# STATE CORONER'S COURT
# OF NEW SOUTH WALES

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| **Inquest:** | **Inquest into the death of Toni Ann Peadon** |
| **File No:** | **2012/246397** |
| **Hearing dates:** | **2-4 June 2014** |
| **Date of findings:** | **11 July 2014** |
| **Place of findings:** | **State Coroner's Court, Glebe** |
| **Coroner:** | **Deputy State Coroner H.C.B. Dillon** |
| **Catchwords:** | **Coronial law –** cause and manner of death – health-related procedure – extraction of cardiac device leads – laser sheath extraction – surgical accident – whether procedure appropriate for this patient – whether consent procedure adequate – whether procedure performed appropriately – whether fatal injury foreseeable or preventable – whether emergency procedures appropriate – need for clarification of emergency procedure guidelines |

**Representation:**

Mr A Casselden (Counsel Assisting) instructed by Ms A McCarthy (Crown Solicitor's Office)

Mr L King QC with Mr K Connor SC (for Mr Brian Peadon)

Mr S Woods instructed by Mr L Sara (Hicksons Lawyers) (for Westmead Hospital and Western Sydney Local Health District)

Mr J Downing instructed by Ms J Brook-Cowden (MDA National Insurance) (for Dr A Hastings)

Ms McFee instructed by Dr S Bird (MDA National Insurance) (for Dr P French)

Ms K Burke instructed by Ms N Sher (Avant Law) (for Dr J Trinh)

Mr G Gregg instructed by Ms S Wallace (MDA National Insurance) (for Dr G Sivagangabalan)

**Findings:**

I find that Toni Ann Peadon died on 6 August 2012 at the Westmead Hospital, Westmead, New South Wales as a result of a laceration of the superior vena cava and right atrium occasioned while she was undergoing a procedure to extract an implanted right atrial defibrillator lead.

**Recommendations:**

I recommend to the Minister for Health that the department of cardiology at Westmead Hospital, in consultation with the NSW Ministry of Health and the Cardiac Society of Australia and New Zealand, consider introducing a specific form of written consent for lead extraction procedures which include the following:

1. The pertinent elements of the planned procedure and all reasonable alternatives
2. The percentage risk of major and minor complications
3. A statement (including Westmead Hospital's rates of extractions and outcomes) that lead

extractions can be potentially life-threatening

4. A statement of the proceduralist's personal level of experience in lead extractions and outcomes

5. The emergency procedures in place should a complication arise.

Insofar as is reasonably practicable I recommend that the patient's consent be obtained in the presence of a family member or friend.

IN THE STATE CORONER'S COURT
GLEBE
SECTION 81 CORONERS ACT 2009

# REASONS FOR DECISION

## Introduction

This is an inquest into the sudden and premature death of Toni Ann Peadon. Dr Peadon, known professionally as Toni Medcalf, died suddenly and unexpectedly during a surgical procedure being carried out to remove and replace internal defibrillator leads in her chest that had become defective. The procedure was carried out at the Westmead Hospital on 6 August 2012. During that operation, while one of the leads was being removed, she sustained a irreparable tear in one of the major heart blood vessels, causing her to bleed suddenly and so profusely that her life was unable to be saved despite emergency surgery.

Under the *Coroners Act 2009*, the sudden and unexpected death of a person following a health-related procedure must be reported to the coroner who may, after reviewing the known facts, order further inquiries to be made and may conduct a public inquest.

## Toni Ann Peadon

This inquest has closely scrutinised the preparation and execution of the procedure and its aftermath. Much of the time spent analysing the case has necessarily been of a technical nature. At the heart of the inquest, however, is the life and story of a much-loved, much-admired woman who, at least in spirit, remains very much alive in the hearts and minds of those who knew her.

Toni was married to Brian Peadon. They had a close and loving relationship. She was the mother of four children who miss her tremendously. She was a skilful, careful and compassionate doctor who specialised in Emergency Medicine and who worked for many years in Dubbo before moving to work at the Canberra Hospital. Her professional career was devoted to saving lives and she made particularly significant contributions to rural medicine and to acute paediatric care. Toni was also a passionate educator, and spent much of her spare time instructing others in advanced paediatric life support skills.

She was a woman of formidable energy and drive who embraced life enthusiastically and with great zest. Apart from her busy family and professional lives, Toni was also an elite athlete who represented Australia in the Masters Games overseas in triathlon events. She loved sports and competition and was, like all top-class triathletes, remarkably fit. She was also a community leader, helping start the Macquarie Anglican Grammar School in Dubbo and involving herself in a multitude of other activities.

Toni touched the lives of many people. Her family and friends and the wider circle of people who knew her through her professional and community activities were left shocked and confused by the sudden loss of such warm and vital person who had been so central to much of what they did. It was also very evident during the inquest that the doctors who were involved in her fatal operation directly or indirectly were deeply upset by her death.

## Role of the coroner

The coroner's role is to investigate sudden and unexpected deaths to identify a deceased person, when and where that person died, the physical cause of death and how that death came about.

In this case, the real questions with which we have grappled are to do with that last question of how this accident happened and whether more could have been done in the attempt to save her life.

