



FINDING OF INQUEST

An Inquest taken on behalf of our Sovereign Lady the Queen at Adelaide in the State of South Australia, on the 16th and 17th days of April 2008, the 5th and 19th days of May and the 19th day of September 2008, by the Coroner's Court of the said State, constituted of Anthony Ernest Schapel, Deputy State Coroner, into the death of Richard Grant Allen.

The said Court finds that Richard Grant Allen aged 60 years, late of 11 Warwick Street, Largs North, South Australia died at Ashford Community Hospital, Anzac Highway, Ashford, South Australia on the 2nd day of November 2005 as a result of haemopericardium due to rupture of right ventricle complicating removal of cardiac pacemaker. The said Court finds that the circumstances of his death were as follows:

1. Introduction

- 1.1. Richard Allen was 60 years of age when he died on 2 November 2005 at the Ashford Hospital (the Ashford). He died during the course of a procedure to remove a cardiac pacemaker and its leads from his body.
- 1.2. Mr Allen originally had a permanent pacemaker inserted in September 1994 when he was approximately 49 years of age. Mr Allen had been diagnosed with a condition known as sick sinus syndrome which manifests itself in a heart arrhythmia. The pacemaker was inserted in order to correct that arrhythmia. From that time onwards, until his death, Mr Allen had a pacemaker constantly in place. In October 2002 it had been replaced due to battery end of life. Aside from the affliction for which the pacemaker had been inserted and worn, there is no suggestion that Mr Allen had suffered any other significant illness. He was active as a horse trainer, and had spent

some time recuperating from an injury sustained in an incident involving a horse, but at the time of the procedure with which this Inquest is concerned there is no reason to believe that Mr Allen was anything other than well.

- 1.3. A cardiac pacemaker is inserted surgically below the skin of the upper chest area. It contains a battery that generates an electrical pulse. Two leads are connected to the pacemaker. One lead extends from the pacemaker to one of the atria of the heart. This is known as the atrial lead. The other lead extends from the pacemaker to the right ventricle of the heart. This is known as the ventricular lead. The right ventricle of the heart is the chamber that is responsible for the ejection of blood into the pulmonary artery that leads to the lungs. Both pacemaker leads consist of a thin flexible wire that is encased in a flexible plastic coating and are anchored to the heart muscle within the relevant chamber of the heart. The leads are usually routed through one of the major veins into the heart itself.
- 1.4. The insertion of the pacemaker and leads had originally been carried out by Dr John Hii at the Ashford. Dr Hii was to remain as Mr Allen's cardiologist until the fatal procedure in November 2005. Dr Hii is a cardiologist who sub-specialises in the area of cardiac electrophysiology which is the treatment and management of patients with cardiac rhythm disturbances. Dr Hii first graduated from the Flinders University in 1982. Together with other cardiologists, Dr Hii occupied rooms at the Ashford precinct.
- 1.5. Mr Allen's history with the permanent pacemaker was relatively uneventful. In May 1995 the atrial lead had to be replaced due to a general concern that the particular type of wire might cause a cardiac injury. There is no suggestion that it had done so in Mr Allen's case, but the lead had nonetheless been replaced out of an abundance of caution. I have already referred to the battery needing to be replaced in October 2002. Dr Hii had performed both procedures in May 1995 and October 2002 without incident. Mr Allen's ventricular lead had constantly been in place from the time of the pacemaker's original insertion in September 1994 to Mr Allen's death in November 2005.
- 1.6. In 2005 Mr Allen's pacemaker became infected. This was quite obvious because a visibly infective process had clearly been identified. The infection meant that Mr Allen's pacemaker and its leads had to be removed. I was told during the course of

this Inquest that infections of pacemakers or of pacemaker leads are notoriously difficult to fight with antibiotics. The usual if not inevitable treatment of choice is the removal of the infected pacemaker and leads. There is no suggestion on the evidence before me that the procedure on 2 November 2005 that led to Mr Allen's death was anything other than an appropriately considered procedure and one that was necessary in order to eradicate Mr Allen's infection. Dr Hii performed this procedure in the Coronary Angiography Suite at the Ashford.

- 1.7. Although the surgical procedure to remove the pacemaker unit and leads is an invasive one, it did not normally take place in an operating theatre. Nor does it usually occur under general anaesthetic. Rather, a level of sedation of the patient is maintained with a view to minimising or eliminating any discomfort. In 2005 the removal of pacemaking wires was a procedure that was not universally performed throughout the cardiological or surgical community. In fact Dr Hii was one of the few medical practitioners in South Australia who routinely performed lead extractions. He told me, and I accept his evidence, that he had performed possibly as many as 200 such procedures.
- 1.8. Although a pacemaker lead extraction is not a complicated procedure, it is sometimes not without its difficulties or risks. Leads that have been in place for several years may become conjoined. Their anchor points within the heart chambers may become affixed with scar tissue. Generally, pacemaker leads are disconnected by a process of simple traction on the leads that is delivered by the force of the proceduralist's hand. For the reasons just explained, a lead that has been in-situ for several years may be difficult to remove by this process. There are a number of tools at the disposal of the proceduralist that assist in the removal of leads that prove difficult to shift. I will return to that matter in a moment. As to the risks of this procedure, one recognised risk is the possibility of perforating the heart muscle known as the myocardium. This risk is obviously enhanced in cases where the leads have become stubbornly affixed to the heart muscle. Open heart surgical removal of the leads in some cases is not unheard of. Surrounding the myocardium is a membrane known as the pericardium. If a perforation of the myocardium occurs, leakage of blood from the right ventricle into the space between the pericardium and the heart muscle (the pericardial space) can cause a build-up of blood known as a haemopericardium. This in turn can place pressure upon the heart itself such that it prevents it from filling properly and

pumping blood to the rest of the body. This is referred to as a cardiac tamponade. A heart that is receiving electrical impulses that should normally make it beat but which for some reason is mechanically incapable of beating properly is said to be in a state of electromechanical dissociation. If these conditions are not reversed, the patient will die. This is what happened in Mr Allen's case. A cardiac tamponade can be definitively diagnosed by ultrasound administered by an echocardiography machine. For very obvious reasons, a rapid diagnosis, that ultrasound provides, is highly desirable.

- 1.9. Another risk associated with lead extraction is the possibility of the creation of a pulmonary embolism which consists of a blood clot that is formed by the exposure of the blood to the bare metal of the lead if its plastic insulation is breached. A pulmonary embolism of sufficient size will block the blood vessels in the lungs and this in turn may also lead to electromechanical dissociation, a cessation of heart function and eventual death. This is not what happened in Mr Allen's case, but it is nevertheless relevant because it was thought during the procedure to have been a possible cause of Mr Allen's eventually fatal electromechanical dissociation. A pulmonary embolism can be diagnosed by a pulmonary angiogram.
- 1.10. Cardiac tamponade and pulmonary embolism are the two major risks associated with this procedure, and are the ones that are relevant to the issues with which this Inquest is concerned. However, on a statistical basis it is said that the risk of a fatality in the course of a lead extraction procedure is not significantly high, approximately 1 in 100. To my mind the incidence of a fatality once in every one hundred procedures cannot be said to be insignificant. This is especially so when it is considered that the risk of ventricular perforation in the removal of a lead might, for reasons I have explained, be intrinsically higher in some procedures than in others. However, it is clear that Dr Hii was a very experienced proceduralist in this regard and I accept the evidence that was adduced in the course of the Inquest that Dr Hii had never experienced any fatality in any of the procedures he had performed. He did tell me, however, that he did once have a perforation but that in the event this had not proved to be detrimental to the patient's wellbeing. In this regard, the larger the perforation the greater the likelihood of a fatal consequence. Mr Allen's perforation was 14mm in size and was catastrophic.

