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CLINICAL FOCUS REPORT

FROM REVIEW OF ROOT CAUSE ANALYSIS AND/OR
INCIDENT INFORMATION MANAGEMENT SYSTEM (IIMS) DATA

Recognition and Management of Sepsis

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This report was prepared by the Clinical Excellence Commission Patient Safety Team and endorsed by the State Root Cause Analysis (RCA) Review Committee, in consultation with the Greater Metropolitan Clinical Taskforce (GMCT), NSW Intensive Care Coordination and Monitoring Unit (ICCMU), NSW Emergency Care Taskforce, Area Health Services (via Directors of Clinical Governance), NSW Ambulance Service and the coordinators of ARISE (The Australian Resuscitation in Sepsis Evaluation Study).

The information contained has been de-identified and analysed in accordance with the Incident Information Management System (IIMS) datasets and where relevant, the classification sets used by the CEC and the RCA Review Sub-committees.

It should be noted that all reviews of incident data, including root cause analysis are retrospective and can reflect both hindsight and outcome bias. Such reviews are conducted to better understand the impact which patient, system and human factors may have on the provision of clinical care and to facilitate ongoing improvement across the health system.

This report is intended to provide a snapshot of issues identified and to make recommendation about system improvements to improve the safety and quality of clinical care.

Clinical Excellence Commission

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Further information about the Severe Infection and Sepsis Project which was initiated following the original distribution of the report can be found at: Sepsis Kills Program <http://www.cec.health.nsw.gov.au/programs/sepsis>



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Background

Sepsis and septic shock are life-threatening conditions which may be difficult to diagnose. This poses challenges for clinicians because the early recognition and management of sepsis is crucial in terms of morbidity and mortality. Although published Australian epidemiologic studies of sepsis are scant, a Victorian study (Sundararajan et al 2005) conducted over a four year period July 1999 - June 2003 suggests that the overall incidence of sepsis was 1.1 per cent of hospital overnight admissions. This study identifies a mortality rate of 18.4 per cent. Twenty-three point eight per cent of the patients with sepsis received care in an intensive care unit (ICU).

Recent literature suggests that 11.8 per hundred admissions to ICU were associated with severe sepsis, with an in-hospital mortality rate of 37.5 per cent increasing to 60 per cent mortality in patients with septic shock. (ARISE 2007).

Sepsis has been identified by the NSW RCA Review Committee as an emerging theme, with many of the SAC1¹ Root Cause Analysis (RCA) reports reflecting a failure to recognise sepsis early or treat adequately. The committee agreed that the issue warranted a more detailed review of RCAs and exploration of IIMS data to identify the extent of the problem. The following example demonstrates the type of incident identified.

¹ The Severity Assessment Code (SAC) is used to rank the outcome for the patient when an incident occurs. SAC1 indicates a serious outcome, such as a procedure involving the wrong patient or an unexpected death. SAC4 indicates there was minimal or no harm and includes near-miss incidents.

CASE 1

An elderly patient was admitted to the ED at 1450 hours with hypotension, oliguria, presumed dehydration and urosepsis. Patient was reviewed by ED team, medical registrar and ICU team. No beds were available in ICU. Patient was kept in ED with no efforts made to transfer her or commence active treatment. Patient remained hypotensive and oliguric overnight. She required resuscitation and transfer to ICU.

Method

Data was extracted on 10 July 2009 from IIMS, using the text search “sepsis” and “septic” for the period 1 January 2008 to 10 July 2009. In addition, RCAs where sepsis was identified as a highlighted clinical risk group were extracted from the CEC database and linked to SAC1 incidents identified during the text search. Two SAC1 RCA reports were not available at the time of the data extraction.

A total of 486 incidents and 21 RCAs with the word sepsis or septic were identified. Of these, 319 incidents were excluded for the following reasons:

- Duplicate notifications
- Where the incident notification was about an unrelated matter but the words septic/aseptic were identified in the text - or the patient was admitted with sepsis
- Incident had been de-activated by the area health service.
- There was insufficient information for further analysis.

Detailed analysis of the remaining 167 incidents was then undertaken. They were reviewed initially across all SAC ratings. SAC1 incidents were then analysed in greater detail.

Findings

The following information is based on information contained within the IIMS notification and RCA reports. Limitations must therefore be acknowledged.

The following table provides actual Severity Assessment Code (SAC) attributed to the incidents. These SAC ratings were attributed by the health service involved and do not represent the views of the Clinical Excellence Commission Patient Safety Team.

