CORONERS COURT

NEW SOUTH WALES

Inquest:	**Inquest into the death of Sheila Drysdale**
Hearing dates:	14-16 June 2016
Date of findings:	15 July 2016
Place of findings:	State Coroner's Court, Glebe
Findings of:	Deputy State Coroner HCB Dillon
Catchwords:	**CORONERS – Cause and manner of death –** Surgical case – "Experimental" therapy for dementia -- Whether appropriate to perform unproven stem-cell procedure – Whether informed consent given – Whether patient properly prepared for procedure – Surgical mishap in procedure – Flaws in post-operative management of patient
File number:	2013/383970

Representation:	Mr A Casselden (Counsel Assisting) instructed by Mr J Herrington, Crown Solicitor's Office Mr M Lynch instructed by Ms Louise Watson, Dibbs Barker (for Dr Bright) Mr Shume instructed by EB Elliott, K&L Gates (for Seaside Aged Care) Mr G Shelton, solicitor, G Shelton & Assoc (for Ms Pelin Bright)
Findings:	I find that Sheila Drysdale died at the Seaside Nursing Home, Garden St, Warriewood, New South Wales on 20 December 2013 due to hypovolaemic shock she suffered following uncontrolled blood loss caused by a mini-liposuction stem cell procedure performed upon her at the Macquarie Stem Cells clinic in Liverpool, New South Wales at a time when her anti-coagulant medication had not been ceased.

Recommendations:	I make the following recommendations: ***To the Health Care Complaints Commission --*** I recommend that the Health Care Complaints Commission investigates the conduct of Dr Bright in relation to this case. ***To the Commonwealth Minister for Health and the NSW Minister for Health --*** I recommend that the Therapeutic Goods Administration (Commonwealth) and the NSW Ministry of Health consider how best to manage and regulate the provision of "experimental" or "innovative" medical or surgical procedures that have not yet been approved following clinical trials or other recognised peer-reviewed evaluation processes. Among the issues to considered, I recommend that the questions of potential conflict of interest and informed consent be given high priority. I recommend that National Health and Medical Research Council and NSW Clinical Excellence Commission consider formulating guidelines and protocols to ensure that "experimental" or "innovative" medical procedures conform with scientifically respectable clinical practice. ***To the Cosmetic Physicians College of Australasia --*** I recommend that College consider formulating guidelines and protocols to ensure that "experimental" or "innovative" medical procedures performed by cosmetic physicians in Australia conform with scientifically respectable clinical practice. Among the issues to considered, I recommend that the questions of potential conflict of interest and informed consent be given high priority.

Recommendations:	***To Macquarie Stem Cells --*** I recommend that Macquarie Stem Cells develops and introduces a pre-operative preparation checklist that is given to patients, their carers and the relevant health professionals at some appropriate time before it carries out any procedures. I further recommend that Macquarie Stem Cells develops and implements another checklist for internal use to ensure that all appropriate preparations have been made before it commences any invasive procedure. That checklist should include a check that blood-thinning medications have been stopped a minimum of 7-10 days before the procedure is conducted. I also recommend that Macquarie Stem Cells undertake no invasive procedures in respect of any patient unless it is satisfied that the pre-operative preparations have been carried out. Finally, I recommend that Macquarie Stem Cells amends its patient consent form to ensure that it outlines in detail for the patient (or his/her carer) the procedure together with the alternatives to the procedure, and the risks and benefits of the procedure. ***To Leading Age Services Australia and the Royal Australian College of Physicians*** I recommend that Leading Age Services Australia and the Royal Australian College of Physicians consider working together and with providers in the nursing home segment of the industry towards the development and implementation of an appropriate patient observation chart of the type used by NSW Health under its *Between the Flags* protocols.

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Introduction

1. Mrs Sheila Drysdale was a 75 year-old woman suffering severe dementia. She died due to blood loss following an "experimental" liposuction stem cell procedure which, it was claimed, might improve her quality of life by reducing her symptoms. The procedure was performed by a cosmetic physician at a private facility. She was discharged and but died shortly after arriving home.

2. The case raises a number of critical issues relating to the lack of science supporting the procedure, whether informed consent was given, the cause of death and the post-operative management of the patient. It raises questions about the ethics of the medical practice and the physician that performed this procedure. On a broader scale, this tragic death also highlights the vulnerability of elderly sick people and their families, desperate for help, to "quack" medicine.

The coroner's role

3. A coroner's primary duty and function is to examine unexpected and unnatural deaths. The Coroners Act requires coroners to make findings, if possible, as to the identity of the person who has died, the date and place of death, the cause of death and the manner or circumstances of the death. A coroner may also make recommendations with a view to preventing or reducing the risk of future deaths of a similar kind.

4. The reasons for conducting coronial inquests are not merely legal. The law reflects a much more profound social purpose. In our society, one of the ways we show respect for those who die unnaturally, and for their families and loved ones, and for human life more generally, is by investigating the circumstances of those deaths. "No man is island", as the English poet John Donne once wrote. We are members of society, connected with each other.

