

IN THE CORONERS COURT

OF VICTORIA

AT MELBOURNE

Court Reference: COR 2014 5930

# FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)

Section 67 of the Coroners Act 2008

Findings of:	Paresa Antoniadis Spanos, Coroner
Deceased:	Matthew John George
Date of birth:	26 March 1969
Date of death:	22 November 2014
Cause of death:	Global cerebral hypoxia following cardio-respiratory collapse due to anaphylaxis following administration of flucloxacillin in a man with diabetes mellitus, widespread sepsis and ischaemic heart disease
Place of death:	Malvern, Victoria

I, PARESA ANTONIADIS SPANOS, Coroner,

having investigated the death of MATTHEW JOHN GEORGE without holding an inquest:

find that the identity of the deceased was MATTHEW JOHN GEORGE

born on 26 March 1969

and that the death occurred on 22 November 2014

at Cabrini Private Hospital, 181-183 Wattletree Road, Malvern, Victoria, 3144

## from:

1 (a) GLOBAL CEREBRAL HYPOXIA FOLLOWING CARDIO-RESPIRATORY COLLAPSE DUE TO ANAPHYLAXIS FOLLOWING ADMINISTRATION OF FLUCLOXACILLIN IN A MAN WITH DIABETES MELLITUS, WIDE SPREAD SEPSIS AND ISCHAEMIC HEART DISEASE

Pursuant to section 67(1) of the *Coroners Act 2008*, I make findings with respect to the following circumstances:

## Background

- 1. Matthew John George was a 45-year-old musician who lived in Cheltenham. He is survived by his parents, Allan and Kay George.
- 2. Mr George had a medical history of poorly controlled diabetes with complications including blindness in his left eye, asthma and renal impairment. From about 2004, he suffered recurrent lower limb infections that led to multiple hospital admissions for antibiotic therapy and surgical procedures, including amputation of toes on the left foot and a right below knee amputation. During those admissions, Mr George was treated with multiple courses of a variety of antibiotics, some of which caused a rash.

## Circumstances immediately proximate to death

3. Late on 12 November 2014, Mr George presented to the Emergency Department (ED) of Cabrini Hospital complaining of nausea and vomiting and feeling warm. Tests conducted by his general practitioner the previous day revealed a raised white cell count suggesting an infective process. The lateral left side of his foot was swollen, and an area of cellulitis was noted. A foot swab was sent to microbiology for investigation. Mr George was also found to be hyperglycaemic with a blood sugar

level of 29mmol/Litre and treatment was initiated to correct this. A degree of renal impairment was also noted.

- 4. ED physicians arranged for blood cultures and commenced antibiotic therapy with meropenem<sup>1</sup>. It was noted at the time that Mr George was <u>allergic to vancomycin</u>, <u>cephazolin, ciprofloxacin and penicillin</u>. Mr George was admitted to the ward with a diagnosis of sepsis, acute/chronic renal failure and unstable diabetes.
- 5. Dr Leon Chapman, a consultant physician in general medicine with a sub-speciality in diabetes, reviewed Mr George on 13 November 2014 and <u>discussed his antibiotic allergies</u>. Mr George stated that he had never had any rash or severe reaction in relation to any antibiotic but following administration of <u>intravenous (IV) antibiotics in hospital, he would develop an itch after several days</u>. Dr Chapman requested an opinion from an Infectious Diseases (ID) physician to identify an appropriate antibiotic to administer on this occasion.
- 6. Dr David Sheffield, ID physician, reviewed Mr George that day. Mr George provided a history of feeling increasingly unwell for the past month with lowered energy levels and a decreased ability to walk. A purulent discharge was emanating from a sinus in his left foot. Dr Sheffield's initial impression was that Mr George had a diabetic foot infection with probable osteomyelitis and possible septicaemia leading to septic arthritis.
- 7. Dr Sheffield had a <u>detailed discussion with Mr George about his past adverse</u> reactions to antibiotics. Mr George was <u>unsure which antibiotics he was allergic to</u>. He could not recall ever having had a reaction to an oral antibiotic. Nor could he recall ever having any immediate reactions to antibiotics. Dr Sheffield decided that Mr George should <u>remain on his current antibiotic</u>, meropenem until the microbiological and blood culture test results were available and that he should also await <u>review by a vascular surgeon</u>, which had already been arranged. He also suggested that Dr Chapman may wish to arrange an <u>orthopaedic review</u> of Mr George's elbow, as septic arthritis requires aspiration.
- 8. Considering Mr George's reported history of multiple drug allergies, the specifics of which were unknown, Dr Sheffield reviewed Mr George's medical records from

<sup>&</sup>lt;sup>1</sup> A broad-spectrum beta lactam antibiotic in the carbapenem sub-group.

<u>Cabrini Hospital</u> and noted that he had a <u>documented history of adverse reactions to</u> <u>multiple medications in the context of co-administration of multiple medications</u> <u>simultaneously</u>. Dr Sheffield <u>contacted Knox Private Hospital</u> (Knox Private) and asked them to fax any additional information about Mr George's antibiotic allergies and past infections when admitted there.

- 9. On 14 November 2014, Mr George went to theatre for left foot wound debridement and the next day for a washout of a septic right elbow and application of a vacuum dressing.
- 10. On 14 and 15 November 2014, the pathology laboratory advised Dr Sheffield that multiple blood cultures were positive for *Staphylococcus aureus*, which suggested Mr George had a potentially serious life-threatening septicaemia or deep-seated infection. As Mr George (and his medical notes) were in the operating theatre on 15 November 2014, Dr Sheffield was unable to review him.
- 11. However, Dr Sheffield and Dr Chapman spoke on the telephone that day and discussed the complexities of Mr George's situation and the options for his ongoing management. Dr Sheffield outlined the outcomes of his review of Mr George's medical history and <u>raised the possibility that flucloxacillin</u> could be considered as a possible future treatment because it appeared that Mr George had previously been administered a penicillin (Timentin) on at least two occasions without an obvious adverse reaction. Dr Chapman recalled that following that verbal advice from Dr Sheffield, he did not alter Mr George's antibiotic management. Overnight, Mr George experienced two temperature spikes.
- 12. On 16 November 2014, Dr Chapman saw Mr George during morning rounds. His temperature was settling, and he had decreased elbow pain post-drainage. However, Mr George had been on meropenem for 72 hours with no improvement in his white cell count and the overnight fevers suggested septicaemia, as did the recent formation of a new abscess in the elbow.
- 13. By this time, the records from the earlier <u>Knox Private</u> admission were available. Dr Chapman reviewed those records and noted that Mr George had suffered <u>a rash as an</u> <u>apparent reaction to one of three antibiotics given to him in 2006 (Flucloxacillin,</u> <u>Clindamycin and Cephazolin) and that he had tolerated Timentin</u>.

