Coroners Act, 1996
[Section 26(1)]

Western  **Australia**

RECORD OF INVESTIGATION INTO DEATH

Ref No:20/12

I, Dominic Hugh Mulligan, Coroner, having investigated the death of ***Carol Freda WHITEFORD****, with an Inquest held at Northam Coroner's Court on* ***9*** *and* ***10 July 2013,*** *find that the identity of the deceased person was* ***Carol Freda WHITEFORD*** *and that death occurred on* ***6 March 2008,*** *at* ***Northam Regional Hospital****, the cause of death being consistent with* ***Anaphylaxis in a Woman with Atherosclerotic Cardiovascular Disease and Emphysema,*** *in the following circumstances:*

Counsel:
Sergeant Lyle Housiaux assisted the Coroner
Mr John Ley appeared for Dr Andrew Stewart
Mr Tim Russell appeared for Northam Hospital
Ms Belinda Burke appeared for Ms Rebecca Nind
Mr Hylton Quail, with Ms P Menon, appeared for Dr Mark Familton

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Introduction

1. Carol Freda Whiteford was a 68-year-old retired woman who lived with her husband at their home in Meckering.

2. Mrs Whiteford underwent eye surgery to remove cataracts and implant a new lens in her left eye at Northam Hospital on 6 March 2008.

3. Dr Andrew Stewart performed the surgery.

4. Dr Stewart began practising medicine in 1967 and ophthalmology in 1974. In 1975 Dr Stewart performed the first lens implantation following cataract surgery in Western Australia.

5. He was elected president of the Royal Australian and New Zealand College of Ophthalmologists in 2006.

6. For approximately 25 years Dr Stewart undertook consultations and surgery on a pro bono basis.

7. Dr Stewart has retired from performing surgery.

8. At the time of the operation Mrs Whiteford was in very poor health. She suffered from chronic obstructive pulmonary disease (emphysema) and undiagnosed, but severe heart disease.

9. Mrs Whiteford's prognosis was very poor. It was expected, on the basis of her diagnosed emphysema, she would not live for more than a year after the eye operation.

10. Mrs Whiteford had significant breathing difficulties and was rendered largely immobile and housebound because of her ill-health.

11. As a consequence of her ill-health, lack of mobility and very poor eyesight there was very little Mrs Whiteford could do to occupy her time. She normally enjoyed doing crafts and watching movies. The surgery was meant to restore her ability to enjoy those small pleasures.

12. Mrs Whiteford was known to be allergic to *Sulphas* (an abbreviation for a group of medications known as sulphonamides).

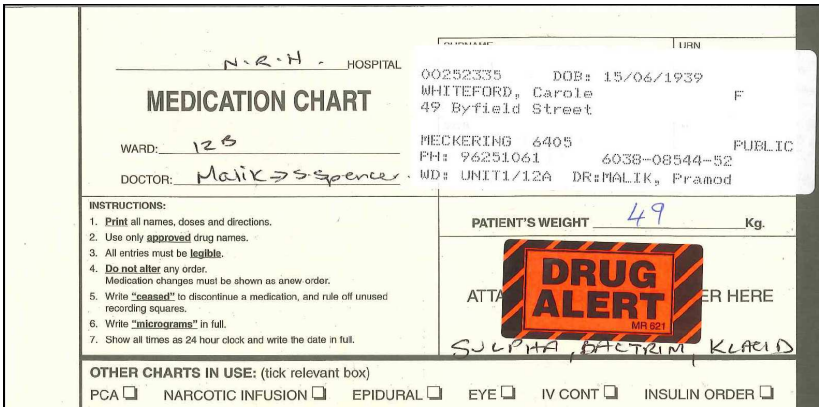
13. The scope of Mrs Whiteford's allergy to sulphonamides is not clear.

14. Sulphonamides fall into one of two groups; antibiotic sulphonamides and non-antibiotic sulphonamides. It is uncertain whether her allergy related to all sulphonamides or to just antibiotic sulphonamides or to only non-antibiotic sulphonamides.

15. It was also known that Mrs Whiteford was allergic to Bactrim (which contains an antibiotic sulphonamide; sulfamethoxazole and a different type of antibiotic, trimethoprim).

16. The deceased was also allergic to codeine and Klacid (a semi-synthetic macrolide antibiotic).

17. The deceased's allergies to these medications were recorded throughout Mrs Whiteford's Northam Hospital medical file. For example one of her medication charts from an earlier admission records her allergy to Sulpha, Bactrim and Klacid.


N·R·H HOSPITAL

MEDICATION CHART

WARD: 12B

DOCTOR: Malik → S. Spencer

URN

00252335 DOB: 15/06/1939
WHITEFORD, Carole F
49 Byfield Street
MECKERING 6405 PUBLIC
PH: 96251061 6038-08544-52
WD: UNIT1/12A DR:MALIK, Pramod

INSTRUCTIONS:
1. Print all names, doses and directions.
2. Use only approved drug names.
3. All entries must be legible.
4. Do not alter any order. Medication changes must be shown as anew order.
5. Write "ceased" to discontinue a medication, and rule off unused recording squares.
6. Write "micrograms" in full.
7. Show all times as 24 hour clock and write the date in full.

PATIENT'S WEIGHT 49 Kg.

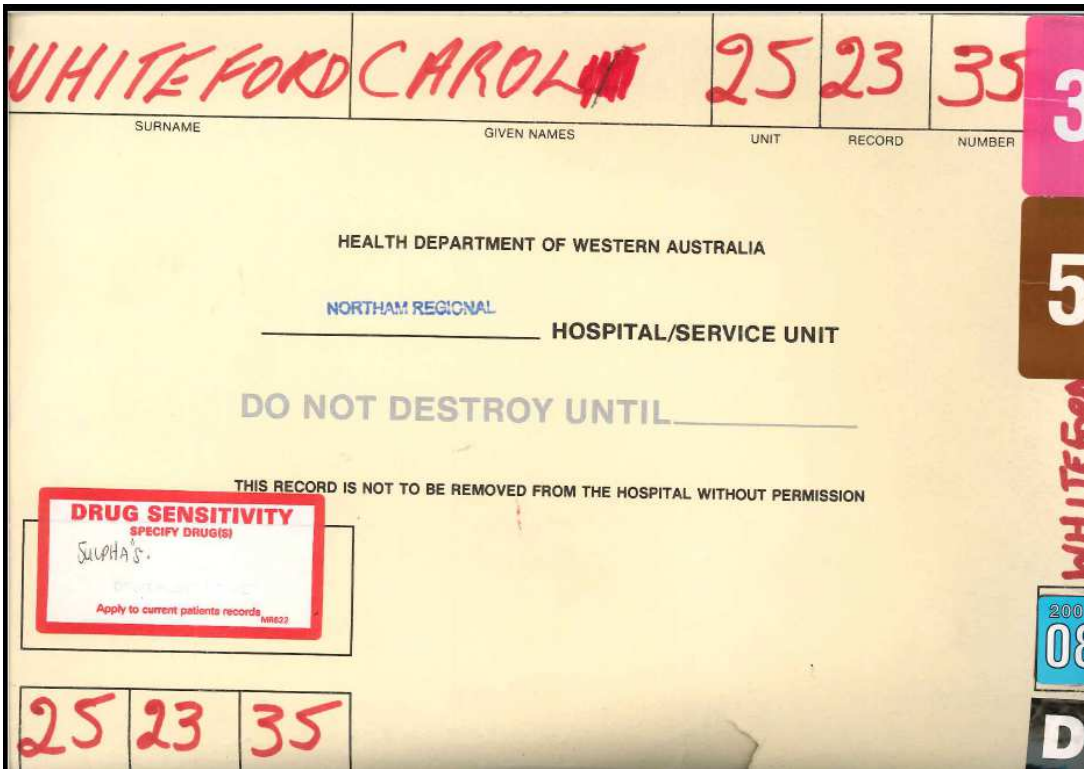
DRUG ALERT MR 621

ATTA ER HERE

SULPHA, BACTRIM, KLACID

OTHER CHARTS IN USE: (tick relevant box)
PCA ☐ NARCOTIC INFUSION ☐ EPIDURAL ☐ EYE ☐ IV CONT ☐ INSULIN ORDER ☐

18. Before surgery the Mrs Whiteford's allergy to *Sulphas* was well known and well recorded in her Northam Hospital medical file. The front cover of Mrs Whiteford's Northam Hospital medical file clearly recorded her allergy to *Sulphas* and there were numerous references to her allergy within the pages contained in her medical file.


WHITEFORD CAROL 25 23 35

SURNAME GIVEN NAMES UNIT RECORD NUMBER

HEALTH DEPARTMENT OF WESTERN AUSTRALIA

NORTHAM REGIONAL HOSPITAL/SERVICE UNIT

DO NOT DESTROY UNTIL

THIS RECORD IS NOT TO BE REMOVED FROM THE HOSPITAL WITHOUT PERMISSION

DRUG SENSITIVITY
SPECIFY DRUG(S)
Sulphas.
Apply to current patients records MR622

25 23 35

19. On admission into the hospital Nurse Edwards secured a red alert bracelet for patients with a known allergy to Mrs Whiteford's right wrist.

20. Most patients are given clear/white identity bands when admitted into hospital.

21. Patients with a known allergy to medications (as well as to food and other substances) are given a red identity band to clearly identify the wearer, to those treating the patient, as a person with an allergy to a medication. The use of red identity bands to identify allergy sufferers is a long standing safety measure common to all West Australian public hospitals.

22. It is incumbent on the physician or nurse of a person wearing a red wristband to look at the patient's medical file in order to find out which medication (or other substance) the patient is allergic to.

23. Mrs Whiteford's allergy to *Sulphas* was recorded on several documents relating to her admission into the Northam Hospital on 5 March 2008, for the eye surgery.

24. Moreover, the same file contained records relating to Mrs Whiteford's earlier admissions into the hospital where her allergies to medications was variously recorded as '*Sulpha, Bactrim, Klacid'* or various combinations of one, two or all three of the words.

25. The surgery to Mrs Whiteford's left eye was unremarkable and apparently successful.

26. Following the operation the deceased's surgeon, Dr Andrew Stewart, wrote his notes in relation to the operation. Whilst writing his notes he wrote a direction, for a nurse who would be looking after Mrs Whiteford on the ward, that she be given a single 250 mg tablet of Diamox.

27. Diamox is a non- antibiotic sulphonamide commonly used by ophthalmologists to reduce intraocular pressure.

28. At the time Dr Stewart prescribed Diamox he was unaware Mrs Whiteford was allergic to any medication.

29. Dr Stewart had not read the deceased's medical file, medication chart or the anaesthetist's notes which contained reference to the deceased's allergy to *Sulphas*.

30. Dr Stewart was unaware that a red wristband was worn by patients in order to identify them as having a known allergy to medication.

31. Mrs Whiteford was initially taken into a recovery room where she was monitored before being taken to a ward in the hospital where she was to recover.

