STATE
CORONER
VICTORIA

18th March, 2003
Case No: 2116/00

FINDINGS

The death of Cheryl Hoggins occurred on 1st July 2000 at the Austin and Repatriation Medical Centre, Heidelberg from 1(a) Cardiorespiratory Arrest 1(b) Cardiac Tamponade as a result of perforation of the heart following central venous catheterization.

The circumstances

Mrs. Hoggins, aged 48, was admitted to the Austin Hospital on 17th May 2000 following about six weeks of suffering what has been described as a *`flu like illness.'* She was diagnosed with acute liver failure and underwent a liver transplant on 23rd May 2000.

Dr. Helen Opdam, was the Intensive Care Consultant, responsible for Hoggins' care about a week prior to her death. Opdam stated that her patient had:

> *`a complicated post-operative course, though was gradually improving. She had the unresolved problems of sepsis with intermittent hypotension requiring noradrenaline and acute renal failure for which she was receiving continuous veno-venous haemofiltration.'*

Dr. Opdam noted that in the week prior to the patient's death:

> *`she had continued to improve, no longer requiring noradrenaline, and underwent a successful trial of haemodialysis on the 29th of June, in preparation for discharge from ICU. She remained febrile and had several investigations in order to determine the source of her sepsis, which remained unclear.'*

Dr. Opdam also noted that, on 29th of June *`the liver transplant team requested that the haemofiltration catheter be changed in case this was the source of sepsis. During the afternoon ward round, I asked Alex Paspaliaris (day ICU registrar) to guide-wire exchange the haemofiltration catheter and send the tip for culture.'*

Apparently Dr. Opdam left the Hospital at about 7pm (but remained on call that evening). During the morning handover (Friday the 30th of June), Justin Brown (overnight ICU registrar) informed Opdam that *`Hoggins had been moved to the high dependency area overnight.'* (underlining added by the Coroner). She was told Hoggins':

> *`haemofiltration catheter had been changed the previous evening - no problems with the procedure were mentioned. She had, however, dropped her blood pressure at approximately 0600 hours that morning and noradrenaline had been restarted. Her blood pressure was stable on 2 meg/min of noradrenaline; mean arterial pressure greater than 70mmHg.'*

Dr. Opdam considered the *`hypotension likely to be secondary to ongoing sepsis'* and the patient was:

> *`moved back into intensive care and remained stable that day on 2 meg/min of noradrenaline. I sent cultures to look for a source of infection and restarted treatment with vancomycin. The vascular access lines were further reviewed and I noted that the central venous catheter had also been in for some time and asked Shiva Malerzadeh (day ICU registrar) to arrange for it to be guide-wire exchanged.'*

Dr. Opdam handed over the management of Hoggins to Geoff Gutteridge at about 6.30pm on 30th June.

Dr. Gutteridge worked as a Specialist in the Intensive Care area of the Hospital and indicated that he had some shared role in the management of Hoggins. From 6pm on 30th June, after the handover from Opdam, until 9am on 3rd July Gutteridge was the sole consultant covering the ICU. Gutteridge also agreed that Hoggins had:

> *`a prolonged and difficult post-operative course in the ICU, however, over a six-week period she showed gradual and progressive improvement. She had ongoing anuric acute renal failure for which she was receiving continuous veno-venous hemofiltration (CVVH). She also had recurrent episodes of sepsis requiring noradrenaline for blood pressure support, and she required continual central venous access and central venous pressure (CVP) monitoring.'*

Dr. Gutteridge indicated that at 11pm on 29th June, the patient *`underwent a planned guidewire exchange of a R subclavian hemofiltration catheter. Her platelet count at this time was 63 x 10^9/l .'*

Significantly, at 6am the next day a chest x-ray was taken. This x-ray was not examined as Mrs. Hoggins had been transferred to the High Dependency Unit and the x-ray had been taken for the early (8am) Ward rounds of the Intensive Care Unit.

Dr. Gutteridge stated that during the course of the day (30th June) Hoggins again required:

> *`low dose noradrenaline for blood pressure support, but otherwise appeared stable. In the evening at about 1900 hours, she suddenly became hypotensive with a mean arterial pressure (MAP) of 50 mm Hg requiring an increase in noradrenaline from 2 to 17 mcg/min to restore her MAP to 70 mm Hg. She was tachycardic (HR 120/min) tachypnoeic (RR 25/min) and was noted to be coughing up purulent sputum. She had an elevated central venous pressure, which had increased from 10 to l8 mm Hg. A chest x-ray was taken, which demonstrated clear lung fields, apart from some L basal atelectasis, and no pneumothorax. However, the CVVH catheter was noted to be in the R atrium.'*

Dr. Gutteridge noted that he *`went home at 2030 hours whilst a ventilation/perfusion scan was performed as an investigation for possible pulmonary embolism.'* He then returned to the ICU at 2200 hours and, on reviewing the patient, noted that she had *`a MAP of 70 CVP of 14 mm Hg on a dose of noradrenaline,'* which he read at the time as *`7 mcg/min.'* Gutteridge noted that *`subsequent review of the ICU observation chart showed this to be 17 mcg/min.'*

