

CLINICAL FOCUS REPORT



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Central Venous Access Devices and Air Embolism



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Acknowledgments: The CEC thanks the clinicians and health managers who provided their time and expertise in the development of this report.

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FOREWORD

Air embolism is a preventable patient safety event.

Patient outcomes from air embolism range from no harm, to neurological impairment and death. It takes only a relatively small volume of air to cause an air embolism, and it also only takes a relatively small amount of time - just one to two seconds to occur.

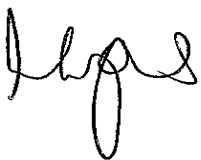
Two circumstances must be present for an air embolism to occur:

1. Direct communication between the atmosphere and blood vessels [for the purpose of this report this circumstance is met by a central venous access device (CVAD), or a patent venous tract after removal of a CVAD]; and
2. A pressure gradient which favours air entry into the vessel, that is the venous or intrathoracic pressure is lower than atmospheric pressure. This occurs during normal breathing and can be influenced by patient factors.

The signs and symptoms of an air embolism can be non-specific, subclinical and transient in nature, making diagnosis difficult. Clinicians should be aware that if there is a temporal relationship between a patient's sudden/unexpected deterioration and a CVAD clinical care activity (e.g. insertion, removal), a high index of suspicion between the two events should be considered.

This report aims to heighten awareness about the preventable patient safety event of air embolism which can result at any time, from the insertion procedure until after CVAD removal. The report explores the extent of the problem within New South Wales (NSW) public health facilities, as reported in the Incident Information Monitoring System (IIMS), and the factors that contributed to their occurrence. Direct excerpts from IIMS notifications and incident investigations, are used throughout the review to depict specific contributory components.

We commend this report and invite all clinicians who care for patients with a CVAD to take the time to read it carefully. We strongly encourage that the recommended practice changes are adopted. These changes are considered a safety priority in order to mitigate the risk of CVAD related air embolism and thereby prevent harm occurring to our patients.



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EXECUTIVE SUMMARY

There were six preventable patient deaths notified into the NSW Health Incident Information Management System (IIMS) between January 2012 and April 2015 by NSW public health facilities from actual or suspected (not confirmed by diagnostic test) air embolism relating to Central Venous Access Device (CVAD) management. There were no peripherally inserted central catheter (PICC) incidents identified. Central Venous Access Devices are frequently used within NSW health care facilities. Exact numbers are not known, but it is estimated that in NSW public hospital intensive care units alone, more than 15,000 devices are inserted each year.

Four of the six identified deaths were related to CVAD removal. One death was related to insertion and one during routine care processes. There were a total of 14 actual or suspected air embolism CVAD-related incidents reported into the IIMS and 51 near miss events identified in the time period.

The literature suggests that air embolism is more likely to occur whilst the CVAD is in situ and during removal, but may also occur during the insertion procedure.

There were a number of common factors identified in the reported incidents, which present improvement opportunities:

- Under-estimation and normalisation of the potential risks related to CVADs
- Clinical practice issues inclusive of incorrect patient positioning during removal
- Device (connector and attachment) issues
- Suboptimal supervision, staff credentialing and ongoing proficiency of insertion and removal.

The incidents also highlighted three patient factors which heighten a patient's risk of developing an air embolism, particularly during removal. These factors were:

- Respiratory compromise (which can generate a large negative intrathoracic pressure increasing the risk and rate of air entrainment);
- Intravascular depletion (which can lead to a greater negative intravascular pressure, increasing the risk and rate of air entrainment); and
- Low body mass index (smaller venous tract between the atmosphere and vessel).

The report highlights clinical and system-wide changes that need to occur to reduce the risk of air embolism from CVAD insertion, routine care and removal; thereby making care delivery of CVADs reliable and safe. The themes identified from the review of incidents implicate skill and knowledge-based deficits that need to be improved.

Following a review of the literature, and in collaboration with an expert clinician group, the following key actions have been identified to address the opportunities for improvement:

At point of care

- Patient consent must include information about routine care and removal of the device
- Decision-support tools, including a requirement to document indication pre-insertion of a CVAD, should be implemented to ensure patients receive the most appropriate vascular access for their care requirements and risk factors.
- Attachments and connections to CVAD that allow direct access of air and disconnection should be avoided
- The requirement for the CVAD for ongoing patient care should be assessed daily
- Transfer of a patient between locations should not occur within 30 minutes of removal of a centrally inserted CVAD
- Time out and risk assessment with checklists should be considered as a means to remind clinicians of the key principles associated with CVAD interventions and must occur at insertion and removal

At a system-wide level

- Review policy, procedure and guidelines in NSW to ensure that consistent information which uses plain language is presented
- Embed credentialing processes into clinical practice for all aspects of CVAD management and include appropriate supervision and maintenance of proficiency
- Engage industry, with a view to sourcing devices and connectors with bonded valves and other safety options (e.g. alert attached to CVAD)

The CEC is committed to working with its health partners to facilitate these improvements.

BACKGROUND: SETTING THE SCENE

The role of the Clinical Excellence Commission is to promote and support safety and quality and improve clinical care across NSW Health. Aggregated data from the NSW IIMS is one source of information used to identify potential gaps in the delivery of quality care and assists in identifying evolving trends affecting patient safety.

What is a Central Venous Access Device (CVAD)?