32. Shortly after arriving in the ward Mrs Whiteford was given a single 250 mg tablet of Diamox by the nurse who was caring for her, Nurse Rebecca Nind.

33. Approximately 10 to 15 minutes after being given the tablet of Diamox the deceased became very unwell and fell into a state of collapse.

34. Mrs Whiteford was taken back to the recovery room where her anaesthetist, Dr Mark Familton, attempted to resuscitate her.

35. During the course of the resuscitative efforts Dr Familton injected the deceased with a dose of Frusemide.

36. Frusemide is also a non-antibiotic sulphonamide.

37. Initially Dr Familton's efforts appeared successful and he believed she had become sufficiently stable to be transferred to a tertiary hospital in Perth for high level care and treatment.

38. Unfortunately, at about 12:23 PM Mrs Whiteford suffered a cardiac event and her condition suddenly deteriorated.

39. Notwithstanding further resuscitative efforts Mrs Whiteford died at about 12:40 PM.

40. On 10 March 2008, a post mortem examination was performed on the deceased by Dr Judith McCreath, a forensic pathologist, who after receiving the results of further investigations on 1 April 2009, formed the opinion that the cause of the deceased's death was consistent with anaphylaxis in a woman with atherosclerotic cardiovascular disease and emphysema.

41. During the course of her evidence Dr McCreath confirmed the anaphylactic shock she spoke of related to Mrs Whiteford's reaction to Diamox rather than Frusemide.

42. During the course of the post mortem examination Dr McCreath found Mrs Whiteford was suffering from severe atherosclerotic cardiovascular disease. Mrs Whiteford had 70% narrowing of her left anterior descending artery. There was a 90% narrowing of the left circumflex artery and an 80% narrowing of the right coronary artery.

43. The inquest was held in order to determine how Mrs Whiteford's death occurred and the cause of her death.

Some preliminary matters of law

44. The inquest into the death of the deceased was held in accordance with the *Coroners Act 1996* (WA) (the Act). Pursuant to section 25 (1) of the Act the coroner must find, if possible-

a) The identity of the deceased;
b) How death occurred;
c) The cause of death; and
d) The particulars needed to register the death under the Births, Deaths and Marriages Registration Act 1998.

45. The obligation to determine the manner of death also arises as part of the enquiry as to how the deceased died pursuant to section 25 (1)(b) of the Act. In this context Buss JA noted that '*in my opinion s 25 (1)(b) confers on the coroner the jurisdiction and obligation to find, if possible, the manner in which the deceased happened to die*.' ***Re The State Coroner; Ex Parte the Minister for Health*** [2009] WASCA 165 [42].

46. Pursuant to the *Births, Deaths and Marriages Registration Act 1998* (WA) the coroner must find, if possible, the manner of death. The manner of death is registrable information under section 49 (2) of that Act and is information that is captured on a BDM204 form which a coroner, or delegate, must provide to the Registrar of Births, Deaths and Marriages.

47. Section 25 (2) of the Act provides that a coroner may comment on any matter connected with the death including public health or safety or the administration of justice.

48. When making findings or comment a coroner needs to be mindful of section 25 (5) of the Act, which places the only statutory limitation upon how a comment or finding may be framed. Section 25 (5) of the Act provides:

> A coroner must not frame a finding or comment in such a way as to appear to determine any question of civil liability or to suggest that any person is guilty of any offence.

49. The analogous provision within the South Australian legislation was considered by the Supreme Court of South Australia in ***Perre v Chivell*** No. SCGRG-99-1218 [2000] SASC 279

(24 August 2000) when considering the appropriateness of a finding that had been made by the South Australian State Coroner in the following terms:

> Accordingly, I find, pursuant to section 25 (1) of the Coroners Act 1975, that the circumstances of the death of Detective Sergeant Geoffrey Leigh Bowen were that he died when he opened a parcel bomb, sent to him by Domenic Perre, and the bomb exploded in his hands.

50. After concluding that the finding didn't appear to determine any question of civil or criminal liability, His Honour considered whether or not the finding offended against the Act as '*suggesting*' that Mr Perre was guilty of a criminal offence or liable in a civil context. At paragraph 57 of the judgment His Honour Nyland J stated:

> As I have already mentioned, section 26 (3)[1] refers not only to findings of criminal or civil liability, but also any "suggestion" thereof. The addition of the word "suggestion" is liable to cause confusion as it might be argued that the mere finding of certain facts can, in cases such as the present, suggest or hint at criminal or civil liability and hence breach the section. This is due to the fact that certain acts, such as, in this case, sending a bomb, appear to have no possible legal justification. However, I do not think that section 26 (3) should be read in such a way. The mere recital of relevant facts cannot truly be said, of itself, to hint at criminal or civil liability. Even though some acts may not seem to be legally justifiable, they may often turn out to be just that. For example a shooting or stabbing will, in some circumstances, be justified as lawful self-defence. As I have stated, criminal or civil liability can only be determined through the application of the relevant law to the facts, and it is only the legal conclusions as to liability flowing from this process which are prohibited by section 26 (3). Thus, the word "suggestion" in this section should properly be read as prohibiting the coroner from making statements such as "upon the evidence before me X may be guilty of murder" or "X may have an action in tort against Y" or statements such as "it appears that X shot Y without legal justification". In other words, the term "suggestion" in section 26 (3) prohibits speculation by the coroner as to criminal or civil liability. In the present case, the coroner has neither found nor suggested that Perre is criminally or civilly liable for his acts.

51. Section 41 of the Act provides that a coroner holding an inquest is not bound by the rules of evidence and may be informed and conduct an inquest in any manner the coroner reasonably thinks fit. This section provides a coroner with latitude as to the types of evidence that can be considered by the coroner and allows a relaxing of the normal rules of evidence.

52. Section 41 does not allow a coroner to disregard the rules of natural justice or fairness developed in a series of cases beginning with ***Annetts v McCann*** (190) 170 CLR 596 FC 90/057 (20 December 1990).

53. It is trite to say that the standard of proof in a coronial matter is the civil standard; on the balance of the probabilities.

54. Caution does need to be taken in circumstances where a finding or comment may be adverse to a person involved in the inquest process.

55. Dixon J in ***Briginshaw v Briginshaw*** (1938) 60 CLR 336 at pp 362 - 3 articulated the concern a tribunal of fact should have when dealing with cases, which could potentially have serious consequences for one or more parties involved in the inquest:

> Reasonable satisfaction is not a state of mind that is attained or established independently of the nature and consequence of the fact or facts to be proved. The seriousness of an allegation made, the inherent unlikelihood of an occurrence of a given description, or the gravity of the consequences flowing from the particular finding are considerations which must affect the

[1] *Analogous to s25 (5) Coroners Act 1996 (WA)*

> answer to the question whether the issue has been proved to the reasonable satisfaction of the Tribunal. In such matters reasonable satisfaction should not be produced by inexact proofs, indefinite testimony, or indirect inferences… when in a civil proceeding, a question arises whether a crime has been committed, the standard of persuasion is, according to the better opinion, the same as upon of the civil issues… but consistently with this opinion weight is given to the presumption of innocence and exactness of proof is expected.

56. I take the comments of Dixon J in ***Briginshaw*** to encourage a more cautious approach, than that represented by the normal standard of persuasion, and to require a higher standard of persuasion, depending on the nature of the adverse finding under consideration. The more serious the allegation, the higher the required standard of persuasion.

57. A coroner also has a power under section 50 to refer individuals to a disciplinary body. Section 50 provides:

> ***50. Reference to a disciplinary body***
>
> (1) A coroner may refer any evidence, information or matter which comes to the coroner's notice in carrying out the coroner's duties to a body having jurisdiction over a person carrying on a trade or profession if the evidence, information or matter —
>
> (a) touches on the conduct of that person in relation to that trade or profession; and
>
> (b) is, in the opinion of the coroner, of such a nature as might lead the body to inquire into or take any other step in respect of the conduct apparently disclosed by the evidence, information or matter so referred.
>
> (2) In subsection (1) ***a body having jurisdiction over a person carrying on a trade or profession*** means a body empowered under a written law to —
>
> (a) register, license or otherwise approve a person as a prerequisite to the person lawfully carrying on that trade or profession; and
>
> (b) impose or recommend any punishment or liability in respect of wrongful, incompetent or otherwise unsatisfactory conduct of that person in relation to that trade or profession.

58. It is with that statutory and legal background that the inquest into the death of Mrs Whiteford (the deceased) has been held and this finding delivered.

The events of June 2007 – 4 March 2008

59. On 8 June 2007, the deceased's GP, Dr Stephanie Spencer, wrote a letter of referral to an ophthalmic surgeon, Dr Andrew Stewart. Dr Spencer asked that Dr Stewart examine the deceased with a view to determining whether or not she would be an appropriate candidate for surgery to improve her vision.

60. In her referral letter, Dr Spencer told Dr Stewart the deceased had seen her optician about a year earlier and had been diagnosed with early cataracts. Since that time the deceased had noticed deterioration in her eyesight. Dr Stewart was also advised the deceased had advanced chronic obstructive pulmonary disease (COPD) and was on an oral medication; prednisolone.

61. On 3 August 2007, Dr Stewart examined the deceased in Northam. The deceased told Dr Stewart she was anxious to have something done about her cataracts because her quality of life was extremely poor. She was largely confined to her home as a consequence of

her severe COPD and she was reliant on oxygen. Her poor eyesight seriously eroded the limited enjoyment of life available to her.

62. Dr Stewart found the deceased had very poor vision and her corrected visual acuity was 6/36 in each eye. Dr Stewart believed the deceased's poor vision was due to her long-term use of corticosteroids used to treat the deceased's severe COPD[2], which had caused dense nuclear sclerosis with posterior sub-capsular opacities.

63. The deceased's intraocular pressure was measured and determined to be in the mid-20s in each eye. The intraocular pressure was higher than normal but not at a level to equate to glaucoma.

64. Dr Stewart was not able to obtain all of the measurements necessary to calculate the strength of the intraocular lenses which might be implanted in the event a decision was made to proceed with surgery. The deceased made an appointment to see Dr Stewart at his Perth rooms so those measurements could be taken. This consultation was scheduled for 10 September 2007.

65. On 10 September 2007, the deceased went to Dr Stewart's rooms where he and his technician undertook a number of measurements and observations. In addition to the deceased's raised intraocular pressure it was found that the deceased's central corneal thickness was below 550 μ, which is a further risk factor for glaucoma.

66. The fact of the deceased having raised intraocular pressure and a thin central cornea meant Dr Stewart was conscious that he would have to take steps to ensure that after the operation the deceased's intraocular pressure was low. In order to lower the deceased's intraocular pressure he intended to perform a trabeculectomy, a procedure which would create a fistula. The fistula would allow drainage from the eye, which in turn would act as a mechanism to reduce intraocular pressure.

67. As part of the consultation Dr Stewart asked the deceased whether she was allergic to three medications; penicillin, chloramphenicol and iodine, which were all likely to be used during the course of the cataract surgery.