The issue of the noradrenaline reading is significant. It should be noted that Gutteridge took a photocopy of the chart which showed the `1' of the `17' to be just on the vertical line of the chart. This `1' was difficult to see (because it was just on the line) and the figure could have easily have been mistaken for a `7'. Subsequently, somebody has interfered with the chart and altered the figures on the **original chart** to make the `1' very clear, so that the `17' is now very easy to read. **Had Gutteridge not taken the photocopy before the alteration to the original document he would have had some difficulty in persuading the court that he could have possibly mistaken the figure `17' for a `7.'** There is no doubt that Gutteridge did inadvertently, and understandably, mistake the figure 17 for a 7 as the correct figure (17) was poorly delineated.

Dr. Gutteridge stated that Hoggins was, at this time:

> *`febrile (T 37.8°C) with a HR of 120/min and RR 22/min.'*

And that Dr. Gutteridge's opinion was *`there was a remote possibility of pericardial tamponade. However, in view of the patient's apparent improvement at 2330 (he) did not undertake any investigation to exclude pericardial tamponade.'* He then gave instructions for *`Drs Wang and Brown for the hemofiltration catheter to be withdrawn from the R atrium before commencing hemofiltration'* and left the ICU at about midnight.

Dr. Justin Brown had a role to supervise residents and had care of patients in the High Dependency and Intensive Care Units. In one of these capacities he also advised Dr. Wang about the withdrawal and replacement of the catheter. Brown was overseas during the inquest and was not returning to the jurisdiction in the foreseeable future. He stated that:

> *`At 2000hrs 29/06/00, I arrived at work as usual. During hand-over from Dr Alex Paspaliaris I learnt that Cheryl had been moved from ICU to the HDU with a view to transfer to the ward. Among other things, Alex told me the right subclavian vascath needed to be guide-wire exchanged. I asked the resident Dr. Otis Wang if he would like to do this and he agreed. He had performed the procedure before, I had confidence in his abilities and the residents are expected to perform central venous cannulation during their ICU attachment.'*

Dr. Brown noted that:

> *`around 23:00 hrs Otis exchanged the right subclavian vascath for another one by inserting a wire down one of the lumens of the original catheter, removing the catheter then, passing a new one over the wire, then removing the wire, all with the usual aseptic technique. I looked in twice during the procedure to check all was well and Otis, the nurse assisting him and Cheryl were happy. At the end of the procedure, I asked Otis if there had been any problems with the insertion of the new catheter and he said there had not. He asked me if we needed to do a chest x-ray to confirm the catheter's position, but I said this was unnecessary as the insertion had been uneventful.'*

Significantly, Dr. Brown based this decision *`on my experience and a research article abstract I had seen (American Journal of Surgery. 176(6):618-21,1998 Dec).'* (underlining added by the Coroner). A copy of this research article was made available to the court and is attached to the finding.

Dr. Brown then explained details about the change in Hoggins' symptoms. He stated that, just before 6am on 30th June the patient became:

> *`hypotensive and more tachycardic - mean arterial pressure (MAP) around 50mm Hg, pulse rate l20 (from 100) I and Dr Wang treated this with a fluid challenge of Haemaccel and small doses of intravenous metaraminol to a total of 2mg. Despite this, she remained a little hypotensive so I restarted a noradrenaline infusion. She required only a small dose -2mcglminute, to stabilise her. I assumed the cause of the hypotension was the ongoing `sepsis' that Cheryl had had over the past few weeks. Her temperature at the time was 37.2°C. Because of the incident we ordered a chest x-ray. At 08:00, we handed over to the day staff while reviewing the x-rays as usual. When discussing Cheryl, there was general agreement that her hypotension was probably secondary to on-going `sepsis' she had required noradrenaline on many occasions before. I do not recall seeing her chest x-ray.*

Dr. Brown noted that he went home at about 9am and returned at 8pm. On his return he found Dr. Gutteridge reviewing Hoggins. He noted that although the patient had been stable during the day but that:

> *`over the preceding couple of hours her central venous pressure (CVP) had gone up from l0 to l9, and her noradrenaline requirements had also increased, peaking at 17mcglmin and currently 7mcg/min, in order to maintain her MAP above 70 mm Hg.'*

Dr. Brown explained that Hoggins':

> *`respiratory rate had also risen a little and an arterial blood gas taken between 21:00 and 22:00 showed a decreased PCO2 to 25mmHg. A repeat chest X-ray was ordered at this time (approx. 20:00). When it arrived back on the unit, we could see the right subclavian vascath was in the right atrium. Catheter needed to be pulled back into a suitable position.'*

Dr. Brown noted that Dr.Gutteridge was concerned about Hoggins and they *`discussed the possible causes of her current deterioration, including pulmonary embolus, fluid overload and pericardial effusion/tamponade.'* Apparently Gutteridge considered that the *`most likely cause was pulmonary embolism.'* Both Brown and Gutteridge then:

