Coroners Act, 1996
[Section 26(1)]

Western Australia

RECORD OF INVESTIGATION INTO DEATH

Ref No: 14/17

I, Evelyn Felicia Vicker, Deputy State Coroner, having investigated the death of ***Edith Catherine BEE*** *with an Inquest held at Perth Coroners Court, Court 58, Central Law Courts, 501 Hay Street, Perth, on 27 March 2017 find the identity of the deceased was* ***Edith Catherine BEE*** *and that death occurred on 4 September 2013 at Hollywood Private Hospital, as a result of Gas Embolism complicating surgical repair of an Atherosclerotic Aortic Aneurysm in an elderly lady with multiple co-morbidities:-*

Counsel Appearing:

Ms F Allen assisted the Deputy State Coroner

Mr D Bruns (instructed by Minter Ellison) appeared on behalf of Ramsay Health Care Australia Pty Ltd & Dr Daniel Heredia
Mr T Palmer (instructed by Avant Law) appeared on behalf of Dr Kishore Sieunarine

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INTRODUCTION

On 4 September 2013 Edith Catherine Bee (the deceased) underwent an endoluminal graft repair of an atherosclerotic aortic aneurysm after extensive investigations to assess her suitability for the procedure.

The procedure was carried out at Hollywood Private Hospital (HPH) by a vascular and general surgeon, Dr Kishore Sieunarine, under anaesthetic, and required the use of CO_2 and a contrast to assist with visualising of the blood vessels during repair of the aneurysm.

After about 1½ hours the deceased suffered a cardiac arrest and required resuscitation. While the anaesthetist was aspirating the central vein catheter he found gas in the tubing, and a cardiologist was called to assist. Dr Michael Davis also found gas in the femoral vein following access to the groin. She could not be revived.

The deceased was 80 years of age.

Following the deceased's death her family were anxious to understand what had happened and sought information from the hospital and Dr Sieunarine. It was some time before the post mortem examination results were finalised which frustrated the ability of the clinicians to be certain as

to the mechanism of the deceased's death, although they suspected gas embolism.

Once the cause of death was established the Office of the State Coroner (OSC) sought the input of an independent vascular surgeon to comment on the procedure carried out on the deceased. There was some criticism in that review of the technique used and the State Coroner determined a coroner should hold an inquest into the circumstances of the death, under section 22 (2) of the *Coroners Act 1996* (WA).

BACKGROUND

Hollywood Private Hospital (HPH)

HPH is a private hospital which provides medical facilities and resources to consultant medical practitioners and their patients who require hospital management. HPH provides theatre and nursing staff and has some resident medical doctors for the purposes of managing private patients, but largely relies on treatment to be directed by its visiting medical consultants. Medical consultants with admission rights are expected to abide by hospital procedures and protocols.

Provision of medical services to patients overall are provided jointly by the hospital, under the direction of the Director of

Medical Services (DMS) and the visiting medical consultants.[1]

In September 2013 Dr Daniel Heredia was the DMS for HPH and still is. He was called for the purposes of the inquest to explain the hospital's role and input surrounding the deceased's death on 4 September 2013.

The Deceased

The deceased was born on 1 June 1933 in Bunbury and was the second oldest of five children in the family. She advised her respiratory physician she had been placed in an orphanage from a young age.[2]

The deceased married at 18 years old and she and her husband had two children, a boy and a girl. Her husband died in 1998.

The deceased was involved with her local community throughout her life. On her children entering high school she joined the St John Ambulance Association to learn first aid, and then participated as a voluntary member in many community events. She undertook part time work and through that eventually ran a successful floristry business.

[1] t 27.03.17, p.53-54
[2] Ex 1, tab 10

The deceased was known to her family as a devoted mother and took her role as a grandmother very seriously, caring for her grandchildren in place of her daughter when her daughter died prematurely. The deceased was viewed by her family as very healthy, and had only been hospitalised to have her children, prior to the events of September 2013, although there is reference in the medical notes to various procedures which appear to have been in a hospital setting.