- 14. Dr Chapman made an order for flucloxacillin and Mr George was <u>administered 1mg of IV flucloxacillin at about 8.40am<sup>2</sup></u> while Dr Chapman was elsewhere on the general ward. A nurse was in attendance for frequent observations. <u>Almost immediately, Mr George felt itchy, nauseous and began vomiting</u>. Dr Chapman was contacted, and he ordered IV hydrocortisone with 100mg being administered. At about 8.58am, 1mg IV adrenaline was administered followed by 3mg at 9.00am. There was an associated drop in blood pressure and oxygen saturations with a Medical Emergency Team (MET) code called at 8.59am.
- 15. Oxygen was administered at a rate of 10 litres/minute via mask with oxygen saturations improving to 91%. Mr George had a pulseless electrical cardiac arrest (PEA) and cardiopulmonary resuscitation (CPR) was commenced. Mr George was intubated and underwent two cycles of CPR with a further 2mg of IV adrenaline. Further IV adrenaline boluses of 0.5-1.0mg were given to maintain his blood pressure. His total downtime was estimated to be between 15 and 20 minutes.
- 16. Mr George was transferred to the Intensive Care Unit (ICU). Tryptase levels<sup>3</sup> were within the normal range and remained so when checked at 1.20pm.
- 17. On 21 November 2014, significantly raised IgE levels<sup>4</sup> supported a clinical diagnosis of anaphylaxis following the IV administration of flucloxacillin. There was evidence of seizure activity with a poor neurological recovery from the period of hypoxia. Considering Mr George's extremely poor prognosis, active treatment was withdrawn, and he was kept comfortable until he passed away on 22 November 2014.

## Medical cause of death

18. On 25 November 2014, Professor Stephen Cordner, from the Victorian Institute of Forensic Medicine (VIFM), reviewed the circumstances of the death as reported by police to the Coroner and the e-medical deposition from Cabrini Private Hospital and performed an autopsy on the body of Mr George in the mortuary.

<sup>&</sup>lt;sup>2</sup> Which was administered slowly over a ten-minute period and completed at about 8.55am.

<sup>&</sup>lt;sup>3</sup> The clinical diagnosis of anaphylaxis can sometimes be supported by documentation of elevated concentrations of serum or plasma total tryptase or plasma histamine. The standardized assay for measurement of total serum or plasma tryptase is widely available in clinical laboratories (normal range 1 to 11.4ng/mL. However, a tryptase level that is within normal limits cannot be used to refute the clinical diagnosis of anaphylaxis.

<sup>&</sup>lt;sup>4</sup> Immunoglobulin E.

- 19. Prof Cordner found evidence of significant natural disease processes. The left anterior descending artery was almost completed occluded with patchy occlusion of the left circumflex of 40 to 50 percent. The right coronary artery was occluded up to 30 to 40 percent. A histological examination of the heart found marked fibrosis, severe coronary atherosclerosis, with one section of the left anterior descending coronary artery showing a sub-total occlusion of the vessel by a fresh thrombus.
- 20. Prof Cordner noted a clinical consensus that Mr George had suffered an anaphylactic reaction to an intravenous dose of flucloxacillin, which resulted in cardio-respiratory collapse. Tryptase and IgE testing were generally supportive of the clinical diagnosis, but Prof Cordner commented that anaphylaxis is best thought of as a clinical diagnosis as blood tests are not particularly sensitive.
- 21. The evidence of ischaemic heart disease (a common form of heart disease that is more common in those with diabetes), may have aggravated Mr George's recovery from the anaphylaxis. The collapse resulted in generalised cerebral hypoxia, that is brain damage because of reduced blood supply and therefore reduced oxygen availability to the brain.
- 22. Routine toxicological analysis of post-mortem samples detected several drugs consistent with hospital administration in the palliative setting including anti-seizure medications levetiracetam and phenytoin, metoclopramide, pantoprazole and metronidazole.
- 23. Prof Cordner attributed Mr George's death to global cerebral hypoxia following cardio-respiratory collapse due to anaphylaxis following administration of flucloxacillin in a man with diabetes mellitus, widespread sepsis and ischaemic heart disease.
- 24. He explained that the term 'widespread sepsis' was intended to include foot sepsis, septic arthritis and the possibility of septicaemia. He further commented that it was clear that the management of Mr George's overall condition was very complicated, even more so because of the nature of his drug allergies in the context of the serious nature of his illness.
- 25. Prof Cordner cautioned that he was not the treating clinician, did not intend to make any clinical judgments and his conclusion that Mr George died because of an

anaphylactic reaction to flucloxacillin ought not be construed as a judgment about the decision to administer the drug or the circumstances in which the drug was administered.

## Sources of evidence and the coronial investigation

- 26. This finding is based on the totality of the material the product of the coronial investigation of Mr George's death. That is, the brief of evidence compiled by Leading Senior Constable Remo Antolini, from the Police Coronial Support Unit (PCSU), further statements, hospital policies and protocols, an expert immunologist's report, the transcript of the mention hearing and the final submissions of the interested parties.
- 27. On 22 June 2017, I held a mention hearing to invite submissions about the need for an Inquest and to settle a discrepancy in the evidence of Dr Chapman and Dr Sheffield in relation to the decision to trial Mr George on flucloxacillin.
- 28. None of the interested parties sought an inquest and I determined that the coronial investigation could be finalised 'on the papers' with the factual discrepancy in the evidence of Drs Chapman and Sheffield to be addressed via the production of further statements clarifying their evidence in relation to their discussions and the decision to administer flucloxacillin.

## The evidence of Dr Chapman and Dr Sheffield

- 29. Over the course of the coronial investigation, Dr Chapman provided three statements to the Court as well as making submissions through his Counsel. In his <u>initial</u> <u>statement dated 23 June 2015</u>, Dr Chapman's evidence was that he discussed Mr George's possible history of multiple antibiotic allergies with Dr Sheffield, but as there was a questionable history of any serious reaction, a decision was taken for IV flucloxacillin to be trialled.
- 30. In his <u>supplementary statement dated 24 July 2017</u>, Dr Chapman clarified that he spoke to Dr Sheffield initially on 13 November 2014 and again on 15 November 2014, at which point they discussed the complexities of Mr George's situation and the options for his ongoing management, with flucloxacillin as a possible future treatment.

