IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2007 671

FINDING INTO DEATH WITH INQUEST[1]

Form 37 Rule 60(1)

*Section 67 of the **Coroners Act 2008***

Inquest into the Death of: CARMELINA SIRIANNI

Hearing Dates:	2 – 3 March 2011 and 20 – 22 June 2011
Appearances:	Mr S. J. Moloney of Counsel on behalf of Austin Health Mr McClosky of Counsel on behalf of Melbourne Health (20-22 June only)
Counsel Assisting the Coroner	Ms Fiona Ellis of Counsel Ms Monika Pekevska, Instructing Solicitor, Victorian Government Solicitor's Office (VGSO)
Findings of:	AUDREY JAMIESON,CORONER
Delivered On:	7 May 2013
Delivered At:	Level 11, 222 Exhibition Street Melbourne, 3000

[1] The finding does not purport to refer to all aspects of the evidence obtained in the course of my investigation. The material relied upon included statements and documents tendered in evidence together with the transcript of proceedings and submissions of legal representatives/counsel. Notes taken by myself and the written submissions of Counsel from 22 June 2011 were also utilised as there was a loss of transcription from that day due to a technical error. The absence of reference to any particular aspect of the evidence, either obtained through a witness or tendered in evidence does not infer that it has not been considered.

I, AUDREY JAMIESON, Coroner having investigated the death of **CARMELINA SIRIANNI** AND having held an inquest in relation to this death on 2-3 March 2011 and 20 -22 June 2011 at Melbourne

find that the identity of the deceased was **CARMELINA RACHELA SIRIANNI**

born on 20 November 1943

and the death occurred on 7 January 2007

at the Austin Hospital, 145 Studley Road, Heidelberg 304

from:

1(a) LYMPHOCYTIC CHORIOMENINGITIS VIRUS (LMCV) – LIKE VIRUS

1(b) POST FAILED RENAL TRANSPLANT

in the following summary of circumstances:

On 4 December 2006, Mrs Carmelina (Lina) Sirianni underwent a cadaveric renal transplant at the Austin Hospital. The donor was Mr Jovo Vranjesevic who had died at Dandenong Hospital from a cerebral haemorrhage. Mrs Sirianni and the other recipients of Mr Vranjesevic's organs subsequently all died within days of one another.

I. BACKGROUND CIRCUMSTANCES

1. Mrs Sirianni was 63 years of age at the time of her death.

2. Mrs Sirianni had a medical history of polycystic kidney disease with end stage renal failure. She was on haemodialysis but kept herself *fairly active physically* and *quite strong* for the purposes of improving her chance of a transplant.[2]

II. SURROUNDING CIRCUMSTANCES

3. On 3 December 2006, Mr Jovo Vranjesevic was admitted to the Dandenong Hospital Emergency Department (ED) by ambulance following his collapse at home. CT examination of the brain showed a large thalamic haemorrhage with extension into the ventricular system and midline shift. Formal brainstem testing confirmed brain death. Mr Vranjesevic's family agreed to organ donation.

4. On 4 December 2006, Transplant surgeon Mr Michael Fink, performed the organ retrieval operation. Mr Fink stated:

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[2] T @ p 101

The liver appeared to be of good quality macroscopically, with no evidence of any infective process or other parenchymal problem. There was a common anatomical variant...these findings were non-specific and would not normally preclude transplantation.... The kidneys perfused well. There was severe atheroma including the orifice of the renal artery in each kidney. This can potentially increase the risk of vascular thrombosis following transplantation and therefore I contacted the recipient surgeons and alerted them to this issue and advised that they asses the kidneys prior to implantation. There were multiple small renal cysts. This would not normally preclude transplantation... The heart was not retrieved because there was no suitable recipient...and because there was evidence of poor left ventricular function and sclerotic heart valves. The lungs were not retrieved because there was no suitable recipient and because the donor was a smoker, with recent weight loss and was Hepatitis B core antibody positive. The pancreatic islets were not transplanted following isolation because of insufficient islet number... [3]

5. There were three solid organ recipients:

- Mrs Carmelina Sirianni received a renal transplant at the Austin Hospital;
- Ms Karen Wilkinson[4] received a renal transplant at the Royal Melbourne Hospital; and
- Ms Gurpal Sandhu[5] received a liver transplant at the Austin Hospital.

6. Mrs Sirianni underwent a renal transplant on 4 December 2006. The operation was without complication. By the following day there was decreased urine output. She required renal dialysis with delayed graft function thought to be due to acute tubular necrosis (ATN). A renal biopsy showed no evidence of rejection. Intravenous antibiotics were initiated on 14 December 2006 after the results of urine and blood cultures identified pseudomonas. On 15 December 2006, Mrs Sirianni reported feeling well. She was walking around the ward. On 21 December 2006, a septic screen was undertaken due to low grade temperatures. She was noted to be slightly disorientated on 24 December 2006. On 26 December 2006, an

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[3] Exhibit 9 – Statement of Mr Michael Fink dated 25 September 2008

[4] Case No. 2007 125

[5] Case No. 2007 126

ultrasound showed multiple renal collections. A renal biopsy showed changes of resolving ATN.

7. On 4 January 2007, Mrs Sirianni required excision of the transplanted kidney. Her condition nevertheless continued to deteriorate. Mrs Sirianni died in the early hours of 7 January 2007.

8. Ms Karen Wilkinson died on 1 January 2007. Ms Gurpal Sandhu died on 3 January 2007.

9. The death of Mrs Sirianni was reported to the State Coroner's Office (as it then was). The coroner was informed that Mrs Sirianni was the third death from the one donor. The report of Mrs Sirianni's death led to the investigation into the deaths of all of the organ recipients and of the donor, Mr Jovo Vranjesevic.

