



IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2015 4647

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)

Section 67 of the Coroners Act 2008

Findings of:	Caitlin English, Coroner
Deceased:	Andrew John O'Dwyer
Date of birth:	7 May 1964
Date of death:	12 September 2015
Cause of death:	I(a) Exsanguination during home haemodialysis in a man with end stage renal failure
Place of death:	19 Fraser Avenue, Anglesea, Victoria

INTRODUCTION

1. Andrew John O'Dwyer was born on 7 May 1964. He was 51 years old and lived with his wife Pauline and one of their four adult children in Anglesea, Victoria. Mr O'Dwyer is survived by his loving wife and children.
2. Mr O'Dwyer had a complex medical history including end-stage renal failure for which he received two transplants, both of which failed. He managed this condition through home haemodialysis using a Fresenius 4008B haemodialysis machine.
3. Mr O'Dwyer was diagnosed with a metastatic squamous cell cancer in 2011 which required surgery, chemotherapy and nasogastric feeding. In 2012 he fractured his ribs whilst surfing which required a pulmonary decortication and evacuation of a haemothorax.
4. Despite these set-backs, he lived a full and happy life continuing his employment as a refrigeration technician, his family commitments and his love of surfing.
5. On 12 September 2015, Mr O'Dwyer died in his home in the course of haemodialysis.

THE CORONIAL INVESTIGATION

6. Mr O'Dwyer's death was reported to the Coroner as it appeared to be unnatural and so fell within the definition of a reportable death in the *Coroners Act (2008)*.
7. The role of a coroner is to independently investigate reportable deaths to establish, if possible, identity, medical cause of death and surrounding circumstances. Surrounding circumstances are limited to events which are sufficiently proximate and causally related to the death. The purpose of a coronial investigation is to establish the facts, not to cast blame or determine criminal or civil liability.
8. A coronial brief was prepared by the member of Victoria Police assigned to be the coroner's investigator, Senior Constable Russell Harrup. The brief includes statements from witnesses including Mrs O'Dwyer, treating medical and nursing staff including Professor John Agar, paramedics, technicians from Fresenius Medical Care responsible for the haemodialysis machine and the forensic pathologist who examined Mr O'Dwyer. The brief also contained a report from the Therapeutic Goods Administration.
9. In response to issues of concern raised by Mrs O'Dwyer, I have made further inquiries with the Renal Unit at Barwon Health and Fresenius Medical Care.

10. On 6 September 2017 I conducted a visit to the Alfred Hospital in order to observe the 'priming' process of a Fresenius 4008B haemodialysis machine at the Alfred Dialysis Unit and to discuss the machine's sensors and alarms. I attended with Dr David Eddey, a Consultant Physician from the Coroners Prevention Unit.
11. I have based this finding on the evidence contained in the coronial brief. In the coronial jurisdiction facts must be established to the standard of proof which is the balance of probabilities.¹

BACKGROUND

12. Mr O'Dwyer suffered from Alport Syndrome, a genetic disorder causing kidney disease. He had his first kidney transplant whilst in his twenties. This transplant lasted just under ten years before he went into renal failure and was placed back on the transplant waiting list.
13. Whilst on the waiting list he started home haemodialysis and became one of the first patients to use nocturnal haemodialysis at home. Haemodialysis is a treatment process that filters substances out of a patient's blood, used when a patient's kidneys are unable to perform this function.
14. After two years of home haemodialysis he received a second transplant in 2002. This transplant lasted for about 7 years. In 2009 he went into renal failure again and resumed using nocturnal haemodialysis at the family home, 19 Fraser Avenue Anglesea.
15. Mr O'Dwyer was diagnosed with throat cancer in 2011. Although his treatment was successful, he had to come off the kidney transplant waiting list and could not go back on the list until he was cancer-free for five years.

Home haemodialysis

16. 19 Fraser Avenue Anglesea had a purpose built bedroom off the living room where a Fresenius 4008B haemodialysis machine was installed. A Gambro Reverse Osmosis machine was also installed to provide purified water suitable for dialysis.

¹ This is subject to the principles enunciated in *Briginshaw v Briginshaw* (1938) 60 CLR 336. The effect of this and similar authorities is that coroners should not make adverse findings against, or comments about, individuals unless the evidence provides a comfortable level of satisfaction as to those matters taking into account the consequences of such findings or comments.