> *`debated which investigations to order including VQ scan, chest CT and ECHO; the decision was made to do a VQ scan. At around 21 :00, I took a new ICU patient to the X-ray department, where I remained until returning the patient to ICU and around 23:00 - 23:30 (I cannot remember the exact time). During this same period, Dr. Shiva Malerzadeh accompanied Cheryl to the nuclear medicine department for her VQ scan. Dr.Gutteridge came and saw me in the X-ray department - he informed me that the VQ scan showed a low probability for pulmonary embolism. He did not feel that a spiral chest CT was necessary, as she now appeared to be stable.'*

Apparently Dr. Wang then was involved in pulling back the catheter, and during this process Hoggins went into respiratory distress and eventually, during resuscitation management, died. It is clear that Wang originally replaced the catheter under the supervision of Brown and was advised by Brown (as a result of his experience and the American Article) not to check the position of the catheter by a chest x-ray.

The Radiological process and systems problems

There was an issue relating to a chest x-ray taken at 6am on 30th June. The x-ray was taken for the 8am Intensive Care Ward Round and would have normally been viewed by the clinicians on that round. The catheter wire extension was observable in the x-ray. Unfortunately, as Mrs. Hoggins had been moved to the High Dependency Unit this x-ray was not viewed by the clinicians on the Intensive Care Ward Round. It was not reported on by the Hospital's Radiologist.

Dr. Craig White, Executive Director Acute Services, Chief Medical Officer, Austin & Repatriation Medical Centre provided a statement on the Radiology process for the Coroner in June 2002 The statement indicated the normal process for routine ICU (Intensive Care Unit) x-rays is that:

> *`the radiographer arrives in ICU at approximately 6am to take the requested films. A dot is placed beside the patient name on a white board in ICU and this indicates the need for an x-ray. A radiology request slip is placed at the foot of the bed of the relevant patient. A radiographer works through ICU from beds 1 to 14 and then the HDU (High Dependency Unit), which is physically co-located. The radiographer then takes the films down to radiology for developing.*
>
> *Films are returned to ICU unreported. This process takes about 1 - 1½ hours, but in time for the 8am ward round. After the ward round, the usual process is that the films are then collected and returned to radiology for reporting. Monday to Friday the films are collected by the radiology registrar for reporting. Reports are then dictated on to the internal reporting system by the registrar and typed by the audio typists. The reports are then checked by the registrar and approved.'*

Dr. White said the *`records indicate that the x-ray film of Mrs. Hoggins taken on the morning of the 30th June 2000 left radiology prior to the 8.00am ward round.'*

And:

> *`the films were not present at the 8.00am ward round. Mrs. Hoggins had been transferred to HDU on Thursday 29/6/00 and then transferred back to ICU on Friday 30/6/00.'*

Dr. White indicated that it was possible that:

> *`the x-rays may have been moved between the units for viewing although we cannot confirm this. The film of Mrs. Hoggins taken on the morning of the 30th June 2000 was not reported, as the radiology registrar did not complete reporting of all the films on this day. These ICU films are allocated a lower priority for reporting than others on the basis that they are usually reviewed by senior clinical staff in ICU during the morning round. If a particular film was required urgently or required some priority then the person who ordered the film would be expected to follow it up if the film and/or the report did not arrive. The film of Mrs. Hoggins, having not been reported on Friday 30 June 2000, would have been reported on the following Monday the 3rd July 2000. However, Mrs. Hoggins died on the 1st July 2000 and the films were not subsequently reported.'*

Expert medical opinion

A number of experts gave evidence or presented reports on the circumstances leading to Mrs. Hoggins' death. These included a Forensic Pathologist, an Intensivist and a Radiologist.

The Forensic Pathologist

Mrs Hoggins' death was not initially reported to the Coroner. However, an autopsy was performed at the Hospital. Following the reporting of the death Associate Professor Ranson, Forensic Pathologist, reviewed the records and was uncertain as to the cause of death (as the body was not examined by a forensic pathologist). He noted that by reference to the notes of the Austin Hospital:

> *`the death certificate cause of death was given as 1 (a) Cardiorespiratory arrest, due to 1 (b) Unknown due to 1 (c) Liver transplant sepsis.'*

Dr. Ranson was critical of the use of the word `Unknown in Clause 1 (b)' and was concerned that the case was not initially reported to the Coroner. He notes:

> *`It would appear therefore that whilst this patient was extremely unwell and that there were indications as to the underlying disease processes that caused her death at that time remains unexplained.'*

Dr. Ranson noted the provisional hospital autopsy findings of Dr Gino Somers the Pathology Registrar, as being.

