QUEENSLAND COURTS

CORONERS COURT OF QUEENSLAND

FINDINGS OF INVESTIGATION

CITATION:	**Non-inquest findings into the death of Mrs NSM**
TITLE OF COURT:	Coroners Court
JURISDICTION:	Southport
DATE:	31 July 2017
FILE NO(s):	2014/1285
FINDINGS OF:	James McDougall, Coroner
CATCHWORDS:	CORONERS: pacemaker insertion, recognising arterial injury, recognising deteriorating patient
Counsel Assisting:	Ms Rhiannon Helsen

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Background

Mrs NSM was 81 years old. She lived at Banora Point with her husband, RAM. She had a history of high blood pressure and high cholesterol for which she was medicated. She also suffered from severe curvature of the spine and osteoporosis.

Three months prior to her death, Mrs NSM was referred by her general practitioner to a Cardiologist at a private hospital to investigate suspected cardiac issues after suffering from fatigue and chest pain. A 24 hour heart monitor was used, which showed that she had sick sinus syndrome, a condition where the heart beats too slowly and results in inadequate perfusion of the body. Mrs NSM was subsequently referred to the tertiary public hospital for the purpose of having a pacemaker insertion.

On 10 April 2014, Mrs NSM was transferred to the Coronary Care Unit (CCU) of the public hospital for an elective pacemaker insertion. The insertion procedure commenced at 12:19 pm and was completed by 1:28 pm. It was described as 'routine' and there were no immediate complications noted. Retrospective notes written by a nurse present state that Mrs NSM was hypertensive prior to the procedure, and a GTN 5mg/24 hr patch was placed. There was difficulty during the initial puncture, and a second puncture had to be performed to allow the wire to be passed successfully. Mrs NSM reportedly complained of pain shortly thereafter and was given Midazolam and Fentanyl. The procedure continued, and she continued to intermittently complain of pain throughout, which she claimed was similar to her normal osteoarthritis pain. Following the procedure, ooze was noted from the insertion site, which was treated by way of digital pressure. No external active bleeding was visible, however, swelling was noted around her neck. She subsequently became hypotensive and the GTN infusion was decreased.

Following the procedure, at around 2:20 pm, Mrs NSM was returned to the CCU, where it was noted that there had been difficulty in placing the pacemaker due to thrombus in the vein. Upon arrival, she complained of ongoing chest pain and appeared pale. An echocardiogram was conducted, and intravenous morphine and Ondansetron for pain and nausea were administered. At 3:00 pm, the supervising Clinical Nurse expressed concern with hypotension, and Mrs NSM was weaned off the GTN infusion. At 4:11 pm, the attending medical officer noted that her blood pressure was 110/55, and that '*the ongoing chest pain is likely secondary to PPM insertion'.* Mrs NSM was subsequently seen by a Consultant, and the plan was to *'maintain BP at 100 – 110 systolic with the GTN infusion'.* At 4:30 pm, her blood pressure was recorded as 90/40, with a mild increase to 90/50 at 5:00 pm.

At around midnight on 11 April 2014, Mrs NSM was woken so observations could be performed. She immediately complained of strong central chest pain, and was given paracetamol and Endone. Her blood pressure by this time had dropped to 80/50. A senior night medical officer was called to conduct a review of her deteriorating condition.

At 1:00 am, a chest x-ray was performed due to Mrs NSM's ongoing chest pain and observed shortness of breath. The senior medical officer requested assistance from the Intensive Care Unit (ICU) medical officer to insert a chest drain for a suspected pneumothorax. Mrs NSM's systolic blood pressure at this time was 60. At 1:38 am, a MET call was initiated and the ICU medical officer performed a needle decompression of a suspected tension pneumothorax, followed by the insertion of an intercostal chest drain. Blood exuded from the drain, and a fluid bolus of 1000mls of saline was administered. She was given 0.5mg of metaraminol in an attempt to raise her blood pressure, with a repeat chest x-ray apparently showing some lung re-inflation. A bedside ultrasound showed a small pericardial effusion with global hypo contractility.