68. The deceased told Dr Stewart she was not allergic to any of those medications.

69. Dr Stewart did not ask whether the deceased was allergic to any other medications or, in particular, whether the deceased was allergic to *Sulphas* or sulphonamide type medications.

70. Dr Stewart had no reason to ask about allergies to *Sulphas* as he was not intending to use any medication of that type. Dr Stewart's plan was to perform a trabeculectomy which would obviate the need for any medication that could otherwise be used to lower the deceased's intraocular pressure.

71. Moreover, it was not Dr Stewart's practice to ask about a patient's allergy to *Sulphas* as he did not believe that it caused an allergic reaction.

72. Dr Stewart told the deceased about the surgery and he advised her of the risks and complications inherent to the operation.

[2] Exhibit 1 Tab 11

73. Dr Stewart advised the deceased that because of the risks associated with her general frailty and respiratory problems the surgery on each eye should take place on separate occasions. He also advised the deceased the surgery should be undertaken at the Lions Eye Surgery Foundation in Perth where there would be ready access to tertiary medical facilities should they be required post operatively.

74. On 11 September 2007, the deceased called Dr Stewart's surgery and advised she wanted to proceed with the surgery and that she wanted it to be undertaken at the Lions Eye Surgery Foundation.

75. The deceased was booked in for the surgery to be undertaken on 29 October 2007.

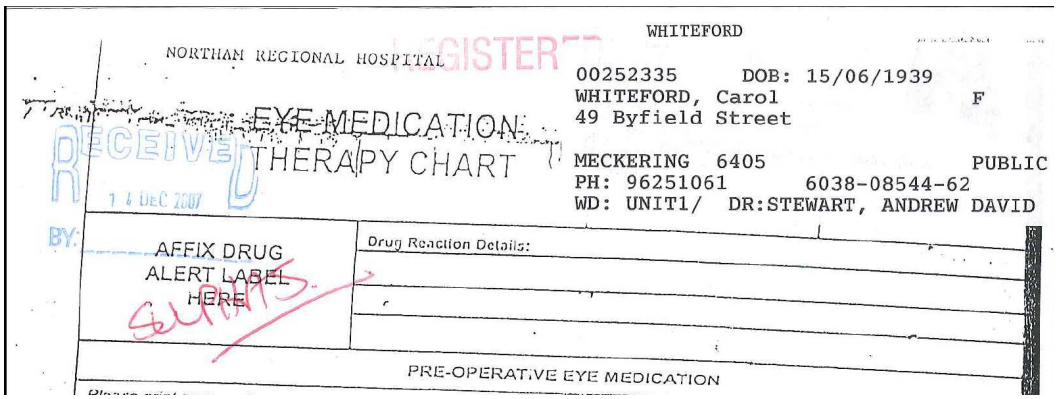
76. The following day, 12 September 2007, the deceased again called Dr Stewart's surgery and advised the receptionist that she had changed her mind and wanted to have the surgery on each of her eyes performed at Northam Hospital.

77. Subsequently, arrangements were made for the deceased to have the surgery undertaken on 6 March 2008 at Northam Hospital.

78. In anticipation of the surgery Dr Stewart forwarded an eye medication therapy chart to the Northam Hospital. The eye medication therapy chart contained a list of the medications the deceased was expected to be given before, during and after the surgery. The eye medication therapy chart did not contain any sulphonamide type medications.

79. The eye medication therapy chart was received at Northam Hospital on 14 December 2007. Before surgery took place a registered nurse, Nurse Nind, wrote the word *Sulpha's* on it in red on its top left hand corner, in order to alert the reader of the document to the deceased's allergy to *Sulphas*.

80. Nurse Nind wrote the word *Sulpha's* on the side of the page which contained the post-operative eye medications which were to be given to the deceased.



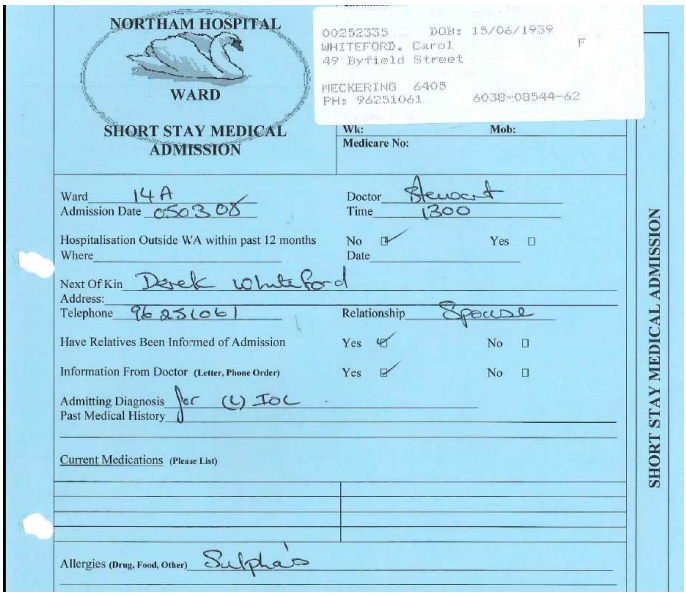
81. On 26 February 2008, a nurse prepared a medication chart which was to be used during the deceased's forthcoming hospitalisation. The chart contained a red box relating to adverse drug reactions. A registered nurse, Nurse O'Driscoll, hand wrote the word *Sulpha's* onto the chart in order to alert the reader to the fact of the deceased's allergy.

The events of 5 - 6 March 2008

82. On 5 March 2008, the deceased went to Northam Hospital where she was to spend the night before having her left eye operated on the following day.

83. The deceased arrived at the hospital at about 4 PM. She was initially seen by a registered nurse, Nurse Edwards. As part of the admissions process two documents were completed. The first document was a surgical pre-admission assessment form and the second document was a short stay medical admission form.

84. The short stay medical admission form asked a question in the following terms '*Allergies (Drug, Food, Other)*' which contained Nurse Edwards written answer '*Sulpha's*'.



NORTHAM HOSPITAL
WARD
SHORT STAY MEDICAL ADMISSION

00252335 DOB: 15/06/1939 F
WHITEFORD, Carol
49 Byfield Street
MECKERING 6405
PH: 96251061 6038-08544-62

Wk: Mob:
Medicare No:

Ward 14A
Admission Date 050308
Doctor Stewart
Time 1300

Hospitalisation Outside WA within past 12 months No ☑ Yes ☐
Where
Date

Next Of Kin Derek Whiteford
Address:
Telephone 96231061 Relationship Spouse

Have Relatives Been Informed of Admission Yes ☑ No ☐

Information From Doctor (Letter, Phone Order) Yes ☑ No ☐

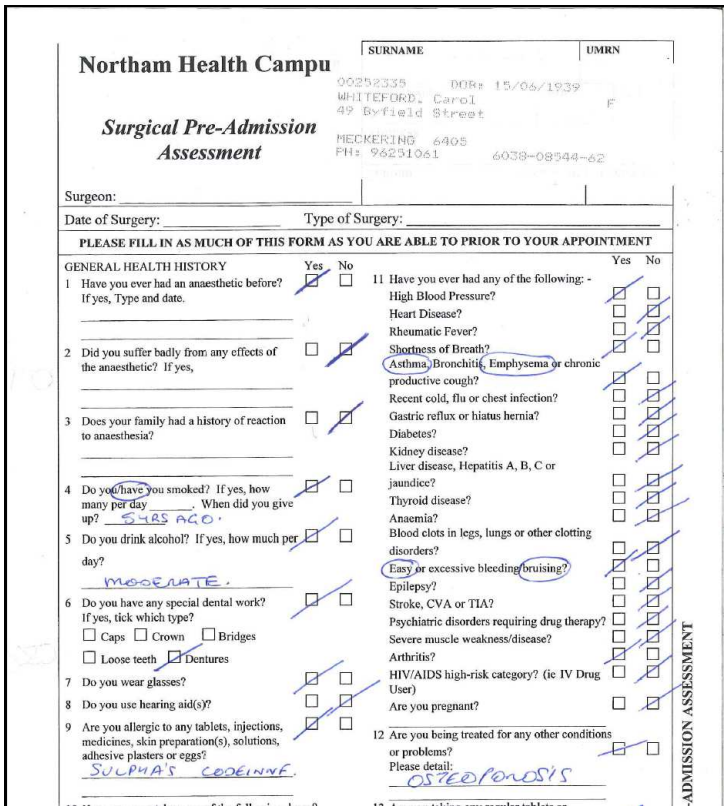
Admitting Diagnosis Ner (L) IOL
Past Medical History 0

Current Medications (Please List)

Allergies (Drug, Food, Other) Sulphas

SHORT STAY MEDICAL ADMISSION

85. The surgical pre-Admission assessment form required the deceased to answer a number of questions relating to her health. In answer to the questions the deceased indicated she suffered from shortness of breath and had both asthma and emphysema. In answer to a question '*Are you allergic to any tablets, injections, medicines, skin preparation(s), solutions, adhesive plasters or eggs*?' The answer was given '*sulpha's codeinne* (sic) *'*. The form also identified the deceased as suffering from asthma and emphysema.



Northam Health Campu

SURNAME UMRN

00252335 DOB: 15/06/1939 F
WHITEFORD, Carol
49 Byfield Street
MECKERING 6405
PH: 96251061 6038-08544-62

Surgical Pre-Admission Assessment

Surgeon:
Date of Surgery: Type of Surgery:

PLEASE FILL IN AS MUCH OF THIS FORM AS YOU ARE ABLE TO PRIOR TO YOUR APPOINTMENT

GENERAL HEALTH HISTORY — Yes / No

1 Have you ever had an anaesthetic before? If yes, Type and date. ☑ Yes ☐ No
2 Did you suffer badly from any effects of the anaesthetic? If yes, ☐ Yes ☑ No
3 Does your family had a history of reaction to anaesthesia? ☐ Yes ☑ No
4 Do you have you smoked? If yes, how many per day ____. When did you give up? 5YRS AGO. ☑ Yes ☐ No
5 Do you drink alcohol? If yes, how much per day? MODERATE. ☑ Yes ☐ No
6 Do you have any special dental work? If yes, tick which type? ☐ Caps ☐ Crown ☐ Bridges ☐ Loose teeth ☑ Dentures ☑ Yes ☐ No
7 Do you wear glasses? ☑ Yes ☐ No
8 Do you use hearing aid(s)? ☐ Yes ☑ No
9 Are you allergic to any tablets, injections, medicines, skin preparation(s), solutions, adhesive plasters or eggs? SULPHA'S CODEINNE. ☑ Yes ☐ No

11 Have you ever had any of the following: - Yes / No
High Blood Pressure? ☑ ☐
Heart Disease? ☐ ☑
Rheumatic Fever? ☐ ☑
Shortness of Breath? ☑ ☐
Asthma, Bronchitis, Emphysema or chronic productive cough? ☑ ☐
Recent cold, flu or chest infection? ☐ ☑
Gastric reflux or hiatus hernia? ☐ ☑
Diabetes? ☐ ☑
Kidney disease? ☐ ☑
Liver disease, Hepatitis A, B, C or jaundice? ☐ ☑
Thyroid disease? ☐ ☑
Anaemia? ☐ ☑
Blood clots in legs, lungs or other clotting disorders? ☐ ☑
Easy or excessive bleeding/bruising? ☑ ☐
Epilepsy? ☐ ☑
Stroke, CVA or TIA? ☐ ☑
Psychiatric disorders requiring drug therapy? ☐ ☑
Severe muscle weakness/disease? ☐ ☑
Arthritis? ☑ ☐
HIV/AIDS high-risk category? (ie IV Drug User) ☐ ☑
Are you pregnant? ☐ ☑

12 Are you being treated for any other conditions or problems? ☑ Yes ☐ No
Please detail: OSTEOPOROSIS

ADMISSION ASSESSMENT

86. After completing the paperwork the deceased was admitted into the hospital. As part of the admissions process the deceased was given an identity band which was secured to her right wrist. Most people receive a clear/white plastic wristband. The deceased however received a red wristband.

