CORONERS COURT
NEW SOUTH WALES

Inquest:	**Inquest into the death of Kerryn Foale**
Hearing dates:	19 & 20 August 2015
Date of findings:	26 September 2015
Place of findings:	State Coroner's Court, Glebe
Findings of:	Deputy State Coroner HCB Dillon
Catchwords:	**CORONERS – Cause and manner of death** – Ventricular fibrillation in a patient with implanted defibrillator – Why defibrillator failed **--** Whether manufacturer gave appropriate warnings of the possibility of failure of the device -- Whether the technological fault in the device has been addressed
File numbers:	2011/00386637

Representation:	Mr A Casselden (Counsel Assisting) instructed by Mr S Hogan (Crown Solicitor's Office) Ms J Lonergan SC instructed by Ms K Bowers, Avant Law (Dr M McGuire) Mr D Villa instructed by Mr A O'Reilly, Kennedys (St Jude Medical Australia Pty Ltd)
Findings:	I find that **Kerryn Foale** died on 5 June 2011 at 56 Railway Avenue, Colo Vale, New South Wales due to ventricular fibrillation resulting from hypertrophic cardiomyopathy when her implantable cardioverter defibrillator failed to terminate the arrhythmia and convert it to normal heart rhythm due to a short circuit in the lead caused by abrasion damage.
Recommendations:	To the **Commonwealth Minister for Health**, the **Chief Executive Officer of the Therapeutic Goods Administration** and the **President of the Cardiac Society of Australia and New Zealand** I recommend that consideration be given to establishing a national registry of implanted cardiac devices that would capture full details of the cardiac device (eg. brand / model) and also details of the patient in whom such device was implanted. To the **Commonwealth Minister for Health** and the **Chief Executive Officer of the Therapeutic Goods Administration**, I recommend that consideration be given, in consultation with the Cardiac Society of Australia and New Zealand, and manufacturers of implantable cardiac devices, to requiring mandatory reporting of failures of, or significant incidents concerning, implanted cardiac devices by clinicians and allied health professionals including device manufacturers or their Australian agents. To the **President of the Cardiac Society of Australia and New Zealand**, I recommend that the Society consider developing guidelines concerning the regular testing of implanted cardiac devices that do not have in-built, regular, painless, circuitry-testing capacity.

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REASONS FOR DECISION

Introduction

1. This is an Inquest into the sudden death of Kerryn Foale. Kerryn was only 22 when she died on 5 June 2011. She was 22 years of age and engaged to be married to her long-time boyfriend Ricky Lyons. The suddenness of her death not only shocked her family but devastated them emotionally. Her treating doctors were equally shocked and, of course, very concerned to establish exactly why she had died.

2. Kerry suffered from a congenital heart condition, hypertrophic cardiomyopathy or HCM. In short, she had a very enlarged heart. Enlarged hearts are less efficient than hearts of normal dimensions and are prone to arrhythmia. Irregular heart rhythms, if not corrected quickly, can be fatal.

3. Kerryn died after experiencing what appears to have been a fast cardiac ventricular tachycardia or VT event. At the time of her death Kerryn was fitted with an implantable cardioverter defibrillator or ICD and a high voltage lead. The purpose of such an ICD is to restore regular rhythm to the heart if it becomes arrhythmic. It does so automatically by applying an electric shock.

4. The ICD that was in place at the time of her death was a St Jude Model V-193 Atlas manufactured by St Jude Medical, an American medical device manufacturer. The high voltage lead was a Riata Model 15 70 also manufactured by St Jude Medical. A device and lead had first been implanted in 2003. A new ICD was implanted in 2006.

The coroner's functions and the nature of the inquest

5. A coroner's functions are primarily investigative. An inquest is not a legal trial but a fact-finding exercise. There are no plaintiffs, defendants, accused persons, prosecutors involved. The coroner's task is not enter judgment for or against any persons or organisation but is obliged to make findings, if possible, as to the identity of the person who has died, the date and place of death, the cause of death and the manner or circumstances of death.

6. The other major function of a coroner is, if it is necessary or desirable, to make recommendations to governments or other organisations that may reduce the risk of death or serious harm to other members of the community in future.