At 2:15 am, Mrs NSM's condition had significantly deteriorated, and she was hypotensive and required intubation and ventilation. At 2:50 am, a blood transfusion of 2 units was commenced. Mrs NSM was then transferred to the ICU, and contact was made with the vascular, thoracic, general and emergency surgical teams.

At 3:15 am, Mrs NSM was observed to be pale, cold and had an endotracheal tube in situ, with her systolic blood pressure recorded as 53. She was receiving a noradrenalin infusion and boluses of adrenal intravenously to maintain adequate cardiac and cerebral perfusion. She was observed to have chest movement on the right side, a left-sided chest drain continued to haemorrhage blood, and she had developed an extremely distended abdomen.

At around 4:00 am, Mrs NSM was taken into the operating theatre for an emergency thoracotomy, where it was found that there was a large amount of blood in the chest cavity. At around 6:00 am, she was provided with a large blood transfusion, and further blood was removed from the chest cavity. Despite attempted surgical and drug treatment, Mrs NSM went into cardiac arrest and was unable to be resuscitated. She was declared deceased at 6:50 am on 11 April 2014.

Autopsy findings

On 14 April 2014, an external and partial internal post-mortem examination was conducted by Pathologist. A CT scan and a number of toxicological tests were also carried out.

At autopsy, the recently inserted pacemaker generated box was found in the soft tissues of the upper left chest, with a lead passing into the left subclavian vein and terminating in the right ventricle of the heart. Haemorrhage was seen around the insertion site of the pacemaker lead into the left subclavian vein in the lower neck, with extension of the haemorrhage into the back of the chest, around the lungs and also under the lining of the chest cavity. No distinct defect could be seen in the pleura of the chest cavity or in the left lung, although there was a small amount of haemorrhage at the top of the left lung. The blood appeared to have spread downwards from the area of the left brachiocephalic and subclavian veins through the soft tissues into the posterior mediastinum and under the pleura. Four defects were noted in the veins, one of which was the site of the placement of the pacemaker lead. No thrombus was present within the vein as was clinically suspected to be cause of the difficulty with the insertion of the lead. There was, however, numerous valves in the vein down from the insertion site of the pacemaker lead, which may have been the cause of the problem with lead insertion. No injuries were seen in the adjacent subclavian artery.

Toxicological analysis of samples taken at autopsy detected numerous prescription drugs all at levels within or below the reported therapeutic ranges. All the medications found were either regularly prescribed, or administered during hospital treatment.

The cause of Mrs NSM's death was found to be as a result of a left haemothorax and mediastinal haemorrhage from the insertion site of the permanent pacemaker lead into the left chest.

Hospital review

Following Mrs NSM's death, a Root Cause Analysis (RCA) was conducted by the public hospital. An RCA is a quality improvement tool, which involves a systematic process for analysing serious clinical incidents in order to identity what and why an event happened and

how it could have been prevented. A report detailing the findings of the RCA was subsequently provided for the purposes of the coronial investigation.

Following the investigation, the RCA Review Team noted that Mrs NSM's death was reasonably unexpected, and found to relate to systemic contributing factors identified during the review process. These factors included the delay to recognise and manage a deteriorating patient due to utilisation of a standard single response system observation chart, and differing practices in relation to risk management between clinicians as demonstrated by pre-procedure venograms and post-procedure chest x-rays.

Accordingly, the following contributing factor recommendations were made to address the issues identified:

I. One of the causes of Mrs NSM's unexpected death was the delay to recognise the arterial injury and haemopneumothorax. This was as a result of a delay initiating a MET call, which should have occurred at 3:00 pm. This was likely because the CCU was using a standard single response system observation chart at the time of the incident, instead of a 'track and trigger' tool for patient observations.