III. JURISDICTION

10. At the time of the death of Mrs Carmelina Sirianni, the *Coroners Act 1985* applied. From 1 November 2009, the ***Coroners Act 2008*** (the new Act) has applied to the finalisation of investigations into deaths that occurred prior to the commencement of the new Act.[6]

11. In the preamble to the new Act, the role of the coronial system in Victoria is stated to involve the independent investigation of deaths for the purpose of finding the causes of those deaths and to contribute to the reduction of the number of preventable deaths and the promotion of public health and safety and the administration of justice. Reference to preventable deaths and public health and safety are referred to in other sections of the new Act.[7]

12. Section 67 of the new Act describes the ambit of the coroners' findings in relation to a death investigation. A Coroner is required to find, if possible, the identity of the deceased, the cause of death and, in some cases, the circumstances in which the death occurred.[8] The 'cause of death' generally relates to the *medical cause of death* and the 'circumstances' relates to the *context* in which the death occurred.

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[6] Section 119 and Schedule 1 – *Coroners Act 2008*

[7] See for example, sections 67(3) & 72 (1) & (2)

[8] Section 67(1)

13. A Coroner may also comment on any matter connected with the death, including matters relating to public health and safety and the administration of justice.[9] A Coroner may also report to the Attorney-General and may make recommendations to any Minister, public statutory authority or entity, on any matter connected with a death which the Coroner has investigated including recommendations relating to public health and safety or the administration of justice.[10]

IV. INVESTIGATION

Identity

14. The identity of Carmelina Sirianni was without dispute and required no additional investigation.

Medical Investigation

15. Dr Michael Burke, Forensic Pathologist at the Victorian Institute of Forensic Medicine was advised of the three organ recipient deaths from the one donor on 7 January 2007. Dr Burke performed an autopsy on the body of Mrs Sirianni on 11 January 2007. Before reporting to the Coroner, Dr Burke initiated a number of investigations and reviewed the medical records of all the recipients and the donor, Mr Vranjesvic. The investigations included the delivery of tissue samples to the CSIRO Australian Animal Health Laboratory for viral testing, comprehensive microbiological series of investigations at the Victorian Infectious Diseases Reference Laboratory (VIDRL) from where material was sent to the United States of America for further testing. Neuropatholgical examination of the tissue showed no evidence of an encephalitis and no agent had been identified in the microbiological investigations.

16. Dr Burke reported[11] that from his review of the medical records of the three transplant recipient deaths, he could see no common therapeutic medication to link the three deaths. Similarly, although each recipient had an enterococcus isolated at sometime during the period of hospitalisation, antibiotic sensitivity testing suggested separate sources of the bacteria in two of the recipients. Dr Burke commented:

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[9] Section 67(3)

[10] Section 72(1) & (2)

[11] Exhibit 2 – Autopsy Report of Dr Michael Burke signed in the presence of a witness on 15 February 2011

From my reading of the literature with respect to transplantation medicine, deaths are relatively uncommon in individuals undergoing solid organ transplantation. Deaths following liver transplantation are more frequent than following renal transplantation. In most instances of deaths following solid organ transplantation, infection is the most common cause of death....The deaths of three solid organ transplant recipients, each occurring approximately one month following transplantation, raises the prospect of a transplant associated infectious agent.

17. At the time of completing his report, Dr Burke indicated that some results (rickettsial serology) were still pending and that upon receipt of the results, he would complete a supplementary report.

18. In a supplementary report dated 5 February 2008,[12] Dr Burke reported that the expert viral investigations showed the presence of a lymphocytic choriomeningitis virus (LCMV) type virus and that the LCMV had been isolated in prior deaths of recipients of solid organ transplants.[13] Dr Burke revised the cause of death for each of the organ recipients. He stated:

Whilst the deaths of the three organ recipients ...in isolation could have the individual causes of death proposed by autopsy and/or the treating clinicians, the prior reporting of post transplant deaths associated with LCMV and the temporal relationship between the three deaths would suggest the LCMV-like virus is the underlying cause of death in each case.

V. INQUEST

19. At the Directions and at the opening of this inquest a number of issues were identified so as to give direction to the scope of the Court's inquiry. Those issues/questions posed were:

(i) The cause of death of each of the four deceased;

(ii) Donor and recipient screening – processes in place, potential to have picked up virus or anomaly in donor pre transplantation;

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[12] Exhibit 3 – Supplementary Report on Case No. 0067/2007 – Dr Michael Burke, dated 5 February 2008

[13] See: Fischer SA et al. "Transmission of lymphocytic choriomeningitis virus by organ transplantation." New England Journal of Medicine 2006;354(21):2235-2249

(iii) Informed consent of recipients (did the general advice incorporate knowledge of the 2003 & 2005 clusters reported in the NEJM and now that these deaths have occurred what changes if any have occurred in relation to what a recipient is told in the consent process);

(iv) What opportunities were there, whether by intra or inter hospital communication, to have learnt earlier of the common deterioration among the recipients and whether this would have changed the outcome for any of the recipients; and

(v) What capacity is there now to screen for the recently detected arenavirus.

20. *Viva voce* evidence was obtained from the following witnesses:

- Dr Michael Burke, Forensic Pathologist
- Ms Rae Moran (partner of Ms Wilkinson)
- Ms Francesca Rourke, President, Australasian Transplant Coordinator Association (ATCA)
- Mr Michael Fink, Transplant Surgeon, Austin & Repatriation Medical Centre
- Mr Sam Sirianni (son of Mrs Sirianni)
- Ms Gordana Vranjesevic (daughter of Mr Jovo Vranesevic, donor)
- Professor Robert Jones, Director, Liver Transplant Unit, Austin Hospital
- Associate Professor Denis Spelman, Head of Department of Microbiology, The Alfred Hospital
- Professor Rowan Walker, Deputy Director Department of Nephrology, Royal Melbourne Hospital
- Ms Amanda Robertson, general & renal Transplant Surgeon, Royal Melbourne Hospital
- Ms Julie (Julijana) Pavlovic, Liver Transplant Co-ordinator, Austin Hospital
- Associate Professor Francesco Ierino, Deputy Director of Nephrology, Austin Hospital
- Mr Ian Michell, Renal Transplant Unit, Austin Hospital
- Ms Violet Marion, Organ Donor Co-ordinator, DonateLife
- Dr Michael Catton, Medical Virologist & Director, Victorian Infectious Diseases Reference Laboratory (VIDRL)