- 1.11. As indicated earlier, the leads are flexible. This fact does not assist in their removal. For this reason, when difficulty is encountered in their removal a device known as a stylet is fed through the hollow interior of the lead and is affixed to the lead tip thus forming a more rigid lead with which to work. In addition, metal or plastic sheaths can be used in conjunction with the stylet. In this particular case we are concerned with the use of a plastic sheath that, as it were, telescopes so as to enable either a bevelled or flat tip of the sheath to be exposed. The sheath can be placed over the problematic lead and fed down towards the lead's anchoring point in the heart. The bevelled edge can be used to remove adhesions to the lead. The flat edge can be used to apply counter traction to the heart muscle at the moment traction is applied to the lead. In that way the force applied to the heart muscle is distributed over a smaller area, thus reducing the risk of a perforation. In other words, the proceduralist pushes on the sheath and at the same time pulls on the lead. Thus the lead is removed through the sheath. If that method of extraction is not successful, I was told that the patient may have to have the leads extracted surgically which would involve the opening of the chest cavity by a cardiothoracic surgeon. Fortunately, that method of extraction is not normally required.
- 1.12. Some might have the impression from the above description that the removal of pacemaker wires is an unsophisticated exercise. In truth it is an exercise that can require a large measure of finesse on the part of the proceduralist. It is a procedure with which Dr Hii was very familiar. He had, as I say, performed many of these procedures without incident. Dr Hii told me, and I accept his evidence, that with experience one develops a feel for the amount of traction and force that needs to be applied to a lead and a feel for the amount of force that would be safe to administer to the patient, bearing in mind the risks I have described. It is for that reason that it is clear that a lead extraction should only be performed by practitioners who have had some significant experience in the procedure. Dr Hii was one such practitioner. In fact it may well have been the case in 2005 that he was the only medical practitioner in South Australia who was either competent enough or experienced enough to perform the procedure. I am told that since these events a local cardiac surgeon has now included lead extraction as part of his practice.
- 1.13. Dr Hii was not a cardiac surgeon or for that matter a surgeon at all. This fact did not preclude him from performing invasive procedures such as cardiac pacemaker and

lead extraction. As I say, the procedure was generally not performed within an operating theatre or other surgical environment. However, Dr Hii performed his procedures in a hospital, generally the Ashford, and with the assistance of a nurse or nurses. In addition, an anaesthetist whose task it was to keep the patient sedated and to monitor the patient's vital signs was also present.

- 1.14. A vital sign that naturally requires monitoring is the patient's blood pressure. The force applied to the heart when a pacemaker lead is pulled in the process of extraction may result in the temporary alteration of the heart's architecture such that the blood pressure significantly and acutely decreases. This is a simple mechanical process, and when traction on the lead is released the blood pressure will almost immediately return to normal. A patient's blood pressure can be monitored in a number of ways. Perhaps the most accurate method involves the insertion of an arterial line into one of the patient's arteries. This is an invasive procedure. Another method is to use an ordinary blood pressure monitoring cuff that can be configured to continuously monitor the patient's blood pressure during the course of the procedure. Another indication of falling blood pressure is afforded by the oximeter that is attached to the patient's finger by way of a peg. When the blood pressure falls significantly, the oxygen levels in the blood will fall accordingly and this fall will be detected by the oximeter. In the case of Mr Allen's procedure, his blood pressure was being monitored by cuff and oximeter. He did not have an arterial line inserted in the first instance.

2. Mr Allen's post mortem examination and cause of death

- 2.1. A post mortem examination of Mr Allen's body was performed by Dr Karen Heath, a forensic pathologist. A haemopericardium was confirmed at autopsy. Clotted blood was present within the pericardial space. A pericardial catheter was still in-situ in the pericardial sac. This had been used to draw off blood from within the pericardium during the attempts to save Mr Allen's life (a procedure known as pericardiocentesis). The most significant finding was the existence of a 14mm rupture of the anterior aspect of the right ventricle near the apex of the heart.
- 2.2. In her post mortem report (Exhibit c1a) Dr Heath expresses the cause of death as having been Haemopericardium due to rupture of right ventricle complicating removal of cardiac pacemaker. I find this to be the cause of Mr Allen's death.

3. Recommended expertise and other requirements for the extraction of chronically implanted pacemaker leads

- 3.1. I received in evidence the declaration of a Ms Lynne Portelli who is the Executive Officer of the Cardiac Society of Australia and New Zealand (CSANZ)¹. Among its functions CSANZ certifies medical practitioners who are permitted to claim an item number under the Medicare Benefits schedule for performing extractions of chronically implanted pacemaker leads. I also heard evidence from Dr Glenn Young who is a cardiologist who has received advanced training in electrophysiology for the treatment of cardiac arrhythmias. Dr Young sits on the CSANZ committee that certifies medical practitioners who may claim that particular item number. Dr Young also sits on the continuing education re-certification committee of the Society. This committee reviews and updates guidelines in respect of various aspects of medical practice in cardiology. Dr Young gave evidence about certification processes and also about policies that relate to clinical and other requirements for lead extraction procedures. It must be emphasised that certification by CSANZ is not a requirement or qualification for a practitioner to perform this procedure. Rather, it is a certification to enable the practitioner to charge the relevant item number under the Medicare Benefits schedule. If a practitioner is not so certified, it does not mean that a practitioner is not entitled or permitted to perform the procedure. It simply means that they will not be able to charge the enhanced fee that is available under the schedule. Dr Hii had not applied for certification under this scheme, but this issue proved to be somewhat of a distraction because it was clear that by any standard Dr Hii was a competent and experienced practitioner in respect of this procedure. Dr Hii's reasons for not applying for certification do not need to be ventilated here, but to my mind they were valid and legitimate and nobody suggested otherwise. In any event he would easily have satisfied the minimum CSANZ requirements for certification had he chosen to apply for it.
- 3.2. There is in existence a document entitled 'Recommendations for Extraction of Chronically Implanted Transvenous Pacing and Defibrillator Leads: Indications, Facilities, Training'². This document was originally promulgated in the year 2000 by the North American Society of Pacing and Electrophysiology (NASPE) as it then was called. NASPE is now known as the Heart Rhythm Society. This document has been

¹ Exhibit C9a

² Exhibit C9c

adopted by the CSANZ Board as the basis for CSANZ certification criteria in respect of the extraction of chronically implanted pacemaker leads. The document sets out in considerable detail essentially what amounts to best practice in performing lead extraction procedures. It deals with and describes such matters as the risks involved in the procedure, indications for lead removal and contraindications for the same, physician qualifications and experience and describes the requirements that the facility in which the procedure occurs should have in place. Dr Hii himself described the document as the guideline or position statement of the premier world body for practitioners dealing with patients with cardiac arrhythmias. The document will be referred to herein as the CSANZ guidelines. Dr Young described the document in these terms:

'The Cardiac Society has endorsed the North American Society for pacing electrophysiology guidelines for lead extraction. That document is freely available from the Heart Rhythm Society and on the web site. So, the Cardiac Society elected not to draw up its own guidelines but to endorse those from the Heart Rhythm Society, which is a large international body that represents the interests of electrophysiologists in particular.'³

The CSANZ guidelines set out what are described as possible complications of the procedure. Major complications are described as those that would require procedural intervention or transfusion to prevent death or threat to life, or any complication that results in death or serious harm to bodily function or structure, cardiac avulsion or tear requiring thoracotomy, pericardiocentesis, chest tube or surgical repair, and pulmonary embolism requiring surgical intervention. The first of those potential complications, namely cardiac tear, is precisely what happened in Mr Allen's case. The reference to pericardiocentesis is a reference to a procedure whereby a hollow needle is inserted into the pericardial space between the pericardium and the heart muscle in order to drain the collection of blood that has collected in the space and which is compressing the heart. The surgical repair of a cardiac tear, as I have already mentioned, would involve general anaesthesia, chest spreading and cardiopulmonary bypass. It would be major surgery designed to physically repair the tear to the heart muscle.