> *`1. Two perforations in the inferior wall of the right atrium, two and three millimetres long, to the immediate left of the inferior vena cava and inferior to the coronary sinus. Surrounded by a 10mm rim of haemorrhage on the visceral pericardial surface.*
>
> *2. 300 ml of blood and clot in pericardial space (haemopericadium).*
>
> *3. 100 ml of blood stained ascites.*
>
> *4. Status liver transplant: liver parenchyma bile-stained but no focal lesions identified. No evidence of necrosis or haemorrhage. Intact anastomoses with no signs of leakage or obstruction. Small (2 cm diameter) thrombus at the right edge of the porta-hepatis, not associated with hepatic artery or portal vein.*
>
> *5. No evidence of a septic focus in the thorax, abdomen or pelvis. Microbiological swabs of porta-hepatis thrombus, pericardial and ascitic fluid taken.'*

Also Dr. Ranson remarked, that whilst *`a note of the preliminary autopsy findings are on file*' he had not been able to identify the full autopsy report including the results of any histology, microbiology or toxicology examinations undertaken at the Hospital.

Dr. Ranson commented that a *`radiology report of the 22nd of June 2000 comments on the presence of a right jugular central venous catheter with its tip projecting over the right atrium.'*

And noted:

> *`It is possible that in association with the insertion of such tubes damage can occur from the tip of the tube to cardiac structures however direct perforation is extremely rare. Erosion over time from the presence of the tip of a catheter in contact with structures is also a possibly but this is an extremely rare occurrence. Other causes of perforation of the heart include penetration of the heart by needles during attempts at resuscitation where intracardiac drugs are injected.'*

Dr. Ranson commented further that it would appear from the medical records:

> *`on the 30th of June 2000 that the patient's condition had deteriorated and pulmonary thromboembolus was being considered. Her heart rate was raised and her blood pressure was decreased. She appeared to be complaining of chest pain. At 0155 hours on the 1st of July she underwent a cardiac arrest and resuscitation was continued until 0219 hours. During her resuscitation the notes indicate that she was intubated at 0201 hours and she received numerous injections of adrenaline. It is not stated whether any of these were intracardiac but it would be entirely possible that intracardiac injections were used.'*

Dr. Ranson opined that as the description of the perforations in the provisional post mortem findings described haemorrhage over the visceral pericardial surface of the heart (outer surface):

> *`this could have occurred as a result of resuscitation attempts as this is risk of intracardiac injections. Whilst cardiopulmonary resuscitation is being maintained with intracardial injections blood may leak from the heart particularly if the needle insertions are associated with tearing rather than simple needle puncture wounds to the surface of the heart. If this is the case then the haemopericardium might only explain the failure of resuscitation so that the original cause of her cardiac arrest remains unexplained. Clinically it was felt that she had evidence of sepsis with an infective process however no evidence of a septic focus was found in the abdomen, thorax or pelvis at autopsy.'*

Dr. Ranson was:

> *`uncertain as to the significance of the haemorrhage around the heart in causing death as I cannot be certain that it was present prior to her cardiorespiratory arrest (when it could have been a predisposing factor to the arrest) and instead consider it equally probable that it had occurred as a result of resuscitative measures undertaken when the patient had already suffered the cardiac arrest.*
>
> *This patient was suffering from renal failure and the problems associated with the management of her liver transplant for liver failure. Infection and sepsis were being considered and local areas of infection associated with intravascular lines may occur and be a source for sepsis. Indeed infection at the tips of catheters may increase the risk of erosion of the catheters through structures such as the wall of the heart.'*

Dr. Ranson summarized the lead up to the vascath exchange thus:

> *`It appears from these notes that the decision was made to replace the vascath on the 29th of June 2000 as a requested by the liver transplant team due to concerns regarding sepsis and unclear source - ?possible line related. The ICU Consultant asked the Registrar to ensure the line was exchanged later that evening during the afternoon ward round.'*

Dr. Ranson noted that the vascath line was changed in preparation for the patient's discharge from the Intensive Care Unit the following day. But that *`due to the need for an ICU bed and inability to discharge the patient to the ward (no bed) the patient was moved to the High Dependency Unit overnight.'* He also observed that at about 6am on 30th June:

> *`Cheryl Hoggins became hypotensive which did not respond to intravascular fluids but an infusion of Noradrenaline maintained her arterial pressure. She was in no other way unwell and this was assumed to be due to ongoing sepsis (similar pattern to previous decrease in blood pressure over the previous weeks). Repeat cultures were taken and she was shifted back to the Intensive Care Unit during the morning ward round. I do not recall seeing her chest X-ray. Throughout that day she was haemodynamically stable on Noradrenaline infusion. She had no other concerning symptoms or features. A decision was made to also change the right jugular CVC line which had been in for more than one week due to recurrent sepsis (presumed).*
>
> *Clearly if a perforation of the heart had occurred as a result of damage from an intravenous line being inserted or removed then the defect in the heart would be likely to bleed immediately and this immediate bleeding would cause impairment of cardiac contraction as a result of cardiac tamponade. As a result I believe that had the heart been torn causing the bleeding as a result of the insertion of removal of the catheter then the bleeding would have led to symptoms being seen almost immediately or within a very short time following the procedure.'*