87. Only patients who have allergies to medications are given red wristbands. All other patients receive clear/white plastic wristbands.

88. The red wristband is intended as a clear visual marker which identifies the wearer as a person who has an allergy to a medication or medications.

89. The red wristband does not state which medication or medications the patient is allergic to. The wristband alerts nursing and medical staff to the existence of an allergy and obliges them to read the patient's medical file in order to determine which medication or medications the patient is allergic to.

90. The deceased brought a number of her own medications to hospital in order that her drug therapies could continue unaffected by her stay in hospital. These medications were recorded on a 24 hour interim medication chart. This medication chart contained an adverse drug reaction sticker, next to which was written the word in red '*Sulphas'.*

91. During the morning of 6 March 2008, the deceased met with the anaesthetist Dr Mark Familton. Dr Familton read the deceased's hospital file, which contained not only the paperwork relating to the operation that was to proceed on that day but it also contained the paperwork relating to the deceased's previous admissions to the Northam Hospital on 11 February 2005, 17 May 2005, 20 July 2005, 4 November 2006, 2 June 2007 and 21 February 2008. On each occasion the deceased's allergy to *Sulphas* was recorded.

92. Whilst talking to the deceased Dr Familton began to complete a document known as an anaesthetic record. In the portion of the document which related to the pre-anaesthetic consultation, Dr Familton placed a tick in a box which indicated the deceased had an allergy. Next to the tick Dr Familton wrote the word '*Sulphas'* indicating the deceased had an allergy to *Sulphas*.

93. Dr Stewart also spoke to the deceased before the surgery. He saw the deceased in an area near the operating theatre. The deceased's condition had markedly declined since he last saw her in September 2007. Dr Stewart decided that he would not perform a trabeculectomy to lower the deceased's intraocular pressure after the operation because he wanted to reduce the time of the operation and the stress placed on the deceased.

94. Dr Stewart decided that instead of performing the trabeculectomy he would give the deceased a medication which would have the effect of lowering her intraocular pressure. The medication in question was a sulphonamide known as Diamox.

95. Dr Stewart did not ask the deceased whether or not she was allergic to sulphonamides or *Sulphas*.

96. Dr Stewart had all of the medical files of the patients he would be operating on during the course of the morning available to him when he undertook his preoperative patient consultations. Dr Stewart did not review the deceased's hospital file. In fact he did not look at any of the Northam Hospital files relating to the patient's he was to operate on that day.

97. The deceased was wearing her red plastic wristband which marked her as a patient with a known allergy to a medication or medications at the time of her consultation with Dr Stewart.

98. Dr Stewart did not notice the deceased's red plastic wristband either during the pre-surgery consultation or later, whilst in the operating theatre.

99. In any event Dr Stewart was unaware of the significance of a red wristband as marking the patient as having a known allergy.

100. At about 9:30 AM Dr Familton administered the local anaesthetics, ropivacaine and lignocaine, which were to be the only anaesthesia during the course of the operation.

101. Because of the deceased's lung function it would not have been possible to have used a general anaesthetic during the course of the operation. Dr Familton said in evidence[3] '*that the choice of general anaesthetic would be catastrophic for her'* because once anaesthetised it would have been exceptionally hard for Mrs Whiteford to regain her capacity to breathe spontaneously.

The operation

102. At about 9:36 AM on 6 March 2008, the deceased arrived at the operating theatre.

103. Those present during the surgery were:

i. the surgeon, Dr Stewart,
ii. the anaesthetist, Dr Familton,
iii. the anaesthetic nurse, Nurse Robbins,
iv. the scrub nurse, Nurse Cork; and,
v. the circulating nurse, Nurse Lawler.

104. Two documents were used to record the preoperative preparations as the events took place; the operation record and the team time out record.

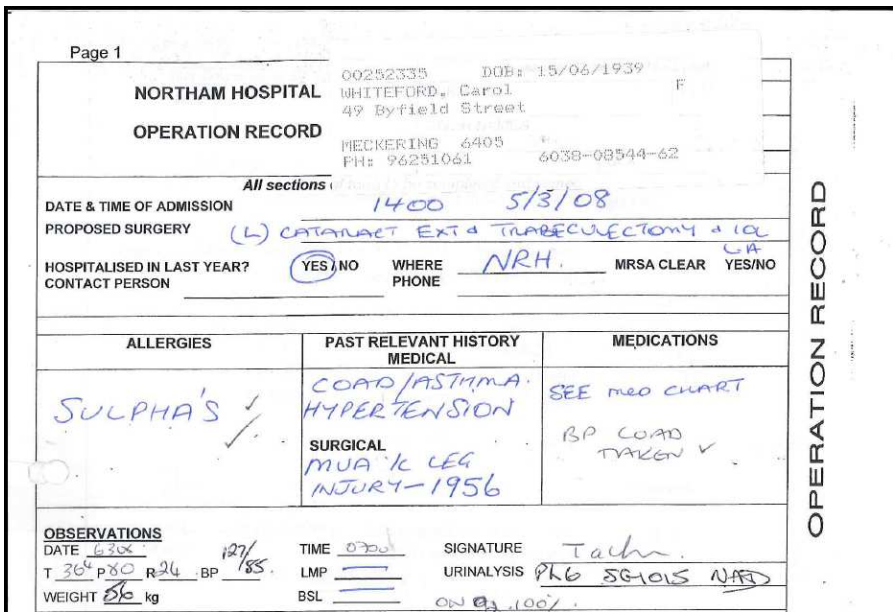
105. The operation record is a four-sided document which records relevant information garnered throughout the surgical process. Each of the four pages relates to a different aspect of the process. Those pages relate to:

i. preoperative information,
ii. intraoperative care information,
iii. the surgeon's record of the surgery together with his instructions or post-operative care on the ward; and,
iv. perioperative care.

106. The preoperative portion of the form is completed by registered nurses. The form requires the provision of a variety of information relating to the proposed surgery.

107. In this case the form recorded the deceased's known allergy to *'Sulpha's'* and also confirmed that theatre checks have been undertaken. The theatre checks required confirmation that the patient's identity bands were correct. This process would necessarily require inspection of the deceased's red identity band, which highlighted her as a person with a known allergy.

[3] Transcript of proceedings 9 July 2013 – Page 92



Page 1

NORTHAM HOSPITAL

OPERATION RECORD

00252335 DOB: 15/06/1939 F
WHITEFORD, Carol
49 Byfield Street
MECKERING 6405
PH: 96251061 6038-08544-62

All sections

DATE & TIME OF ADMISSION 1400 5/3/08

PROPOSED SURGERY (L) CATARACT EXT & TRABECULECTOMY & IOL

HOSPITALISED IN LAST YEAR? YES / NO WHERE NRH. MRSA CLEAR YES/NO

CONTACT PERSON PHONE

ALLERGIES	PAST RELEVANT HISTORY MEDICAL	MEDICATIONS
SULPHA'S ✓	COAD/ASTHMA. HYPERTENSION SURGICAL MUA & LEG INJURY-1956	SEE MED CHART BP COAD TAKEN ✓

OBSERVATIONS

DATE 6308 TIME 0700 SIGNATURE Tachn.

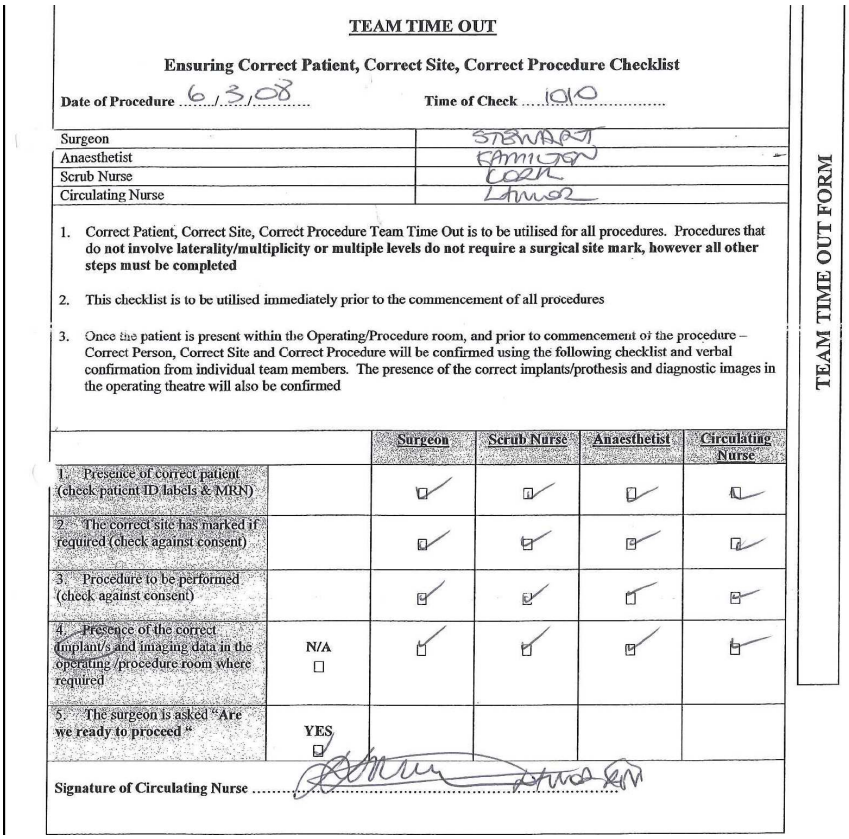
T 36⁴ P80 R24 BP 127/85 LMP URINALYSIS PH6 SG1015 NAD

WEIGHT 56 kg BSL ON O2 100%.

OPERATION RECORD

108. In addition to the requirement imposed on the circulating nurse to complete the operation record, a separate process required the surgeon, scrub nurse, anaesthetist and circulating nurse to specifically consider the circumstances of the individual about to be operated on. Each of those individuals was required to give verbal confirmation that the patient was the correct patient. This process required consideration of the patient's ID labels & MRN. This process would necessarily involve looking at the patient's red wristband in order to properly identify Mrs Whiteford as the correct patient about to undergo surgery.