A CVAD is a 'catheter introduced via a large vein into the superior vena cava or right atrium for the administration of parental fluids, medications or the measurement of central venous pressure' [1]. CVADs are frequently used in patient care in both the acute and community setting. Exact usage within NSW health care facilities cannot be quantified but it is estimated that in NSW public hospital intensive care units alone, more than 15,000 devices are inserted each year [2]. Due to the high frequency of use and the potential risk for tragic outcome, CVAD placement should be considered a *high-risk* intervention.

What is an air embolism?

An air embolism is an air bubble that has entered the circulation and may be venous or arterial. Small amounts of air introduced into the blood stream, or air introduced at a slow rate may be tolerated with no symptomology or sequela, as the air is absorbed [3, 4]. As the volume and rate of air entrained increases, the severity of the patient outcome also increases [5]. In addition, the closer to the heart the air enters the circulation, the smaller the volume of air required to precipitate a poor patient outcome [3, 6, 7].

Distinguishing venous and arterial air embolism

Venous air embolism associated with CVADs results when air enters the venous circulation and migrates to the right side of the heart and pulmonary vessels; resulting in cardiac and respiratory symptoms. Air in the right side of the heart may also pass through a patent foramen ovale (present in 30 per cent of the population) or atrial septal defect and enter the cerebral or coronary circulation resulting in stroke, myocardial infarction and cardiac arrest [3]. A venous air embolism can also become arterial if the volume of entrained air exceeds the capacity of the pulmonary capillaries to completely filter the air [8]; the rate at which the pulmonary capillaries are unable to filter is considered to be 0.30mL/kg per minute [9]. Paradoxical air embolism may also occur and is more likely when CVAD removal is performed in the upright position, during forced expiration, cough or Valsalva manoeuvre [10].

What is the mechanism by which an air embolism occurs?

Two conditions must be present for an air embolism to occur:

1. Direct communication between the atmosphere and the venous or arterial circulation; and
2. The presence of a pressure gradient which favours air entry into the circulation [3, 8].

The mechanism by which the above conditions are met is either by active injection or through the passive entrainment of air [3, 8]. For the context of this review, the conduit of passive entrainment is through a CVAD that ends in the thoracic cavity and where the venous / intrathoracic pressure is lower than atmospheric pressure e.g. when a patient takes a breath or coughs and the resulting pressure gradient favours air entrainment [3, 8]. In some instances a 'late embolism' may occur following CVAD removal with the conduit for the air entrainment being the venous tract established by the CVAD.

There are six determinants that influence the severity of a patient's outcome from an air embolism [3, 5, 6, 11, 12]. These are:

1. Volume of air entry into the circulation
2. Rate of air entry into the circulation
3. Patient position at the time of the incident
4. Insertion site of the CVAD
5. Route by which the air enters (venous or arterial)
6. End location of where the air embolism migrates

The actual volume of air causing detrimental effects is inconclusive. It is estimated that a volume of air as small as 70 mL can be fatal (less than a single breath). The literature references a range of 70 to 500mL of air [5, 6, 11, 13, 14]. A volume of 100mL of air per second may enter the circulation through a 14 gauge catheter with a pressure gradient of only 3.7mmHg (5 cm of H₂O) [6, 7, 11, 15]. This illustrates that a small change in pressure may lead to a large change in the volume of gas entrained.

The severity of the patient outcome relating to the rate and volume of air entrainment is also influenced by two additional factors: the size of the CVAD lumen; and the degree of pressure gradient difference. That is, the larger the CVAD lumen or greater the pressure gradient, the greater the volume of gas entrained [6, 16].

Patient positioning influences the degree of the pressure gradient. Patients should be supine [17] and if possible head slightly down (Trendelenberg) for insertion and removal of CVADs inserted to the neck or chest [1]. This positioning increases the central venous pressure at the insertion site and reduces risk of air entrainment. When patients are sitting up the pressure gradient favours air entry into the circulation.

It is recognised that internal jugular and subclavian CVADs have a higher risk of air embolism compared to femoral CVAD or Peripherally Inserted Central Catheters (PICC) [16]. However, these insertion sites in the chest and neck are the most commonly used due to accessibility and a lower infection risk associated with the insertion procedure. The jugular site is the most commonly used site in NSW Intensive Care Units (ICU) [2]. The preference of the chest and neck insertion sites were also demonstrated in the case studies reported in the literature (Appendix B).

Insertion, removal or routine care, what is the more risky intervention?

There is debate as to which CVAD procedure has the highest potential risk of air embolism [16]. Some authors consider ongoing management or the removal of the CVADs to be associated with the greater risk of air embolism rather than insertion. [9,18]

Signs and symptoms of an air embolism

There are many clinical signs and symptoms of an air embolism. These can be respiratory, cardiac or neurological in nature.

Patient outcome and outcome severity

Patient outcomes following an air embolism range from complete recovery to death. Patients that survive an air embolism may have ongoing pulmonary, cardiac and neurological impairments.

Difficulties with identification

Air embolism incidents are difficult to accurately determine due to the non-specific, subclinical and transient nature of exhibited symptoms and varied patient outcomes. It has been reported in the literature that symptoms of air embolism are sometimes attributed to the patient's underlying comorbidities rather than CVAD management [5, 19, 20]. The temporal relationship between a patient's sudden deterioration, inclusive of respiratory, cardiac and neurological, and the insertion, removal or routine care of a CVAD, should prompt clinicians to have a high index of suspicion of a relationship between the two events [14].

