STATE CORONER'S COURT
OF NEW SOUTH WALES

Inquest:	Inquest into the death of Ida Romeo
Hearing dates:	9-12 February 2016
Date of findings:	8 April 2016
Place of findings:	State Coroners Court, Glebe
Findings of:	Magistrate Derek Lee, Deputy State Coroner
Catchwords:	CORONIAL LAW – cause and manner of death, Liverpool Hospital, cardiology, constrictive pericarditis, pressure wire, mechanical aortic valve, consent
File number:	2012/210648
Representation:	Mr I Bourke SC, Counsel Assisting the Coroner instructed by Ms B Haider
	Mr D Baran for Mrs Romeo's family
	Ms K Burke for Dr S Lo
	Ms L Boyd for South Western Sydney Local Health District
	Mr A Davey for Dr K Rachakonda
	Mr N Dawson for NSW Nurses & Midwives' Association
	Mr C Jackson for Associate Professor B French
	Mr M Lynch for Dr K Leow

Findings: I find that Ida Romeo died on 5 July 2012 at Liverpool Hospital, Liverpool NSW 2170 during a medical procedure when a pressure wire became trapped in her mechanical aortic valve causing it to malfunction. The cause of death was acute cardiogenic shock, with acute mechanical obstruction of a remote mechanical aortic valve replacement and intraprocedural displacement of a cardiac catheterisation wire across the valve being antecedent causes.

Recommendations: ***To the Director, Medical Services, Liverpool Hospital:***

I recommend that consideration be given to having an appropriately qualified medical practitioner prepare a summary of, or article about, Ida Romeo's case for submission to an appropriate medical journal and/or circulation to other cardiology departments in NSW hospitals, contingent upon Mrs Romeo's name not being published.

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Introduction

1. Mrs Ida Romeo was a beloved wife, mother and grandmother. She loved nothing more than to be surrounded by her family. She took great joy in caring for them, cooking for them and being surrounded by their adoration for her.

2. Sadly, Ida's quality of life in her later years was affected by a number of serious health issues, including heart disease. Ida underwent a medical procedure on 5 July 2012 at Liverpool Hospital. It was hoped that the procedure would provide information that would help improve Ida's condition. Tragically, Ida died during the procedure. This inquest has examined the circumstances of Ida's death.

The role of a Coroner and purpose of this inquest

3. Section 81(1) of the *Coroners Act 2009* (the Act) requires that when an inquest is held the coroner must record his or her findings as to various aspects of the death. These are the findings of an inquest into Ida's death[1].

4. The role of a Coroner, as set out in section 81 of the Act, is to make findings as to:

   (a) the identity of the person who died;
   (b) the date and place of the person's death;
   (c) the physical or medical cause of death; and
   (d) the manner of death; in other words, the circumstances surrounding the death.

5. Section 82 of the Act allows a Coroner to make recommendations concerning any public health or safety issues arising out of the death in question.

The life of Ida Romeo

6. On the last day of the inquest, the court was honoured and privileged to hear some heartfelt and moving words spoken by Ida's daughters about their mother's life. A few paragraphs on paper do not do justice to how much Ida meant to her family, and how much she is missed, but I will attempt to provide the following very brief glimpse into Ida's life.

7. Ida was born in Italy on 8 June 1953. She migrated to Australia in 1972. She was the loving wife of Charlie Romeo and together they raised four children: Josie, Fran, Bruno and Tony.

8. Ida was a very spiritual person and was known for her love of her faith. She was a modest, kind, and sensitive person. Her daughters said that she often fussed over Charlie and cared deeply for him. They described Ida as someone who was very humble and who graciously never accepted thanks from anyone.

[1] These findings have been prepared without the benefit of a transcript of the proceedings.

9. Ida loved her family most of all. Monday nights in the Romeo household was family night. It was a time for feasting, for celebration and for tradition. This was when Ida was at her happiest, being surrounded by her husband, children, grandchildren and other friends and family. Having her noisy grandchildren around her just made Ida feel young and she delighted in their company.

10. The family were at their happiest too, enveloped by Ida's love and well fed by her wonderful, rustic, Southern Italian cooking. Family nights will not be the same without Ida but it is something the family have continued in her honour. It is distressing to know that Ida's grandchildren will miss spending time with their grandmother and be deprived of the love which Ida so warmly had for all of her family.

Ida's medical history

11. Unfortunately, Ida suffered from a number of serious health problems in her later life. Many of the problems related to her heart. In 2002 Ida experienced heart palpitations and chest pain and she was found to have an ejection systole murmur (turbulent blood flow). Her general practitioner, Dr Pasquale Romeo, referred Ida to a cardiologist, Dr Newman, who diagnosed her as having moderate to severe aortic stenosis (abnormal narrowing of the aortic valve).

12. Ida eventually had surgery on 30 September 2002 to try to address the problem. Associate Professor Bruce French, a cardiothoracic surgeon, carried out a procedure which involved the insertion of an artificial mechanical aortic valve (MAV) in Ida's heart.

13. Ida had further heart issues in 2003 and 2004, and in 2010 she developed renal (kidney) impairment. Two years later, she experienced further health problems, including shortness of breath and chest pains. Ida was referred to a number of specialists for a variety of investigations. One of those specialists was Dr Greg Conner, cardiologist.

14. It was suspected that Ida had a condition known as constrictive pericarditis (CP), or inflammation of the pericardium. The pericardium is the membrane, or sac, that surrounds the heart. CP is a condition where the heart is constricted and prevented from filling, which in turn restricts blood output.

15. With this in mind Dr Conner performed a transthoracic echocardiogram on 6 March 2012 hoping to identify the cause of Ida's heart problems and confirm whether or not she was suffering from CP. The results of the procedure were forwarded to Associate Professor French to review.

16. CP is treated with a procedure known as a pericardiectomy. This involves surgical removal of part, or all, of the pericardium. It was critical to establish whether or not Ida had CP for two reasons. Firstly, Ida's symptoms suggested that she may have been suffering from a different condition called restrictive cardiomyopathy (RC). In this condition, the walls of the heart chambers are atypically rigid which prevents them from filling normally, causing reduced blood flow. Whilst surgery can usually correct CP, it cannot be used to correct RC.

17. Secondly, Ida's condition meant that surgery would be a major undertaking for her. Associate Professor French was reluctant to proceed with a pericardiectomy without a clear diagnosis of CP.

18. After discussion, Dr French and Dr Connor agreed that Ida should have a transoesophageal echocardiogram (TOE). This is a procedure where sound waves are used to create images of the heart and blood vessels. Dr Sidney Lo performed the TOE at Liverpool Hospital on 13 April 2012. The TOE proceeded without any complications but the results from it were regarded as being inconclusive.

19. Associate Professor French and Dr Lo agreed that a more invasive procedure was required to hopefully confirm the suspected diagnosis of CP. As a result, Ida was referred for a procedure known as a right heart study with fluid loading. The aim of the study was to measure pressure in Ida's right ventricle. This is the chamber of the heart from which oxygen-depleted blood is pumped to the lungs via the pulmonary artery. The left atrium and left ventricle receives oxygen-rich blood from the lungs. From there it is pumped through the aorta to the rest of the body. Fluid loading (or fluid challenge) is a reference to a test where saline is introduced intravenously and measurements are taken of changes in heart pressure caused by this introduction.