VI. FINDINGS and COMMENTS pursuant to section 67(1) and (3) of the *Coroners Act 2008*

(i) Cause of death of Mrs Sirianni, Ms Wilkinson, Ms Sandhu and Mr Vranjesevic

21. Only Mrs Sirianni underwent a full post mortem examination performed by Dr Burke, Forensic Pathologist at the VIFM.

22. In relation to the deaths of the three organ donor recipients, Ms Wilkinson, Ms Sandhu and Mrs Sirianni, Dr Burke gave evidence[14] confirming his opinion as expressed in his supplementary report of 5 February 2008[15] that is, that *the LCMV-like virus is the underlying cause of death in each case.*

23. The cause of death of Mr Vranjesevic however remained unchanged – *he died of a stroke....with the virus as opposed to "of the virus".*[16]

24. Associate Professor Spelman, Head of Microbiology, Deputy Director Infectious Diseases Unit, at The Alfred Hospital, gave evidence that was consistent with the evidence of Dr Burke but qualified in that he said:

> *The recipients had other possible causes from a clinical point of view and they had bad bacterial sepsis and that could be at least a part of their death as well. So, my opinion would be that I couldn't be as firm as this that this was the only cause contributing to their death.*[17]

25. The evidence supports a finding that the LCMV was a contributing cause to the deaths of Mrs Lina Siriani, Ms Karen Wilkinson and Ms Garpul Sandhu. The cause of death for each of the donor recipients will be amended to reflect this finding and the Registrar of Births, Deaths and Marriages will be requested to re-register the cause of each of the deaths accordingly.

26. In relation to Mr Vranjesevic's death, Dr Burke gave evidence that the cause was thalamic haemorrhage with ventricular extension.[18]

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[14] Transcript (T) @ p 15 and 17

[15] Exhibit 3

[16] T @ p 15

[17] T @ p 170

[18] T @ p 14

27. Professor Jones, Director, Liver Transplant Unit, Austin Hospital who performed the liver transplant on Mrs Sandhu gave evidence that the LCM virus usually causes a relatively benign illness and that it was extremely unlikely that the LCM virus caused the cerebral haemorrhage in Mr Vranjesevic.[19]

28. In the absence of any evidence that the LCMV caused Mr Vranjesevic's death, I accept and adopt the cause of death as identified by Dr Michael Burke and find that Mr Jovo Vranjesevic died from natural causes being thalamic haemorrhage with ventricular extension.

(ii) Donor And Recipient Screening - processes in place, potential to have picked up virus or anomaly in donor pre-transplantation

Confidential Donor Referral Form

29. Ms Francesca Rourke, President of the Australasian Transplant Coordinators' Association (ATCA) gave evidence[20] that the donor co-ordinator from the relevant State Agency (in this case LifeGift, now known as DonateLife,) attends at the hospital for the purpose of completing the Confidential Donor Referral Form (CDRF).

30. The CDRF requires the donor co-ordinator to review the patient's medical records, past and present, perform a medical chart review, family interview, physical examination and where possible, to contact the general practitioner of the prospective donor. It is also routine practice that prospective virology/serology screening is performed on all potential donors.[21]

31. According to the evidence of Ms Rourke the CDRF is a national document developed by ATCA and reviewed and endorsed by TSANZ (Transplantation Society of Australia and New Zealand). The review process of the CDRF is undertaken in collaboration with TSANZ and a medical specialist in infectious diseases.[22]

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[19] T @ p 150, 14-28

[20] Exhibit 8 – Statement of Francesca Rourke dated 9 September 2010 and T @ pp 50-71

[21] T@ p 52

[22] T @ p 52

32. In order to fully understand the screening process that took place in respect of Mr Vranjesevic, statements were obtained from Ms Violet Marion and Ms Bernie Dwyer – both whose initials appear on the CDRF.

33. Ms Marion was called to give evidence as she was the donor co-ordinator who completed the CDRF and engaged in the family interview as required by the CDRF. She said that the donor co-ordinator has two priorities when they attend hospital:

> *..to meet with the donor family and obtain their consent, and equally to send off bloods for tissue typing, because that's one of the major delays to organ donation. It takes somewhere between six to eight hours....then in amongst (sic) juggling of ordering different tests, assessing the medical records, (sic) and just obtaining all the information that we need to complete this form and make the organ referral.*[23]

34. At the time she gave evidence it became evident that the CDRF in this case was beyond the six pages in the Inquest Brief.[24] In the CDRF proffered at inquest and completed by Ms Marion it became apparent that Ms Marion was informed that Mr Vranjesevic had been both lethargic and vague since his return from Serbia.[25] Ms Marion gave evidence that she would have, as per her usual practice, passed this information onto Ms Pavlovic, liver transplant co-ordinator at the time she made initial contact with her. Ms Pavlovic however, gave evidence that she was not informed that the donor had had a recent history of lethargy but rather was told that he had been unwell.[26]

35. The evidence of Ms Marion was that it was apparent at the time that she was initially contacted by the ICU Registrar, Dr Mee at Dandenong Hospital that the issue of weight loss had been identified.[27] Ms Marion raised this issue with Dr Helen Opdam, medical consutant on-call that night and sought guidance from her in respect of it.[28] The issue of weight loss was specifically explored in the interview conducted by Ms Marion with Mr Vranjesevic's

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[23] T @ p 405

[24] Exhibits 30 & 32. For a blank copy of the CDRF formulated in December 2004 and that was in use in December 2006, see Exhibit 27

[25] Exhibit 32 – Full CDRF

[26] T @ p 253

[27] Exhibit 30 – 'Donor Referral Checklist'

[28] *Ibid*, T @ pp 376-377,382

daughter, Daniella, who had been nominated as the family spokes person.[29] It was apparent to Ms Marion that Mr Vranejesevic's wife was in the room and contributed to Daniella's responses over the telephone.[30]