- 3.3. The CSANZ guidelines recognise that the duration of the implant, the presence of calcification involving the leads and the experience of the physician are all relevant

³ Transcript, page 224

matters to be taken into consideration when deciding whether or not to remove the lead.

- 3.4. The qualifications of the practitioner are also dealt with in the guidelines and it is recognised that lower complication rates are associated with prior experience of 50 procedures. It is also stipulated that a minimal number of procedures should be performed on an annual basis in order to retain skills. Dr Hii told me that he had performed around 200 procedures and performed a significant number per year.
- 3.5. The document also deals with a number of facility and equipment requirements in respect of the performance of a lead “extraction”. The term “lead extraction”, as opposed to “lead removal”, can carry one of two implications. First, it may involve the removal of a lead that requires the assistance of specialised equipment regardless of the implant duration. Such equipment includes tools such as stylets and sheaths as were required in Mr Allen’s case. In the alternative, the term lead extraction can involve the removal of a lead that has been implanted for more than one year, again, as was the case with Mr Allen. Mr Allen’s procedure was therefore, under the guidelines, to be characterised as a lead “extraction” by any definition. Recognising as it does the risks involved in such a procedure, the document states:

'As the possibility of vascular catastrophe is very real, the physician and the institution must both be capable of responding immediately and appropriately. To achieve this level of preparedness, the hospital must have the following services on-site and immediately available during the lead extraction procedure:'⁴

The document then sets out a number of facility requirements for lead extraction that relevantly include the following:

1. An accredited cardiac surgery program on-site.
3. At least one physician who is properly trained and proficient in the technique of transvenous lead extraction (Dr Hii was so properly trained and proficient).
4. Cardiothoracic surgeon on-site and capable of initiating an emergent procedure promptly.
7. High quality fluoroscopy.
8. Transthoracic ultrasound and transesophageal ultrasound capability immediately available.
9. Monitoring equipment for arterial pressure (invasive or noninvasive) and oxygen saturation.
12. Temporary pacing and defibrillation/cardioversion equipment in the procedure room.

⁴ Exhibit C9c, page 5

13. Fluids, pressors, and other emergency medication available in the procedure room.⁵

As well, the document sets out under the heading ‘Patient Preparation Requirements for Lead Extraction’, a number of requirements that include continuous blood pressure monitoring, preferably by way of intra-arterial catheter. However, it goes on to state that automatic non-invasive monitoring may be used but cautions that this does not provide the immediate feedback that may be required.

3.6. It will be observed that within these requirements a distinction is apparently drawn between services and equipment that must be ‘on-site and immediately available’ and equipment that must be ‘in the procedure room’. During the course of the Inquest there was some little debate about the niceties allegedly involved in this distinction. I return to this issue when discussing the requirement of the availability of ultrasound equipment referred to in requirement 8 above. This requirement I find was not complied with in Mr Allen’s case as the resource had not been immediately available.

4. Mr Allen’s extraction procedure

4.1. Mr Allen and his wife attended at the Ashford on the afternoon of 2 November 2005. It was a Wednesday. The procedure was scheduled to commence in the late afternoon. The Ashford clinical record in respect of this admission was tendered in the Inquest⁶. The procedure took place in the Angiography Suite and commenced at 4:50pm⁷. In attendance were Dr Hii, who was to perform the procedure, the anaesthetist Dr Andrew Bashford and a number of nursing staff, one of whom had the specific task of assisting Dr Hii. Handwritten accounts of the procedure, which include reference to Mr Allen’s cardiac arrest and the resuscitation efforts, were compiled afterwards by Dr Hii and Dr Bashford respectively.

4.2. Dr Bashford also kept the anaesthetic record⁸. This document, as best as Dr Bashford could manage in the circumstances, records the administration of various anaesthetic drugs and records Mr Allen’s vital signs at various times including his blood pressure.

4.3. The pacemaker itself was removed without incident. The leads themselves proved very difficult to extract due to adhesions between the leads themselves and because of

⁵ Exhibit C9c, page 5

⁶ Exhibit C6

⁷ Exhibit C6, page 23

⁸ Exhibit C6, page 22

fibrosis in the endocardium. However, Dr Hii was able successfully to separate the leads using steel sheaths. The atrial lead was successfully removed using a different kind of sheath. Dr Hii attempted to extract the ventricular lead. There were a number of instances where he applied traction to the ventricular lead which had two adverse effects. Firstly, traction on the heart muscle was causing Mr Allen's blood pressure to descend to unacceptable levels. Secondly, the traction was causing Mr Allen a measure of discomfort notwithstanding his sedation. The falls in blood pressure were detected by Dr Bashford who, on each occasion, advised Dr Hii that traction on the ventricular lead was having that effect. Whenever this occurred, Dr Hii desisted from applying traction to the lead and on each occasion Mr Allen's blood pressure returned to normal.

- 4.4. It became increasingly clear that the ventricular lead was not going to come away without some form of mechanical assistance. Dr Hii therefore applied a stylet to the tip of the lead.
- 4.5. To relieve Mr Allen's discomfort, it was decided that Dr Bashford should administer a general anaesthetic that would render Mr Allen unconscious. Dr Bashford administered anaesthetic medication to Mr Allen with the result that he was generally anaesthetised.
- 4.6. Following the administration of the general anaesthetic, Dr Hii continued in his efforts to extract the ventricular lead. It is clear that at one point traction was applied to the ventricular lead with sufficient force to break it away from its position inside the right ventricle. The precise circumstances in which the lead came away are not entirely crystal clear on the evidence. Dr Hii told me in evidence that he had asked his nurse to take hold of the lead and to apply just enough traction to keep the lead straight while Dr Hii fed a sheath over the lead and advanced it towards the tip in the heart. Dr Hii said that it was while he was performing this task that the lead came away.
- 4.7. Whether or not Mr Allen crashed immediately upon the lead coming away is the subject of divergent evidence. Dr Bashford told me that his impression was that Mr Allen's vital signs, including his blood pressure, descended to life threatening levels almost immediately. Dr Hii on the other hand had an impression that this had not been immediate, but had happened somewhat gradually. In any event, Mr Allen's blood pressure was observed to descend to a fatal level and he suffered a cardiac

arrest. In the event we know what happened anatomically and that is that when the lead was extracted a perforation of a size of approximately 14mm was created in the wall of the right ventricle. Blood from the right ventricle was pumped through the perforation into the space between the outer wall of the heart muscle and the surrounding pericardium – a haemopericardium. The build-up of blood in the pericardial space exerted pressure on the heart such that it could not beat. Mr Allen suffered a cardiac tamponade. In spite of resuscitative efforts, Mr Allen was certified life extinct at 7:10pm.