- 31. He also stated that on 16 November 2014, he spoke to Dr Sheffield and they agreed to change the antibiotics to flucloxacillin, delivered intravenously at a dose of 1 gram every six hours, under observation. Dr Chapman explained that he specifically noted the agreed change in the medical records, and that he would not make such an annotation without agreement from the ID specialist he was consulting.
- 32. However, it was the evidence of Dr Sheffield in his statement dated 31 July 2015 that following review of Mr George on 13 November 2014, his plan was to continue meroprenam until the outcome of microbiological testing was known. On 15 November 2014, Dr Sheffield spoke to Dr Chapman and raised the possibility that flucloxacillin be considered as a possible future treatment. Dr Sheffield specifically recalled telling Dr Chapman that he would review Mr George again on 16 November 2014 and form a plan about when, how or if a trial of flucloxacillin should be considered. That was because he was still waiting to see the medical records from Knox Private Hospital and had not yet been apprised of the operative findings or operative procedures. Dr Sheffield specified that he would ordinarily base his clinical decision-making on such findings.
- 33. Dr Sheffield submitted a <u>supplementary statement</u> to the Court dated <u>24 August 2017</u> and remained firm that he did not administer or recommend the administration of flucloxacillin on 16 November 2014. He noted that Dr Chapman indicated he documented in Mr George's medical record that he had advised him to change Mr George's antibiotics to 1g flucloxacillin four times a day. Dr Sheffield disputed that this occurred and maintained that he <u>planned to review Mr George's medical records from Knox Private before he made a final decision about changing his antibiotic.</u>
- 34. Dr Sheffield also stated that he was <u>not aware of Dr Chapman's decision to</u> <u>commence Mr George on flucloxacillin on the morning of 16 November 2014 and</u> <u>that his advice was not sought about the timing, dose or precautions necessary prior to</u> <u>a penicillin challenge.</u> Indeed, had the decision been made to commence flucloxacillin, Dr Sheffield stated that he would have administered it in a completely different manner (including a penicillin challenge) and dosage, and would have remained with Mr George to monitor his response. Had that occurred, he would also have comprehensively documented his clinical rationale in the same way that he did at his initial review of Mr George on 13 November 2014.

- 35. In response to the supplementary statement of Dr Sheffield, in submissions, <u>Dr</u> <u>Chapman accepted Dr Sheffield's recollection of their final clinical discussion over</u> <u>the telephone, which likely occurred on 15 November 2014</u>. Dr Chapman acknowledged that they discussed the fact that flucloxacillin would be ideal for Mr George but for his possible allergy, that Mr George's past tolerance of Timentin tended to make a flucloxacillin allergy less likely and confirmed that Dr Sheffield did not explicitly advise or recommend the administration of flucloxacillin.
- 36. Dr Chapman did not recall discussing a course of desensitisation with Dr Sheffield or the notion of not taking any further step until further discussion and chose to make no submissions on that subject. Accordingly, Dr Chapman submitted there were no outstanding issues of fact between himself and Dr Sheffield.
- 37. To the extent of inconsistency, I prefer Dr Sheffield's recollection of events.

## **Coroners Prevention Unit**

- 38. As part of the coronial investigation of Mr George's death, I asked a clinician from the Health and Medical Investigation Team (HMIT) to review the clinical management and care provided to him during his last admission to Cabrini Hospital. The HMIT is part of the Coroners Prevention Unit (CPU), which was established in 2008 to strengthen the prevention role of the Coroner.<sup>5</sup>
- 39. The HMIT clinician noted that <u>Mr George's blood cultures tested positive for</u> <u>staphylococcus aureus</u>, indicative of life-threatening infection with possible deeper infection elsewhere such as endocarditis or osteomyelitis.
- 40. Furthermore, following the administration of flucloxacillin, Mr George experienced an anaphylactic reaction. Anaphylaxis is a serious allergic reaction that is rapid in onset and may cause death. Fatal anaphylaxis can occur following a variety of triggers, although the most common triggers are medications, foods and insect stings. The most common medication triggers are Beta-lactam antibiotics<sup>6</sup>.

<sup>&</sup>lt;sup>5</sup> The CPU assists the Coroner to formulate prevention recommendations and comments and monitors and evaluates their effectiveness once published. The HMIT is staffed by practising physicians and nurses who are independent of the health professionals or institutions involved. They assist the Coroner's investigation of deaths occurring in a healthcare setting by evaluating the clinical management and care provided and identifying areas of improvement so that similar deaths may be avoided in the future.

<sup>&</sup>lt;sup>6</sup> Penicillin and cephalosporin antibiotics

- 41. Most anaphylaxis episodes are triggered through an immunologic mechanism involving immunoglobulin (IgE). Anaphylaxis is not always easy to recognise clinically with the sudden onset of signs and symptoms from one minute to many hours following exposure. The patterns of organ involvement are variable and may differ among individuals, as well as among episodes in the same individual.
- 42. It is important to recognise anaphylaxis in its earlier stages because once shock has developed, anaphylaxis may be much more difficult to treat. Many of the dramatic physical signs associated with hypoxia and hypotension in anaphylaxis are non-specific, such as shortness of breath, stridor, wheeze, confusion, collapse, unconsciousness and incontinence.
- 43. The HMIT clinician noted that co-morbidities and concurrent medications may impact the severity of symptoms and signs and response to treatment in patients with anaphylaxis. <u>Asthma and cardiovascular disease are the most important risk factors</u> for a poor outcome from anaphylaxis.
- 44. There are several anaphylaxis guidelines, all of which are consistent as regards initial first aid required. Initial attention is paid to the airway, breathing and circulation, followed by removal of the antigen (that is removal of the IV infusion of the suspect medication), call for help and lay the person flat. Supplemental oxygen, eight to ten litres by mask, up to 100 percent should be administered along with volume resuscitation by the administration of IV fluids.
- 45. The HMIT clinician advised that intramuscular (IM) adrenaline<sup>7</sup> is the drug of choice in anaphylaxis, with an immediate IM injection into the mid-lateral thigh. It is the only medication that prevents or reverses obstruction to airflow in the upper and lower respiratory tracts and prevents or reverses cardiovascular collapse. Intramuscular injection is recommended over subcutaneous injection because it consistently provides a more rapid increase in the plasma and tissue concentrations of epinephrine. If symptoms are severe, an intravenous adrenaline infusion should be prepared.
- 46. It appears that the consensus that has developed over the last few decades is that even mild systemic reactions are best treated immediately with IM adrenaline as this

<sup>&</sup>lt;sup>7</sup> 300-500 micrograms per dose, up to three doses 20 minutes apart to a maximum dose of 1mg

appears to prevent progression to more severe symptoms more effectively than any other available therapies.<sup>8</sup> Accordingly, successive guidelines for treatment of immunotherapy reactions have called for IM adrenaline to be administered as soon as a systemic reaction of any severity is detected.

- 47. The HMIT clinician commented that anaphylaxis can unmask subclinical coronary artery disease, myocardial infarction and/or arrhythmias and considered it plausible that these co-morbid conditions directly contributed to the fatal outcome, noting that the heart and lungs are the primary shock organs in anaphylaxis and could be expected to fail more readily if compromised by pre-existing disease. Moreover, myocardial infarction and/or cardiac arrhythmias can occur during anaphylaxis, even if adrenaline is not injected. Indeed, anaphylaxis itself is known to cause vasospasm, arrhythmias and myocardial infarctions in patients (including children) with healthy hearts.
- 48. An overdose of adrenaline may lead to ventricular arrhythmias, angina, myocardial infarctions, pulmonary oedema, a sudden increase in blood pressure and intracranial haemorrhage. These serious adverse effects most commonly occur after an IV bolus injection or an overly rapid IV infusion, particularly in patients who do not have continuous blood pressure and heart rate and function monitoring.<sup>9</sup>
- 49. The HMIT clinician noted that noted that Dr Chapman prescribed flucloxacillin following an apparently misunderstood telephone conversation with Dr Sheffield and that it was administered intravenously <u>on a Sunday morning</u> when he was being cared for in a general ward <u>in an isolation room designed for infectious diseases.</u>
- 50. In addition to the cardiac factors noted above, the adrenaline was administered via IV rather than IM whilst he was not attached to a cardiac monitor. After the administration of the IV adrenaline, Mr George suffered a PEA arrest, however, the precise interplay between the IV adrenaline, his pre-existing cardiovascular disease and anaphylaxis was unclear. Fatal anaphylaxis is unpredictable, although certain

<sup>&</sup>lt;sup>8</sup> In the community, those with a systemic reaction to an allergen are provided with an auto-injector (an EpiPen) and a written anaphylaxis plan.