20. In order to perform the right heart study a procedure called a right heart catheterisation was required. This involves the surgical insertion of a catheter (a thin, flexible tube) into a vein which is then guided to the right side of the heart. It was hoped that the pressure measurements taken during the study would confirm whether or not Ida had CP.

What happened on 18 June 2012?

21. Ida saw Dr Leow Khang Leng at the Cardiac outpatient clinic at Liverpool Hospital on 18 June 2012. At the time, Dr Leow was a visiting cardiologist from Singapore who was completing his Fellowship in interventional cardiology at Liverpool Hospital.

22. Dr Leow explained to Ida what was involved with a right heart catheterisation. He also explained to Ida that there was a 0.1% to 1 % risk of complications which included bleeding, stroke, kidney failure and death.

23. Ida signed two consent forms on 18 June 2012. The first form was a generic form titled ***Request/Consent for Medical Procedure/Treatment***. The procedure to be performed was handwritten on the form by Dr Leow and was recorded as "(R) heart study". The second form was a more specific consent form titled ***Cardiac Catheterisation Consent***.

What happened on 5 July 2012?

24. Ida arrived at Liverpool Hospital with her daughter, Francesca, at about 6:00am on 5 July 2012. Francesca asked if she could stay with her mother but was told that it was against

hospital policy.[2] Francesca was told to call back at midday. When she did so she was told that the procedure had not started yet. Francesca called back on a number of further occasions and each time was told that the procedure had not started as emergency matters were taking priority.

25. At about 8:15am a nurse, Ms Sezana Tamid, saw Ida in the Cardiac Catheter Laboratory (commonly referred to as the cath lab). The cath lab consists of four rooms where procedures are conducted, a control room which has a view into each of the procedure rooms, and a recovery room. Ms Tamid carried out some observations which were unremarkable. A routine electrocardiogram (ECG) was performed on Ida, and samples of her blood were taken and sent to pathology. At about 2:00pm Ms Tamid measured Mrs Romeo's blood sugar level.

26. At about 3:10pm another nurse, Ms Jacqualine Downey (nee Lord), completed the "timeout procedure" with Ida. This is a procedure to confirm that a patient's details are correct, to check whether a patient has any allergies, and to check that a patient's consent forms have been completed and signed.

27. The procedure began at approximately 3:30pm. By prior arrangement, a sonographer and an echocardiography machine were present to assist with the procedure. Dr Leow began inserting a catheter into Ida's femoral artery in order to perform a coronary angiogram (an x-ray to examine the coronary arteries) to check Ida's blood supply. This procedure was uneventful and revealed that Ida's coronary arteries were in good condition.

28. Dr Leow then accessed Ida's femoral vein in order to perform the right heart catheterisation with fluid loading. A litre of normal saline was introduced during the study to assess haemodynamic changes (changes in blood flow).

29. After the right heart study, Dr Lo noted that Ida's right ventricle (RV) pressure was slightly elevated but considered that the pressure was already fairly high before the procedure. Dr Lo formed the opinion that the test results were insufficient to make a conclusive diagnosis of CP.[3] Dr Leow agreed with this assessment. Dr Lo sought a second opinion from Dr Leung, the director of the cath lab. Dr Leung was not available as he was involved in another procedure at the time.[4]

30. Dr Lo decided that in order to obtain sufficient evidence to confirm, or reject, a diagnosis of CP, a simultaneous measurement of Ida's RV and left ventricle (LV) pressure was required. This was regarded as the "gold standard" test for diagnosing the presence of CP. The catheter was already in place to measure pressure in the RV. What was now required was measuring the pressure in Ida's LV at the same time using a device known as a pressure wire. This was a type of catheter, that is much thinner (0.036cm in diameter) than an ordinary catheter, with sensors to measure blood pressure. It was agreed that Dr Leow would perform the procedure involving the pressure the wire whilst Dr Lo supervised.

[2] Exhibit 1, page 153.
[3] Exhibit 1, page 85.
[4] Ibid.

31. At about 4:00pm Dr Leow, with the aid of fluoroscopy (x-ray imaging), passed a guiding catheter to the ascending aorta. He then attempted to pass the pressure wire across the MAV. Unfortunately, the pressure wire became caught in the valve almost immediately. This caused the valve to jam shut. The catastrophic result was that output of blood from Ida's heart was completely shut off, causing cardiac arrest.

32. Dr Lo instructed Dr Leow to remove the pressure wire but Dr Leow felt resistance on the wire and was unable to do so. Dr Lo took over the procedure and attempted to advance the catheter to free the valve, whilst at the same time attempting to gently withdraw the wire. Neither attempt was successful, and the pressure wire remained stuck in the MAV.

33. After a short period of time the tip of the pressure wire broke, leaving a small fragment caught in the MAV. This caused the MAV to stop functioning in the closed position leaving Mrs Romeo with no cardiac output. Cardiopulmonary resuscitation (CPR) was immediately commenced.

What was done to try to resuscitate Ida?

34. A call was made to the hospital's Medical Emergency Team (MET) at about 4:02pm. The MET arrived in the cath lab about 5 minutes later. Dr Saradha Srinivasan, the Intensive Care Unit (ICU) registrar, together with nurses Margaret Nicholson and Nicholas Mifflin, attended as part of the team. Ryan Walker, another nurse, was not part of the MET but attended to assist. The MET continued CPR and Dr Srinivasan intubated Ida with an endotracheal (breathing) tube (ETT). Intubation was straight forward but Dr Srinivasan saw blood through the ETT. By this time, Ida had no cardiac output for about 10 minutes.

35. Whilst the MET performed CPR, Dr Lo tried multiple times with different catheters to dislodge the wire and re-activate the MAV. Eventually the wire fragment dislodged and passed into the region of the femoral artery. At this stage monitors showed that Ida was registering blood pressure and sinus rhythm.

36. Further rapid intravenous (bolus) doses of adrenaline were given to Ida, resulting in the spontaneous return of circulation, restoration of cardiac output and a heart rate. By this stage Ida had had no cardiac output for about 25 minutes.[5] At some stage, Dr Srinivasan called Dr Kanaka Rachakonda, the ICU staff specialist. Dr Rachakonda instructed Dr Srinivasan to continue CPR with the MET, to keep him updated regarding Ida's condition, and to page him if he was required.

37. Ida later suffered a second cardiac arrest and had no cardiac output for a further 5 minutes. The MET again performed CPR and Ida was given a further dose of adrenaline. Dr Rachakonda arrived in the cath lab at about 4:45pm. He saw that Ida had a large amount of blood coming from her ETT, which suggested the likelihood of pulmonary haemorrhage (bleeding from the lungs).

[5] Exhibit 1, page 125.

38. Ida had a third cardiac arrest and CPR was continued for a further 2 minutes. An emergency echocardiogram showed no evidence of pericardial effusion (abnormal build-up of fluid around the heart). A chest ray showed that the ETT was placed correctly and that there were no pneumothoraces (abnormal collection of air or gas in the space between the membranes surrounding the lungs).