   In addition, medical reviews conducted were done so by staff who were not of the appropriate skill level and speciality. It was noted that reviews by inappropriate medical officers for patients who have a deteriorating condition occurred in this case because, at the time of the incident, the CCU was using a standard single response observation chart. This resulted in a vital signs recording system that did not prompt initiation of a MET call. At the time, the CCU was not using the Q-ADDS observation scoring system.

   It was recommended that Cardiology service line staff review, implements and evaluates the previous locally developed cardiac-specific Q-ADDs chart. This was thought to be able to be achieved with the Cardiac Thoracic Service Line Director as lead, in collaboration between the Cardiology NUM, Cardiology Educator, Quality Officer and Resuscitation Co-coordinator, in consultation with the Cardiologists, CTC's and the State-wide 'Recognition and Responding to Clinical Deterioration in Acute Healthcare' group to establish evidence based, best practice aggregate weighted scoring systems that trigger graded responses in comparable cardiac units in Australia.

   Furthermore, it was recommended that the possibility of a cardiac specific Q-ADDS be referred to a State-wide 'Recognition and Responding to Clinical Deterioration in Acute Healthcare' group to consider a pilot trial of a cardiac Q-ADDs, which can be shared with other Hospital and Health Services.

II. The failure to conduct a chest x-ray when her condition clinically indicated it was required (when she reported chest pain at 3:15 pm on 10 April), was also identified to have contributed to Mrs NSM's death. It was noted that a chest x-ray was not conducted because there was no 'trigger' from the existing document 'Clinical Pathway Pacemaker/AICD' or the vital signs recording document. It was acknowledged that the optimal time for a non-symptomatic patient to receive a post-procedure chest x-ray is a clinical decision, and as such there is variance in practice between clinicians.

   It was recommended that amendment be made to 'Clinical Pathway Pacemaker / AICD' to include indications of arterial injury as per recommendations of the Interventional Cardiologists.

III. A further contributing factor identified was that the sub-clavian punctures inflicted during the pacemaker insertion were 'blind' punctures (i.e. the subsequent re-punctures were performed without the guidance of prior imaging). It was noted that there is currently no evidence-based best practice guidelines of imaging prior to arterial puncture.

It was recommended that collaborative literature review and peer practice benchmarking between Interventional Cardiologists and Cardiology to establish evidence based best practice workplace protocol for implementing ultra-sound-guided cannulation of the sub-clavian vein instead of landmark method prior to repeated sub-clavian arterial puncture.

In relation to the implementation of the above recommendations by the public hospital, the following actions have been undertaken to date:

I. As of February 2015, the service line have reviewed the State-wide QADDs Telemetry chart. Trial and implementation of this change commenced on the 16 February 2015. Education to clinical units undertaken prior to the introduction of this chart and ongoing in-services continue. Weekly audits of the QADDs Telemetry charges are conducted via CHARMERS system. Results are discussed with the nurse unit manager, Educator and clinical facilitators and strategies are implemented to address any areas for improvement. Reports are available at the time of the audit.

A Cardiology Quality and Safety Plan 2015 was also developed, which set out the necessary audits to be conducted, the clinical governance requirements, divisional meetings and various risk management strategies to be employed.

II. The Clinical Pathway for Pacemaker/AICD has been amended to include indications of arterial injury. An education and communication plan was also completed and includes tabling and discussion of revised pathway at Quality and Safety meetings, ward meetings, M&M meetings and ward in-service meetings.

III. Workplace instruction for the interventional cardiologists to provide clinical practice in obtaining imaging prior to repeated sub-clavian punctures has been developed and endorsed by the Director of Cardiology.

A number of lessons learnt were also identified during the review process. These lessons, and the subsequent actions taken to address the issues cited, are as follows:

a. Issues associated with retrospective documentation in the patient's records. It was noted that contemporaneous documentation facilitates optimal identification of emergent patient care risks, and facilitates earliest implementation of mitigation strategies.

It was recommended that a Cardiology service line review existing or develop and implement quality improvement or quality assurance plan to provide improved reliability of adherence to procedure GCDPRO0971- Clinical Documentation Patient/Client record and Clinical Pathways.