Kerryn Foale

7. Although this inquest, naturally, was largely concentrated on medical and technical evidence, the true subject matter of this inquest is not the technological details the much-loved young woman whose death has caused such a profound sense of loss for her family and her fiancé and her other loving friends. Her family were too upset to come to the inquest.

8. Professor Chris Semsarian, her cardiologist, who had cared for her for about 10 years, and who knew the family well, described Kerryn as a 'very happy girl' whom he had watched grow up. She was 'full of life' and very excited about getting married. She loved her family was very close to them. Their profound sense of loss must have been heightened not only by her death but the fact that it took place shortly before the wedding towards she and her family had been looking forward with such happy anticipation.

Kerryn's ICD history

9. Kerryn had a diagnosis of hypertrophic cardiomyopathy with severe septal hypertrophy (42rnrn). Hypertrophic cardiomyopathy is an inherited condition. It is a dangerous condition that, left untreated, carries with it significant risk of abnormal heart rhythms which are potentially fatal. It was diagnosed in 2003. Professor Semsarian recommended that an ICD be implanted as protection against arrhythmia.

10. Kerryn's first ICD was implanted in November 2003. In an uncomplicated procedure a St Jude Medical Riata 1570 lead was implanted and attached to V-199 Atlas ICD. Prior to discharge the lCD was tested and found to be functioning satisfactorily.. She was then reviewed regularly every six months or so. In 2006, because the battery was becoming depleted, the ICD (but not the lead) was replaced.

11. The procedure was uncomplicated and a new St Jude V -193 Atlas lCD was implanted. During the procedure the lead was tested and was functioning normally with good defibrillation threshold and excellent pacing and sensing thresholds and normal impedances. It is normal practice to not replace the lead in this situation.

12. At that time, ICDs did not automatically test themselves or download their own data. For a cardiac surgeon or cardiologist to test the ICD's circuitry, therefore, the circuitry had to be given an electric shock. If that test was undertaken, the voltage was about 12V. Many patients did not like that experience and therefore many, perhaps most, clinicians did not like to inflict it.

13. Apart from the pain or discomfort this inflicted on the patients, the testing of the circuitry in this was also problematic for two more reasons: first, it was a test at only one point in time. All it told the clinician was that the circuitry *at the time of the test* was functioning. It had no predictive value. Second, the value of a low voltage test of 12V might not have given an accurate picture of the state of the circuitry anyway. To test the circuitry fully, a high voltage test would be needed. To undertake such a test, however, would require that the patient be put under general anaesthetic. Very few, if any, clinicians would recommend such a procedure merely for the sake of testing circuitry that was apparently in working order.

14. On the 24 July 2006 she had several inappropriate shocks likely related to sinus tachycardia following a family argument. All device parameters at that time appeared normal including the high voltage impedances. The device was reprogrammed to slightly higher detection rate. Kerryn remained asymptomatic until the time of her death.

15. In 2008 the V-193 Atlas lCD was subject to a Hazard alert. A software fix was applied as per the recommendations of the manufacturer St Jude Medical.

16. She was followed regularly on a 6 monthly basis in Associate Professor McGuire's lCD clinic which is normal practice. At every check the device appeared to be functioning normally with stable sensing, pacing thresholds and pacing impedances.

There was no evidence of electrical noise. The high voltage impedances on this device had not been tested. This device can test the high voltage impedances with a 12 volt shock but a significant number of patients find this quite distressing so it is not usually done unless a problem is suspected.

17. She was last seen in the clinic on the 15th December 2010 where she was asymptomatic, the device was checked and found to be functioning normally.

18. On the 5 June 2011 Kerryn suffered a fatal ventricular arrhythmia that the device failed to convert to a normal rhythm despite delivering a high-voltage shock.

19. Subsequently the ICD and lead were removed and sent for further examination. Evidence of abrasion lead, with molten insulation and an arc mark on the ICD casing was found.

The issues

20. The sudden death of a young person with an implanted ICD is a very rare event. Neither Professor Semsarian nor her cardiac surgeon, Dr Mark McGuire, had experience of such an event previously. The sudden unexplained death of a member of our community is a matter of concern to our society as well as to Kerryn's family. So it is important not only to discover what brought about Kerryn's death to enable her family to understand the event but also for public health and safety reasons.