<sup>&</sup>lt;sup>9</sup> They also occur after erroneous intravenous injection of a 1mg/mL adrenaline solution instead of an appropriately diluted 0.1mg/mL or 0.01mg/mL adrenaline solution.

patients are at a higher risk, such as those with concomitant asthma or cardiopulmonary disease.

51. The HMIT clinician concluded that a review of the circumstances of Mr George's death <u>highlighted the inter-relationship relationship between his pre-existing clinical</u> conditions and the anaphylactic reaction, as well as systemic issues, such as the need for clear communication, precise documentation and knowledge of the correct first aid response and the need for a suitable setting to manage a potential antibiotic allergy.

#### Mr George's exposure to antibiotics

- 52. As part of the coronial investigation, I obtained an <u>expert report from Dr Olga</u> <u>Martinez, a Consultant Immunologist with a sub-speciality in drug hypersensitivity.</u> Using the medical records, Dr Martinez provided a comprehensive and detailed summary of Mr George's antibiotic history, outlined below, which was of tremendous assistance to the coronial investigation.
- 53. Among the types of antibiotics administered, <u>Mr George was treated with several different beta lactam antibiotics</u>. Beta lactam antibiotics are characterised as having a molecular structure that includes a 'beta lactam ring'. This structure is present in penicillins<sup>10</sup>, cephalosporins<sup>11</sup>, carbapenems<sup>12</sup> and monobactams<sup>13</sup>. The "Penicillins" also include Timentin and Tazocin.
- 54. Dr Martinez noted that Mr George was treated with multiple intravenous doses of flucloxacillin during at least five admissions to the Knox Private between December 2004 and May 2006, all of which he tolerated.
- 55. In May 2006, while being treated with a combination of Tazocin<sup>14</sup> and clindamycin, he developed an <u>itchy rash that was attributed to the Tazocin</u>, which was then ceased. This was the <u>first recorded antibiotic allergy</u>.

<sup>&</sup>lt;sup>10</sup> Including flucloxacillin, amoxicillin, ticarcillin and piperacillin.

<sup>&</sup>lt;sup>11</sup> Including cephazolin, ceftriaxone and cephalexin.

<sup>&</sup>lt;sup>12</sup> Including ertapenem or meropenem.

<sup>&</sup>lt;sup>13</sup> Aztreonam.

<sup>&</sup>lt;sup>14</sup> Piperacillin.

- 56. On 31 July 2006, Mr George was commenced on IV flucloxacillin. Clindamycin was added on 2 August 2006. The flucloxacillin was ceased on 6 August 2006 and Mr George started on <u>cephazolin</u>. That day, it was documented that Mr George was <u>given Phenergan (an antihistamine) for a rash</u>. The following day, Phenergan was administered for a rash on his face, neck, back and chest.
- 57. Dr Martinez commented that there was <u>no clear documentation of the reason for</u> <u>changing from flucloxacillin to cephazolin</u>. She hypothesised that perhaps clinicians thought the flucloxacillin had caused the itching and rash. However, Mr George was taking both flucloxacillin and clindamycin, meaning either could potentially have been the cause. It may have been the case that because Mr George had reportedly reacted to Tazocin two months earlier, a reaction to another penicillin-type antibiotic was thought to be more likely. Similarly, either could have been the cause for the skin rash documented the next day. Dr Martinez commented that there was no documentation of the skin rash or whether an antibiotic allergy was suspected to be the cause in the discharge summary.
- 58. In a discharge summary from The Epworth Hospital (the Epworth) dated 30 August 2006, it was documented that Mr George had an allergic reaction to cephazolin and had been changed to vancomycin and had a <u>skin rash that was thought to be due to the vancomycin.</u>
- 59. When Mr George was admitted to Cabrini Hospital on 14 September 2006 for the management of a diabetic foot infection, the nursing admission assessment noted an allergy to Tazocin and cephazolin but there was no mention of the rash that was suspected to be due to vancomycin. Mr George was treated with vancomycin and meropenem and developed a <u>high fever and skin rash</u> that was thought to possibly relate to the beta lactam antibiotic (that is the <u>meropenem</u>). However, Dr Martinez considered that the reaction could have been due to the vancomycin.
- 60. About one week later, Mr George was noted to have a worsening rash and deteriorating kidney function, thought due to interstitial nephritis caused by the vancomycin<sup>15</sup>. All antibiotics were ceased, and the rash, itch and renal function improved. An ID physician reviewed Mr George and obtained information from the

<sup>&</sup>lt;sup>15</sup> Dr Martinez commented that fluoroquinalones are more likely to cause interstitial nephritis than vancomycin

Hospital in the Home (HITH) service at The Epworth, which documented that Mr George had been <u>noted to have a rash with penicillin, cephalosporins and Vancomycin.</u>

- 61. Mr George's second admission to Cabrini Hospital occurred between 26 November 2006 and 20 December 2006 for a persistent diabetic foot infection. He was treated with IV tigecycline, a <u>glycylcycline</u>, which is a tetracycline derivative. Dr Martinez explained that it does not have a beta lactam ring and is not related to any antibiotics Mr George had taken in the past. This was <u>discontinued 12 days later and replaced</u> with doxycycline (a tetracycline) <u>due to a skin rash</u>. Development of urticaria<sup>16</sup> was documented nine days later but Dr Martinez did not find any evidence of an assessment to determine the cause of the rash, and it was not mentioned on the transfer documents to the HITH Team.
- 62. Mr George's third admission to Cabrini Hospital was on 18 January 2007 for a persistent diabetic foot infection and planned below the knee amputation. He was commenced on <u>IV tigecycline but after three doses</u>, developed fever, itching and eosinophilia, consistent with an allergic reaction. He was commenced on <u>teicoplanin</u>, which was continued for eight days and ceased seven days prior to discharge. <u>Persistent itching was documented</u> one day prior to discharge. Dr Martinez commented that the development of an itchy skin rash after three doses of tigecycline on the same day is consistent with an IgE mediated allergic reaction. She was not surprised by this, given the history of an itchy rash the last time it was administered to Mr George, and the development of urticaria while being treated with doxycycline, a structurally similar drug.
- 63. Dr Martinez advised that there is cross reactivity between teicoplanin and vancomycin and it is not surprising that a skin rash would develop with both drugs.
- 64. On Mr George's fifth admission to Cabrini Hospital in 2012, he received 12 doses of Timentin, which were well tolerated before he was changed to cephalexin.
- 65. Dr Martinez noted that <u>during all of Mr George's previous admissions</u>, <u>documentation</u> of allergies was variable in relation to the antibiotics implicated and the type and the severity of any allergic reaction</u>. Some of the information may have been based on

<sup>&</sup>lt;sup>16</sup> Hives

responses from Mr George, while others may have been obtained from previous admissions.

