were reviewed. Of these, 68 (95.8%) had evidence that this review occurred. There was no data collected on the timeframe of antimicrobial review after commencement of initial antimicrobial therapy.

In the medical record review, the provisional diagnosis and their source of infection were also collected. A summary of the provisional diagnosis source of infection for the in-scope sample is presented in Table 22.

Table 22: Provisional diagnosis source of infection (n=123)

Source of infection	Number
Respiratory	32
Urinary tract source	36
Biliary or gastrointestinal	22
Skin source	6
Meningitis	1
Intravascular device	2
Bone or joint	6

Endocarditis	1
Female genital tract	2
Other	15

Discharge

There was a total of 159 records with a discharge summary available, where 140 were judged as sepsis by the clinical reviewer and 19 were unable to be determined. In the majority of cases for which information about the discharge summary was available, there was no mention of sepsis. However, for the 140 cases the clinical reviewer judged to be sepsis, 72 (51.4%) had a mention of sepsis in the discharge summary. When the clinical reviewer was unable to determine sepsis, there was no mention of sepsis in 16 of 19 (84%) of cases in the discharge summary (Table 23). When “sepsis” or “septic” appeared in the clinical notes, the discharge summary included a diagnosis of sepsis for 73 of the 136 records (53.7%) for which data were available (Table 26). Information was also collected about whether there was evidence of follow-up appointments booked for the patient with healthcare specialists in relation to sepsis. For the 75 records for which this information was available, a third (30.6%) had evidence of follow up care.

Table 23: Mention of sepsis (or not) in discharge summary by cases judged as sepsis by the clinical reviewer (n=159)

Judged as sepsis by clinical reviewer	Discharge summary included a diagnosis of sepsis	Discharge summary did not include a diagnosis of sepsis
Sepsis	72	68
Not sepsis	No data	No data
Unable to determine	3	16

Table 24: Mention of sepsis (or not) in discharge summary by “sepsis” or “septic” appearing in clinical notes (n=159)

“sepsis” or “septic” appeared in clinical notes	Discharge summary included a diagnosis of sepsis	Discharge summary did not include diagnosis of sepsis
Yes	73	63
No	2	21

Key insights – Sepsis management

- If the documentation of “sepsis” or “septic” in the medical record is a reliable indicator that the clinical team thought the patient may have sepsis, it would appear that this differential or diagnosis was not associated in the escalation of care to a senior clinician.
- Patients with high (>2 mM) serum lactate were more likely (80%) to be in the care of, or have their care escalated to, a senior clinician.
- Most cases that were judged as sepsis by a clinical reviewer (87.1%) had blood cultures taken.
- Most patients (70%) had IV fluids administered, with more than half (53.6%) receiving a second bolus.
- The vast majority of patients (90.7%) who were desaturating received supplemental oxygen.
- Most cases of suspected sepsis (84.9%) received adequate antimicrobial coverage for provisional diagnosis, however the majority (74%) of cases with suspected sepsis that presented to ED did not receive antimicrobials within 60 minutes of triage.
- Approximately two thirds of the medical records (69.6%) had a documented plan that the clinical treating team were to review and / or modify antimicrobials after the blood culture results were reviewed. Of these, nearly all (95.8%) had evidence that this review occurred.
- Sepsis was not mentioned in the discharge summary for about half (53%) of the cases of suspected sepsis, and very few records had evidence of follow-up for sepsis-related issues in the discharge summary.

2.3 Paediatric sepsis recognition and management in Australian hospitals

In this medical record review, a total of nine medical record reviews were for paediatric cases. Of these, only three had the word “sepsis” or “septic” written in the medical record, as shown in Table 25.

Table 25: Recording of the word “sepsis” or “septic” in the medical record for paediatric cases (n=9)

Was the word “sepsis” or “septic” documented	Number of cases reviewed
Yes	3
No	6

Table 26 shows that of the three records for paediatric cases, none were considered sepsis by the clinical reviewer, seven were considered not to be sepsis, and two were unable to be determined.

Table 26: Whether the episode was sepsis in the opinion of the clinical reviewer by whether the word "sepsis" or "septic" appeared in the medical record for paediatric cases (n=9)

Judged as sepsis by the clinical reviewer	"sepsis" or "septic" appeared in medical record	"sepsis" or "septic" did not appear in medical record
Sepsis	0	0
Not sepsis	1	6
Unable to determine	2	0

As part of the pilot study protocol, where clinical reviewers judged cases not to be sepsis in their opinion, data collection was limited to a small amount of information. As such, data were not collected about the investigations and management of the nine paediatric cases and is not included in this analysis.