5. It should also go without saying – but is worth emphasising yet again -- that the most vulnerable people in our society must be protected and, if one of them dies unnaturally, that that death be thoroughly investigated.

6. If lives are precious, the very least we can do to show respect for those who have died, and those who mourn them, is to learn the harsh lessons such deaths may be able to teach us.

Sheila Drysdale

7. Sheila Drysdale was the wife of Kenneth Drysdale and mother of three children, her daughters Fiona and Anita and her son David. She and Ken had met 50 years before her death and had been married for about 48 years. It was very evident at the inquest that she was much loved and that her deterioration, late in her life, due to Frontal Lobe Dementia had been extremely distressing for her family and friends who admired her so much.

8. Sheila[1] was kind and caring and intelligent. But in about 2009 her health became concerning. She was diagnosed with early dementia. One of the most distressing features of her condition for her family and for Sheila herself was that it altered her personality. At times she would be become aggressive. She also suffered a number of physical ailments that eventually became too much for her family to manage by themselves. She was admitted permanently to the Seaside Nursing Home in 2011. Between 2011 and 2013 her mental and physical conditions continued to deteriorate significantly. By 2013, her condition was severe. Two of the most distressing aspects of this disease are that it inflicts so much indignity on the sufferer and that their families and carers are so helpless in the face of it. For all that, Sheila remains for them the vibrant, warm, loving woman who was so central to the life of the Drysdale family.

The issues

9. Under the Coroners Act, I am obliged to make findings of fact, if possible, as to the identity of the deceased person, the date and place of her death, the immediate physical cause of death and manner of death. In this case, it is the manner of death that is most complex and controversial. To determine "manner of death" for the purposes of the Act it is necessary to inquire into the surrounding circumstances and ask how Sheila's death came about.

10. That in turn raises further questions:

- What was the procedure that resulted in her death?
- Was it reasonable or appropriate to conduct that procedure?
- Was informed consent given for it to be performed?
- Was Sheila Drysdale properly prepared for the procedure?
- What went wrong during the procedure?
- How was she managed post-operatively?
- What went wrong?
- What lessons might be learned from Sheila's death?
- Are there recommendations that are necessary or desirable to make?

[1] I will refer to Mrs Drysdale as "Sheila" throughout this document as this is how she was referred to during the hearing.

The procedure

11. There is at present no scientifically proven cure for Alzheimer's Disease or other forms of dementia. Mr Drysdale was desperate to help Sheila and do anything he could in a practical way to reduce her suffering. He had conducted internet research into stem cell research and found an American clinic called Stem Cell America. He got in touch with SCA who referred him to articles on the internet that suggested that dementia could be treated with stem cell therapy.[2]

12. In March 2013, Mr Drysdale heard a radio advertisement for Macquarie Stem Cells. It stated that stem cell therapy could assist arthritic patients. He suffered from arthritis himself. He consulted Dr Ralph Bright, the principal of Macquarie Stem Cells, and in August 2013 was treated for arthritis. Mr Drysdale thought he had received some benefit from the treatment.

13. Satisfied with the result in his own case, Mr Drysdale then consulted Dr Bright about the possibility of treating Sheila Drysdale. One 20 December 2013, Mr Drysdale and his daughter Fiona drove Sheila to the Macquarie Stem Cells clinic in Liverpool for the operation. They arrived shortly before 9.00am and the procedure was over by late morning.

14. In summary, after the application of local anaesthetic, an incision is made and liposuction is used to extract about 500 ml of fat from the flanks and buttocks of the patient. The fat is processed, stem cells are extracted then re-infused into the patient's body via an intravenous drip.

15. Following Mrs Drysdale's death, Dr Bright gave a statement to police in which he described the basis of the therapy in broad terms as follows:

> *Stromal cells[3] are a mixture of cells, 2/3 are stem cells, the remainder are immune modulating cells such as T-reg lymphocytes. These cells have been used extensively in the treatment of dogs and horses since 2006 to treat various musculo-skeletal disorders. Use in humans started in 2009 initially to treat osteoarthritis, rheumatoid arthritis and tendon injuries. It was noted that co-morbidities were seen to improve at the same time as osteoarthritis and it soon became obvious that cells leave the joint and travel all over the body to improve disease in distant sites*

[2] As at 11 July 2016, SCA's website has letters posted that imply that their stem cell treatment has cured or reversed Alzheimer's Disease in two patients. It has also posted letters from patients that imply their treatments have cured or reversed the effects of strokes, anoxic brain injury, autism, brain damage, cerebral palsy, epilepsy, and many other conditions. See http://stemcellofamerica.com/patient-reviews/ Curiously, however, the website also posts references to *real* scientific research including a paper on experiments in mice in relation to the possible use of stem cells in treating dementia. That paper warns: "***Many important questions remain before we could envision moving forward with early-stage trials [with humans***]" http://stemcellofamerica.com/stem-cell-treatment-may-reduce-impairment-caused-by-dementia/

[3]

including lungs and brain, vision, mentation, and pain. It was also noted that energy and stamina improve.