- 66. The Cabrini records included an <u>alert dated 12 November 2014</u> that indicated Mr George has experienced a <u>rash and itch with vancomycin, cephazolin, ciproxin and penicillin.</u>
- 67. According to Dr Martinez, Dr Chapman appeared to have made four entries in Mr George's medical records that concerned allergies between his admission and the administration of flucloxacillin. She considered Dr Chapman did not appear to have determined the nature and significance of any of Mr George's previous reactions to antibiotics.
- 68. Dr Martinez observed that the information contained in the alert on Mr George's file dated 12 November 2014 may well have come from Mr George himself, and there was a real possibility that the information was questionable. She posited several theories as to why Mr George was an unreliable historian. He was acutely unwell with an infected foot and probable septicaemia. There was evidence of biochemical derangement due to hyperglycaemia, which could make him vague and confused. Indeed, Mr George indicated that he did not have any allergies or reactions to medications in the Standard Patient Assessment Tool that he completed upon admission. Dr Sheffield also observed and documented in the medical records that Mr George was vague about information concerning antibiotic allergies.

#### The appropriateness IV flucloxacillin and the setting of its administration

69. With respect to the appropriateness of the administration of flucloxacillin, Dr Sheffield maintained that it was <u>not unreasonable to discuss flucloxacillin as a</u> <u>possible future treatment as Mr George was administered Timentin in 2006 and 2012</u> <u>without suffering any adverse reaction</u>. He noted that Mr George had a potentially life-threatening infection with *Staphylococcus aureus* bacteraemia, and that the Australian Infectious Diseases Guidelines advise that the choice of antibiotic should be based on the known pathogen and directed to the narrowest spectrum of activity required. Dr Sheffield advised that the <u>first line treatment for *Staphylococcus aureus* <u>bacteraemia is flucloxacillin</u>.</u>

- 70. Mr George was being treated with meropenem, which is not only a very broadspectrum antibiotic, but a last line effective defence against several other bacteria. Dr Sheffield's opinion was that if removal of infected tissue from Mr George's foot was adequate, targeted treatment for *Staphylococcus aureus* would be preferred and the antibiotic of choice in that setting would be flucloxacillin.
- 71. Nevertheless, it <u>would not have been Dr Sheffield's usual practice to narrow the</u> <u>spectrum of antibiotics without first reviewing the Knox Private records</u> and investigating any other complications contributing to Mr George's clinical state, such as further abscess, osteomyelitis or endocarditis that would have mandated an opinion from a cardiothoracic surgeon.
- 72. <u>Dr Chapman's rationale for the administration of flucloxacillin</u> was in the setting of ongoing *Staphylococcal* sepsis, an inadequate response to meropenem, questionable multiple antibiotic allergies and the absence of any severe reaction to flucloxacillin in the past, apart from pruritus after six days of usage in 2006.
- 73. Dr Martinez advised that when deciding whether a specific antibiotic is prescribed, consideration of important factors must be considered, including whether there are any absolute or relative contraindications for its use. She recommended that in the event of contraindications, equally effective alternatives should be considered, especially with absolute contraindications.
- 74. She explained that Mr George was reported to be allergic to *penicillin*, a term that may refer to one or more of a group of antibiotics including penicillin G, penicillin V, benzathine penicillin or more commonly, as a generic term that also includes penicillin families that share the same basic structure (a beta-lactam ring) but which differ from those listed by having additional side chains in their structure that contribute to the pharmacological and antibacterial effects.
- 75. Flucloxacillin is a beta-lactam antibiotic of the penicillin class, with a narrow spectrum of activity. It is the resistant to the effects of the enzyme B-lactamase, which is produced by some microorganisms. This resistance makes flucloxacillin an extremely useful agent against B-lactamase producing organisms such as *Staphylococcus aureus*.<sup>17</sup>

<sup>&</sup>lt;sup>17</sup> But not methicillin resistant *Staphylococcus aureus* (MRSA).

- 76. The effects of B-lactamase may also be inhibited by clavulanic acid and tazobactam, which may be combined with susceptible B-lactams. Examples include Timentin and Tazocin.
- 77. Mr George had been treated in the past with penicillins in the form of Tazocin, Timentin, flucloxacillin and amoxicillin. Allergy to Tazocin was documented in May 2006. <u>Despite the development of itch and rash while on flucloxacillin and clindamycin in August 2006, neither of those antibiotics were included in Mr George's list of allergies.</u>
- 78. With respect to the development of allergies to beta-lactam antibiotics, Dr Martinez explained that the allergic response may be directed towards the beta-lactam ring, the additional 'rings' or the side chains. Due to some of the structures being present in several different antibiotics, there is a potential for allergic cross-reactivity. That means that a person allergic to one compound can respond to another with a similar structure.
- 79. Cross reactivity studies have reported individuals who have reacted to semi-synthetic penicillins (including piperacillin, [flu]cloxacillin and others) having shown positive responses to testing with semi-synthetic penicillins other than the one they have reacted to. In the case of Mr George, Dr Martinez considered that it was possible that there was cross-reactivity between Tazocin (pipperacillin) and flucloxacillin.
- 80. Apart from the 'penicillins', Dr Martinez explained that the beta-lactam ring is also the basic structure for other antimicrobial agents, including the 'cephalosporins'. Mr George was treated with antibiotics belonging to this group during many of his admissions in the form of cephazolin, ceftriaxone, cephalothin and cephalexin. The list of antibiotics to which he was said to be allergic included cephalothin and cephazolin and cross reactivity between these and flucloxacillin was also possible in Dr Martinez's opinion.
- 81. Dr Martinez recommended a risk versus benefit analysis when determining whether it was appropriate for Mr George to receive flucloxacillin. The benefit would have been the administration of an antibiotic that targeted the specific bacteria that Mr George was infected with. However, clinicians would run a parallel risk because of the existence of a documented penicillin allergy as well as cross-reactivity between the penicillin and cephalosporin antibiotics.