36. The CDRF sets out the information obtained by the donor co-ordinator during the interview with the family member. In this case it appears that the donor co-ordinator spoke to Mr Vranjesevic's daughter Daniella however Gordana gave evidence at the inquest. The risk identified on the CDRF was "15 kg weight loss over past 3 mths while on holiday o/seas."[31] The CDRF reveals that the donor co-ordinator had also been informed that Mr Vranjesevic had spent three months in Serbia returning a week earlier.[32] In the additional comments section of the CDRF the donor co-ordinator notes:

> *Daughter states that her father was more active while overseas on holiday. He stayed in a small village and did a lot of walking. Was away for 3 months and returned last week.*[33]

37. Whilst Ms Marion spoke to the liver transplant co-ordinator about the donor (who then completes in this case the ARMC Liver Transplant: Donor Referral Form)[34] she spoke directly to the renal physicians in respect of the kidneys. This divergence relates to the fact that the allocation of the kidneys is according to NOMS[35] (National Organ Matching System) and the fact that kidney transplant co-ordinators usually work normal office hours.

38. A hard copy of the CDRF is provided with the organ and at that time made available to the transplant physician and/or surgeon.

39. Of import to the question of whether there was a potential to have picked up the virus or anomaly in donor pre-transplantation is the evidence of A/P Spelman in respect of the mechanism of the virus. His evidence was that it is not possible to say how the LCM virus

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[29] T @ p 381

[30] Exhibit 26 – Statement of Violet Marion dated 23 May 2011 @ p6

[31] Exhibit 31 - Inquest Brief (IB) @ p102

[32] Exhibit 31, IB @ p98

[33] Exhibit 31, IB@ p 99

[34] Exhibit 19 - Statement of Julie Pavlovic dated 13 October 2010 and attachment 'JP01'

[35] Exhibit 24 – National Organ Matching System Allocation Final List (and is part of the CDRF document)

behaved in the donor and thus it is difficult to conclude that it was responsible for the symptoms Mr Vranjesevic complained of or exhibited, particularly his weight loss.[36]

40. Ms Julie Pavlovic, Liver Transplant Co-ordinator, Clinical Nurse Consultant at the Victorian Liver Transplant Unit at the Austin Hospital also gave evidence. Her statement[37] summarises the screening process and annexes the Liver Transplant Work Up Assessment Booklet for 2005 in respect of Mrs Sandhu.

41. There were other matters identified that related to Mr Vranjesevic but were not reflected in the CDRF and which may well have been of assistance to those conducting the transplantation process. These matters included:

- At the Dandenong Hospital Mr Vranjesevic had a temperature of 38.3°C.[38] Professor Jones stated: *certainly fever is a significant marker of infection, however, it is also unusual perhaps to be febrile with chronic sepsis if this is a low grade illness. It is also quite common to have temperature derangements with intracerebral haemorrhage. So again - ...fever is not uncommon in our donor population.*[39]

- Whilst in Serbia Mr Vranjesevic apparently complained of headache. Professor Jones gave evidence that: *In retrospect a new onset of unusual headaches over a sustained period would have been I guess an issue to have been aware of and certainly would have added to perhaps us thinking bout what was going on with this particular donor.*[40]

- Ms Gordana Vranjesevic refers to the pain that her father complained of in his right arm and leg. To this, Professor Jones gave evidence: *...this is a unique and unusual viral infection. I don't think any of us understands what it causes. So, I suspect again, if we had heard that story from his mother or while he was in Serbia it perhaps would have added to our concern that the weight loss may be due to something else.*[41]

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[36] T @ p181-2

[37] Exhibit 19

[38] Exhibit 30 'Southern Health – Dandenong Emergency Department notes Mr Vranjesevic's temperature – this document was within the bundle of documents provided at inquest by DonateLife and came from the file of DonateLife

[39] T@ p 140, 9-14

[40] T @ p 139

[41] T @ p 139

- Over the approximate 10 days from Mr Vranjesevic's return from Serbia and his death he had been complaining of lethargy.[42] To this information, Professor Jones stated: *It certainly would have added to our concern if there was a known risk that the patient was unwell in addition to weight loss.*[43]

42. Professor Jones says that whilst the above additional information would have made them more concerned as to what was happening with Mr Vranjesevic, it possibly would not have altered their decision to proceed to transplant:

> *...it may have influenced our decision. Whether it would have influenced our decision to the point we said we should not use this donor because of a hidden potential risk, I'm less certain of that. I think with that information I would certainly be more concerned – and I would've been looking for explanations to explain ...this illness that he had.*[44]

43. Again, with reference to the evidence of Professor Jones, the additional information if provided may not have influenced the post operative management of the recipients.[45]

(iii) Communication to the transplant team of the information obtained by the donor co-ordinator and contained in the CDRF.

44. Professor Jones gave evidence about the role of the CDRF and donor co-ordinators. He said that for the purposes of transplant they are very dependant on the organ donation agency for the information they provide. The transplant team do not however receive the CDRF or any other material in hard or soft copy:

> *We actually do not get any paper copy, this is all done by telephone, so its relayed by telephone to our recipient co-ordinator who documents it by hand and then relays it by telephone usually to the transplant team or the responsible person.*[46]

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[42] Exhibit 32 – this matter is noted on the CDRF that was provided by **DonateLife Victoria** at the Inquest

[43] T @ p 135

[44] T @ p 141

[45] T @ p 142

[46] T @ p 132

45. In the present case enquiries were made to find out more about the weight loss. Professor Jones gave evidence that:... *it was clearly a significant issue that registered as something that should be explained, we needed an explanation.*[47]

State of organs offered for donation

46. Dr Fink, surgeon who performed the retrieval of organs from the donor, noted severe atheromas to the renal artery of both the left and the right kidney. He noted this on the CDRF and believes that he contacted the transplanting surgeons about his concern in respect of the arteries.[48] Dr Michele gave evidence that he does not recall such contact and Miss Amanda Robertson, too did not recall such contact however did not dismiss it as having 47. occurred.