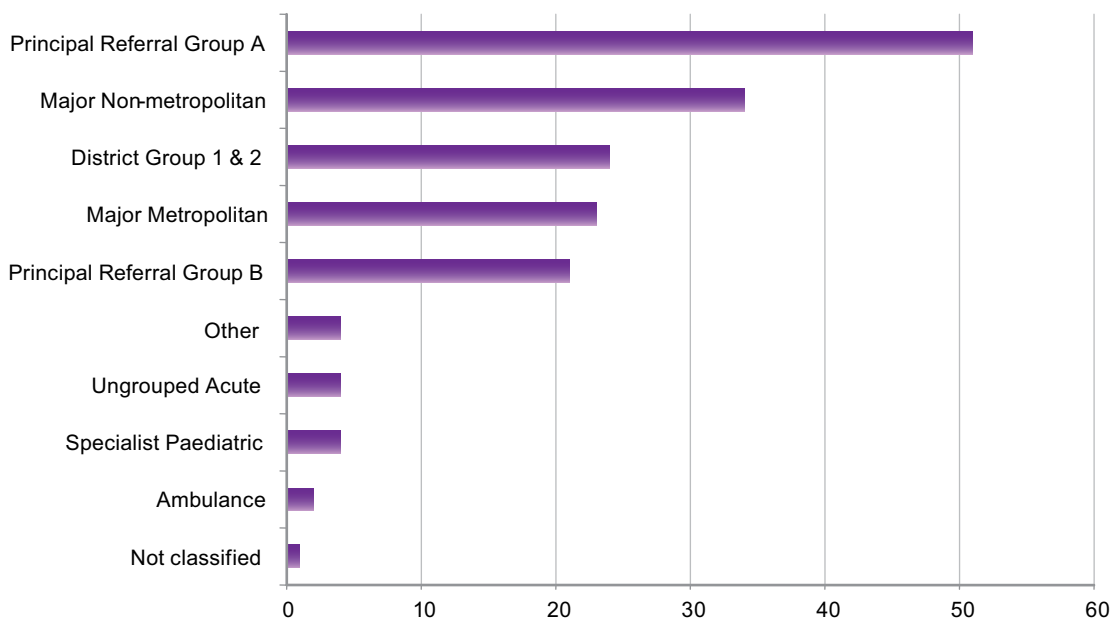
Table 1: Sepsis Incidents by Actual Severity Assessment Code (SAC)

Actual SAC Rating	1	2	3	4	No SAC allocated	TOTAL
Number	23	27	81	27	9	167

Incidents by hospital peer group (like hospitals)

The incidents were then considered by peer group. As indicated below (Figure 1), Principal Referral Group A hospitals had the highest number of reported incidents. This finding may simply be a reflection of higher activity levels or reporting rates, rather than a greater frequency of adverse events/incidents.

Figure 1: Sepsis Incidents by Peer Hospital Group



Note: the “not classified” incident relates to a mental health service and “other” relates to hospitals smaller than District 1 & 2.

Incidents by time band

Most (163) incidents had the time band of the incident recorded. Of these, 28.2 per cent occurred over a weekend or public holiday. Forty-one per cent of all incidents occurred overnight - between the hours of 1700-0800.