39. Ida had a fourth cardiac arrest and ICU staff continued with CPR for a further 20 minutes. Ida remained unresponsive. Dr Lo and Dr Rachakonda discussed Ida's condition and decided that further resuscitation attempts would not be useful. By this stage, almost 90 minutes had passed since Ida first went into cardiac arrest. Resuscitation attempts stopped and, tragically, Ida was declared deceased at 5:30pm.

The issues at inquest

40. Ida's identity, where she died and the date of her death are not in issue.

41. Dr Rebecca Irvine, forensic pathologist, performed an autopsy on 9 July 2012. Dr Irvine reached the conclusion that the direct cause of Ida's death was acute cardiogenic shock. Dr Irvine also found that acute mechanical obstruction of a remote mechanical aortic valve replacement and intraprocedural displacement of a cardiac catheterisation wire across the valve were antecedent causes.[6] The cause of Ida's death is therefore also not in issue.

42. This inquest has investigated the manner of Ida's death and a number of issues associated with it. The issues are as follows:

    (a) Was it appropriate to refer Ida for a right heart study?
    (b) Was appropriate consent given by Ida on 18 June 2012?
    (c) Why was Ida not allowed to have anybody stay with her on 5 July 2012?
    (d) What was the reason for the delay on 5 July 2012?
    (e) Was appropriate consent given by Ida on 5 July 2012?
    (f) Did Ida withdraw her consent in the procedure room?
    (g) Were any alternative procedures available?
    (h) Were the procedures carried out on 5 July 2012 necessary and appropriate?
    (i) Were the procedures on 5 July 2012 carried out appropriately?
    (j) Was the response of the Medical Emergency Team appropriate?

43. The inquest received written, and heard oral, evidence from two independent interventional cardiologists, Dr Peter Hansen and Associate Professor Harry Lowe. Their evidence considered a number of the issues referred to above.

44. I will consider each of these issues in turn.

[6] Exhibit 1, tab 2.

Issue 1: Was it appropriate to refer Ida for a right heart study?

45. On 6 March 2012, Dr Conner wrote to Associate Professor French outlining some of Ida's symptoms and commented that "this seems to relate to constrictive pericarditis".[7] Dr Conner expressed his feeling that Ida's symptoms "most likely relate to the pericardial change". Finally, Dr Conner indicated that Ida had not had a right heart catheter at that stage but said, "I think the clinical picture is such that we appear to already have the diagnosis".

46. Associate Professor French explained in evidence that when he saw Ida in April 2012 there was no definitive diagnosis of CP and that the available information was insufficient to justify a pericardiectomy. This prompted his request for a TOE to be performed.[8] This procedure did not produce definitive evidence of constriction.[9] It was suggested that an invasive procedure to examine blood flow would be helpful. Dr French therefore requested the right heart study, expressing his reluctance to operate unless he could actually improve Ida's condition.[10]

47. Due to the similar presentation of both CP and RC, and the differences in how each is treated, it was critical to obtain sufficient evidence to allow for a definitive diagnosis. Although Dr Conner expressed the thought that a diagnosis of CP was available as at March 2012, his reference to a right heart catheter strongly suggests the option of using this procedure to obtain a definitive diagnosis.

48. Dr Hansen explained that a definitive diagnosis of CP could be obtained from three sources: clinical findings, non-invasive imaging, and invasive haemodynamic assessment.[11] Examples of non-invasive imaging include: TTE, TOE, cardiac computed tomography (CT) scan and cardiac magnetic resonance imaging (MRI). Examples of invasive haemodynamic assessment include: right and left heart catheterisation.

49. In evidence Associate Professor French said that he did not consider the option of using either cardiac CT or MRI, and explained that neither procedure was commonly used or available at Liverpool Hospital in 2012. Associate Professor French went on to say that he did not think that CT was capable of providing an accurate diagnosis of CP, but that it may have been possible with use of state-of-the-art MRI. However, Associate Professor French explained that he had never previously diagnosed a patient with CP using MRI, and that in all cases he had used invasive pressure monitoring.

50. Associate Professor French was asked about the post-mortem finding of generalised pericardial fibrosis[12] (thickening of the pericardium) and whether that confirmed the presence of CP. Dr French explained that the fibrosis is consistent with CP but that the condition itself is a physiological phenomenon that can only be measured in a functioning heart.

[7] Exhibit 1, page 241.
[8] Exhibit 1, page 428.
[9] Exhibit 1, page 437.
[10] Exhibit 1, page 443.
[11] Exhibit 1, page 41.
[12] Exhibit 1, page 20.

51. In his evidence Dr Hansen acknowledged that cardiac MRI testing is more widely used today[13] than in 2012. Both he and Associate Professor Lowe agreed that non-invasive imaging could help confirm, or reject, the diagnosis of CP, but could not replace the need for invasive testing. Dr Hansen described non-invasive imaging as additional testing that could add to the clinical picture, but not as an alternative to invasive assessment. Associate Professor Lowe explained that even if an MRI showed an abnormality consistent with CP, invasive haemodynamic confirmation would still have very likely been required.[14]

52. Associate Professor French exercised appropriate caution in seeking to obtain a definitive diagnosis of CP before considering surgery. A pericardiectomy would not help Ida unless she had CP. The procedure itself would have been a major undertaking for Ida with increased risk to her if complicating factors, such as calcification, were found. Having considered the clinical findings and the results of non-invasive imaging, the next step in the testing process was invasive haemodynamic assessment. As explained by Dr Hansen and Associate Professor Lowe, further non-invasive imaging by CT and MRI would not have provided definitive evidence of CP. For these reasons, it was appropriate to refer Ida for a right heart study.

Issue 2: Was appropriate consent given by Ida on 18 June 2012?

53. Dr Leow believes that Ida had a relative with her on 18 June 2012 when he saw her at the cardiac outpatient clinic. There is no other evidence to establish whether this was the case or not. In any event, there is no evidence to suggest that Ida had any difficulty understanding either the oral explanation given by Dr Leow, nor the content of the forms that she signed.

54. The first form[15] signed by Ida, titled ***Request/Consent for Medical Procedure/Treatment***, is clearly a generic form used at Liverpool Hospital for a number of different procedures. No specific treatment or procedure is nominated on the form. It only requires the person taking consent to handwrite on the form the actual procedure or treatment being consented to. In Ida's case this was a right heart study.

55. The form is deficient for two reasons. Firstly, the section titled "Patient Consent" contains an acknowledgment by the patient that a doctor has told the patient a number of things, namely what the procedure may involve (in broad terms) and that there are risks associated with it (again in broad terms). The section concludes with the words, "I request and consent to the procedure/treatment described above for me". One might logically expect that immediately below these words there would be an area for a patient to sign their name and date the form. There is no such area. Instead, there is a box in which a patient can record their refusal to any aspects of the procedure. In fact, on the entire form there is no area for a patient to actually give their consent, by signing and dating the form, to the procedure that is to be performed.

56. Secondly, the only area on the form where a patient may sign and date it relates to giving consent for anaesthetics, medicines, other treatments and a blood transfusion. This is the section which Ida signed. However, even this section of the form is problematic because it

[13] As at the date of the inquest in February 2016.
[14] Exhibit 1, page 56-5.
[15] Exhibit 1, page 118.

allows a patient to indicate (by striking out certain words) whether they do or do not consent to a blood transfusion. In Ida's case, this was left completely ambiguous because one of the two alternatives was not struck out.