17. Mr O'Dwyer performed haemodialysis at home rather than in hospital in order to maximise his quality of life. It allowed him to have haemodialysis overnight so that during daylight hours he was able to work and spend with friends and family. He would routinely perform home haemodialysis overnight for eight hours, four to five nights a week.
18. Haemodialysis requires access to the patient's vascular system in order to remove unfiltered blood from the patient and to return filtered blood to the bloodstream. In Mr O'Dwyer's case, vascular access was through an arteriovenous fistula (AVF), a location where an artery and a vein are joined together.
19. For the haemodialysis procedure, two needles are inserted into the vascular access. One of these needles, the 'arterial needle', is used to remove the unfiltered blood from the patient. The other needle, the 'venous needle', is used to return the filtered blood into the patient's vascular system.²
20. After being removed from the patient through the arterial needle, blood passes through an 'extracorporeal circuit' which includes a 'dialyser' to filter the blood. The blood is pumped from the arterial needle through an 'arterial line' into the machine, passed through the dialyser, then returned to the patient through a 'venous line' which connects to the venous needle.³
21. The dialyser acts as an '*artificial kidney*', removing uraemic toxins and excess fluids from the blood.⁴

Difficulties with home haemodialysis in the year preceding death

22. In the seven months prior to his death, Mr O'Dwyer was experiencing difficulties with home dialysis, in particular the fistula site whereby he attached himself to the haemodialysis machine.
23. Mrs O'Dwyer described how the key hole method of attachment using a blunt needle, which had worked well for more than five years, became difficult and she described it sometimes taking as long as an hour and a half for Mr O'Dwyer to attach himself to the machine. Sometimes the attachment would fail and he would have to come off the machine and receive dialysis at hospital the next day.

² Statement of Vanessa Wilson dated 29 January 2016, Coronial Brief p 41.

³ Statement of Vanessa Wilson dated 29 January 2016, Coronial Brief p 41.

⁴ Statement of Vanessa Wilson dated 29 January 2016, Coronial Brief p 41.

24. Mrs O'Dwyer also estimated that Mr O'Dwyer had to call a technician to assist with the machine four times in the year preceding his death. Mrs O'Dwyer thought Mr O'Dwyer had concerns about the pressure of the machine, which may have explained his attachment difficulties.

CIRCUMSTANCES IN WHICH THE DEATH OCCURRED

25. On 12 September 2015 Mr O'Dwyer woke up early and had a surf at Hutt Gully with his friend, Rob Benning. After a coffee, Mr O'Dwyer went for another surf at Jarosite.
26. He then attended a meeting at the Anglesea Op-Shop, following which he and Mrs O'Dwyer drove to Skilled Stadium in Geelong to watch their daughter's partner play football. After the football, they drove home, eating dinner at Hi Sushi in Waurin Ponds on the way.
27. That evening, Mr O'Dwyer prepared for his dialysis as usual. He weighed himself, and had a shower as usual. He was attached to the dialysis machine when Mrs O'Dwyer took him in a cup of tea twenty minutes later. She stated he was eating cashew nuts and chocolate and indicated to her he was fine. She said she needed to make a couple of phone calls.
28. Mrs O'Dwyer stated she did not recall anything out of the ordinary about Mr O'Dwyer or the machine at that stage.
29. After making her two phone calls, Mrs O'Dwyer returned to the living room to watch the football which was on the TV. She heard the dialysis machine beeping. As she was watching the football and the machine would beep fairly regularly she thought Mr O'Dwyer would sort it out.
30. When she realised the beeping was continuing, she went into the room. She found Mr O'Dwyer slumped across his bed, on his back with his head slightly leant up against the wall. She could not hear or feel him breathing. His eyes and mouth were open.
31. Mrs O'Dwyer removed his dentures, and as he had been eating she checked his airways. She called for her daughter to call an ambulance, thinking Mr O'Dwyer had had a heart attack.
32. She then commenced CPR where Mr O'Dwyer was lying on the bed, whilst her daughter called an ambulance. Mrs O'Dwyer had done a CPR course the week prior so was clear on what to do.

33. As she was doing CPR compressions she remembered seeing that his dialysis tubes seemed to be attached properly. After two minutes Mr O'Dwyer started to make some gasping noises and Mrs O'Dwyer thought this was his heart starting. Although she kept talking to him he did not respond.
34. At one point whilst Mrs O'Dwyer was doing compressions, her daughter left the room to check the door was open for the ambulance. As she did she caught one of the tubes from the dialysis with her foot and a clear line became dislodged.
35. The 000 call taker and Mrs O'Dwyer's daughter counted the compressions so that Mrs O'Dwyer could keep rhythm.
36. Mrs O'Dwyer kept up the compressions for nine minutes until the ambulance arrived. The ambulance officer moved Mr O'Dwyer to the floor and took over compressions from Mrs O'Dwyer.
37. Ambulance officer Jordan Rau states he was first to arrive. After moving Mr O'Dwyer to the floor, he attached the defibrillator and commenced CPR. After his partner arrived he began airways intervention and continued standard cardiac arrest protocol.⁵
38. Mr Rau noted, *'there was a bag containing a large amount of blood on the front of the machine.'*⁶
39. MICA paramedic Shane Brooks arrived and found the Anglesea ambulance crew performing CPR as Mr O'Dwyer was pulseless and non-breathing, with the ECG showing pulseless electrical activity.
40. Mr Brooks noted when he attended Mr O'Dwyer's room he saw: *'Hanging from an IV pole on the top right side of the dialysis machine was an overly extended bag with no identifiable markers, containing what appeared to be blood, liquid red in colour and bag warm to touch. The amount of pressure the bag was under appeared abnormal as the bag looked as if it was on the brink of bursting.'*⁷
41. Ambulance officers worked for one hour and four minutes to resuscitate Mr O'Dwyer. This included CPR, adrenaline and he was defibrillated 11 times. A decision was also made after

⁵ Statement of Jordan Rau dated 26 January 2016, Coronial brief p 24.