Incident sources for this report

Two information sources were accessed during May 2015 to identify patients with CVAD related air embolism (actual/suspected or near miss):

1. Clinical Excellence Commission (CEC) Clinical Management Root Cause Analysis (RCA) review sub-committee analysis of RCAs and
2. IIMS database

There were 16,816 IIMS notifications and associated RCA reports reviewed for applicability to air embolism and CVAD management, where the incident occurred between 1 January 2012 and 30 April 2015. The following filters were used:

1. Root Cause Analysis reports that were assigned a Clinical Risk Group category of 'air embolism'
2. SAC2-4 IIMS notifications where the notifier used the following terms in the 'incident description' or 'review of incident' section of the IIMS notification
 - embolism, embolus, embo, gas, air, intravascular
 - central venous catheter, central line, CVC, CVL, PICC, Vas-Cath, tunnel, port
 - disconnect
 - response

The subsequent findings from these data sources were reviewed and categorised for commonality.

Limitations

The incident review is based only on information contained in the RCA reports received and the 'incident description' and 'review of incident' section in IIMS notifications. If the information was not documented in these sections, or the selected search terms were not used or were spelt differently, the incidents will not have been captured during this review.

Incidence of air embolism - New South Wales : 2004 - 2013

Air embolism resulting in death or neurological damage is one of the eight national sentinel events that require reporting by all states and territories within Australia. In NSW, sentinel events are reported into the IIMS and are assigned a SAC1 status requiring a Root Cause Analysis to be conducted. Table 1 delineates the Australian and NSW (all cause) reported incidence of air embolism during the period 2004 to 2013. Reported air embolism incidents during this period ranged from zero to three per year nationally. Since 2008-09, NSW reported 71 per cent (5 of 7) of all nationally reported air embolism incidents that led to death or serious neurological outcome for a patient; NSW accounted for all air embolism reported nationally in 2008-09, 50 per cent of air embolisms 2010-11 and all air embolisms in 2012-13.

Table 1: Australian incidence of air embolism, all cause and NSW CVAD related air embolism.

	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13
NSW - all cause	∞0	∞0	∞∞0	0	##2	##0	##1	##0	##2
National - all cause	*1	**2	**3	**1	#2	#1	#2	#0	#2

National incidence data for 2014/15 was not available at the time of writing this report.

Source:

*Australian Institute of Health and Welfare & Australian Commission on Safety and Quality in Health Care 2007. Sentinel events in Australian public hospitals 2004-05. P. 12

**Australian Commission on Safety and Quality in Health Care (2011), Windows into Safety and Quality in Health Care 2011, ACSQHC, Sydney. P. 5.

∞Australian Government Productivity Commission, Report on Government Services Public Hospitals 2008, Australia selected sentinel events, Table 10A.81

∞∞Australian Government Productivity Commission, Report on Government Services Public Hospitals 2009, Australia selected sentinel events, Table 10.16

§Up until April 2015

#Australian Government Productivity Commission, Report on Government Services Public Hospitals 2015, Australia selected sentinel events, Table 11A.97

Incidence of air embolism – New South Wales : 2012 - 2015

In NSW, from January 2012 to April 2015, there were 14 actual or suspected air embolism incidents related to CVAD management notified into IIMS. There were 51 notifications during this period reporting the potential for an air embolism secondary to CVAD management. The breakdown of the severity assessment code (SAC) applied to these notifications is detailed in Appendix A.

In the international literature incidence rates for CVAD related air embolisms range from 1 in 47 CVAD insertions to 1 in 3000 [5, 12] with some sources implying incidence rates as high as 0.1-2.0 per cent of all CVADs used [7, 13].

Air embolism is recognised to be difficult to diagnose due to its non-specific, transient and subclinical characteristics. This results in a potential for under recognition and subsequent under reporting of this preventable patient safety incident.

The reasons for the comparatively higher incidence of air embolism in New South Wales are not known, but may be reflective of the strong reporting culture in NSW.

FINDINGS IN NEW SOUTH WALES

Patient outcomes

Forty three per cent (n=6) of patients identified in NSW health facilities with an air embolism died. NSW health mortality rates are congruent with mortality rates found in the literature which range between 23 to 50 per cent [3, 21]. It is likely that the air embolism incidents in NSW resulting in death were a consequence of large volumes of air being entrained, i.e. > 2.0 mL/kg.

The patients who died in NSW health facilities either died immediately, or survived between four to 40 days post incident (Table 2). Those that died either experienced a cardiac arrest, neurological compromise or respiratory and neurologic compromise.

Of the eight patients who survived post-air embolism, their long-term outcomes were unable to be ascertained in the information provided. It appears that those patients who only exhibited respiratory symptoms had better outcomes and it is probable that in these incidents only small volumes of air were entrained.

Table 2: Patient outcomes with actual or suspected air embolism based on initial exhibited symptoms

Symptom	Patient Outcome		Symptom	Patient Outcome	
Cardiac Arrest	Death	3*	Cardiac and respiratory compromise	Death	0
	Survived	3		Survived	1
Respiratory compromise	Death	0	Respiratory and neurological compromise	Death	2 [§]
	Survived	4		Survived	0
Neurological compromise	Death	1 [#]			
	Survived	0			

* Death was immediate, 7 and 9 days after incident

§ Death within 4 and 40 days of incident

Death within 4 days of incident

Case 1

“The CVC was removed while the patient was sitting in the chair. Ten minutes later the patient was found unconscious...” The patient had not lost cardiac output and the initial rhythm was sinus tachycardia with runs of ventricular tachycardia. The blood pressure was 85/40mmHg, with agonal breathing, pupils 4+ with bilateral down ward gaze. The Glasgow Coma Scale was documented as 6/15.

A bedside trans thoracic echo (TTE) was performed and the findings documented to be hyperdynamic left ventricle/right ventricle, bubbles in left ventricle, and a possible patent foramen ovale (PFO).