57. The second form[16] signed by Ida is titled ***Cardiac Catheterisation Consent***. There is information on the form explaining to the patient what the procedure involves and what the risks are. There is, however, no mention of the risk of death. However, I accept Dr Leow's evidence that he explained this risk orally to Ida in person on 18 June 2012.[17] There is no evidence to suggest that he did not do so.

58. As both Dr Hansen and Associate Professor Lowe explained in evidence, a consent form does not contain the entirety of a discussion between a doctor and patient. It is this discussion which forms the basis of consent. The form itself is simply written evidence from which it can be inferred that the discussion took place. It is clear that Ida signed both forms, I accept Dr Leow's evidence about what he explained to her, and it is obvious that Ida attended the hospital on 5 July 2012 for the procedure to be carried out. Notwithstanding the identified deficiencies with the format of one of the forms, I am satisfied that Ida intended to give, and did in fact give, her informed consent on 18 June 2012 for a right heart study with fluid loading and cardiac catheterisation to be performed.

59. One question remains: on 18 June 2012 did Ida give her consent for a pressure wire to be used or for a left heart study to be performed on 5 July 2012? Consideration of this question requires further examination.

60. The ***Request/Consent for Medical Procedure/Treatment*** form indicates that by signing the form the patient acknowledges that a doctor has told the patient a number of things. One of those things is that "additional procedures or treatments may be needed if the doctor finds something unexpected". However, in Ida's case, I do not consider this reference to amount to informed consent regarding the use of a pressure wire or attempting to access the LV via the MAV. As explained further below, neither Dr Lo nor Dr Leow found something unexpected on 5 July 2012. The decision to attempt to pass the pressure wire across the MAV was clearly a reasoned one based on the absence of conclusive diagnostic evidence in the opinions of Dr Lo and Dr Leow. This reasoning process should have been discussed with Ida so that she could make an informed decision about whether consent would, or would not, be given.

61. In evidence Dr Leow said that Ida's referral letter[18] requested a right heart study and volume (fluid) loading, with no other investigation specified. Dr Leow went on to explain that at no stage did he discuss using a pressure wire with Ida. Finally, Dr Leow said that as at 18 June 2012 he had no understanding that there was any intention to use a pressure wire at all on 5 July 2012.

62. Dr Leow obtained appropriate consent from Ida on 18 June 2012 in relation to a right heart study with fluid loading and cardiac catheterisation. However no consent was obtained from

[16] Exhibit 1, page 120.
[17] Exhibit 1, page 116.
[18] Exhibit 1, pages 112, 113.

Ida in relation to the use of a pressure wire to perform any procedure, nor was consent obtained from Ida in relation to any procedure concerning the left heart or, more specifically, the left ventricle. According to the evidence of Dr Leow, these matters were not even within his contemplation on 18 June 2012.

Issue 3: Why was Ida not allowed to have anybody stay with her on 5 July 2012?

63. Ida presented to the front desk of the cath lab when she and Francesca arrived at the hospital. After "checking in", Ida was escorted from the front desk to the recovery room. This is an area similar to a ward room with about 12 or 13 beds. It is used as a waiting area for patients who have not yet had their procedure performed and, as the name implies, an area for patients to recover afterwards. According to hospital policy, family members and friends who accompany patients are not permitted past the front desk area. The rationale for this seems clear. Allowing persons other than patients in the recovery room impacts upon patient privacy and also the need for patients to recover without disturbance.

64. In exceptional cases, persons other than patients are sometimes permitted in the recovery room. Ms Tahmid explained that there are no set guidelines as to what may amount to an exception and that it depends on individual discretion, presumably by the senior nurse or physician. Ms Tahmid said that examples of an exception would include if a patient was extremely agitated or out of control, or if there was no means to communicate with a patient because of a language barrier.

65. When Ms Tamid saw that Ida was visibly upset during the afternoon she asked her whether she would like to use the phone to call one of her daughters. Ida indicated that she did not want to and said that she would speak to them after the procedure.

66. It is regrettable that Ida had no further communication with her family after leaving the front desk area. Having someone with her would no doubt have made her feel more at ease. However, the reasoning behind not allowing persons other than patients in the recovery room appears to be sound. Ida was offered the chance to contact one of her daughters but she politely declined. This was entirely in keeping with how Ida's daughters described her at the end of the inquest: gracious and never wanting to impose on anyone.

67. Whilst having her daughter with her would have comforted Ida and helped to relieve some of her obvious distress, sadly this did not happen. However, there is no evidence available to me to suggest that this factor contributed to Ida's death in any way.

Issue 4: What was the reason for the delay on 5 July 2012?

68. None of the staff on duty on 5 July 2012 know why it took about 8 hours for Ida's procedure to begin. Ida was an outpatient and would ordinarily be given priority over patients who were expected to have to remain at hospital overnight. There is no evidence available to establish how many other outpatients were having procedures performed in the cath lab that day.

69. Ms Tamid described the cath lab as typically being busy every day. She went on to say that the cath lab did not have a booking or appointment system for procedures and that staff worked off a list written on a whiteboard. Exactly how the list was prioritised is unclear on the available evidence. What is known, as Dr Lo explained, is that urgent matters were given priority and that complicated procedures could delay other waiting patients, sometimes for up to hours.

70. There is no doubt that by 3:00pm Ida would have been feeling upset and anxious by having to wait so long, without a family member present, and not knowing when her procedure was going to start. Indeed, Ms Tamid said that Ida was teary in the afternoon and that she sat with Ida for a while to help comfort her. I accept that Ms Tahmid acted appropriately and compassionately towards Ida. Hopefully, this helped to ease some of Ida's distress. Although the reason for the lengthy delay in Ida's case is unknown, there is no evidence to suggest that it contributed to her death in any way.

Issue 5: Was appropriate consent given by Ida on 5 July 2012?

71. The simple answer is no. This is because Ida was never told that Dr Lo and Dr Leow had decided to perform any study of her left heart, let alone use a pressure wire to cross her MAV. As a result Ida's consent was never sought. During the timeout procedure Ms Downey checked the consent forms that Ida signed on 18 June 2012 and verified with her that they were correct. But, for reasons already explained, neither of these forms related to the procedure involving the pressure wire.

72. Both Dr Lo and Dr Leow agree that it was Dr Lo who raised the possibility of using the pressure wire. However, there is disagreement between them as to when it was raised. Dr Lo said that it was raised outside the procedure room whilst Ida was being prepared for catheterisation. Dr Leow's recollection is that it was discussed inside the procedure room and not until after the right heart study had been completed.

73. The only other people in the procedure room (before the MET arrived) were Ms Downey (as the scout nurse) and Ms Mary Caraballo, a trainee nurse who had scrubbed in and was assisting with the procedure. Dr Adam Lee, a cath lab registrar, and Ms Judy McKechnie, a radiographer, were in the control room but still able to communicate with the people inside the procedure room. Ms Downey and Dr Lee have no recollection of hearing any discussion concerning a pressure wire before the procedure itself. However Ms Caraballo said that she heard some discussion regarding simultaneous pressure measurement[19], and Ms McKechnie said that she heard mention of a pressure wire.