Key insights – Paediatric sepsis

- There were insufficient data in this study to derive insight about the recognition or management of sepsis in Australian hospitals for paediatric patients.

2.4 Recognition and Management of Sepsis in Aboriginal and Torres Strait Islander people

In this medical record review, there were 23 Aboriginal and Torres Strait Islander people captured in the sample. Of the 23, 15 (65.2%) of these had "sepsis" or "septic" appear in their clinical notes. Ten (43.5%) had a discharge summary that included a diagnosis of sepsis.

Table 27: Whether the word "sepsis" or "septic" appeared in the medical record by whether the discharge summary included a diagnosis of sepsis for Aboriginal and Torres Strait Islander patients (n=15)

"sepsis" or "septic" appeared in clinical notes	Discharge summary included a diagnosis of sepsis	Discharge summary did not include diagnosis of sepsis
Yes	10	5
No	0	0

Of the 23 cases, 12 (52.2%) were judged as sepsis, 8 (34.8%) as not sepsis and 3 (13%) were unable to be determined.

Table 28: Number of Aboriginal and Torres Strait Islander patient’s medical records judged by a clinical reviewer as sepsis or not (n=23)

Judged as sepsis by clinical reviewer	Cases
Sepsis	12
Not sepsis	8
Unable to determine	3

Key insights – Aboriginal and Torres Strait Islander sepsis

- There were insufficient data in this study to derive insight about the recognition or management of sepsis in Australian hospitals for Aboriginal and Torres Strait Islander patients.

2.5 Sepsis recognition and management in an Australian pre-hospital service

In this medical record review, there were data from a total of 100 reviews available from ambulance cases. Of these, there were 87 (87%) in which the word “sepsis” or “septic” appeared in the medical record.

Table 28: Whether the episode was sepsis in the opinion of the clinical reviewer by whether or not the word "sepsis" or "septic" appeared in the medical record for ambulance cases (n=100)

Was this sepsis in the opinion of the clinical reviewer	“sepsis” or “septic” appeared in medial record	“sepsis” or “septic” did not appear in medical record
Sepsis	33	2
Not sepsis	4	6
Unable to determine	50	5

In the opinion of the clinical reviewer, 35 of the 100 cases were sepsis, 10 were not considered to be sepsis, and over half (55) were unable to be determined. When the clinical reviewer judged the episode not to be sepsis, it was more likely that “sepsis” or “septic” did not appear in the medical record (six vs. four cases, respectively), in contrast to the cases judged to be sepsis (two vs. 33, respectively), as shown in Table 28. These results suggest that the presence of the word “sepsis” was not indicative of the episode being determined sepsis.

For cases involving paediatric patients in the pre-hospital setting, the clinical reviewer was asked whether during the visit, the patient exhibited at least one of the following signs:

Glasgow Coma Score <15; SpO₂% <95%; Temperature ≥39°C. There were only four cases for this question (two “no”, two “yes”). For cases involving adults in the pre-hospital setting, the clinical reviewer was asked whether during the visit, the patient exhibited at least two of the three following signs: GCS <15; Systolic BP <100mmHg; Respiratory rate ≥22. Information was available for 96 answers for this question, where there were 43 “yes” and 53 “no”.

There was no data provided by the pre-hospital setting regarding investigations as they are not usually performed in the pre-hospital setting.

Key insights – Pre-hospital sepsis

- More than half of the cases contained insufficient information for the clinical reviewer to determine sepsis status, despite “sepsis” or “septic” appearing in the medical record.

2.6 Sepsis guidelines and pathways in Australian hospitals

The data used to inform this section was collected in an organisational survey from the five participating Australian hospital sites. These data were used to examine Review Question 3, “What factors influence deviation from local sepsis guidelines and pathways?”

The study originally intended to examine this question through two lenses:

1. Whether or not health services had sepsis guidelines and pathways
2. The influence of a range of factors on the recognition and management of sepsis (such as care setting, state / territory, remoteness, time of day, day of week, time of year, and patient characteristics / risk factors).

As outlined in Section 1, the sample size was limited due to the impacts of COVID-19. As a result, there was insufficient data to conduct the planned analysis to examine the influence of various factors on sepsis care. As such, this section is limited to the analysis of whether or not health services had sepsis guidelines and pathways.