47. In terms of the atheromas to the kidneys identified by Dr Fink the risk is that they can potentially increase the risk of thrombosis following transplantation.[49] The issue is technical and Dr Fink was concerned that the atheromas would make the arterial anastamosis difficult and thus it was important that the surgeons performing transplantation should be made aware of this macroscopic finding.[50] From Mr Fink's perspective, the presence of atheroma did not render the kidneys unsuitable for transplant.[51]

> *The liver appeared good macroscopically with no evidence of any infective process or other parietal problem. There was an anatomical variant left...rising from the left gastric artery which does not preclude transplantation. There was severe aortic atheroma. A biopsy was performed and this revealed normal architecture, mild portal fibrosis (State 1), mild portal triaditis, no interface hepatitis and macro vesicular steatosis of less than five per cent. These findings were non-specific and would normally not preclude transplantation.*[52]

Confining his evidence as to the quality of the liver Professor Jones gave evidence that:

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[47] T @ p 134

[48] T @ p 83

[49] T @ p 78

[50] T @ pp 77-8; see also T @ pp 83-4

[51] T @ pp 83-84

[52] Exhibit 9 – Statement of Mr Fink dated 25 September 2008 and T @ p 72

This particular liver donor from our donor in Dandenong was in fact a very good organ and it worked very well and so there was certainly no concern. [53]

He went on to say;

..we would have to feel there was a significant risk in the donor before we would turn the donor down. As I say, every donor we accept we're accepting risks that this organ may not work or it may transmit disease or it may cause other problems and we're weighing that against a recipient who may die otherwise."[54]

48. In Professor Jones' opinion, Ms Sandhu's need for transplant was starting to become urgent.[55]

49. Miss Amanda Robertson gave evidence that she would not accept a kidney whose main artery was 95% occluded. The assessment of occlusion is performed macroscopically. When Miss Robertson was taken to the histopathology report in respect of the grafted kidney which describes: "The main renal artery and its branches" showing "severe atherosclerosis with focal calcification, narrowing the lumen to less than 5% of normal"[56]she stated that that finding was inconsistent with her own visual assessment of the kidney and could have been caused by clamping of the artery. Dr Michele gave evidence that the renal artery post operatively may undergo changes that render the lumen of the artery narrow.

50. In terms of the operation that Mr Michele performed on Mrs Sirianni he gave evidence that he trimmed back the atheromatous section of the artery and proceeded to anastomosis without difficulty.[57]

Extended Donor Criteria

51. The report of Professor Walker[58] refers to the existence of extended donor criteria (EDC). These extended criteria have evolved in response to the evidence-base underpinning the

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[53] T @ p 143

[54] T @ p 144

[55] T @ p 144

[56] IB @ p 464

[57] Exhibit 25

[58] Exhibit 16

desirability of transplanting patients rather than leaving them for long periods of maintenance dialysis. From the evidence of A/P Ierino, Professor Walker and Dr Michele it can be said that the clinical features giving rise to a kidney falling into the extended donor criteria may be contentious. Clinical features or circumstances such as hypertension, death as a result of cerebral haemorrhage and Hepatitis B core antibody positive, may or may not cause a donor to fall into the EDC. Where however a donor does fall into the EDC then those features are conveyed by the accepting physician to the potential transplant physician.[59]

(iv) Informed Consent of Recipients (did the general advice incorporate knowledge of the 2003 & 2005 clusters reported in the NEJM and now that these deaths have occurred what changes if any have occurred in relation to what a recipient is told in the consent process)

52. I accept that the general risks as they relate to mortality and morbidity were explained to each of the recipients. The specific issue that arose in respect of the deaths of the three recipients stems from the fact that the donor was Hepatitis core antigen positive.

53. Attached to the statement of Scott Campbell[60] are the Guidelines on Hepatitis B testing and use of HBV core antibody donors.[61] This document includes the following statement:

> Non-liver organ recipients of organs from donors known to be Hepatitis B surface antigen negative but Hepatitis B core antibody positive should ideally be immune and/or vaccinated to Hepatitis B and must be transplanted only after specific informed consent has been obtained.[62]

54. The Medical Director of the transplant program Dr Frank Ierino informed Mrs Sirianni of the availability of a compatible kidney and informed her of the donor's hepatitis status[63] and the associated risks of transmission of Hepatitis B Virus from the donor to the recipient.

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[59] *ibid* @ p 2

[60] Chairman of the Renal Transplant Standing Committee TSANZ

[61] IB @ p 114

[62] IB @ p 116

[63] Mr Vranjesevic was known to be Hepatitis B surface antigen negative but Hepatitis B core antibody positive – indicating a past infection with Hepatitis B. Ideally, a recipient should either be immune and/or vaccinated to Hepatitis B - Mrs Sirianni was vaccinated and was immune to Hepatitis B (see exhibit 23 – Statement of Dr Ian Michele dated 23 July 2010).

...the risk with Hepatitis B virus transmission was additional to the usual (standard) risks associated with transplantation (surgery, immunosuppression, other infectious agents, malignancy etc).[64]

55. Mrs Sirianni was informed that *because she had been immunised against hepatitis the chances of getting it were slim.*[65] *Mrs Sirianni had clear evidence of protective antibody levels (hepatitis B surface antibody) to hepatitis B.*[66]

56. Mrs Sirianni's son, Sam also had a discussion with Dr Ierino about the hepatitis status of the donor and the risks that might pose for his mother as a recipient.[67] On admission to the ward on 4 December 2006, renal registrar Dr Rajakumar also discussed the overall risks of the procedure as well the issues of Hepatitis B with Mrs Sirianni. Sam Sirianni was present. Mrs Sirianni signed the consent form which was witnessed by and in the presence of Dr Rajakumar.[68]

57. Mr Vranjesevic's Hepatitis B status, had been discussed with Mrs Sirianni and her family in accordance with the TSANZ Guidelines.