A further role for a coroner is to assess whether there has been an appropriate response to a catastrophe and whether more needs to be done to protect others from a similar death. I will come back those questions.

## The issues

An issues list, which raised questions concerning the circumstances of Toni Peadon's death, was circulated before the hearing. The list outlined the following topics for inquiry during the inquest:

- The decision to remove and replace the leads on the existing defibrillator rather than installing a new device (and decommissioning but not removing the old one);
- The decision to replace all the leads and whether the basis of that decision was properly explained to Toni Peadon;
- The consent process and whether Toni Peadon had sufficient opportunity to consider the risks;
- Whether the procedure ought to have been done as an open procedure rather than under imaging;
- Whether the procedure was performed properly and, in particular, whether there was any failure of technique;
- Whether the injury to Toni Peadon could have been foreseen or prevented;
- Whether the procedure should have been performed in a hybrid operating theatre;

- Whether appropriate procedures for dealing with an emergency had been established; and

- Whether the emergency procedures followed in the event were appropriate.

## The background

In 2007, Toni suffered a number of episodes of syncope. She was found to have a mitral valve prolapse. While this condition is generally benign, it is associated in some cases with sudden death due to cardiac arrhythmia. She then had coronary angiography which revealed no coronary disease. Other investigations followed. Although a definitive diagnosis was never reached, her treating cardiologist, Dr Peter French and others whom he consulted, including Professor Denniss, strongly suspected that these episodes were cardiac in origin and perhaps related to her regime of intense exercise.

Because of her history, and because of her intense athletic activity, in consultation with her cardiologist she had a defibrillator implanted. In 2009, one of the leads of her defibrillator fractured. This led to the implantation of another lead and revision of the defibrillator.

In 2012, Toni had a skiing accident which may have caused the pacemaker's alarm to be activated. Toni's husband telephoned the manufacturer of the defibrillator, Medtronic Australasia Pty Ltd ("Medtronic") and Toni's cardiologist, Dr Peter French, on the day after the accident. Medtronic informed the Peadons that the alarm indicated that a lead in the device was faulty or damaged. The Peadons were assured that the situation was not life threatening, and an appointment was scheduled for Toni with a Medtronic technician at Dr French's office.

At this appointment, it was determined that a new lead would need to be inserted. In order for this to occur, at least one of the old leads would need to be removed. Toni and her husband, in consultation with Dr French, decided that if one of the leads was to be removed then both of the faulty or fractured leads should also be removed in the one procedure to reduce the chance of complications. The lead replacement procedure was scheduled for 6 August 2012 at Westmead Hospital. It was the only medical facility that had the required laser sheath and specialist cardiothoracic surgeons available in case of an emergency.

Mr Peadon also stated that, prior to the surgery date, he and Toni conducted research on Professor David Ross, the doctor who they understood would be performing the procedure, and on the type of lead that would be inserted. Professor Ross is an expert in this type of procedure.

At about 10am on 6 August 2012, Toni, her husband and children, and a family friend, Dr Suzanne Smallbane, attended Westmead Hospital for her procedure. Mr Peadon states that, at about midday, they were attended by a doctor who appeared to them to have the wrong set of notes and that this caused them some concern and that they asked to speak to

the principal proceduralist who they assumed was Dr Ross. They were then attended by Dr Gopal Sivagangabalan.

Mr Peadon gave evidence that Dr Sivagangabalan indicated that they would be inserting a different type of lead to the Medtronic Quatro lead that he and his wife had discussed with Dr French and that they had researched. Mr Peadon also stated that Dr Sivagangabalan indicated that all three of the leads may need to be removed, rather than just the two faulty leads.

Mr Peadon also asserted that he and Toni were given inaccurate information by Dr Sivagangabalan as to the risk involved in the procedure and that, had they been told there was a risk of death, they would not have consented to the procedure. This is disputed by Dr Sivagangabalan.

Toni was then taken to the Cardiac Catheter Laboratory for the procedure and given a general anaesthetic by Dr Adam Hastings. A transoesophageal echocardiogram probe (TOE) was inserted to monitor the anatomy of the chambers of the heart during the procedure. The procedure commenced at about 2.30pm. Dr Sivagangabalan was assisted in the surgery by Professor Ross. A representative from Medtronic, the defibrillator manufacturer was also present in the Cath Lab.

One of the leads was successfully removed but, at about 4pm, during the removal of the atrial lead, Toni's superior vena cava was torn, causing a massive bleed and her condition to suddenly deteriorate. Resuscitation attempts were commenced and aspiration of blood from the pericardial cavity was attempted. A call was made to the cardiothoracic team which was answered by Dr Nicholas Cocco, a junior cardiothoracic registrar, who then called the senior cardiothoracic registrar, Dr Padmanabhan for assistance. Dr Padmanabhan attended the 'cath lab' and determined that a sternotomy would need to be performed to release the pressure and to control the bleeding. As the 'cath lab' was not equipped to allow an emergency sternotomy to be performed, Toni was transferred to an operating theatre. Dr Padmanabhan on the way to theatre, contacted his supervising consultant Dr Meldrum Hanna (who was not at the Hospital, but was on-call) and informed him of Toni's condition.