Information was captured at the organisational level regarding sepsis management protocols for each participating acute care facility.

Three of the five facilities had a dedicated education package regarding sepsis education for clinical staff, however, it was not generally compulsory. Most facilities (four of the five) had a dedicated sepsis pathway for adult patients. None of the facilities had a policy to guide sepsis management for end-of-life patients.

Table 29: Organisational sepsis management protocols and pathways for adult patients' summary

Question	Yes	No
When the patients become unwell / deteriorate, does your site transfer patients to another hospital for access to critical care?	1	4
Is there a dedicated sepsis education package at your facility for clinical staff?	3	2
Is this education package available to nursing and medical staff?	3	2
Is there a local sepsis pathway at the facility / service for adults?	4	1
Does your facility have a policy to guide sepsis management for patients on an end-of-life care pathway?	0	5

Key insights – Sepsis guidelines and pathways

- Most acute care facilities selected for this study had a dedicated sepsis education package for staff, and a dedicated sepsis pathway.
- However, no sites had a policy to guide sepsis management for patients on an end-of-life care pathway.

2.7 Feedback from pilot sites

Data collection for this study was undertaken by both clinical and coding reviewers across the five hospital sites, and a clinical reviewer for the pre-hospital site. After the data collection was completed, the review team invited those involved in data collection to provide feedback through videoconference consultations. During these interviews, clinical and coding reviewers were asked to comment on:

- The effectiveness of the training and resources provided to reviews
- The utility of the survey tool as a means to collect data
- Specific feedback regarding the questions asked, including their clarity, order, completeness and appropriateness of response options, including suggestions as to how questions or the question set could be strengthened / improved
- Perceptions regarding whether or not the questions could be used for future data collections.

Training and support resources

All clinical and coding reviewers reported that the training was useful in orienting them to the study, its requirements, and how they were to undertake the data collection. The specific nature of the training and training document was considered to be key in helping the review process progress smoothly.

Utility of the survey platform

The majority of reviewers reported that the survey tool was easily accessible, and simple to navigate.

Clarity of questions

Most clinical reviewers commented that the questions were worded very specifically and that this helped them look for the exact information required to answer the question.

Question order

All clinical reviewers reported that the question order was logical for the majority of their reviews.

Completeness of questions

All reviewers reported that the questions asked were all relevant to the purpose of the study. Some suggestions were made regarding potential additional questions that could be asked in future data collections, such as:

- As most private hospitals do not routinely complete a discharge summary which is as comprehensive as those completed in the public system (it may be a discharge letter or statement of attendance), one clinical reviewer suggested the survey should consider rephrasing the question as “was there a comprehensive discharge summary or correspondence issued to the patient” before asking “was sepsis written in the discharge summary or correspondence”.
- Clinical reviewers suggested that the survey should include questions to capture information which was gathered prior to a patient’s presentation at their facility in cases where the patient was transferred. This would allow for the survey to capture information about sepsis recognition and management prior to their admission or transfer. For example, there was limited ability to record the information about inter-hospital transfer patients with sepsis as the date(s) and time(s) of their assessments and recognition of sepsis were outside the duration of their admission at the local site where the reviewers were based. As a result, due to the wording of the questions and from the data recorded, the results could suggest that the patient may have been under-recognised for sepsis or under-treated for sepsis.
- The pre-hospital clinical reviewer suggested that, in cases where a call is transferred from non-emergency to emergency, both case files should be considered as part of the review. Only reviewing one file risks not capturing the full set of information available about the status, assessments and care of the patient.
- Two coding reviewers thought it was beneficial to ask “has the hospital coder raised a query on sepsis” to assess whether or not queries were raised to the treating team for a particular file by the hospital coder.
- One coding reviewer suggested there would be a benefit to having a free text option at the end of the review so they can provide supplementary comments regarding the code selections made on the medical record.

- Most coding reviewers suggested splitting the coding review question into principal diagnosis and additional diagnosis. It was suggested that this would facilitate the coding reviewer to capture all relevant codes associated with the medical record.