Finally Dr. Ranson said that he remained *`confused about the final mechanisms relating to this woman's death and indeed as to the nature of her underlying disease process which caused her liver failure in the first place and required her to have a liver transplant.'* He considered that she *`died as a result of complications associated with her unexplained liver failure for which she had undergone liver transplantation.'*

Dr. Ranson was concerned that *`despite the word Unknown being recorded on part 1 (b) of the death certificate'* and *`evidence that there was uncertainty as to what had happened around the time'* of Mrs. Hoggins cardiac arrest *`the case was thought not to be reportable to the Coroner and a hospital autopsy undertaken.'*

Mr. Green examined Assoc. Prof. Ranson's report and his concerns about *`the possibility of the blood in the pericardium resulting from intracardiac injection during attempts to resuscitate Mrs. Hoggins from cardiac arrest.'* He considered that this was *`very unlikely'* for the following reasons:

- *`while intracardiac adrenaline has been recommended treatment in the past, it is no longer practised, nor recommended;*
- *this patient, in particular would have been unlikely to have intracardiac injection, as she had a central venous catheter in place, by which medications could be administered almost directly to the heart;*
- *in the setting of such detailed medical and nursing notes about the resuscitation, it is unlikely that an extraordinary measure as intracardiac injection would not be noted;*
- *the visceral pericardium where a 10 mm rim of haemorrhage was noted, is the surface against the heart, not against the fibrous (outer) pericardium. This is consistent with perforation of the heart from within, rather than from without by a cardiac injection.'*

In conclusion it is more likely that Mrs. Hoggins died as a result of 1(a) Cardiorespiratory Arrest 1(b) Cardiac Tamponade as a result of perforation of the heart following central venous catheterization. Although she was very ill following the liver transplantation, and being managed for potential sepsis, she was on the improve and there was no initial sign of sepsis following the Hospital autopsy.

A delay in the perforation from the time the catheter was replaced to shortly before the time of death is the likely explanation. Dr. Ranson pointed to the rare nature of this complication:

> *`It is possible that in association with the insertion of such tubes damage can occur from the tip of the tube to cardiac structures however direct perforation is extremely rare. Erosion over time from the presence of the tip of a catheter in contact with structures is also a possibly but this is an extremely rare occurrence. Other causes of perforation of the heart include penetration of the heart by needles during attempts at resuscitation where intracardiac drugs are injected.'*

The Intensivist

Mr. John Green, a Specialist in Intensive Care, was requested to give an opinion on Hoggins' care and on the issue of cause of death. He summarised the patient's history as being:

> *`a stormy postoperative course, with shock requiring inotrope/pressor infusion, thrombocytopenia, fluctuating encephalopathy and persisting oliguric renal failure. This syndrome was suggestive of sepsis and she was treated with repeated courses of empiric broad spectrum antibiotics. There was an ongoing exhaustive search for the focus and pathogen causing the presumed sepsis.*
>
> *As part of this search for and prevention of catheter-related sepsis, the venous catheters were changed periodically. There was a suggestion of a colonised/infected dialysis catheter ("Vas-cath") being a source of sepsis, with multiple resistant staphylococcus being reportedly cultured from the tip of a catheter removed on 14th June. On 29th June, the right subclavian Vas-cath was replaced with a new Vas-cath using a standard guidewire exchange technique.'*

Mr. Green noted that within four hours of this procedure:

> *`there was evidence of hypotension, with elevated central venous pressure. Attempts were made to identify the cause of the deterioration (including sepsis, pulmonary embolism and myocardial infarction). Despite treatment with antibiotics, intravenous fluids and noradrenaline infusion, she died 27 hours after the Vas-cath insertion.'*

Mr. Green also noted that an autopsy was performed, showing perforation of the right atrium inferiorly, to the left of the inferior vena cava and 300 mL blood and clot within the pericardium. He considered:

> *`Hoggins died from cardiac tamponade complicating insertion of the Vas-cath.'*

Mr. Green noted that:

> *`Cardiac tamponade from perforation of the heart is a well recognised but rare complication of central venous catheterisation. To prevent this problem, numerous authors, the American Food and Drug Authority and manufacturers of central venous catheters (CVCs) warn against right atrial placement of tips of CVCs. Mrs Hoggins' Vas-cath was noted to be inserted into the right atrium (although the radiologist's report was not present in the case notes), and was withdrawn after a delay of about 24 hours.*
>
> *The onset of new hypotension soon after initial placement of the Vas-cath is suggestive of its being the cause of the problem, and the tachypnoea and catecholamine resistant shock in association with high central venous pressure is consistent. Without seeing the film or the report of the X-ray taken after placement of the Vas-cath, I cannot say where the tip of the catheter lay. However, the site of perforation of the atrium ("in the inferior wall of the right atrium" ..... "to the immediate left of the IVC and inferior to the coronary sinus") is consistent with damage from a catheter from the right subclavian vein. The time from placement of the Vas-cath until death was about 30 hours, consistent with the time course reported by Ellis et a1.'*

The Radiologist

Dr. Chris O'Donnell, Radiologist reviewed the radiographs and provided an opinion. He summarised the procedures as follows:

> *`From 16/6/00 till 22/6/00 the patient had bilateral central lines in situ. On the right there was a large bore double lumen catheter entering the right jugular vein and terminating in the distal SVC.This was replaced by a second double lumen catheter on 17/6/00 entering via the right subclavian rather than jugular vein and again terminating in the distal SVC. On the left a single lumen smaller calibre catheter was in situ with its tip in the distal left brachiocephalic vein (entering via the jugular vein). On 22/6/00, the left single lumen tube was removed and a further right sided single lumen catheter inserted via the jugular vein.*

On all occasions until 29/6/00 these fine bore, single lumen catheter tips were in the distal SVC or proximal right atrium.'