16. Dr Bright referred in general terms to observations of co-morbidities being improved and it becoming obvious that stem cells moved from joints to other parts of the bodies where they repaired tissue but did not provide scientific papers or references to studies or even anecdotal evidence (beyond his own statement) to investigators.

17. Stromal cells are connective tissue cells found in all organs. Some stromal cells can develop into into distinct mesenchymal tissue such as bone, tendons, muscles, adipose tissue, cartilage, nerve tissue, and blood and blood vessels. They are generally derived from bone marrow but are found in most tissues and organs.

18. The Macquarie Stem Cells consent form signed on behalf of Sheila by Mr Drysdale states, among other things:

> *The possible complications associated with moving cells from one part of your body to another are not fully known due to the extent that the procedure involves the reinjection of this particular form of highly process lipoaspirate, the procedure may be classified as innovative or experimental. The experimental component of the procedure has only recently been performed in humans. The first case in Australia was on 17th April 2009. From what we have seen in dogs and from what we have read in our literature searches the procedure would appear to be safe. Our safety survey spans 3 years and has not uncovered any problems. The procedure may provide health benefits.*

What preparation was undertaken for the operation?

19. In preparation for the procedure, Sheila's General Practitioner, Dr Norrie, completed a Macquarie Stem Cells patient medical history form on 21 November 2013. He noted that Sheila suffered from frontal lobe dementia and atrial flutter. It was noted on the form by Dr Norrie that Sheila took aspirin as a blood thinner. Mr Drysdale, who had power of attorney for Sheila, signed a consent form for the procedure on 9 December 2013, as well as another one on the day of the procedure. A copy of Sheila's list of medications was faxed to Dr Bright on 16 December 2013 by the nursing home. Sheila's listed medications included aspirin 100mg in the morning and krill oil. She was also using coconut oil as a supplement. Aspirin has the effect of thinning the blood as does krill oil[4] and possibly coconut oil. She was also on Cymbalta, an anti-depressant with a minor blood-thinning effect. She was also on a Beta blocker which reduces the effect of adrenaline and lowers both blood pressure and pulse rate.

20. Dr Bright has stated that at around this time, four days prior to the procedure, he had a conversation with Mr Drysdale and told him the Sheila should stop taking the aspirin.

[4] Note that the website Drugs.com advises that krill oil should be ceased two weeks before surgery due to its anti-coagulant properties: see https://www.drugs.com/krill-oil.html accessed 14 July 2016.

Mr Drysdale does not recall this conversation. The aspirin and krill oil were not stopped. Expert evidence was given that, in any event, aspirin and other anti-coagulants should be stopped at least 7-10 days before a surgical procedure.

What happened at Macquarie Stem Cells?

21. At 7am on 20 December 2013, Mr. Drysdale and his daughter Fiona picked up Mrs Drysdale from the Seaside Nursing Home and drove to Macquarie Stem Cells in Liverpool, arriving at about 8.45am.

22. On admission to the clinic, Sheila's blood pressure was taken and recorded as 155/85. Her heart rate was 51 bpm. A "Day Procedure Nursing Admission Form" was completed recording that Sheila had last taken her regular medications that morning. Those medications are not specified on the form. Nursing home records show that all of Sheila's regular medications had been administered to her as prescribed at the nursing home that morning, including aspirin, Cymbalta and Sotalol. None had been ceased and all had been given to her on each day in the lead up to her procedure. Krill oil and coconut oil remained on her medications list.

23. Dr Bright did not inquire that morning whether Sheila's aspirin had been stopped. This was a very important oversight. This meant that the possibility of a fatal bleed occurring was significantly increased.

24. Before the operation, between 9.00 and 9.15am Sheila was given Pethidine, Maxalon, and Ativan (a benzodiazepine), among other medications. A test dose of Keflin, an antibiotic, was also given, followed 37 minutes later by further Keflin.

25. At about 9.40am Dr Bright made a 3 mm incision and 2 L of dilute tumescent local anaesthetic was infiltrated under the skin of Sheila's flanks and outer thigh. Dr Bright states he removed 500 ml of fat from under her skin in a mini-liposuction procedure. Dr Bright stated that the procedure went smoothly and without event. Dr Bright's notes record that Sheila slept through the procedure and that there was minimal blood loss. Mr. Drysdale was present during the procedure and held Sheila's hand.

26. Intra-operative vital signs were recorded at 9:30 and 10:10am. At 9:30 Sheila's heart rate was 64 beats per minute. Her blood pressure was 158/90. At 10:10am her blood pressure was not recorded and her heart rate was 63 beats per minute.