- 4.8. That in broad outline is what transpired in relation to Mr Allen's procedure and his death.
- 4.9. During the course of the Inquest much effort was devoted to an attempt to reconstruct these events with precision using Dr Bashford's anaesthetic record. Dr Bashford has noted a number of instances where Mr Allen's blood pressure decreased to a level of about 60. The times at which these instances occurred can be seen from the blood pressure chart. The time at which the sedation was converted to a general anaesthetic can also be reconstructed within limits. I have not found it necessary to decide whether the reconstruction that was attempted during the course of the evidence was accurate or not. I am perfectly satisfied that there were a number of attempts by Dr Hii to extract the ventricular lead by way of traction and that on each of these occasions he was told by Dr Bashford that the traction was causing Mr Allen's blood pressure to fall dramatically. I am equally satisfied that Dr Hii on each of those occasions desisted from applying traction. I have no reason to believe that Dr Hii's persistence in attempting to extract the lead was inappropriate. At the time that the lead finally gave way, Dr Hii had yet to exhaust his repertoire of available methods of extraction. He was in the process of applying the sheath to the lead in an attempt to apply counter traction. As Dr Hii pointed out in his evidence, it may have been considered irresponsible to have abandoned the procedure without attempting every available means to extract the lead mechanically. The alternative, removal by cardiac surgery, clearly would have been an unattractive one.
- 4.10. I have already referred briefly to what appears to be a measure of divergence between the evidence of Dr Bashford and that of Dr Hii in respect of the time lapse, if any, between the ventricular lead giving way and the catastrophic drop in blood pressure

and cardiac arrest. Dr Bashford in his note compiled after the event records the incident in these terms:

'Pulling on leads by Dr Hii resulted in hypotension and bradycardia. This rapidly returned to previous levels when tension released. Dr Hii informed. This recurred with each attempt. Arterial line set up. During attempted insertion of arterial line in ® radial artery, further traction by Dr Hii on leads led to hypotension and bradycardia which did not revert to more normal levels. Patient became clinically pulseless. Cardiac arrest called.'⁹

Dr Bashford was also interviewed by the police following these events, albeit over a year later. Dr Bashford also provided what amounts to a statement¹⁰. In that statement he described the sequence of events in these terms:

'I began to insert the cannula in Mr Allen's right (radial artery). I was directly opposite and watching the monitor. The blood pressure machine was in 'stat' mode. At this point Dr Hii applied traction again to the ventricular lead. The pulse oximeter wave flattened. The ventricular lead came out at this point, but the wave form did not recover. I immediately left what I was doing and went to the head of the bed. There was no carotid pulse and cardiopulmonary resuscitation was immediately commenced. The propofol infusion was ceased.'¹¹

Both of those descriptions suggest that there was an association, at least in Dr Bashford's mind, between Dr Hii's final application of traction to the ventricular lead and the sudden drop in blood pressure which did not recover. The latter description might also suggest that there had also been the almost immediate detection of the fact that Mr Allen was pulseless. Dr Bashford did not describe things any differently when he gave evidence in the Inquest.

- 4.11. Dr Hii's version of events is that at the time the lead came free he was endeavouring to place a sheath over it and that the only traction on the lead itself was that exerted by the nurse and then only enough to keep the lead straight. In addition, Dr Hii told me that in his view the patient's deterioration was not as dramatic as had been suggested by Dr Bashford. He said:

'So I don't recall that dramatic kind of an emergency situation as soon as the lead came out from the body.'¹²

⁹ Exhibit C6, page 20

¹⁰ Exhibit C7

¹¹ Exhibit C7, page 3

¹² Transcript, page 151

Dr Hii suggested that it was not as if, when the lead came out, there was no blood pressure at all. He did not recall a dramatic situation like that having immediately developed. On the other hand, when Dr Hii was interviewed by the police in July 2006 he said in his interview:

'So after the lead came out I think that's when all the problems started, that he developed low blood pressure ...'¹³

The point of distinction between Dr Bashford and Dr Hii is this. Dr Hii suggests that to him a gradual collapse was not necessarily indicative of a sudden cardiac perforation. Dr Hii told me that he was at that point concerned about the possibility of clots having formed on the lead because the insulation on the metal lead had been compromised. This may have caused a pulmonary embolism.

- 4.12. Be all that as it may, there was a clear connection between the lead coming free and the deterioration of Mr Allen, particularly in relation to his blood pressure descending and then not recovering. Irrespective of whether or not the patient became pulseless immediately, the connection between the lead coming free and the deterioration in Mr Allen must have been clear to all of those present including Dr Hii. I return to this aspect of the matter in due course. The suggestion is that from Mr Allen's clinical picture alone a diagnosis of a cardiac tamponade resulting from a perforation of the ventricular wall should have been the obvious one.

5. What caused the perforation of the right ventricle?

- 5.1. Dr Bashford's account of these events could support the contention that the ventricular lead came away when Dr Hii deliberately applied traction to the lead. Dr Hii said that this was not the case and that at the time the lead came free he was endeavouring to place a sheath over the lead which would then have enabled him to apply counter traction in order to lessen the risk of perforation when traction was applied to the lead. Dr Hii said in effect that that point had not been reached because the sheath had not been fully advanced, or if it had, he had yet to apply traction. Dr Hii said that the nurse was simply at that stage applying sufficient pressure to keep the lead straight. In his interview with the police in July 2006, Dr Hii said:

¹³ Exhibit C10e, page 11

'I was very confident of the nurse was not pulling excessively because I let them usually give them very specific instruction don't pull the lead just hold it there, just maintain it there.'¹⁴

- 5.2. As to the circumstances in which the lead came free, I prefer the evidence of Dr Hii. Dr Hii was the proceduralist actually performing the extraction and to my mind would clearly have a much better perception and recollection of what was taking place at various times in respect of that procedure. Dr Bashford's focus was upon the patient's vital signs and his anaesthesia. He would not have been paying as much attention to the actual steps in the procedure itself.
- 5.3. Clearly, whatever was taking place precisely at the time the lead came free sufficient force must have been applied not only to remove it from the ventricular wall, but also to cause a perforation to the wall that was either 14mm in size immediately or which quickly developed to that size.
- 5.4. I was quite satisfied having heard Dr Hii give evidence, and having regard also to what he told the police, that Dr Hii was telling me the truth when he said that he was endeavouring to place the sheath over the lead at the time the lead came free. In any event, there is no evidence that the lead came free because of any deliberate or careless action on the part of any person. Dr Hii told me, and I accept his evidence, that in the 200 or so procedures that he had conducted he had only ever had one perforation and that was something that required no serious intervention and resolved itself quickly. Dr Hii had never had any event of this nature occur in the past.
- 5.5. In short there is simply no evidence to suggest that Dr Hii applied an undue amount of force on the lead. I accept Dr Hii's evidence that it came away in the course of the application of the sheath. As to why it came away, and in particular how an amount of force sufficient to cause the perforation was applied to the lead before Dr Hii was ready with the sheath is unfortunately a matter that will never be fully understood.
- 5.6. Mr Allen's procedure and the circumstances of his death were examined by an independent expert, Dr Glenn Young, who provided three reports. In none of these reports did Dr Young suggest that Dr Hii's decision to persist with the extraction was wrong or that his methods of extraction were either inappropriate or ineptly executed. In fact in his first report Dr Young said:

¹⁴ Exhibit C10e, page 11

'It is evident from my viewing of the case documentation that the procedure was performed for entirely appropriate indications.'¹⁵

The only observation that Dr Young appears to make about the ventricular lead extraction was that it did not appear from the clinical record that a telescopic sheath had been used. However, as earlier indicated, I accept Dr Hii's evidence that it was in the process of his endeavouring to secure the sheath that the ventricular lead, as it were, accidentally came away.

- 5.7. As will be seen, however, Dr Young commented unfavourably upon the absence of backup measures, particularly diagnostic measures, during the performance of the procedure. In particular, Dr Young was critical of the fact that a diagnosis of a ventricular perforation was not made in a timely manner and that attempts to rectify the resulting cardiac tamponade were consequently delayed. I will return to that issue in due course.