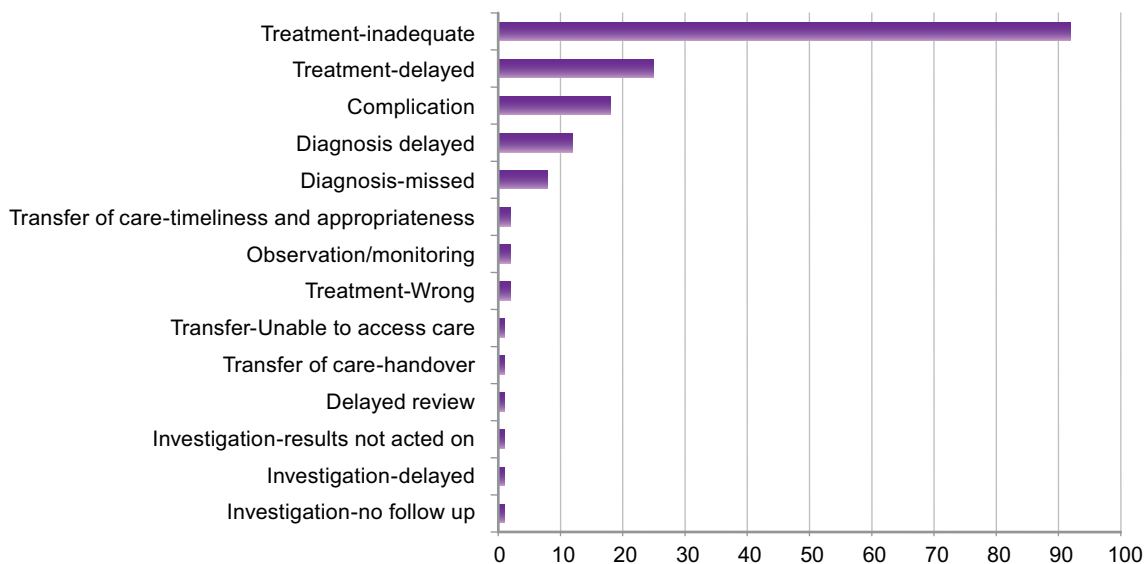
Incidents by age band

Where the patient’s age was indicated, the largest group (45.2 per cent) was aged between 65 and 79. A further 35.6 per cent were between 30 and 64 years and 14 per cent were 80 or older.

Clinical management sub-classifications

Each incident reviewed was assigned a clinical management sub-classification. These are based on the IIMS sub-sets and are used by the RCA Review Committee to confirm the classification of RCAs.

Figure 2: Clinical Management Classifications all Incidents



As indicated above, the inadequacy of treatment was the most common feature identified. While it is not possible to establish the underlying reasons, some incident summaries indicated a failure to recognise and/or respond to a deteriorating patient. Issues associated with supervision were also identified. The following examples demonstrate these factors.



CASE 2

A 48-year old presented to ED with a blood pressure of 81/52 at 2215 and was triaged as category 4. Observations were repeated at 2245 with continued hypotension present. No further observations were done until 0220, when the patient was found to also be febrile. No nursing documentation until 0220 and no medical documentation until 0430, when a provisional diagnosis of sepsis was noted. No urinary output following commencement of intravenous therapy at 0130 and no indwelling catheter inserted until 0800. The patient remained hypotensive until 1100, when resuscitation and inotropes was required.

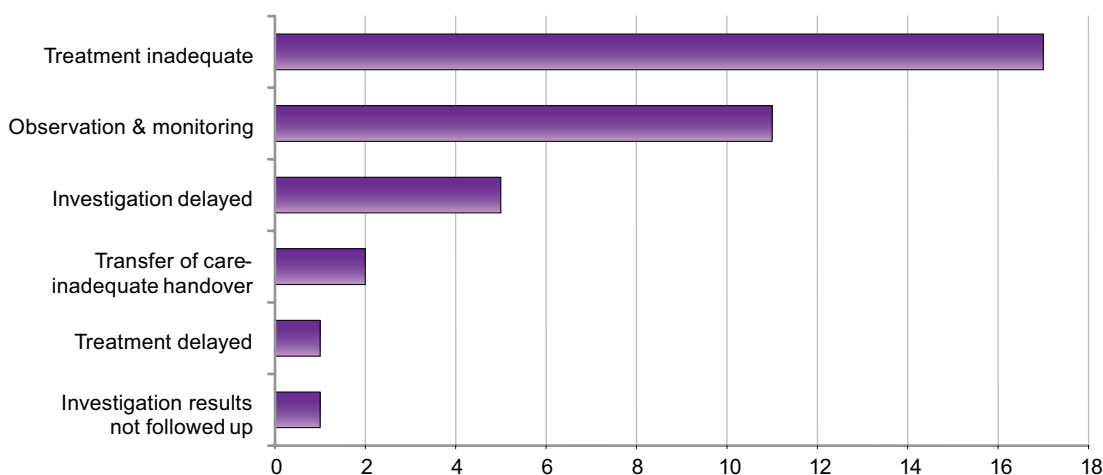
CASE 3

A patient was noted to have decreased white cell count and neutrophils and increased platelets. A haematology consult was arranged and the patient was seen at 1430 hrs. The impression was neutropenic sepsis. Cefepime, gentamicin and Filgrastim (G-CSF) were recommended but not ordered/written up. Later in the day, the ICU team reviewed the patient and a stat dose of gentamicin was charted but not given. When the medication was ordered, the gentamicin only was given at 1800 and the cefepime was given at 2400 and charted as 2gm once daily rather than every eight hours and the G-CSF given at 2000. Contributing factors identified by notifier include: lack of understanding of the severity of the problem, the importance of prompt administration of antibiotics, over-reliance on the intern to order the medication and unfamiliarity with the process for obtaining non-imprest items after hours. The patient was transferred to ICU at 2300.