Since this time, regular medico-legal and Patient Care Plan (including pathways) audits, per the Hospital & Health Service schedule, have been conducted. Results of these audits tabled at the departmental quality and safety meetings, with action

plans then developed. Discussion at departmental M&M meeting and Quality and Safety meetings regarding information and requirements for retrospective notes in the medical record are also carried out.

b. There was also delay experienced accessing a competent medical officer for insertion of the ICC out of hours. It was noted that the delay to definitive treatment of an identified acute issue may significantly impact morbidity and mortality outcomes.

   It was recommended that the Hospital & Health Service requires a clear and definitive process for accessing the appropriately skilled Medical Officer out of hours for ICC insertion identifying who to contact and what order each officer should be contacted. As such, a simple contact algorithm for accessing the appropriate medical officer was to be developed.

   In March 2015, a meeting was held to discuss this lesson learnt with relevant staff, including the Clinical Director of Diagnostics, Emergency and Medical Services and other Senior Medical Staff. The outcome was that (1) all intercostal drains required afterhours to be referred to Intensive Care Specialists via ICU registrar, excluding those inserted within the ED or theatre; (2) Once discussed, if decision confirmed that drain placement is required after hours, patient to be transferred to 'HDU bed' either within the ICU or if not available on respiratory ward; (3) patient will have drain inserted within the HDU environment and will remain observed there until stable and normal working hours; and (4) In hours drain insertions for those patients who are inpatients at the time to be referred to the respiratory or thoracic surgery teams.

c. Significant negotiation also had to occur in order to obtain an after-hours mobile medical imaging (chest x-ray) device for use on Mrs NSM, which compromises patient safety if they are required to be transferred.

   It was recommended that this issue be identified with Radiography to determine if this requires investigation of the demand for out of hour's medical imaging, and if the allocated resourcing is sufficient.

   Review of allocated resourcing has been completed and a deficit in resources wasn't identified. A review to determine the basis for the radiographers out of hours questioning of the request for a mobile chest x-ray found it to be an isolated event, and therefore the current process related to the use of mobile x-ray requests and orders was not revised. The Director of Medical Imaging Technology committed to review the checklist applicable to the triaging of mobile x-ray requests.

Expert report by Cardiologist, Dr Kenneth Hossack

On 28 March 2015, Cardiologist, Dr Kenneth Hossack provided a report detailing his view as to the sufficiency of care and treatment provided to Mrs NSM at the Hospital & Health Service, particularly the pacemaker insertion surgery and post-operative care.

In relation to the pacemaker insertion surgery, Dr Hossack notes the following:

- The complications experienced during Mrs NSM's surgery are recognised complications of pacemaker insertion. The risk of these complications occurring is less than 1%.

- During the post-mortem examination, four defects in the venous system were identified, which indicates that multiple punctures were performed to gain access to the left subclavian vein. The presence of a defect at the junction of the left and right brachiocephalic veins raises the possibility that the guide wire that had been inserted into the needle following the first puncture may have exited the vein at this point, and hence the difficulty encountered in passing the wire down into the cardiac chambers. The finding that the subclavian vein was patent at the time of autopsy indicates that Dr R misinterpreted the venogram as showing that the subclavian vein was occluded. Dr Hossack notes that upon his review of the venogram it does not appear that the left subclavian vein was occluded.

- The pneumothorax suffered by Mrs NSM is a recognised complication of attempting to gain access to the subclavian vein percutaneously. She had a number of risk factors for this complication, including being of an older age, her gender and multiple punctures.

In relation to the post-operative care provided to Mrs NSM, Dr Hossack is of the view that there were a number of factors in her clinical presentation, which were misinterpreted or ignored. Specifically, he cites the following:

- Strong pain experienced during the procedure, which was thought to be related to her osteoarthritis. Dr Hossack notes that this pain was likely related to the problems, which occurred with venous puncture.