Toni arrived in the operating theatre about 20 minutes after going into cardiac arrest. An emergency sternotomy was performed by Dr Padmanabhan at about 4.22pm. Dr Meldrum Hanna and Dr Ross Mejia later joined Dr Padmanabhan in the operating theatre. Dr Padmanabhan stated that when he opened Toni's pericardial cavity he observed no cardiac activity, a significant amount of blood collected around the heart and significant on-going bleeding from a full-length tear of the superior vena cava. Dr Padmanabhan attempted to control the bleeding by applying digital pressure and continued with resuscitation and internal cardiac massage. After about half an hour, a decision was made by Dr Meldrum Hanna to cease medical intervention. Toni was declared dead at 5pm.

In her autopsy report, forensic pathologist Dr Jennifer Pokorny noted the direct cause of death as haemophericardium/operative exsanguination. Dr Pokorny identified two antecedent causes, being "vena caval laceration followed operative manipulation of defibrillator leads" and "intrinsic dysrhythmia and mitral valve prolapse". Significantly, Dr Pokorny noted a "large irregular ragged laceration of the superior vena cava" of "45 x 15mm" extending from the innominate vein to the right atrium". She also observed a 3mm perforation at the tip of the right atrial appendage closed by a suture around the base of the appendage.

In short, Toni died as a result of massive blood loss that occurred as a result of the laser instrument cutting into the wall of her superior vena cava. The 3mm perforation at the tip of the right atrial appendage may also have contributed to the loss of blood but much larger tear in the SVC was the primary injury causing the fatal blood loss.

An expert opinion was obtained from Dr Paul Hendel, a consultant cardiothoracic surgeon. Dr Hendel noted the "risk of major vascular injury" with pacemaker lead extraction and that "this may be fatal even if appropriate cardiothoracic surgical intervention is immediately available". Dr Hendel's opinion is that the procedure should have been conducted in a hybrid operating theatre rather than the 'cath lab' and that there should have been cardiothoracic surgeons present and equipment ready should an emergency sternotomy be required.

Dr Hendel noted that the "window of opportunity to effect control of bleeding and attempt repair is short" and considered that there was a "significant delay" in transporting Toni to the operating theatre and in opening her pericardial cavity.

## The decision to remove and replace the defibrillator leads

For a number of reasons, the decision to remove and replace the failed defibrillator leads was reasonable. Although it may have been theoretically possible to insert a new lead to replace the one that had failed at the time of Toni's skiing accident without extracting the old lead, there is limited space for additional leads in the narrow space between the clavicle (collar bone) and the first rib.

Because Toni was a very active tri-athlete, it was thought that the mechanical movements of swimming (rotation of arms and movement within the shoulders) may have caused or contributed to the fracturing of the old leads. Accumulating leads in that narrow space would have increased the likelihood of friction and wear on the casing of the leads. Her cardiologist, Dr French, and Dr Gopal Sivagangabalan, the cardiologist who led the procedure, advised Toni that they would prefer her to reduce her athletic activities, especially the swimming. She considered that the advice carefully but decided that she wanted to continue swimming and competing in triathalons.

If another lead was inserted without extracting the old lead, this would also complicate future extractions and make the extraction process more risky.

Finally, implanting a new lead without extracting the failed lead could result in stenosis or obstruction of the venous system with all the possible complications they may entail.

## The decision to replace both failed the leads in the same procedure

In my view, the decision to attempt to remove both failed leads in the same procedure was reasonable for similar reasons. Every operation carries risks. It is commonsense that increasing the number of lead extractions increases the risk of complications but, according to Professor Ross, the incremental risk in removing both leads was marginal. General anaesthetics also carry risks. The additional risk, however, must be weighed against the risks of the alternatives, including the long-term consequences or potential consequences of taking a minimalist approach.

Dr Peadon was a highly intelligent woman and skilled doctor. She and Mr Peadon conducted their own research into the procedure, the risks involved and into Professor Ross's experience. I understand that she also had some discussions – at least in general terms – with colleagues in the cardiology department at Canberra Hospital. Professor Ross and Dr Sivagangabalan are highly-trained and experienced in this procedure and the techniques involved. According to Dr Sivagangabalan, he spoke with Dr French and Toni by telephone before he saw her on the day of the operation at Westmead Hospital. He also discussed the case with Professor Ross, with Professor Pramesh Kavoor, head of the cardiology department at Westmead Public Hospital, and with Professor Robert Denniss, a consultant cardiologist at Westmead and Blacktown Hospitals.

This was a carefully considered decision and, given that before the operation the risks of the additional lead extraction appeared to be low, was well justified. In the event, the ventricular lead was removed without a hitch.

## The consent process and whether Toni Peadon had sufficient opportunity to consider the risks

Mr Peadon and Toni's family had a natural concern that Toni may not have made a fully informed decision concerning the procedure. The first time either Mr Peadon or Toni had met Dr Sivagangabalan face-to-face was at the hospital shortly before the procedure itself. This was unusual.

