IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2015 5382

FINDING INTO DEATH WITH INQUEST

Form 37 Rule 60(1)
Section 67 of the Coroners Act 2008

Inquest into the Death of LOUIS OLIVER TATE

Delivered On:	26 February 2018
Delivered At:	THE CORONERS COURT OF VICTORIA 65 KAVANAGH STREET, SOUTHBANK
Hearing Dates:	12 December 2017 – 15 December 2017, & 21 December 2017
Findings of:	MR PHILLIP BYRNE, CORONER
Representation:	Mr Chris Winneke, QC, of counsel, instructed by Maurice Blackburn for Ms Gabrielle Catan and Mr Simon Tate, parents of Louis. Dr Paul Halley, of counsel, instructed by Minter Ellison, for Peninsula Health. Leading Senior Constable King Taylor of the Police Coronial Support Unit, assisting.

The Finding does not purport to refer to all aspects of the evidence obtained in the course of the Investigation. The material relied upon included statements and documents tendered in evidence together with the Transcript of proceedings and submissions of Counsel. The absence of reference to any particular aspect of the evidence, either obtained through a witness or tendered in evidence does not infer that it has not been considered.

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I, PHILLIP BYRNE, Coroner, having investigated the death of Louis Oliver Tate
AND having held an inquest in relation to this death on 23 October 2015
at The Coroners Court of Victoria
find that the identity of the deceased was Louis Oliver Tate
born on 23 April 2002
and the death occurred on 23 October 2015
at Frankston Hospital, 2 Hastings Road, Frankston, VIC, 3199 in the following circumstances:

BACKGROUND

1. Louis Oliver Tate, 13 years of age at the time of his death, resided with his parents Ms Gabrielle Catan and Mr Simon Tate and his younger brother at 31 Marguerita Avenue, Mount Martha.

2. Louis had a past medical history of asthma and previously established allergies to cow's milk, raw egg, peanuts and tree nuts. In spite of these conditions, which were well managed and controlled by Louis and his parents, Louis lived a normal active life. Therein lies the cruel irony of the events under investigation in this coronial investigation.

BROAD CIRCUMSTANCES

3. On the evening of 21 October 2015, Louis was experiencing an exacerbation of his asthma for which Ventolin and Prednisolone was administered. He attended school the following day, using Ventolin as required. However, later in the day and into the evening of 22 October 2015, as Louis' asthma was not being relieved by Ventolin, Ms Catan took Louis to the Emergency Department (ED) at Frankston Hospital.

4. In the ED at 10:20pm, Louis was reviewed by Paediatric Resident, Dr James Phillips. At the review, Dr Phillips concluded Louis was suffering from "moderate asthma with mildly increased work of breathing and wheezing and required oxygen" (Paragraph 7 Dr Phillip statement – Exhibit G). Louis was admitted overnight to the paediatric ward for observation and oxygen therapy.

5. Shortly prior to 1am on 23 October 2015 in the paediatric ward, Ms Catan advised Registered Nurse Brenda-Lee Hanisch, who was to care for Louis overnight, of Louis' food allergies. She further advised that he had his EpiPen in his bag and for breakfast could be given Weetbix, soy milk and fruit; but was not to be given cow's milk due to this established food allergy. This information was formally documented by Nurse Hanisch. Ms Catan left the ward at 1:45am.

6. Nurse Hanisch, in her formal statement (Exhibit Q paragraph 8) stated she regularly checked Louis overnight. She stated Louis was administered Ventolin at 1:50am, 3:30am and 5am. Oxygen therapy was ceased at 5am. At approximately 7am Nurse Hanisch spoke with Louis who indicated he felt better. Dr Cara Baillie, Paediatric Registrar, reviewed Louis at 7am. He was reported as looking well and Dr Baillie concluded Louis could be discharged if he did not require Salbutamol for 3 hours. Louis' asthma had for all intents and purposes resolved.