During the review process a number of incidents were given a secondary clinical management sub-classification, as it was often difficult to clearly identify the primary contributing factor.

The following figure again indicates that treatment may have been inadequate. Issues related to observations and monitoring were also a key feature.

Figure 3: Secondary Clinical Management Classifications



A number of incidents clearly identified that patients had experienced a complication of treatment. Some of these incidents also reflected that once a complication occurred, it was not always adequately treated.

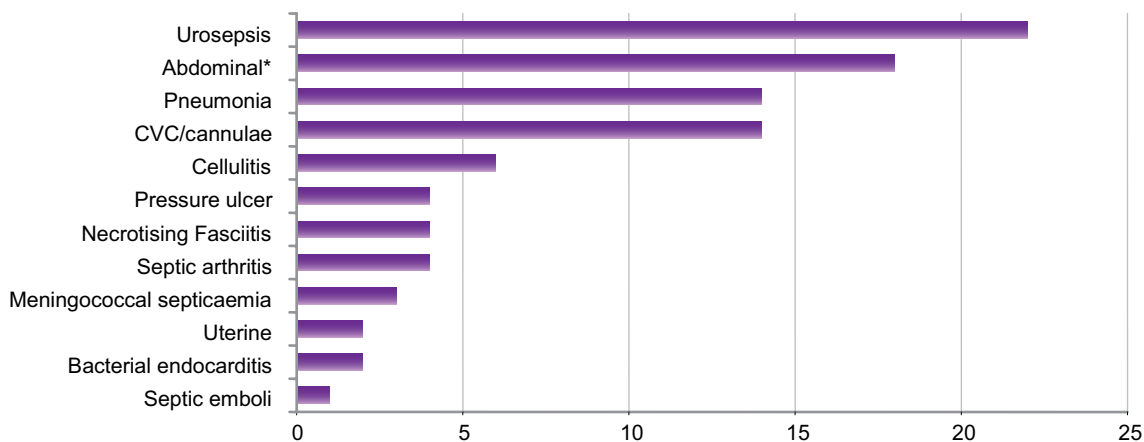
Highlighted diagnostic/clinical risk groups

This is a grouping used by the RCA Review Committee and is based on common themes found in RCAs. Many of the incidents reviewed fitted into these clinical risk groups. This type of grouping has proved over time to be a rich source of information in terms of clinical risks. Some degree of sepsis is a given in each of the incidents in the cohort. Other clinical risk categories attributed to these incidents included:

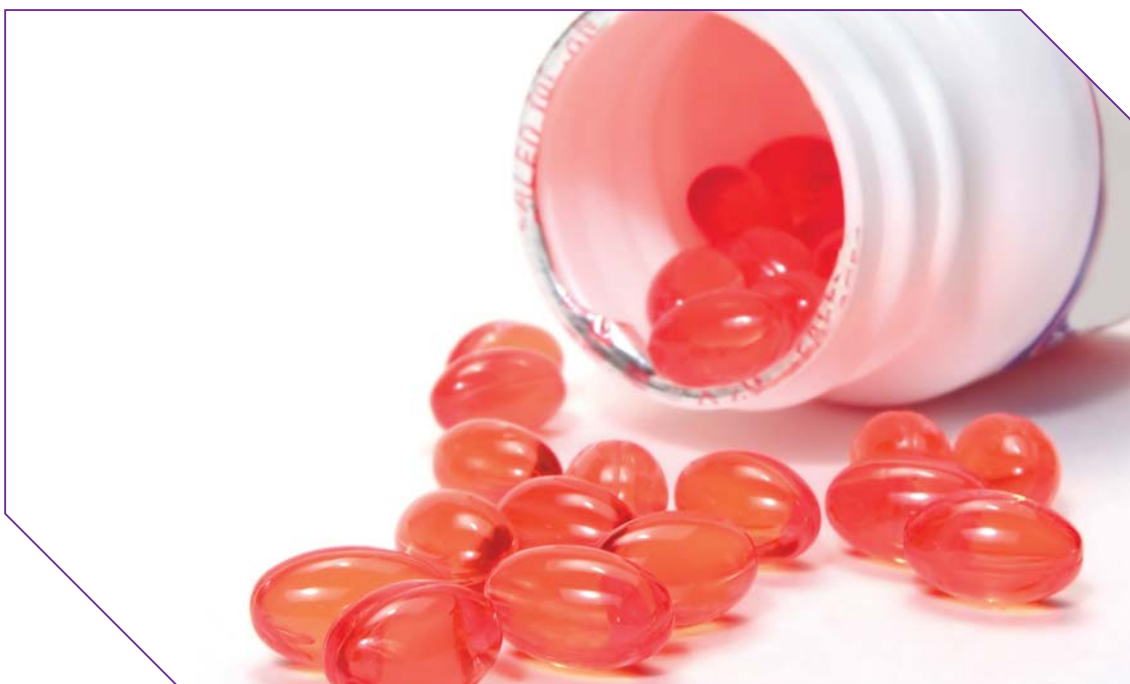
- recognition and response to a deteriorating patient (61)
- health care associated infection (19)
- neutropenia (11)