27. The liposuction concluded at about 10.10am and Sheila was taken to recovery. During this time Dr Bright's wife, Pelin Bright, processed Sheila's extracted fat in the clinic's laboratory and returned the product of that process to Dr Bright, who administered it intravenously to Sheila. A report written by Ms Bright states that 1.5 billion stem cells had been administered to Sheila.

28. Sheila was slow to wake up from the procedure. She was noted to have poor postural control of blood pressure and to have fainted on standing. She was pale and sweaty. Dr Bright administered one litre of Hartman's solution and fitted Sheila with compression

stockings. At 3:05pm, Dr Bright further administered Anexate 500mg, a medication used to counteract the effect of benzodiazepines, after which Sheila became more alert. During this period, Sheila's vital signs were recorded at 12:50 as being blood pressure 162/84 and heart rate as low as 42 beats per minute. At 2:30pm her blood pressure was 126 over 78 and heart rate 52. At 3:40pm her blood pressure was 116/71 and her heart rate was 69.

29. Sometime between 5 and 5.30pm, Sheila was discharged from the clinic and taken in a wheelchair to Mr. Drysdale's car. It does not appear that vital sign observations were recorded upon her discharge. Dr Bright noticed that Sheila was sleepy again.

What happened after the procedure?

30. Sometime between 5 and 5.30pm, Sheila was discharged from the clinic and taken in a wheelchair to Mr. Drysdale's car. It does not appear that vital sign observations were recorded upon her discharge. Dr Bright noticed that Sheila was sleepy again.

31. Mr. Drysdale drove his wife back to the nursing home. En route, Mr. Drysdale phoned the nursing home and stated to Registered Nurse Zwatongwa that he was on his way back with Sheila, but that he felt he should take his wife to the hospital. He then apparently stated "Maybe I will just follow what the doctor said and bring here there." RN Zvatongwa suggested that he bring her to the home first so that they could assess her there before deciding whether she needed to go to hospital.

32. Dr Bright also phoned the nursing home around 5:30pm. A note of that conversation made by RN Zwatongwa states that Dr Bright informed the nurse that fat cells had been collected from Sheila's upper buttocks. He informed the nurse that the risk on Sheila's return was of fainting and that her blood pressure was low. He said Sheila should go straight to bed and that she had dressings on her back and thighs.

33. Mr. Drysdale and his wife returned to the nursing home at approximately 6:30pm. RN Zvatongwa checked the pads on her back at this stage. They were apparently wet with blood but not soaked through. At 6.45pm, Sheila's blood pressure was recorded as 96/59 and her heart rate was 86 beats per minute.

34. Mr. Drysdale again stated that he thought Sheila should go to hospital. RN Zvatongwa telephoned Dr Bright and relayed this. Dr Bright indicated that he did not think it was necessary for Sheila to go to hospital at that stage as her blood pressure had improved. He suggested that she should be closely monitored.

35. At about 7.15pm, RN Zvatongwa again took Sheila's observations. Her blood pressure was then 106/60 and her heart rate had risen to 90. She again telephoned Dr Bright, who indicated that Sheila's observations were satisfactory and that he did not consider that she needed to be transferred to hospital.

36. At 7.30pm, RN Zvatongwa tested Sheila's blood sugar levels. Her reading was 7.4, which is apparently acceptable. No recording was made of her blood pressure or her heart rate at this time. Mr. Drysdale left the nursing home at around this time.

37. 15 minutes later, at 7.45pm, RN Zvatongwa again checked on Sheila. She was unconscious and did not have a pulse. RN Zvatongwa telephoned her manager and informed them that Sheila had died. It does not appear that any attempt to resuscitate her was made.

Was it reasonable or appropriate to conduct that procedure?

38. The reasonableness or appropriateness of applying this experimental procedure to Sheila Drysdale is highly questionable. On the evidence available to me, it seems highly unlikely to have been significantly beneficial to Sheila even if she had lived. The operation is unproven scientifically. It has not been the subject of rigorous clinical trials in humans. It was described even by Macquarie Stem Cells's own literature as "experimental" but the procedure was not conducted in accordance with protocols for the conduct of clinical trials or scientific experiments.

39. No explanation is given in the materials supplied to the patient or to this court as to how the stem-cell therapy may work to improve serious brain lesions such as the Frontal Lobe Dementia from which Sheila Drysdale suffered. As far as it is possible to tell, Dr Bright appears to have no idea whether the procedure has any genuine therapeutic value for the treatment of brain lesions. He is not a specialist in neurology or neuropathology or geriatric medicine. No scientific literature has been presented to the court by Dr Bright justifying his use of the procedure upon Sheila Drysdale. Nor have independent specialists from whom this court has received reports provided any such material.