⁶ Statement of Jordan Rau dated 26 January 2016, Coronial Brief p 24.

⁷ Statement of Shane Brooks dated 13 March 2016, Coronial Brief p 26.

consultations between ambulance officers and the Ambulance Victoria clinician to reinfuse Mr O'Dwyer's blood during resuscitation.

42. After the initial ambulance officer arrived, Mrs O'Dwyer stopped CPR and switched off the dialysis machine which had continued beeping. She then noted a large bag of blood and fluid hanging off the machine and knew something was very wrong as '*There's never supposed to be any blood in any bag that's attached to the machine.*'⁸
43. Mrs O'Dwyer stated the blood should only ever be in the blood lines and she noted at the time there was blood in both Mr O'Dwyer's blood lines.
44. She recalls disconnecting the heparin needle and the blood lines so that Mr O'Dwyer could be moved from the bedroom to give the ambulance officers more room. Six paramedics worked to revive Mr O'Dwyer in the lounge room but were unsuccessful.

Post mortem investigation

45. On 15 September 2015, Forensic Pathologist Dr Michael Burke at the Victorian Institute of Forensic Medicine, conducted a post mortem examination. Dr Burke formulated the cause of death as '*I(a) Exsanguination during home haemodialysis in a man with end stage renal failure*'. I accept Dr Burke's opinion as to the medical cause of death.
46. Post mortem toxicological analysis detected drugs which may have been administered in a therapeutic setting.
47. In his report, Dr Burke notes that a bag of blood weighing 1.9kg and containing 1.7 litres of fluid blood accompanied Mr O'Dwyer's body to the Victorian Institute of Forensic Medicine.
48. The autopsy revealed end stage small shrunken kidneys and significant heart disease. Dr Burke found that the heart was enlarged and that there was associated coronary artery disease.
49. Dr Burke noted the bag of blood attached to the dialysis machine was full and bulging. He noted it was his understanding there should be nowhere near this amount of blood within the

⁸ Statement Pauline O'Dwyer dated 23 December 2015 Coronial Brief p 17.

bag of the dialysis machine and it indicates either a fault with the machine or overriding of the haemodialysis system.⁹

FURTHER INVESTIGATIONS

50. The Fresenius 4008B Machine installed in Mr O'Dwyer's home performed the exsanguination that led to his death. This can be explained either by a fault with the machine or operator error.
51. Mrs O'Dwyer has also raised concerns including possible issues with Mr O'Dwyer's medical management regarding his arteriovenous fistula and his connection to the machine.

Inspection of machine

52. On 14 September 2015, Rosemary Simmonds, Nurse Practitioner and Nurse Unit Manager of the Home Therapies Unit attended Mr O'Dwyer's home with two technicians from the University Hospital Geelong Biomedical Engineering Department. They did so with permission from Mr O'Dwyer's family and police to remove the Fresenius 4008B haemodialysis machine, the Gambro Reverse Osmosis machine and any surplus dialysis equipment.
53. On arrival Ms Simmonds noted the haemodialysis machine had been almost fully dismantled. The arterial and venous blood lines of the extracorporeal circuit had been removed from their positions on the dialysis machine and the patient connection end of both lines had been cut. The 'venous drain bag' was missing.¹⁰
54. Anthony Sharpin, Biomedical Technical officer with Clinical Engineering Department at Barwon Health attended with Ms Simmonds at 19 Fraser Avenue Anglesea to collect the haemodialysis machine.
55. He reported that at the South Geelong Renal Unit a T1 performance test of the machine was carried out. The test was carried out and passed.¹¹
56. Field Service Engineer Kim Timberlake from Fresenius Medical Care, stated that on 16 September 2015 at the South Geelong Renal Unit, he conducted a full functional check and calibration and a simulated treatment on haemodialysis machine serial number 2V5AVR09.

⁹ Report by Dr Michael Burke dated 27/10/2015

¹⁰ Statement of Rosemary Simmonds dated 18 January 2016, Coronial Brief p 30.

¹¹ Statement of Anthony Sharpin dated 16 January 2016, Coronial Brief p 32.