Before elective surgery is performed, a surgeon or proceduralist normally meets the patient at least once beforehand face to face. This enables each party to assess the other and for them to speak to each other about the relevant issues in as natural an atmosphere as is practicable. Critically, the surgeon can explain the procedure, the alternatives, the risks, the prognosis, the aftermath and answer relevant questions from the patients or family members who accompany them. This usual procedure was varied only because Toni lived and worked in Canberra, had pressing commitments there, and was a doctor who was able to communicate well with Dr Sivagangabalan over the telephone.

At the hospital, Toni and the Peadon family met Dr Sivagangabalan. He spoke with them as a group but at some point spoke to Toni by herself.

Mr Peadon's recollection of the conversation to which he was privy differ from Dr Sivagangabalan's in some respects. I have had the advantage of reading their statements but also of seeing both of them give evidence and have their evidence and recollections tested by experienced and skilful counsel.

My impression of both of them is that they had each been through experiences that had been emotionally highly charged and, indeed, devastating but that each was attempting as best he could to give frank and honest evidence. It is unsurprising, given the calamity that had befallen them both in different ways that their recollections were different.

I accept that if Toni had believed that there was a serious risk of death or significant morbidity she might well have refused to undergo the procedure. Mr Peadon gave evidence that he and Toni, in the course of their research, had found that the risk of serious complications reduced the more experience the proceduralist had. This is in line with general medical studies demonstrating that high-volume hospitals (usually teaching hospitals or specialist centres) have lower incidence of complications than centres in which particular procedures are carried out irregularly. This demonstrates that experience builds skill and expertise. Both Dr Sivagangabalan and Professor Ross had developed significant expertise in this procedure and had a low rate of complications. Before Toni's death, although a patient suffered a serious tear during a procedure about two months before, there had been no deaths at Westmead Hospital due to laser lead extraction.

Her good friend, Dr Susan Smallbane, gave evidence that Toni was the sort of person who would fully inform herself about the procedure and the potential risks as appears to have been the case. This suggests to me that Toni would have understood the procedure well Had she understood that Dr Sivagangabalan had done about 60 lead extractions previously, this would have been reassuring to her (and Mr Peadon). Although we do not know whether this question was asked by Toni, she almost certainly would have sought to confirm with Dr Sivagangabalan that the team was experienced. Finally, Dr Sivagangabalan gave plausible evidence that he had explained the procedure and possible risks to Toni. Indeed, given what I now know about her, it seems unlikely that she would not have quizzed him if he had not. For these reasons, it seems more likely than not that Toni gave informed consent to the procedure.

To ensure, however, that in future patients are fully apprised of the relevant risks associated with lead extraction procedures I propose to make a recommendation that the Westmead Hospital develop a specific consent form that would be attached as an annexure to the generic NSW Health consent form used in relation to all surgical procedures.

## Should the procedure have been done as an open procedure rather than under imaging?

It is possible to extract defibrillator leads by means of open heart surgery. In general terms it has been found that percutaneous lead extraction is safer than the open procedure. Patients tend to survive longer, require less hospital time and have fewer complications than patients undergoing the open procedure.[1]

In this case the evidence all clearly indicated that the procedure used in Toni's case is generally preferable to the open procedure. There were no unusual features of her case indicating otherwise.

## Was the procedure performed properly and, in particular, was there any failure of technique?

There are few medical practitioners trained in laser lead extraction working in Australia – less than 10. The procedure is delicate and, in some instances, nerve-wracking. Dr Hendel gave evidence that he had done a small number of lead extractions but had not enjoyed the experience for this reason. Because there are so few practitioners of laser lead extraction working in Australia, none were available to provide expert reports to me on this operation. The evidence at the inquest concerning the procedure and what went wrong therefore came mainly from Professor Ross and Dr Sivagangabalan. It is pertinent to note, however, that none of the interested parties, especially the Peadon family's legal representatives, produced reports to contradict that evidence.

My firm impression is that Professor Ross, Dr Sivagangabalan and the whole cardiology department at the Westmead Hospital were very troubled by Toni's death and made a conscientious effort to analyse the operation and what had happened. There was no attempt made by either of them to obfuscate or dissemble. It is my firm impression that they gave frank and full evidence concerning their review and analysis.

Internal defibrillators are designed to deliver a shock converting dangerous rapid heart rhythms (ventricular tachycardia or fibrillation) back to a normal rhythm. Leads from the device are passed through a vein under the collarbone that connects to the right side of the heart (right atrium and right ventricle). The leads have either a small screw or hooks at the end to attach them to the heart tissue. Within a few months, the body's natural healing process forms scar tissue along the lead and at its tip, which fastens it even more securely

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[1] Camboni D, Wollmann CG, Löher A, Gradaus R, Scheld HH, Schmid C. "Explantation of implantable defibrillator leads using open heart surgery or percutaneous techniques." *Ann Thorac Surg.* 2008 Jan; 85(1):50-5.

in the patient's body. Although it increases the strength of the attachment, this fibrous tissue also makes it more difficult to extract leads than to implant them.

Before the development of laser sheaths, leads were extracted by a combination of manual disruption of the fibrous adhesions and traction. Such techniques could cause damage to vessels, the heart or the leads. Laser sheaths enabled the proceduralists operating them to apply tiny lasers that vaporise fibrous tissue, in effect cutting leads away from the adhesions more cleanly and efficiently than manual sheaths, thereby reducing the risk to patients.