40. While all medical and surgical procedures necessarily start off experimentally, there is a world of difference between rigorously and ethically conducted clinical trials that are reviewed at every stage by qualified peers and this procedure which, in relation to treatment of dementia at least, has some of the troubling hallmarks of "quack" medicine: desperate patients, pseudo-science and large amounts of money being charged for unproven therapies.

41. (In fairness, in this case, Dr Bright did not charge a fee but, because Mr Drysdale could not afford the procedure for his wife, initially agreed to accept a large number of shares in a project being developed by Mr Drysdale who is an inventor. The shares were, at the time, worthless but, if Mr Drysdale's invention succeeded, might have become valuable. After Sheila Drysdale's death, however, Dr Bright did not accept the shares.)

42. Dr John Obeid, an independent consultant geriatrician, offered an opinion that there is no objection to experimental procedures being conducted but that if they are, they should be conducted as proper clinical trials subject to relevant protocols.

43. The procedure that was performed on Sheila could in no way be classified as a clinical trial. On this ground, and others that I will come to shortly, I propose to refer the case to the Health Care Complaints Commission for further investigation. I also propose to make a recommendation that the NSW Ministry of Health and the Commonwealth Therapeutic Goods Administration consider investigating and regulating this procedure.

Was informed consent given?

44. Informed consent requires three criteria to be satisfied. First, the person must have the capacity to give consent, that is, the person must be able to understand the implications of having the treatment. Consent must be freely given. Finally, the consent must be specific, and is valid only in relation to the treatment or procedure for which the patient has been informed and has agreed to.

45. Due to her condition, Sheila Drysdale lacked capacity to consent to any medical procedure. Consent was therefore given by Mr Ken Drysdale on her behalf. He gave that consent freely and in relation to the specific procedure.

46. The difficulty here, however, is that the consent form did not, and indeed could not, adequately describe the risks that may flow from this procedure. It stated that the main surgical risks were infection and bruising and adverted to the possibility of allergic reaction to disinfectants or medications, persistent oedema, fainting, pigmentation change, sensory nerve damage, scars, ulceration or necrosis.

47. But it went on to say that "the possible complications associated with moving cells from one part of your body to another are not fully known" and that the procedure "may be classified as innovative or experimental". How, in the light of that warning with virtually no detail, anyone could make an informed decision is difficult to understand.

48. To further compound the problem of informed consent, or lack of it, there is no reference in the consent form at all to the possibility of severe haemorrhage due to the incision or insertion of a medical instrument into the body to extract fat cells.

49. Dr Obeid was severely critical of the consent process conducted by Macquarie Stem Cells. In his view, informed consent had not been obtained because the risks of the procedure had not been fully disclosed and there had been no discussion in the consent document of alternatives to the proposed treatment, the purported benefits. Apart from the risk of haemorrhage, other risks not mentioned in the document included the risk of delirium, a common risk for dementia sufferers, and, of course, death.

Was Sheila Drysdale properly prepared for the procedure?

50. The short answer to this crucial question is that Sheila Drysdale was not properly prepared for the procedure. Expert medical evidence was given that she ought to have been taken off blood-thinning medication 7-10 days before the procedure was conducted. Even Dr Bright gave evidence that he told Mr Drysdale to ensure that the

anti-coagulants were ceased at least four days before the operation, evidence of his recognition of the risk of uncontrolled haemorrhage.

51. The medical records, however, show that Sheila continued to receive her medications according to her chart up to the day of the procedure. It is also clear that her records travelled with her to the clinic and that, if he or his assistants had checked, Dr Bright would have seen that Sheila was still on anti-coagulants. There is no evidence that Dr Bright knew that she was on her medications but operated notwithstanding this. The most favourable, and most likely, explanation is that there was a failure to check that the blood-thinners had been stopped.

52. That failure placed Sheila Drysdale at risk of the very insult that she received during the procedure. Whether Dr Bright told Mr Drysdale to have Sheila taken off aspirin and other anti-coagulants is immaterial given that he or his assistants failed to ensure that she had been.

53. Dr Bright also failed to conduct, or have conducted, a full pre-operative medical assessment. Dr Obeid gave evidence that this is a fundamental and "mandatory" part of preparing a geriatric patient for a surgical procedure. Issues that should be checked and assessed by the medical practitioner about to perform a procedure include whether or not the diagnosis is correct; the risks to the patient; and likely benefits. Dr Obeid found no evidence that any of these questions had been considered by Dr Bright.

What went wrong during the procedure?

54. During the procedure and afterwards, Dr Bright noticed nothing out of the ordinary that might have alerted him to the fact that Sheila was in fact bleeding too much and needed to be treated for that haemorrhage.

55. The post mortem examination, however, revealed that Sheila had extensive bruising on her buttocks and subcutaneous haemorrhage. Blood-soaked absorbent sheets were present under her body and plasters, gauze and absorbent pads were blood-soaked. Her organs were pale and the heart was pale with subendocardial haemorrhages.