6. Events following Mr Allen's deterioration

- 6.1. Although one is not able to reconstruct to the minute the time at which Mr Allen's collapse occurred, Dr Bashford's anaesthetic record would lead to a reasonable conclusion that Mr Allen's deterioration occurred somewhere between 6:20pm and 6:30pm. For the purposes of these findings, I shall assume 6:30pm. Dr Hii told me that he believed that the cause of Mr Allen's drop in blood pressure and cardiac arrest was one of two things, either a pulmonary embolism caused by a possible blood clot entering the pulmonary artery or a cardiac tamponade caused by a perforation of the ventricular wall and entry of blood into the pericardial space. It will be noted here that the means by which a rapid and definitive diagnosis of a cardiac tamponade could be made were absent. Although I was told that the fluoroscopy that was being utilised during the course of the lead extraction procedure might have been of some diagnostic assistance, it does not appear to have been used for the same and in any event an echocardiography machine that would have had ultrasound capability, and which could have provided a definitive diagnosis of a cardiac tamponade, was not in the room or in the environs of the suite.
- 6.2. A raft of resuscitative measures were implemented in respect of which no particular comment needs to be made. A number of other medical practitioners who were

¹⁵ Exhibit C11

working at the hospital came into the room and assisted as best they could to resolve the catastrophic situation that had developed. Dr Bashford told me, however, that Mr Allen's pupils became fixed and dilated within two or three minutes which was a very poor sign as far as Mr Allen's recovery was concerned and signified that brain death was taking place quite rapidly. Of course, the initial question that confronted Dr Hii was what was causing Mr Allen's difficulties. Dr Hii, believing that it was possible that Mr Allen had suffered a pulmonary embolism, undertook certain diagnostic measures in relation to this. He performed a pulmonary angiogram which naturally took some time and this revealed that there was no pulmonary embolism of significance, and in any event it was clear that a pulmonary embolism was not the cause of Mr Allen's cardiac arrest. Dr Hii told me in evidence that a pulmonary embolism could be caused by a blood clot having formed as a result of the blood having come into contact with the bare metal of the extracted lead. Normally the lead is coated with a non-metal substance that prevents the formation of a clot while the lead is in situ. However, in this particular case it appears that the coating had been stripped from the lead and the bare metal had quite possibly come into contact with Mr Allen's blood and might have, as far as Dr Hii's thinking at the time was concerned, caused a clot to be formed. Dr Young on the other hand voiced the opinion that there was a more obvious diagnosis to begin with, namely a perforation of the ventricular wall, a condition that could not necessarily be definitively diagnosed with the equipment that was available in the room. I return to this issue in due course, and in particular why it was that Dr Hii elected to perform a time consuming diagnostic procedure which failed to reveal the true cause of Mr Allen's dramatic deterioration.

- 6.3. All during this, resuscitative measures were still being implemented. When Dr Hii concluded that there was no pulmonary embolism, he administered pericardiocentesis to Mr Allen in the belief that the cause of the cardiac arrest was a cardiac tamponade as a result of a perforation. A pericardiocentesis is the introduction of a narrow needle into the pericardial space. It is introduced through the chest wall and is a procedure that carries its own risks and is one that should be performed by a very experienced clinician. Dr Hii was such a clinician. As it transpired, of course, there had been significant bleeding from the heart into the pericardial space and this had resulted in the cardiac tamponade. Dr Hii was able to draw off about 200 millilitres of blood through the needle, but this did not produce any relief. The probability was that the

bleeding into the pericardial space from the heart was overwhelmingly greater than what could be relieved by way of pericardiocentesis. All through this, of course, the heart is not beating. Because the heart itself is not receiving any oxygen supply due to lack of circulation, the heart itself will not recover unless that situation is reversed.

- 6.4. It will be seen that the correct diagnosis was not made by Dr Hii until after the possible diagnosis of a pulmonary embolism had been eliminated.
- 6.5. At one point in time during the course of Mr Allen's attempted resuscitation, a cardiologist who had been working within the hospital and who was a colleague of Dr Hii's, Dr Bronte Ayres, came to the room and witnessed what was taking place. There is some divergence in the evidence as to the stage at which Dr Ayres came to the room. Suffice it to say at this stage Dr Ayres decided to obtain an echocardiography machine that had diagnostic ultrasound capability and which belonged to their practice. The machine at that time was situated in their clinic and it would have taken some time to obtain. Dr Ayres told me that the device is about the size of a washing machine and he had to physically wheel it from the clinic to the Angiography Suite, a distance of approximately 100 metres. Dr Ayres definitively diagnosed the existence of a cardiac tamponade once he was able to set up the machine in the suite. The ultrasound diagnostic capability that this machine provides is a resource that the CSANZ guidelines stipulate as one that ought to be 'immediately available'.
- 6.6. It became evident that no amount of pericardiocentesis or resuscitation generally was going to revive Mr Allen or restore his circulation and so life was declared extinct at 7:10pm. Dr Bashford has recorded that at that time resuscitative efforts were discontinued by 'general consensus', there being by then a number of experienced medical practitioners on hand.
- 6.7. Dr Young provided three reports to the Inquest and gave evidence as well. He questions a number of aspects of Mr Allen's care during the course of the procedure. Dr Young would query the following:
 - a) A lack of cardiothoracic surgical backup immediately available within the hospital;

- b) The lack of blood pressure monitoring by way of intra-arterial line from the beginning of the procedure or from the time that repetitive hypotension was noted;
- c) The failure to diagnose immediately a vascular rupture and haemopericardium (blood within the pericardium) as the most likely explanation for Mr Allen's collapse;
- d) The lack of any diagnostic ultrasound capability that would be provided by an echocardiography machine.

6.8. One of these concerns in my opinion can be put to one side at once. The evidence did not demonstrate that Mr Allen was put to any disadvantage by not having his blood pressure monitored by means of an arterial line. In fact when Mr Allen's sedation was converted to general anaesthesia, Dr Bashford had intended to insert an intra-arterial line to better monitor the blood pressure but events were overtaken by Mr Allen's collapse. In any event, prior to his collapse Mr Allen's blood pressure had in fact been measured, albeit by the less accurate method by way of a cuff. In addition, any significant drop in Mr Allen's blood pressure was also being revealed by the oximeter that was attached to his finger. The falls in blood pressure that occurred simultaneously with traction on the ventricular lead were quite obvious to Dr Bashford whenever they occurred. On every occasion other than the last, the blood pressure was seen to return to a normal level as Dr Hii released traction. When the fatal collapse occurred, the drop in blood pressure that was never again to return to a normal level was noticed virtually simultaneously with the lead being extracted. I did not understand there to be any suggestion on the evidence that any drop in Mr Allen's blood pressure was either not noted or noted belatedly, and there is certainly no evidence that Mr Allen suffered any disadvantage by not having an intra-arterial line.

6.9. Furthermore, the CSANZ guidelines do not describe the requirement of blood pressure monitoring by intra-arterial catheter in dogmatic terms. It simply states that continuous blood pressure monitoring should preferably be achieved by way of intra-arterial catheter. It specifically states that automatic non-invasive monitoring may be used. In any case the reductions in blood pressure were noted almost immediately and the precise figures to which the blood pressure descended had no special relevance.

- 6.10. As to whether there had been surgical backup present in the Ashford at the time of Mr Allen's procedure, Dr Hii told me that as far as possible he conducted lead extraction procedures on a Wednesday afternoon when he knew that there would be a cardiac surgeon working in the hospital. The requirement or need for the presence within the hospital of a cardiac surgeon owes itself to the possibility of there being complications that might require surgical intervention. In Mr Allen's case, that would have involved his chest being opened and open heart surgery being performed to repair the perforation in time for him not to suffer any permanent deficit. I heard evidence that such a surgery would require a general anaesthetic. I note here of course that Mr Allen had already been placed under a general anaesthetic and according to Dr Bashford it would only have taken a matter of minutes to administer the necessary muscle relaxant to enable an invasive surgical procedure to take place. However, surgery of the kind that would have been required to rectify Mr Allen's situation would have involved the need for chest spreaders as well as cardiopulmonary bypass that would be required to maintain Mr Allen's circulation during surgery. All of that would not have taken place in the Angiography Suite in any event and would have needed to take place in an operating theatre. I return to that aspect in due course in discussing whether or not anything could have been done to save Mr Allen. In any event, it seems clear that at no stage did any cardiothoracic surgeon enter the room after Mr Allen collapsed and I draw the inference that no cardiac surgeon was present or at least available within the hospital to attend to Mr Allen on this particular occasion.
- 6.11. The issues as to whether the haemopericardium should have been more readily diagnosed and whether the necessary diagnostic equipment in the form of an echocardiography machine should have been more readily available are intertwined. Mr Allen's unresolved hypotension and collapse occurred at about 6:30pm. The pulmonary angiogram which revealed nothing of consequence seems to have been performed some time between 6:39pm and 6:45pm. There was some divergence in the evidence as to when and at what stage of proceedings the echocardiography machine became available. Dr Bashford thought that Dr Hii did not perform the pericardiocentesis until after the arrival of the machine and until after the correct diagnosis had been made by Dr Ayres through the use of that machine¹⁶. Dr Hii, on the other hand, believed that he had commenced pericardiocentesis before Dr Ayres