57. He stated all machine parameters were within normal limits except for the ultrafiltration, pump volume, temperature and transmembrane pressure which were slightly out of normal limits and would not have led to the machine failing its T1 test before treatment.
58. The T1 test and simulated test treatment was completed without fault, and a heat disinfect was also completed without fault.¹²
59. Ms Simmonds has assumed that the missing venous drain bag is the '*bag of blood*' noted by paramedics who attended Mr O'Dwyer. She states that it is not normal for the venous drain bag to be contaminated with blood as the sole purpose of the bag is to collect normal saline during 'priming'.¹³
60. Vanessa Wilson, Senior Director, Clinical Education from Fresenius Medical Care, manufacturer of the machine, provided three statements for the coronial investigation. She stated: '*The Haemodialysis machine in-question was checked by two biomedical technicians – one from the company and one from the hospital. Both found the machine to be in good working order and performed as intended.*'¹⁴

Mrs O'Dwyer's concerns – fistula management and machine service history

61. In her statement dated 23 December 2015 Mrs O'Dwyer raises some concerns regarding difficulties Mr O'Dwyer had had with his fistula in the seven months prior to his death.
62. Mrs O'Dwyer also raised concerns about the machine in the seven months prior to his death. She noted '*Because of the problems he was having with his home dialysis in the last seven months or so, Andrew had to call [a technician] more often than usual for help.*'
63. She estimated the technician might have come out '*four times in the last year.*'¹⁵
64. In response to these concerns, I made further inquiries with the Renal Unit at Barwon Health.
65. The nursing notes from the Home Therapies Unit indicate in November 2014 Mr O'Dwyer was experiencing difficulties with his fistula button hole site.

¹² Statement by Kim Timberlake dated 22 January 2015 Coronial Brief p 33.

¹³ Statement by Rosemary Simmonds dated 18 January 2016 Coronial Brief p 30.

¹⁴ Statement by Vanessa Wilson, dated 29 January 2016 Coronial Brief p 43.

¹⁵ Statement Pauline O'Dwyer dated 23 December 2015 Coronial Brief p 13.

66. Materials provided from Rosemary Simmonds, Nurse Unit Manager note that Mr O'Dwyer had two clinical reviews with Dr Agar on 28 April 2015 and 5 August 2015 and it was routine for his arteriovenous fistula (AVF) to be examined, although there is no specific reference to the AVF in the notes of those consultations.
67. In June 2015 Mr O'Dwyer had an ultrasound of the buttonhole site and on 17 July 2015 it is noted he continued to have issues with his venous buttonhole. The note recorded by Hannah Miller states: '*Site looks clean and dry with nil signs of infection. Andrew is going to try three sharps and a dull on the fourth run before creating a new site.*'¹⁶
68. The further note from 19 August 2015 indicates Mr O'Dwyer has been unable to develop a new venous buttonhole site and had decided to use the rope ladder technique. Janeane Boddington provided sharp needles for that purpose.
69. On 9 September Mr O'Dwyer said he had been '*area puncturing his AVF.*' The note indicates Rodney Christian instructed him to use the '*rope ladder technique*' to prevent weakening of vessel wall.
70. The notes confirm the difficulties Mr O'Dwyer was having managing his fistula. The care treatment and advice provided by the Renal Unit appears to be responsive, reasonable and appropriate.
71. The records of service of the haemodialysis machine (which commence in 2009) indicate that during 2014, there were 5 call outs during October and November of that year for problems with the upper flow alarms.
72. During 2015 there is no record of a call out regarding problems with the haemodialysis machine.

MR O'DWYER'S OPERATION OF THE 4008B HAEMODIALYSIS MACHINE

73. Ms Simmonds and Professor John Agar have provided information on the operation of the Fresenius 4008B haemodialysis machine, including a checklist from the Barwon Health Home Therapies Unit titled '*Connecting to machine for haemodialysis*'. (The description given in this section is simplified and only covers those aspects relevant to Mr O'Dwyer's death.)

¹⁶ Nursing Notes from RenalNet (Digital record, Barwon Health Renal Unit.)

74. Before initiating dialysis, the lines of the extracorporeal circuit should be 'primed' by pumping 0.9% normal saline through the lines and into a 'venous drain bag' connected to the lines. The purpose of this procedure is to wash out any impurities that may remain in the extracorporeal circuit after it has been sterilised.¹⁷
75. Once priming is complete, the pump should be turned off and the venous drain bag should be disconnected from the lines. At this point there will remain approximately 150mL of saline in the lines and the dialyser.¹⁸
76. According to the Barwon Health Home Therapies Unit Training Manual, the patient should then connect the venous and arterial lines of the machine to the venous and arterial needles of their vascular access. All lines and needles should be unclamped and the blood pump turned on.¹⁹
77. The machine will pump blood through the extracorporeal circuit until an adequate concentration of blood is detected by the 'optical detector'. (If the lines of the machine have been properly set up, the optical detector should be located on the venous line after the dialyser. The optical detector measures the concentration of blood passing through the venous line.)²⁰ At this point the blood pump will automatically stop, the venous line will be clamped, and there will be an audible alarm.²¹
78. The patient must then press a '*Dialysis Start / Reset Alarm*' button to commence dialysis, at which point the pump will restart and the alarm will cease.
79. According to Professor John Agar, after arterial blood influxes into the extracorporeal circuit, '*the force of the arterial blood then flushes the ... normal saline ... that has primed the circuit back into the patient through the unclamped venous needle. At the same time, any residual air that might be retained in the circuit is extruded and collected in the venous bubble trap*'.²²
80. The machine will then commence the dialysis process of pumping blood out of the patient through the arterial line, through the dialyser, then back into the patient through the venous line.