- Moderate bleeding was observed coming from the puncture site at the completion of the procedure. Digital pressure, as opposed to diathermy to cauterize the bleeding points, was carried out.

- Swelling to the neck was noted after the catheter was removed. The surgeon thought that she may be experiencing elevated venous pressure, and subsequently prescribed Lasix. In Dr Hossack's opinion, this elevated pressure was likely due to partial venous obstruction as a result of accumulating haematoma in the neck and not as a result of fluid overload.

- Mrs NSM experienced a significant drop in blood pressure following the pacemaker procedure. It remained low during her stay in the CCU, however, was only recorded at midnight, when it had been low for some 6 hours. The presence of a fall in the haemoglobin and persistently low blood pressure should have alerted the treating staff that Mrs NSM was bleeding.

- A chest x-ray upon return to the CCU following the procedure would have been appropriate given the pain experienced during the surgery, the need for multiple punctures to be made, and the excessive bleeding following completion of the insertion.

- When Mrs NSM developed left-sided pleuritic pain and had a blood pressure of 80/60 at midnight, Dr Hossack is of the view that the seriousness of this situation was underestimated by the junior medical staff.

- It would have been prudent to transfer Mrs NSM to the ICU at 1:05 am to undertake treatment of the pneumothorax. It seems that there was difficulty obtaining assistance to perform the chest drain procedure.

- Had more senior medical staff been involved in Mrs NSM's treatment prior to 3:00 am, particularly given three procedures were performed to treat the pneumohemothorax, Dr Hossack believes that a more favourable outcome may have eventuated.

Dr Hossack is of the view that offering Mrs NSM a permanent pacemaker was appropriate. He is critical of the initial management of the hemopneumothorax because of the lack of personal involvement of senior medical staff at that stage. In particular, he raises concern as to the fact that Mrs NSM was only commenced on a blood transfusion at 2:50 am, despite evidence of blood loss, and that only 2 units of blood were given. It wasn't until 6:00 am, shortly before her death, that a large blood transfusion was commenced. In Dr Hossack's opinion, the delay in identifying her significant blood loss and providing appropriate treatment, was a major factor, which lead to her death.

Hospital & Health Service response to expert report

Following receipt of Dr Hossack's report, the Hospital & Health Service were invited to consider and provide a response to the concerns and criticisms raised.

Accordingly, Hospital & Health Service made the following submissions:

- Mrs NSM was an 81 year old lady, who only weighed 41 kilograms. She had severe curvature of the spine, which made it difficult to use normal anatomical landmarks during the pacemaker insertion procedure. As such, anticipation of her venous system was challenging, despite intraoperative mapping of the vein by venogram.

- The post-mortem findings indicated, and it was accepted, that there were 4 defects in the venous system, with multiple punctures performed to gain access to the subclavian vein. In response, it was noted that multiple punctures during subclavian vein access is a risk factor for pneumothorax, with the average number of attempts to achieve insertion was around 2.56, with 3.2 being the average for failed attempts. In Mrs NSM's case, it was submitted, that this number of punctures was reasonable given her co-morbidities and is in accordance with normal practice.

- In response to Dr Hossack's finding that the surgeon erred in concluding that the venogram showed an occluded subclavian vein, it was noted that a venogram may have low diagnostic accuracy, and other causes such as vein narrowing, streaming of contrast and collection of blood around a vessel, can cause a similar appearance.

- In relation to the pain Mrs NSM complained of during the procedure, it was noted that it is not unusual for this to occur as only a local anaesthetic is used. In this case, she suffered from osteoarthritis for which she required strong pain relief medication. Her severe kyphosis (curvature of the spin) also made it difficult to lie her flat on the operation table without a pillow. The pain Mrs NSM complained of following insertion of the wire was done so after the removal of the supporting pillow, so as to open the space between the rib and clavicle in order to gain access to the subclavian vein with the needle. Mrs NSM described the pain as 'osteoarthritis pain', which settled after around 5 minutes.