¹⁶ Transcript, page 63

arrived with the machine. Dr Ayres who had brought the machine to the suite, and had operated it and made the correct diagnosis, told me that after he had been alerted to the tragedy that was unfolding, it took him about two to three minutes to move from where he was in the hospital to the suite in which Mr Allen was undergoing his procedure. At the stage he arrived resuscitation efforts were taking place and when he asked if there was anything he could do to help he was requested to obtain the echocardiography machine and a technician. In order to obtain the machine, Dr Ayres had to proceed to his consulting rooms which are in a building attached to the Ashford. The rooms are on the second floor and the machine had to be retrieved therefrom, wheeled to an elevator and taken down. As well, there was the unplugging of the machine, the obtaining of ultrasound gel and some other necessities and he then had to transport the machine approximately 100 metres. He said that it took him about 10 to 15 minutes from the time he first went to the angiography suite to the time he returned with the machine. Dr Ayres told me that it was on the second occasion that he arrived at the suite, having obtained the machine, that he noticed that Dr Hii was endeavouring to put a needle into the pericardium. Dr Ayres told me that during normal working hours the equipment would have been available within minutes. However, on this particular occasion it took longer because it was at the end of the working day and I infer from that that the machine had been put away and the practice had been closed for the day. Dr Ayres suggested that if the pulmonary angiogram had been performed by 6:45pm as suggested by the evidence, the timing of his diagnostic echo test would have been within 5 to 10 minutes of that, so that the time of the diagnosis that Mr Allen was suffering from a haemopericardium was made at about 6:50pm to 6:55pm approximately¹⁷. It will be seen that this was some 20 to 25 minutes after Mr Allen had collapsed. Dr Ayres' evidence did not preclude the possibility that Dr Hii had been attempting pericardiocentesis at the time Dr Ayres first came to the room, but it will be remembered in any event that pericardiocentesis was not performed until after the pulmonary angiogram was completed.

- 6.12. Dr Hii's handwritten notes within Mr Allen's clinical record would suggest that when a pulmonary embolism had been discounted following angiography, he performed the pericardiocentesis and was able to aspirate approximately 200 millilitres of blood. He records that Dr Ayres arrived with the echo equipment and confirmed the haemopericardium. In his evidence Dr Hii said that he had started performing the

¹⁷ Transcript, page 103

pericardiocentesis before Dr Ayres arrived with the machine and so he was by then working on the basis that haemopericardium was the likely diagnosis.

- 6.13. In my opinion the evidence of Dr Hii is to be preferred to that of Dr Bashford. I find that Dr Hii had at least commenced performing the pericardiocentesis before Dr Ayres arrived at the suite with the echocardiography machine. It is also possible that Dr Hii had successfully extracted 200 millilitres of blood from the pericardial sac by that time. In my view it is more likely that once the possible diagnosis of pulmonary embolism had been discounted, Dr Hii would immediately have performed the pericardiocentesis. Once an embolism had been discounted, the only other diagnosis sensibly available was a haemopericardium from a ruptured ventricular wall and I think it highly unlikely that Dr Hii would have done nothing until Dr Ayres arrived with the diagnostic equipment. I would therefore reject Dr Bashford's evidence that Dr Hii did not begin pericardiocentesis until after the diagnosis of haemopericardium had been definitively made by Dr Ayres using the echocardiography machine.
- 6.14. The time lapse between Mr Allen's collapse and Dr Hii commencing the pericardiocentesis is impossible to state in precise terms. No notes were made of these events at the time. However, if it is correct that the pulmonary angiogram was not performed until between 6:39pm and 6:45pm, there must have been a delay in commencing pericardiocentesis until some time after that. The collapse had occurred at about 6:30pm. If on the other hand the echocardiography machine had been immediately available within the room, and a diagnosis of haemopericardium had been made straight away, or if Dr Hii immediately following Mr Allen's collapse had worked on the assumption that there had been a haemopericardium as opposed to a pulmonary embolism, it seems clear that pericardiocentesis would have been commenced at an earlier point in time and quite proximate to Mr Allen's collapse.
- 6.15. There was a great deal of argument during the course of the Inquest about whether Dr Hii should have indeed worked on the assumption that there was a haemopericardium rather than spend time executing a diagnostic procedure for a pulmonary embolism that simply was not there. For Dr Young, the development of major clots on the lead in the period of approximately one to one and a half hours before the collapse occurred would be relatively unlikely. Accordingly, Dr Young was of the view that a pulmonary embolism should have been seen as an unlikely explanation. For him, the implementation of diagnostic measures that were focused on such an explanation may

not have represented the most appropriate order of resuscitative action. In Dr Young's view a diagnosis of a cardiac tamponade caused by a haemopericardium would have been the more likely diagnosis and that efforts designed to correct that should probably have been implemented first.

- 6.16. On the other hand, Dr Hii's explanation for wanting to eliminate a pulmonary embolism first is understandable in the unfavourable diagnostic circumstances that prevailed. Although a cardiac perforation would have seemed likely merely from the rapidity at which Mr Allen crashed after the lead came away, I accept Dr Hii's evidence that although Mr Allen's blood pressure had irretrievably fallen virtually at the same time as the lead had given way, other vital signs such as his pulse did not necessarily descend to alarming levels immediately. In addition, as Dr Hii said, there were two competing possible diagnoses and he had the immediate means to confirm or eliminate one of them, namely the pulmonary embolism. At that stage the only available method that he had at his disposal to detect a haemopericardium was to insert a needle more or less blindly into the pericardium in the hope that blood would be extracted, thereby confirming a perforation. I can understand why Dr Hii would be reluctant to do that in the first instance, even if a haemopericardium was expected to be the more likely diagnosis.
- 6.17. To my mind the real explanation for the sequence of events that saw an unproductive diagnostic measure for a pulmonary embolism occur first involved two elements. First, there was the fact that the means to make a definitive diagnosis of a haemopericardium were simply not available and would not be available for several minutes. Second, the only other diagnostic measure, pericardiocentesis, presented a significant risk. In support of this observation I point to Dr Hii's own evidence that he would usually be reluctant to:

'... stick a needle blindly into someone's chest, especially when you have time. If you have time, you want to see there's fluid around the heart by an ultrasound. If you're dealing with an emergency situation where the patient has no blood pressure, in that case you can't wait for an echo machine, you have to stick a needle in to see whether it suck (sic) any blood out and, even then, that has the potential of actually making the situation worse. So, for me, at that time the blood pressure was low and I was definitely reluctant to stick a needle in, because if there's a clot and there's no fluid, I'll be jabbing a big needle into his heart muscle, I can lacerate the heart muscle and create a perforation

which wasn't there. The other possibility is you may hit a coronary artery, which will be also a catastrophe, a disaster.'¹⁸

The other factor that convinces me that the real reason Dr Hii pursued a diagnosis of pulmonary embolism was because he did not have the means to diagnose anything else, is his admission that:

'If an echo was sitting in the room, I would have applied the echo straightaway, sure.'¹⁹

Dr Hii went on to explain that he would preferably have employed that diagnostic measure because of its immediate availability and the fact that once it is operational one can see immediately whether there is a haemopericardium present. Another reason one would prefer to utilise that diagnostic measure, if it had been immediately available, was the direness of the consequences if indeed a perforation of the ventricular muscle had occurred and it remained undiagnosed and uncorrected.