The patient was found on magnetic resonance imaging (MRI) of the brain to have extensive bilateral cortical infarctions in both cerebral hemispheres, with additional infarction of the splenium of the corpus callosum”.

The patient passed away four days later.

Case 2

“The CVC was removed... the patient was then noted to be acutely distressed and stated they could not breathe and rapidly deteriorated into pulseless electrical activity cardiac arrest. Post resuscitation significant neurological injury as a result of the prolonged cardiac arrest and resuscitation” was identified.

Profile of the patients affected in NSW health facilities

The age range of the patients with an air embolism was between 39 and 74 years, with males being predominately affected. There were some common patient characteristics in the reported incidents. These are listed in Table 3 and are recognised in the literature as independent risk factors for experiencing an air embolism (Appendix B).

Table 3: Identified independent risk factors for experiencing an air embolism

Risk factor	Results in	NSW findings
Respiratory distress/ compromise	Greater negative intrathoracic pressure gradient which favours air entrainment	Five (40%) of the patients had a reason for admission as respiratory. Four (33%) had a respiratory comorbidity. Four (33%) described that the patient was either breathless or had a higher than normal respiratory rate immediately prior to CVAD removal/insertion.
Low body mass index (BMI)	Shorter space between the point of skin insertion to the vessel meaning that there is less subcutaneous tissue to occlude the CVAD tract after removal	Five (40%) patients had a low BMI
Low intravascular volume	Intravascular volume depletion reduces central venous pressure producing a favourable pressure gradient (low/negative intrathoracic pressure) for air entrainment	Four (33%) patients had an admission reason including gastrointestinal issues. It may be possible intravascular volume was sub-optimal in these patients. This was not stated in the reports.

Case 3

“Prior to removal of the CVC the nurse discussed the patient’s respiratory rate and effort with the bedside nurse. The patient was found to be a little breathless; however, it was determined that this was normal for the patient.....The RCA team learned that the patient was extremely anxious and had a cachectic appearance and consider that these patient factors may have increased the risk of complications with the removal of the CVC”.

Signs and symptoms reported

Air embolism symptomology is nonspecific and can be subclinical in nature. Symptoms that were described in the NSW incidents were extracted and tabulated (Table 4) against the symptoms that are documented in the literature (Appendix B).

Many of these symptoms can be attributed to other causes and diagnoses. The most common symptoms described were acute dyspnea, oxygen desaturation, loss of consciousness and cardiac arrhythmias – tachycardia and bradycardia.

Cases 4-6

“they became acutely dyspnoeic with respiratory distress ...unrecordable blood pressure and oxygen saturations, sinus tachycardia”

“the patient was cyanosed in the face and lips and not responding to verbal demands, and made a grunt noise... before they went into an asystolic cardiac arrest “

“the patient was diaphoretic, tachypnea with low oxygen saturations, chest pain and wheezy”

Table 4: Signs and Symptoms of Air Embolism and reported NSW events [6, 8, 12, 16, 18, 19, 22]

Respiratory	NSW	Cardiac	NSW	Neurologic	NSW
Acute dyspnoea	9	Tachycardia / bradycardia	6	Unconsciousness / collapse	7
Oxygen desaturation	8	Sub-sternal chest pain / tightness	3	Altered mental state/ agitation/Anxiety	3
Cyanosis	3	Hypotension	2	Focal neurological deficits	1
Tachypnea	3	Pulseless electrical activity arrest	2	Sense of impending doom	-
Continuous cough	1	Circulatory shock / collapse	2	Headache / Light headedness	-
Wheeze	1	Right heart failure	-	Unequal pupils	-
Gasp reflex	-	ST segment & T- wave changes, RV strain	-	Hemianopia	-
Decreased end tidal CO ₂	-	Jugular venous distension	-	Seizures	-
Ventilation / perfusion mismatch	-	Elevated central venous pressures	-		
Elevated pulmonary pressures	-	Mill-wheel murmur over precordium	-		
Intrapulmonary shunting	-	Increased haematocrit	-		
Pulmonary oedema	-				
Bronchospasm	-				

Other characteristics of the incidents

Insertion site and lumen size of the CVAD

In eight of the incidents, the CVAD insertion site was stated as the internal jugular vein (Table 5). Nearly all case studies reported in the literature were jugular insertion sites (Appendix B). There were no reported PICC incidents in the 14 NSW incidents. The size of the CVAD lumens were unable to be ascertained from the information provided. Twenty one per cent (3 of 14) of the incidents involved vas cath. Vas cath generally have a large bore due to their function.

Table 5: CVAD insertion sites in the incidents

CVAD Insertion Site		Side	
Internal jugular	8	Right	7
		Side not specified	1
Site not specified	6		

CVAD intervention preceding the patient incident

In the NSW CVAD related air embolism incidents, 14 per cent resulted from unintentional CVAD disconnections, and 86 per cent (acute patient deterioration) were immediately preceded by either CVAD removal (64 per cent) or CVAD insertion (21 percent). Table 6 lists the temporal relationship between precipitating event and patient outcome.

Case 7

“On insertion as the wire was removed from the sheath a sucking noise lasting one second was heard....the patient complained of feeling unwell, there was a rapid drop in oxygen saturation from 95% to 50% which occurred in one minute. A MET was called and an air embolism was confirmed”.

Case 8

“Immediately following the removal the CVAD the patient complained of difficulty breathing and rapidly became unresponsive....” “...A bedside echocardiogram demonstrated the presence of air bubbles in the left cardiac chamber”

Where the time between CVAD management and patient deterioration was specified the time ranged from immediate to a 5-10 minute time lapse.