In terms of sepsis, the source of the infection is not clear in the majority of the incidents, however the following provides some insight to the suspected/suggested source as indicated by the notifier.

Figure 4: Suspected/Suggested Infection Source



* Includes post operative abdominal sepsis



System issues

It is not always possible to identify system issues in incidents notifications other than the SAC1 RCAs, however the following key issues were identified:

- Intra-hospital/inter-hospital transfer of the unstable patient (22)
- Supervision of clinical staff (16)

The following table provides an indication of where issues around the transfer of unstable patients occurred. Incidents related to inter-hospital transfer suggest that once the transfer of the patient is arranged, treatment may not be pursued as actively as is required. This suggestion is only based on information within IIMS and may not reflect the reality documented within medical records.

Table 2: Transfer of an Unstable Patient – Inter/Intra-hospital

Transfer from	Transfer to	Number	Comment
Emergency	Medical Assessment & Planning Unit/Ward / CCU/HDU/Other	10	Six patients met the Medical Emergency Team criteria on transfer 50% of the patients were transferred after hours.
C1 & 2 Hospital	Higher level care	6	
General Medical	Discharged	2	Both patients represented within hours of discharge acutely ill
General Medical / Surgical ward	Rehabilitation	3	
HDU	Radiology	1	

System issues are discussed further under the SAC1 section of the report.

SAC1 Incident Analysis

The following information is for the most part based on the classification attributed to each RCA. Twenty-three SAC1 incidents were identified. RCA reports for the two most recent incidents were not available at the time of this analysis and therefore the notification has been used to classify the incidents.

SAC1 Incidents by Principal Incident Type (PIT)

The following table provides details of the principal incident type as indicated within IIMS notification. As expected most incidents have the PIT: Clinical Management