Dr. O'Donnell considered that:

`between 29/6/00 at 11.53 hrs and 30/6/00 06:11 hrs, the right subclavian double lumen catheter was exchanged for another (this is confirmed in the clinical notes as occurring at 23:00hrs on 29/6/00). Radiologically (i.e. based on 2 chest radiographs performed after the exchange i.e. 30/6/00 at 06:11 hrs and 30/6/00 at 20:30 hrs) the catheter appearance was significantly different i.e. the new catheter length was substantially longer than the original and located in the distal right atrium (tip heading towards the left of midline). This is concerning and although not indicative of "perforation" at least suggestive of that complication - see attached appendix of a schematic from a common Radiology text book. Normally it should be positioned within the SVC or proximal right atrium.'

Dr. O'Donnell commented that no chest radiograph was provided following the *`final subclavian double lumen catheter "pull back" and exchange of the single lumen right internal jugular line that occurred some 2 hours prior to death.'* He opined that the CT of the abdomen which was performed on 27th June did not disclose any:

`evidence of a pericardial "effusion" or low lying catheter tip in the right atrium, and T-tube cholangiogram performed on 29/6 at 14:39 hrs (i.e. prior to the first catheter exchange) in which a low lying right atrial catheter is not evident.'

Dr. O'Donnell concluded that:

`between 29/6/00 at 11.53 hrs and 30/6/00 06:11 (presumably at the stated time of 23:00 hrs, 29/6/00 - 27 hrs prior to death) the double lumen right subclavian line was exchanged for another longer double lumen catheter and inadvertently placed distally in the right atrium. Two chest radiographs performed after this time i.e. - 7 and 21.5 hrs post exchange, showed the catheter tip to be sitting low and pointing towards the left in a recognised pattern (i.e. found in a common Radiological text book) that should raise the concern for cardiac wall "perforation".

And that:

`(despite the submitted article - Routine chest radiographs following central venous recatheterization over a wire are not justified. Am J Surg 1998; 176: 618 - 621) that following insertion, manipulation or exchange of a central venous catheter, chest radiography or fluoroscopy should be routinely performed and reviewed in order to confirm satisfactory tip position. This is also a recommendation of the manufacturer (as clearly printed on the product insert for the Medcomp@ Duo-SpliFM catheter).'

Conclusion

Mrs. Hoggins died as a result penetration of the heart by a guide wire following central venous catheterisation. There was a failure by the clinicians to follow both the Hospital and a product Manufacturer's procedures and advice. Had the procedure been followed and a chest x-ray immediately taken to check the positioning of the catheter there is a distinct possibility that Hoggins may have survived and recovered from her transplant operation.

As indicated by the conclusion of Dr. O'Donnell:

> *`between 29/6/00 at 11.53 hrs and 30/6/00 06:11 (presumably at the stated time of 23:00 hrs, 29/6/00 - 27 hrs prior to death) the double lumen right subclavian line was exchanged for another longer double lumen catheter and inadvertently placed distally in the right atrium. Two chest radiographs performed after this time i.e. - 7 and 21.5 hrs post exchange, showed the catheter tip to be sitting low and pointing towards the left in a recognised pattern (i.e. found in a common Radiological text book) that should raise the concern for cardiac wall "perforation".'*

There was no checking radiograph immediately following the exchange of the catheter as the doctor performing the exchange procedure was advised by a more senior doctor that this process was not necessary. The more senior doctor made this decision and gave the advice as a result of his experience and research conclusions in an article in the *American Journal of Surgery (176(6):618-21,1998 Dec)*. This was against the Hospital's own procedures (which were unwritten) which required a check x-ray. It was also contrary to the advice of the manufacturer.

COMMENTS AND RECOMMENDATIONS

The preventable nature of Mrs. Hoggins' death

It is proposed to forward a copy of the finding, the comments and recommendations to the Victorian Minister of Health. The finding will also be forwarded to the various medical colleges and nursing associations as well as the agencies referred to in the comments and recommendations.

The failure to follow Hospital/Manufacturer's recommended procedures designed to avoid the hazard

Mrs. Hoggins' death was potentially preventable. Had undocumented Hospital procedures (or the manufacturer's advice) been followed and a check x-ray been preformed shortly after the guide-wire exchange and the wire immediately withdrawn, there was some potential for a different outcome. Whilst it must be clearly acknowledged that Hoggins was very ill, prior

to this event she was apparently on the improve, having just been moved from Intensive Care to the Hospital's High Dependency Unit.