#### What was the risk of administering flucloxacillin to Mr George?

- 82. According to Dr Martinez, adverse reactions can be divided into allergic and nonallergic reactions. Allergic reactions can be further divided as immediate or nonimmediate, the former occurring within one hour of administration. The underlying immunological mechanism and the clinical manifestation of immediate reactions differ from non-immediate reactions. Immediate reactions are related to the presence of IgE antibodies that react specifically to a medication and manifest clinically with urticaria, angioedema, nasal congestion, shortness of breath and anaphylaxis. Nonimmediate reactions elicit an IgE mediated response.
- 83. More delayed reactions can be severe and manifest as skin blistering and/or affect the internal organs including the liver and kidneys. <u>Dr Martinez warned that re-exposure for these delayed, severe reactions is absolutely contraindicated.</u>
- 84. Dr Martinez's review of the medical records showed that Mr George's symptoms of suspected antibiotic allergies were mostly itchy skin and rash. However, as he was usually treated with at least two different antibiotics, it is difficult to identify the causative agent. The precise history of the reaction was also not available, nor whether it was immediate or non-immediate. Significantly, there was no documentation of more severe systemic reactions such as the involvement of the mucous membranes or skin blistering, which would have required life-long avoidance of the offending medication.
- 85. She also commented that the length of time since the allergic episode is relevant, as specific IgE antibodies may disappear progressively over time, followed by a loss of skin test reactivity. The time since the last exposure to flucloxacillin was eight years, but there had been exposure to a penicillin Timentin and cephalexin in the meantime in 2012.
- 86. Dr Martinez recommended that when the benefit outweighs the risk, measures to mitigate the risk should be employed. In her view, that did not occur in the case of Mr George prior to the administration of flucloxacillin. Best practice in her view was to give the drug in the setting where close cardiac monitoring was available with full resuscitation facilities readily available and medical staff on hand trained in the acute management of anaphylaxis. I accept Dr Martinez's opinion in this regard.

- 87. In his submissions, Dr Chapman accepted the Dr Martinez opinion about the manner or setting in which flucloxacillin ought to have been administered but stressed that the Coroner should find that the clinical decision to administer it was made in good faith and on the balance of clinical considerations.
- 88. That is, Dr Chapman says he took into account the possibility that Mr George was allergic to flucloxacillin and could be seriously allergic to it but considered that he nevertheless required timely treatment with an appropriate antibiotic. Dr Chapman submitted that left untreated or inadequately treated, Mr George's septicaemia could have deteriorated, and rapid death could have ensued. Indeed, Dr Chapman submitted that a failure to provide adequate treatment would have led to a further deterioration such as the development of end stage renal failure in the setting of Mr George's already parlous health.

#### The quality of medical documentation

- 89. Standard Four of the National Safety and Quality Service Standards<sup>18</sup> deals with documentation of a patient's previously known adverse drug reactions on initial presentation and the requirement to update it if an adverse reaction occurs during an episode of care. Adverse reactions are also to be reported to the Therapeutic Goods Administration (TGA).
- 90. According to Dr Martinez, there was a <u>paucity of accurate and complete</u> <u>documentation of clinical symptoms and signs in most of the hospital admissions and</u> <u>other medical records that she examined.</u> There was little documentation that dealt with changes in antibiotic therapy and it was not clear whether changes were made due to side effects, lack of efficacy, based on microbiological results, or because of an adverse reaction. The consequence of such a lack of documentation of signs and symptoms is that it could lead to a failure to recognise that they represent an allergic reaction.
- 91. In response to Dr Martinez's comments, which identified deficiencies in the documentation of Mr George's reactions to medications prior to his admission to Cabrini, the <u>Executive Director of Clinical Services at The Epworth, Adjunct</u> <u>Professor Sharon Donovan provided their current policies and protocols for the care</u>

<sup>&</sup>lt;sup>18</sup> September 2012 at Criterion 4.7.

and management of patients at risk of, or who experience, adverse drug reactions, allergies and anaphylaxis.

- 92. It is now the case that any patient who presents at any Epworth HealthCare Group (EHCG) hospital, a history of allergies is obtained as part of the triage process in the ED and is recorded on the triage record. An alert card is completed for every inpatient admission and prominently positioned on the first page. If a clinical alert such as a drug allergy is identified, the patient is required to wear a specially coloured wristband that refers the clinician back to their medical record. However, in the case of Mr George, he was unable to provide an accurate account of his history of allergies and reactions.
- 93. In addition to the completion of the alert card, EHCG's *Health Information Documentation Protocol* emphasises the importance of contemporaneous documentation in the medical record of any factors that might render a patient vulnerable to any adverse reaction. The adequacy of compliance with this protocol is audited annually.
- 94. EHCG's *Medication Administration Protocol* prohibits administration of a drug to which the patient has a known adverse reaction or allergy and requires patients to be observed for any adverse reaction. The *Medication Administration Protocol* details the documentation, reporting and patient counselling required when an adverse drug reaction is identified. A 'RiskMan' incident report and a report to the TGA are to be completed whenever an adverse reaction is suspected or confirmed.
- 95. Notwithstanding the measures EHCG already had in place to mitigate and manage the risk of adverse drug reactions, Adjunct Professor Donovan commented that they had initiated a review of all the relevant Epworth policies and protocols to ensure the issue of drug reactions, allergens, and clinical alerts are sufficiently covered.
- 96. Australian Hospital Care Pty Ltd (AHC) responded to the criticisms made by Dr Martinez in respect of their apparent lack of documentation of Mr George's allergies at <u>Knox Private Hospital</u>. They contended that whether more details were contained in their documentation is not relevant in this instance as it had no impact upon Mr George's treatment at Cabrini. AHC submitted that all that is relevant is that what they knew about Mr George's drug sensitivities and allergies was included in the

documents furnished to Cabrini on 14 November 2014, which Dr Chapman read prior to his decision to commence Mr George on flucloxacillin on 16 November 2014.

- 97. AHC noted that during Mr George's admission between 31 July 2006 and 9 August 2006, it was concluded that he was sensitive to Tazocin. The submit that although that information was not recorded on their discharge summary, it was recorded in a prominent position on three of the 18 pages forwarded to Cabrini Health, and Dr Chapman read those pages prior to his clinical decision to prescribe flucloxacillin.
- 98. It was submitted by AHC that all the information they had in respect of Mr George's drug sensitivities was appropriately conveyed to the clinicians at Cabrini. Even if additional information had been conveyed, that would still not have changed the treatment decisions made, and it was not open to find that the contents of Mr George's admission or discharge summary contributed to his death. Even if a finding were made that it would have been preferable for such information to have been recorded in the Knox Private discharge summary, its absence did not adversely impact upon the treatment decisions made in relation to Mr George, nor did it contribute to his death.