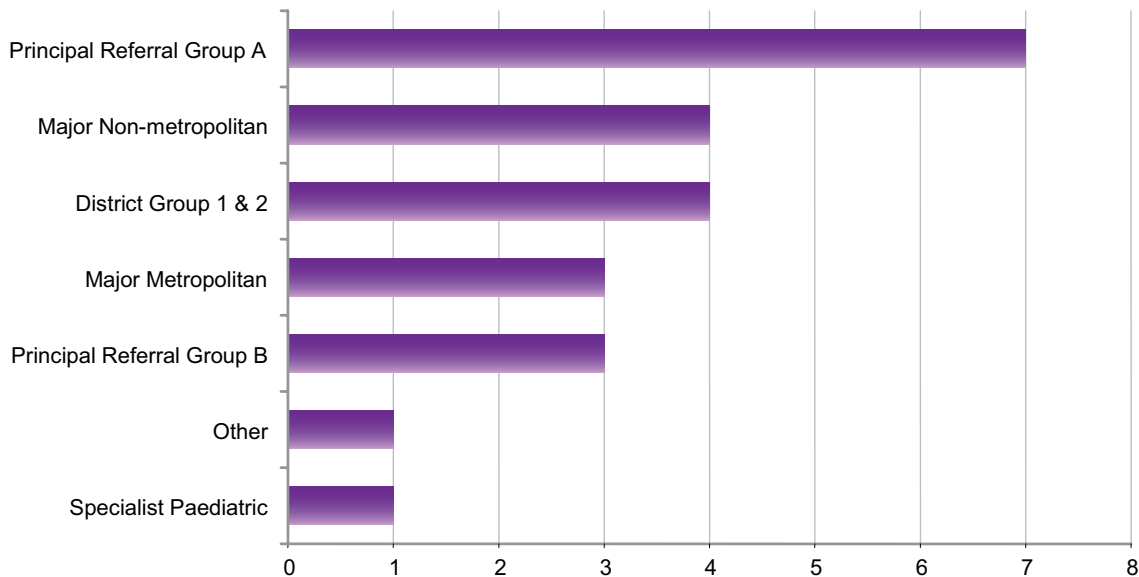
Table 3: SAC1 Incidents by PIT

PIT	Clinical Management	Complaint	Medication/IV fluid	Total
Number	18	4	1	23

SAC1 INCIDENTS BY PEER GROUP

As reflected within Figure 1 Principal Referral Group A hospitals had the highest number of incidents including SAC1 incidents.

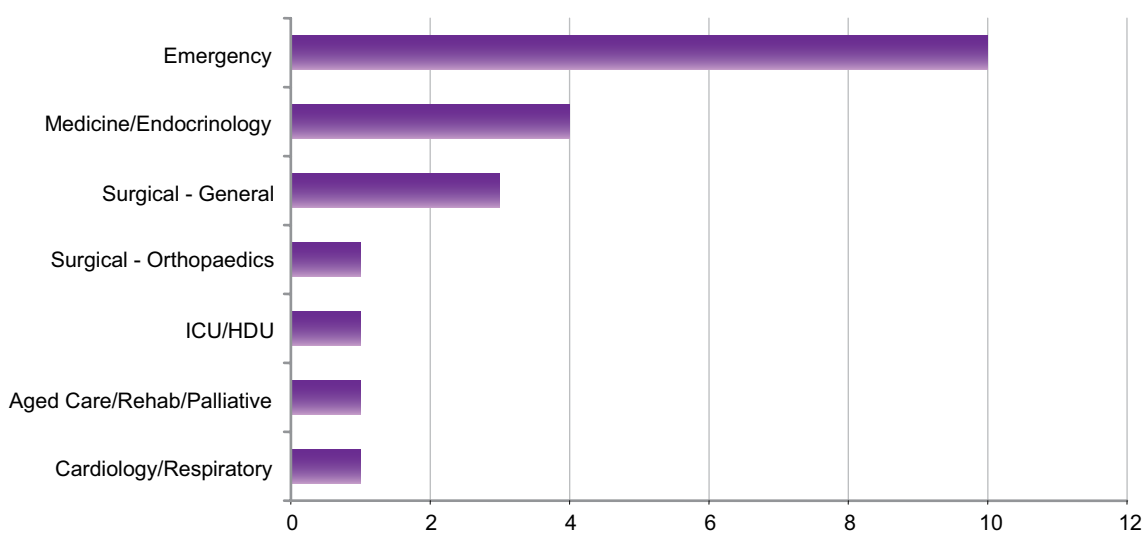
Figure 5: SAC 1 Incidents by Peer Group



SAC 1 Incidents by Specific Service

The data indicates that sepsis-related SAC1 incidents are most likely to occur in the emergency department.

Figure 6: SAC1 Sepsis Incidents by Specific Service



Highlighted Clinical Risk Group

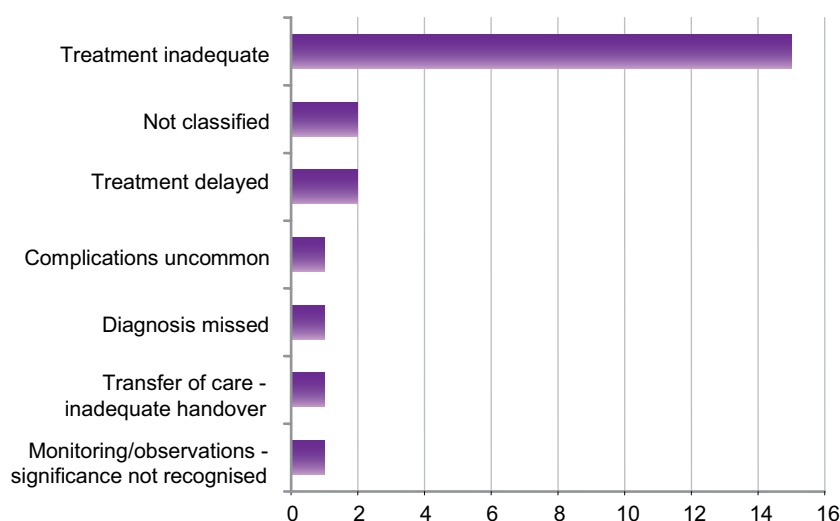
In addition to sepsis, the following clinical risk classification were attributed to the SAC1 incidents:

- Failure to recognise and/or respond to a deteriorating patient (11)
- Acute Abdominal Pain (1)
- HAI (1)
- Post Fall Management (1)
- Transfer from ED/ICU after hours (1)

SAC1 Clinical Management Sub-Classification

The following clinical management sub-classifications were attributed by the RCA review committee during their routine review processes.

Figure 7: Clinical Management Sub-classifications



Two SAC1 incidents were not able to be classified, as there was insufficient information within the RCA report. Again, 17 RCAs reflected issues related to treatment (both inadequate and delayed).

RCA Team Recommendations

Recommendations were made in all 21 RCAs reviewed. The presence of sepsis was not always articulated by the RCA team who investigated the incident. In some cases therefore, no recommendations were made about the management of sepsis. The following is a summary of recommendations made by RCA teams.

Education

Many recommendations focused on training and retraining of staff around practice issues e.g. competency-based education related to cannulation for junior medical officers (JMOs) and education around the implementation of observation/vital signs minimum standards in the adult acute care setting.

Policy/Guidelines

The development/application of guidelines is also a frequently suggested recommendation. Examples include:

1. A guideline for the management of the seriously ill, complex, unstable patient in emergency departments (ED) to be developed in consultation with ED general medical teams, ICU and other relevant stakeholders. This guideline should consider the process for allocation to speciality (admitting team), allocation of responsibility for patient care while awaiting transfer and action to be taken if no local ICU bed is available.
2. The management of all patients with staphylococcal bacteraemia should include referral to the Therapeutic Guidelines (Antibiotics) 2006 and expert advice from an appropriately qualified infectious disease specialist or clinical microbiologist.

Process Review/Redesign

Review of pathology results, particularly related to patients being discharged, is an ongoing issue. Development of a robust process which ensures these results are reviewed and action taken if required, continues to be cited. This suggests the challenges remain.

Examples of Incidents from all SAC ratings

The following examples are selected from all incidents reviewed and demonstrate the key findings:

- Failure to recognise or respond to a deteriorating patient
- Treatment delayed/inadequate
- Transfer of an unstable patient
- Clinical Supervision

1)

An eight-year old child was brought to the emergency department with shortness of breath and fever. Provisional diagnosis was pneumonia/sepsis on a background of bulbar palsy, neurological developmental disorder and recent aspiration. Triaged as category 3. Observations on arrival were temperature 38.3, heart rate 161 and oxygen saturations 68 per cent in room air. The child was transferred to the ward four hours after arrival. Observations on transfer were noted to be temperature 37.7, respirations 60 and oxygen saturations 91 per cent on six litres of oxygen. The child was reviewed by a resident medical officer (RMO) four hours after transfer because of increasing oxygen needs: oxygen saturations 87 per cent in 10 litres oxygen. The medical emergency team (MET) was called one hour later and then neonatal emergency transport service (NETS) was called. The child was intubated by NETS, but continued to deteriorate and was considered too unstable to transfer. The child died from septic shock secondary to severe bronchopneumonia.



2)

A 59-year old patient presented to ED with respiratory distress and shock. The patient was reviewed by a number of teams, but none would accept responsibility for ongoing management of the patient. There was a failure to include septic shock as a possible working diagnosis. Aggressive management did not occur until 20 hours after the patient's presentation. The patient was transferred to another facility, but died shortly after transfer.

3)

Patient septic – tachycardic and hypotensive during the entire time in ED. No consideration given to a review by the ICU team. Patient transferred to a medical ward (time not documented). The patient remained hypotensive overnight and required admission to ICU the next day.

4)

An 80-year old patient, who had recently been diagnosed with renal failure, had a 10-day history of a urinary tract infection. The patient had been commenced on antibiotics, but had stopped taking antibiotics 3-4 days after commencing treatment because of thrush. The patient presented to ED at 2200. On arrival the patient had a blood pressure of 104/37 (patient informed staff she normally had high blood pressure). No further observations until 0100 when the patient's blood pressure was noted to be 82/60. Only two further sets of observations were done over the next four hours despite BP of 82/60 & SBP 60. Medical registrar not notified until 0540. The patient was then seen by ICU registrar at 0620. No indwelling catheter (IDC) was inserted until eight hours after presentation, despite the patient being anuric and having had some fluid resuscitation. IV antibiotics were not prescribed/given until 0600 - again eight hours after presentation*. A contributing factor identified by the notifier was that monitoring of the patient was inadequate. (Only five sets of observations done in a nine-hour period, despite severe hypotension). The patient died.