In addition, had the x-ray that had been performed at about 6am on the morning for the Intensive Care Unit's early morning ward round been reviewed, there was also a potential for identification of the problem with the guide-wire and withdrawal at that time. Whilst it is not possible to determine precisely when the fatal injury occurred, the earlier the withdrawal of the protruding guide-wire the better.

The Hospital had procedures (undocumented) that were not followed by the junior clinician performing the guide-wire exchange, albeit on advice from a more experienced clinician. Those procedures were clearly designed to avoid the rare complication (hazard) associated with this particular medical procedure. In addition, the instruction manual for use of the catheter (Medcomp, *`Duo-Flow Soft Line'*, *`Directions for use for Temporary Access Catheters'*) provides a number of warnings:

> *`Confirm final position of catheter with chest x-ray. Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.'*

And:

> `CAUTION: FAILURE TO VERIFY CATHETER PLACEMENT MAY RESULT IN SERIOUS TRAUMA OR FATAL COMPLICATIONS.'

As indicated, Dr. O'Donnell (Radiologist) concluded that:

> *`between 29/6/00 at 11.53 hrs and 30/6/00 06:11 (presumably at the stated time of 23:00 hrs, 29/6/00 - 27 hrs prior to death) the double lumen right subclavian line was exchanged for another longer double lumen catheter and inadvertently placed distally in the right atrium. Two chest radiographs performed after this time i.e. - 7 and 21.5 hrs post exchange, showed the catheter tip to be sitting low and pointing towards the left in a recognised pattern (i.e. found in a common Radiological text book) that should raise the concern for cardiac wall "perforation".'*

And that:

> *`(despite the submitted article - Routine chest radiographs following central venous recatheterization over a wire are not justified. Am J Surg 1998; 176: 618 - 621)* ***that following insertion, manipulation or exchange of a central venous catheter, chest radiography or fluoroscopy should be routinely performed and reviewed in order to confirm satisfactory tip position. (Coroner's emphasis)*** *This is also a recommendation of the manufacturer (as clearly printed on the product insert for the Medcomp@ Duo-SpliFM catheter).'*

All Victorian Hospitals should be notified of the facts of this case and attention drawn to the consequences of the failure to follow a manufacturer's instruction (or hospital procedures

without very well reviewed reasons) and thus adequately manage the hazard (also called a complication).

It is noted the Austin Hospital has introduced a documented policy following Mrs. Hoggins' death - `CENTRAL VENUS and HAEMOFILTRATION LINE INSERTION' (copy attached).

Recommendation 1

That Hospital documented procedures ensure that following insertion, manipulation or exchange of a central venous catheter, chest radiography or fluoroscopy should be routinely performed and reviewed in order to confirm a satisfactory tip position.

Understandably, this check review should occur in a timely way.

(It is noted that procedure effectively follows the catheter manufacturer's instructions and warning).

The failure to examine an X-Ray in the circumstances of the transfer to another Ward

In spite of the failure to perform the check x-ray immediately following the guide-wire exchange there was another opportunity to intervene and potentially avoid the outcome. This opportunity was during the 8am Ward Round in the Intensive Care Unit. Unfortunately, the opportunity was lost as Mrs. Hoggins had already been transferred to the High Dependency Unit and the x-ray (taken about 6am) that would have been reviewed by clinicians during the Intensive Care Unit ward round, presumably went with her to the other unit (and was not viewed by any clinician or radiologist). As the x-ray was taken on a Friday, the normal radiological report would not have been undertaken until the following Monday. As Hoggins had died over the intervening weekend no report was undertaken by the Hospital's Radiological Department.

X-rays can be critical for early assessment of a problem and can result in changes to management to avoid an unsatisfactory outcome. Unfortunately, x-ray films are sometimes filed without review, or if reviewed by a radiologist, the discovery of the problem is too late for effective management.

If an x-ray film is taken (and not reviewed by a clinician or radiologist) for a ward round assessment and the patient is moved to another unit it should be an essential part of management practice that the film is reviewed as if it was for the ward round assessment of the patient's previous ward (clinicians responsible for the patient's management on the previous ward should view the x-ray and report).

If this is not practical, on transfer, as a minimum, any x-ray should be seen, as a matter of priority, by the clinician responsible for the patient's management on arrival of the patient at the new ward. If the patient is transferred over the period after order of the x-ray, and before

clinical review this fact should be noted on the file in a way that alerts the new clinicians of the existence of a new x-ray that should be obtained for clinical review.

Recommendation 2

That the Austin Hospital develop procedures relating to the checking of x-rays by clinicians (or radiologists) to ensure that system errors like those applying in Mrs. Hoggins' case are avoided. Transfer to another ward should not avoid normal and prompt review processes of x-rays (or other similar tests) that have potential to identify problems with procedures or help in early diagnosis.