¹⁷ Statement of Professor John Agar dated 18 February 2016, Coronial Brief p 34.

¹⁸ Report of Professor John Agar dated 18 February 2016, Coronial Brief p 36.

¹⁹ '*Connecting to Machine for Haemodialysis*' checklist from Barwon Health Home Therapies Unit Training Manual.

²⁰ Statement of Vanessa Wilson dated 29 January 2016, Coronial Brief p 41; '*4008 B Dialysis System*' Flow Chart retrieved from <http://fmc-au.com/machines/item/4008b-2> on 9 August 2018.

²¹ '*Connecting to Machine for Haemodialysis*' checklist from Barwon Health Home Therapies Unit Training Manual.

²² Report of Professor John Agar dated 18 February 2016, Coronial Brief p 36.

81. If there is no fault in the Fresenius 4008B machine, and it is operated correctly as above, at no point should blood enter the venous drain bag.²³

Sensors and alarms

82. The Fresenius 4008B machine has a number of sensors and alarms equipped in order to prevent adverse events from occurring.
83. The venous line should be seated in the optical detector described above, which detects whether blood is flowing through the venous line. When the optical detector first detects blood, it stops the blood pump, clamps the venous line, displays a visual alarm and sounds an audible alarm. In order to turn off the alarm and restart flow, the patient must press a '*Dialysis Start / Reset Alarm*' button.
84. There are also sensors measuring arterial pressure and venous pressure. If the blood pressure entering the arterial or venous line is too low or too high, the arterial or venous pressure alarm will be triggered. This will stop the blood pump, clamp the venous line and sound a continuous audible alarm.²⁴
85. Prior to each dialysis, the machine performs a 'functional test' to test safety and operational aspects. A patient cannot dialyse if this test is not passed.

How blood might have entered the venous drain bag

86. In the case that there was no fault in the machine, Ms Simmonds proposed a scenario which might lead to blood entering the venous drain bag of a home haemodialysis patient.²⁵
87. First, the dialysis machine must pass its functional T1 test and be set up ready for the dialysis procedure. Next, the arterial blood line of the extracorporeal circuit must be connected to the arterial needle in the patient's arteriovenous fistula. The venous blood line of the extracorporeal circuit must then be connected to the venous drain bag. (Ms Simmonds notes that the Home Therapies Unit teaches patients that they should never connect the venous blood line to the venous drain bag during haemodialysis.)²⁶

²³ Statement of Rosemary Simmonds dated 18 January 2016, Coronial Brief p 31; Report of Professor John Agar dated 18 February 2016, Coronial Brief p 36.

²⁴ Letter from Rosemary Simmonds and Professor John Agar to the Court dated 20 September 2017.

²⁵ Statement of Rosemary Simmonds dated 18 January 2016, Coronial Brief p 30.

²⁶ Ibid.

88. The blood pump of the dialysis machine must then be turned on, pumping blood from the patient into the extracorporeal circuit.²⁷
89. At this point, the blood in the extracorporeal circuit should reach the machine's optical detector. When blood is detected, as described above, the pump will stop and a line clamp will be triggered below the venous chamber, resulting in no further blood flow from the patient. In addition, a visual alarm will be displayed and an audible alarm will sound.²⁸
90. If the optical detector stops blood flow in this manner, the patient must press the '*Dialysis Start / Reset Alarm*' button to restart the blood pump.²⁹
91. Ms Simmonds noted, alternately, a second scenario: if the venous blood line were *not* inserted into the optical detector when setting up the machine, this alarm would not be triggered, the blood pump would not automatically stop, and it would not be necessary to press the '*Dialysis Start / Reset Alarm*' button for blood to flow into the venous drain bag.³⁰
92. As the machine had been partially disassembled during the attempts to resuscitate Mr O'Dwyer, there is no direct evidence of how he was connected to the dialysis machine at the time of his death.

Connection of venous line to venous drain bag – possibility of 'short-cut'

93. Both of Ms Simmonds' scenarios require that the venous line of the extracorporeal circuit be connected to the venous drain bag while blood is being actively pumped from Mr O'Dwyer via the arterial line.
94. The coronial brief includes a report and supplementary comments, dated 18 February 2016, by Professor John Agar, Conjoint Clinical Professor of Medicine at University Hospital Geelong and Deakin University School of Medicine.
95. Professor Agar qualified his remarks with the proviso that, due to the dismantling of the extracorporeal circuit and the removal of consumables by the time Ms Simmonds attended 19 Fraser Avenue Anglesea, it was impossible to be sure how the lines of the extracorporeal

²⁷ Ibid.

²⁸ Ibid.

²⁹ Ibid.