*Kumar et al 2006 suggest that for every additional hour to effective antimicrobial initiation in the first six hours after the onset of hypotension, survival dropped by an average of 7.6 per cent.



5)

Patient presented with increasing confusion. Diagnosed with urosepsis. Transferred to the ward and required a MET call 20 minutes after transfer. Found to be in acute pulmonary oedema and required transfer to ICU. Medical record indicates that the patient was hypoxic, tachypnea and hypertensive prior to transfer from ED.

6)

54-year old patient was admitted under neurology, with an infected pressure sore. Noted to be febrile overnight. Blood cultures were taken. White cell count increased to 21,000. The patient was, however, discharged by the neurology team but re-presented to ED two hours after discharge, febrile, septic and with decreased level of consciousness. The patient required admission to ICU.

7)

Patient presented to ED with urosepsis. Hypotensive BP 85/45, pulse 107. Elevated renal markers present on transfer to a medical ward. BP on transfer 75/40 – nursing staff contacted the medical registrar, who advised to repeat BP in 30 minutes. Patient continued to be hypotensive overnight SBP <66. No escalation or review by ICU team, despite the patient's obvious clinical deterioration. Patient reviewed the following day and transferred to ICU.



Conclusion

Within the limitations of the data, there is evidence that the responsiveness of the system to patients presenting with or developing severe sepsis or septic shock in hospital, is not optimal. The reason for this is not clear. Challenges related to early diagnosis and/or capacity to recognise and respond to patients with subtle signs of deterioration were evident throughout the incident data.

The management of sepsis may need to be considered in terms of which guidelines are available to assist junior staff to identify and manage sepsis and septic shock in all locations, but particularly in emergency departments.

Recommendations

The Patient Safety Team of the Clinical Excellence Commission make the following recommendations:

1. The Emergency Care Taskforce in collaboration with NSW Health/CEC undertake a project to promote early recognition and appropriate fluid resuscitation of patients presenting to emergency departments with sepsis. This includes the development of an audit process which enables monitoring of time to first antibiotics.
2. Early recognition and prompt treatment of patients presenting with sepsis or developing sepsis as a complication is critical to the long-term outcome for the patient. Consideration should be given to the development of an awareness campaign through a safety alert or other mechanisms to increase all clinicians' (paramedic, medical and nursing) level of awareness.
3. Sepsis should be actively excluded when patients present with hypotension, oliguria and tachycardia, with or without fever.
4. Reiterate with medical and nursing staff that observations/monitoring and responsiveness to abnormal and deteriorating observations is critical in the early stages of sepsis management. Escalation criteria and pathways are clearly articulated to junior medical and nursing staff.
5. If sepsis is suspected the escalation pathway must ensure early review and management supervised by senior medical staff.
6. There be a process of education for all clinical staff (hospital and pre hospital) that sepsis represents an urgent medical problem with substantial mortality and that escalation pathways include early consultation and referral to higher levels of care (including NETS/AMRS).



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www.cec.health.nsw.gov.au/programs/sepsis

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Hicks P & Cooper, D (2008) on behalf of the ANZICS Board and ANZICS Clinical Trials Committee: *The Surviving Sepsis Campaign: International Guidelines for management of severe sepsis and septic shock*: 2008 and the Australian and New Zealand Intensive Care Society, Critical Care and Resuscitation, Volume 10 Number 1 March 2008 6-8.

The guidelines also include a simple evaluation for severe sepsis screening tool for use in all departments.

Surviving Sepsis Campaign and the Institute for Healthcare Improvement – Evaluation of Severe Sepsis Screening Tool <http://www.survivingsepsis.org/Bundles/Pages/default.aspx>

Sundararajan, V., MacIsaac, C. M., Presneil J.J., Cade, J. F. & Visvanathan, K. (2005), *Epidemiology of Sepsis in Victoria, Australia*, Critical Care Medicine 2005 Vol 33 No 1

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Report endorsed by **Professor Clifford Hughes, Chief Executive Officer**



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