7. Ms Irene Fisher, Personal Care Assistant spoke with Louis and asked what he would like for breakfast. Louis requested Weetbix with soy milk. Nurse Hanisch stated she advised Ms Fisher that Louis could be served Weetbix and soy milk. Ms Fisher prepared Louis' breakfast and shortly prior to 7:15am presented it to Louis in his room. It is noteworthy that there was nothing on the whiteboard in the paediatric ward kitchen as to Louis' food allergies. Ms Hanisch had apparently not complied with the requirement to list patients' allergies on the board. Furthermore there was nothing recorded at the bedside as to Louis' food allergies.

8. At about 7:19am, Louis attended the nurses' station and advised Registered Nurse Helen Hutchins that virtually immediately upon tasting his Weetbix and milk, he experienced a "tingling" on his lips. Nurse Hutchins walked with Louis back to his room and asked the ward clerk to page the paediatric resident Dr Phillips. She also asked Nurse Hanisch, who had noticed the ward bell and returned to the room, to perform a full set of observations.

9. Dr Phillips immediately attended and reviewed Louis. In his formal statement (Exhibit G) Dr Phillips said Louis looked "distressed, had trouble breathing and was wheezing on auscultation." Louis also advised Dr Phillips that he was experiencing "mild tingling in his throat." Dr Phillips asked that Louis be given 12 puffs of Salbutamol and asked Nurse Hutchins to draw up 0.4mgs of adrenaline. Dr Phillips made a differential diagnosis of asthma and/or anaphylactic reaction. At 7:36am Dr Phillips called the Paediatric Registrar Dr Baillie who attended shortly thereafter.

10. Dr Baillie in her statement, (Exhibit F) said that upon reviewing Louis, who was sitting in a tripod position, she noted he was "working hard to breathe." She further stated her "immediate and primary impression was that Louis was suffering an anaphylaxis reaction", with a differential diagnosis of asthma.

11. Dr Baillie said that at 7:40am, the first dose of adrenaline that Dr Phillips had ordered be drawn up, was administered intra-muscularly. At approximately 7:45am, Dr Baillie noted Louis' condition suddenly deteriorated with increased difficulty breathing and his "eyes rolling back." Dr Baillie requested a MET call and ordered a further dose of adrenaline. The second dose of adrenaline was administered intra-muscularly between 7:55am and 8am. Dr

Baillie maintains Louis' condition initially improved after the second administration and she decided to move Louis to the nearby treatment room. Louis walked with assistance of nursing staff to the treatment room where shortly after the MET team attended, together with paediatric consultants Drs Pillay and Blair (the latter having come on duty at 8am). At the request of Critical Care Liaison Nurse Dr Chris Bowden, the Clinical Director Anaesthetics at the hospital, also attended the treatment room. He noted Louis was "acutely short of breath, tachypneic and that his breathing was laboured." Dr Bowden remained for a short while as the paediatric team reviewed Louis, but did not personally examine Louis. Dr Bowden stated that he concluded at that time that Louis' vital signs did "not indicate a need for airway intervention." (Exhibit T paragraph 6)

12. At approximately 8:10am, Louis' condition deteriorated and Dr Baillie ordered another dose of adrenaline. At 8:14am a third dose of adrenaline was administered, again intra-muscularly. A decision had previously been made that if Louis required a third dose of adrenaline, the Paediatric Infant Perinatal Emergency Retrieval Team (PIPER) would be requested to attend to transfer Louis to a tertiary hospital. At 8:16am Dr Baillie asked that PIPER be summoned.

13. After a short period, Louis' condition improved with his oxygen saturations at 99%. However, at approximately 8:20am, Louis' oxygen saturations dropped to 87%. Dr Baillie, noting Louis' condition had again deteriorated, made a second MET call. At 8:42am, a fourth dose of intra-muscular adrenaline was administered and a decision was made in conjunction with the anaesthetic team (Drs Bowden and Hales) to transfer Louis to theatre for intubation awaiting the arrival of the PIPER team.