Response options

All reviewers reported that the response options for the questions in the survey were appropriate. Some suggestions were made about additional response options:

- Several clinical reviewers reported that there were patients who met two of the three qSOFA criteria due to a combination of medical conditions that, in their opinion, did not include sepsis. There was no ability to reflect this in the data collection and it was highlighted that, in turn, there were some patients who would be classified as meeting qSOFA criteria when the clinical reviewer did not believe they had sepsis.
- All reviewers suggested there would be benefit in having free text options to provide supplementary explanation of their selection choice to the existing closed response options.
- Some reviewers highlighted that there were instances in the medical record where “sepsis” was documented as a differential or provisional diagnosis but ended up not being documented as the final diagnosis. However, for the purpose of the review and way the question was worded, the reviewer still selected “yes” in the response to the question “was ‘sepsis’ or ‘septic’ documented in the medical record”. It was recommended that a response option that allowed for the clinical reviewer to capture this information should be included to ensure this data point was interpreted correctly.
- The pre-hospital clinical reviewer suggested that there should be a response option to capture instances where the suggestion of “sepsis” or “septic” was made by a doctor on scene or a general practitioner.

Access to information to inform medical record reviews

- The majority of reviewers reported that they were able to easily identify the necessary information to respond to the questions in the medical record review.
- Reviewers reported there was a high degree of variation in the quality of documentation available in individual medical records. The quality of documentation, in turn, impacted the reviewer’s ability to select the most suitable or accurate response(s). For example, all coding reviewers highlighted that they are not clinicians and, as such, rely on certain words or phrases to be documented in order to determine whether or not the patient has sepsis, for example, but not limited to terms such as “blood stream infection”, “sepsis” and “bacteraemia”.
- Some clinical and coding reviewers reported that having to navigate multiple information sources and systems to find the necessary information to respond to the survey questions (which at one site included a paper-based record). This was reported to be associated with a less efficient medical record review than sites where information was available in an integrated or single platform.

Usefulness of the questions for future data collections

All reviewers agreed that the questions asked in the study were all valuable questions and should be considered in future sepsis data collections.

Other feedback shared

In addition to the feedback outlined above, additional feedback was provided by coding reviewers.

- Some coding reviewers reported significant variation in the experience of coders and how familiar one coder might be with the documentation style of one facility. It was suggested that this experience could affect the reliability of coding practices.
- Some coding reviewers stated that coding approaches change regularly to ensure they are fit for purpose and remain clinically relevant. As some medical records reviewed were from 2018, the codes assigned by the hospital coding reviewer and coding reviewer may differ. Further, it was suggested that some coding reviewers have not changed their coding approach and may still follow the old protocol which may result in inaccurate coding of the medical record.

3 Discussion

The Commission conducted a national retrospective medical record review to assess the clinical documentation of patients with sepsis and suspected sepsis across hospital and pre-hospital settings to examine three questions: 1) To what extent are cases of sepsis recognised (by the hospital coder and clinical treating team)? 2) Are there cases of gold standard sepsis management? and 3) What factors influence deviation from local sepsis guidelines and pathways?

The original intent was to conduct a pilot study to test the study methodology, followed by a larger and more comprehensive review informed by the findings and recommendations from the pilot study. However, the main review was not able to be progressed due to the impact of the COVID-19 Omicron outbreak on staff availability in the participating sites.

3.1 Adult sepsis recognition in hospital

Despite selecting a sample of patients who were allocated sepsis-related codes (either explicit or implicit codes for sepsis), the results revealed that approximately one-quarter of reviewed records were judged not to be sepsis by the clinical reviewer. These results suggest there may be a discrepancy between cases judged as sepsis by the clinical reviewer and the coding of sepsis in data collections. However, further investigation is required to understand the processes that result in this outcome. For example, a non-sepsis patient may initially present to the ED as having suspected sepsis, and given a provisional diagnosis for sepsis out of an abundance of caution, this ED provisional diagnosis guides care until a clinical decision is made that the patient does not have sepsis when further clinical information is available. Given the serious outcome of missing sepsis is significant, this risk management approach is important. The ED provisional diagnosis is not made for the purposes of coding, yet this would be recorded in the clinical notes. It is conceivable that the hospital coder included the diagnosis code for sepsis based on these notes.

In this study, the clinical reviewer's judgement of sepsis was considered the analytical anchor point and can be compared and contrasted with other assessments. The results suggest there was a significant discrepancy between cases judged as sepsis by the clinical reviewer and cases where the patient met two of the three criteria of qSOFA. A similar discrepancy was evident when comparing cases judged as sepsis by the clinical reviewer and where patients met the criteria of lactate + qSOFA.