58. Mr Sirianni gave evidence of the discussions he and his family had with Associate Professor Ierino about the proposed transplant in general and the issue of Hepatitis B specifically.[69] Mr Sirianni said:

> *The concern was that the donor had hepatitis. That message was relayed to Mum, Mum relayed that message to me by phone...There was a discussion between me and him [A/P Ierino] and the discussion centred around the fact that the donor had hepatitis and whether that disease could be passed onto Mum and what the risks were associated with that...Having discussions after Mum died and all this type of stuff, we are led to understand that if someone has hepatitis it's probably not a good*

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[64] Exhibit 21 – Statement of Associate Professor Francesco Ierino dated 21 October 2010

[65] Exhibit 21 – Statement of Associate Professor Francesco Ierino dated 21 October 2010, Exhibit 10 – Statement of Sam Sirianni dated 26 February 2010, T @ p 102

[66] Exhibit 21 – Statement of Associate Professor Francesco Ierino dated 21 October 2010

[67] *Op cit,* T @ p 102, 106

[68] Exhibit 23 – Statement of Dr Ian Michelel dated 23 July 2010, T p 108

[69] T @ pp 99-104; 109-110

thing to take the person's organs and that it should be considered like someone that has HIV or cancer, ...I think that's the case for hepatitis only in the sense that if the recipient is on deathbed and there's no other option that they (sic) give them a chance and see if it works or not.[70]

59. Mr Sirianni did not accept in evidence that the donors Hepatitis status had nothing to do with his mother's death.[71]

60. The evidence of the significance of the Hepatitis B status of the donor was not consistent. According to Professor Walker there is no evidence-base upon which it can be said that a donor who is Hepatitis B core antibody positive can transmit that virus (or risks the same) via donation of an organ to a recipient. Professor Walker's evidence was inconsistent with the TSANZ guidelines, and the evidence of A/P Ierino and Dr Michele. Miss Robertson on the other hand deferred to the opinion of Professor Walker.[72]

61. A/P Ierino did not agree that a donor who is Hepatitis B core antibody positive should be regarded as in the same category as a donor who has had cancer or is HIV positive. This accords with the TSANZ Guidelines and the evidence of Professor Jones that in the event that the virus is transmitted it can be treated and the evidence of A/P Ierino that the risk of transmission is reduced from 2-5% to less where the patient as Mrs Sirianni was, is immune to Hepatitis B.

62. Dr Fink gave evidence that whilst a recipient may be negative, it can be treated. He said:

We have pretty powerful hepatitis B virus drugs available...that can prevent infection in the recipient so even in that case it can be done." [73]

63. Dr Fink gave evidence that the fact that a donor was core antibody positive is "not an absolute contraindication to transplanting that organ." He said:

...if we had a recipient who was Hepatitis B virus immune that usually not be an issue for us...there's very useful Hepatitis B virus drugs that were also available in

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[70] T @ pp 100 - 101

[71] T @ p 113

[72] T @ p 237

[73] T@ p 79

2006 that can be sued in the recipient after transplantation to prevent replication of the virus. So it's a relative risk but it's routine and it's policy that these organs can be used because...we have a high waiting list mortality, so we can't waste organs that might be able to be transplanted.[74]

64. Dr Stephen Munn, Chairperson, Liver Transplant Standing Committee, TSANZ, provided a statement in which he says that at the time of these events the guidelines for serological testing for transmissible infectious disease section did not refer to arena viruses given that its discovery is only recent. The extent of information to be provided to potential recipients to enable informed consent has not been standardised within the auspices of the TSANZ Liver Transplant Standing Committee however all units would provide advice about the origins of the organ (living or deceased), the fact that such donors undergo tests to try to exclude transmissible diseases and the fact that such testing can never be exhaustive.[75]

(v) Was There An Opportunity Through Intra Or Inter Hospital Communication To Learn Earlier Of The Common Deterioration Among The Recipients And Whether This Would Have Changed The Outcome For Any Of The Recipients

65. Professor Jones gave evidence that in the last week of Mrs Sandhu's illness enquiries were being made of the renal unit regarding the progress of the Austin Hospital recipient of one of the donor kidneys. As Ms Sandhu died on 7 January this suggests that this communication may have commenced in late December 2006 or early January 2007. Professor Jones gave evidence that the donor kidney recipient Mrs Sirianni was also reported to be deteriorating with an encephalopathic illness. At the same time a medical enquiry from the Royal Melbourne Hospital suggested a similar deterioration within the second renal transplant recipient.[76]

66. A/P Ierino stated that there were discussions inter and intra hospital in relation to the progress of the recipients. He does not recall the precise date.[77] Once it was known that the all of the patients had neurological symptoms then consideration was given as to a common

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[74] T @ p76

[75] IB @ p 109

[76] T @ p 130

[77] Exhibit 21- Statement of Associate professor Francesco Ierino dated 21 October 2010

cause of their decline. Alternative diagnoses noted in the history by the Infectious Disease Unit included but were not limited to LCMV.[78]

67. In her statement[79], Ms Pavlovic says:

> *Once it was discovered that the renal transplant recipient was also not doing well a meeting was arranged to discuss the situation. I think that this occurred before Christmas in 2006.*

68. Ms Pavlovic gave evidence that she believes notes of this meeting would have been taken although none were produced at the inquest.

69. Ms Marion in her statement[80] and in the CDRF she completed, refers to contact being made with her by the RMH in relation to the progress of the patient. She believes that contact is made with the donor co-ordinator as transplant teams are often not aware to what other hospitals organs from the same donor may go to.[81]

70. I accept that when reference is made to the notes of Ms Marion in the CDRF, the most likely and probable explanation is that the contact from RMH on 29 December 2006 to her was the first time (both inter and intra hospital) at which enquiry was made about the progress of recipients from the same donor. Ms Marion gave evidence that she could not be absolutely certain that this was the case. It was Ms Marion who then contacted the NUM from the Austin Renal Unit with the information she had received about the condition of the recipient at RMH – Ms Wilkinson. Ms Marion then contacted the Austin liver transplant team. She passed on advice received internally at DonateLife that the transplant teams were to communicate with each other. Ms Marion also briefed A/P Ierino and Professor Walker on the same date. She gave evidence that she believed that she was telling each of them something that they previously had not known before.