14. In his formal statement, Anaesthetist Dr Hales (Exhibit U, paragraph 12), described the intubation of Louis at 9am as "straightforward," with Louis remaining "cardiovascularly stable throughout." Shortly after, an adrenaline infusion was commenced. Dr Hales described how after a period of relative stability his management of Louis became increasingly difficult as Louis' end-tidal CO2 (ETCO2) increased from 70–80mmHgs shortly after intubation, suggestive of severe bronchospasm, decreasing to approximately 58mmHgs, until rising alarmingly to over 100mmHgs, followed by a rapid deterioration of Louis' condition with ETCO2 rising to 108mmHgs. Dr Hales sought further anaesthetic support resulting in the return of Dr Bowden (and another anaesthetist Dr Ding). It was concluded that Louis was suffering from malignant hyperthermia, a very rare condition. The malignant hyperthermia protocol was commenced; Louis was administered Dantrolene via femoral venous catheter.

15. At approximately 10:49am, Louis suffered a cardiac arrest from which, in spite of lengthy, full resuscitation measures, he could not be revived. CPR was abandoned as futile and Louis was declared deceased.

REPORT TO THE CORONER

16. Louis' untimely death was reported to the Coroner. Having regard to the circumstances, having conferred with the forensic pathologist and being aware Louis' parents consented to autopsy and wanted to know the cause of death, I directed an autopsy and ancillary tests.

17. In early March 2016, I received from Forensic Pathologist Dr Yeliena Baber a 17 page Autopsy report, together with toxicology reports relating to the analysis of post mortem samples and a soy milk sample provided by the hospital.

18. In her report, Dr Baber advised that in her view, Louis' death was due to:

    I (a) Malignant hyperthermia complicating the management of acute asthma.

    Contributing factors

    History of food allergy.

    In broad terms, that cause of death, opined by Dr Baber based on the material available to her at the time, was asthma related, not directly due to an anaphylactic reaction to breakfast. That is where from the outset, Louis' parents were in furious disagreement.

19. Shortly after Dr Baber's autopsy and toxicological reports became available, a family meeting with Ms Catan and Mr Tate took place. Family meetings are undertaken under the auspices of the Victorian Institute of Forensic Medicine, not the coroner, but in any event I am supportive of this process, particularly where the cause of death formulated by a forensic pathologist who performed the autopsy is queried/challenged. I was subsequently advised that Louis' parents (and perhaps others) took issue with the cause of death provided by Dr Baber in her report.

20. At quite an early stage, I concluded these contentions would in all likelihood require use of the forensic judicial process.

21. Over a period of time, I received from Mr Tate and Ms Catan a number of communications/submissions in which strident criticisms of medical mismanagement were articulated. On 11 January 2016, a letter from Mr Tate was received together with a formal request for inquest. The family's concerns at that time are demonstrated in the following excerpts from Mr Tate's letter. He wrote;

    "In our opinion Louis would still be alive if it were not for two key areas of failings at hospital in respect to allergy management

- *In hospital food service*
- *Anaphylaxis identification and management"*

and,

> *"During a meeting with medical staff at Frankston Hospital and in Louis' medical file it is clearly indicated that Louis Tate had anaphylaxis as a result of breakfast whilst in hospital."*

Of course, I was aware from the outset that that contention went to the fundamental core findings I would ultimately be required to make.

22. At times, my investigation has been somewhat tortuous; progress was slow for various reasons, particularly identifying medical practitioners with the appropriate experience and expertise to provide independent expert opinions on the medical management of Louis.

23. I sought and received independent expert opinions from:

    - Professor John Ziegler, Paediatric Immunologist, Department of Immunology of Infectious Diseases, Sydney Children's Hospital
    - Dr Andrew Numa, Intensive Care Respiratory Physician, Director, Intensive Care Unit, Sydney Children's Hospital.

    There reports were made available to solicitors for both Louis' parents and Peninsula Health.

24. By March 2017, I concluded I had accumulated sufficient material to list the matter for a Mention/Directions Hearing at which I hoped to determine the future course of the matter and the scope and parameters of the proposed hearing. I finally felt progress was being made.