Case 9

“The CVC was removed, “10 minutes later the patient was found unresponsive”

Case 10

“Five minutes post CVC removal; the patient developed shortness of breath and complained of chest heaviness and tightness”

Table 6: Precipitating event and patient outcome resulting from an actual/suspected air embolism.

CVAD precipitating activity	Patient survived with / without confirmed deficit (n=8)	Death (n=6)
CVAD removal (n=9)	5	4
CVAD insertion (n=3)	2	1
CVAD disconnection (n=2)	1	1

Patient positioning

Where an air embolism occurred during the insertion procedure and the position of the patient was stated, all patients were positioned with their head tilted down in the Trendelenburg position as per PD2011_060.

Case 11

“The patient was put in the Trendelenburg position ...just prior to dilation of the vein the patient’s Trendelenburg position was increased slightly”

Case 12

“The patient was on a tilting table to allow the patient to be in a Trendelenburg position (head down)...”

During the removal procedure 78 per cent (7/9) of patient’s were in a sitting position (bed/chair) or supine with the head of bed elevated to 30 degrees. This positioning is contrary to best practice stipulated in PD2011_060 and the Agency for Clinical Innovation (ACI) Central Venous Access Device Post Insertion Management guideline [17]. Both documents stipulate lying flat or head tilted down for the removal procedure. Fifty per cent of the RCAs found that the patient position was root causal or contributory to the incident.

Case 13

“The lack of clinical experience and knowledge by the clinician led to the clinician removing the CVAD while the patient was upright, which resulted in a patient sustaining an asystolic cardiac arrest immediately post CVAD removal”

Case 14

“The RCA team determined that the root cause in the matter was removal of the CVAD while the patient was not positioned according to policy”

In those incidents where the line was disconnected, the patient was either walking or sitting. Table 7 lists the patient’s position immediately prior to the air embolism occurring.

Table 7: Patient’s positions at time of air embolism occurring

CVAD process	Sitting	Supine 30°	Supine	Trendelenburg	Mobilising	Not stated
CVAD insertion (n=3)				2		1
CVAD removal (n=9)	5	2	1	1		
Disconnection (n=2)					2	

In two of the RCA narratives, the patient was stated to be positioned in the correct position for removal but sat upright immediately after the procedure. PD 2011_060 states that *'the patient must be supine for removal ...and remain supine or semi-fowlers for between 30 and 60 minutes following removal'* [1]. However, the ACI Central Venous Access Device Post Insertion Management guideline [17] does not stipulate the requirement to remain supine post-removal. There are also differences in terminologies used to describe patient positioning in the two documents. These inconsistencies could lead to confusion.

Case 15

"the patient was then sat up in bed 30 degrees... the patient was still finding it hard to breathe and requested to sit on the side of the bed. The patient sat on the edge of the bed...patient complained of shortness of breath and rapidly deteriorated"

Case 16

"the patient was sat up in bed to 15 degrees thereafter"

Patient respiratory cycle and CVAD removal

Thirteen of the 14 patients were self-ventilating at the time of the incident. Some were described as having an increased respiratory rate. This increased work of breathing may have led to a pressure gradient that favours air entrainment and risk of air embolism.

The ACI Central Venous Access Device Post Insertion Management guideline [17] states that when removing a CVAD the removal should be *'timed to occur at end inspiration or during expiration for patients who are not on a ventilator'*. No respiratory timing recommendation is made in PD2011_060. Only one of the 14 patients was ventilated at the time of the incident. Five of the 14 incident narratives made reference to the respiratory phase and timing of the CVAD insertion/removal. One of these five stated that no instruction was given to the patient in relation to how they should breathe during the procedure. The following are descriptions of the respiratory manoeuvres performed by patients during CVAD removal:

Case 17

"Instructed to inhale & hold breath";

Case 18

"Breathed in and held breath, still holding breath as applying dressing";

Case 19

"Removed device during peak inspiration";

Case 20

"Held breath"

From these accounts, procedural instructions were given to the patients prior to removal of the CVAD but the differing instructions illustrate the confusion about respiratory cycle and pressure generation in the intrathoracic cavity.

Post-CVAD removal management

Four of the 14 incidents made reference to the post removal care management of the insertion site, with only two stating that digital pressure and an occlusive dressing were applied. Two referred to no blood being observed coming from the site post-removal. The length of time the CVADs had been *in situ* (where stated) ranged between 3 and 11 days. This period of time is long enough for a venous tract to be established. It is difficult to make any assumptions between the presence of a potential patent venous tract and patient outcome, due to the lack of exact incident descriptions, but collapse of the venous tract as a part of the removal procedure is a practice point to consider.

Case 21

"An occlusive dressing was applied the patient was then sat up in bed 30 degrees"

The incident description provided in Case 21 (above) is not congruent with the mechanism of air entry described in this report. If the dressing was occlusive, there would be no direct communication between the air and patient circulation. As dressings were not often described in the incident descriptions, it is difficult to understand how often a venous tract was the mechanism of air entry. There are explicit recommendations in the ACI Central Venous Access Device Post Insertion Management guideline [17] related to removal and dressing requirements to reduce this risk of late air embolism.

Other findings

Ward / Unit location of patient

The majority of the air embolism incidents occurred in metropolitan facilities, with 64 per cent (n=9) of patients at the time of their deterioration being cared for in a critical care area (Table 8). Fifty three per cent (n=27) of the near miss events also occurred in critical care areas.