- 6.18. To my mind it is difficult to understand Dr Hii's election to proceed with a diagnostic measure that was focused on the possibility of a pulmonary embolism other than by reference to the fact that an echocardiography machine was not immediately available to diagnose a possible haemopericardium. In my view, the real reason Dr Hii explored the possibility of a pulmonary embolism was because he did not have the means to rapidly diagnose anything else. As Dr Young said in his evidence, there had been difficulty in extracting the ventricular lead and all attempts at extraction had been met with a fall in blood pressure and associated pain. As well, the most serious complication of a lead extraction is perforation of a blood vessel or the heart which would have led him to believe that one or the other was the most likely differential diagnosis. The reality was that when Mr Allen collapsed a ruptured pericardium was a diagnosis that was very much on the cards and it is a telling admission on Dr Hii's part that he would have explored that possibility first if he had possessed the diagnostic means to do so. Where Dr Young might differ from Dr Hii is that Dr Young would have thought it 'very reasonable' to undertake blind pericardiocentesis in any event and under fluoroscopic guidance²⁰ even if a haemopericardium was not absolutely certain²¹. Dr Young did, however, add that one might conduct this risky

¹⁸ Transcript, page 156

¹⁹ Transcript, page 181

²⁰ Transcript, page 230

²¹ Transcript, page 232

procedure ‘particularly if other diagnoses had been excluded’²². I take it from this observation that Dr Young might himself be reluctant to conduct a blind pericardiocentesis unless a diagnosis of pulmonary embolism had been excluded. As well, Dr Young added that he would require some ‘reasonable surety’ that a pericardial fusion or tamponade was present before a blind pericardiocentesis was performed²³. In the event, I did not understand that Dr Young would necessarily have adopted an approach that was any more robust than Dr Hii’s. But the difficulty was that there was no means by which a diagnosis of a tamponade that was both speedy and definitive could be made without the echocardiography machine being immediately available.

- 6.19. There was also debate in the Inquest as to whether or not the CSANZ guidelines as to the immediate availability of diagnostic ultrasound equipment had been properly met. It will be remembered that the requirement is that diagnostic ultrasound capability should be ‘immediately available’. The expression ‘immediately available’ can be contrasted with another expression that is used within these requirements, namely that certain other devices should be ‘in the procedure room’. Arguably, therefore, there is no requirement that the diagnostic ultrasound capability afforded by an echocardiography machine should actually be in the procedure room at the time the procedure is conducted. To Dr Young the expression ‘immediately available’, as used in the CSANZ guidelines, does not mean that the machine should be sitting there physically located in the room because in the vast majority of cases the machine will not be required. Dr Young thought that notwithstanding this, one could make a case for the machine being in the room. As will be seen, I agree with this observation. In any event Dr Young believed that it was important that the machine be immediately accessible²⁴ and that this would mean that it was accessible within minutes rather than half an hour or an hour.
- 6.20. Whichever way the matter is examined, in my opinion the echocardiography machine and its diagnostic capability was not ‘immediately available’ in Mr Allen’s case. It was situated within Dr Hii’s and Dr Ayres’ clinic which was in a different building from the building that housed the Ashford Angiography Suite. It was approximately 100 metres away and had to be physically wheeled to the suite. In my opinion the

²² Transcript, page 232

²³ Transcript, page 234

²⁴ Transcript, page 244

expression 'immediately available' implies an availability within a time such that it has some diagnostic utility. As a measure of its limited diagnostic utility in this instance, Dr Hii elected to perform another time consuming diagnostic procedure that he otherwise would not have had to perform. On his own admission, he would preferably have used the echocardiography machine in the first instance if it had been there in the suite. By the time the machine arrived in the suite, it was virtually redundant. Clearly it had not been immediately available and I so find.

- 6.21. In the event, if the machine had been immediately available, it would have been immediately utilised and it would have diagnosed the haemopericardium. There would have been no need to embark upon any other diagnostic exercise such as the pulmonary angiogram. I find, therefore, that there was a significant delay in the diagnosis of the haemopericardium and a consequent delay in establishing any corrective measures.

7. Could Mr Allen's death have been prevented

- 7.1. In this regard it will be remembered that the size of the tear to Mr Allen's ventricular wall was 14mm. The focus of any enquiry as to whether or not Mr Allen could have survived such a traumatic insult to his heart is whether or not a more timely diagnosis of the true cause of his collapse would have made any difference to his chances of survival. In my opinion the probabilities are that if an echocardiography machine had been more readily available, the diagnosis would have been made sooner, especially if such a machine had been either in the room or retrievable within a minute or two.
- 7.2. Of course a tear of the ventricular wall of such a magnitude was not going to resolve itself naturally. Surgical intervention would have been required. There can be little doubt that with a tear of that magnitude the flow of blood into the pericardial space would have been copious. As pointed out during the course of the evidence, however, it is not the blood loss that is the difficulty but the compression of the heart by the blood accumulating in the pericardial sac. This leads to electromechanical dissociation and a cessation of circulation. The difficulty lies in being able to extract, by means of pericardiocentesis, a sufficient quantity of blood to keep up with the bleeding from the heart into the pericardial space. In his report of 15 February 2007 Dr Young suggested that it was impossible to know whether early pericardiocentesis may have been able to alleviate the situation long enough for urgent cardiac surgery to

have been effective. In order for surgery to be undertaken a surgeon would have to have been available. As well, the necessary equipment to open and spread the patient's chest and to bypass the circulation would have to be obtained. All of that takes some time. When asked whether in his opinion it would have made a difference to the outcome for Mr Allen had an echocardiogram machine been available and the cardiac tamponade diagnosed and treated within minutes of his collapse, Dr Young had the following to say:

'That depends, I believe, to a large degree on whether or not the extent of bleeding could have been managed by drainage. As I mentioned before, people generally die from cardiac tamponade in this situation because the heart is compressed. When the heart is compressed it can't fill with blood. If it can't fill with blood, it can't pump blood out. If you can relieve the pressure on the heart by putting in a drain, then that can allow the heart to start filling and pumping again. If the bleeding is so rapid that you can't - because this is a relatively small drain. What we can place in the angiography lab is a relatively small calibre drain. I can't recall off the top of my head but perhaps about 2.6 mm in diameter, so that's quite a small tube. Blood is quite viscous. You can't actually extract a large volume of blood through that drain quickly. If the bleeding is at a very fast rate, even if you put a drain in and do your best to extract blood as quickly as possible, you still will end up with cardiac tamponade because the bleeding is faster than the rate at which you can take blood out. I have no personal experience in being able to quantitate how quickly the bleeding will have occurred from the sort of tear that occurred in Mr Allen's heart. Certainly from the description, from the autopsy, it sounded like it was a large tear rather than just a tiny hole. It would seem likely that the bleeding would have been significant in which case just simply putting in a drain and extracting some blood wouldn't probably have been sufficient. It would have needed probably a cardiothoracic approach to open the chest and actually sew up the hole.'²⁵

- 7.3. In his undated second report Dr Young expressed the view that the delay between the onset of hypotension and the subsequent diagnosis of pericardial tamponade, which he believed was of the order of 30 minutes, may have significantly impacted on the outcome of the procedure and its subsequent complications. However, to my mind even if it could be said that at best Mr Allen's chances of survival may have been improved if an earlier diagnosis had been made, a debatable proposition in itself, the suggestion that Mr Allen would actually have survived is unsupportable. In Dr Young's first report he said that the profound nature of the cardiac collapse and rapid demise of Mr Allen would render it unlikely that he could have been successfully transferred to cardiothoracic theatre for surgical intervention. If the procedure had taken place under the hands of a cardiothoracic surgeon in an operating theatre the

²⁵ Transcript, pages 236 and 237

situation may well have been different. However, the evidence is that lead extraction procedures are not generally conducted in such an environment because the risks and infrequency of adverse events occurring are thought not to warrant it.