25. On 31 March 2017, a Mention/Directions Hearing proceeded. At the hearing, Mr C J Winneke, QC, briefed by Maurice Blackburn, appeared on behalf of Ms Catan and Mr Tate, Dr Paul Halley, briefed by Minter Ellison, appeared for Peninsula Health and Ms Rebecca Johnston-Ryan of this Court appeared to assist.

26. At that hearing, Mr Winneke made an application that I exercise my discretion to require Peninsula Health to provide to the Court (and ultimately to his instructors) the formal Root Cause Analysis that we were aware had been undertaken. In fact, I had earlier asked Peninsula Health, through their solicitor, to provide a copy of, or at least details of, the internal review. Not surprisingly my request was denied on the basis of claimed public interest immunity. In the event, at the Mention Hearing, Dr Halley confirmed that his client maintained the objection of the basis of "public policy," a protection apparently based upon the same rationale.

27. I indicated that I thought a second Mention/Direction Hearing would be required prior to listing the matter for formal inquest. I wanted to settle a list of witnesses, seek to determine precisely how many experts would be providing reports and giving evidence, and hear submissions in relation to Mr Winnekes' request that I direct Peninsula Health to provide their formal Root Cause Analysis.

28. A second, more fruitful, Mention/Directions Hearing took place on 11 August 2017; again Mr Winneke and Dr Halley appeared. I heard argument from both counsel on the issue of production of the Root Cause Analysis, with Dr Halley, on behalf of his client, maintaining the objection to it being produced.

29. I made an *extempore* ruling requiring Peninsula Health to provide to the court a copy of the Root Cause Analysis and advised that I would carefully examine the document upon receipt and then determine whether I would release it to Maurice Blackburn. I did however give a strong indication that the likelihood was that it would be so released. Subsequently, upon receipt of the Root Cause Analysis a copy was made available to Maurice Blackburn.

30. At this second hearing, a tentative list of witnesses was discussed to enable a reasoned assessment to be made as to the period that would be required to hear vive voce evidence from some dozen plus witnesses. I also indicated that my preferred option in relation to hearing from expert witnesses, of whom it was thought there would be eight, was to have a "hot tub," (I prefer the term "conclave"), after which we would hear concurrent evidence.

THE INQUEST

31. The matter was listed for inquest from 12 to 15 December 2017. Over the first three days, evidence was received from Ms Catan, the doctors, nurses and the personal care assistant directly involved in the management/care of Louis. I had hoped to hear from witnesses in chronological order of their involvement, but due to issues of availability of witnesses, that could not be achieved. In the event, I heard vive voce evidence, in order, from:

    - Ms Gabrielle Catan, Louis' mother.
    - Ms Irene Fisher, Personal Care Assistant.
    - Ms Helen Hutchins, Registered Nurse.
    - Dr Cara Baillie, Paediatric Registrar.
    - Dr James Phillips, Paediatric Resident.
    - Dr Simon Blair, Consultant Paediatrician.

- Ms Heather Gilbertson, Dietician and Manager of Nutrition and Food/Service Royal Children's Hospital.
- Dr John Kerr, Chief Medical Officer, Austin Health (at the time Executive Director of Medical Services Frankston Hospital).
- Ms Brenda Lee Hanisch, Registered Nurse.
- Dr Melanie Pillay, Consultant Paediatrician.
- Dr Christopher Bowden, Consultant Anaesthetist.
- Dr Paul Hales, Consultant Anaesthetist.

32. On day four of the inquest, the experts entered the conclave. Forensic Pathologist Dr Yeliena Baber was not available. In that circumstance, the week prior to the hearing I had approached Professor Noel Woodford, Director of the Victorian Institute of Forensic Medicine (who coincidentally was involved in the family meeting early in 2016), to stand in Dr Baber's stead. Before the doctors entered the conclave, I advised counsel that I had asked Professor Woodford if he could undertake the role of facilitator with a view to conveying to the court the deliberations/conclusions of the conclave. Of the experts who had provided reports; those engaged by Maurice Blackburn and those engaged by Minter Ellison, Dr Ross became unavailable at the eleventh hour and Drs Reeves and Jacobe participated by video link and some other similar technology. Personally participating in the conclave were:

    - Professor Woodford.
    - Professor Ziegler.
    - Dr Numa.
    - Dr Daley.
    - Dr Costello (who although in the conclave was excused prior to hearing concurrent evidence).