109. According to the team time out record Dr Stewart verbally confirmed that Mrs Whiteford was the correct patient for the proposed surgery. This information was recorded in the team time out record.



TEAM TIME OUT

Ensuring Correct Patient, Correct Site, Correct Procedure Checklist

Date of Procedure 6/3/08 Time of Check 1010

Surgeon	STEWART
Anaesthetist	FANNIN
Scrub Nurse	CORR
Circulating Nurse	LAWSON

1. Correct Patient, Correct Site, Correct Procedure Team Time Out is to be utilised for all procedures. Procedures that do **not involve laterality/multiplicity or multiple levels do not require a surgical site mark, however all other steps must be completed**
2. This checklist is to be utilised immediately prior to the commencement of all procedures
3. Once the patient is present within the Operating/Procedure room, and prior to commencement of the procedure – Correct Person, Correct Site and Correct Procedure will be confirmed using the following checklist and verbal confirmation from individual team members. The presence of the correct implants/prothesis and diagnostic images in the operating theatre will also be confirmed

		Surgeon	Scrub Nurse	Anaesthetist	Circulating Nurse
1. Presence of correct patient (check patient ID labels & MRN)		☑	☑	☑	☑
2. The correct site has marked if required (check against consent)		☑	☑	☑	☑
3. Procedure to be performed (check against consent)		☑	☑	☑	☑
4. Presence of the correct implant/s and imaging data in the operating /procedure room where required	N/A ☐	☑	☑	☑	☑
5. The surgeon is asked "Are we ready to proceed "	YES ☑				

Signature of Circulating Nurse .....

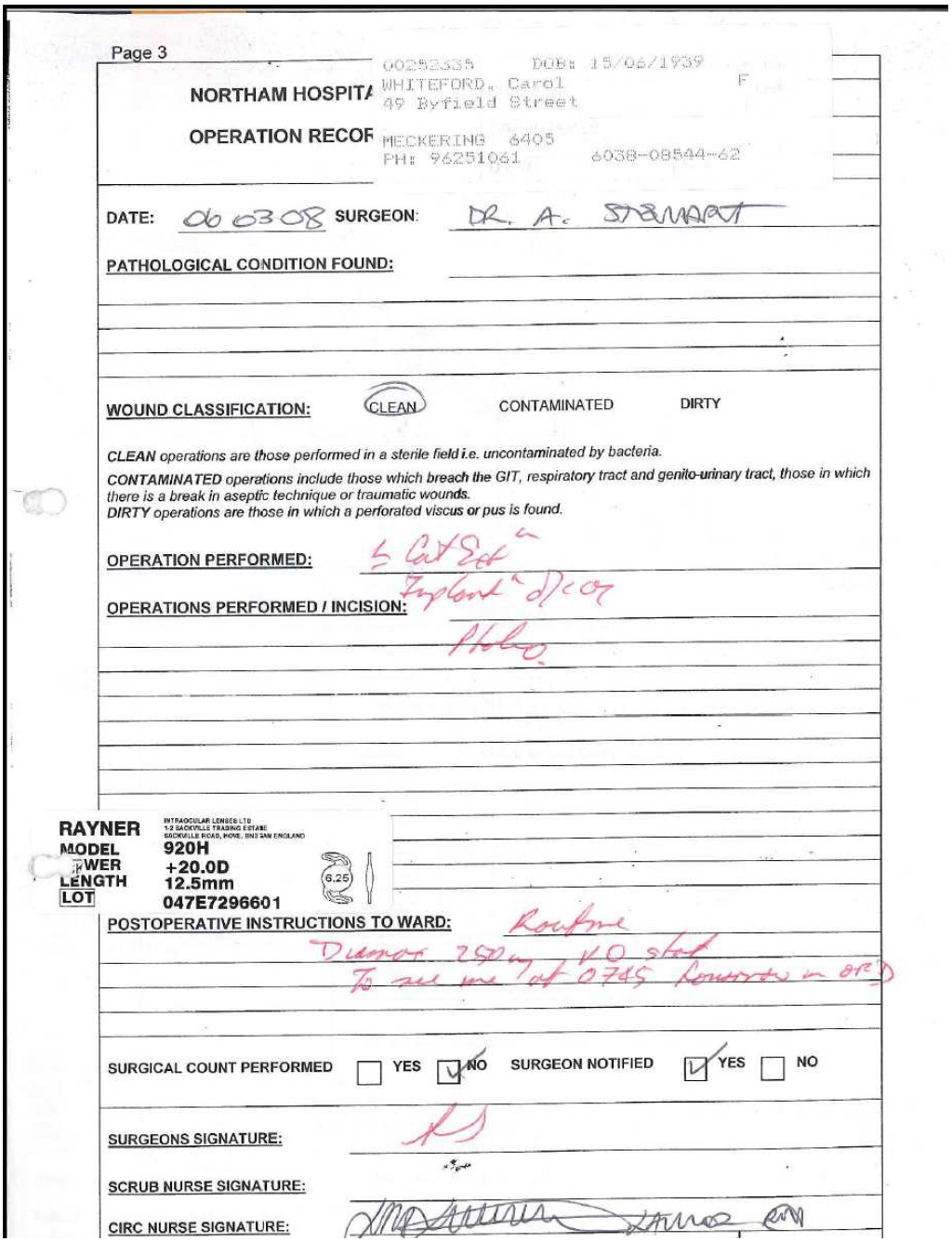
TEAM TIME OUT FORM

110. The surgery began at about 10:15 AM. It was finished about 20 minutes later, at about 10: 35 AM. The operation appeared to have been successful and was completed without complication.

111. After the operation was finished the deceased was taken into the recovery room where she was supervised as she recovered from the anaesthetic.

112. Dr Stewart completed his own records relating to the deceased which he had brought with him from Perth.

113. Dr Stewart also completed the third page of the Northam Hospital operation record in which he wrote the details of the operation he had just performed. Dr Stewart also wrote the relevant post-operative instructions to the nurse in the ward where Mrs Whiteford was to be taken. The instructions were for [4] *'routine observations and then Diamox 250 mg per RM stat and to see me at 7.45 the next day in the outpatient department'*



Page 3

NORTHAM HOSPITA
OPERATION RECOR

00252335 DOB: 15/06/1939
WHITEFORD, Carol F
49 Byfield Street
MECKERING 6405
PH: 96251061 6038-08544-62

DATE: 06 03 08 SURGEON: DR. A. STEWART

PATHOLOGICAL CONDITION FOUND:

WOUND CLASSIFICATION: (CLEAN) CONTAMINATED DIRTY

CLEAN operations are those performed in a sterile field i.e. uncontaminated by bacteria.
CONTAMINATED operations include those which breach the GIT, respiratory tract and genito-urinary tract, those in which there is a break in aseptic technique or traumatic wounds.
DIRTY operations are those in which a perforated viscus or pus is found.

OPERATION PERFORMED: L Cat Ext
OPERATIONS PERFORMED / INCISION: Implant "d" IOL

RAYNER
MODEL 920H
POWER +20.0D
LENGTH 12.5mm
LOT 047E7296601

POSTOPERATIVE INSTRUCTIONS TO WARD: Routine
Diamox 250mg PO stat
To see me at 0745 tomorrow in OPD

SURGICAL COUNT PERFORMED ☐ YES ☑ NO SURGEON NOTIFIED ☑ YES ☐ NO

SURGEONS SIGNATURE:

SCRUB NURSE SIGNATURE:

CIRC NURSE SIGNATURE:

[4] Transcript of proceedings of 10 July 2013, Page 39

114. When Dr Stewart made the instruction that the deceased should be given a 250 mg Diamox tablet, he had with him a number of documents which expressly recorded the fact of Mrs Whiteford's allergy to *Sulphas*.

115. He had page 1 of the operation record, the hospital generated medication chart, the 24 hour intra-medication chart and the medication chart he had created and sent to Northam Hospital in advance of the surgery.

116. According to Dr Stewart he did not look at any of those documents and he only had regard to page 3 of the operation record when he wrote the instruction the deceased be given a 250 mg tablet of Diamox.

117. Whilst the other documents may have been present Dr Stewart only looked at page 3 of the operation record which was folded open to that page. Dr Stewart believed he only needed to look at page 3 as it was the only portion of the operation record he was required to complete.

118. Dr Stewart was unaware of Mrs Whiteford's recorded allergy to *Sulphas* and he instructed that Mrs Whiteford be given Diamox when she was recovering in her hospital ward.

119. It should be noted there were alternatives to using Diamox to lower the deceased's intraocular pressure.

120. Dr Stewart could have performed the procedure he initially envisaged employing; a trabeculectomy and created a fistula which would act as a physical drain within the deceased's eye and would have mechanically lowered the deceased's intraocular pressure.

121. Alternatively, Dr Stewart could have directed that Mrs Whiteford be given a non-sulphonamide medication, such as Timolol eye drops, which would have acted to lower the deceased's intraocular pressure without exposing her to the potential of an allergic reaction to Diamox.

122. Dr Stewart was asked whether Timolol was an option in Mrs Whiteford's case. He said[5]:

> In somebody without chronic obstructive pulmonary disease, yes, that is true. In this particular instance there are certain problems with that. Firstly, Timolol would not have been available in the hospital. It is not the sort of drug which would be kept in a limited hospital pharmacy, so we would have entailed the – somebody from the understaffed hospital going to the chemist to get some and bring it in.

123. Northam Hospital reject the suggestion that it could not have obtained Timolol had that been required or requested.

124. Dr Stewart went on to say[6]:

> Secondly, and most importantly, I would be very reluctant to use Timolol in somebody in her condition because although I was not aware that she had asthma, it is quite likely she would be susceptible to asthma concomitantly with her obstructed airways disease and Timolol is known to provoke asthmatic attacks in susceptible patients. So I personally would not – I would feel it would be risky to use Timolol, far more so than the risk of using Diamox.

125. There was no good reason why Dr Stewart should have been unaware as to whether or not Mrs Whiteford suffered from asthma.

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[5] Transcript of proceedings of 10 July 2013, Page 14
[6] Transcript of proceedings of 10 July 2013, Page 14

126. Mrs Whiteford's medical records made repeated reference to the fact she was an asthmatic. Had he read the medical notes his suspicion Mrs Whiteford suffered from asthma would have been confirmed.

127. Likewise Dr Stewart could have asked Mrs Whiteford on any of the previous occasions when he spoke to her, including the morning of the operation, whether she was an asthmatic.

128. There was no reason Dr Stewart had to guess or make assumptions as to what was the best way of lowering Mrs Whiteford's intraocular pressure. The notes spoke of her being an asthmatic and also suffering from an allergy to *Sulphas*. Dr Stewart simply omitted to read those records. If he had read the records he would have been in a position to make a medically sound decision as to whether it was appropriate to reduce the deceased's post-operative intraocular pressure surgically with a trabeculectomy or whether her intraocular pressure could be reduced with either Timolol or Diamox.

