QUEENSLAND COURTS

OFFICE OF THE STATE CORONER

FINDINGS OF INQUEST

CITATION:	**Inquest into the death of Darryl Robert Smith**
TITLE OF COURT:	Coroner's Court
JURISDICTION:	Brisbane
FILE NO(s):	2009/355
DELIVERED ON:	4 November 2011
DELIVERED AT:	Brisbane
HEARING DATE(s):	8 August 2011, 4-7 October 2011
FINDINGS OF:	Magistrate John Lock, Brisbane Coroner
CATCHWORDS:	CORONERS: Inquest – death in a medical setting, adequacy of surgical equipment & management

REPRESENTATION:

Counsel Assisting:	Melinda Zerner, Office of State Coroner
Counsel for Dr Nutting:	Mr Diehm, SC instructed by Quinlan, Miller & Treston
Counsel for Sunnybank Private Hospital :	Ms Farr instructed by Minter Ellison
Counsel for Drs Zerk and Airey:	Ms Gallagher instructed by Norton Rose
Lawyer for Smith &: Nephew Surgical Pty Ltd	Mr Bloemendal, Clayton Utz
Counsel for Drs Kruger & Wills:	Mr A.J. Edwards instructed by Avant Law
Lawyer for Synthes Aus. Pty Ltd:	Mr Berry, Atkinson Vinden

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Introduction

1. On 7 April 2009 Darryl Smith, fell and fractured his clavicle (collarbone). On 11 June 2009 he underwent surgery to repair his collarbone. This involved placing a clavicle locking plate which was attached with surgical screws. For that purpose the orthopaedic surgeon performing the procedure used a drill he was not familiar with and a plating system he had not used before. During surgery Mr Smith's right subclavian vein was perforated and this led to complications. Despite resuscitation attempts Darryl Smith did not survive.

2. Other than those issues required to be considered by legislation, the main issues for the inquest were:

   - How the right subclavian vein came to be perforated during the surgery;
   - Whether the surgical equipment provided the necessary safeguards for the surgery;
   - Whether the surgical equipment was appropriately used during the surgery;
   - The adequacy of the management of the complications which arose from the perforated right subclavian vein; and
   - The adequacy of the policies and procedures of the Sunnybank Private Hospital (SPH).

3. Section 45 of the Coroners Act 2003 ("the Act") provides that a coroner's written inquest findings must be given to the family of the person who died, and each of those persons or organizations granted leave to appear at the inquest and to various officials with responsibility for the subject matter of any recommendations. These findings will be distributed in accordance with the requirements of the Act and posted on the website of the Office of the State Coroner.

The scope of the Coroner's inquiry and findings

4. A coroner has jurisdiction to inquire into the cause and the circumstances of a reportable death. If possible he/she is required to find:-

   a. whether a death in fact happened;
   b. the identity of the deceased;
   c. when, where and how the death occurred; and
   d. what caused the person to die.

5. There has been considerable litigation concerning the extent of a coroner's jurisdiction to inquire into the circumstances of a death. The authorities clearly establish that the scope of an inquest goes beyond merely establishing the medical cause of death.

6. An inquest is not a trial between opposing parties but an inquiry into the death. In a leading English case it was described in this way:- *"It is an inquisitorial process, a process of investigation quite unlike a criminal trial where the prosecutor accuses and the accused defends… The function of an inquest is to seek out and record as many of the facts concerning the death as the public interest requires."* [1]

7. The focus is on discovering what happened, not on ascribing guilt, attributing blame or apportioning liability. The purpose is to inform the family and the public of how the death occurred with a view to reducing the likelihood of similar deaths.

[1] *R v South London Coroner; ex parte Thompson* (1982) 126 S.J. 625

As a result, the Act authorises a coroner to make preventive recommendations concerning public health or safety, the administration of justice or ways to prevent deaths from happening in similar circumstances in future.[2] However, a coroner must not include in the findings or any comments or recommendations, statements that a person is or maybe guilty of an offence or is or maybe civilly liable for something.[3]

The Admissibility of Evidence and the Standard of Proof

8. Proceedings in a coroner's court are not bound by the rules of evidence because the Act provides that the court "*may inform itself in any way it considers appropriate."*[4] That does not mean that any and every piece of information however unreliable will be admitted into evidence and acted upon. However, it does give a coroner greater scope to receive information that may not be admissible in other proceedings and to have regard to its origin or source when determining what weight should be given to the information.

9. This flexibility has been explained as a consequence of an inquest being a fact-finding exercise rather than a means of apportioning guilt: an inquiry rather than a trial.[5]

10. A coroner should apply the civil standard of proof, namely the balance of probabilities but the approach referred to as the *Briginshaw* sliding scale is applicable.[6] This means that the more significant the issue to be determined, the more serious an allegation or the more inherently unlikely an occurrence, the clearer and more persuasive the evidence needed for the trier of fact to be sufficiently satisfied that it has been proven to the civil standard.[7]

11. It is also clear that a coroner is obliged to comply with the rules of natural justice and to act judicially.[8] This means that no findings adverse to the interest of any party may be made without that party first being given a right to be heard in opposition to that finding. As *Annetts v McCann*[9] makes clear that includes being given an opportunity to make submissions against findings that might be damaging to the reputation of any individual or organisation.

12. If, from information obtained at an inquest or during the investigation, a coroner reasonably believes that the information may cause a disciplinary body or a person's profession or trade to inquire into or take steps in relation to the person's conduct, then the coroner may give that information to that body.[10]

BACKGROUND OVERVIEW

13. Darryl Robert Smith was aged 34. He was in a long term relationship with Nicole Underwood and they had 3 young children together namely Zane aged 12, Brock

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[2] s46
[3] s45(5) and 46(3)
[4] s35
[5] *R v South London Coroner; ex parte Thompson* per Lord Lane CJ, (1982) 126 S.J. 625
[6] *Anderson v Blashki* [1993] 2 VR 89 at 96 per Gobbo J
[7] *Briginshaw v Briginshaw* (1938) 60 CLR 336 at 361 per Sir Owen Dixon J
[8] *Harmsworth v State Coroner* [1989] VR 989 at 994 and see a useful discussion of the issue in Freckelton I., "Inquest Law" in *The inquest handbook*, Selby H., Federation Press, 1998 at 13
[9] (1990) 65 ALJR 167 at 168
[10] S 48(4)

aged 7 and Rory aged 2 1/2. Mr Smith also had a daughter Codyann aged 17 from a previous relationship.

14. His mother, Mrs Robyn Turnbull, told the court he was a great father and a devoted partner who loved and adored his children. He was kind and considerate to everyone he met.

15. She said he was a very reliable and hard worker and was respected by all who knew him. He was full on and loved life. His loss affects them all every day especially his children.

16. The Court was shown a touching video of aspects of his life which was produced for his funeral.

17. On 7 April 2009 Mr Smith was working. He fell approximately six feet off a boat onto grass and injured his shoulder. He was taken by ambulance to the Redland Hospital Emergency Department. There he was diagnosed with a fractured mid shaft right clavicle, provided pain relief and a sling and referred to the fracture clinic as an outpatient.

18. Mr Smith attended the Redland Hospital Fracture Clinic on 14 April 2009, where a check x-ray was undertaken. It revealed a communicated right clavicle fracture with marked displacement. As a result, Mr Smith was referred to an orthopaedic – upper limb surgeon at the Princess Alexandra Hospital ('PAH').

19. On 20 April 2009, Mr Smith attended Dr Prem Adhar at the Redland Bay Family Practice. Dr Adhar referred Mr Smith to Dr Nutting, a private orthopaedic surgeon.

20. Mr Smith was reviewed at the PAH fracture clinic on 23 April 2009 where it was decided he would be reviewed in a further three weeks and if there was still non union they would consider performing an open reduction and internal fixation to the fractured clavicle.