Table 8: Patient clinical location at the time of incident

Patient location	Metropolitan	Rural
Critical Care Area (ICU/HDU/Cardiothoracic ICU) (n=9)	8	1
Radiology (General/Interventional)(n=2)	2	0
Ward (Surgical/Cardiothoracic)(n=2)	1	1
Cardiac Catheter Laboratory (n=1)	1	0

In critical care areas, CVADs are common place due to the nature of the patient population; conversely, the clinicians managing these devices are usually the more experienced staff in CVAD management. Despite the high level of training, available guidelines and experience, safe practice was not always evident. The high frequency of use has potentially led to an underestimation and normalisation of the potential risks associated with their use. Leading to an 'illegal-normal'; that is there has been a gradual shift in the boundary of safe practice, with these deviations becoming accepted as the routine or normal practice [23].

WHAT THE ROOT CAUSE ANALYSIS REVIEWS IDENTIFIED

Eight of the 14 actual / suspected air embolism incidents were subject to a RCA review.

Root cause / contributory factors

Four of the eight RCA investigations identified a root cause/contributing factors. This highlights the difficulty when identifying temporal relationships between the two events, even with the advantage of hindsight. Table 9 details these causal/contributory factors. System issues were identified in 75 per cent of the RCAs conducted. In some of the RCAs, the root causes were also found to be system issues and vice versa.

Table 9: Root Cause Analysis causation and contributory factors

Root cause / contributory factors
<p>Suboptimal supervision (n=2)</p> <p>Absence of regular allocated time and location for scheduling and performing vascular catheters for patients affect planning and availability of supervision. This contributed to <i>suboptimal supervision</i> and non-removal of the stylet and wire together during the procedure.</p> <p>Absence of a <i>formalised credentialing process</i> for determining competence and <i>suitability to supervise</i> led to non-removal of the stylet and wire together during the procedure.</p> <p><i>Inadequate supervision</i> of a clinician during the removal of a CVAD breached NSW Health Policy Directive PD 2011_060 Central Venous Access Device Insertion and Post Insertion Care which led to an asystolic cardiac arrest immediately following CVAD removal.</p>
<p>Incorrect patient position during removal – sitting (n=2)</p> <p>The root cause in the matter was removal of the CVAD while the patient was <i>not positioned</i> according to policy.</p> <p>The lack of clinical experience and knowledge by the clinician led to the clinician removing the CVAD while the <i>patient was upright</i>, which resulted in a patient sustaining an asystolic cardiac arrest immediately post CVAD removal.</p>
<p>Credentialing /scope of practice - clinician knowledge and skills (n=1)</p> <p>The failure to have a <i>competent</i> clinician remove the CVAD led to an asystolic cardiac arrest immediately post CVAD removal.</p>
<p>Device issue (n=1)</p> <p>The absence of a <i>secure locking mechanism</i> on the lumens resulted in an unplanned disconnection and air being able to enter the vascular system which resulted in the patient developing an air embolus and subsequent death.</p>

Suboptimal supervision and inappropriate positioning of the patient were stated in four RCA causal/contributory statements. Incorrect patient position was only identified as an issue for CVAD removal. One RCA describes the reason for incorrect patient positioning in that case as:

The clinician “did not have a good understanding of the mechanics of air pressures and why the patient needed to be lying flat”

Supervision alone was stated in two of the four RCAs as a root cause/contributing factor. In both of these cases, there was a lack of confirmation whether the clinicians posed the required clinical skills to perform the procedure. In both instances, it involved insertion. There is a training framework for credentialing clinicians for insertion of CVADs which stipulates supervision requirements. These are echoed in PD2011_060.

Other issues of no formal process to define credentialing for supervision of CVAD management procedures and scope of practice were also identified.

Seventy five per cent of the RCAs identified that clinicians were trained or accredited in CVAD management. Of the clinicians not trained, all were identified as medical staff. This suggests that there is a skill based issue for insertion and a knowledge based issue for removal.

Identified system factors

'System issues' identified in the RCAs were:

1. Inappropriate patient positioning for removal
2. Inappropriate staffing levels for patient acuity and activity of the clinical area
3. Inconsistent clinical information (unclear policy) regarding at what point in the respiratory cycle the CVAD should be removed. One RCA identified that their current local policy was "in conflict with what is conventionally taught and recommended that this local policy be reviewed regarding the phase of the respiratory cycle which CVADs should be removed". Currently there are two state wide documents 'Central Venous Access Device Insertion and Post Insertion Care' (PD2011_060) and 'Central Venous Access Device Post Insertion Management'. These documents do not align in some of their procedural steps.
4. Lack of centralised monitoring of staff competencies for advanced practice
5. Inadequate documentation for CVAD management, including an order to remove the line.

Additional issues identified by the Clinical Excellence Commission RCA Review Committee were:

1. Inadequate care planning
2. Inadequate information or education to the patient and/or their carer about the risk of removal and why it is necessary to lie flat or be in bed for the removal
3. Inadequate communication between care providers.

Other influencing factors

There were some common features influencing decision making within the RCA narratives which warrant highlighting but which were not clearly articulated in the root cause/contributory or system factors. These factors included time pressures, suboptimal care planning associated with an under appreciation of the potential risks associated with CVADs and patient factors.

Time pressures effecting care planning were evident. Three of the incidents stated that the CVADs were removed just prior to the patient transfer to another ward, resulting in a sense of urgency to remove the CVAD before transfer and a potential for suboptimal planning for the procedure.