33. Prior to the conclave, I had formulated a number of specific issues/questions I wanted the experts to consider. Because of their significance I include them in this finding:

    - The broad principal question I would like addressed is – was the medical/nursing management of Louis appropriate (and timely) and was it in accordance with published guidelines?
    - Does anyone take issue with the actual cause of death as advised by Forensic Pathologist Baber (malignant hyperthermia)?

- What do you consider were the precise reasons for Louis' sudden deterioration?:
    - Anaphylactic reaction to the breakfast served
    - Exacerbation of asthma
    - A combination of both asthma and anaphylaxis
    - Some other less obvious cause
- Should nursing/medical staff have been aware Louis had an EpiPen? If so, should it have been utilised, and if so, at what point in time?
- Was the decision to intubate Louis reasonable and timely?
- Had Louis not been intubated is it more likely than not he would have survived?
- Were the anaesthetic agents used to intubate appropriate?
- If the severe deterioration in Louis' condition was due to a reaction to the anaesthetic administered could, or should, that deterioration have been foreseen?
- Are the guidelines relating to individuals with both asthma and allergy consistent throughout the country and are they adequate?

34. I also invited Maurice Blackburn and Minter Ellison to indicate specific questions they would like the experts to consider in the conclave. Both firms lodged questions they would like considered; Maurice Blackburn some 28 and Minter Ellison some 32. I "pulled" some of the questions posed by the parties basically because I concluded they were adequately canvassed in the 9 questions I had formulated. I also considered they went to issues I would need to determine after considering the evidence.

RELEVANT LAW

35. Before turning to make findings in relation to the critical issues in this matter, I propose to refer to aspects of the law to which I am required to have regard. Firstly, S 67 of the Coroners Act 2008 provides the core findings I am, if possible, required to make; they are:

    a) The identity of the deceased.

    b) The cause of death.

    c) The circumstances in which death occurred.

There is no controversy in relation to the first. However, the cause of Louis' death and the circumstances of this death are the primary issues in respect of which there is contention.

FUNDAMENTAL ROLE OF THE CORONER

36. From my perspective, the judgment of Callaway JA in *Keown v Khan* (1999) (VR 69) was a landmark judgement. Adopting a statement in the Broderick Committee (UK) Report[1] His Honour said:

> *"In future the function of an inquest should be simply to seek out and record as many of the facts concerning the death as public interest required, without deducing from those facts any determination or blame".*[2]

and added:

> *"In many cases, perhaps the majority, the facts themselves will demonstrate quite clearly whether anyone bears any responsibility for the death; there is a difference between a form of proceeding which affords to others the opportunity to judge an issue and one which appears to judge the issue itself."*[3]

37. In *R v South London Coroner; ex-parte Thompson* [1982] 126 SJ 625 Lord Lane commented:

> *"It should not be forgotten that an inquest is a fact finding exercise and not a method of apportioning blame".*

I had made this important point, hopefully clearly, in the presence of Ms Catan and Mr Tate at the earlier hearings.

38. Several New Zealand cases assist in adequately explaining the apparent conundrum between concluding an entity has caused or contributed to a death, but not laying, or apportioning blame. See *Louw v McLean* (1998 High Court of New Zealand unreported 12 January 1988) and *Coroners Court v Susan Newton and Fairfax New Zealand* [2006] NZAR 312. The notion is that in finding causation, or contribution to a death the implicit attribution of blame is unavoidable.

39. Again in *Keown v Khan* Justice Callaway made a ruling which assists in determining whether an act or omission can reasonably be considered a casual, or contributing factor, as distinct from a "background circumstance," that is a non-causal factor. In considering this dichotomy His Honour said one should consider whether an act complained of departed from a norm or standard, or an omission was in breach of a recognized duty.