21. On 8 May 2009, Mr Smith was seen by Dr Nutting. Dr Nutting noted the x-rays demonstrated a fracture with a butterfly fragment at the right clavicle and in his opinion it would be best managed by an internal fixation and grafting rather than conservative management.

22. Dr Nutting wrote to WorkCover Queensland on 21 May 2009 advising of the above and WorkCover approved the procedure.

23. On 11 June, Mr Smith presented to Sunnybank Private Hospital (SPH) and was admitted for surgery. Mr Smith was assessed by nursing staff and Dr Airey (anaesthetist).The operation commenced at 4.25pm under general anaesthesia.

24. Dr Nutting fixed the plate to the fractured clavicle using screws which are inserted into holes drilled by him while a Bristow elevator plate was placed below the clavicle to protect underlying tissue.

25. At 5.50pm, immediately after the drill bit was withdrawn on the sixth and final hole, Mr Smith suffered what was termed as 'profuse bleeding' from dark venous blood (not arterial) that sprayed out of the drill guide.

26. Dr Airey began a rapid infusion of IV fluid over the next 30 minutes.

27. The plate was lifted to gain access to the punctured vein underneath. Dr Nutting was able to partly control the bleeding in a few minutes. Dr Nutting applied direct pressure to stop the bleeding and vascular loops were then applied to ligate the bleeding vessel.

28. Despite the infusion of fluid Mr Smith's heart rate (HR) and blood pressure (BP) continued to deteriorate. There was then a dramatic change in heart rate (HR) and blood pressure (BP) indicating he was in circulatory shock.

29. At 6.25pm Mr Smith was intubated by Dr Airey and mechanically ventilated as oxygen saturation was low. As there was further deterioration, cardiopulmonary resuscitation ('CPR') was started with adrenalin at 6.30pm.

30. Mr Smith's condition did not improve, and an alternative diagnosis of tension pneumothorax (air in the pleural cavity) was suggested. This was managed by Dr Zerk who put in two forms of chest drain to no effect, indicating it was not a tension pneumothorax. There was no improvement in Mr Smith's condition.

31. Dr Kruger (Vascular Surgeon) stated he received a call at 6.17pm requesting his assistance but he was then told this was not required. This was followed by a call at 6.30pm to attend.

32. At 6.50pm Dr Kruger arrived. Sometime after arriving he voiced the possibility of an air embolism and a central venous line was then placed in the heart, air was aspirated before blood could be aspirated which consequently increased the likelihood of a diagnosis of air embolism.

33. Mr Smith's condition did not improve and at 7.55pm resuscitation efforts terminated and he was declared deceased.

THE INVESTIGATION

34. The Queensland Police Service ('QPS') were advised of Mr Smith's death by the medical staff and attended the SPH on 11 June 2009. They were present when members of Mr Smith's family were informed of his death. His family were understandably very distressed. His death was totally unexpected.

35. QPS commenced an investigation, taking statements from Dr Nutting and Dr Airey. Police Scenes of Crime attended for photographs.[11]

36. On 18 June 2009, a Comprehensive Incident Report was completed by SPH. Under investigations/findings it states: "*Incident is a coroners case therefore there are no findings at the time of notification*". Further on 13 July 2009, a Mortality Review was undertaken by A Pointing. The clinical summary states *"® subclavian v injury resulting in haemorrhage (intrathoracic). Subsequent cardiac arrest. Prolonged CPR. Coroner notified.*"

37. Subsequent to the QPS investigation, SPH provided statements to the Coroner from all nursing staff involved in treating Mr Smith whilst in the operating theatre. Additionally, the Coroner sought statements from all doctors involved.

[11] Exhibit A1, p9

38. Further material has been obtained from Smith & Nephew Surgical Pty Ltd who supplied the locking plate and instrument set equipment, and Synthes Australia, the distributor of the drill.

39. The perforation of the subclavian vein during the repair of a fractured clavicle appears to be a rare complication. The Therapeutic Goods Administration; the Queensland and Northern Territory Audits of Surgical Mortality – The College of Surgeons of Australia and New Zealand; and the Queensland Health, Patient Safety and Quality Improvement Service, do not have any reported incidents concerning the perforation of a vessel during surgical repair of a fractured clavicle.

40. Once a decision to hold an inquest was made further investigations were commenced and other issues have been raised. The Coroner sought an expert opinion from Dr Philip Duke, orthopaedic surgeon, Dr Simon Jenkins, anaesthetist, and Dr Lance Wilson, biomedical engineer.

Key Particulars

Personnel

41. Besides Dr Nutting, the key personnel involved in the surgery were:

    a. Dr Ian Airey, treating anaesthetist;
    b. Dr Annette Zerk, surgical assistant;
    c. Mr James Hayes, Endorsed Enrolled Nurse (scrub nurse); and
    d. Ms Wendy Grainger, Registered Nurse (anaesthetic nurse).

42. After it was noted Mr Smith was bleeding and his condition was deteriorating, a number of other visiting medical officers and nursing staff were involved in the resuscitation of Mr Smith. These included, but were not limited to:

    a. Dr Gregor Wills (assisted Dr Airey);
    b. Dr Alan Kruger, vascular surgeon (repaired the perforated vessel and investigated for an air embolism); and
    c. Ms Cheryl Jenkinson, Registered Nurse (assisted in and recorded the resuscitation).

Clavicle Locking Plate

43. Prior to the surgery, Dr Nutting had chosen to use the Smith & Nephew Peri-Loc system and in particular the Superior Distal Clavicle – Right Locking Plate to hold the fractured clavicle. The stainless steel plate has six larger holes at the distal end and eight smaller holes at the medial end. The plate accommodates both locking and non-locking screws.

44. To drill a hole for a non-locking screw, a drill guide may be held in place on the plate using the drill guide handle and the drill is inserted through the drill guide. For a locking screw, a drill guide is screwed into the plate and the drill is inserted through the guide. The difference between a locking screw and a non-locking screw is that the head of the locking screw is threaded so it locks into the plate thereby creating a fixed angle with a precise screw trajectory. A range of different size screws are available to suit different thickness of bone.

45. The fixation of a fracture using a locking plate requires a range of specialised tools. Smith & Nephew Surgical Pty Ltd and its local distributors maintain a number of instrument sets which are loaned to hospitals for the purpose of

conducting surgery. In this instance, the local distributor was Dot Dash Australia Pty Ltd ('Dot Dash') and the loan set provided was a PERI-LOC Small Fragment Set.

The Drills

46. The drill used by Dr Nutting in the surgery on Mr Smith was a Synthes Trauma Recon System ('TRS') drill. The drill was being trialled at SPH as it was considering purchasing a new drill. The Synthes TRS drill is a modular power tool designed for traumatology and reconstructive surgery.

47. In addition to the Synthes TRS drill, the Synthes Colibri drill was also on trial at SPH. The Colibri drill is a universal battery power tool system for use in traumatology, spine and maxillofacial surgery.

48. Had the Synthes drill trial not been occurring, the drill which would have been made available to Dr Nutting at SPH was a Hall Series 4 Drill/Reamer. The intended use of this drill is in large bone surgery.

Bristow Elevator

49. The Bristow elevator is a standard surgical tool which has a number of surgical uses.

Air Embolism

50. An air embolism can occur during surgery when small amounts of air get into the blood circulation. If a large enough air bubble enters in the venous system it can become lodged in the heart and stop blood flowing from the right ventricle to the lungs and death can occur.

Pneumothorax

51. This is a collection of air in the pleural cavity of the chest between the lung and chest wall. A Tension Pneumothorax can lead to low blood pressure and low oxygen in the lungs and consequent cardiac arrest.

The Autopsy Examination

52. An Autopsy report was provided by Dr Alex Olumbe and Professor Ansford.[12]

53. An external and full internal post mortem examination was conducted on 13 June 2009. A CT scan of the body performed on 12 June 2009, showed emphysema on the right chest wall, right tension pneumothorax, collapse of the right lung and shift of the cardiac shadow to the left.