74. Ms Caraballo and Ms McKechnie would not have heard any conversation between Dr Lo and Dr Leow outside the procedure room before the right heart catheterisation started. Given that they both recall some mention of a pressure wire or alternate procedure, their evidence is consistent with Dr Lo's recollection that the pressure wire was first mentioned inside the procedure room. Further, there would not have been a need for Dr Lo to raise the possibility

[19] Exhibit 1, page 123.

of using a pressure wire until the inconclusive results from the right heart study were known. For these reasons I conclude that the possibility of using the pressure wire was first raised by Dr Lo inside the procedure room after the right heart study had been completed.

75. The timing is important. By this stage Ida was already under sedation but she was conscious and still able to speak. However, as Dr Lo acknowledged, even if Ida's consent had been sought at this stage it would have been problematic. Due to the sedation she may not have fully understood anything that was being explained to her. Both Dr Hansen and Associate Professor Lowe agreed in evidence that it would be inappropriate to attempt to obtain a patient's consent after sedation.

76. In Ida's case there were a number of additional considerations. Some of these will be discussed further below. Neither Dr Lo nor Dr Leow had ever attempted to pass a pressure wire across a MAV before. The procedure is rarely performed because it is rarely required.[20] In July 2012 there were no known published case studies of it having been performed on a live patient with a single leaflet disc valve. Dr Lo did not examine a sample of the type of valve that Ida had. Even though he was aware that Associate Professor Lowe had performed the procedure in 2011 with a bi-leaflet valve[21], Dr Lo did not consult Associate Professor Lowe. The procedure was elective and not an emergency. All of these considerations only serve to emphasise the importance of obtaining informed consent from Ida. Regrettably, this was not done.

Issue 6: Did Ida withdraw her consent in the procedure room?

77. Ms Caraballo suggests that when the fluid loading was performed during the right heart study Ida said, "Stop it. I don't want to do this anymore".[22] Ms Caraballo said that she walked over to Ida and told her, "It's OK. It will be over soon". No other witness recalls Ida saying these words. However, Ms McKechnie and Dr Lo[23] agree that Ida complained of a headache at this time.

78. Dr Lo, Ms Caraballo and Ms McKechnie all agree that Ida was given Midazolam (a benzodiazepine used to cause drowsiness and relieve anxiety) and Fentanyl (an opiate used as part of anaesthesia to manage pain) on Dr Lo's instructions. The procedure medication chart[24] records Ida was given Fentanyl, but there is no mention of Midazolam.

79. In cross-examination Ms Caraballo acknowledged that her statement was made in August 2014, more than two years after the event. She did not make a contemporaneous record of what Ida said. She relied solely on her memory. However there was nothing about her evidence which provided a basis to conclude that her memory was deficient. I conclude that it is more probable than not that Ms Caraballo's recollection is correct for the following reasons: the events of 5 July 2012 would have stood out in Ms Caraballo's mind because (as she explained in evidence) it was the first time she had scrubbed in for a right heart study and

[20] Exhibit 1, page 56-5.
[21] Exhibit 1, page 56-63.
[22] Exhibit 1, page 123.
[23] Exhibit 1, page 85.
[24] Exhibit 1, page 575.

because of what eventually happened to Ida, it is likely Dr Lo would have been concentrating more on the procedure itself, and Ms McKechnie was not in the procedure room.

80. After the Fentanyl and Midazolam were given to Ida, there is no evidence that she repeated her request to stop the procedure. By inference, she was content for it to continue. Dr Hansen explained that it is not uncommon for patients to be anxious and mildly distressed during procedures such as the one being performed on Ida.[25] He went on to explain (and Dr Leow agreed) that medication such as Fentanyl and Midazolam is regularly used to help relieve such anxiety and distress. Given that Ida's request was not an uncommon one, and that she did not repeat it, I do not consider that she withdrew the consent that she gave on 18 June 2012 in the procedure room.

Issue 7: Were any alternative procedures available?

81. There were two alternative procedures available. The first was a transeptal puncture (TSP) which involves the use of a specifically designed needle to gain access to the left atrium. The second was direct apical LV puncture (DALVP) which again involved the use of a special needle.

82. Both Dr Hansen and Associate Professor Lowe agreed that there is risk of death and cardiac tamponade (excess pressure on the heart) associated with both procedures, with medical literature estimating the risks to be less than 5%.

83. It is not necessary, nor appropriate, for me to make any finding about the general appropriateness of the alternative procedures and whether one was more appropriate than the other. The fact is that alternatives were available and in evidence Dr Lo acknowledged that he considered them.

84. The possibility of alternatives and their associated risks should have been the subject of careful discussion between Ida and her doctors. The fact that this discussion did not take place underlines the extreme importance of doctors providing patients with all necessary information upon which they can make an informed decision, with the advice of the doctor, as to what course to take. This is a fundamental part of a patient giving their informed consent. It should have occurred in Ida's case but, regrettably, it did not.

Issue 8: Were the procedures carried out on 5 July 2012 necessary and appropriate?

85. As I have already explained above, it was necessary for Ida to have a right heart study (with fluid loading and cardiac catheterisation). That procedure was required to confirm, or refute, the suspected diagnosis of CP. The procedure was also appropriate because Ida gave her informed consent to it.

86. The real issue is whether using the pressure wire to cross the MAV in order to take pressure readings from Ida's LV was, firstly, necessary and, secondly, appropriate.

[25] Exhibit 1, page 45.

87. The first question can be answered, simply, in the negative. It was not necessary to pass the pressure wire across Ida's MAV on 5 July 2012. This is because Ida was not facing an emergency life-threatening situation which made the procedure a necessity. The procedure was elective. There were alternatives available. The procedure did not have to be performed on that day immediately after the right heart study with Ida unable to give informed consent because she was sedated.

88. Although it is accepted that simultaneous pressure measurement in both the RV and LV would have offered the "gold standard" for diagnosis of possible CP, the passing of the pressure wire on 5 July 2012 was not a medical necessity. It was for Ida to decide, following discussion with her doctors, whether it should have been done.

89. The second question can also be answered, simply, in the negative. The use of the pressure wire to cross the MAV was inappropriate because Ida never gave her consent for the procedure to be performed. Furthermore, she was not even aware that it was going to occur. I do not doubt that Dr Lo and Dr Leow were only seeking to obtain as much information as possible to provide to Associate Professor French so that a conclusive diagnosis could be made. But, without Ida's consent, the procedure should not have been performed.

90. I acknowledge that different views were taken in evidence as to what should have been discussed with Ida in the process of obtaining consent. For example, Dr Lo agreed with Counsel Assisting that Ida was entitled to know that he (and Dr Leow) had never performed the procedure before and that there was no academic literature to support the procedure's performance. However, Associate Professor Lowe expressed some reservation about whether Ida should have been told this fact. Associate Professor Lowe explained that on the one hand frankness between doctor and patient should be encouraged, but on the other hand such frankness might be detrimental to the attitude of the patient because, in Ida's case, the passing of the wire was not, of itself, a complex physical act. Dr Hansen also expressed some reservation about whether Ida should have been told that Dr Lo and Leow had never performed the procedure before. However Dr Hansen was of the view that what was most important was whether the person performing the procedure had the necessary expertise.