- 7.4. Dr Young, an experienced cardiologist, did not suggest that as a matter of course potentially difficult lead extractions should be undertaken in an operating theatre with a surgeon present or one actually conducting the procedure. It will be remembered that existing CSANZ guidelines go no further than to suggest that cardiothoracic surgical facilities should be on-site such that an emergent procedure can be initiated promptly.

8. Recommendations

- 8.1. Pursuant to section 25(2) of the Coroner's Act 2003 I am empowered to make recommendations that in the opinion of the Court might prevent, or reduce the likelihood of, a recurrence of an event similar to the event that was the subject of the Inquest.
- 8.2. The assessment of whether any recommendation that this Court might make would prevent, or reduce the likelihood of, an event such as this happening again is not free from difficulty. Complicating the matter of course is the fact that even if proper diagnostic measures had been present at the time of Mr Allen's collapse, or cardiac surgical resources had been available, the outcome may well have been the same. In addition, there appear to be already in existence a set of relevant guidelines that seem to be reasonably clear in their application and interpretation. I have already passed comment that in my view, even allowing for the fact that the expression 'immediately available' is open to different interpretations, the necessary diagnostic equipment that would have enabled a rapid diagnosis of a haemopericardium in Mr Allen's case was not available by any standard of immediacy. This was in my opinion a departure from the CSANZ guidelines, and a departure that in other circumstances may have made all the difference between a patient who suffers a cardiac perforation surviving or dying. It will be remembered that Mr Allen had his ventricular lead in place for about 11 years. The fact that it was difficult to extract could have come as no real surprise in those circumstances. Indeed, the degree of difficulty of extraction was, if not predictable, evident quite early in the piece. Indeed Dr Hii first endeavoured to extract the ventricular lead and when he found that it was difficult to extract then

proceeded to work on the atrial lead. It was only when the atrial lead was successfully removed that he returned to the task of removing the other lead which still proved to be stubborn and problematic. In short, this was a procedure that carried an appreciable level of risk in terms of its potential to involve a cardiac perforation. If the risk was not apparent before the procedure was commenced it certainly became apparent as it progressed. A proper diagnostic regime to cater for an adverse event such as a cardiac perforation was not there. Nor was it immediately available.

- 8.3. The fact that there was no diagnostic machine present may have been the result of the hour at which the procedure was conducted. There was simply no echocardiography machine available except that or those that were housed in Dr Hii's practice. The practice apparently had been closed for the day and it had to be reopened by Dr Ayres so that a machine could be obtained. Again, it may well be the case, although the evidence is not entirely clear, that by 6:30pm or so when Mr Allen collapsed any cardiothoracic surgical resource was gone, if it had been there in the first place.
- 8.4. I have considered very carefully whether the CSANZ guidelines that are meant to be followed in respect of these procedures are adequate, or whether they perhaps need some form of revitalisation in the light of the events with which this Inquest is concerned. If a patient suffers a cardiac perforation in the course of one of these procedures, and if an echocardiogram machine is the 'gold standard' diagnostic measure, as it was described by Dr Young, for my part it is difficult to see how such a machine can have any diagnostic utility unless it is at hand, and at hand straight away. Although it may not have saved Mr Allen's life, it is very easy to envisage situations involving cardiac perforations less catastrophic than his where an immediate diagnosis could well lead to a patient's survival. The converse of that of course is that if the machine is not immediately at hand, and as a consequence a correct diagnosis is not immediately made, or is delayed because other fruitless diagnostic journeys are undertaken, then the person's chances of survival may be put at risk. From the evidence that I heard, I gather that clinicians would resist the suggestion that a machine ought to be actually there in the room. They would point to the fact that in 99 cases out of 100 it simply would not be used. As a consequence it would not be cost effective. A technician would have to be there to operate it. These arguments have a superficial attraction only in my view. It needs to be borne in mind that the machine in this setting is a diagnostic tool that will not have constant use. It sits there

waiting for a diagnostic scenario to arise. The possible diagnosis that it is intended to address is one that implies the possibility of rapid death. In Mr Allen's case it perhaps needs to be repeated that on Dr Hii's own evidence he would have used an echocardiography machine first, rather than embarking upon what turned out to be an unproductive diagnostic exercise. If the test as to whether or not an echocardiogram machine should actually be immediately at hand, if not in the room, is the fact that its absence meant that in Mr Allen's case other less productive diagnostic exercises were conducted first, then clearly the machine should have been either in the room or just outside of the room and have been, in literal terms, immediately available.

- 8.5. It is difficult to escape the conclusion that to cater for the one case in one hundred that proves to be problematic, and that figure might even be higher in cases involving an obvious risk such as was the case here, there ought to be an echocardiography machine in the room.
- 8.6. As to the availability of a cardiothoracic surgeon, again the CSANZ guidelines are reasonably clear in that there ought to be such a resource on-site within the hospital. If there was in this case such a resource present at the time Mr Allen collapsed, then the resource was either conspicuous by its absence or was not utilised. To my mind a requirement that a cardiothoracic surgeon be present in the procedure room awaiting the unlikely event that open heart surgery will be required would be an unreasonable one. The requirement that there is surgical backup somewhere in the establishment is, on the other hand, not only reasonable but essential. It seems to me also that a requirement that a lead extraction procedure that is attended by risk, as was the case here, be conducted in an operating theatre with all of the necessary surgical equipment right there would also not be an unreasonable one. I was told in this Inquest that since these events a cardiothoracic surgeon is now conducting these procedures in this State.
- 8.7. The requirements that the CSANZ guidelines impose to my mind are of profound importance. One would have thought that they not only speak to the proceduralist conducting a lead extraction, but also to the hospital in which the procedure is being performed. Hospitals presumably have some interest in ensuring that procedures conducted within their four walls are being conducted in accordance with applicable guidelines.

8.8. I make the following recommendations:

- 1) That the Executive Officer of the Cardiac Society of Australia and New Zealand and the Convener of the Lead Extraction Advisory Committee of the said Society, take the necessary steps to clarify the minimal requirements for facilities for the performance of lead extraction as set out in the NASPE policy statement that has been adopted by the said Society in the following ways:
 - a) To further emphasise the need for a cardiothoracic surgeon to be on-site and be capable of initiating an emergency procedure promptly during the course of a lead extraction procedure;
 - b) To recommend that lead extraction procedures, as defined in the guidelines, take place in an operating theatre;
 - c) Define the expression 'immediately available' in terms that convey to proceduralists the necessity for diagnostic ultrasound capability to be available within such a time as to have significant diagnostic utility, and preferably to be within the room during the course of a lead extraction procedure.
- 2) That the Minister for Health and the Chief Executive Officer of the Medical Board of South Australia take the necessary steps to encourage the Executive Officer and the Convener of the Lead Extraction Advisory Committee of the said Society to take the steps described in Recommendation 1 herein.
- 3) That the Minister for Health and the Chief Executive Officer of the Medical Board of South Australia take the necessary steps to ensure that cardiac pacemaker lead extraction procedures are conducted in accordance with CSANZ guidelines.
- 4) That the Chief Executive Officers or equivalent of all hospitals or clinics within South Australia in which cardiac pacemaker lead extraction procedures are performed take the necessary steps to ensure that these procedures are performed in their institutions in accordance with CSANZ guidelines.

Key Words: Medical Treatment; Pacemaker Lead Extraction

In witness whereof the said Coroner has hereunto set and subscribed his hand and

Seal the 19th day of September, 2008.

Deputy State Coroner

Inquest Number 13/2008 (2862/2005)