54. There was no clinical evidence of a right tension pneumothorax during the resuscitation and it is probable the pneumothorax found at autopsy was caused by the insertion of a drainage tube into the right chest cavity during resuscitation. There was no evidence of an air embolism when the autopsy was performed, but a diagnosis of air embolism post-mortem may not be possible.

55. Other findings from the autopsy showed the presence of the surgical operation including an incision over the right clavicle with a plate with three lateral screws in situ. A dissection of the right subclavian vein confirmed the presence of two ligatures (vascular loops) adjacent to the lacerated component in the medial loop

[12] Exhibit A2, p10

measuring 20mm by 5mm. There was a small amount of haemorrhage adjacent to the ligated vein. T

56. Dr Olumbe states in a further statement that the perforation is directly under the last hole in the clavicle plate which is clearly shown in the autopsy photographs showing the punctured vein and two sutures.

57. There was natural disease in the form of severe emphysema and dilated cardiomyopathy which could have contributed to his death.

58. Dr Olumbe spoke with Dr Airey at approximately 8.30pm on 11 June 2009 (day of death) and with Dr Nutting on 12 June 2009.[13]

59. The Autopsy Report records that Dr Airey advised in addition to the lacerated right subclavian vein, there was a right pneumothorax and air measuring 20ml to 30ml was aspirated from the right atrium, which suggested there was an air embolism.

60. The report records Dr Nutting advised Dr Olumbe that whilst drilling the hole for the sixth screw it was noted the drill passed through a guide which resulted in a puncture/hole in the top of the right subclavian vein at the medial end of the clavicle with an extensive blood loss of approximately 2.5 to 3 litres of blood. Further, Dr Nutting advised there was a suspicion of a right tension pneumothorax which was not demonstrable, and a probable air embolism.

61. The report concludes: "*Considering the alleged circumstances of death, review of medical charts from Sunnybank Private Hospital and Princess Alexandra Hospital, my conversation with the operating surgeon, my reading of the post mortem CT scan report and my examination; the cause of death is indicated below and I have issued a certificate to that effect*:

Cause of Death

62. 1(a) Fractured right clavicle (surgery) due to or a consequence of,

1(b) Fall."[14]

THE ISSUES

63. I do not intend to summarise all the information contained in the exhibits and statements but to understand the findings, I consider it appropriate to record the important parts of the evidence under the relevant issues.

How the right subclavian vein came to be perforated during the surgery

64. Mr Smith was supine (lying down with the face up) on the operating table with his right shoulder elevated with a sandbag.

65. The position of the body appears to be a matter for individual surgeons. The use of a sandbag to elevate the shoulder is a procedure which is commonly utilised and reference to this is noted in some of the recent medical literature which was

[13] Exhibit A2, p9
[14] Exhibit A2, p10

tendered in this case.[15] This article stated that the data would suggest the safest position to internally fix a mid shaft fracture would be with the patient's arms adducted by their side and not to use a posterior sandbag or bolster.

66. Dr Duke's technique at the present time is to not have the patient in a supine position but what he referred to as a beach chair position.

67. Despite surgeons using different techniques there is no criticism made of Dr Nutting's method and Dr Duke stated Dr Nutting was using a standard technique.

68. As a result of Dr Nutting choosing to use the Smith & Nephew Peri-Loc plate, Ms Esther Moir, a sales representative with a nursing degree from Dot Dash was requested to attend the SPH theatres for Mr Smith's procedure. Ms Moir had only recently commenced working with Dot Dash and this was the first time she had attended a procedure on her own.

69. Ms Moir had not met Dr Nutting previously so she introduced herself and says she had a conversation with Dr Nutting about the clavicle plates and options available to him. It is apparent she does not recall any precise content of that conversation. Whilst the operation took place she retrieved the Smith & Nephew packages for the nurses to open as and when Dr Nutting asked for them.

70. Prior to the perforation of the subclavian vein, Dr Nutting had drilled five holes and inserted five screws (two of which were locking screws) into the plate. He was in the process of drilling the last hole to insert a locking screw in the most medial hole on the plate when profuse bleeding was noted.

71. Dr Nutting says regardless of whether he is inserting a locking or non-locking screw, he uses a Bristow elevator placed inferiorly to the clavical in order to prevent any protruding drill bit engaging soft tissue below the clavicle.

72. In his first statement to the Coroner on 24 June 2009 Dr Nutting explained he drilled a sixth hole through the drill guide, which was fixed to the plate and a Bristow elevator was placed underneath the clavicle.[16] It was unclear from that statement whether Dr Nutting held the Bristow elevator in one hand and the drill in the other at the time of perforation. However, a subsequent statement provided by Dr Nutting on 16 May 2011 confirms both his hands were on the drill and Dr Zerk was holding the Bristow elevator in place.

73. Dr Nutting says the technique he adopted for drilling a hole for a locking screw allowed both of his hands to be free to control the body of the drill. For non-locking screws he would use the drill in one hand and the drill guide in the other. The drill guide ensures a hole is drilled at the correct angle and does not deviate.

74. The drill guide does not control the depth of the drill entry and this is controlled by the surgeon. Dr Zerk who was assisting Dr Nutting describes the process of drilling as, "*Initially the drill encounters the bone cortex, then it passes through the softer bone marrow and then it encounters the cortex on the other side. Lastly it encounters the Bristow. The surgeon drills carefully by feel, applying pressure and backing off alternatively until the Bristow is encountered*".

[15] Exhibit C5 Galley I, Watts A, Bain G, The anatomic relationship of the axillary artery and vein to the clavicle: A cadaveric study, *J Shoulder and Elbow Surgery* (2009) 18, e21-e25 at e24

[16] Exhibit B10

75. The Smith & Nephew Peri-Loc specifications refers specifically to using the 3.5mm locking screw guide with insert which provides for a drill guide which does not penetrate as deeply.

76. Dr Zerk makes mention in her statement of the use of a drill guide "*about 2 cm in height*". In evidence she stated the ones she had seen used were probably taller than 2cm. There are two drill guides provided with the set and Dr Zerk could not identify which one was used and Dr Nutting could not advance the position. Ultimately the use of the smaller guide if it was the one used is not significant. Dr Duke stated the drill guide is not used for the purpose of a drill stop.

77. Dr Zerk says Dr Nutting placed the Bristow under Mr Smith's clavicle and passed the handle to her. She says it was her role to hold the Bristow still, in position, and she did that.

78. In his statement Dr Nutting describes what occurred immediately prior to drilling the hole. He says: *"I had made mention of the fact that the great vessels were in close proximity and that we should keep everything relatively still whilst I proceeded to use a 2.7mm drill bit and did this in repeated movements so that any sudden penetration of the cortex would not be accompanied by a sudden downward movement of the drill bit into the danger area*".

79. It is apparent that unless the anatomy is unusual (there is no reference to that being the case here) the centre of the subclavian vein will lie under the junction of the medial and middle thirds of the clavicle. This is regarded as the "at risk zone" for injury.

80. Dr Zerk, Ms Moir and Ms Grainger in oral evidence did not recall any instructions being given by Dr Nutting prior to drilling the hole but acknowledged he could have said words to that effect. Ms Moir in her written report made shortly after the operation to her employer does make reference to Dr Nutting saying to his assistant *"big red and big blue are under there."* I accept there is ample evidence to find that Dr Nutting provided a warning before drilling the last hole and recognised this was a danger zone.