56. What could and should have alerted Dr Bright to the fact that Sheila was doing badly and needed immediate post-operative hospital care were the facts that during the procedure her blood pressure dropped and did not significantly rise afterwards and that she was still on anti-coagulents. He assumed that her low blood pressure was a normal reaction to the procedure and would gradually rise to normal levels. As we have noted, he probably had not noticed that she was on blood thinners.

Post-operative errors

57. Sheila Drysdale should have been taken to hospital following her procedure when it became clear, as it quickly did, that she was not recovering from the operation. Dr Obeid emphasised this point. Blood loss results in a rising pulse rate as the heart works harder to maintain sufficient blood pressure to infuse the organs of the body, especially the

brain, with blood and oxygen. Blood pressure will decrease as volume of blood is lost within the circulatory system. When about 20 per cent of blood volume is lost the patient will go into shock and is likely to die if not immediately resuscitated with fluids to increase volume and medications that keep the heart pumping to circulate blood. Dr Obeid gave evidence that it is the relative change in blood pressure and pulse rate that is the primary sign that indicates developing haemodynamic instability and the potential for hypovolaemic shock.

58. In Dr Obeid's view, the observations indicate that at 2.30pm Sheila was haemodynamically unstable – her blood pressure was down and her pulse rate was up. At 3.40pm, she was pale and sweaty and her pulse rate was high and blood pressure low. This was a definite indication of blood loss in his opinion. He said that at this point she need observations at least hourly and fluids. He said that consideration should have been given at this point at least to transferring Sheila to hospital. By 5.30pm, Dr Obeid said, it was "absolutely clear" that she needed to be in hospital. He said that "no reasonable medical approach would support sending her home."

59. A further factor complicating the clinical picture was that Sheila was on a Beta blocker medication that had not been ceased before the operation. Dr Obeid gave evidence that because these medications reduce pulse rate and blood pressure this may to some extent have masked what was going on. Even so in the last six hours at Macquarie Stem Cells her pulse rate rose from about 50 to about 90 beats per minute, a very large relative change in the circumstances.

60. Mr Drysdale was so concerned that he wanted to take Sheila to hospital because he felt that she was very unwell. RN Zvatongwa was also concerned about her and considered calling an ambulance to have Sheila taken to hospital. Both, however, relied on Dr Bright's indication that it was premature to take her to hospital and that she would probably recover with rest. Although he did not ignore them, Dr Bright gave insufficient weight to the concerns expressed by both Mr Drysdale and RN Zvatongwa.

61. Although RN Zvatongwa was concerned about the low blood pressure, her training was to the effect that if the BP fell below 100 systolic she should escalate the case and call an ambulance. Unfortunately, Sheila's BP rose temporarily from 96/59 to 106/60 in the two observations made by RN Zvatongwa. This suggested to RN Zvatongwa that Sheila was slowly recovering. Sheila's pulse rate, however, had also increased from 86 to 90. This was a relatively small and, indeed, ambiguous change but, in retrospect, probably indicated that the reason for the increase in BP was that the heart was working harder to circulate blood. We can see now that it was not the reassuring sign it appeared to be.

62. Three other subtle factors were also operating to mislead RN Zvatongwa as to how critical Sheila's situation was. First, and most importantly, she had been trained to regard a systolic blood pressure reading of 100 as the line below which a case should be escalated. But this is an arbitrary line that does not necessarily relate closely to the individual patient's normal baseline blood pressure.

63. Second, to escalate the case by sending Sheila to hospital would have required another nurse to be called to replace the nurse who accompanied Sheila to hospital. I do not in any way imply that RN Zvatongwa neglected Sheila but it is natural in such circumstances to "wait-and-see" for a period before taking steps that will cause administrative (and possibly personal) inconvenience to others.

64. Thirdly, of course, it is evident that the "doctor knows best" mindset was operative in this situation.

What went wrong – a cluster of errors

65. In summary, a number of things combined to result in Sheila Drysdale's death:

66. First, she was subjected to a procedure that, given the unproven nature and efficacy of the procedure, and the severity of her dementia, was unlikely to be beneficial to any significant degree.

67. Second, the consent form and process was inadequate to provide Mr Drysdale with sufficient information to give fully informed consent to the procedure on behalf of his wife.

68. Third, the preparation for the procedure failed in fundamental respects.

69. Fourth, there was no consultation between Dr Norrie, Sheila's treating GP, and Dr Bright about the patient or the procedure.

70. Fifth, a basic error was made by Macquarie Stem Cells in failing to check Sheila's medication chart.

71. Sixth, Sheila's slow recovery and low blood pressure were not recognised by Dr Bright as signs of significant blood loss and risk of hypovolaemic shock.

72. Seventh, she was prematurely discharged to the nursing home, rather than being taken to a hospital for emergency treatment.