If the word "sepsis" or "septic" was documented in the clinical notes, it is suggestive that the treating clinical team thought the patient may have had sepsis. Most cases where the treating clinical team thought the patient had sepsis were also judged as sepsis by the clinical reviewer.

The results from this study also revealed that nearly one-third of records originally coded as explicit sepsis in the sample taken from the admitted patient collections were not coded with a sepsis code by a coding reviewer. These results suggest there appears to be variation between coders with respect to coding of sepsis.

3.2 Adult sepsis management in hospital

Sepsis is a deadly and costly condition, and early identification and rapid intervention is critical for reducing the risk of death or complications from sepsis and improving patient outcomes. The results of this study revealed that most sepsis cases are escalated to senior clinicians, however, up to 30% of cases of suspected sepsis were not escalated. If the documentation of "sepsis" or "septic" in the medical record is a reliable indicator that the clinical team thought the patient may have sepsis, it would appear that this differential or

diagnosis was not associated in the escalation of care to a senior clinician. Further investigation is required to uncover the factors that result in a patient not having care escalated, and understand the consequence in terms of patient outcomes.

Investigations are critical in reliably determining the status of suspected sepsis cases. In this study, it was found that most records that were judged as sepsis by a clinical reviewer (87.1%) had blood cultures taken, and that patients with high (>2 mM) maximum serum lactate were more likely to be in the care of, or have their care escalated to, a senior clinician. This would suggest that escalation of care to the senior clinician is more likely to occur when the diagnosis of sepsis is clearer to the clinical treating team.

Effective and timely interventions are also critical for reducing the risk of mortality from sepsis, as patients can deteriorate quickly. The vast majority of patients (90.7%) who were desaturating received supplemental oxygen. Most cases of suspected sepsis in this study (84.9%) received adequate microbial coverage for provisional diagnosis, and most patients (70%) had IV fluids administered, with more than half (53.6%) receiving a second bolus. However, the majority (74%) of cases with suspected sepsis that presented to ED did not receive antimicrobials within the recommended 60 minutes of triage. Where there was a documented plan in the medical record to review and / or modify antimicrobials after the blood culture results were reviewed, the majority had evidence that this review occurred. For patients who were admitted through the ED, the average time from triage and first bolus of IV fluid was 446 minutes. This timeframe surpasses the recommendation that IV fluid is to be commenced within the hour and completed within the first three hours following presentation of sepsis.¹²

When the clinical reviewer was unable to determine sepsis, there was no mention of sepsis in most of the discharge summaries. Patient follow-up is also a critical part of reducing the risk of adverse outcomes for patients who had a suspected septic episode.

3.3 Sepsis recognition and management in paediatrics in hospitals and patients in pre-hospital setting

There was insufficient data in this study to derive insight about the recognition or management of sepsis in paediatric patients, or in pre-hospital (ambulance) settings. However, it is just as critical that sepsis be recognised early in these cases, and these warrant further investigation.

4 Conclusion

Sepsis is a time-critical medical emergency that arises when the body's response to an infection damages its own tissues and organs leading to failure of multiple organs, and death if not recognised and treated promptly.

The purpose of this study was to assess the clinical documentation of patients with sepsis and suspected sepsis across hospital and pre-hospital settings to examine sepsis recognition, management and the current local sepsis guidelines and pathways. The original intention was to conduct a pilot study to test the methodology, and use the findings to inform a larger, more comprehensive review. The larger review however was not able to be progressed due to the impact of the COVID-19 Omicron outbreak on staff availability in the participating sites. This report provides the findings and lessons learned from the pilot study which have been used to update the study protocol for future research.

The pilot study demonstrated that using implicit and explicit codes to determine the sample size was successful in enabling medical record data collection on the recognition and management of sepsis across different health settings in Australia. The data collected also provides initial insights as to the nature of sepsis care in these settings. These insights, as well as the lessons learned from the conduct of the pilot have informed a number of recommendations which should be considered in future practices of sepsis recognition and management, as well as, future reviews of medical records.