Medical Background

The deceased was diagnosed with osteoporosis in 1996, chronic obstructive pulmonary disease (COPD), diverticulosis, gastroesophageal reflux disease (GORD), hay fever, hypercholesterolemia, and hypertension, all within 2008, renal impairment and recurrence of pain from osteoporosis in 2009, and left ventricular hypertrophy and renal issues in 2011.[3]

In March 2013 the deceased had a CT scan for her spinal problems and co-incidentally a thoracoabdominal aortic aneurysm (TAAA) of 57mm was diagnosed in association with significant stenosis from atherosclerosis.

A TAAA is bulging and weakness in the wall of the aorta as it extends from the heart into the abdomen through the diaphragm. The aorta delivers oxygenated blood from the heart to the rest of the body. A TAAA can rupture, which

[3] Ex 1, tab 8

can cause life threatening uncontrolled bleeding very rapidly. Atherosclerosis plays a key role in the development of TAAAs.

The deceased was referred to a vascular and general surgeon, Dr Sieunarine, who noted her medical history placed her in a high risk category for corrective surgery by way of endoluminal graft.

An endoluminal graft is a technique which has been developed to repair an aneurysm by inserting a fabricated graft into the lumin of the effected blood vessel, in the vicinity of the aneurysm, to prevent its rupture. If the aneurysm is in an area from which other blood vessels originate then the branching of those vessels has to be accommodated by specific manufacture into the fabricated graft.

Dr Sieunarine first saw the deceased on 21 March 2013 and, due to her cardiac, renal and respiratory co-morbidities, Dr Sieunarine referred the deceased to consultants in all those specialties to assess her suitability for the proposed surgery, suggest ways to optimise her management, and also to familiarise the deceased with those specialists should their assistance be necessary in the future.[4]

[4] Ex 1, tab 14

The deceased had a left ventricular coronary angiogram on 28 March 2013 which found her left ventricular function to be well preserved with no withdrawal gradient across the aortic valve, and some mild irregularities in her coronary arteries.[5] Overall, Dr Richard Clugston, interventional cardiologist, assessed the deceased as *"fit to proceed to repair of her TAA"* … "*despite her multiplicity of risk factors*", from a cardiac perspective.[6]

Dr Kevin Warr, a renal physician, saw the deceased on 24 April 2013 and noted her impaired renal function with stage 4 renal disease.[7] Dr Warr discussed with the deceased the high risk of rupture of her aorta and death without surgery to repair the TAAA, and the issue with her renal disease and possible renal failure.[8] Dr Warr indicated he believed the deceased was suitable for endoluminal repair provided there was pre-hydration and the amount of contrast used for the procedure was reduced with close monitoring of the deceased's creatinine levels.[9] Dr Sieunarine explained the creatinine levels were to monitor renal function, the reduced contrast was necessary because iodine is the standard contrast material used and can damage kidneys further in a person with renal damage. The reduction in iodine is compensated for by the use of CO_2 as an imaging agent to assist visualisation during the

[5] Ex 1, tab 14 F
[6] Ex 1, tab 9
[7] Ex 1, tab 14
[8] Ex 1, tab 14 E
[9] Ex 1, tab 14 A

procedure. CO_2 is soluble in blood if used in small and safe amounts and is the recognised imaging agent used in these circumstances.[10]

The pre-hydration is achieved by filling the kidneys so they are at maximum excretion, and in this way protect and assist the kidneys in excreting the contrast material.[11]

Professor Bruce Robinson, consultant chest physician, reviewed the deceased to assess her asthma. He advised Dr Sieunarine the deceased suffered mild COPD arising out of her history of smoking and asthma, but that she was suitable for the intended surgery provided there was care taken with respect to post-operative infection (the deceased had a penicillin allergy) and her renal failure.[12]

Following all these specialists' review and advice with respect to the deceased's operative and post-operative care, Dr Sieunarine again spoke to the deceased and discussed with her the high risks of surgery, including the risk of death.