73. Eighth, Dr Bright failed to give sufficient and proper weight to the concerns and personal knowledge of Mr Drysdale;

74. Ninth, both Mr Drysdale and RN Zvatongwa relied on and deferred to erroneous advice given to them by Dr Bright;

75. Tenth, probably due principally to that reliance, but also other factors outlined above, the signs of serious deterioration were not recognised in time at the nursing home.

What lessons might be learned from Sheila Drysdale's death?

76. The preventable and unnecessary death of Sheila Drysdale, in my view, imparts or reinforces a number of severe lessons upon us. They include the following:

- That legal protection against the exploitation of severely and chronically ill people by purveyors of scientifically dubious "therapies" is needed;

- That there is potential for a conflict of interest where a medical practitioner is offering "experimental" or "innovative" procedures to severely and chronically ill people;

- That "experimental" or "innovative" medical procedures ought therefore only be conducted according to strict, reviewable, scientifically recognised clinical protocols[5];

- That appropriate pre-operative preparation of patients for elective surgery is critical in minimising risk to patients;

- That before any surgery, however minor, is undertaken, a standard check should be conducted to ensure that the appropriate pre-operative preparation has been carried out and that, if it has not, the operation does not proceed until it has been;

- That surgeons and other health professionals should not assume that, following any surgical procedure, clinical signs of unwellness and deterioration in a patient they do not know well are "normal" reactions to treatment;

- That the people who know the patient best are in the best position to decide whether they are unwell and need help, not necessarily the doctor(s) and nurse(s) who treat or manage them;

- That if there is any real uncertainty as to whether a patient is deteriorating it is better to apply the precautionary principle than the "wait-and-see" principle.

What recommendations are necessary or desirable?

77. A number of recommendations therefore suggest themselves in this case:

78. First, I propose to recommend that the Health Care Complaints Commission assesses and investigates the conduct of Dr Bright in relation to this case.

79. Second, I propose to recommend to the NSW Ministry of Health and the Therapeutic Goods Administration (Commonwealth) that they consider how best to manage and regulate the provision of "experimental" or "innovative" medical or surgical procedures that have not yet been approved following clinical trials or other recognised peer-reviewed evaluation processes. While the TGA's Special Access Scheme is focussed primarily on new medications rather than experimental procedures, it may provide a framework for the management of procedures such as those performed by Macquarie

[5] See, for example, the Special Access Scheme operated by the Therapeutic Goods Administration https://www.tga.gov.au/form/special-access-scheme accessed 14 July 2016 and the TGA's guidelines for clinical trials https://www.tga.gov.au/clinical-trials accessed 14 July 2016.

Stem Cells. The National Health and Medical Research Council and NSW Clinical Excellence Commission may also have a useful role in developing guidelines to ensure that "experimental" or "innovative" medical or surgical procedures conform with scientifically respectable clinical practice.

80. Third, I propose to recommend to those authorities that in any regime that is developed that appropriate guidelines and protocols be developed to ensure that "experimental" or "innovative" procedures conform with scientifically respectable clinical practice.

81. Fourth, I propose to recommend that the problem of potential conflicts of interest in the provision of "experimental" or "innovative" medical or surgical procedures be considered by the relevant authorities.

82. Fifth, I also propose to recommend that the issue of informed consent in relation to "experimental" surgical procedures or therapies be closely considered by the relevant authorities and that guidelines as to the proper content and warnings be issued by the Cosmetic Physicians College of Australasia.

83. Sixth, I will recommend that Macquarie Stem Cells develops and introduces a pre-operative preparation checklist that is given to patients, their carers and the relevant health professionals at some appropriate time before it carries out any procedures. I will further recommend that Macquarie Stem Cells develops and implements another checklist for internal use to ensure that all appropriate preparations have been made before it commences any invasive procedure. That checklist should include a check that blood-thinning medications have been stopped a minimum of 7-10 days before the procedure is conducted. Further, I will recommend to Macquarie Stem Cells that no invasive procedures be undertaken in respect of any patient unless it is satisfied that the pre-operative preparations have been carried out. Finally, I will recommend that Macquarie Stem Cells amends its consent form to clearly indicate to patients and their carers in sufficient detail to enable informed consent to be given or refused the alternatives to its treatments, and the risks and benefits of its procedures.

84. Seventh, I will recommend to peak bodies representing nursing homes and the Royal Australian College of Physicians that they consult together to develop and implement an appropriate patient observation chart of the type used by NSW Health under its "Between the Flags" protocols. It is critical to note, however, that a "one-size fits all" approach is not suitable for nursing homes. Patients' normal baselines must first be established so that significant *relative* changes can be observed on an observation chart.

85. I note that Dr Obeid was firmly of the opinion that such protocols would be very useful as was Ms Narelle Bath the facility manager at the Seaside Nursing Home. I agree with his opinion that such protocols should be developed by joint consultation between peak bodies of the nursing home industry and the Royal Australian College of Physicians to which specialist geriatricians belong. I also note that the Opal group that runs Seaside and other nursing homes has developed and implemented its own version of the "Between the Flags" patient observation chart.