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[78] *ibid*

[79] Exhibit 19

[80] Exhibit 26 @ p 7 and Exhibit 32

[81] There are 6 hospitals that perform transplants in Victoria

(vi) Capacity To Screen For The Recently Detected Arenavirus

71. On 15 January 2007, Dr Michael Catton Medical Virologist, Director of VIDRL, received specimens from each of the three organ recipients with a request from the Coroner for testing. He said:

> *Because of the striking epidemiological features of the incident, notably 3 fatalities within days of one another, among 3 recipients of tissue from a common donor, I considered the involvement of a novel or difficult to characterise infectious agent to be possible, and worth pursuing.* [82]

72. The VIDRL in collaboration with the Greene Laboratory in New York led to the *discovery of an arenavirus with properties similar to, but distinct from lymphocytic choriomeningitis virus (LCMV). Evidence of infection with this virus was obtained from testing of samples of the three transplantation recipients and the donor.*[83]

73. From the investigation, Dr Catton concluded:

(i) A hitherto unknown arenavirus infected the donor and each of the three recipients.

(ii) Infection with this arenavirus cannot be demonstrated in other Victorian transplant patients unrelated to this cluster.

(iii) Transmission of such an agent by transplantation is biologically plausible, based on the known properties of arenaviruses and two similar episodes of transmission occurring in the USA.

(iv) The time course of the recipient's illness and death are consistent with arenavirus infection in general and with those recipients infected with LCMV in the USA;

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[82] Exhibit 28 – Statement of Dr Michael Catton dated 10 June 2008. See also article: "A New Arenavirus in a Cluster of Fatal Transplant– Associated Diseases", The New England Journal of Medicine – IB @ pp26-33

[83] *ibid*

74. In an addendum[84] to his first statement Dr Catton responded to a number of queries about the availability of testing for the new virus, about research being undertaken to develop such a test and the practicality and utility of such testing. He stated:

> *Laboratory tests for the novel arenavirus were developed during the investigation of the 2007 deaths. Based on their performance during that exercise, and our understanding of the general performance capability of the underlying technology, I believe that they are capable of detecting clinical cases of infection with this virus with acceptable accuracy. I believe that this represents as much laboratory testing capability as we are reasonably able to develop, and are currently likely to need.*
>
> *A much higher degree of accuracy is required of tests used to screen a blood or organ donor population. I do not believe that data is available or is likely to be available to validate current diagnostics tests for the novel arenavirus as sufficiently accurate for this purpose...We lack evidence of ongoing risk to transplantation patients from this arenavirus...in my opinion an unquantifiable potential for harm would be associated with donor screening, and validation tests to better refine this risk is not likely to be possible. Balanced against this potential harm is a lack of evidence regrading the existence of a significant risk that donor screening might be intended to mitigate.*[85]

75. Dr Catton in his evidence confirmed his view in relation to the ability (or rather impediments to) to screen for the virus. The ability to detect the virus is not the same as the capacity to screen for the same. The fact that the incidence of the virus occurring is so low in turn means that there is insufficient evidence upon which any screening process can be scientifically validated.

76. The discovery of the LMCV-like virus occurred some months after the deaths of the three recipients of Mr Vranjesevic's donated organs. Until that discovery I accept that it was a strain of virus that was unknown in humans and thus not capable of being identified at the time of retrieval and transplantation by those involved with either of those processes.

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[84] Exhibit 29 – Statement of Dr Michael Catton dated 6 April 2010

[85] *ibid*

VII. CONCLUSION

77. There is no evidence to suggest that earlier nephrectomy or the provision antiviral therapy would have altered the tragic outcome for each of the recipients in this case. In this respect the evidence of Dr Catton was of assistance. With reference to Dr Catton's first report[86] it is apparent that the virus had extended into the organs other than the grafted organs of the recipients. Having reference to the NEJM and the evidence of Dr Catton, treatment with the antiviral agent Ribavarin[87] cannot be said to be responsible for the positive outcome in the patient referred to in that study. According to Dr Catton consideration however may be given to the administration of Ribavarin (which has not inconsequential side effects) together with all other relevant matters in relation to clinical management and treatment.

Counsel Assisting, Ms Ellis submitted that the evidence highlighted the potential for recommendations based on the following:

1. The information obtained from the family by the donor coordinator is recorded on a form. The donor co-ordinator is not a member of the transplant team and for reasons more cogent than logistic is not on site at the hospital at which transplantation is to occur. The hand-over from the donor co-ordinator to the recipient co-ordinator is by telephone. The recipient co-ordinator they relays the information obtained to the transplant team. In such circumstances there is the real potential that information may be lost. With this in mind Professor Jones gave the following evidence which may be the basis of a like recommendation:

> ...it would be ideal if we did have access to them (CDRFs) because we would see exactly what's written and it would not be filtered and in fact there is an attempt to do that in the transplant community. So if these documents, for example, were online and the co-ordinator in the donor hospital...would put them into the computer centrally and we could go and look at that document. In other words we would be seeing without filtering exactly what was there. There would have been attempts and discussions about whether that would be feasible. I think it would be an ideal arrangement and it would allow the entire transplant community who are involved with that donor to log and look at those documents and not have it filtered by

[86] Exhibit 28

[87] see NEJM, 2005 Cluster, Kidney recipient A - IB @ p 142

telephone calls which, in my case, its second and becoming third hand information. It would be an ideal situation to actually see that document.

2. A/P Spelman referred to the recommendations in the United States that transplant recipients should minimise their contact with rodents/hamsters.[88] When asked himself whether donors should be screened by enquiring as to their contact with such pets he answered: "...I'm not a member of the transplant team but to me it does make some sense to ask that question."[89] Dr Catton gave evidence that was consistent with this.