The deceased was determined to proceed and frustrated over the delays.[13] The delays included the necessary imaging to custom make a graft specific to her individual vessel configuration. The deceased's aneurysm was in an

[10] Ex 1, tab 14 A & D
[11] Ex 1, tab 14 A
[12] Ex 1, tab 10
[13] Ex 1, tab 14 A & D, t 27.03.17, p34

area of the aorta from which four significant blood vessels branched. The coeliac artery, superior mesenteric artery and both renal arteries needed to be accommodated by the graft.

This was never going to be a simple procedure. It was always going to be complex and time consuming. All of which increased the risk of surgery.[14]

Once the specifics of the surgery had been decided a two-part endoluminal graft was designed, with fenestration for the branching arteries, which would require cannulation of all four originating vessels and the insertion of stents.

The extent of the procedure necessitated the use of a large amount of contrast for imaging during the procedures. To reduce the amount used due to the deceased's renal impairment, CO_2 was to be used in conjunction with the standard iodine contrast, especially for the latter part of the procedure, to minimise the impact on the deceased's kidneys. This is standard for this procedure in patients such as the deceased, and was a procedure in which Dr Sieunarine had about 15 to 16 years experience in 2013. CO_2 is used because it dissolves quickly in the blood and is expired through the lungs.

[14] t 27.03.17, p37

Surgery

The deceased was admitted to HPH on 3 September 2013 under the care of Dr Sieunarine. She required a full medical work up including echocardiogram, routine bloods, chest X-ray and IV hydration. She was to be placed in ICU post operatively due to her comorbidities and the complexity and length of the procedures.[15]

Surgery commenced at about 8.00 am on 4 September 2013. Due to the extent of pre-operative workup for the deceased, Dr Sieunarine had already established the points at which he would inject CO_2 for imaging during the procedure for optimal safety. These were to be after the initial graft was placed in the distal thoracic aorta and CO_2 could be introduced below the dome of the diaphragm, while the intercostal arteries were covered by the first part of the graft.

The deceased was also to be provided with a spinal catheter to reduce spinal cord pressure by draining cerebral spinal fluid before insertion of the graft but post general anaesthesia, while in the supine position.[16]

In order to administer the CO_2 injections at appropriate times and in appropriate amounts, Dr Sieunarine had designed a customised two-way tap to control the flow of

[15] Ex 1, tab 13
[16] Ex 1, tab 14 D

CO_2 from the pressurised cylinder to a syringe, and then separately from the syringe into the patient's vessels. There is a Therapeutic Goods Administration (TGA) approved commercial kit available which achieves the same result which comes in one system (OptiMed), but in Dr Sieunarine's experience it frequently broke, necessitating a change in kit. Dr Sieunarine did not experience this delay in his own customised system which required a separate two-way tap to be attached between the syringe and cylinder.

While setting up the CO_2 delivery system Dr Sieunarine was advised there was not a separate two-way tap available in the theatre. He was offered a three-way tap as an alternative which he accepted.[17]

The dynamics of the three-way tap and the customisation necessary to achieve delivery of CO_2 from the pressurised cylinder, to the syringe, and then catheter allowed direct delivery of pressurised CO_2 into the catheter, if one of the taps was accidentally allowed to open. This is not possible with the customised two-way tap, or the sealed commercial two-way system.

Dr Sieunarine was aware of this but, because he was in control of the system, did not believe he would erroneously control the taps which he tested before use to ensure a

[17] Ex 1, tab 14 D

closed system. He tested the system for leaks and thoroughly flushed the system to remove residual atmospheric air. Dr Sieunarine believed there would be no direct connection between the pressurised CO_2 cylinder and the catheter to the deceased.[18]

Once the deceased was appropriately in theatre, Dr Sieunarine and the anaesthetist commenced and continued with the procedure as had been planned. The first part of the graft was placed in the distal thoracic aorta and the CO_2 delivery system used as planned, below the dome of the diaphragm, during the procedure to visualise the placing of the second part of the graft within the aorta.