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[1] Report of the Committee on Death Certification and Coroners (1971) (UK) ("The Brodrick Report" Cmnd. 4810)
[2] (1999) 1 VR 69, 75
[3] (1999) 1 VR 59, 75

CAUSATION

40. Causation is a fundamental consideration in forming concluded views about events surrounding a death under investigation. It has been the subject of considerable judicial attention. In *Fitzgerald v Penn* (1954) 91 CLR 268 & 278 the issue of cause was considered by the High Court and described as all ultimately a matter of common sense; adding to the concept *"is not susceptible of reduction to a satisfactory formula."*[4]

In *March v Stramare* (1991) 171 CLR 506 the Chief Justice of the High Court of Australia stated.

> *"What was the cause of an occurrence is a question of fact which must be determined by applying common sense to the facts of each particular case."*[5]

The issue has been considered in the coronial context in the Supreme Court of Victoria. In a robust judgement Hedigan J in *Chief Commissioner of Police v Hallenstein* (1996) 2 VR 1 adopted the "common sense" approach stating:

> *"In March v Stramare (1991) 171 CLR 506, the High Court of Australia considered the fundamentals of causation in the negligence context. The statements of principle in relation to causation are, in my view, applicable to the concept of contribution within the Act, is concerned with the causes of death and who contributed to it".*[6] ("The Act" in that case was the *Coroners Court Act 1985*)

For an act or omission to be a cause, or one of several causes, of a death the connection between the act and/or the omission and death must be logical, proximate, and readily understandable; not illogical, strained or artificial. The circumstances of Louis' death raise challenges.

STANDARD OF PROOF

41. The issue of the standard of proof that I must bring to bear requires consideration. Fundamentally, the time honoured "Briginshaw test" (*Briginshaw v Briginshaw* (1938) 60 CLR 336) is appropriate. The Supreme Court of Victoria has discussed the "Briginshaw test" in several matters involving coroners, canvasing the standard of proof to be applied in considering whether an act or omission by someone acting in a professional capacity, such as a doctor or nurse, is a causal or contributing factor in a death (see *Anderson v Blashki* (1993) 2VR89 and *Health and Community Services v Gurvich* (1995) 2 VR 69). In essence those

[4] *Fitzgerald v Penn* (1954) 91 CLR 268 & 278
[5] *March v Stramare* (1991) 171 CLR 506, 17
[6] *Chief Commissioner of Police v Hallenstein* (1996) 2 VR 1, 14

authorities dictate that findings of causation/contribution should not be made on "inexact proofs, indefinite testimony or indirect inferences", but only on cogent and persuasive proofs – in the final analysis a comfortable degree of satisfaction must be reached to conclude an act or omission was causal, or contributing factor in a death.

42. I make one further comment on the relevant law. While it may be obiter, in a short judgement in *Keown v Khan*, Justice Batt, in a timely reminder to coroners, made the following observation:

> *"Finally, I desire to make some comments with regard to the record of investigation. There is no doubt that coroners may discuss the evidence and explain their findings. But I have the impression that any rate in more contentious inquests coroner's reports have of late tended to be prolix. At least as a general rule, that is unnecessary."*[7]

Rather than including in a finding great tracts of transcripts of evidence, I merely seek to include, succinctly, the evidence which supports the conclusions at which I have arrived.

APPROACH TO ASSESSEMENT OF PERFORMANCE

43. Before seeking to assess the adequacy of medical management, there are several further matters upon which I propose to make comment, because they go to the important issues I am required to consider. The first is the issue of hindsight/retrospection. I am required to consider the adequacy/efficacy of the medical management of Louis without the not inconsiderable benefit of hindsight. I believe I have to assess the performance of the doctors, those involved in Louis's assessment and treatment with the knowledge they had, or reasonably should have had at the time, without knowledge of subsequent events. In my view, this presents quite a challenge; I add that this often also represents a challenge for an expert providing an opinion on medical management.

44. The second point I make in the present context is the test to be applied in assessing treatment is, was it reasonable and appropriate in the circumstances, not whether it was optimal. It is one thing to consider performance in the artificial context of the courtroom many months after events, and another putting myself in the shoes of those involved at the time, faced with an emergency.