81. The issue of the danger zone and possible trajectory utilised by Dr Nutting when drilling the last hole was the cause of some discussion and opinion and two medical research articles were tendered in evidence to assist the Court.[17]

82. It is of interest and even surprising that both of these articles have been produced in very recent times (2009 and September 2011) and their purposes are, to quote one article[18] *"to accurately describe the dimensions of the normal clavicle and define the relationship of the axillary artery and vein to the clavicle and coracoid process. A detailed understanding of these elements may ensure all safe surgery at a site where the role of open reduction-internal fixation techniques is increasing"* and in the other[19] *"to establish safe zones for drilling screw holes*

[17] Exhibit C4 Sinha A, Edwin J, Sreeharsha B, Bhalaik V, Brownson, A radiological study to define safe zones for drilling during plating of clavicle fractures, *J Bone Joint Surgery Br 2011, 93-B:1247-52,* Exhibit C5 Galley I, Watts A, Bain G, The anatomic relationship of the axillary artery and vein to the clavicle: A cadaveric study, *J Shoulder and Elbow Surgery* (2009) 18, e21-e25

[18] Exhibit C5

[19] Exhibit C4

during osteo-synthesis of the clavicle, by defining the proximity of the adjacent major blood vessels using reconstructed three-dimensional CT angiograms."

Figures 8 and 9 of Exhibit C4 Sinha A, Edwin J, Sreeharsha B, Bhalaik V, Brownson, A radiological study to define safe zones for drilling during plating of clavicle fractures, *J Bone Joint Surgery Br 2011, 93-B:1247-52 at 125.*

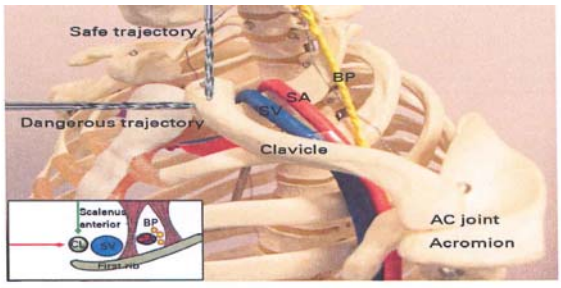

Fig. 8

Photograph of a model showing the medial end (point A) of the clavicle and the subclavian vessels, with two drills showing anteroposterior and craniocaudal trajectories (SV, subclavian vein, SA, subclavian artery; BP, brachial plexus).

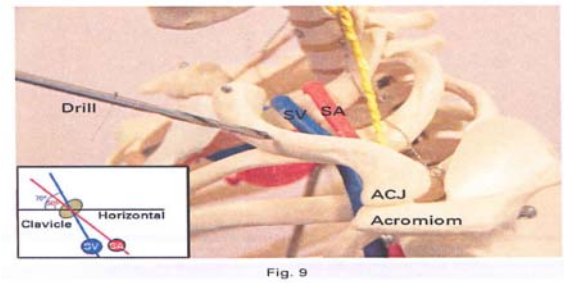

Fig. 9

Photograph of a model showing a dangerous trajectory represented by a drill at point B (middle one-third). Inset image shows the mean angles of the subclavian artery (SA) and vein (SV) with the horizontal in relation to the clavicle.

83. Both Dr Nutting and Dr Zerk described in their statements their recollections of what occurred when the vein was perforated. Dr Nutting says it appeared: *"that the drill bit skived off the Bristow sufficient enough to make a nick in the superior aspect of the subclavian vein*". Dr Zerk said *"…I felt the drill make some contact with the Bristow I was holding (which is to be expected) and then it felt as if it skived off the Bristow*".

84. It is apparent from the use of the word "skived" by both Dr Nutting and Dr Zerk that at some stage soon after the operation they both spoke about what had happened. Whether this was by way of simply exchanging information to work out what had happened or as a reconstruction (and this is not said as a criticism) becomes important as will soon be evident.

85. Dr Zerk was questioned in relation to the use of the word "skived" and was consistent in her evidence that she felt an impact by the drill and then it skiving off with there being a loss of resistance sideways. She does not know why the Bristow retractor failed to stop the drill going deeper but she did think it had to go deeper as she recalls there being a loss of resistance and Dr Nutting "jerking back" at which time the blood came out.

86. Ms Moir told the inquest she was standing about 4 metres away when the last hole was being drilled. She described that it seemed to go down something in the order of 14 to 25mm more than her experience would have expected and she then saw the bleeding.

87. Ms Wendy Grainger was the anaesthetic nurse during the surgery. She says in her statement she recalls when Dr Nutting was using the drill she thought the drill seemed to go down further than usual and as she was thinking this he pulled out the drill and blood became apparent.

88. Dr Nutting stated in his evidence he disagreed with the descriptions of Ms Moir and Ms Grainger, suggesting "*they must have been at different operations*".

89. Dr Nutting was asked how he thought the subclavian vein had been punctured. He stated that in all of his previous statements he had worked back with the assistance of himself and other members of the surgical team as to what the most likely cause was and they had come up with an assumption the drill "skived" off the Bristow elevator. He said he now had a theory as to how it happened which he had only recently considered and partly due to reading the recent medical article, Exhibit C4.

90. Dr Nutting started with the fact that in the most medial part of the clavicle, the subclavian vein is posterior or behind it. He was using a superior clavicle locking plate and a drill guide that sits 90° to the locking plate which will not allow the drill to deviate. Given he was drilling superior to inferior he thought the vein could not have been underneath it.

91. His theory is that most likely with inspiration (the act of breathing air into the lungs) the calibre of the vein increased at that particular moment and was building up and became larger and presented one aspect of the circumference of the vein to the side of the drill. In particular he partly relied on the post-mortem study saying it showed it was the side of the vein and not the top of the vein that was punctured. When questioned about this aspect he stated he was particularly referring to the post-mortem photographs.

92. It is noted the autopsy report refers to a puncture but on the superior aspect of the vessel and not the anterior. Dr Nutting stated if the drill bit had hit the Bristow elevator it (the drill bit) would have shattered. He does not recall it hitting the Bristow elevator at all. He stated during drilling of the last hole he did not feel anything untoward.

93. However this does not reconcile with the evidence of Dr Zerk in particular and is completely contradictory to all of his previous statements. I accept Dr Nutting emphasised this was a theory only among a "thousand" theories he had considered and this one he resurrected due to the matters raised in the recent research article.

94. Dr Zerk's version that the drill went in deeper than expected is supported by the evidence of Ms Moir and Ms Grainger. Both Ms Moir and Ms Grainger were at some disadvantage in respect to their position for viewing what happened, and Dr Duke considers and I accept they would not be able to give precise evidence as to the extent of the depth of the drill, but their impressions are still valuable. However even rejecting their evidence on this issue, this still leaves the evidence of Dr Zerk who was in the best position to say what happened.

95. In that regard and to the extent it is necessary, I reject the theory Dr Nutting has proposed as being not supported by the evidence.

96. What is clear is despite the caution taken, the drill passed through the clavicle and impacted with the Bristow elevator, but unexpectedly the drill was not stopped by the Bristow and it continued into the soft tissue under the bone. This resulted in a perforation in the top of the right subclavian vein at the medial end of the clavicle.

97. Whether this was caused by (1) miscalculation of the depth or trajectory of the drill; (2) excess pressure on the drill or trigger, (3) the Bristow elevator being placed in the incorrect position or (4) a shift in the Bristow elevator position, is unclear. It is possible it was a combination of all or any of the above.

98. Whatever is the case it occurred during and as a direct result of the surgery. There is no evidence to suggest Dr Zerk moved the Bristow elevator and there is no evidence it moved until the drill impacted with it. Given her evidence a matter of a few millimetres in the placement of the Bristow may have been significant.

99. Dr Duke, the expert orthopaedic surgeon engaged, concluded the decision to perform surgery on Mr Smith was appropriate. He says Dr Nutting was using a standard technique, including an appropriate plate and appropriate instrumentation.

100. Dr Duke does not use the anatomical profile locking plates that were utilised in this case but he recognises they were appropriate.

101. For reasons with respect to his concern as to dissecting tissue around the clavicle he personally does not use a Bristow elevator or other similar device but recognises its use as a protective device in this particular procedure is standard.

102. With respect to the drill he believes he could have used a similar drill in the past but he has no particular concerns as to the choice of drills. Other than those drills which are required for small hand surgery and drills for much larger bones, ultimately the drills in the middle range such as these are used for most bones.