The three way tap delivery system was placed beside the deceased at times when not in use with the taps turned off. The procedure is conducted via cameras and the surgeon's attention is on the screens during the procedure.

The deceased's parameters were stable until about 10.10 am when the consultant anaesthetist, Dr Ramin Gharbi, noticed the monitors showed an increase in her pulse rate to 75/min, SBP 130/100 mmHg, airway pressure to 30cm H_2O, so provided 20mg of Rocuronium to assist her breathing.[19]

[18] Ex 1, tab 14 D
[19] Ex 1, tab 15

A total of 160mls of CO_2 had been provided in 40ml aliquots in place of contrast during the procedure to that point.[20]

The deceased arrested and aggressive resuscitation was commenced while efforts were made to try and assess what had happened, including an open incision to see if there was evidence of a ruptured blood vessel. Dr Gharbi aspirated 400mls of gas from the central venous line before blood could be aspirated and there was concern about the placement or migration of the catheter tip into the thorax. CO_2 levels were recorded as rising and the assistance of a cardiologist was urgently requested in theatre.

Dr Michael Davies, cardiologist, instructed the deceased be tilted head down as he suspected an air/gas embolism.[21] There was no ECG evidence of cardiac electrical activity and Dr Davies also aspirated air/gas from the femoral vein when he placed a line in an attempt to introduce a pacing lead to the heart to achieve a cardiac response.[22] Ultrasound was unsuccessful in visualising the heart and spontaneous rhythm or output was never achieved.

Resuscitation attempts were ceased and the deceased's family were advised of the death.[23]

[20] Ex 1, tab 15
[21] Ex 1, tab 16
[22] Ex 1, tab 16
[23] Ex 1, tab 14

In his report to the coroner of 18 October 2013, Dr Sieunarine explained that he had been solely responsible for administering the CO_2 to the deceased and for turning the tap on and off. The only other person who may have come into contact with the CO_2 delivery system was, potentially, the scout nurse, but that person would not be responsible for operating the tap. Dr Sieunarine could only explain the high CO_2 levels recorded as the tap having been accidentally knocked during the procedure and so allowing CO_2 to flow directly into the deceased. Because of the dynamics of the system, this would have been under pressure, and resulted in her death.[24]

Dr Heredia and Dr Sieunarine met with the family of the deceased on 5 October 2013 and explained they suspected this was the reason for the deceased's death but could not confirm it because the post mortem results were not finalised.

POST MORTEM REPORT

The post mortem examination of the deceased was carried out by Dr D Moss, forensic pathologist, at PathWest Laboratory of Medicine, WA on 6 September 2013.[25]

Dr Moss found extensive evidence of medical intervention, including stents in the aorta. There was severe hardening

[24] Ex 1, tab 14 & t 27.03.17, p26-28
[25] Ex 1, tab 17

(atherosclerosis) of the aorta with a swelling (aneurysm) and apparent gas within the heart. Dr Moss was not in a position to determine the cause of the deceased's death without further investigation and the preliminary diagnosis was undetermined. As part of the further investigation Dr Moss asked for medical reports to try and elucidate the history of the medical intervention in particular.

Dr Sieunarine provided a detailed preliminary report to the OSC in October 2013 in which he described the deceased's medical history as well as the attempted repair of the aortic aneurysm.[26] These reports are provided confidentially to the OSC for the purposes of the investigation and are not provided to other parties without specific authorisation.

Following microscopic examination of the tissues, Dr Moss confirmed emphysematous changes in the lungs and chronic kidney disease. Neuropathology did not reveal significant abnormalities in the brain, and toxicology showed prescription medication consistent with the deceased's medical history.

The post mortem findings, medical history and operative report from Dr Sieunarine satisfied Dr Moss that during the course of the endoluminal aneurysm repair a large volume of gas had entered the deceased's circulation leading to a fatal cardiac arrest.