The laser sheath is fitted over the lead through an incision. Under imaging, the operator then manipulates the sheath along the lead cutting through any adhesions encountered along the way until it gets close to the tip of the lead. The laser sheath is then withdrawn a short distance and the screw or hook is manipulated out of the heart tissue. Once the hook is detached the lead slides up inside the sheath and the whole apparatus is withdrawn back along the route it had previously followed.

At the time of Toni's operation, this procedure was performed in the Westmead Hospital's cardiac catheter laboratory. A 'cath lab' is an examination room in a hospital or clinic with powerful diagnostic imaging equipment used to visualize the arteries of the heart and the chambers of the heart. The reason for performing laser lead extraction in the 'cath lab' is that Professor Ross had then (and still has) a strong view that the image intensification equipment in the 'cath lab' was significantly more powerful and accurate than the equipment available in the general operating theatres. In his view, the better the imaging, the more accurate the operator of the laser sheath was likely to be and, therefore, the safer the patient was likely to be.

Toni's procedure was carried out by Dr Sivagangabalan who was operating the laser sheath and Professor Ross who was assisting him. The operation was carried out under general anaesthetic, the anaesthetist being Dr Adam Hastings. One of the features of the procedure was that Dr Hastings was asked to insert a transoesophogeal echocardiogram ('TOE') so that the cardiologists could monitor heart chamber anatomy for evidence of wall inversion when the tip of the lead was being extracted from wall of the heart.

As I have previously noted, the first lead extracted was the venticular lead. This extraction passed without incident. Dr Sivagangabalan and Professor Ross then moved to the atrial lead. The procedure appeared to go uneventfully until there was a sudden onset of profound hypotension. Dr Hastings noticed that there was a trace amount of pericardial fluid showing in the TOE, a not unexpected finding but Toni's blood pressure had collapsed and there were other indications of loss of cardiac output. On checking the TOE again about 10-20 seconds after his first observation, he saw a large amount of pericardial fluid. The pericardium was flooded with blood, stopping cardiac output.

What had happened? The best evidence is the theory that Professor Ross and Dr Sivagangabalan developed when they reviewed the tragedy soon afterwards. They believe

that the lead had become embedded in the wall of the superior vena cava during the period after its insertion. The laser was vaporising adhesions surrounding the lead. In doing so, because the lead was not merely adhering to the wall of the SVC but was actually embedded in the wall, the laser cut into the wall itself either cutting right through it or so far into it that it tore apart.

Their theory is that the sheath probably sealed the tear off until the tip of the lead was removed and the sheath was being withdrawn, unmasking the laceration in the SVC wall through which blood suddenly burst in a torrent causing cardiac tamponade.

This is not a case of *res ipsa loquitur* – of the accident proving by the very fact that it happened that there was carelessness or poor technique being applied. The theory put forward by Dr Sivagangabalan and Professor Ross was not only uncontradicted by other evidence but is plausible and explains the known facts. To remove the lead, they had to follow it wherever it went.Unfortunately, even with the powerful image intensification machine they were able to deploy in the 'cath lab', they were unable to distinguish the SVC wall from other forms of adhesions. There is no evidence of carelessness or inexperience or that the cardiologists, especially the laser sheath operator, Dr Sivagangabalan, were doing anything unusual at the time the tear was inflicted.

The great preponderance of evidence suggests that all reasonable care was taken by Dr Sivagangabalan and Professor Ross and that the fatal injury came about due to an unusual, unpredictable, undetectable and invisible situation within Toni's SVC. She was appallingly unlucky that the lead had become embedded in her blood vessel wall.

## Could the injury to Toni have been foreseen or prevented?

Dr Hendel commented that the only way to have prevented the injury was not to undertake the procedure. As my previous comments have indicated, I do not believe that this injury could have been foreseen. Therefore, because the laser extraction was, on all the evidence known before the procedure, the optimal method of removing the leads, the accident could not have been prevented. .

## Should the procedure have been performed in a hybrid operating theatre?

Although the gravity of Toni's injury was so great that it was almost certainly unsurvivable in the best of circumstances, it is clear that the ideal environment for lead extractions is a hybrid operating theatre combining the facilities of a cardiac 'cath lab' with the facilities (and staff) of a cardiac operating theatre. If an emergency requiring rapid open heart surgery should arise, the sternotomy can be commenced almost straight away in the same room. Unfortunately, at the time of Toni's surgery, a hybrid theatre was not available at Westmead Hospital.

## Were there appropriate procedures for dealing with an emergency ?

Westmead Hospital had procedures for dealing with an emergency. The question of their adequacy, however, is more difficult to judge.

Before the operation took place, the procedure was to send a blood sample for 'group and hold', i.e., the blood group would be determined and a stock of that blood group would be held for the patient in case of need.

The system then operating also stipulated that before lead extraction took place the cardiothoracic team was to be notified. They were not required to be present in the 'cath lab' but to be available in the hospital to respond. An operating theatre was not, however, prepared for surgery nor was the cardiothoracic team scrubbed.