"The unit was particularly busy and there was enormous pressure on beds"

Two cases stated that the removal was not performed by the primary care nurse. This was appropriate in one instance as the primary care clinician was not accredited for removal of the CVAD. In the other instance, it occurred while the primary care clinician went on a meal break prior to transfer of the patient. This implies that management of a CVAD has been normalised with an under-appreciation of the potential risks associated with their use.

Patient factors such as difficulty lying flat, resistance to lying flat and difficulty with mobility also influenced decision making.

Case 22

“ Plan was for the patient to be transferred to ward and the CVAD removed before transfer...the patient was sitting out of bed.....the patient asked if the line could be taken out in the chair.....the clinician did not want to upset patient and push them back to bed”.. so removed the CVAD while the patient was sitting in the chair.

Case 23

The patient was sitting in a chair... “the family said that the patient was too heavy to move, taking several people to move them and to remove the CVAD while sitting out”

Near miss incidents (SAC2-4)

Fifty one near miss incidents where the notifier identified the risk of air embolism were identified. There were five key themes which are listed in Table 10. Limited comment can be made about these events due to the lack of detail about the circumstances in the narratives.

Table 10: CVAD near miss themes

Near miss incidents (SAC2-4)
1. Near miss disconnection
<i>“Whilst doing the bed check, and checking the central line, noted that the luer lock device was not attaching properly. This can lead to a total disconnection of the minimum volume extension set from the central and pose high risk of air embolism”.</i>
<i>“After attending CT scan, during which patient was moved from bed to bed and back, it was noticed that the R) CS CVC distal lumen was disconnected from the central line and opened to air”.</i>
2. Lumens left unclamped with no caps insitu
<i>“One lumen on the central line was left unclamped with no cap on, and fluid was leaking from this lumen. The patient became hypotensive and was at severe risk of an air embolus”</i>
<i>“The IV medication line was disconnected from CVC without clamping the CVC lumen. Immediately the line was clamped and aspirated to ensure air wasn't in the line”</i>
3. Cracked IV lines/lumens
<i>“The minimal volume extension set on the central noted to have cracked line at the male luer connector, the connection had a potential to disconnect from the central line with a risk of air embolism and infection”</i>
4. Air in line
<i>“At the commencement of the shift, the PICC line burette did not have enough fluids for what was dialed up on the machine, causing air to be in the line”.</i>
<i>“Two ten centimeter air emboli found in IV line. It had passed the machine (safety point) infusing directly into portacath”.</i>
5. Lumens being cut and tied off
<i>“On arrival it was noted that a left internal jugular vein central line was in-situ with inotropes running. It was also noted that one of the lumen hubs had been removed (? cut) and the lumen had been clamped off with artery forceps”.</i>
<i>“2 x lumens of Hickman's catheter accessed. Noted that one line was accessed with transfusion set which had one spike clamped and cut off with scissors. There was no seal or bung on the line at all. The line had been modified. Patient at risk of air embolism, line infection”.</i>

STRATEGIES FOR IMPROVEMENT

Following a review of the literature, and in collaboration with an expert clinician group, the following key actions have been identified to reduce the risk of air embolism from CVAD insertion and make care delivery of CVADs reliable and safe. The principals of these are also relevant to peripherally inserted central catheters.

At point of care

- Patient consent must include information about routine care and removal of the device to ensure patients/families are informed and empowered to support best practice.
- Decision support tools, including a requirement to document indication pre-insertion of a CVAD, should be implemented to ensure patients receive the most appropriate vascular access for their care requirements and risk factors. This strategy aims to decrease unnecessary insertion of CVADs and increase the awareness of risk associated with these devices.
- Attachments and connections used with CVAD that allow direct access of air and possible disconnection should be avoided. The report details many actual and near miss incidents involving human factors related to device usability.
- The requirement for the CVAD as a part of the ongoing patient care should be assessed daily. This aims to assist care planning, reduce the number of potentially no longer required CVADs and reduce time pressure associated with removal of CVADs just prior to transfer of care.
- Transfer of a patient between locations should not occur within 30 minutes of removal of a centrally inserted CVAD. The time factor is intended to support planning and increase the profile of the risk associated with the procedure and allow for compliance with policy and guidelines
- Time out and risk assessment with checklists at insertion and removal should be considered as a means to highlight to clinicians the key principles/risks associated with CVAD interventions. It aims to support improvement around knowledge based errors.

System wide

- Policy procedure and guidelines in NSW should be reviewed to ensure that consistent information which uses plain language is presented. This will remove the current inconsistencies within key guiding documents and confusion around terminology and practice.
- CVAD insertion, routine care and removal are advanced practice skills. Credentialing processes for all aspects of CVAD management should be embedded into clinical practice and include appropriate supervision and maintenance of proficiency.
- Engage industry, with a view to sourcing devices and connectors with bonded valves and other safety options (e.g. alert attached to CVAD).

The CEC is committed to working with its health partners to facilitate these improvements.

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APPENDICES

Appendix A

Severity Assessment Code of incidents

The SAC applied to the actual and suspected air embolism incidents and near miss events notified in IIMS from 1 January 2012 to 30 April 2015. The number of SAC1 air embolism events equates to 0.7 per cent (8 of 1138) of all incidents investigated by RCA during the time period under review.