It may be appropriate for the Austin Hospital to consider involving work systems and related experts to help design a new process to avoid this type of systems problem.

In the event that the Austin Hospital designs new work methods for early x-ray assessment to avoid the type of problems that occurred in Mrs. Hoggins' case this information should be disseminated to other Hospitals in Victoria.

Clear delineation of readings on charts and the alteration of the chart

The alteration of the chart

Clearly and understandably, Mr. Gutteridge misread the figure on the original chart showing the Noradrenaline readings. Had he not immediately taken a photocopy of the chart (prior to the inappropriate alteration) he would have had some considerable difficulty explaining how he read the chart at a reading of `7'.

There have been a small but significant number of coronial cases where medical notes or charts have been altered after the death of a patient (without any ethical or disclosed reason for the change). These cases are of serious concern as they may seriously effect interpretation of what happened and why. One is left with the inevitable conclusion that this was what was intended by the person altering the document. Whilst one can understand the need to document what has happened in a patient's management (and this may occur post death) the fact that the documentation or record completion occurs after the event needs to be clearly recorded. Any alteration needs to be explained.

However, alteration of records to give a different impression of what was on the original records is another matter. In this case Dr.Gutteridge's professional standing and honesty could have been adversely affected by the alteration (had he not, luckily, taken the photocopy). This should be seen as a clear warning to those working within the health sector not to alter records (without a full note recording the alteration and why).

Recommendation 3

That the circumstances surrounding the alteration of the chart be disseminated to all those working in the nursing and medical profession with the warning that this type of alteration should not be made without an appropriate reason. Any alteration to documents needs to be fully documented with the time, date, reason for alteration and identity of the person making the alteration.

Clearly, the clinician who misread the original unaltered chart acted appropriately and professionally (albeit he was mistaken).

The clear and legible recording of figures/readings on charts

The original figure on the chart was unclear. The correct figure was capable of being misread as the `1' was masked by the vertical line on the chart. Unclear documentation of chart figures has potential, in other circumstances, to lead to mistakes in diagnosis of a patient's condition (copy of original and altered chart attached to demonstrate difficulties).

The importance of clear and legible numbering needs to be emphasised.

Recommendation 4

With chart design and form layout it should be possible to avoid the consequences of 'printed lines' on charts potentially confusing accurate reading of figures.

That the Austin Hospital consider reviewing its generic chart design and layout processes (with the help of specialist form designers and those working with the charts) to ensure that, when new charts are to be introduced (or old charts are about to be reprinted) the risk of this type of confusion or mistaken reading is minimised.

In the event that the Austin Hospital designs an appropriate generic chart layout method this should be disseminated to other Hospitals in Victoria.

Recommendation 5

Staff in all Hospitals be advised of the facts in relation to the unclear numbering of the Chart in this case and of the resultant need to clearly and legibly write numbers, etc.

The general consequences of failure follow manufacturer's instructions - the need for research into this cause of iatrogenic injury

The failure to follow Hospital/Manufacturer's recommended procedures - the consequences

Mrs. Hoggins' death, in the circumstances of a failure to follow the product manufacturer's instructions, is not unusual. There have been other coroners' cases involving deaths in major Victorian hospitals where, had the manufacturer's instruction, warning or guidelines been followed the death would probably not have occurred (for example, Jones and Ainalidis - findings attached). Significantly, each of these deaths have occurred in different hospitals.

The issue of failure, by those working within the hospital health sector, to follow instructions, warnings or guidelines contained in a product manufacturer's instruction manual and the resultant link to iatrogenic injury and death may need to be further researched. This type of research should be regarded as being urgent and necessary to identify the extent of the problem and, if required, to work out appropriate countermeasures.

Recommendation 6

That the Department of Human Services (Acute Health Care Division) consider undertaking a major research project to identify the extent (and circumstances) of iatrogenic injury and death in the hospital setting and associated, either directly or indirectly, with the failure to follow a product manufacturer's instructions, warnings or guidelines.

Such a project may well be undertaken in co-operation with the Victorian Managed Insurance Authority, Department of Epidemiological and Preventative Medicine, Monash University, Monash University Accident Research Centre, the various medical colleges and the Clinical Liaison Service at the Coronial Services Centre.

Once the extent of the problem is identified appropriate countermeasures would then need to be introduced to reduce the risks of these types of systems failures.

Reporting of deaths in hospital to the Coroner

Where a cause of death is ***`unknown'*** or there is some uncertainty about how a patient died the medical profession should report the matter to the Coroner. As indicated Dr. Ranson (Forensic Pathologist) was concerned that, *`despite the word Unknown being recorded on part 1 (b) of the death certificate'* and *'evidence that there was uncertainty as to what had happened around the time'* of Mrs. Hoggins cardiac arrest *`the case was thought not to be reportable to the Coroner and a hospital autopsy undertaken.'*

Where in doubt, advice should be sought from staff at the State Coroner's Office or a Coroner.

Graeme Johnstone
State Coroner
19th March 2003