21. A number of issues, therefore, have been explored during the preliminary investigation and the inquest:

- what caused Kerryn Foale's ICD and lead to fail;
- whether the manufacturer gave appropriate warnings of the possibility of failure of the device;
- whether the care and treatment of Kerry by her treating cardiologist and surgeon were appropriate;
- whether the technological fault in the device has been addressed;
- whether there are recommendations that may improve patient safety.

I will deal with each in turn.

Why did the defibrillator fail?

22. The human body is not static or inert. The heart is a powerful muscle that is in constant motion. This means that leads inserted into the heart or placed in its nearly vicinity are subjected to a range of forces that, over time, have the tendency to wear away the protective material placed around cardiac leads.

23. Cardiologists and other clinicians in this field also have a number of studies that have found varying rates of insulation failure in different models of lead. Dr Denman, in his report, noted younger patients and females were at highest risk from insulation failure.

24. While it is rare in Professor Semsarian's and Dr McGuire's experience for leads to fail in the way Kerryn's did, and the fact that such events are rare shows that leads are well-designed and manufactured, they also have to be designed in such a way that can do be implanted where they have to go.

25. This places physical limits on their size and the amount of protective material that can used to coat them. The body's immune system and the need for leads to be flexible place further limits on the design and manufacture of leads.

26. Dr Russell Denman, a consultant electrophysiologist retained as an independent expert to examine the case, concluded that the evidence suggested that the device had failed because of a short circuit between the high voltage conductors and the ICD related to this abrasion of the insulation.

27. When it was delivered, therefore, the shock was shunted across this break and away from the heart and therefore unable to terminate the episode of ventricular arrhythmia. Dr Denman's view is that this would probably have damaged the internal circuitry of the ICD and that any further shocks would have been ineffective. He noted that the failure mechanism in this case is typical of that communicated in the important product information and Hazard Alert from St Jude Medical issued in December 2010 and November 2011.

28. The evidence in this case demonstrates that the designers, manufacturers and clinicians are constantly working towards better, safer products that will last longer, be less invasive, and reduce the risk of adverse complications. This is an evolutionary process.

29. In Kerryn's case, although her ICD and lead appeared to operating as they were designed to, without major surgery, her doctors were unable to see or assess the degree to which her lead was wearing out. They had to rely on the best estimates of those who collect the data – the manufacturers, the Therapeutic Goods Administration, the US Food and Drug Administration, and the medical literature.

Manufacturer's warnings

30. The manufacturer had given notice in 2010 of a potential fault that may develop over time in older Riata leads. The warning letter noted a reported failure rate of 0.47% over a nine-year period. It also stated that the new leads that had been insulated with optimium coating had a far lower failure rate than the older silicon-coated leads.

The clinicians

31. The problem for clinicians is what to do with that information. The removal of leads carries certain risks, even of a fatal event. The insertion of a new lead and the decommissioning of the old is not an easy process and is very dependent on the circumstances of individual patients for its success. The problem for clinicians is compounded by the issue of testing which I have commented upon above. In short, there are risks on both sides of the question and it is matter of careful clinical judgment as to how doctors should proceed.

32. There has been no criticism of the care and treatment of Kerryn either from her family or from the independent experts. In my view, the treating doctors were highly professional and careful and caring in their approach to Kerryn's case. Beyond the general manufacturer's warning, they had no warning signs of the potential malfunction of Kerryn's device. It was a shock to them and they were very anxious after Kerryn died to take steps to seek answers. They were interested in her as a person, as a patient and as clinicians caring for others with such devices.

Advances in technology

33. One of the unfortunate and sad features of Kerryn's case is that she had been fitted with a device that did not have an automatic data collection and warning function. The model of ICD which was implanted in her has now been superseded by devices that test themselves without discomfort to the patient. They download data on a daily basis. This is sent wirelessly to a laboratory that analyses the data and immediately picks ups any evidence of failure or potential failure and makes the necessary notifications so that the patient can receive timely advice and treatment.