**Allocation of the Severity Assessment Code (SAC)
to air embolism CVAD related IIMS notifications**

Severity Assessment Code	Air embolism actual / suspected applied SAC (<i>n=14</i>)	Air embolism near miss events applied SAC (<i>n=51</i>)
SAC1	8	0
SAC2	4	0
SAC3	1	21
SAC4	1	30

Appendix B

Case studies from the literature

Search Strategy: Database Medline

	Term/Limit	Number of records
1	Embolism, Air (keyword)	2353
2	English Language/Human (limit)	1844
3	Case reports (limit)	1136
4	2007-current (limit)	599
5	Catheterization, Central Venous (keyword)	9861
6	Combine 4 and 5	41
7	Hand search duplicates (2)	39
8	Exclusions - abstract or article review - <i>other procedures</i> (4) - <i>fictional case</i> (1) - <i>other language</i> (10)	24

	Author	Year Published	Gender	Age	Line position / type	Contributing	When	Signs and Symptoms	Differentials	Risk Factor	Impact
1	Bartolini L; Burger K [24]	2015	F	95	RIJ	30° head elevation	Removal	Respiratory distress, Hypertension, altered LOC, flaccid limbs	Stroke	Presentation included dehydration	Large neurological deficit
2	Chung H; Pleass HC; et al [25]	2014	M	67	Femoral		Insertion	VF arrest			Recovery
3	Jalota, L [26]	2013	F	Late 40s	R Femoral		Insertion			Respiratory failure	
4	Wosko, J [27]	2012		23	LSC- Triple lumen	15° head elevation	Removal	Coughing, forced expiration, SVT/ST changes, tachycardia, wide QRS, VF, collapse	Nil	Traumatic lung injuries - (tachycardia)	Recovery
5	Oyama, N [28]	2012	F	49	RIJ	Residual track in jugular vein	Removal	Unconscious, respiratory distress 6hr later limb numbness	Stroke		
6	Law AD; Gulati A; et al [14]	2012	F	60	RIJ		Insertion				Died
7	de Blauw, MH [29]	2012	F	46	LSC	Residual track	Insertion	Hypertension, headache, mandibular trismus, upward eye deviation, progressive LOC which resolved followed by motor deficit of all four limbs and persistent ocular disorders. Seizures			Resolved
8	Capozzoli, G [30]	2012	F	73	LIJ		Removal				Resolved
9	Pearson F; Browell C; et al [31]	2011	M	75	RIJ	Lumen lacerated/cut while upright (shaving)	Maintenance	Hypoxic, tachycardic tachypnoea, hypotensive	Nil	Pulmonary issues (COPD)	Resolved
10	Fracasso T; Karger B; et al [10]	2011	F	62	RIJ	Upright with probable disconnection		Dyspnoea, coma		Low BMI, pulmonary disease	
11	Clark DK; Plaizier E [32]	2011	M	84	RIJ	Gauze and tape as dressing only	Removal	Sudden collapse and seizures, respiratory distress	Stroke	Pulmonary issues, possible compromise to fluid state	
12	Badin J; Coudroy R; et al [33]	2011	F	20	RIJ	Tract not sealed (sutures insufficient)	Removal	Loss of consciousness, dyspnoea	Cardiogenic pulmonary oedema	Potentially hypovolemic	Resolved
13	Menon R; Allford M [34]	2010	M	72	IJ	Lumen lacerated/cut while upright (shaving)	Maintenance	Collapse, cardiac arrest	Nil		Resolved

	Author	Year Published	Gender	Age	Line position / type	Contributing	When	Signs and Symptoms	Differentials	Risk Factor	Impact
14	Kariya S; Tanigawa N; et al [35]	2010	M	65	RIJ (Hickman's)	Supine (not trendelengberg) during insertion	Insertion procedure	Respiratory distress	Nil	Pulmonary issues (pneumonia pneumothorax)	Resolved
15	Han SS; Kim SS; et al [21]	2010	M	85	RIJ	Undetermined	Insertion	Obtunded	Acute cerebral infarct	Hypovolaemia, pulmonary issues	Died
16	Cameli M; Lisi M; et al [36]	2010	F	46	RIJ	Line clamp insufficient? Large negative pressures PFO	Maintenance	Confusion dyspnoea tachypnoea tachycardic desaturation	Left hemiparesis	Low BMI, pulmonary issues (lung transplant)	Resolved
17	Zickler P; Hartung HP; et al [37]	2009	F	27	RSC	Upright with disconnection	Maintenance	Seizure and syncope			
18	Seeburger J; Borger MA; et al [38]	2009	F	50			Removal				
19	Eichhorn V; Bender A; et al [39]	2009	F	66	RIJ	Upright	Removal	Loss of consciousness	STEMI	Suboptimal volume	Resolved
20	Brockmeyer J; Simon T; et al [9]	2009	F	57	RIJ	Gauze and tape as dressing only	Removal	Dizziness, collapse, decerebrate posture and dyspnoea	CVA	? Suboptimal volume PFO	Ongoing morbidity - left weakness reduced mobility
21	Scruggs JE; Joffe A; et al [40]	2008	M	46	SC (Hickman's)	Unknown PFO	Maintenance	Shortness of breath, diaphoresis, confusion leading to unresponsiveness	CVA	PFO	Resolved
22	Ku SC; Wei YF; et al [41]	2007	M	49	RIJ		Insertion procedure		Pneumonia	Suboptimal volume	Died
23	Deceuninck O; De Roy L; et al [42]	2007	M	66	L	Suboptimal dressing	Removal	Breathless, somnolent, millwheel murmur	Nil		Resolved
24	Collyer TC; Yates DR; et al [43]	2007	M	41	RIJ	Open stopcock due to use of perforated manufacturers cap	Maintenance	Severe chest pain hypoxia respiratory distress haemodynamic compromise millwheel murmur	Nil	Low BMI	Resolved

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