91. In my view, these differences in opinion do not detract from the fact that it was of fundamental importance that some discussion should have been had with Ida so that she could give her consent or not. Clearly, this did not occur.

Issue 9: Were the procedures on 5 July 2012 carried out appropriately?

92. Both Dr Hansen and Associate Professor Lowe agreed that the cardiac catheterisation and right heart study with fluid loading were performed appropriately and according to reasonable standards of care. There is no evidence to suggest otherwise.

93. Much of the evidence at the inquest focused on a number of matters related to the question of whether the passing of the pressure wire was carried out appropriately. A number of questions

were raised. Why did Dr Lo only supervise the passing of the pressure wire, and not perform the procedure himself? Did Dr Lo and Dr Leow have the necessary experience to attempt the procedure? Was the procedure too risky to even perform?

(i) Why did Dr Leow perform the procedure?

94. Dr Lo was unable to offer a precise explanation why, being the more senior physician in the procedure room, he did not perform the procedure himself. In evidence he agreed that it would have been "better" if he had done so. He explained that having Dr Leow perform the procedure was likely a reflex action on his part due to Liverpool Hospital being a teaching hospital where trainee physicians regularly performed procedures under supervision.

95. Dr Leow was also unable to shed any light on how he came to be asked or instructed to perform the procedure. In evidence, he said that he told Dr Lo he had never performed the procedure before and that Dr Lo said that he would guide him through it. Dr Leow said that he did not ask Dr Lo if he had ever performed the procedure before.

96. It is, of course, impossible to say whether the eventual outcome would have been different if Dr Lo had performed the procedure. Both Dr Hansen and Associate Professor Lowe agreed that the physical act of attempting to pass the pressure wire across the MAV was not a complex one.[26] Dr Leow was an experienced medical practitioner. Physicians are only able to develop skills and experience if given opportunities to perform procedures under appropriate supervision. Given these factors, there is no evidence to indicate that Dr Leow performed the procedure inappropriately and without due skill and care.

(ii) Did Dr Lo and Dr Leow have the necessary skill and experience?

97. Both Dr Hansen and Associate Professor Lowe agreed that Dr Lo and Dr Leow had the necessary skill and experience to perform the procedure. At the time Dr Leow was a qualified cardiologist, with 10 years experience as a medical practitioner, who had commenced his Fellowship at Liverpool Hospital almost 12 months earlier. In his report Dr Hansen described Dr Lo as being "recognised as one of the most experienced and skilful interventionist cardiologists in NSW".[27] There is no evidence to indicate that Dr Lo and Dr Leow lacked the necessary skill and experience to perform the procedure. For these reasons it could not be said that the procedure was performed inappropriately.

(iii) Was the procedure too risky to even perform?

98. The question of risk was discussed at length during the concurrent evidence of Dr Hansen and Associate Professor Lowe. Both doctors agreed that passing a pressure wire across a mechanical or prosthetic valve was riskier than doing so across a natural valve. Dr Hansen agreed that performing the procedure with a single leaflet valve was riskier than with a bi-leaflet valve. This is because with a single leaflet valve any malfunction would lead to complete valve failure, whereas with a bi-leaflet valve if one leaflet malfunctioned, the other

[26] See also Exhibit 1, pages 48 & 56-6.
[27] Exhibit 1, page 48.

could still remain functional. Whilst Dr Hansen and Associate Professor Lowe both agreed that the passing of the pressure wire was by far the most uncommon procedure performed on 5 July 2012, neither doctor was prepared to agree with the suggestion from Counsel Assisting that it was also the riskiest.

99. All medical procedures carry some degree of risk. In Ida's case both Dr Hansen and Associate Professor Lowe took the view that the degree of risk was undefined, or could not be quantified. It is necessary to briefly discuss what Dr Hansen and Associate Professor Lowe meant by this.

100. At the time of Ida's procedure there were two types of mechanical tilting disc aortic valves in use: single leaflet and bi-leaflet. As the names imply, a bi-leaflet valve has two discs which open and close when the heart pumps blood through the valve, whereas a single leaflet valve only has one disc. As at July 2012 there were no known case studies published in academic literature concerning any complications involved with the passing of a pressure wire across a single-leaflet disc valve, such as the one Ida had. Since July 2012 there has been only one published case study.[28] This study was published in 2013 and involved a single leaflet valve (of a different kind to Ida's) where a pressure wire became trapped causing the patient to suffer cardiac arrest. However, in that case the wire was successfully freed, the patient was resuscitated and was eventually discharged from hospital two days after the procedure.

101. Furthermore, in 2011 ex vivo (experiments outside of natural conditions) testing was conducted using a catheter and different pressure wires to cross different kinds of mechanical aortic valves. The tests[29] found that the catheter caused some valves to malfunction. However a pressure wire with the same diameter as the one used in Ida's case did not cause any valve malfunction. The only problems encountered were the valve leaking, or the pressure wire becoming kinked or losing the ability to transmit information.

102. Although the available data did not allow Dr Hansen or Associate Professor Lowe to define the risk involved, both agreed that the passing of the pressure wire across the MAV was by far the most uncommon procedure performed on 5 July 2012. Both doctors also agreed that when obtaining consent from a patient it is fundamental to inform the patient of any risk involved. When it is not possible to define the risk associated with a procedure, both agreed it is important to:

    (a) provide the patient with sufficient information about the procedure;
    (b) explain to the patient the extent of the problem that the procedure is seeking to address;
    (c) explain to the patient the dilemma in not being able to quantify the risk;
    (d) put in a frank manner to the patient what it is hoped that the procedure will achieve.

103. None of these things were done in Ida's case.

[28] Exhibit 1, page 56-99.
[29] Exhibit 1, page 56-65.

104. It is a fundamental part of the doctor-patient relationship that a patient is provided with as much information as possible so that informed consent may be given. This principle clearly applied in Ida's case.

105. Given the available evidence it is not possible for me to reach a conclusion regarding the degree of risk associated with the procedure. Therefore it cannot be said that the degree of risk made the performing of the procedure inappropriate. As Dr Hansen explained, when asked questions by counsel for Dr Leow, drawing conclusions from single cases is difficult. As an example Dr Hansen explained, on the one hand, one could draw a logical conclusion (from the 2011 published case study by Associate Professor Lowe) that passing a pressure wire across a bi-leaflet valve carries less risk than single-leaflet valve. But, on the other hand, as Dr Hansen explained, a bi-leaflet valve has four hinges and, therefore, has more sites for a wire to potentially become trapped, as opposed to two hinges in a single leaflet valve.

106. What is important is that the element of risk should have been discussed with Ida, and this was not done. Both Dr Hansen and Associate Professor Lowe agreed that the passing of the wire across the MAV carried the risk of death and that Ida should have been told this, even if the risk could not be quantified in numbers or as a percentage. As Dr Lo himself explained in evidence, the procedure carried a risk that the wire could become jammed and that if this occurred, this created the risk of a fatal outcome. This fact alone made it imperative that informed consent should have been obtained from Ida before the procedure took place. As there was no actual discussion with Ida about the risk involved this made performance of the procedure inappropriate.

Issue 10: Was the response of the Medical Emergency Team appropriate?