#### **Cabrini Hospital Review**

- 99. Cabrini Hospital conducted a multi-disciplinary committee review of the circumstances that surrounded Mr George's death, a copy of which was provided to the court. <u>Associate Professor Peter Lowthian, Executive Director of Medical Services and Clinical Government at Cabrini</u> Private Hospital (Cabrini), provided the following summary of issues identified in that review:
  - a) The need for better documentation outlining the reasoning behind critical decision making in cases involving medication allergies;
  - b) Due to the risk of anaphylaxis caused by beta lactam antibiotics such as penicillins, if the use of a penicillin antibiotics is clinically essential, then desensitisation for the beta lactam can be considered;
  - c) The decreased visibility of Mr George due to his physical location within the ward when he was administered the antibiotics in the context of previous antibiotic reactions and significant co-morbidities was an identified issue. It was advisable to manage Mr George like an antibiotic desensitisation patient, with the IV antibiotic administration occurring in a critical care environment;

- d) A MET call was initiated rather than a Code Blue when Mr George's condition began to deteriorate. Given the potential to rapidly deteriorate, it would be recommended to initiate a Code Blue in the first instance in the event of hypotension or breathing difficulties in the setting of potential antimicrobial adverse drug reactions;
- e) Hydrocortisone was administered initially after Mr George's condition deteriorated. The various anaphylaxis guidelines state hypersensitivity reactions are to be treated by the IM administration of adrenaline, rather than hydrocortisone; and
- f) Adrenaline was ordered and administered intravenously rather than subcutaneously (IM) when Mr George's condition deteriorated. This is not in accordance with standard anaphylaxis guidelines but at the time of the review, Cabrini Health did not have its own anaphylaxis guideline.
- 100. It was the view of Cabrini that while the issues identified would not have affected the ultimate outcome, there were systems improvement opportunities and changes that have been implemented.
- 101. The Cabrini review made several recommendations for improvement. Feedback was to be provided to the clinician (Dr Chapman) in relation to the setting of the antibiotic administration, the need for better documentation outlining the reasoning behind critical decision making in cases involving medication allergies and a preference for further consultation with an ID physician before ordering flucloxacillin.
- 102. The Cabrini Health Allergy and Adverse Drug Reaction: Documentation and General Management Protocol was to be updated and implemented with the addition of medication alert cards to patients/carers when an allergy/adverse drug reaction has occurred. The Cabrini Health Suspected Adverse Drug Reaction Reporting Procedure was also introduced.
- 103. Education was to be provided to clinicians, nursing, medical and pharmacy staff about beta-lactam hypersensitivity and penicillin containing antimicrobial agents, particularly combination agents such as Tazocin and Augmentin. The provision of further information regarding recognition of hypersensitivity reactions including

anaphylaxis and anaphylaxis management<sup>19</sup> for hypotension or breathing difficulties in the setting of potential antimicrobial adverse drug reactions was also to be provided. In that regard, the correct dose and route of adrenalin and that hypersensitivity reactions should be managed with adrenaline was reinforced.

104. Cabrini Health also committed to developing an anaphylaxis protocol and to review their current policies on allergy and adverse drug reactions to provide for circumstances where a patient is undergoing antibiotic desensitisation.

## Was Mr George's death preventable?

- 105. Dr Chapman maintained that throughout Mr George's final admission in November 2014, he was acutely unwell due to widespread *Staphylococcus aureas* sepsis, which had manifested as a foot abscess, likely septic arthritis and possible endocarditis or osteomyelitis. The sepsis was in the setting of multiple chronic conditions comprising poorly controlled diabetes and ischaemic heart disease. Dr Chapman submitted that it was obvious that Mr George required antibiotic therapy to counter the infection that was rife within his body.
- 106. He submitted that as at 16 November 2014 Mr George's condition was deteriorating and clinical indications were that he had an acute systemic infection. Dr Chapman considered that any further deterioration in Mr George's condition would have led to his death within a short time or to further morbidity that would have complicated efforts to save his life. Accordingly, swift administration of antibiotics was warranted, even though Mr George was allergic to most of them.
- 107. Cabrini Hospital made submissions as to setting in which the flucloxacillin was administered. Associate Professor Lowthian noted that considering Mr George's penicillin allergy and discussions with Dr Chapman, the nursing staff who were charged with administering the flucloxacillin had a heightened awareness of the potential for Mr George to have an adverse drug reaction. Accordingly, nursing staff remained to monitor Mr George while the flucloxacillin was administered slowly over a ten-minute period.
- 108. With respect to Dr Martinez's opinion (and the HMIT's) that the flucloxacillin should have been administered in an area where close cardiac monitoring could be

<sup>&</sup>lt;sup>19</sup> Including the requirement to call a Code Blue and not a MET call.

undertaken with full resuscitation facilities and with medical staff in attendance who were trained in anaphylaxis management, Cabrini Hospital submitted that they should not be criticised for this failure. The decision to administer flucloxacillin and any conditions surrounding its administration (including the location), were medical decisions made by Dr Chapman and not the decision of Cabrini Health.

## National Allergy Strategy<sup>20</sup>

- 109. Allergic diseases are amongst the fastest growing chronic health conditions, affecting one in five Australians. The Australasian Society of Clinical Immunology and Allergy (ASCIA) and Allergy & Anaphylaxis Australia (A&AA), the leading medical and patient organisations for allergy in Australia, have developed a National Allergy Strategy in collaboration with key stakeholder organisations. ASCIA and A&AA are progressing with the implementation of the National Allergy Strategy.
- 110. The National Allergy Strategy received federal funding in July 2016 for several projects, one of which was a scoping project regarding improving drug allergy management to reduce deaths in hospitals. In 2016-17 with funding from the Australian Government, the National Allergy Strategy sought to scope the development of a database and clinical education to improve drug allergy management and reduce drug allergy deaths in hospitals.
- 111. One identified issue was poor documentation and communication of drug allergies. On average, 18% of all hospital patients report an antibiotic allergy. Overall, the documentation of these drug allergies was poor. In the published literature, it is established that most drug allergy entries in clinical records incomplete and vague and a review of national medication charts revealed incomplete entries in the majority of cases<sup>21</sup>.
- 112. Recommendations arose out of the 2016-17 scoping project, including the development of a drug allergy database. It was identified that the My Health Record (MHR) had the potential to provide access to a patient's complete medical record. The MHR in its current form does not allow for the most current or accurate allergy

<sup>&</sup>lt;sup>20</sup> National Allergy Strategy Drug allergy project funding request, 31 January 2019 pre-budget submission for the 2019-20 Federal budget.

<sup>&</sup>lt;sup>21</sup> Shah NS, Ridgway JP, Pettit N, et al. *Documenting penicillin allergy: the impact of inconsistency*. PLoS One 2016; 11: e0150514.

information to easily identified and accessed. The ASCIA Drug Allergy Working Party recommended among other things that:

- a) Allergy information in MHR must be prominent such as an alert type mechanism;
- b) Consumers need to be educated about the clinical risks of hiding allergy information;
- c) Standardised Adverse Drug Reaction (ADR) nomenclature should be used in all hospitals in Australia;
- d) Standards set by the Australian Digital Health Agency (**ADHA**) for state and territory digital health platforms to interact with MHR;
- e) A coordinated process to avoid unnecessary duplication of data entry;
- f) Private and public hospitals need to meet the ADHA standards to share patient data with MHR; and
- g) Hospital electronic health systems should have an alert system that is triggered when a clinician seeks to change a patient's allergy status.
- 113. The scoping study also identified that health professionals must have a good understanding of adverse drug reactions, drug allergy labels and the consequences of administering a drug to a patient with a drug allergy. Relevant recommendations that arose included implementing standardised education on how to complete the Australian Commission for Safety and Quality in Health Care standard medication chart and standardised clinical education for all emergency clinicians and first responders in relation to the identification, classification and treatment of drug allergies and reactions.
- 114. The Working Party also recommended clinical education about cross-reactivities with cephalosporins and penicillin antibiotics, site specific education for all staff who enter data into patient records to ensure current and accurate data entry into the hospital's electronic health system. Clinical education about drug allergy coding to ensure the accurate entry of information was also identified as being essential.
- 115. Following a referral on 27 August 2019 from the Minister for Health, The Honourable Greg Hunt, an inquiry into allergies and anaphylaxis was announced.