103. Dr Duke found from Dr Nutting's statement, as well as from other observers in the room, that Dr Nutting took a great deal of precaution and caution in his use of the drill and in his control of the drill bit depth.

104. Dr Duke stated this was a very unusual outcome and the death of Mr Smith in these circumstances had become common knowledge in the orthopaedic community within a short period of time.

105. As a result Dr Duke has discussed with his anaesthetic team how to manage a haemorrhage and also avoid an air embolism and a number of measures have been put in place by his surgical team.

106. He now warns patients there is a possibility of death in these cases.

107. Dr Duke was referred to the research articles concerning the use of sandbags when the patient is in a supine position and he was not aware this would have made much of a difference.

108. He thought it was highly unlikely the drill was drilled in a trajectory as indicated as the safe trajectory in accordance with the Diagrams 8 and 9.

109. His said it was likely it was an angle somewhere between the safe and unsafe trajectory. He said it was possible the Bristow elevator caused the damage but it was unlikely that this occurred when it was inserted as the bleeding would have been observed then. He said it was possible the damage could have been caused when the Bristow was struck and moved by the drill and damaged the vein as distinct from the drill itself.

110. Dr Duke was unable to say with confidence when shown the autopsy photographs that they assisted him in determining the trajectory and to that extent that evidence is inconclusive.

111. It was put to Dr Duke and he agreed that given the evidence of Dr Zerk that the drill bit proceeded through the clavicle and then touched the Bristow elevator; that there was a slight jolt and the drill bit then skived off the Bristow; and given that the technique being used and the equipment was correct; and assuming the Bristow elevator was in the correct place; then it could be concluded that there was some human error in relation to what occurred.

Whether the surgical equipment provided the necessary safeguards for the surgery

112. The surgical equipment in issue was the:

    Smith & Nephew Superior Distal Clavicle – Right Locking Plate;

    The Bristow Elevator; and

    The Synthes TRS drill.

The Clavicle Locking Plate

113. There is no mechanism such as a drill stop on the drill bit or any tools recommended by Smith & Nephew to limit the depth of the hole being drilled by the surgeon. However, after the hole is drilled, a surgeon can use a depth guide to measure the depth of the hole drilled. This can be undertaken using the depth gauge or by using the gauge markings on the drill bit. This ensures the correct length screw is chosen to fasten the plate to the bone.

114. The Smith & Nephew Peri-Loc Upper Extremity Locked Plating System product brochure (Clavicle Surgical Technique) states: "*Care must be taken not to over penetrate the far cortex of the clavicle during reduction and screw insertion in order to avoid injury to neurovascular structures deep into the clavicular area*".

115. Mr Rex Nagao, the General Manager of Smith & Nephew Surgical Pty Ltd, advised in his statement that whilst the product brochure states this, the particular techniques used by surgeons to protect against this risk are matters of technique and judgment for the surgeon. He says Smith & Nephew do not provide advice to surgeons about such techniques. Further, he advises Smith & Nephew do not provide any training in surgical technique and that such training is reserved for a surgeon's educational institution and professional body.

116. Mr Nagao has advised there have been a total of 7,212 Peri-Loc Clavicle Locking Plates (of any type) supplied worldwide as at or about 26 July 2011. Of these, 959 were Superior Right Distal Clavicle Plates. He says there have been no previously reported incidents in the global Smith & Nephew complaint database concerning the perforation of blood vessels during surgery using the Peri-Loc Clavicle Locking plate system.

The Bristow Elevator

117. The Bristow elevator is a standard surgical tool which has a number of surgical uses. The Bristow elevator measures 10-12mm wide.[20]

118. The choice of this tool or any other form of inferior retractor to protect the underlying tissue, if any, is at the discretion of the surgeon.

The Synthes TRS drill

119. Smith & Nephew Surgical supplies surgical drill bits which are designed to be used in conjunction with its screws and Peri-Loc plates. The drill bits have a standard coupling mechanism which enables the drill bits to be used with any one of a range of powered surgical drills. Synthes confirmed the Smith & Nephew drill bits are compatible with the AO/ASIF Quick Coupling provided in the Synthes TRS Modular Power Drill set.

120. The Instructions for Use for the Synthes TRS drill states: *"The Trauma Recon System is only to be used for patient treatment after careful consultation with the instructions for use*" and "*The user of the product is responsible for proper use of the equipment during surgery*".

121. The speed of the drill is controlled by the operator applying finger pressure to a trigger control on the drill handle. There are two triggers on the handle of the drill, the bottom is for forward. When both the bottom and top are pressed together the drill is in reverse. Besides drilling, the other modes the drill can operate for oscillating and sawing.

122. Mr Simon Pratt, the Group Manager – Trauma, for Synthes Australia has confirmed Synthes is unaware of any previous incidents concerning the perforation of blood vessels during surgery whilst using the drill.

Conclusion

123. There is no evidence that suggests the surgical equipment, which would have undergone rigorous quality standards, was faulty and there is no evidence of any concern as to the equipment that was used. There may be some capacity for drill stops to be used. It does not appear to be part of any known current product development although it has been the subject of some conjecture in the medical literature.[21]

124. It is apparent there has been some experimental testing on prototypes of orthopaedic drill stop devices in the course of university research. This research has also indicated further testing and development is required.

125. It was submitted given this research is in its early days it is not possible to make conclusions as to whether future technology will be commercially feasible to provide a drill stop with a variable dynamic depth adjustment for use in

[20] Exhibit H3.8 and Exhibit B10.2
[21] Exhibit C5 24-25

orthopaedic surgery and therefore should not be the subject of a particular recommendation.

126. I agree it is not possible at this time and based on the limited technical evidence available to the Court, to make a recommendation that a drill stop be developed. However as the literature suggests there has been an increased interest in internal fixation of clavicle fractures and this case should certainly provide some impetus to the consideration of such devices. Ms Zerner submitted I should refer Mr Smith's case to the research and development departments of Synthes Australia and Smith & Nephew Surgical Pty Ltd to assist them in informing future design choices for drill bits. That is an appropriate submission which I intend to adopt.

Whether the surgical equipment was appropriately used during the surgery

The Clavicle Locking Plate

127. There was no suggestion the selection of the Superior Distal Clavicle – Right Locking Plate was not suitable to be used for the repair of Mr Smith's fractured clavicle. Dr Duke confirmed Dr Nutting used the appropriate plate.

128. Dr Nutting says it was the first time he had used the Superior Distal Clavicle – Right Locking Plate and the devices he had previously used did not allow for any locking of the screw into the plate. As a result the hand which would have usually held the drill guide handle was also used on the drill.

The Bristow Elevator

129. The Bristow elevator is a standard surgical tool. Dr Nutting says he uses the Bristow retractor in this type of procedure as it was a technique taught to him during his training and he has not seen any reason to use another device since that time. Dr Duke does not use any device.

The Synthes TRS Drill

130. Dr Nutting says he does not know the make and model of the drill he used on Mr Smith, but used the drill and associated equipment made available to him as is the usual practice and procedure at SPH and at many other hospitals at which he has worked over the past 40 years.

131. Ms Hazel Douglas, the Nursing Unit Manager of SPH, confirmed that when a drill becomes available in theatres, it is up to the relevant scrub nurse to select it for use in a particular surgery when they are setting up the theatres. However she says, it is ultimately up to the surgeon whether they use the drill chosen by the scrub nurse. In this instance, the scrub nurse was Endorsed Enrolled Nurse James Hayes.

132. Ms Douglas said the hospital usually makes visiting medical officers aware of a trial but was unable to confirm what occurred in this situation. In relation to product information to surgeons, she says she would ordinarily provide the drill sales representative(s) with the names of the relevant visiting medical officers for the representative to follow up directly.

133. Mr Paul Treadwell, the Peri-operative Nurse Educator of SPH, said as SPH is a private hospital it generally does not have any control over the education and training of visiting medical officers with new equipment. He says for this reason

it is standard practice for the sales representatives themselves to approach the visiting medical officers and see if education is needed.