107. It has been suggested that after going into cardiac arrest Ida should have been moved from the cath lab to the ICU. However Dr Srinivasan explained that there was no point moving Ida until her heart function was stable. Indeed, Dr Srinivasan pointed out that until this was achieved it would be potentially dangerous to move Ida at all.

108. It has also been suggested that Dr Rachakonda did not attend the cath lab in a timely manner. When Dr Srinivasan called Dr Rachakonda he was in the middle of a patient handover process that involved up to 30 patients. Dr Srinivasan told Dr Rachakonda that Ida had been intubated and that CPR was occurring. Dr Rachakonda instructed Dr Srinivasan to continue CPR, to keep him updated, and to page him if he was required.

109. After completing his handover process Dr Rachakonda arrived in the cath lab at about 4:45pm to 4:50pm. He took part in the resuscitation attempts and reviewed the results of Ida's blood gas tests. Dr Rachakonda explained that the first test results at about 4:50pm provided some room for optimism, but that the second test results at about 5:17pm were dire. Given the poor outlook, Dr Rachakonda and Dr Lo, decided to cease resuscitation attempts.

110. Dr Rachakonda said that when considering all the factors he did not think anything more could have been done to save Ida. I agree. The team arrived in a timely manner and

immediately assisted with intubating Ida and with chest compressions. Resuscitation efforts continued for approximately 90 minutes despite four cardiac arrests. There is no evidence to suggest that the response by, and actions of, the MET were anything other than appropriate.

Should any recommendations be made?

111. Section 82 of the Act allows a coroner to make any recommendations that a coroner considers is necessary or desirable in relation to any matter connected with the death that the inquest is concerned with. Issues of public health and safety can be, and often are, the subject of recommendations.

112. The inquest heard evidence about a number of matters where recommendations might be made. Several of the matters related to changes made at Liverpool Hospital following Ida's death. Associate Professor Russ Schedlich (Director, Medical Services, Liverpool Hospital) provided evidence about these changes which have either been implemented or are in the process of final review. They relate to the development of procedure-specific consent forms by the Liverpool Cardiac Investigation Unit (CIU), discussion and planning of complex or high risk cases by the CIU, developing local clinical procedure safety checklists, and the consideration and approval of new interventional procedures.

113. I will consider each of these matters in turn, together other matters which might be the subject of recommendations.

(i) Consent

114. I have already discussed at length the importance of obtaining informed consent from a patient in relation to any medical procedure. This is a fundamental concept in the doctor-patient relationship. Although it has not been possible, even in the minds of two very experienced interventional cardiologists, to define the degree of risk associated with the passing of a pressure wire across a MAV, the evidence clearly establishes that it was an uncommon and rarely performed procedure that carried with it the risk of death. These factors only serve to reinforce the conclusion that it was critical that consent should have been obtained from Ida before the procedure. However, unlike the procedure itself, these concepts are not novel or uncommon. As I have already stated they are fundamental, and matters of common sense. For this reason, I do not think it is necessary to make any formal recommendation in this regard.

115. On behalf of Ida's family it was submitted that I should recommend that the NSW Ministry of Health introduce a uniform consent policy. A uniform policy directive of this kind is already in existence.[30] No recommendation is therefore necessary.

116. It was also submitted on behalf of Ida's family that any such policy should make it clear that consent should only be obtained before the administration of any medication (except in

[30] Exhibit 1, page 582.

emergency situations). This stipulation is already part of the existing policy directive[31] and no recommendation is therefore necessary.

(ii) Consent forms

117. Associate Professor Schedlich gave evidence that drafts of the proposed procedure-specific consent forms were (at the time of inquest) before a review committee and expected to be approved within four to six weeks. Having examined the draft forms it appears that the deficiencies associated with the forms signed by Ida have been addressed. There are now distinct forms for different procedures. An area for a patient to give their consent is clearly identified. The forms specify the type of procedure to be performed, what a patient can expect, the risks associated with the procedure, and specify what a patient acknowledges by giving their consent. These are all encouraging measures to provide clarity and reassurance for both doctor and patient in the consent process.

118. I have contemplated whether I should make a recommendation that the NSW Ministry of Health consider introducing uniform procedure-specific consent forms, such as the ones being drafted by Liverpool Hospital, across all hospitals in NSW. Whilst there are many benefits to consistency, there also cannot be a universal solution given the differences in operation and resources at the individual hospital level. From the evidence, it is clear that Local Health Districts retain the autonomy to create or amend documents such as consent forms to suit individual hospitals.

119. However, in my view, the benefits of shared experience and knowledge ought to be encouraged. Associate Professor Schedlich explained that procedure-specific consent forms from the Queensland health system had been reviewed by Liverpool Hospital for adoption. Associate Professor Lowe explained that Concord Repatriation General Hospital (in the Sydney Local Health District) had developed its own procedure-specific consent forms for certain cardiac procedures. It therefore seems to me that the circulation of such forms would only aid Local Health Districts to develop forms specific to their needs and resources. In my view, the circulation of such information should be strongly encouraged by the NSW Ministry of Health.

120. It was submitted on behalf of Ida's family that I should recommend that the Ministry of Health consider assessing warnings from medical device manufacturers and incorporating such warnings on consent forms. In evidence Professor Hansen explained that the practice of interventional cardiology changes so frequently that, in his experience, there are often discrepancies between what a manufacturer includes as part of a product description and what that manufacturer will suggest a product be used for. Dr Hansen opined that anything included on a product description would be reflective of the most conservative approach possible and perhaps be without concern for the due care and treatment of an individual patient.

121. It was submitted on behalf of South Western Sydney Local Health District that I should not make such a recommendation. One reason advanced was that the issue was insufficiently

[31] Exhibit 1, page 598.

canvassed at the inquest. Another reason was that it would be inappropriate to recommend that the Ministry undertake such a task. I agree with both reasons. The issue was only canvassed with Dr Hanson and not, for example, Dr Lo. Evidence was not taken from the manufacturer of the pressure wire used in Ida's case. Evidence was not sought from the Therapeutic Goods Administration which is the federal body responsible for (amongst other things) regulating the manufacturing, supply and advertising of medical devices in Australia. There was no evidence at inquest that the limited evidence on this issue in Ida's case had demonstrated applicability to any other medical device used in any other area of medicine. Finally, given the assumed number and diversity of medical devices and the variety in their applications, the task of incorporating warnings on consent forms in areas of medicine which are dynamic and ever-changing does not seem practical, let alone possible. For these reasons, and accepting the evidence of Dr Hansen, the making of any recommendation on this point is not desirable.

(iii) Planning for complex and/or high risk cases

122. The Liverpool CIU now has a weekly Heart Team meeting at which complex cases are discussed and planned. The meetings are multidisciplinary and aim to use the broad knowledge and experience from those who attend them to formulate the best treatment plan possible for patients. The sharing of such knowledge and experience would appear to be of great potential benefit to patients. The continuation of such meetings is strongly encouraged.

(iv) Safety checklists

123. The CIU is also in the process of developing a local version of the Ministry of Health's Clinical Procedure Safety Policy Directive and Clinical Procedure Safety Checklist. One of the aims is to improve communication within the procedural team, and between the team and the patient. Specifically, the changes address the need to ensure that the planned procedure matches the consent given by a patient.[32] Given what has already been discussed regarding consent in Ida's case, such an improvement can only be a positive one.