The House of Representatives Standing Committee on Health, Aged Care and Sport will inquire and report on:<sup>22</sup>

- a) The potential and known causes, prevalence, impacts and costs of anaphylaxis in Australia;
- b) The adequacy of food and drug safety process and food and drug allergy management, auditing and compliance;
- c) The adequacy and consistency of professional education, training, management/treatment standards and patient record systems for allergy and anaphylaxis;
- d) Access to and cost of services, including diagnosis, testing, management, treatment and support;
- e) Developments in research into allergy and anaphylaxis, including prevention, causes, treatment and emerging treatments (such as oral immunotherapy);
- f) Unscientific diagnosis and treatments being recommended and used by some consumers; and
- g) The impact of unnecessary drug avoidance due to unconfirmed drug allergies and its management.

## **Findings/Conclusions**

- 116. The standard of proof for coronial findings is the civil standard of proof on the balance of probabilities, with the *Briginshaw* gloss or explication.<sup>23</sup>
- 117. With respect to adverse comments or findings, the effect of the authorities is that they should not be made unless the evidence provides a comfortable level of satisfaction that an individual (or institution) caused or contributed to the death, and in the case of individuals acting in a professional capacity, that they departed materially from the standards of their profession.

<sup>&</sup>lt;sup>22</sup>https://www.aph.gov.au/Parliamentary\_Business/Committees/House/Health\_Aged\_Care\_and\_Sport/Allergiesa ndanaphylaxis/Terms\_of\_Reference

<sup>&</sup>lt;sup>23</sup> <u>Briginshaw v Briginshaw</u> (1938) 60 C.L.R. 336, especially at 362-363 "The seriousness of an allegation made, the inherent unlikelihood of an occurrence of a given description, or the gravity of the consequences flowing from a particular finding, are consideration which must affect the answer to the question whether the issues had 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…"

118. It is axiomatic that the assessment of any departure from norms or standards must be judged strictly without the benefit of hindsight. The trajectory that leads to a death may well be obvious after the event. Patterns or causal connections that can be traced from the privileged position of knowing the fatal outcome, may not have been obvious or even appreciable before that outcome.

#### 119. <u>Having applied that standard to the available evidence, I find that:</u>

- a. Mr George died as a result of global cerebral hypoxia following cardiorespiratory collapse due to anaphylaxis following administration of flucloxacillin in a man with diabetes mellitus, widespread sepsis and ischaemic heart disease.
- b. Dr Chapman appropriately consulted Dr Sheffield, an infectious disease specialist, and sought his input into Mr George's further management.
- c. Both Dr Chapman and Dr Sheffield discussed Mr George's past adverse reactions to antibiotics with him on 13 November 2014.
- d. As he reported a history of multiple drug allergies but was a vague historian, Dr Sheffield reviewed his medical records from Cabrini Hospital and noted a documented history of adverse reactions to multiple medications in the context of co-administration of multiple medication simultaneously, and also sought Knox Private Hospital to fax their medical records for Mr George.
- e. Investigations on 14 and 15 November 2014 confirmed that multiple blood cultures were positive for *Staphylococcus aureas*, indicating that Mr George had a life-threatening septicaemia or deep-seated infection.
- f. On 15 November 2014, Dr Chapman and Dr Sheffield discussed the *possibility* that flucloxacillin might be considered as a future treatment, however, Dr Sheffield planned to review the Knox Private Hospital records before making a final decision.
- g. Mr George's clinical condition did not improve following the administration of meropenem (for some 72 hours) and surgical procedures to wash out areas of infection.

- h. Moreover, overnight on 15-16 November 2014, Mr George experienced two temperature spikes suggesting septicaemia and a new abscess had formed in his elbow.
- i. On the morning of 16 November 2014, Dr Chapman reviewed the Knox Private Hospital records himself and noted that Mr George had suffered a rash as an apparent reaction to one of three antibiotics administered in 2006 (flucloxacillin, clindamycin and cephalozin) and that he had tolerated Timentin.
- j. Without further consultation with Dr Sheffield, Dr Chapman ordered the administration of flucloxacillin (1mg four times daily) and nursing staff administered 1mg at 8.40am setting off a cascading anaphylactic response that ultimately led to Mr George's death.
- k. Dr Chapman's decision to administer flucloxacillin was made in the setting of a potentially life-threatening infection in a deteriorating patient with complex co-morbidities.
- However, Mr George was not so unwell that Dr Chapman needed to proceed without specialist infectious disease input he had sought from Dr Sheffield as to the choice of antibiotic, the appropriate dose, the need for a penicillin challenge and the taking of necessary precautions.
- m. Mr George's death was *potentially or possibly* preventable either by the administration of an antibiotic other than flucloxacillin or with the administration of flucloxacillin with specialist infectious diseases input.
- n. However, the evidence does not support a finding that Mr George's death was preventable in the sense that with different management he would *probably* have survived the infection which was proving difficult to manage.

#### Comments

Pursuant to section 67(3) of the Coroners Act 2008, I make the following comments in connection with the death:

- 1. The circumstance in which Mr George died highlight the importance of readily accessible and accurate information about a patient's past adverse reactions to antibiotics (and other medications) being available to treating clinicians. Such information needs to be accurate both in terms of the precise antibiotics implicated and the nature of the allergic response.
- Treatment across several campuses or hospitals poses obvious challenges to the ready accessibility of such information, particularly where medical records are kept in hard copy.
- 3. While electronic health records or databases should improve accessibility, the challenge remains for all clinical staff to be aware of the need for accuracy of information and diligently ensure it is appropriately recorded.
- 4. Mr George and other patients may not be competent historians in this regard and while there is a role for good patient education about their own allergy status, healthcare professionals will continue to need recourse to medical records as a source of information about past adverse reactions for patients who are poor historians, whether because they are unwell, or have a complex allergy status or otherwise.

## **Publication of finding**

Pursuant to section 72(1A) of the Act, I order publication of this finding on the Internet in accordance with the rules.

## **Distribution of finding**

I direct that a copy of this finding be provided to the following:

The family of Mr George Epworth HealthCare Cabrini Hospital Australian Hospital Care (Knox) Pty Ltd Dr Olga Martinez Dr Andrew Sheffield Dr Leon Chapman Safer Care Victoria

Signature:

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PARESA ANTONIADIS SPANOS

Coroner

Date: 26 March 2020