Recommendations

Based on the findings presented in this report and stakeholder consultation, the following recommendations are proposed as potential actions to support improvement in the recognition and management of sepsis across different health settings in Australia:

- Explore causes of variation between coders with respect to the method of coding sepsis and identify strategies to ensure more consistency.
- Identify strategies to improve clinical documentation of sepsis or suspected sepsis in the medical records.
- Identify strategies to improve documentation of sepsis-related issues in the discharge summary.
- Consider further investigation of sepsis recognition and management:
 - For high-risk populations, including Paediatric, Aboriginal and Torres Strait Islander, Pregnant and postpartum
 - In pre-hospital settings.
- Consider developing a medical record audit tool to support clinicians and health service organisations to improve in sepsis recognition and management.
- Consult with the states and territories, associated peak bodies and professional colleges on:
 - Approaches to develop and implement policies to guide sepsis management for patients on an end-of-life care pathway
 - Approaches to improve practice in relation to the documentation of sepsis within discharge summaries
 - Approaches to improving the follow up of patients with sepsis when they are discharged from hospital
 - Approaches to improving the escalation of care to clinicians with experience in managing sepsis

- Approaches to improve practices in relation to antimicrobial choice and timing of administration
- Approaches to improve clinical documentation and coding practices related to sepsis.
- If a larger review was to occur, consider the following in its conduct:
 - Consider expanding the data set questions to collect individual components of the qSOFA criterion to allow expansion of analysis to include LqSOFA.Consider expanding the sample size to include early and late onset of neonatal sepsis as they are more vulnerable when diagnosed with sepsis.

Appendix A – Rationale of qSOFA, lactate + qSOFA, pSOFA and modified pre-hospital criterion

qSOFA (Quick Sequential Organ Failure Assessment)

Data were collected about whether or not there was evidence that patients met the criteria of a number of sepsis screening tools. The Quick Sequential Organ Failure Assessment (qSOFA), was selected for this review because it is more easily administered across a range of clinical settings (e.g. Emergency, Inpatient setting etc.) than other sepsis screening tools / trigger tools.

What is qSOFA?

Singer et al¹³ note that:

“Sepsis should be defined as life-threatening organ dysfunction caused by a dysregulated host response to infection”.

They argue that this organ dysfunction:

“can be represented by an increase in the Sequential [Sepsis-related] Organ Failure Assessment (SOFA) score of 2 points or more, which is associated with an in-hospital mortality greater than 10%.”

However, assessment of the full SOFA score requires a combination of clinical and laboratory measures that are not necessarily routinely collected when managing patients with sepsis, particularly outside an ICU setting.

Singer et al¹³ also developed a qSOFA score which they argue provides a simple bedside criteria to identify adult patients “with suspected infection who are likely to have a prolonged ICU stay or to die in the hospital”.

Among adult patients with suspected infection, to meet the qSOFA criteria requires two or more of the following:

qSOFA variable	qSOFA criteria	Score
Systolic blood pressure	≤ 100mmHg	1
Altered mental status	Glasgow Coma Scale <15	1
Respiratory rate	≥ 22	1

This is because “organ dysfunction can be identified as an acute change in total SOFA score ≥2 points consequent to the infection.”¹³

Rationale for using qSOFA

Singer et al⁵ found that, when compared to the full SOFA, the qSOFA offered similar predictive validity for screening patients likely to have sepsis outside an ICU environment. Among patients in ICU, they acknowledged that while the qSOFA was less robust than the full SOFA:

“it [the qSOFA] does not require laboratory tests and can be assessed quickly and repeatedly.”

Given that the criteria used to assess qSOFA are more likely to be collected across patients managed in multiple clinical and geographical settings nationally, this review collected data about whether or not patients met the criteria of the qSOFA sepsis screening tool.

Rationale for using lactate + qSOFA

The rapid lactate measurement and qSOFA (LqSOFA) score is considered a superior measure in early identification of sepsis in hospital patients with the literature review performed by the George Institute.⁶ Given that the criteria of the qSOFA score is commonly collected, and the ability to add blood lactate to increase sensitivity to match that of other scores, the LqSOFA score is recommended for use across the healthcare system.⁹ LqSOFA is also a pragmatic screening tool that could be used in any clinical setting, including rural and remote sites.

As the individual criterion of LqSOFA was not collected in this medical record review, this analysis instead examines a modified criterion (lactate + qSOFA) comprised of a lactate measurement greater than 2mmol/L and a positive qSOFA.

Rationale for using pSOFA in paediatric patients

Neither the qSOFA nor the SOFA were developed specifically for paediatric patients. Singer et al⁷ noted that:

“The task force focused on adult patients yet recognises the need to develop similar updated definitions for paediatric populations and the use of clinical criteria that take into account their age dependent variation in normal physiologic ranges and in pathophysiologic responses”.