134. Mr Nielsen who was the sales representative for Synthes has made a number of references in the material of the TRS being better suited to larger bones including a number of emails to SPH representatives to that effect. He said in his statement "*I provided specific education around the fact that the TRS was better suited to larger bones and joint procedures where there is a requirement for more power, and that the Colibri was better suited to small bones"*.

135. The information guides for the Synthes TRS and the Synthes Colibri drills do not specifically identify the clavicle in each of the drills listed uses. The uses listed for the Colibri drill in the product guide include: general traumatology; hand surgery; foot surgery; maxillofacial surgery; spine surgery; DHS/DCS or intra medullary reaming. The uses listed for the TRS drill in the product guide include: prosthetics; trauma heavy duty; trauma light duty; foot; hand; maxillofacial neuro; and spine.

136. The Synthes North American website provides an electronic guide to the use of its tools. Under the title 'Synthes Know Your Options', when the clavicle bone is selected, the power tools recommended for use are the Air Pen Drive; the Colibri; and the Electric Pen Drive.

137. Ultimately Mr Nielsen agreed the material and information he was providing to staff might not be clear in relation to indications for use of the drills and the differentiation was more about what the Colibri is not suited for (bigger joints and bones) than what the TRS is suited for.

138. The drill which would have been available to Dr Nutting at SPH had the trial not been occurring was the Hall Series 4 Drill/Reamer (5067-01) 100 PSI. It is a slightly lighter drill than the Synthes TRS and is operated by pneumatic air rather than by a battery pack attached to the drill.

139. The drill specifications for the Synthes TRS, Synthes Colibri, and the Hall Series Drill/Reamer were provided to Dr Lance Wilson, a biomedical engineer for comment. Dr Wilson concluded all of the drills are applicable for operating on the clavicle with no indication any of the drills are more suitable. He states: "*The three drills in question are all designed for orthopaedic applications, specifically the drilling and cutting of bones of the size of the clavicle (e.g. fibular, radius and ulnar) in trauma setting. There is no clear indication any of the drills available would be more or less suitable*".

140. Whilst Synthes and Mr Nielsen may consider the Colibri was a more suitable drill for the surgery, it was not inappropriate for Dr Nutting to use the Synthes TRS for the surgery on Mr Smith, and the evidence would place the clavicle as something between a small and large bone with both able to be used.

141. Even though the Synthes TRS drill has been found to be appropriate in the circumstances, Dr Nutting was not aware of the specifications, functions and use of the drill before he used it.

142. Dr Nutting says he would not use any equipment if it was apparent to him it was inappropriate. The question though is how he would know if it was appropriate or not if he did not have any knowledge of the drill prior to using it.

143. Dr Duke believed Dr Nutting to be familiar with a vast array of orthopaedic drilling equipment and this would not have been a factor. In particular the use of the drill and measures taken to ensure the drill depth was controlled and was in his opinion appropriate.

The adequacy of the management of the complications which arose from the perforated right subclavian vein

144. Once the right subclavian vein was perforated, Mr Smith went into shock as indicated by the changes in heart rate and blood pressure. Dr Airey was alerted. He was on the telephone in the scrub area at the time and when called by Dr Nutting he returned to the head of the operating table and began pushing fluid into the patient.

145. At first glance this might seem unusual but it is noted it is not uncommon for an anaesthetist to leave the immediate area for a short period when the patient is stable. It is apparent Dr Airey was only a few metres away through the scrub area door and had sight of his instruments and machine. There is no criticism of Dr Airey leaving the head of the table for this short time and this had no impact on the outcome.

146. As soon as the vein was perforated, Dr Nutting immediately applied pressure to the vessel, and says he was able to control the bleeding by the use of vascular tapes inserted proximal and distal to the perforation. Some time into the repair Dr Nutting requested a vascular surgeon but then decided he could repair the vein and had the bleeding under control and called off the attendance of the vascular surgeon.

147. Dr Nutting says he immediately reconsidered his decision to call off the vascular surgeon and thought a better result would be achieved if a vascular surgeon undertook the repair.

148. There was some evidence from Dr Airey that this was because of the bleeding and not that a better repair could be achieved. On that issue the evidence would support the reason for recalling the vascular surgeon was in relation to achieving a better result and not to stem the bleeding. That is supported by the evidence of Dr Nutting, Dr Wills and Dr Kruger. However it is clear the decision by Dr Nutting was not immediate and it was closer to 15 minutes later when Dr Kruger was called again.

149. The evidence also supports a finding the bleeding became under control at about 6.12pm when Dr Kruger was being spoken to and advised he now did not need to attend. By this time somewhere between 2.5 and 3 litres of blood was lost.

150. Registered Nurse ('RN') Cheryl Jenkinson documented contemporaneous notes of the resuscitation of Mr Smith. RN Jenkinson was not initially involved in the operation and was passing by the operating theatre during a break and was asked to come in and assist. She attended to a few tasks as requested and then noted no-one was taking notes as was the usual policy and commenced to do so. She states she commenced documenting management at 6.10pm and up until 6.30pm CPR was not commenced as Mr Smith still had a heart rhythm but this became irregular and faint.

151. In the first 20 minutes Dr Airey says he would have given atropine, intravenous fluids and maybe adrenaline. At some point another anaesthetist, Dr Wills, entered the theatre and offered assistance which was accepted.

152. The time estimate provided by Dr Kruger concerning his arrival time to the theatre is approximately 5 minutes later than recorded by RN Jenkinson. RN Jenkinson was recording time from a clock in the theatre whilst Dr Kruger took his times from his mobile telephone records. It may be the theatre clock was slightly out of time.

153. Combining the material from various sources, once it was noted Mr Smith was bleeding, and taking the times from RN Jenkinson and the hospital clock, the following events are recorded in the material as occurring:

    5.50pm, profuse bleeding was noted[22]

    5.55pm, Mr Smith's blood pressure dropped from 138/81 to 86/59 and his oxygen saturations dropped from 96% to 94%[23]

    6.10pm, Mr Smith's blood pressure continued to fall to 42/17 and his oxygen saturations to 71%[24]

    6.12pm, Dr Kruger, vascular surgeon initially called (he says 6.17)[25]

    6.25pm, Mr Smith was intubated and an additional IV (intravenous) cannula was inserted into Mr Smith's arm[26]

    6.27pm, haemoglobin tested (10.1)[27]

    6.28pm, the first dose of adrenaline was administered[28]

    6.30pm, cardiopulmonary resuscitation ('CPR') was commenced[29]

    6.30pm, Dr Kruger received a further call asking if he would attend the theatres to repair the vein[30]

    6.40pm, urgent cross-match of Mr Smith's blood was ordered[31]

    6.45pm, Dr Kruger arrived to the theatre[32] (Dr Kruger says he arrived at 6.50pm)

    6.47pm, femoral infusion commenced[33]

[22] Exhibit B9,p2
[23] Exhibit D2, p22
[24] Exhibit D2, p22
[25] Exhibit B20,p1
[26] Exhibit B5, p1
[27] Exhibit B5, p2
[28] Exhibit B5, p2
[29] Exhibit B5, p3
[30] Exhibit B20,p1
[31] Exhibit B5, p2
[32] Exhibit B5,p3; Exhibit B20,p1
[33] Exhibit B5, p3

7.17pm, 1st defibrillated (VT/Asystole)[34]

7.23pm, central cardiac line inserted by Dr Kruger[35]

7.30pm, first unit of cross matched (O Positive blood) was administered[36]

7.42pm, Arterial Blood Gases – pH 7.0, PaO2 325 mmHg, Hb 51[37]

7.50pm, CPR was ceased[38].