3. In order to ensure that there is routine and regular post operative communication between and within hospitals who receive organs from the same donor enquiries should be made and recorded by the donor co-ordinator as to the progress of the recipients on days 7, 14, and 18. In the event that any unusual signs and or symptoms are noted then the donor co-ordinator is to inform each of the transplant teams of the existence of the other and requests that they communicate directly with each other about their patient's progress.[90]

FINDINGS

I accept and adopt the conclusions of Dr Michael Burke that the temporal relationship between the deaths of Karen Wilkinson, Gurpal Sandhu and Carmelina Sirianni and the underlying cause of death in each case, is the LCMV-like virus. Karen Wilkinson, Gurpal Sandhu and Carmelina Sirianni were the recipients of organs donated by Jovo Vranjesevic.

The LCMV-like virus is a novel arena virus – not previously seen or seen since, in Victoria.

AND I accept the evidence of Dr Burke that Mr Vranjesevic *died with the LCMV-like virus as opposed to "of the virus"*[91].

AND I find that the screening process which identified Mr Vranjesevic as a suitable donor was reasonable and appropriate in the circumstances and of itself could not have added any additional information that was likely to have altered the outcome. The history of recent significant weight

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[88] note: evidence of A/P Spelman (@ T p 182) LCMV has been identified in colonies of rodents including hamsters

[89] T @ p 182

[90] DonateLife in any event albeit for a different purpose make contact with the recipients. In this case initial contact occurred on 12 December – some 8 days post transplant

[91] T @ p 15

loss as it was understood by the family was communicated to the transplant team. As Mr Fink stated:

> *The potential clues in this donor that some infective process may have occurred were the facts that he had spent 3 months in Serbia and that he had lost 15 kg in weight over 3 moths. However, our unit was informed that his weight loss had been deliberate. The decisions regarding whether a donor organ should be used or not are complex and involve an assessment of the balance of risks to the potential recipient of transplanting the organ versus the risk of waiting for the next suitable organ.*[92]

The real or actual significance of the weight loss remains speculative.

AND I heard no evidence that the organ donation and transplantation procedures in Victoria are not rigorous. Potential donors and their families and recipients and potential recipients and their families have no reason not to have confidence in organ donation and transplant procedures arising from the circumstances of these tragic deaths. Mr Vranjesevic's death was sudden and unexpected yet his family altruistically consented to the donation of his organs at a time when they had barely come to terms with their own loss. The three recipients all required transplantation. They had all provided consent to the procedure once a donor became available. The potential opportunities for improvements to quality of life and prolongation of life that a transplant offered each of them was not realised and instead tragically, they succumbed to the novel virus.

As Dr Fink stated:

> *We (sic) need to bear in mind that we don't want to lose potential good organ donors because there is a great need in the community for transplantation and we have quite a low donor rate in this country, so we need to do everything we can for the transplant side while maintaining safety.*[93]

AND I find that the deaths from this novel arena virus of the three organ recipients, Karen Wilkinson, Garpul Sandhu and Carmelina Sirianni was neither foreseeable nor in all probability, preventable. Earlier identification and communication of the like complications being experienced by the three recipients in the post operative period would have lead the clinicians to consider sooner

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[92] Exhibit 9 – Statement of Mr Michael Fink dated 25 September 2008

[93] T @ p 87

that the likely cause of deterioration emanated from the donated organs and enabled better and more accurate communication with the families, however, it is not possible to say that it would have in fact altered the tragic outcomes.

RECOMMENDATIONS

Pursuant to section 72(2) of the **Coroners Act 2008**, I make the following recommendation(s) connected with the death:

1. **Inter and intra hospital communication post transplant**

(a) To improve on intra and inter hospital communication and minimise the risk of adverse outcomes, **I recommend** that DonateLife be authorised by the hospitals performing transplant surgery to extend their liaison role in the post transplant period to accept responsibility for intra and inter hospital communication regarding the progress and /or usual/unusual symptoms and/or complications of donor organ recipients in circumstances where there are more than one recipient of organs from one donor.

(b) AND having regard to the evidence of Mr Michele who stated:

> *...the average length of stay would be seven days, that if there are significant issues around about a week after transplant, that (sic) we should be sure to communicate with the other teams.*[94]

I recommend that DonateLife commence this liaison with the transplant teams seven days post operatively and continue with this intra and inter hospital communication every 48 hours thereafter until the discharge of the recipients.

(c) AND to facilitate this intra and inter hospital liaison and communication in circumstances where the *sage* physician[95] is consider more appropriate than the transplant co-ordinator, **I recommend** that on the occasion of each recipient organ transplant procedure the hospital nominate who is to be the designated contact person for DonateLife to communicate/liaise with.

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[94] T @ p 322

[95] T @ p 324

FURTHER CONCLUDING COMMENTS

Poor communication to a patient's family is a constant theme which was highlighted in the evidence of Sam Sirianni.

> *Nobody communicated anything to us unless we demanded information. It seemed that nobody was doing anything.*[96]

A confounding concern for Mrs Sirianni's family was their distress observing her deterioration during her post operative period and their perception of the lack of concern and lack of attention to her care by the health care providers. Unfortunately, similar such reporting by family members of a deceased is not uncommon in this jurisdiction. Complaints of poor communication and/or the lack thereof from the professionals to a family arises with such frequency that it compels comment. The comment may appear trite but cannot be underestimated in importance. Health care providers need to improve on the time and attention they give to family members concerned for the welfare of their loved ones with whom they have trusted to the health professional's for care. Regular communication in plain language cannot be underestimated in importance particularly when care is prolonged, complicated and critical. But I am confident that health care providers per se appreciate the power of knowledge but often fail to deliver. If a family actually know and understand what is happening during the course of hospitalisation their ability to come to terms with the death of their loved one greatly improves. Anger and allegations of poor care are too, often diminished.

Pursuant to section 73(1) of the **Coroners Act 2008**, I order that this Finding be published on the internet.

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[96] Exhibit 10 – Statement of Sam Sirianni dated 26 February 2010, T @ p 97

I direct that a copy of this finding be provided to the following:

Mr Salvatore (Sam) Sirianni

Ms Jan Moffat, Donaldson Trumble Lawyers

DLA Piper Australia
DonateLife Victoria

Signature:

AUDREY JAMIESON
CORONER
Date: 7 May 2013