Romaine et al¹⁴ noted that:

“The presence of ≥ 2 of the 3 qSOFA components, altered mentation, raised respiratory rate (RR), and low systolic blood pressure (BP), was associated with an increased risk of mortality, but the derivation and validation of Sepsis-3 and the qSOFA did not involve paediatric data”.

Recognising that qSOFA criteria were not developed for paediatric patients, Schlapbach et al¹⁵ developed age-specific criteria for paediatric patients. In alignment with the criteria in Singer et al, Schlapbach et al composed the criteria around the same three clinical parameters: tachypnoea, altered mentation and hypotension). In order to establish age-specific qSOFA scores, tachypnoea and hypotension were defined:

“by applying age-specific cut-offs for respiratory rate, and systolic blood pressure, respectively, as per the 2005 Paediatric Sepsis definitions”.

The authors concluded that:

“In our study, the performance of our adapted qSOFA score to identify children who subsequently died or had prolonged length of stay was only moderate,”

and,

“the performance of qSOFA to identify patients with organ dysfunction at risk for worse outcomes was poor, and may not be of sufficient clinical value to be recommended as a screening tool for paediatric age groups within the ICU”.

Romaine et al¹⁴, seeking to explain the pathophysiological mechanism for this difference between paediatric and adult patients, argued that:

“In contrast to adults, hypotension represents a late sign of paediatric septic shock.”

What is pSOFA?

Matics & Sanchez-Pinto¹⁶ developed a paediatric version of the SOFA score (pSOFA). They found they were able to evaluate the Sepsis-3 definitions in paediatric intensive care unit patients using this pSOFA score.

Matics & Sanchez-Pinto modified the SOFA for paediatric patients through two approaches:

“First, the age-dependent cardiovascular and renal variables of the original SOFA score were modified using validated cutoffs from the PELOD-2 scoring system. Second, the respiratory subscore was expanded to include the SpO₂:FiO₂ ratio as an alternative surrogate of lung injury”.

This review collected data to determine Matics & Sanchez-Pinto’s modified pSOFA score. This pSOFA score includes Glasgow Coma Scale based on using a paediatric scale. Based on the advice of experts consulted in developing this protocol, the review will collect AVPU (Alert, Verbal, Pain, Unresponsive) data, then map these to GCS. Matics & Sanchez-Pinto’s¹⁶ modified pSOFA score with the AVPU alterations are included in the table below.

For the purpose of this review, we considered that paediatric patients meet pSOFA criteria if:

- They are a patient in ED and have a pSOFA score of ≥ 2 - driven by one or a combination of any of the variables listed in the table below - on the basis that their baseline score is zero
- They are an inpatient and have a change in their pSOFA score of ≥ 2 , driven by a change in one or a combination of any of the variables listed in the table below, over a 24 hour period.

Modified pSOFA (Matics & Sanchez-Pinto¹⁶) with GCS tailored to AVPU based on expert advice

Variables	Score*				
	0	1	2	3	4
Respiratory Use PaO ₂ :FiO ₂ OR SpO ₂ :FiO ₂					

Modified pSOFA (Matics & Sanchez-Pinto¹⁶) with GCS tailored to AVPU based on expert advice

PaO₂:FiO₂[†]	≥400	300-399	200-299	100-199 with respiratory support (anything over high flow nasal cannulae oxygen (HFNCO ₂) greater than 2L/kg/min)	<100 with respiratory support (anything over high flow nasal cannulae oxygen (HFNCO ₂) greater than 2L/kg/min)
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S_pO₂:FiO₂[§]	≥292	264-291	221-264	148-220 with respiratory support (anything over high flow nasal cannulae oxygen (HFNCO ₂) greater than 2L/kg/min)	<148 with respiratory support (anything over high flow nasal cannulae oxygen (HFNCO ₂) greater than 2L/kg/min)
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Coagulation

Platelet count, x10³ / μL	≥150	100-149	50-99	20-49	<20
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Hepatic

Bilirubin, mg/dL	<1.2	1.2-1.9	2.0-5.9	6.0-11.9	>12.0
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Cardiovascular

Mean arterial pressure by age group or vasoactive infusion mmHg or μg / kg/ min[#]