154. In terms of fluid replacement to treat the bleeding, Mr Smith was administered nine, 500ml bags of Gelofusine; one litre of Hartmans; one, 500ml bottle of Albumex; four units of O negative blood; and one unit of O positive blood. Further, Mr Smith was administered 19 doses of 1mg Adrenaline (one being intra cardiac), one dose of Sodium Bicarbonate, and was defibrillated (shocked) three times.[39]

155. RN Jenkinson was delayed in contacting Sullivan and Nicolaides to request an urgent cross match. She estimates she was on hold for approximately 12 minutes before the phone was answered. This did not have any impact on the resuscitation as there was an adequate supply of emergency hospital blood stocks.

156. At sometime prior to Dr Kruger's arrival and after CPR had commenced, Dr Zerk was directed by Dr Wills to perform a large-bore cannula throacostomy in the 2nd intercostal space in the mid-clavicular line, then proceeded to place a chest tube in the 5th intercostal space in the axillary line.[40] This was to treat a suspected tension pneumothorax.[41] All witnesses agree there was no tension pneumothorax.

157. Dr Wills told the court he was very disappointed when there was no evidence of a pneumothorax and those in the operating theatre were most confused as to why Mr Smith was not getting better notwithstanding the bleeding.

158. Dr Wills stated it was a disappointment to him no one had entertained an air embolism. He said the perforation of the subclavian vein could be an expected complication but it was a long way from his thoughts that there could be an air embolism.

159. Dr Wills, as did Dr Airey, spoke about other operations particularly neurosurgery where air embolism is not an unexpected complication and everything is set up to deal with that issue if it arises. Both of them recall being involved in operations where air embolism occurred in such situations which were rectified quickly and the patient survived.

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[34] Exhibit B5, p3
[35] Exhibit B5, p4
[36] Exhibit B5, p4
[37] Exhibit B9.2, p8
[38] Exhibit B5
[39] Exhibit B5
[40] Exhibit B12 and exhibit B12.1
[41] Exhibit B12.1

160. Dr Wills and Dr Kruger agree the technique used if it was thought there was an air embolism is to ask the surgeon to stop what he was doing, flood the wound to stop the air entering, and roll the operating table head down and to the left.

161. Dr Kruger says when he arrived most of the bleeding was under control. He noted some bleeding arising from the medial end of the wound and opened the wound medially to the sternum. He observed one of the external jugular veins was bleeding and this was controlled. He then repaired the perforated subclavian vein. The patient however, remained hypoxic.

162. Dr Kruger says he then identified the subclavian artery was under filled with no pulse unless cardiac massage was performed. He could see the veins seemed full but there was low blood pressure.

163. He then considered an air embolism. As a result he inserted a single bore central line and some air was aspirated as part of frothy blood which most likely was an air embolism. Although the volume of air that enters into the heart is important even 20ml of air in a minute would be fatal and Dr Kruger stated a large enough air embolism is not something that can be treated easily and there is a high mortality rate.

164. Dr Kruger agreed if there was anything to be learnt for this type of surgery, it would be that as part of the anaesthetic procedure the patient should be positively ventilated similar to what he would use in root of neck procedures and which apparently was also used in neurosurgery.

165. Dr Simon Jenkins, Director of Anaesthesia at Lyell McEwin Hospital in South Australia, provided an independent assessment of the peri-mortem management of Mr Smith.

166. In his opinion, the treatment provided to Mr Smith immediately after it was identified he was bleeding profusely from the wound was adequate. The overall attempted resuscitation followed a logical progression and the procedures followed were consistent with the recommendations of Advanced Life Support by the Australian Resuscitation Council.

167. Dr Jenkins provided evidence that the management of the resuscitation was reasonable under difficult circumstances where the diagnosis was unclear and multiple causes might have contributed. Dr Jenkins was of the opinion it is doubtful whether the outcome would have changed, had an earlier diagnosis of an air embolism been established.

168. He stated an air embolism in orthopaedic surgery was an extremely rare complication which would have been well off the list of possible complications being considered by an anaesthetist during resuscitation. He stated this case would certainly be of interest to surgical and anaesthetic professional associations highlighting the possibility of an air embolism not being isolated to potential complications in neurosurgery or vascular surgery.

169. Dr Jenkins was not able to state with any confidence at what time the air embolism occurred as there was a number of other issues occurring which could account for a cardiac arrest, in particular hypovolaemia as a result of the blood loss.

170. One of the difficulties in this case is even if an air embolism had been diagnosed earlier there was still the issue of the extensive haemorrhage and both would have been needed to be treated concurrently.

171. Similarly, in the expert opinion of Dr Duke the decision to contact the vascular surgeon in the circumstances was made at an appropriate time. Should the vascular surgeon have been called earlier, he stated the outcome may not have been much different given the problem was an air embolism.

The adequacy of the policies and procedures of the Sunnybank Private Hospital

172. The relevant policies and procedures identified are related to:

- The trial of surgical equipment;
- Obtaining urgent cross match of blood in emergencies; and
- Investigations of unexpected patient deaths.

The trial of surgical equipment

173. Mr Nielsen was liaising with Ms Anna Sale, Ms Hazel Douglas, and Mr Paul Treadwell from SPH concerning the trial of the drills. Inservice training was provided by Mr Nielsen to staff at SPH on 3 and 9 June 2009.

174. Mr Nielsen states when training medical staff at SPH he worked through the TRS instruction manual as well as the TRS fact sheet. It is standard practice when training to follow the index of the use manual of the device in question. He used practical instructions with hands on training of the TRS and the associated drill attachments.

175. Mr Nielsen says he made it very clear during both training sessions that wherever possible staff should call a Synthes representative before using the Synthes TRS drill for any procedure. He says it was important for the trial that a Snythes representative would be present to help answer any questions that may arise.

176. I accept in general he had made it clear he would like to be called to attend. In any event he says if called his experience is that any discussion with the surgeons would be short and part of his job is about selling the drill as much as communicating about its use. Many surgeons would say a “drill is a drill”.

177. Ms Hazel Douglas says for capital purchases such as drills, it is not imperative to have a sales representative in the theatres. She says this is particularly so when the relevant staff are familiar with the equipment or have received training. The scrub nurse for Mr Smith’s surgery was Endorsed Enrolled Nurse James Hayes who Dr Nutting considered experienced.

178. SPH agreed to trial the Synthes TRS and the Colibri drills in June 2009. Inservices were organised and provided to staff by Synthes on 3 and 9 June 2009. Dr Nutting says his only knowledge of any ‘trial’ of a Synthes drill was that at some stage on 11 June 2009 he was asked by a person (he does not recall who) whether he would ‘trial’ a Synthes drill.

179. Mr Nielsen was not asked to attend the SPH theatres on 11 June 2009 even though he telephoned the day before and has confirmed Dr Nutting did not attend the inservice sessions provided at the SPH.

180. Mr Hayes says he had attended a Synthes workshop in November 2008 which involved all of the Synthes products, including the TRS drill. He does not mention any inservice training provided at the hospital on 3 or 9 June 2009. The November 2008 workshop has been clarified by Synthes who confirmed the TRS drill only became available in Australia in April 2009, so any training provided in 2008 would not have covered the Synthes TRS drill unless there was an advanced sample present.

181. Despite this, Mr Paul Treadwell says he recalls attending the November 2008 workshop and believes the TRS drill was available for use at that training. Further he says, Mr Hayes was one of the main orthopaedic scrub nurses at the hospital, so he would have ensured he had the necessary training in the equipment.

182. The evidence is somewhat inconclusive as to whether Mr Hayes had any training on the TRS. He had relocated back to the USA and could not be contacted to explore that issue. He was apparently experienced and well regarded and there is no evidence there was any difficulty in respect to the setting up of the drill or its use in surgery and it would appear this issue has not impacted on the outcome of this case.

183. The SPH Medical Company Representatives Assisting with Procedures Policy states: *"Wherever possible Healthscope staff must be knowledgeable and competent at assisting with procedures and in the use of the associated equipment. However if new technology is being utilized, suitably qualified and experienced Medical Company Representatives may need to assist with equipment preparation"*.