45. Although in a different context, the assessment of the performance of a police officer, the rationale behind the decision in *Woodley v Boyd* [2001] NSWCA 35 can in my view be transported to the present case. In that matter Heydon J said:

[7] (1999) 1 VR 69, 79

"... in evaluating the police conduct, the matter must be judged by reference to the pressure of the event and the agony of the moment, not by reference to hindsight."

It is clear that what confronted Drs Phillips and Baillie was an emergency. Similarly, again in the context of the conduct of a police officer, in assessing performance in this case I am required to take into account that decisions had to be made by Drs Phillips and Baillie under the pressures of the emergency confronting them (see *Walker v Hamm* [2008] VSC-596).

46. I believe I am also required to have regard to the levels of experience of Dr Phillips the Paediatric Resident, and Dr Baillie the Paediatric Registrar.

ISSUES FOR DETERMINATION

47. In broad terms, the principal areas upon which I need to make formal findings are:

- Did Louis suffer an anaphylactic reaction to the breakfast served at approximately 7:15am by Ms Irene Fisher? In that context, I need to examine the adequacy of what I will call the "food preparation and presentation regime" in place in the paediatric ward at Frankston Hospital at the time of Louis death.
- If Louis did suffer an anaphylactic episode upon tasting his breakfast, was a diagnosis, formal or differential, made in a timely manner?
- Were the steps taken to treat Louis, once an anaphylactic reaction was suspected, reasonable and appropriate? In this context, I will consider whether medical management was in compliance with the relevant guideline in place at the time.
- Again in that context, were the medical resources (personnel) brought to bear timely and appropriate in the circumstances?
- Was the decision to intubate Louis appropriate and timely?
- Were the anaesthetic agents utilised to facilitate intubation in accordance with standard practice?
- Was the realisation Louis suffered malignant hyperthermia timely and was the subsequent treatment provided to the rare condition appropriate?

I indicated at the second Mention/Directions Hearing that the resolution of most of those issues would likely involve a "battle of the experts."

48. In relation to the food regime, on behalf of Frankston Hospital, Dr Halley presented a document containing what I will call "concessions;" concessions which, on the material to hand, really had to be conceded. The concessions made are as follows;

    1. There was a lack of a written policy regarding food handling pertinent to patients with allergies on the paediatric ward as at the time of Louis' admission.
    2. Any policy that was in place was ad hoc in that it relied (at least in part) on a PSA orally communicating with a nurse as to what food a patient could be given.
    3. Any policy that was in place did not ensure that a nurse checked the food prepared for an allergic patient prior to it being given to the patient.
    4. Insofar as the policy required the documentation of the name and food allergies of Louis on the kitchen white board, this did not occur.
    5. The above led to an inadequate food handling policy which was a systemic failure (rather than a failure of any individual).
    6. It is not conceded that Louis was given food or drink to which he was known to be allergic. However, given the temporal connection between the delivery of breakfast and the onset of Louis' throat tingling, it is possible that an allergic reaction was triggered by the breakfast.
    7. The inadequate food handling policy allowed for potential error to be introduced in the process of preparing and providing Louis with his breakfast.

    There were, it was conceded, significant systemic failures in the food handling practices/policies in place at the time. As noted above it was not conceded that the breakfast provided to Louis contained anything that it was known Louis was allergic to.

THE CONCLAVE – "HOT TUB"

49. In matters such as this, where an assessment of medical management is to be made, the Court has of necessity to rely upon the opinions of individual experts in their field. Therefore the evidence which will determine the principal findings is that of the experts; two independent experts commissioned by the Court, three engaged on behalf of Louis' parents and two engaged by Peninsula Health.

50. Earlier in this finding, I listed the nine questions I wanted the conclave to address. I believed the responses by the panel of experts to those specific questions should provide answers to most of the principal issues I was required to resolve. In relation to some of the issues, there was not unanimity, but in many there was a consensus of opinion.

51. In seeking to articulate the conclusions I have reached, I have done my best to encapsulate what conclusions the panel came to and indicate where there was some contention, or non-consensus by a member or members of the panel, what the difference of opinion was and the basis, or bases for that divergence of opinion.