129. Alternatively, it may have been the case that after reviewing the deceased's medical file and learning of her asthma and allergy to *Sulphas* and considering the risks associated with the trabeculectomy Dr Stewart weighed the competing risks and determined the risks of proceeding with the surgery were simply too great, as there was no appropriate mechanism to reduce the deceased's post-operative intraocular pressure.

130. Dr Stewart's observation that it was too risky to use Timolol on Mrs Whiteford nevertheless highlights her precarious state of health and the risks posed by a relatively minor insult to her system.

The deceased's recovery

131. The deceased was in the post operative recovery area from between about 10:35 AM and 10:50 AM. During that time she had elevated but stable systolic blood pressure (140 at 10:35 AM, 140 at 10:40 AM, 130 at 10:45 AM and 140 at 10:50 AM) and relatively stable and normal diastolic blood pressure.

132. The deceased's other vital signs were normal whilst she was recovering from the local anaesthetic.

133. Whilst in the recovery area the deceased complained of pain to her left shoulder, which was likely caused by her having to lie flat on her back during the course of the operation. Dr Familton explained that people with severe chronic pulmonary disease can't lay flat for long and they are more comfortable when in an upright seated position[7].

134. Dr Familton gave evidence that Mrs Whiteford suffered from osteoporosis. He thought the deceased's backache sounded '*musculoskeletal*'[8]. Dr Familton expanded on his view that the deceased's position on the operating table was likely the source of the deceased's backache. He said[9] '*having been on one myself, I can tell you (it) is pretty uncomfortable. So it does not surprise me that she'd have some, some mild musculoskeletal pain at some point in the back*'.

135. At about 11 AM a decision was made that the deceased's recovery from the procedure was sufficiently advanced for her to be safely returned to a ward. At that time the

[7] Transcript of proceedings on 9 July 2013, Page 90
[8] Transcript of proceedings on 9 July 2013, Page 99
[9] Transcript of proceedings on 9 July 2013, Page 99

recovery nurse called the registered nurse who would be responsible for looking after the deceased on the ward, Nurse Rebecca Nind.

136. Nurse Nind together with a porter went to the recovery area and returned the deceased to the ward. At that time she was receiving oxygen therapy at a rate of two litres per minute. She was supplied oxygen by nasal prongs.

137. Mrs Whiteford had complained of pain on the left side of her back between her shoulder blades. Mrs Whiteford was offered analgesia (paracetamol) which she declined. Nurse Nind tried to relieve the pain by massaging Mrs Whiteford's back.

138. At that time Nurse Nind also undertook a range of observations relating to the deceased's vital signs. Her temperature was normal. Her pulse was minimally elevated (90 bpm) her oxygen saturation level was 96% and her blood pressure was 140 (systolic) over 70 (diastolic), which Nurse Nind considered to be within normal limits[10].

139. After recording the observations Nurse Nind obtained a 250 mg tablet of Diamox which she then *administered*[11] *to Mrs Whiteford*.

140. According to Nurse Nind[12] '*within 10 to 15 minutes, the patient was clearly having an allergic reaction with difficulty in breathing, shortness of breath and diaphoresis'*.

141. Nurse Nind immediately called the recovery area and sought assistance. Nurse Nind increased the flow of oxygen to the deceased. Then, with the help of an orderly she helped take the deceased back to the recovery room where she was looked after by the anaesthetist Dr Familton.

142. When first contacted Dr Familton was in the operating theatre supporting another patient. He was told the deceased had been given a Diamox tablet. He was aware from his pre-anaesthetic review of the deceased's medical file that she was allergic to *Sulphas*. He told the anaesthetic nurse to monitor his patient as[13] *'I knew this was going to be a catastrophe. I felt it. I've come across it before'.*

143. Dr Familton was asked by Mr Quail to expand on his concerns[14]:

> Mr Quail: What did you believe it was at that point? What were you concerned about?
>
> Dr Familton: I was told that this was – it was 20 minutes after being given Diamox. So to me, regardless of what the cause of the reaction is, this is a drug reaction. Drug reaction ready means something along the lines of anaphylaxis. Like I said, I don't like the word, it means bronchospasm. It will mean possibly pulmonary oedema. It often means hypertension.

144. Dr Familton saw the deceased back in the recovery room at about 11:30 AM.

145. When Dr Familton first saw the deceased in the recovery room she was sitting bolt upright but unable to talk. She had shortage of breath (dyspnoea) and a pulse of 135 bpm. Her blood pressure had risen dramatically and was 235 (systolic) over 110 (diastolic). Dr Familton noticed the deceased was having great difficulty breathing and using a stethoscope he could hear a slight wheeze and crackles in her chest.

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[10] Transcript of proceedings on 9 July 2013, Page 66
[11] Transcript of proceedings on 9 July 2013, Page 68
[12] Transcript of proceedings on 9 July 2013, Page 68
[13] Transcript of proceedings on 9 July 2013, Page 120
[14] Transcript of proceedings on 9 July 2013, Page 120

146. The wheeze suggested the deceased had a spasm of the bronchi whilst the crackles suggested the deceased had a pulmonary oedema, that is fluid accumulating in her lungs.

147. The deceased's oxygen saturation level had fallen from 96% (when measured on the ward at 11:10 AM) and then rapidly dropped to 24% (at 11:35 AM) and then to 18% (at 11:40 AM).

148. Dr Familton's assessment was the deceased had developed pulmonary oedema secondary to allergy[15]. The deceased's condition was critical and required immediate high level intervention.

149. Dr Familton set about trying to save the deceased's life by treating the symptoms he encountered.

150. He gave the deceased adrenaline in order to overcome the bronchospasm caused by Mrs Whiteford's reaction to the Diamox.

151. Generally speaking adrenaline has the effect of increasing a patient's blood pressure. However after administering adrenaline to Mrs Whiteford her blood pressure fell. Dr Stewart believes her blood pressure fell because of the improvement in her level of oxygenation. Dr Familton explained that the paradox of the deceased's blood pressure falling after being given adrenaline in the following terms[16]:

> My feeling about Mrs Whiteford is that she was having to use her heart so hard to pump around oxygen to the vital organs that that's why her blood pressure was like that and once her blood was able to be oxygenated better with less bronchospasm, the heart can relax a bit. That's my feeling about that.

152. Dr Familton provided the deceased with a range of medications including Salbutamol (used for the relief of bronchospasm), hydrocortisone (an anti-inflammatory), more adrenaline, Ventolin (a bronchodilator), and an Atrovent nebuliser (a bronchodilator).

153. At about 11:50 AM the deceased was given 80 mg of Frusemide (a sulphonamide which acts as a venous dilator, causes urine production and reduces pulmonary oedema) in order to get rid of the fluid in the deceased's lungs. The Frusemide was delivered intravenously.

154. The deceased urgently needed a venous dilator in order to reduce her extremely high blood pressure. At the time the Frusemide was administered there was no other drug available to Dr Familton which would achieve this aim.

155. The deceased was later given a GTN (glyceryl trinitrate) infusion. Glyceryl trinitrate is not a sulphonamide. It has the same effect as Frusemide, but takes some minutes to prepare, and therefore can't be used as readily as Frusemide which is pre-prepared and packaged in a vial.

156. By about 12 PM the deceased's condition had improved. Her blood pressure dropped from 235/110 (at 11:30 AM) to 147/80. Her oxygen saturation level had improved from 18% (at 11:40 AM) to 76%.

157. At about 12 PM Dr Familton believed the deceased was sufficiently stabilised for her to be given a chest x-ray in order to visualise the pulmonary oedema. He also took the

[15] Transcript of proceedings on 9 July 2013, Page 102
[16] Transcript of proceedings on 9 July 2013, Page 113

opportunity to call an intensive care consultant at Royal Perth Hospital in order to arrange the deceased's transfer to Royal Perth Hospital and in order to get his advice as to whether there was more Dr Familton could do to assist the deceased.

158. Dr Familton was advised that Mrs Whiteford could be transferred to the intensive care unit at Royal Perth Hospital and that the consultant could think of no further steps Dr Familton could take in order to help the deceased.

159. By about 12:15 PM Dr Familton was able to see the deceased's chest x-rays. The x-rays showed the deceased had pulmonary oedema.

160. At about 12:20 PM Dr Familton called the Royal Flying Doctor Service in order to arrange the transfer of Mrs Whiteford to Royal Perth Hospital.

161. As Dr Familton was speaking to the Royal Flying Doctor Service he was observing the monitors attached to Mrs Whiteford. He saw her cardiac complex change on one of the monitors as she went into cardiac arrest.

162. Dr Familton and members of the nursing staff then tried to resuscitate the deceased. Their efforts continued until about 12:40 PM at which time Dr Familton reluctantly concluded the deceased was beyond resuscitation and had died.

163. On 10 March 2008, a post mortem examination was performed on the deceased by Dr Judith McCreath, a forensic pathologist who, after receiving the results of further investigations on 1 April 2009, determined the cause of death to be '*consistent with anaphylaxis in a woman with atherosclerotic cardiovascular disease and emphysema'.*

164. During the course of the post-mortem examination Dr McCreath found the deceased had emphysema, a condition she was known to have for many years before her death.

165. Dr McCreath also found Mrs Whiteford suffered from severe atherosclerotic cardiovascular disease. Mrs Whiteford was not known to have had heart disease and had not previously shown any symptoms of heart disease. Mrs Whiteford was found to have 70% narrowing of her left anterior descending artery. She had 90% narrowing of the left circumflex artery and 80% narrowing of the right coronary artery.

166. Mr Ley asked Dr McCreath a number of questions relating to the level of arterial occlusion and the fact that the level of occlusion suffered by the deceased could be fatal whether she was at home, or elsewhere, including the hospital[17]:

> Mr Ley: And you said before with somebody with this level of occlusion of their coronary arteries, if they died at home with no other apparent factor you'd say they have died of their coronary artery disease?
>
> Dr McCreath: Yes.
>
> Mr Ley: It could be the same, though, wherever they died, could it not?
>
> Dr McCreath: Oh, certainly, yes.

167. People who die of anaphylaxis sometimes have tell-tale markers which can be identified during post-mortem. These can include swelling in the airways, raised tryptase levels and abnormal swelling. In this case none of those markers were identified. Their absence neither proves nor disproves whether the deceased suffered an allergic response to Diamox.

[17] Transcript of proceedings on 10 July 2013, Page 69

168. The absence of discernible swelling in the deceased's bronchi is likely explicable, at least in part, by the number of anti-inflammatory and bronchodilator medications used by Dr Familton to improve the deceased's ability to breathe after she was returned to the recovery room in a state of collapse. The effectiveness of those medications is demonstrated by the fact that Dr Familton detected audible wheeze when he initially examined the deceased at about 11:30 AM and she had extreme difficulty breathing, but after the introduction of the medications the deceased's breathing dramatically improved.

169. Likewise, the absence of a raised tryptase level is explicable by post mortem decay of the blood sample used to detect tryptase compounded by the four-day delay in taking the sample.