34. Had Kerryn lives longer, it is likely that she would have received such a device to replace her old ICD.

Can more done for patient safety?

35. During the course of the inquest, it was agreed by the expert witnesses that there are a number of major deficiencies in the current system of monitoring the performance of ICDs and leads. Mr James Ramshaw of St Jude's made the salient point that there are good data concerning what devices are implanted but not on the follow up. This means that there is an immeasurable but probably significant degree of under-reporting of failures or incidents. Capturing accurate data would enhance epidemiology in this field, thereby focussing and improving research and development, increase device reliability and ultimately advance patient safety.

36. Mandatory reporting of failures or notable incidents concerning the performance of devices to the Therapeutic Goods Administration and the manufacturer of the device is not required at present. As a result, gaps are left in the data series. This evidence suggests that there would be significant merit in mandatory reporting of such incidents to a central registry of devices and the manufacturers.

37. Such a mandatory reporting system, if established, should, if possible, include interrogation of a device following a patient's death.

38. I do not underestimate the scope of the logistical effort required in setting up such a system. Nevertheless, when the expert advice is that such a system would be greatly beneficial, it must be considered. I propose to make a recommendation to the Commonwealth Minister for Health, the Therapeutic Goods Administration and the Cardiac Society of Australia and New Zealand that consideration be given to establishing such a system.

39. There are differing views concerning the shock-testing of the older leads. Clinicians, naturally, do not like causing pain or significant discomfort to the patients. Relatively few patients, I understand, are still using the older style ICDs and leads of the type that were used by Kerryn. Nevertheless, for those patients and their treating doctors, a guideline from the Cardiac Society on the testing of leads may be a useful tool. I will recommend that the Cardiac Society considers issuing such a guideline.

Conclusions

40. There are few more painful experiences a human being may suffer than the sudden and unexpected loss of a child, especially a young one. So affected by the distress and sense of loss that Kerryn's death caused them, they were unable to participate in this inquest. In fact, they would have preferred that there be no inquest but understood my decision to

hold one because they recognised the possible benefit for others. I appreciate their position and am grateful for their understanding and apologise for the distress this inquest may have caused them.

41. There is, I think, no such thing as 'closure', and it would be a foolish and, indeed, presumptuous coroner who believed that he or she can provide 'closure' for grieving families. I hope, however, that Kerryn's family, and Ricky Lyons, will find some small measure of comfort or solace in knowing that this inquest has explored Kerryn's death with a view to finding ways of making other people, especially young people like her, safer in future.

42. And I hope that they will accept the very sincere and respectful condolences that the coronial team and I offer them. We hope that their many happy memories of Kerryn will in time outlast and outweigh the sadness and distress they have suffered in losing her like this.

43. I now turn to the formal findings I must make under the Coroners Act, together with my recommendations.

Findings s 81 Coroners Act 2009

44. I find that Kerryn Foale died on 5 June 2011 at 56 Railway Avenue, Colo Vale, New South Wales due to ventricular fibrillation resulting from hypertrophic cardiomyopathy when her implantable cardioverter defibrillator failed to terminate the arrhythmia and convert it to normal heart rhythm due to a short circuit in the lead caused by abrasion damage.

Recommendations

45. To the Commonwealth Minister for Health, the Chief Executive Officer of the Therapeutic Goods Administration and the President of the Cardiac Society of Australia and New Zealand I recommend that consideration be given to establishing a national registry of implanted cardiac devices would capture full details of the cardiac device (eg. brand / model) and also details of the patient in whom such device was implanted.

46. To the Commonwealth Minister for Health and the Chief Executive Officer of the Therapeutic Goods Administration, I recommend that consideration be given, in consultation with the Cardiac Society of Australia and New Zealand, and manufacturers of implantable cardiac devices, to requiring mandatory reporting of failures of, or significant incidents concerning, implanted cardiac devices by clinicians and allied health professionals including device manufacturers or their Australian agents.

47. To the President of the Cardiac Society of Australia and New Zealand, I recommend that the Society consider developing guidelines concerning the regular testing of implanted cardiac devices that do not have in-built, regular, painless, circuitry-testing capacity.

Magistrate Hugh Dillon
Deputy State Coroner