³⁰ Ibid.

circuit had been connected at the time of Mr O'Dwyer's death. According to Professor Agar, *'this makes any interpretation of what occurred simple conjecture.'*³¹

96. Professor Agar, like Ms Simmonds, advised that the venous drain bag should never become contaminated with blood. In particular, once priming with saline solution is completed and saline flush is collected in the venous drain bag, *'the bag should be disconnected from the circuit, [and] the now primed and flushed circuit lines should be connected to the venous needle in preparation to start dialysis connected to the venous needle.'*³²
97. In proposing an explanation for why Mr O'Dwyer might have set up his machine in such a manner as to pump blood into the venous drain bag, Professor Agar identified a *'temptation to cut corners'*.³³
98. Professor Agar drew attention to the point that *'one of the primary roles of dialysis is to remove the excess salt and water that had accumulated in the patient's circulation and tissues since the last dialysis. This is especially an issue for long-term dialysis patients who are commonly anuric and thus depend fully on the dialysis process for salt and water removal. [Mr O'Dwyer] was one such anuric patient.'*³⁴
99. With respect to such patients, Professor Agar commented that *'these patients in particular may view any additional salt and water added as a result of the priming process to be counterproductive, as it is simply adding to the salt and water load that must then be removed during dialysis'*.³⁵
100. Professor Agar raised the possibility that such patients might *'try to lessen the salt and water (saline) load that is being infused from the saline-primed circuit into the circulation by collecting this ... priming volume in the [venous drain bag] through late disconnection of the bag instead of connecting immediately to the venous needle and allowing the priming volume to enter the circulation through the venous limb of the fistula'*. Professor Agar describes this as a *'short-cut'*.³⁶
101. In describing patients who might attempt this *'short-cut'*, Professor Agar commented that *'it often seems to be the longer-term dialysis patients who, at their risk, against all their*

³¹ Report of Professor John Agar dated 18 February 2016, Coronial Brief p 35.

³² Ibid.

³³ Ibid.

³⁴ Ibid.

³⁵ Ibid.

³⁶ Ibid.

training advice, and with misplaced faith in their experience, seek to minimise their additional saline burden' in this way.³⁷

102. Professor Agar concluded that *'while the venous blood line should never be connected to the venous drain bag, we think it likely that [Mr O'Dwyer] may have done this on this occasion – whether by unwitting error, or by short-cut intent ... and which, we will never know – with a tragically fatal outcome. It should be noted that in other reported literature of home haemodialysis deaths, similar errors have been made by similarly experienced home patients.'*³⁸

103. Vanessa Wilson from Fresenius Medical Care indicates awareness of the dangers of what is referred to as the *'run off'* connect and recommends the *'direct'* connect method, namely connection as a single step, to reduce any potential risk.³⁹

Placement of the venous line in the optical detector

104. Ms Simmonds' second scenario requires that the venous line not be properly seated in the machine's optical detector.

105. Ms Simmonds emphasised in her statement that, in the Home Therapies Unit, *'the correct placement of the venous blood line in the "optical detector" forms part of an everyday check when going on dialysis; it is expected that all patients fill out this chart acknowledging the correct placement of the line at every dialysis'*.⁴⁰

106. Professor Agar noted: *'Patients are repeatedly reminded and advised not to take any short cuts...and to be especially careful with their fail safe protection...yet it is known... that some patients, especially some of the more experienced ones- do still ignore this advice. While our check charts list the optical detector as amongst a range of fail-safe checks the patient should conduct as a routine before 'going on', the final decision remains with the patient whether these charts are followed to the letter, or not.'*⁴¹

³⁷ Ibid.

³⁸ Ibid.

³⁹ Statement Vanessa Wilson dated 29 January 2016, Coronial Brief p 41.

⁴⁰ Statement of Rosemary Simmonds dated 18 January 2016, Coronial Brief p 30.

⁴¹ Report of Professor John Agar dated 18 February 2016, Coronial brief p 36.

107. Vanessa Wilson of Fresenius Medical Care, manufacturers of the Fresenius 4008B haemodialysis machine, has confirmed that it is possible for the machine to be activated *without* inserting the venous line into the optical detector.⁴²
108. In the case where the venous line is connected to the venous drain bag, Professor Agar stated that: *'If the venous line is not accurately seated into the optical detector, the machine cannot detect if there is blood in the extracorporeal circuit, nor can it trigger an audible alarm to alert the patient to the presence of blood in the circuit. This would mean the blood pump would continue to pump blood into the venous drain bag- as seems likely to have happened on this tragic occasion.'*⁴³

Alarm heard by Mrs O'Dwyer

109. Mrs O'Dwyer recalls hearing a continuous beeping before she went to check on Mr O'Dwyer to find him unresponsive. This implies that one of the machine's alarms was sounding at this time, and that therefore the blood pump would have been stopped. The venous drain bag had already filled with blood.
110. The alarm heard by Mrs O'Dwyer could not have been the alarm associated with the optical detector. The possible scenarios for Mr O'Dwyer's blood flowing into the venous drain bag require either that the optical detector never be triggered at all or that Mr O'Dwyer pressed the *'Dialysis Start / Reset Alarm'* button after the alarm is triggered in order to restart the pump.
111. Ms Simmonds and Professor Agar were asked to comment on this issue. They informed the Court in a joint letter that *'Given the scenario, one possible explanation could be that the arterial pressure alarm may have been set off as the blood volume supplying the machine diminished; another could be that a high venous pressure alarm was activated as the venous drain bag overfilled. Both cases would have activated the venous line clamp, stopped the blood pump and set-off the audible and visual alarms on the machine.'*⁴⁴
112. I concur with their analysis. I find that either the venous or arterial pressure alarm was the continuous beeping heard by Mrs O'Dwyer.