184. In this case the sales representative was not present in the theatre and it is possible the scrub nurse and certainly the surgeon had no training on the new drill they were trialling. Whilst this does not appear to have had impact on the outcome concerning Mr Smith, it suggests the SPH procedure concerning the trialling of medical equipment should be looked at.

Cross Match of Blood

185. The delay in ordering the urgent cross match had no impact on the resuscitation of Mr Smith because on this occasion there was enough reserve blood stocks in the hospital. In any event, the hospital has undertaken a review of its Emergency Blood Collection for Cross Match procedure. It has also developed a flow chart called 'Procedure for emergency cross match and supply of blood and blood products' for display in prominent places in the hospital.

186. The new procedure is to ensure a timely response is provided by the pathology companies and puts in place an emergency plan to obtain blood from the QEII hospital should it be necessary.

Investigation of the Unexpected Death

187. Section 144 of the *Private Health Facilities Act 1999* requires licensees of private health facilities to submit Sentinel Event Reports to the Chief Health Officer.

188. On 12 June 2009 a Sentinel Event Notification Form ('the Form') was forwarded to the Queensland Health, Private Health Unit from SPH. The summary states *"Male Patient 34 years of age, DOB 17/12/1974. History of fracture to right clavicle requiring open reduction, internal fixation and possible bone grafting. Operation commenced 1605hrs. At 1715hrs during the course of the surgery apparent damage to the Subclavian Vein occurred. Hypovolemia occurred, replacement blood and plasma expanders initiated. Vascular Surgeon called in and attended. Patient continued to have reduced cardiac function and all cardiopulmonary resuscitation measures undertaken. Patient pronounced "life extinct" at 1955 hours"*.

189. On the bottom of the Form, it is noted the death will be reviewed in line with HQCC approved methodology. The HQCC methodology is a reference to the Health Quality and Complaints Commission 'Review of hospital-related deaths standard'. The purpose of the standard is that all hospital-related deaths are reviewed to identify quality improvement opportunities, and recommendations from reviews, are implemented. The current standard was introduced on 1 July 2010. At the time of Mr Smith's death, the standard set out three categories of review:

    - Category 1: required an investigation by the medical officer who wrote the Cause of Death certificate and the immediate clinical team within one week of the incident occurring;

    - Category 2: required an investigation by Independent Peer Group (Mortality Review Committee/may include RCA) within six weeks; and

    - Category 3: required investigation by external review group (e.g. HQCC, the Coroner) with commencement of the investigation within three months.

190. A number of criteria are listed in the HQCC standard for escalating an investigation from a Category 1 to a Category 2 investigation. The triggers are only a guide with a health service provider determining their own processes and criteria on the basis they meet or exceed the requirements of the standard.

191. On 18 June 2009, a Comprehensive Incident Report was completed by SPH. The death of Mr Smith was investigated by GM Sue Thurbon and Procedural Manager Hazel Douglas.

192. On 12 July 2009, a Mortality Review was undertaken by A.Pointing. In the brief clinical summary it says "*the subclavian injury resulted in intrathoracic haemorrhage. Subsequent cardiac arrest*."

193. SPH have advised that in accordance with the Healthscope policies and procedures, the death and known circumstances at the time were reviewed by Healthscope. The only systemic issues identified referrable to the hospital was related to obtaining urgent blood products for theatre which resulted in all relevant policies and procedures across Healthscope nationally being updated.

194. SPH has confirmed the policies and procedures regarding reviews of hospital related deaths in accordance with the HQCC standard were in development stages at the SPH at the time of Mr Smith's death. Prior to this time, it says it relied on the HQCC standard. The relevant polices and procedures were updated with the release of category one and two review forms in October 2009.

195. It is accepted that SPH has complied with its legislative and internal policy responsibilities in conducting its internal review. It did not need to, but could have, conducted a Root Cause Analysis. By way of general comment and not specifically directed at SPH, it is the view of the Office of the State Coroner that a thorough review by a health care agency at the time of the death of a patient may avert the need for a coronial inquest or may limit the issues that need to be explored at an inquest.

CONCLUSIONS

196. Mr Smith died as a result of complications from the surgical repair of his collarbone. At that time the orthopaedic surgeon, Dr Nutting, was using a clavicle locking plate and a drill he was not familiar with. The investigation and the evidence gathered during the inquest leads to the conclusion there are no concerns regarding the equipment used and this is unlikely to have had any impact on the outcome.

197. Dr Nutting was using a standard technique and there is no criticism of his approach to the operation. However when drilling the last hole for the clavicle locking plate he perforated the top of the subclavian vein with the drill bit. I have noted there are a number of possible reasons why that occurred including the trajectory of the drill bit, the depth it advanced, and the placement of the Bristow elevator. In fact it may be a combination of those factors. All of those factors were in the control of the surgeon.

198. There was extensive haemorrhage and blood loss which Dr Nutting was able to eventually control. The surgical team received assistance from a number of other medical personnel and aggressively did all it could to keep Mr Smith alive. However Mr Smith unexpectedly did not respond and it was not until sometime into the resuscitation that an air embolism was diagnosed.

199. There is evidence to support a finding an air embolism resulting from a perforated subclavian vein is rare. All the evidence would suggest due to the attention of the surgical team in focusing on the obvious and life-threatening haemorrhage they would not have expected this rare complication. Given however the high mortality rate in the event of an air embolism the evidence supports a finding that the late diagnosis of this life threatening condition would not have changed the adverse outcome for Mr Smith.

200. Of course, the air embolism would not have occurred if the subclavian vein had not been perforated.

201. I have considered whether this is an appropriate case to exercise my discretion in referring information about the professional conduct of the surgeon to the Medical Board of Australia. That body would investigate whether the professional conduct of a medical practitioner may be of a lesser standard than expected by the public or the practitioner's professional peers or that the professional's knowledge, skill

or judgement in the practice of their profession is or maybe below the standard reasonably expected.

202. Given the evidence I have determined this is not a case that supports exercising such discretion.

203. There are however a number of lessons that could be learnt and I agree these findings together with any other relevant information should be forwarded to relevant professional organisations so that deaths may be avoided in similar circumstances.

204. I accept that making this determination may not provide any solace to the family of Mr Smith.

Findings required by s45

205. I am required to find, as far as is possible, the medical cause of death, who the deceased person was and when, where and how that person came by his/her death. As a result of considering all of the material contained in the exhibits and the evidence from the inquest, I make the following findings:

Identity of the deceased-	Darryl Robert Smith
How he died--	Darryl Robert Smith died as a result of complications of surgery for the repair of a fractured clavicle which occurred as a result of a fall at work. During surgery his right subclavian vein was punctured. This resulted in severe blood loss and then entry of air into the vein resulting in an air embolism. Mr Smith could not be revived.
Place of death-	Sunnybank Private Hospital Sunnybank Qld 4109
Date of death-	11 June 2009
Cause of death-	1 (a) Air embolism and severe haemorrhage, due to or as a consequence of; 1(b) Perforation of the right subclavian vein during surgery for the repair of a fractured right clavicle, due to or as a consequence of; 1(c) Fall

Concerns, comments and recommendations

206. Section 46, insofar as it is relevant to this matter, provides that a coroner may comment on anything connected with a death that relates to public health or safety, the administration of justice or ways to prevent deaths from happening in similar circumstances in the future.

207. After having considered the evidence, in particular of Dr Duke and Dr Jenkins, I consider this is an appropriate case to refer to the Royal College of Surgeons, the Royal College of Anaesthetists of Australia and New Zealand and to the Shoulder and Elbow Society of Australia, as a case study for discussion and learning amongst its members.

208. I also intend to request Synthes Australia and Smith & Nephew Surgical to consider referring the case to their research and development departments in to assist them in informing future design choices for drill bits and particularly in relation to the commercial and technical feasibility for the design of drills stops for orthopaedic surgery.

The Court expresses its condolence to the family of Darryl Smith for their loss. I close the inquest.

John Lock
Brisbane Coroner
BRISBANE
4 November 2011