(v) Approval for new procedures

124. As a result of an update to previous policies, any new interventional procedures within Liverpool Hospital from November 2015 now require the consideration and approval of a committee. The aim is to ensure that new procedures are performed safely, that clinicians have the required experience and training to perform them, and that required resources and equipment are available to perform them.

125. When a new procedure is submitted for approval a description of the procedure is required together with whether it has been undertaken elsewhere in Australia or overseas. What amounts to a new interventional procedure is defined in the new policy. Submission of a procedure for approval relies upon the individual doctor recognising that a procedure is new

[32] Exhibit 1, page 692.

and that it requires approval, or that doctor seeking advice if there is uncertainty whether a procedure meets the definition.

126. Such a system is not without its potential difficulties because it relies upon individual doctors being able to recognise what amounts to a new procedure and then submitting an application for approval. But no system is flawless. There are safeguards in place for a doctor to seek advice in situations of uncertainty.[33] Associate Professor Schedlich gave evidence that in his experience, doctors will consult their colleagues if unsure about what is a new procedure. This new policy appears to put appropriate safeguards in place to ensure that new procedures are performed safely and skilfully. It seeks to prevent a situation like Ida's case where an uncommon procedure was performed without appropriate planning. The continuation of the policy is encouraged.

(vi) Referrals to external bodies

127. It was submitted by counsel for Ida's family that I should recommend that a "copy of the report in respect of the inquest" be referred to the NSW Health Care Complaints Commission (HCCC) and the Medical Council of NSW to take any action as they deem fit. Counsel for Dr Lo submits that no such recommendation should be made.

128. It appears that counsel for Dr Lo has taken the reference to the "copy of the report in respect of the inquest" to mean a case study prepared by Dr Lo for the purposes of submission to an academic journal for publication. On this basis, counsel for Dr Lo submits that it would be procedurally unfair to make any such recommendation because counsel for Ida's family never disclosed to Dr Lo any intention to seek such a recommendation. The issue also does not appear to have ever been raised with Counsel Assisting during the inquest. Counsel for Dr Lo also submitted that if the matter had been raised during the inquest, consideration may have been given to raising an objection to giving evidence under section 61 of the Act.

129. I think, with respect, that there has been a misunderstanding regarding the words, "copy of the report in respect of the inquest". I have taken these words used by counsel for Ida's family to be a reference to my findings, and not to a case study for academic literature.

130. All inquests are to be conducted in accordance with principles of natural justice and procedural fairness. All persons and organisations whose interests are sufficiently affected in an inquest are entitled to be heard on an issue affecting them before any finding is made.

131. A list of issues that the inquest would examine was circulated prior to the inquest. One of the issues concerned the nature of all medical procedures carried out on Ida on 5 July 2012, including whether the procedures were appropriately carried out and whether Ida gave appropriate consent to them. Therefore, notice had been given to all persons with sufficient interest (including Dr Lo) about the issues that the inquest would examine. Furthermore the question of whether to potentially seek the application of section 61 of the Act remained a forensic decision for Dr Lo.

[33] Exhibit 1, page 706.

132. However, I accept that the specific possibility of a recommendation to the HCCC was not raised in evidence (and does not appear to have been disclosed by counsel for Ida's family to Dr Lo, or to Counsel Assisting). If it had been raised either prior to, or during the inquest, then it would no doubt have informed the forensic decision that Dr Lo potentially had to make.

133. Any person may, of course, make a complaint to the HCCC about a health care professional or health care provider. Section 82(2)(b) of the Act also specifically allows a coroner to recommend that a matter be investigated or reviewed by a specified person or body. However, I note that the purpose of any inquest is not to determine whether or not a health professional is guilty of unsatisfactory professional conduct or professional misconduct. Use of such language in an inquest, or in findings, is inappropriate as it may suggest that grounds for disciplinary action have already been established.

134. Given that:

(a) the issue of a possible recommendation to the HCCC was only raised in submissions, and not in the evidence;
(b) any person has the ability to make a complaint to the HCCC;
(c) a copy of these findings will be published and made publicly available; and
(d) noting what I have said about the undesirability of suggesting that grounds for professional disciplinary action have been established at an inquest;

in my view it is neither necessary nor desirable that I make any recommendation concerning a referral to any external body.

(vii) Publication or circulation of Ida's case

135. In his evidence Dr Hansen emphasised that an important distinction had to be drawn between what was known in 2012 about passing a pressure wire across a MAV, and what was known in 2016. He said that had he been asked to write his report in 2012, without knowing about Ida's case, he would be more hesitant about making a strong recommendation against the use a pressure wire to cross a MAV. He explained that in 2012 there was only speculation about the possibility of wire entrapment in a MAV, but no actual evidence of it.

136. However, with the benefit of knowing about Ida's case, Dr Hansen explained that in 2016 he would not contemplate performing the procedure. Instead, he said that he would rely on non-invasive testing as much as possible. If he had to consider invasive tests, Dr Hansen said that he would think carefully about alternative procedures and probably recommend performing a TSP in order to obtain any pressure measurements from the LV.

137. It is clear that simply knowing about Ida's cause would cause an experienced interventional cardiologist such as Dr Hansen to take a significantly different approach. Such a substantial change clearly impacts upon patient safety. If a single case can cause such a major shift in

approach, then it is equally clear that it is in the public interest that other clinicians in the cardiology community should be informed of the particulars of Ida's case.

138. As Dr Hansen pointed out[34] if Ida's case were to be published and/or circulated there would then be information available to the cardiology community about two cases involving the passing of a pressure wire across a single leaflet MAV with fatal or near fatal outcomes. In such circumstances I agree with Associate Professor Lowe's view, expressed in evidence, that it is imperative that Ida's case be published and/or circulated.

Recommendation

139. I make the following recommendation:

To the Director, Medical Services, Liverpool Hospital:

I recommend that consideration be given to having an appropriately qualified medical practitioner prepare a summary of, or article about, Ida's case for submission to an appropriate medical journal and/or circulation to other cardiology departments in NSW hospitals. I note that consent for this to occur seems to have been implied in submissions filed on behalf of Ida's family, contingent upon Ida's name not being published.

Findings

140. I now turn to the formal findings that I am required to make under section 81(1) of the Act.

Identity
The person who died was Ida Romeo.

Date of death
Ida died on 5 July 2012.

Place of death
Ida died at Liverpool Hospital, Liverpool NSW 2170.

Cause of death
The cause of Ida's death was acute cardiogenic shock, with acute mechanical obstruction of a remote mechanical aortic valve replacement and intraprocedural displacement of a cardiac catheterisation wire across the valve being antecedent causes.

Manner of death
Ida died during a medical procedure when a pressure wire became trapped in her mechanical aortic valve causing it to malfunction.

[34] Exhibit 1, page 50.

141. On behalf of the coronial team I would like to offer my sincere condolences to Ida's family and friends, especially her husband and children. She is no doubt greatly missed but lovingly remembered and honoured at weekly family nights.

142. I close this inquest.

Derek Lee
Deputy State Coroner
8 April 2016
NSW State Coroners Court, Glebe