170. Sgt Housiaux explored with Dr McCreath what part of the deceased's lung disease, heart disease and reaction to the drug played in her death[18]:

Sgt Housiaux:	(speaking in relation to Dr McCreath's post-mortem report) You have written here and you have found it to be atherosclerotic cardiovascular disease and emphysema?
Dr McCreath:	Yes.
Sgt Housiaux:	Could you just explain how that can be connected to the anaphylaxis part of your finding?
Dr McCreath:	So, the deceased had severe heart disease, with narrowing of the vessels, and she also had severe lung disease. When someone has these problems any small event can have an additive effect, so it's hard to say exactly what the contribution of the anaphylaxis, the heart disease and the lung disease had. It's probably a combination of all three that has led to her death.

171. She also found evidence of pulmonary oedema, which can be a response to a cardiac arrest or anaphylaxis.

172. Dr McCreath microscopically examined samples of the deceased's heart muscle. According to Dr McCreath '*microscopically there was nothing to show there was an acute heart attac*k'. The absence of detectable changes (dead cells) in the deceased's heart muscle does not necessarily mean the deceased did not suffer a cardiac event. Dr McCreath provided the following explanation in this regard:

> If there is decreased blood supply to the heart muscle, the muscle will stop functioning and then you will start to get signs, you will get pain, et cetera. However, if the blood flow then improves and the muscle starts functioning again and hasn't died, we won't see anything at post-mortem.
>
> … We only see it when the cells die, we will see changes at post-mortem, but that often take survive in the incident longer than an hour or so certainly.

173. A toxicological analysis of samples of the deceased's blood and urine was undertaken by the Chemistry Centre of Western Australia. The analysis of the deceased's blood detected:

- Lignocaine (approximately 0.2 mg/L)
- Ropivacaine (approximately 0.4 mg/L)
- Frusemide (approximately 9 mg/L)

[18] Transcript of proceedings on 10 July 2013, Page 62

174. The analysis of the deceased's urine detected:

- Lignocaine and its metabolite
- Ropivacaine
- Tropicamide
- Frusemide

175. Samples of the deceased's bile, liver and stomach contents were not analysed.

176. The toxicological analysis did not detect a number of medications administered to the deceased including Diamox, adrenaline (a substance which naturally occurs in the body and which is extraordinarily unlikely to be detected), Salbutamol, hydrocortisone, Ventolin and Atrovent or glyceryl trinitrate. The fact the medications were not detected does not mean they were not administered to the deceased.

177. By letter dated 13 July 2010 the senior chemist and research officer who undertook the analysis, Ms Bianca Stevens wrote to the court in relation to the fact Diamox was not detected during the course of the toxicological analysis. Ms Stevens stated that[19] '*a single 250 mg normal-released tablet given orally to 12 healthy young men produced an average peak plasma concentration of 18 mg/L at 2.0 hours'*. Ms Stevens went on to say that the[20] '*plasma drug levels were found to be elevated by 200% in elderly patients, apparently as a result of decreasing renal function'*.

178. The absence of Diamox from the list of medications detected during the course of the toxicological analysis may be explicable for a number of reasons. Ms Stevens, stated[21]:

> The non-detection of acetazolamide (Diamox) could be due to a number of possibilities, these being;
>
> - acetazolamide was not present in the sample, either due to it not being administered to the deceased, or due to it having been eliminated from the blood prior to that blood sample being drawn.
> - acetazolamide was present in the blood sample but at a level below the limit of detection of the strike using routine screening procedures. The limit of detection of acetazolamide in blood using routine screening procedures is 0.6 mg/L which is considerably lower than the anticipated therapeutic concentration, as quoted above.

179. It should also be remembered that unlike the 12 healthy young men referred to by Ms Stevens, the deceased was not a healthy woman. Far from it, before the surgery she was extremely ill and shortly after the administration of the medication she went into a state of collapse, became very unwell and was fighting for life.

180. Dr McCreath explained that a medication which has been swallowed in the form of a pill may not be absorbed if the patient becomes unwell. Dr McCreath said [22] '*once someone is very unwell they will stop absorbing drugs too. The blood flow diverts from the stomach to where it's needed, the brain, the heart, so anything that was in her stomach isn't going to be digested'.*

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[19] Exhibit 1 Tab 8
[20] Exhibit 1 Tab 8
[21] Exhibit 1 Tab 8
[22] Transcript of proceedings on 10 July 2013, Page 74

181. Given the deceased's extremely poor health it is likely the deceased only needed a mild insult to her system before she became extremely unwell. It is probable the deceased swallowed the Diamox tablet, absorbed a small quantity of the drug, which resulted in an allergic reaction which caused her to collapse. She then ceased absorbing any more of the medication as her blood flow was diverted elsewhere. It is probable the deceased's collapse occurred at a time when the level of Diamox in her system was below that which was detectable by the Chemistry Centre of Western Australia.

182. Under Dr Familton's care the deceased began to recover from the allergic response. However at about 12:23 PM she suffered a cardiac event which resulted in a further collapse and her death.

The nature of the deceased's allergic reaction.

183. Dr Familton believed that when he saw the deceased in the recovery room after her collapse in the ward she was having a reaction to the Diamox. In this context Dr Familton said[23]:

> Well, I was told that Diamox has got a reputation for causing very rare, but catastrophic problems. The timeline suggests that. The findings of my examination suggested an allergic reaction was anaphylaxis, like I say I don't like the word. It was a severe reaction to the drug.

184. Whilst I am satisfied the deceased took Diamox and it caused the reaction noted by Dr Familton, I do not know whether the reaction was a true allergic reaction or an idiosyncratic response to the medication.

185. I am uncertain in this regard because I do not know, just as Dr Stewart did not know, whether Mrs Whiteford was allergic to antibiotic sulphonamides, non-antibiotic sulphonamides or all sulphonamides.

186. It is likely Mrs Whiteford was allergic to antibiotic sulphonamides.

187. It was known that Mrs Whiteford was allergic to Bactrim (which contains an antibiotic sulphonamide; sulfamethoxazole and a different type of antibiotic, trimethoprim).

188. According to the West Australian Therapeutic Advisory Group [24] when hypersensitivity to this preparation occurs it may be to the sulfamethoxazole or to trimethoprim or to both medications. The deceased's medical notes did not provide an answer as to which of the medications found in Bactrim the deceased was allergic to.

189. The deceased's recorded allergy to Bactrim is suggestive of an allergy to an antibiotic sulphonamide, but not conclusive of this view.

190. Mrs Whiteford's hospital notes relating to her earlier admissions into the hospital recorded her allergies as '*Sulphas, Bactrim, Klacid*' or various combinations of one, two or all three of the words. The conjoint use of the words *Sulphas* and Bactrim, seem to suggest the deceased was not only allergic to Bactrim, but to some other form of sulphonamide as well.

191. Dr Familton recalled speaking to Mrs Whiteford about her allergy during the course of his pre-anaesthetic consultation with the deceased on 6 March 2008. During the course of the consultation Mrs Whiteford told him she had an allergy to *Sulphas*.

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[23] Transcript of proceedings on 9 July 2013, Page 127
[24] Exhibit 1 Tab 18

192. Mr Ley asked Dr Familton a number of questions relating to the allergy during the course of his cross-examination [25]:

> Dr Familton: (speaking about her allergy to *Sulphas*) She told me that she got rashes with it. I didn't write that down but, you know, it's something which I did, you know I do actually remember she told me.
>
> Mr Ley: And that's a common – that's a common reaction?
>
> Dr Familton: Very common with the sulphonamide antibiotics.
>
> Mr Ley: But not the only reaction though, is it?
>
> Dr Familton: No.
>
> Mr Ley: And one of the other ones is swelling of the airways?
>
> Dr Familton: Absolutely.
>
> Mr Ley: Are there others as well?
>
> Dr Familton: You can die from it.
>
> Mr Ley: Yeah. Is that because of the constriction?
>
> Dr Familton: Yeah, it's it's probably due to that and it's really sort of the allergic – it's the anaphylaxis in the true sense which would cause that.

193. Mrs Whiteford's comment to Dr Familton is suggestive of the deceased having an allergy to antibiotic sulphonamides.

194. The comment does not negate the possibility Mrs Whiteford had an allergy to non-antibiotic sulphonamides

195. The manufacturer of Diamox produces product information for the benefit of prescribers and others interested in knowing about the qualities of the medication.

196. The product information sheet relating to Diamox[26] (properly known as acetazolamide), states that acetazolamide (Diamox) is contraindicated in the presence of hypersensitivity to sulphonamides, or sulphonamide derivatives, or any excipients in the formulation. The manufacturer notes that cross sensitivity between acetazolamide (Diamox), sulphonamides and other sulphonamide derivatives is possible.

197. The product information sheet states the risks and consequences the manufacturer believes may arise in situations where Diamox (acetazolamide) is given to a person who has a hypersensitivity to sulphonamides, or sulphonamide derivatives. The product information sheet states[27]:

> **Hypersensitivity**
> Fatalities have occurred, due to severe reactions to sulfonamides and sulphonamide derivatives, including acetazolamide. Adverse reactions common to all sulfonamide derivatives may occur: fever, rash (including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis), fulminant hepatic necrosis, agranulocytosis, aplastic anaemia and other blood dyscrasias, anaphylaxis, renal and ureteral colic and renal lesions (see also **ADVERSE REACTIONS**).
>
> Serious and occasionally fatal hypersensitivity (anaphylactic/anaphylactoid [including shock]) reactions have been reported in patients receiving acetazolamide.

[25] Transcript of proceedings 9 July 2013 – Page 111
[26] Exhibit 9 Page 2
[27] Exhibit 9 Pages 2 – 3

> Hypersensitivity reactions may recur if a sulfonamide or sulfonamide derivative is re-administered, irrespective of the route of administration. The drug should be discontinued and appropriate therapy instituted if such reactions are detected.

198. Dr Stewart was aware the manufacturer believed the use of Diamox was contraindicated in situations where a person had a sulphonamide allergy. Dr Stewart believed[28]:

> Drug manufacturers tend to be extraordinarily conservative about their recommendations and I believe this is probably because the risk of litigation in the United States and am also aware that Diamox is used successfully with extremely rare complications.

199. I asked Dr Stewart questions about using Diamox in a situation where the manufacturer believed it to be contraindicated[29]:

Coroner:	You spoke of your knowledge in relation to Diamox being contraindicated by the manufacturers of the medication and you put that down to the timidity to litigation?
Dr Stewart:	Yes.
Coroner:	If the manufacturers are timid of litigation or timid of adverse reactions, doesn't it behove the surgeon to share that degree of caution?
Dr Stewart:	One would have (to) exercise a degree of caution, but I think – I weighed up at the time the risks of damage to the eye following successful surgery from a spike in pressure which potentially could obstruct the artery – central artery to the optic nerve and obliterate her vision were infinitely greater than any risks from Diamox which are reported to be extremely rare.
Coroner:	All right. But you took that decision and made that judgement in the absence of knowledge that the deceased, in fact, had a sulphur allergy?
Dr Stewart:	That is true, but I believe that – I believe more firmly now, having read recently since these issues have come up, that there is probably no – almost certainly no relationship between the sulphonamide antibiotics and other sulphonamide non-antibiotic drugs. There is no cross reaction and any reaction to Diamox would be an idiosyncratic one which would be unforeseeable.