Professor Ross's view is that when an emergency arises, the immediate problem is to drain the cardiac tamponade and regain cardiac output while at the same time alerting the cardiothoracic team that they will be needed to carry out emergency open surgery to repair the damage. His evidence was that while he and Dr Sivagangabalan were dealing with the tamponade and attempting to regain cardiac output, the cardiothoracic team arrived and the necessary steps for transferring Toni to an operating theatre were put in motion.

Dr Hendel's opinion is that there is so little time available to save a patient from a catastrophe that this procedure ought ideally be carried out in a hybrid operating theatre with a cardiothoracic team present in the room. In his report he stated:

> *This may seem overkill, as the risk of a major complication is fairly low, however by far the most likely major complication is a major vascular or cardiac injury with exsanguinating haemorrhage. The window of opportunity to effect control of bleeding and attempt repair is short. Cardiac massage is ineffective as the heart is empty so that arrest times of longer than 5 minutes or so carry increasing risks of brain damage. There is no likelihood that transfusion will be able to keep up with the rate of blood loss through such injury and there is likely to be cardiac tamponade preventing the heart from filling. Intravenous drugs and fluids will probably be lost through the laceration even if a femoral line has been placed.*
>
> *Only emergency sternotomy and control of bleeding, if possible, will allow establishment of cardiopulmonary bypass, cooling and the possibility of repair of any injury larger than a localised laceration.*

Dr Hendel also thought that if a hybrid theatre was not available that the procedure could be done in the 'cath lab' but with the cardiothoracic team present and equipped to carry out an emergency sternotomy if necessary. He also recommended that before the extraction procedure began, the patient should be prepared for a possible sternotomy including placement of guide wires to a femoral artery and vein to allow emergency cannulation for bypass.

Regardless of the appropriateness of the emergency procedures at the time of the procedure, Professor Ross and Dr Sivagangabalan frankly admitted that there had been failures on the part of their team to prepare properly for an emergency. The Registrar whose job it had been to notify the cardiothoracic team of the upcoming lead extraction had not done so; nor had the 'cath lab' staff warned the operating theatre staff of the procedure so that they were on standby. Professor Ross said that he would ordinarily check that all the appropriate notifications had been made but he got to the 'cath lab' late and did not do so. Finally, he commented that the anaesthetist also had not notified others of the procedure. (I make no criticism of Dr Hastings – clearly it was the responsibility of the lead extraction team and the 'cath lab' staff to do this.)

## Were the emergency procedures followed appropriate?

The Cardiac Society of Australia and New Zealand has produced a policy statement concerning the extraction of cardiac device leads and the provision of surgical support. It purports to outline the Society's Lead Extraction Advisory Committee views on best practice for the provision of surgical support in case of emergency during lead extraction procedures[2]:

> *Lead extraction must only be performed in hospital with a cardiac surgical unit. The proceduralist performing lead extraction must have a close working relationship with the cardiac surgical unit. The cardiac surgical team must be aware of all lead extraction procedures being performed in the hospital.*
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> *Transfer of a patient to a cardiac operating theatre in the event of a perforation is usually too slow to save the patients life and should not be relied upon. Lead extraction must be performed in an environment in which an immediate thoracotomy can be performed immediately. This requirement needs to be balanced against the need for high quality fluoroscopy. A hybrid cath lab/operating theatre is the ideal situation but is rarely found in Australian hospitals. For most procedures, portable fluoroscopy will be adequate and they should be performed in a cardiac surgical operating theatre. In other cases, a cardiac catheterisation laboratory is required to provide better imaging. Wherever lead extraction is performed, thoracotomy equipment including sternal saw and surgical instruments must be readily available and appropriately trained nursing and technical staff must be present. A cardiac surgeon should be in the room or able to come into the room immediately, at the time that lead traction and sheath delivery is being performed. The surgeon does not have to be available for the whole case, but must be available during the time of greatest risk of perforation.*
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> *High-quality fluoroscopy, whether by portable unit or in a catheterisation laboratory is essential.*

[2] I say "purports" because no one from the Society was called to give evidence except Professor Ross and Dr S. Professor Ross questioned the status and formulation of the guidelines as he was a member of the group that had been developing the guidelines and did not agree with some of their contents.

*An anaesthetist should be present. General anaesthesia is usually required for these procedures. Monitoring of the arterial blood pressure by intra-arterial catheter is essential to rapidly diagnose cardiovascular collapse. Good intravenous access is essential. Central venous access should be obtained in higher risk patients. All resuscitation equipment and medications must be available. At least 2 units of blood should be cross-matched and immediately available.*

*Temporary pacing and defibrillation equipment should be available. Percutaneous pericardiocentesis equipment should be available. All appropriate lead extraction equipment should be available including stylets, lead locking devices and passive and powered sheaths.*

*Echocardiography and trained staff must be available in the room. Transoesophageal echocardiography (TOE) throughout the procedure is recommended to allow early diagnosis of tamponade. However, if the patient suffers a haemodynamic collapse, it should be assumed that cardiac perforation has occurred, whatever is seen on the TOE.*

*The patient should be prepared as if for sternotomy with appropriate shaving, washing, antiseptic and draping. The femoral veins should usually be included in the operative field to allow for rapid access. A femoral venous sheath may be placed to allow both high quality venous access and insertion of a temporary pacing wire if required.*