- Following the procedure until midnight, it was submitted that Mrs NSM was clinically stable. In support of this it was noted that she had a normal unchanged pulse rate, normal oxygen saturation levels, and normal respiration rates and maintained a low normal blood pressure (which must be considered in conjunction with the fact that she had been given intense blood pressure lowering medication that afternoon for high blood pressure). The first Mrs NSM complained of sudden severe pain was at midnight.

- During the procedure, the surgeon checked the lung apex and did not see any evidence of a pneumothorax. He did so again during aspiration. When Mrs NSM was moved from the catheter laboratory, the surgeon examined the patient again and found her to be stable.

- In relation to the use of diathermy, the surgeon is of the view that the most effective method used in cardiology is 'manual pressure', which is applied for pacemaker and angiography related bleeding. He notes that diathermy cannot stop bleeding from subclavian veins in a pacemaker procedure.

- In relation to the neck swelling observed in Mrs NSM's case, it was submitted that the most likely cause was intra-arterial pressure due to a combination of a number of factors, including intravenous fluid, her age and history of hypertension, as well as the fact that she was significantly underweight.

- In relation to Mrs NSM's fall in haemoglobin, it was noted that the clinical measurement of total haemoglobin has inherent variability. As such, the fall of haemoglobin, in the absence of other signs of bleeding, such as increasing pulse rate and increasing respiratory rate, in that order over the period was not in itself clinically alarming.

- In relation to Mrs NSM's low blood pressure, it was stated that she was found to have persistently stable, albeit low, blood pressure, which was in an acceptable range given the administration of medication to treat her hypertension prior to the procedure.

It was acknowledged, as identified in the RCA, that there was a delay in accessing a competent medical officer for insertion of the intercostal tube out of hours. Since Mrs NSM's death, the team have developed a simple contact algorithm for accessing the appropriate medical officer for insertion of an ICC.

Conclusion

Mrs NSM was 81 years of age when she died on 11 April 2014 of a left haemothorax and mediastinal haemorrhage from the insertion site of a permanent pacemaker. It was clearly appropriate for Mrs NSM to be offered a permanent pacemaker to treat her diagnosis of sick sinus syndrome. She was of a slight build, and had a number of co-morbidities, especially severe curvature of her spine, which made the procedure, and elements of her post-operative care, difficult. The complications, which lead to her death, whilst rare, are known and documented.

It does appear that there was some delay in recognising that Mrs NSM's condition was deteriorating. Dr Hossack raises concern as to the lack of senior staff involved in her clinical post-operative management. He cites her persistently low blood pressure, drop in haemoglobin and the pain experienced during the procedure, as signs that she was bleeding, which required further attention. Once the pneumothorax was identified, there was difficulty for staff to obtain assistance to perform the necessary chest drain procedure. In Dr Hossack's

opinion, the delay in identifying Mrs NSM's significant blood loss and providing appropriate treatment was a major factor, which contributed to her death.

I am satisfied that the concerns raised by Dr Hossack have been carefully and extensively considered by the Hospital and those involved in Mrs NSM's surgical management and post-operative care. As a result, various changes have been implemented to address these failings. Whilst there is not complete agreement as to all of the issues raised by Dr Hossack, the Hospital has acknowledged the evident issues with delay in recognising her deteriorating state and being able to have the necessary chest drain inserted. Appropriate actions have now been taken to remedy these issues for future patients. All of the RCA recommendations and lessons learnt have now been implemented, I am satisfied that these changes will undoubtedly assist to ensure that there is earlier recognition of a deteriorating cardiac patient.

Given the extensive investigation conducted by the Hospital and the implementation of the widespread recommendations made, I am satisfied that the clinical treatment and care concerns, which arise in this matter, have been satisfactorily addressed. As such, an inquest into Mrs NSM's death would not be in the public interest, and I close the matter by way of written findings.

James McDougall
Southeastern Coroner
Southport
31 July 2017