[26] Ex 1, tab 14 A

On 31 March 2014 Dr Moss gave the cause of death of the deceased as, *"Gas embolism complicating surgical repair of an atherosclerotic aortic aneurysm in an elderly lady with multiple co-morbidities".* This was communicated to the family by letter on 15 April 2014.

It was not possible to determine from the post mortem examination which gas was responsible for the embolism, although the circumstances of the repair procedure would make it likely it was CO_2.[27]

REVIEW BY DR JOHN TEASDALE

The OSC asked an endovascular and specialist vascular surgeon, Dr John Teasdale, to review the medical management of the deceased for the endoluminal aneurysm repair which necessitated a custom made, fenestrated two piece graft which involved the coeliac, superior mesenteric and two renal arteries.

Dr Teasdale was critical of the methodology of the procedure, which he accepted would need CO_2 to assist in imaging due to the deceased's renal disease. Overall, Dr Teasdale believed surgery should not have proceeded in view of the deceased's serious underlying comorbidities.[28]

[27] Ex 1, tab 14 A
[28] Ex 1, tab 7, t. 27.03.17, p12

The critical issue was the ability for CO_2 to be delivered directly to the deceased's vascular system, under pressure from the CO_2 cylinder, and by-pass the syringe.

Dr Teasdale was also concerned the length and complexity of this particular procedure was especially risky for the deceased due to the need to cannulate and stent the renal arteries where renal function was already an issue. He was concerned about the position of the deceased during the procedure, prior to resuscitation, and the delivery of CO_2 in the vicinity of the diaphragm. He agreed CO_2 is an accepted, and very useful, aid in imaging and angioplasty in vascular procedures, provided sufficient care, knowledge and precautions surround its appropriate use.

Dr Teasdale also referred to gas delivery systems in use in other countries which are not TGA approved for use in Australia.[29] This was confirmed by Dr Sieunarine,[30] who also pointed out the flow of CO_2 from the cylinder was not uncontrolled, but set at a pre-determined volume via a regulator.[31]

Shortly prior to the inquest Dr Sieunarine provided an additional report to the OSC in which he detailed his use of

[29] t 27.03.17, p12
[30] t 27.03.17, p31, 33
[31] t 27.03.17, p40

a three-way tap during the procedure, instead of his preferred two-way tap.[32]

Dr Sieunarine accepted the three-way tap had allowed for the potential of a direct injection of CO_2 under pressure, to the deceased's vascular system. This could not occur with a two-way tap with a proper locking mechanism between the CO_2 cylinder, syringe and patient. He believed this must have occurred accidentally during the procedure when the delivery system was placed alongside the deceased while not in use. He was certain he had properly turned off the taps at the appropriate times when he used CO_2 for imaging. He was very aware of the dangers of the direct injection of CO_2 into a patient, under pressure and in unsupervised amounts. It was because of these concerns he had customised his own delivery system utilising the two-way tap.

Dr Teasdale remained of the view surgery should not have proceeded for the deceased with the system used.[33]

MANNER AND CAUSE OF DEATH

I am satisfied the deceased died as a result of gas embolism complicating surgical repair of an atherosclerotic aortic aneurysm, and that the deceased's age and multiple comorbidities necessitated the use of CO_2 in conjunction

[32] Ex 1, tab 14 D
[33] t 27.03.17, p12

with standard contrast to visualise the vascular system appropriately during the procedure.

Dr Sieunarine accepted use of the three-way tap, not his usual preferred method for the delivery of CO_2 during angioplasty, allowed CO_2 to accidentally enter the deceased's vascular system in an unsupervised and pressurised manner. This caused a fatal gas embolism and her death.

I find death occurred by way of Misadventure.

CONCLUSIONS AS TO THE DEATH OF THE DECEASED

Appropriateness of Surgery

The deceased's lifestyle, despite her age, meant she was, and wished to be, an active participant in her community. She was not a person who would wish to be uninvolved and non-contributory to those around her. While I accept the deceased had seldom been hospitalised, despite her established comorbidities, I am satisfied the deceased would not wish to live her life in such a way as to be consistently in fear of the rupture of her TAAA once she was aware of it, and that repair was her only acceptable option.