*A percutaneous procedure should be abandoned if the risk of perforation or other cardiovascular damage becomes too great. Open removal by thoracotomy should be considered in these cases.*

*In summary, percutaneous lead removal, is generally safe but can lead to catastrophic haemodynamic consequences. It must be expected that these complications will occur at some time, so back-up cardiac surgery must be immediately available.*

Professor Ross and, to some extent, Dr Sivagangabalan, took issue with the definition of the phrase "immediately available". On its face, and taken in the context of a statement that also asserts that "transfer of a patient to a cardiac operating theatre in the event of a perforation is usually too slow to save the patient's life and should not be relied upon" and "Lead extraction must be performed in an environment in which an immediate thoracotomy can be performed immediately", the policy statement appears to require that lead extractions be performed either in operating theatres or hybrid theatres with a cardiothoracic team on standby for an emergency. This is Dr Hendel's view.

On the other hand, Professor Ross argued that the critical issue is draining the pericardial tamponade and restoring cardiac output. This, he said, could be done in the 'cath lab' without resorting to sternotomy there and then. Indeed, he argued that a full sternotomy in the 'cath lab' would be immediately fatal to the patient. In his view, the cardiac tamponade could be drained and circulation restored in the 'cath lab' by the cardiologists

performing the lead extraction (with the help of the anaesthetist) while the operating theatre was simultaneously made ready for open heart surgery. Both he and Dr Sivagangabalan gave evidence that there had been no significant delay in getting Toni to the operating theatre because the cardiothoracic team had responded immediately to the emergency call and the theatre was ready by the time Toni was able to be moved.

In Professor Ross's opinion, the requirement that 'back-up cardiac surgery must be immediately available' had to be interpreted as being available 'within minutes':

> *… it comes down to what they mean by "immediately available". I take that to mean within a few minutes. Now, the idea that somebody, a surgeon, as soon as a disaster happens, should immediately open the chest is silly. We can drain the pericardium with a percutaneous catheter within a few minutes, quicker than they could, well, at the same sort of rate. There's no point in opening the chest if you can drain it with a percutaneous drain. It would have been of no earthly use because it wouldn't have solved this particular problem, and it won't solve the great majority of these tamponades. They can all be done by us immediately, and what you need is the ability to, to get a surgeon in a hurry, that means in a few minutes, who might need to take them to the operating theatre or go on cardiopulmonary bypass to rescue a situation, and that's, that's, you know, that can be satisfactory several minutes down the track. You don't need them immediately.* [3]

If Professor Ross's interpretation is accepted, the requirement for surgical support to be 'immediately available' had been met in Toni's case. If, on the other hand, the guideline is interpreted literally (and thereby accords with Dr Hendel's opinion) it was not met.

In my view, it is the Cardiac Society that is in the best position to clarify its statement and to ensure that all proceduralists and centres undertaking cardiac lead extractions can precisely identify what is needed to done at what times and to produce clear checklists or protocols based on best practice guidelines.

The second major problem that Toni's death highlights is that, although such catastrophes are rare, when they occur there are, at best, but a few minutes to save the patient's life. This is emphasised in the current Cardiac Society policy statement. This raises the difficult issue of where such procedures should be undertaken absent a hybrid theatre. Westmead Hospital has made a firm policy decision that they must be performed in an operating theatre with surgical back-up. Professor Ross strenuously argued, however, that they should be undertaken in a 'cath lab' because of the superior imaging equipment available there.

For hospitals without a hybrid theatre, the Cardiac Society's advice is as follows:

[3] Transcript 4 June 2014 p.54

> *Lead extraction must be performed in an environment in which an immediate thoracotomy can be performed immediately. This requirement needs to be balanced against the need for high quality fluoroscopy. A hybrid cath lab/operating theatre is the ideal situation but is rarely found in Australian hospitals. For most procedures, portable fluoroscopy will be adequate and they should be performed in a cardiac surgical operating theatre. In other cases, a cardiac catheterisation laboratory is required to provide better imaging.*

As this inquest has demonstrated, there is a difference of views among the specialist practitioners of the difficult art of cardiac lead extraction about the emphasis they place on particular aspects of the procedure.

The North American Society of Pacing and Electrophysical Lead Extraction ('NASPE') guidelines set out 'minimal requirements' for centres conducting lead extractions. They include 'cardiothoracic surgeon on site and capable of initiating an emergent procedure promptly'; 'high quality fluoroscopy' and 'thoracotomy tray immediately available'.[4] Of significance is NASPE's statement that 'Of these items, the value of a high-quality fluoroscopy system cannot be overstressed. Visualisation of small lead components, such as the position of fixation screws on leads with retractable screws, is necessary for the safe application of extraction technique.' That statement supports the argument made by Professor Ross for the procedure to be undertaken in 'cath labs' or hybrid theatres rather than in standard operating theatres.

I make no criticism of the members of the committee who drafted the Cardiac Society's policy statement and imply none when I say that, with the benefit of the hindsight granted to us by this case, the policy statement could provide clearer guidance.