200. Despite the manufacturers clear statement that Diamox is contraindicated in any situation where a person has an allergy or hypersensitivity to a sulphonamide, there is debate within the scientific and medical communities as to whether a person with an allergy to a non-antibiotic sulphonamide will have an allergic reaction if he or she consumes an antibiotic sulphonamide.

201. The most recent and authoritative statement of thought in relation to the nature of allergic reactions to sulphonamides was published by the Western Australian Therapeutics Advisory Group (WATAG). In 2010 they published a Medication Safety Alert entitled *'Allergies To Sulphonamide Antibiotics And Cross-Reactivities'* [30].

202. The WATAG medication safety alert highlighted the fact that antibiotic sulphonamides contain an arylamine group which is commonly associated with allergies and hypersensitivity issues.

203. The WATAG medication safety alert highlighted the fact that those with an allergy or hypersensitivity to an antibiotic sulphonamide should not be treated with another form

[28] Transcript of proceedings of 10 July 2013, Page 14
[29] Transcript of proceedings of 10 July 2013, Pages 14 – 15
[30] Exhibit 1 Tab 18

of antibiotic sulphonamide because there is a substantial risk of allergic cross-reactivity between the different types of antibiotic sulphonamides.

204. WATAG believe that no cross-reactivity would be expected between antibiotic sulphonamides and non-antibiotic sulphonamides. Therefore non-antibiotic sulphonamide drugs are generally not considered as contraindicated in those with a history of hypersensitivity to antibiotic sulphonamides.

205. The WATAG safety alert said that a small number of cases of possible cross-reactivities have been reported, these appear due to allergic susceptibility of the patient rather than a true cross-reactivity. In these cases WATAG believes an idiosyncratic response leads to the patient's reaction rather than a true allergic response.

206. If one accepts the view espoused by the WATAG over the view taken by the manufacturer, the position seems to be that if Mrs Whiteford's allergy to *Sulphas* was to both antibiotic and non-antibiotic sulphonamides, then the use of Diamox was contraindicated and likely to result in an allergic reaction.

207. If Mrs Whiteford's allergy to *Sulphas* was limited to non-antibiotic sulphonamides, then the prescription of another non-antibiotic sulphonamide like Diamox, was contraindicated and likely to lead to an allergic reaction.

208. If Mrs Whiteford's allergy to *Sulphas* was limited to antibiotic sulphonamides then Dr Stewart's decision to administer a non-antibiotic sulphonamide, Diamox, was not likely to result in an allergic reaction, however in rare cases it may lead to an idiosyncratic reaction.

209. The deceased's medical notes which speak of her allergy to *Sulphas* did not record whether her allergy to *Sulphas* was limited to antibiotic sulphonamides, non-antibiotic sulphonamides or both types of sulphonamides.

210. In evidence Dr Stewart stated his belief that there is almost certainly no relationship between the sulphonamide antibiotics and other non-antibiotic sulphonamide drugs. He believed that any reaction the deceased had to Diamox would be an unforeseeable idiosyncratic response.

211. Unfortunately, it is simply not known whether her allergy was to all forms of sulphonamides or to only antibiotic sulphonamides or to only non-antibiotic sulphonamides.

212. I think Dr Stewart's belief would be reasonable if Mrs Whiteford's allergy was confined to antibiotic sulphonamides and if her state of health had not been so poor as to only require a relatively minor insult before she suffered a severe reaction.

213. I think it likely that had Dr Stewart been aware of Mrs Whiteford having any allergy to any form of sulphonamide he would have acted differently. In this regard Dr Stewart wrote to Sgt Housiaux (who acted as counsel assisting during the course of the inquest) by letter dated 17 November 2009, and said what he would have done had he known of the deceased's allergy to sulphonamides. Dr Stewart said[31]:

> *Whether or not I would have prescribed Diamox in the knowledge of a sensitivity to sulphonamides is unclear to me, because to my knowledge there is uncertainty about*

[31] Exhibit 1 Tab 11

> *any such relationship. I would have been cautious given that reactions have been reported.*

214. Prof Ian Constable of the Lions Eye Institute provided an opinion to the court[32], in which he adopted the reasoning of the WATAG in relation to the cross-reactivity of antibiotic and non-antibiotic sulphonamides. During the course of his report he said:

> Many ophthalmic surgeons would follow the advice of the product insert and not prescribe Diamox in somebody with a sulphur allergy but as pointed out above the logic of this advice is debatable. On the sole basis that the risk of an allergic reaction to Diamox is increased in anyone that has had any previous allergic reaction to any other unrelated drugs, I would still want to follow the advice personally.

215. I think Prof Constable's approach has much to recommend it, particularly given the very poor state of Mrs Whiteford's health at the time she was undergoing the cataract surgery.

Comments

216. Mrs Whiteford was well cared for by nursing staff employed by Northam Hospital. They took care to admit Mrs Whiteford on the day prior to her operation. They correctly identified she had an allergy to *Sulphas*.

217. The fact of the allergy was recorded throughout the documents relating to Mrs Whiteford's admission for cataract surgery.

218. The fact of Mrs Whiteford's allergy to *Sulphas* was recorded on and throughout her Northam Hospital file. Seven documents relating to the deceased's operation on 6 March 2008 expressly recorded her allergy to *Sulpha*s. These documents were:

- the outer cover of her Northam Hospital file
- the surgical pre-admission assessment form
- the short stay medical admission form
- the eye medication therapy chart
- the medication chart
- the 24 hour interim medication chart; and,
- the operation record

219. Having identified Mrs Whiteford as a person with a known allergy to a medication Nurse Edwards took the appropriate step and issued her with a red wristband which was intended to alert medical and nursing staff to the fact of the allergy.

220. After the deceased took the Diamox tablet and went into a state of collapse Nurse Nind, together with other nurses, worked with Dr Familton in order to try and save Mrs Whiteford's life. Regrettably their considerable efforts were unsuccessful and Mrs Whiteford died.

221. Northam Hospital has taken steps to improve its processes in order to ensure that doctors who are about to perform surgery are, unambiguously, aware of a patient's allergy. The hospital has made a change to the team timeout process, which takes place immediately before surgery is about to commence. The team timeout process has been enhanced by

[32] Exhibit 1 Tab 12

making it obligatory for all of those involved in the surgery, including the surgeon, to acknowledge the fact of an allergy before the surgery can commence. This is a significant improvement which in my opinion will enhance patient safety at Northam Hospital.

222. The improvement goes a long way to ensuring the surgeon is aware of an allergy however it does not necessarily provide a definitive answer as to the nature of the allergy or assist the surgeon with making his or her determination as to whether it is safe to prescribe a particular type of sulphonamide where there is a known allergy to *Sulphas*. The patient may be allergic:

- to all sulphonamides; or,
- to an antibiotic sulphonamide; or,
- to a non-antibiotic sulphonamide; or,
- to the non-sulphonamide component of a medication such as Bactrim, which is described as a *Sulpha*.

223. This case highlights the need for precision when describing a patient's allergy. The term *Sulphas* is not sufficiently precise to provide a nurse, doctor or surgeon with sufficient information as to the nature of the allergy.

Recommendation One

I recommend the Director-General of Health circulate a directive to all nurses, doctors and surgeons employed by the Department of Health at Northam Hospital to remind and require them to appropriately record the precise nature of each patient's known allergy to medications, in order to ensure the precise nature of the allergy is known to the prescriber of any subsequent medication.

224. In this case Mrs Whiteford was placed in unnecessary risk as her surgeon:

i. had not read her hospital file.

ii. was unaware of her allergy to *Sulphas* (and other substances) and the fact she was an asthmatic.

iii. was unaware of the significance of his patient wearing a red wristband.

225. The Department of Health has a long-standing practice of using red alert bracelets for patients with a known allergy. The policy applies to all Western Australian public hospitals and to all patients treated in public hospitals, except mental health inpatients. The policy requires the use of a red alert bracelet for inpatients with a known allergy including, but not exclusive to, drugs, food, lotions and latex.

226. The use of a red alert bracelet is a requirement under a quality improvement strategy aimed at addressing safety and quality issues associated with medication management. The strategy is known as the National Inpatient Medication Chart.

227. On 10 July 2006, Dr Neale Fong, the director-general of the Department of Health, issued an operational circular[33] to all Department of Health staff employed as:

[33] Exhibit 1, Tab 22, Sub Tab 2

- clinicians (medical, nursing, midwifery, pharmacy and allied health staff);
- relevant clerical and ward staff (including ward clerks and catering staff); and
- quality/clinical governance coordinators.

228. The operational circular reminded all the relevant employees[34]:

> The purpose of placing a red alert bracelet on a patient's wrist and/or ankle is to prompt health service staff to seek further information from the patient's notes about the known allergen. The absence of a red alert bracelet should not be used as certainty that the patient has no known allergies. Clinical staff (medical, nursing, allied health and pharmacy staff) should confirm allergy information regularly.

229. Dr Stewart was not an employee of the Department of Health or Northam Hospital and consequently he did not receive a copy of the operational circular. When asked about his knowledge of the red alert bracelet Dr Stewart said[35]:

> I don't recall being made aware of it in 2006 or subsequently specifically at any stage. I can't recall when I became aware of there – the significance of a red wristband.

230. Northam Hospital had no system in place which set the minimum standards which doctors and surgeons, not employed by the Department of Health, were required to adopt before being allowed to operate in the public hospital.

231. In my opinion patients treated in Northam Hospital should not be placed at risk by doctors or surgeons, who are not employed directly by the Department of Health, who are unaware of important information and procedures which enhance patient safety and which have been adopted by the hospital.

Recommendation Two

I recommend the Director-General of Health develop a protocol which mandates the minimum acceptable standards of practice which doctors and surgeons, not employed by the Department of Health, agree to adopt before being allowed to practice in Northam Hospital.

These protocols should highlight, to the physician, the existence of any protective procedures or systems such as the wearing of a red identity wristband which signify the wearer as suffering from a known allergy including an allergy to a medication.

Conclusion

232. On the evidence available to me I am satisfied Mrs Whiteford underwent cataract surgery on her left eye in Northam Hospital on 6 March 2008.

233. Following the surgery the deceased was given 250 mg of Diamox to reduce post-operative intraocular pressure.

[34] Exhibit 1, Tab 22, Sub Tab 2, Page 1
[35] Transcript of proceedings of 10 July 2013, Page 33

234. The deceased suffered a severe reaction to the drug and later died, the cause of death being consistent with anaphylaxis in a woman with atherosclerotic cardiovascular disease and emphysema.

235. I find death arose by way of Misadventure.

DH Mulligan
Coroner
24 September 2013