⁴² Letter from Vanessa Wilson to the Court dated 30 October 2017.

⁴³ Report of Professor John Agar dated 18 February 2016, Coronial Brief p 37.

⁴⁴ Letter from Rosemary Simmonds and Professor John Agar to the Court dated 20 September 2017.

Conclusions - connection and operation of haemodialysis machine on 12 September 2015

113. Although Mr O'Dwyer's machine was dismantled prior to his death leaving little direct evidence of how it was connected, some conclusions can be drawn.
114. In order for blood to have entered the venous drain bag, it is necessary that the venous line of the extracorporeal circuit was connected to the venous drain bag and that the arterial line was connected to Mr O'Dwyer's vascular access. Mr O'Dwyer must have started the blood pump with the lines connected in this manner.
115. These actions are inconsistent with the training provided to Mr O'Dwyer by Barwon Health. They are, however, consistent with the 'short-cut' described by Professor Agar.
116. It cannot be determined whether or not the venous line of the extracorporeal circuit was properly seated in the optical detector. This gives rise to two possible scenarios, neither of which is supported or excluded to any greater extent by the evidence:
- (a) If the venous line was *not* properly seated, then blood could have been pumped into the venous drain bag without being interrupted by the failsafe of the optical detector.
 - (b) If the venous line *was* properly seated, the following sequence of events would have occurred: Mr O'Dwyer's blood would have reached the optical detector, an alarm would have sounded, the blood pump would have automatically stopped and the venous line would have been clamped. In order for blood to continue being pumped into the venous drain bag, Mr O'Dwyer would have been required to press the '*Dialysis Start / Reset Alarm*' button in order to turn off the alarm and restart the pump.
117. I put forward these speculations only to indicate there is insufficient evidence to make a finding as to which scenario occurred.
118. Despite this uncertainty, by one of those scenarios the situation arose where the arterial line was connected to Mr O'Dwyer's vascular access, the venous line was connected to the venous drain bag, and blood was being pumped through the venous line into the venous drain bag. If the optical detector had been in place to interrupt this process, Mr O'Dwyer must have pressed the '*Dialysis Start / Reset Alarm*' button after it was triggered.
119. At this point, the machine pumped blood from Mr O'Dwyer into the venous drain bag until setting off either the arterial or venous pressure alarm. Although this later alarm would have

stopped the pump and clamped the venous line, Mr O'Dwyer had lost sufficient blood at this point that he could not be resuscitated.

COMMENTS PURSUANT TO SECTION 67(3) OF THE ACT

120. According to Kidney Health Australia, 12,706 people in Australia were receiving dialysis treatment at the end of 2016, and 28% of these patients used home dialysis.⁴⁵
121. It is unknown how many patients might use a 'short-cut' as described by Dr Agar when commencing haemodialysis at home.
122. Barwon Health train all of the home haemodialysis patients they support to never commence haemodialysis with the venous line connected to the venous drain bag, and '*drill patients in the importance of correctly inserting the venous blood line into the optical detector*'.⁴⁶
123. However, it is impossible to ensure that patients are always compliant with their training. More specifically, Professor Agar makes clear that it is known that some patients, particularly experienced ones, can take the 'short-cut' he describes.

Failsafe mechanisms in home haemodialysis

124. The Fresenius 4008B haemodialysis machine is used in both hospital and home settings, and the safety features are the same in both settings.⁴⁷
125. Professor Agar referred the Court to a report describing a case in New Zealand where a home haemodialysis patient exsanguinated as a result of misconnected lines. The authors of that report came to the following conclusion:
- 'Despite successful training, critical procedural errors can still be made by patients on home hemodialysis. In this case, the error involved misconnection of the saline bag for wash back. ... Manufacturers of dialysis machinery should be encouraged to design machines specifically for home hemodialysis ... to prevent occurrences such as these in the future.'*⁴⁸
126. Mr O'Dwyer's death appears to have occurred in the context of an intentional short-cut rather than an unintentional procedural error, but the importance of considering the home

⁴⁵ Kidney Health Australia, 'Kidney Fast Facts' last reviewed July 2018, retrieved from kidney.org.au.

⁴⁶ Report of Professor John Agar dated 18 February 2016, Coronial Brief p 36.