<1 month	≥46	<46	Dopamine hydrochloride ≤5 or dopamine hydrochloride (any)	Dopamine hydrochloride >5 or epinephrine ≤0.1 or norepinephrine bitartate ≤0.1	Dopamine hydrochloride >15 or epinephrine >0.1 or norepinephrine bitartate >0.1
1 – 11 months	≥55	<55			
12 – 23 months	≥60	<60			
24 – 59 months	≥62	<62			
60 – 143 months	≥65	<65			
144 – 216 months	≥67	<67			
>216 months	≥70	<70			

Neurological

AVPU	Alert (15)	Verbal (10-14)	Pain (6-9)	Unresponsive (<6)
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Modified pSOFA (Matics & Sanchez-Pinto¹⁶) with GCS tailored to AVPU based on expert advice

(Glasgow Coma Scale)

Renal

Creatinine by age group, umol/L (mg/dL)

<1 month	<70.7 (<0.8)	70.7-79.6 (0.8-0.9)	88.4-97.3 (1.0-1.1)	106.1-132.6 (1.2-1.5)	≥141.5 (≥1.6)
1 – 11 months	<26.5 (<0.3)	26.5-35.4 (0.3-0.4)	44.2-61.9 (0.5-0.7)	70.7-97.3 (0.8-1.1)	≥106.1 (≥1.2)
12 – 23 months	<35.4 (<0.4)	35.4-44.2 (0.4-0.5)	53-88.4 (0.6-1.0)	97.3-123.8 (1.1-1.4)	132.6 (≥1.5)
24 – 59 months	<53 (<0.6)	53-70.7 (0.6-0.8)	79.6-132.6 (0.9-1.5)	141.5-194.5 (1.6-2.2)	≥203.4 (≥2.3)
60 – 143 months	<61.9 (<0.7)	61.9-88.4 (0.7-1.0)	97.3-150.3 (1.1-1.7)	159.2-221.1 (1.8-2.5)	≥229.9 (≥2.6)
144 – 216 months	<88.4 (<1.0)	88.4-141.5 (1.0-1.6)	150.3-247.6 (1.7-2.8)	256.4-362.5 (2.9-4.1)	≥371.4 (≥4.2)
>216 months	<106.1 (<1.2)	106.1-168 (1.2-1.9)	176.8-300.6 (2.0-3.4)	309.5-433.3 (3.5-4.9)	≥442.1 (≥5)

Abbreviations: FiO₂, fraction of inspired oxygen; MAP, mean arterial pressure; pSOFA, paediatric Sequential Organ Failure Assessment; SpO₂, peripheral oxygen saturation. SI conversion factors: To convert bilirubin to micromoles per litre, multiply by 17.104; creatinine to micromoles per litre, multiply by 88.4; and platelet count to ×10⁹/L, multiply by 1.

* The pSOFA score was calculated for every 24-hour period. The worst value for every variable in each 24-hour period was used to calculate the sub-score for each of the six organ systems. If a variable was not recorded in a given 24-hour period, it was assumed to be normal and a score of 0 was used. The daily pSOFA score was the sum of the six sub-scores (range, 0-24 points; higher scores indicate a worse outcome).

† PaO₂ was measured in millimetres of mercury.

§ Only SpO₂ measurements of 97% or lower were used in the calculation.

MAP (measured in millimetres of mercury) was used for scores 0 and 1; vasoactive infusion (measured in micrograms per kilogram per minute), for scores 2 to 4. Maximum continuous vasoactive infusion was administered for at least one hour.

** Cut-offs for patients older than 18 years (216 months) were identical to the original SOFA score.

‡ AVPU equivalent to GCS based on expert advice

Source: Matics & Sanchez-Pinto¹⁶

Pre-hospital

In the pre-hospital setting, among patients 18 years of age and over with suspected infection, to meet the qSOFA criteria requires two or more of the following:

qSOFA variable	qSOFA criteria	Score
Systolic blood pressure	≤ 100mmHg	1
Altered mental status	Glasgow Coma Scale < 15	1
Respiratory rate	≥ 22	1

This is because “organ dysfunction can be identified as an acute change in total SOFA score ≥2 points consequent to the infection.”^{Error! Bookmark not defined.}

Due to the setting and available equipment in the pre-hospital setting, if the patient was less than 18 years of age, a score was calculated using the following criteria. The criteria considered three observations which are possible to assess and utilised by the paramedic service – oxygen saturation, mental state (GCS) and temperature. The patient was required to meet one or more of the following:

- GCS Score <15¹⁶
- SPO₂% <95%^{1,17}
- Temperature ≥39°C.^{1,18}

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