It may be helpful if it distinguishes between cases that ought be dealt with in a 'cath lab' and those that ought be dealt with in an operating theatre. Or perhaps, as Dr Sivagangabalan prefers, no distinction should be made and, unless a hybrid theatre is available, all lead extractions should be conducted in operating theatres. If lead extractions are to be performed, as Professor Ross prefers, in 'cath labs', it would be helpful if the policy statement set exactly what surgical support should be available before the procedure commences.

As the Cardiac Society is not a party or witness in these proceedings, I do not propose to make formal recommendations to it under the Coroners Act. I intend, however, to write to

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[4] North American Society of Pacing and Electrophysiology Lead Extraction Conference Faculty*,Charles J. Love, Bruce L. Wilkoff,Charles L. Byrd, Peter H. Belott, Jeffrey A. Brinker, Neal E. Fearnot, Richard A. Friedman, Seymour Furman, Louis B. Goode,David L. Hayes, David T. Kawanishi, Victor Parsonnet, Christopher Reiser and Heidi J. Van Zandt additional consultant "Recommendations for Extraction of Chronically Implanted Transvenous Pacing and Defibrillator Leads: Indications, Facilities, Training" *Pacing and Clinical Electrophysiology* Vol 23, Issue 4, 544–551, April 2000 at p.548.

the President of the Society enclosing a copy of these findings and inviting the Society to consider the matters I have raised concerning the current guidelines for lead extraction procedures.

## Conclusion

During the inquest it became sadly evident that, once the long laceration was made in Toni's superior vena cava, she had a minimal chance of survival regardless of the immediate availability of surgical help for her. The injury was almost certainly unsurvivable.

In the 16th century, the Dutch philosopher Erasmus described Thomas More as being "born for friendship". Toni Peadon could also be described that way. Her capacity for friendship made her an outstanding healer and teacher and leader. The Australian community has lost a superb doctor and she is, and will continue to be, much missed.

But even the finest doctors are replaceable. Brian Peadon, however, has lost a soulmate and Toni's children have lost their loving mother. Toni's multitude of friends mourn her. For them, Toni is *irreplaceable.* They have, however, honoured her with projects to carry on her work of improving emergency medicine and supporting women doctors and rural medicine. She has left an enormous legacy that will benefit our whole community for years to come.

Toni's death brought about significant changes in the practice of lead extractions in the cardiology department at Westmead Hospital. A hybrid theatre is being planned and it is hoped by the hospital administration that it will be built at some time in the future. In the meantime, interim arrangements have been made following a review of the hospital's guidelines and protocols for carrying out lead extractions. Perhaps the most significant of these is that, until the hybrid theatre is built, lead extractions will be undertaken in the cardiac operating theatre with a cardiothoracic team on standby.

Her death also clearly had a powerful effect on Professor Ross and Dr Sivagangabalan. Dr Sivagangabalan asked to make a personal statement in court to the Peadon family. He said:

> *I'm really sorry about what happened. The motivation for me in treating Dr Peadon the whole time was to try to help her and I tried my best to try and help her. Personally, it's a devastating experience. It's shattering to lose a patient and I'm very sorry that this has happened.*

He also explained that he had wanted to speak to Mr Peadon but had been unable to do so because he was prevented by the Clinical Governance department of the hospital. I did not receive evidence about this but the exchange between Dr Sivagangabalan and Mr Peadon suggested that whatever had followed Toni's death had been unsatisfactory for both parties.

It has been NSW Health's policy and practice for several years to undertake 'open disclosure' following serious or fatal incidents in public hospitals. The Open Disclosure guidelines are a public document.[5] The key principles of open disclosure are openness and timeliness of communication; acknowledgement of error; expression of regret; recognition of the reasonable expectations of the patient and their support person; support for health staff; and confidentiality.

If the open disclosure process did not work either for Mr Peadon or for Dr Sivagangabalan, I hope that, although it is outside the scope of this inquest, that more can be done, even at this late stage to enable them – if they wish – to speak to one another in the way that the open disclosure policy envisages. Toni Peadon was a healer. I believe that it would honour her memory if, out of this inquest, some healing for Mr Peadon and the doctors can be generated.

## Findings s 81 Coroners Act 2009

I find that Toni Ann Peadon died on 6 August 2012 at the Westmead Hospital, Westmead, New South Wales as a result of a laceration of the superior vena cava and right atrium occasioned while she was undergoing a procedure to extract an implanted right atrial defibrillator lead.

## Recommendation

I recommend to the Minister for Health that the department of cardiology at Westmead Hospital, in consultation with the NSW Ministry of Health and the Cardiac Society of Australia and New Zealand, consider introducing a specific form of written consent for lead extraction procedures which include the following:

1. The pertinent elements of the planned procedure and all reasonable alternatives
2. The percentage risk of major and minor complications
3. A statement (including Westmead Hospital's rates of extractions and outcomes) that lead extractions can be potentially life-threatening
4. A statement of the proceduralist's personal level of experience in lead extractions and outcomes
5. The emergency procedures in place should a complication arise.
6. Insofar as is reasonably practicable I recommend that the patient's consent be obtained in the presence of a family member or friend.

[5] http://www0.health.nsw.gov.au/policies/gl/2007/pdf/GL2007_007.pdf

Magistrate Hugh Dillon
Deputy State Coroner