I am satisfied Dr Sieunarine advised the deceased of the considerable risks involved in both repairing and not repairing her TAAA, including death. He required she

undergo a review by three consultants with respect to each of her greatest areas of vulnerability. This must have further impressed upon the deceased she was at risk with respect to the specific surgery necessary, and that risk included death.[34] This was also one of the risks of failing to have the repair.

While I note Dr Teasdale's concern the advising consultant physicians were not aware of the detail, or the extent of the necessary repair, at the time of their assessments the deceased was fit to undergo surgery, I am not of the view that would have altered those assessments. I accept the length and complexity of the procedure further exposed the deceased to the risk of an accidental error.[35]

It was the accidental introduction of CO_2 directly into the deceased's vascular system, in an unsupervised manner, which caused the death. The use of CO_2 was necessary due to the deceased's pre-existing co-morbidities and it was also her pre-existing co-morbidities which made the procedure long and complicated.

I am satisfied Dr Sieunarine no longer contemplates the use of any CO_2 delivery system, other than the TGA approved OptiMed.[36] This device has a locking system which does not allow CO_2 to enter the vascular system under pressure or in

[34] Ex 1, tab 14 E & F
[35] t. 27.03.17, p 9
[36] Ex 2

an unsupervised manner. It is similar to Dr Sieunarine's customised delivery system using a two-way tap, but not solely reliant on human input as to the locking component, although it can be prone to requiring replacement during a long procedure.

I am unaware as to whether TGA have now approved any other CO_2 delivery systems, as noted by Dr Teasdale and Dr Sieunarine.

I am also satisfied HPH has reviewed its theatre resources and now only provides or allows TGA approved CO_2 delivery systems to its visiting physicians when using HPH facilities.[37]

I note it was not entirely clear from the evidence as to the availability of OptiMed in theatre on 4 September 2013, but am satisfied it was Dr Sieunarine's preference to customise a CO_2 delivery system due to his experience use of OptiMed could prolong an already complicated procedure.[38]

Communication with the Family

I accept, as confirmed by the deceased's son, Mr Roland Bee, that at the time of the deceased's death both Dr Sieunarine and Dr Heredia spoke to the family in an

[37] Ex 1, tab 13 A & C
[38] t 27.03.17, p29/30 & 52

attempt to explain the possible/probable cause of the deceased's death.

I further accept that due to the fact the death of the deceased was a reportable death (s.3(b)) under the *Coroners Act 1996* (WA), it was difficult for Dr Heredia, on behalf of HPH, to confirm the cause of death before finalisation of the cause of death by OSC. Due to the circumstances of the death there was some delay before this could be done despite the cooperation of Dr Sieunarine in providing a detailed report of the procedure. That report was for the purposes of the coronial investigation and not available for distribution to the family of the deceased, by anyone other than Dr Sieunarine.

A coronial investigation relies on input from a number of sources before it is finalised and provided to a coroner in a completed format suitable for assessment. It is regrettable that delay caused the family of the deceased to feel they were being denied answers by HPH. HPH is not responsible for its visiting consultants and Dr Sieunarine did not realise the family wished to speak to him further.

It is difficult for a consultant surgeon, in Dr Sieunarine's position, following the death of a deceased to confirm a cause of death. Dr Sieunarine had offered to speak to the family, but did not hear from them. This would have made him unsure as to whether they wished his input. OSC does

not make reports provided to it for the purposes of an investigation available to families unless the consent of the source of the report had been obtained or an inquest is on foot.

The steps taken by HPH and Dr Sieunarine to ensure only TGA approved CO_2 delivery systems are to be used in theatre appear appropriate.

The deceased's death took her family by surprise and she is sorely missed by her son, four grandchildren and six great grandchildren.

E F Vicker
Deputy State Coroner
3 May 2017