Conclusions

86. I cannot say what motivated Dr Bright to perform this unproven, dubious procedure on Sheila Drysdale. For all I know he may have been moved by pity for her. Although he was willing to accept a large bundle of shares of unknown future value, he made no profit from the procedure because he did not accept them. And certainly, Mr Ken Drysdale bears him no ill-will. This does Mr Drysdale great credit.

87. But regardless of his motivation, Dr Bright's performance as a medical practitioner was, for the reasons outlined above, poor and resulted in Sheila Drysdale's death.

88. On a broader scale, it is disturbing that he (and presumably others) would market this "experimental" or "innovative" therapy for profit to vulnerable and desperate people in the full knowledge both that there is little scientific support for the "therapy" in relation to dementia and that he is not conducting a clinical trial of any scientific standing or worth. The obvious potential for the providers of such purported remedies and therapies to exploit such consumers is great and therefore troubling. So too is the potential conflict of interest between the principle of harm minimisation and commercial medicine.

89. So too are many other aspects of this case as has been discussed above, the question of informed consent in such a context being particularly complex, ambiguous and disconcerting.

90. Mr Drysdale's motivation in approaching Dr Bright is, however, much clearer. He loved Sheila and sought to mitigate her suffering and, if possible, to restore her fine mind and kindly nature. Although I suspect he may have pangs of guilt for arranging the procedure and perhaps for not following his instinct to take her to hospital rather than driving Sheila back to the nursing home, I hope that he will not feel he should bear that burden. He did nothing wrong. He sought help for his wife when conventional medical advice was that her condition was dire and would only get worse. He relied on Dr Bright's expertise before, during and after the operation. He bears no responsibility for the sad outcome. Although it is not the way he would have liked Sheila to pass away, she seems to have done so peacefully and she did so in the company of those she loved and who loved her.

91. The coronial team and I hope that the family's many happy memories of Sheila in her prime will outweigh the sorrow and distress that her death, and the manner of it, has caused them. And we hope that they will accept our very sincere condolences.

Findings s 81 Coroners Act 2009

92. I find that Sheila Drysdale died at the Seaside Nursing Home, Garden St, Warriewood, New South Wales on 20 December 2013 due to hypovolaemic shock she suffered following uncontrolled blood loss caused by a mini-liposuction stem cell procedure performed upon her at the Macquarie Stem Cells clinic in Liverpool, New South Wales at a time when her anti-coagulant medication had not been ceased.

Recommendations s 82 Coroners Act 2009

93. I make the following recommendations:

To the Health Care Complaints Commission --

- I recommend that the Health Care Complaints Commission investigates the conduct of Dr Bright in relation to this case.

To the Commonwealth Minister for Health and the NSW Minister for Health --

- I recommend that the Therapeutic Goods Administration (Commonwealth) and the NSW Ministry of Health consider how best to manage and regulate the provision of "experimental" or "innovative" medical or surgical procedures that have not yet been approved following clinical trials or other recognised peer-reviewed evaluation processes.
- Among the issues to considered, I recommend that the questions of potential conflict of interest and informed consent be given high priority.
- I recommend that National Health and Medical Research Council and NSW Clinical Excellence Commission consider formulating guidelines and protocols to ensure that "experimental" or "innovative" medical procedures conform with scientifically respectable clinical practice.

To the Cosmetic Physicians College of Australasia --

- I recommend that the College consider formulating guidelines and protocols to ensure that "experimental" or "innovative" medical procedures performed by cosmetic physicians in Australia conform with scientifically respectable clinical practice.
- Among the issues to considered, I recommend that the questions of potential conflict of interest and informed consent be given high priority.

To Macquarie Stem Cells --

- I recommend that Macquarie Stem Cells develops and introduces a pre-operative preparation checklist that is given to patients, their carers and the relevant health professionals at some appropriate time before it carries out any procedures.
- I further recommend that Macquarie Stem Cells develops and implements another checklist for internal use to ensure that all appropriate preparations have been made before it commences any invasive procedure. That checklist should include a check that blood-thinning medications have been stopped a minimum of 7-10 days before the procedure is conducted.

- I also recommend that Macquarie Stem Cells undertake no invasive procedures in respect of any patient unless it is satisfied that the pre-operative preparations have been carried out.
- Finally, I recommend that Macquarie Stem Cells amends its patient consent form to ensure that it outlines in detail for the patient (or his/her carer) the procedure together with the alternatives to the procedure, and the risks and benefits of the procedure.

To Leading Age Services Australia and the Royal Australian College of Physicians

- I recommend that Leading Age Services Australia and the Royal Australian College of Physicians consider working together and with providers in the nursing home segment of the industry towards the development and implementation of an appropriate patient observation chart of the type used by NSW Health under its *Between the Flags* protocols.

Magistrate Hugh Dillon
Deputy State Coroner for New South Wales