⁴⁷ Letter from Vanessa Wilson to the Court dated 30 October 2017.

⁴⁸ Kerryanne Allcock et al., 'Exsanguination of a home hemodialysis patient as a result of misconnected blood-lines during the wash back procedure: A case report' (2012) *BMC Nephrology* 13:28.

environment in designing machinery is equally relevant. It is unrealistic for safety features to rely on patients always being compliant with their training.

127. It cannot be determined whether Mr O'Dwyer's venous line was properly seated in the optical detector on the night of his death. In the case that it was not, his death would likely have been prevented if, for example, the blood pump were unable to start without the line being properly seated. Such a failsafe would recognise the differences between a hospital environment and use in a home setting where there is an absence of supervising medical and nursing staff.
128. In the event that manufacturers do not design machines specifically for use in the home, the safety of a particular machine in the home environment should be a factor when patients and their physicians consider which machine to use for home haemodialysis. It may also be feasible to modify existing machines to make them safer for home use.
129. For these reasons, I direct a copy of this finding be distributed to Fresenius Medical Care for their consideration regarding the design of safety features in their haemodialysis machines used in the home setting.
130. I also make a recommendation below that Safer Care Victoria conduct a review considering these matters.

Dismantling of machine

131. A constant source of difficulty in the coronial investigation was the lack of direct evidence of how Mr O'Dwyer's machine was connected on the night of his death due to its dismantling.
132. The first priority of paramedics should be treatment of the patient rather than preserving evidence; however, these goals will not always be in conflict. In his report to the Court, Professor Agar made the following comments:

'It might be helpful to advise paramedic crews, should they ever be called to an emergency at the home of a home dialysis patient, that they should not under any circumstances disrupt or dismantle the dialysis lines or systems – regardless of whether the patient is simply unwell during dialysis and needs to have their treatment discontinued, or whether the patient has been found deceased.'

Rather, the machine should simply be turned off at the wall plug and, if the patient needs to be disconnected from the machine, the arterial and venous lines should be double-clamped near the skin exit and entry sites and cut between the clamps in a manoeuvre akin to the method used for the cutting of the umbilical cord of an infant. The lines, systems and the set-up “map” of the machine and the attached consumables should be left untouched to allow later expert assessment and photography of any errors that may or may not have occurred in the set-up procedure.’⁴⁹

133. Professor Agar also described an event which occurred in 2015 where a treating expert team was barred from entry to the scene of a death of a home haemodialysis patient, *‘the scene being regarded by the attending police as more of a crime scene than as the site of a medical mishap or misadventure. In this instance, by the time the ... expert team were permitted entry, the machine had been stripped down and dismantled, thus preventing a full understanding of the sequence of events. It appeared ... that the attending police may have regarded the issue as one of machine malfunction, rather than operator error. In our experience, this is unlikely to be the case with all similar past reported deaths in home dialysis patients around the world being due to operator error.’⁵⁰*

134. With respect to these issues, Professor Agar concludes:

‘Only by ensuring an untouched machine and the early (but accompanied) entry of an expert dialysis team to the machine site for system examination and set-up photography will we learn from any future events. As tragic as these occurrences are – and, sadly but truthfully, there will likely be others from time to time in the future, the site should, in my view be regarded as a medical scene from which to learn medical facts and lessons, and not as a crime scene.’⁵¹

135. I direct that copies of this finding be distributed to Ambulance Victoria and to the Chief Commissioner of Victoria Police for their consideration when training paramedics and police to attend the scenes of deaths in home haemodialysis patients.

RECOMMENDATION PURSUANT TO SECTION 72(2) OF THE ACT

136. I recommend that Safer Care Victoria review the safety of haemodialysis machines used by home haemodialysis patients supported by Victorian public health services, with a particular

⁴⁹ Report of Professor John Agar dated 16 February 2016, Coronial Brief.

⁵⁰ Ibid.

⁵¹ Ibid.

focus on failsafe mechanisms and ways to avoid potentially dangerous short cuts when used in the home setting.

FINDINGS

137. I find that Andrew John O'Dwyer died on 12 September 2015 at Anglesea from I(a) Exsanguination during home haemodialysis while suffering end stage renal failure in the circumstances described above.
138. Although there are difficulties regarding evidence of the machine's functioning, the available evidence does not indicate that any mechanical fault was responsible for Mr O'Dwyer's death.
139. I express my sincere condolences to Mr O'Dwyer's family for their loss.
140. Pursuant to section 73(1A) of the *Coroners Act 2008*, I order that this finding be published on the internet.
141. I direct that a copy of this finding be provided to the following:

Mrs Pauline O'Dwyer, senior next of kin, c/o Tim Connor Law.

Safer Care Victoria.

Fresenius Medical Care.

Ambulance Victoria.

Chief Commissioner, Victoria Police.

Professor John Agar, Barwon Health.

Senior Constable Russell Harrup, Coroner's Investigator.

Signature:



CAITLIN ENGLISH
CORONER

Date: 30 August 2018