52. The evidence of the experts (except Drs Ross and Costello) was provided in three stages:

    - Their written expert opinions, all of which are in evidence.
    - The position each took in relations to the issues discussed in the conclave, as advised by Professor Woodford, whether it be agreement with, or divergence from, the position of others.
    - Their evidence in response to questions put by counsel, or me, in concurrent evidence.

    In relation to stages two and three, Dr Ross was not involved, due to being unavailable on 15 December, and Dr Costello although involved in the conclave, was excused from further attendance due to an important engagement prior to concurrent evidence being given.

FOOD HANDLING IN THE PAEDIATRIC WARD

53. Leaving aside for the moment the question of precisely what in the breakfast provided by Ms Fisher was the cause of the anaphylactic episode Louis experienced, it was conceded that the food handling procedures/processes in place at Frankston Hospital/training were deficient, the deficiencies being systemic. Mr Winneke supported by Dr Halley submitted it would not in the circumstances, be appropriate for me to make adverse findings against either Ms Fisher, or Ms Hanisch. As Dr Halley stated they, (Ms Fisher and Nurse Hanisch) *"...only worked within the system they did not design the system and the system allowed for errors."* While from one perspective that may appear a little magnanimous, ultimately I am comfortable adopting that approach. It is sufficient, in my view, to accept that the food handling regime in place at the time was clearly deficient. As Dr Gilbertson, Manager, Nutrition and Food Services Royal Children's Hospital in her statement (Exhibit "N") said, aspects of it *"posed a potential risk of error."*[8] The most important aspect of the independent review undertaken by

[8] Statement of Dr Gilberton. P151 of Coronial Brief

Dr Gilbertson was that it formed the basis of the implementation of new Food Services Allergy Management Policies Procedures and Guidelines at Peninsula Health.

54. Dr John Kerr, Executive Director of Medical Services, Peninsula Health gave evidence as to Peninsula Health's response to Louis' death. In his statement (Statement Exhibit "P") Dr Kerr conveniently listed the findings and recommendation of what I will call the "Gilbertson Review." For completeness, and due to their importance, I include the relevant excerpt from his statement:

> *"9. In addition to the external audit performed by Frankston City Council, the Royal Children's Hospital* ***(RCH)*** *performed an independent review of Peninsula Health's paediatric food services allergy management policies, procedures, guidelines and practices, at Peninsula Health's request. The site was inspected on 23 December 2015. The RCH made the following recommendations:*
>
> *a. cease decanting of milk on the ward and provide single serve, unopened tetrapacks to patients instead. -This recommendation was implemented on 18 January 2016 as follows:*
>
> *(i) patients identified as having an allergy to dairy are provided with soy milk in single serve tetrapacks; and*
>
> *(ii) an additional check is completed by the PSA by crosschecking the UR number on the tray ticket and the red alert patient ID band;*
>
> *b. provide a label of ingredients for cereals which have been decanted. This recommendation was implemented on 14 January 2016. Nutritional panels are now clearly placed on all cereals on the ward for easy reference by PSAs, nursing staff or parents;*
>
> *c. produce an allergen matrix for the three week menu cycle that clearly indicates whether each menu item contains any of the eight main food allergens. - This recommendation was implemented on 18 January 2016. An allergen matrix for the three week paediatric menu cycle clearly indicating any of the eight main food allergens for each menu item is displayed in the paediatric ward. Allergens are identified on the CBORD menu management system for all other acute and subacute wards;*

d. *produce written documentation of the meal serving procedure in the ward pantry, for full ward diet, allergy patients and other special diet codes, ideally as a flow chart. - This recommendation was implemented on 29 January 2016. The paediatric allergen management process flowchart is displayed on the wall next to the allergen matrix. The flowcharts were rolled out to other wards such as the Frankston Hospital Emergency Department and Dialysis Unit by 26 February 2016;*

e. *any patient with a food allergy be managed by the menu monitor and entered into the CBORD menu management system so all food items can be checked and tracked. All three meals should be produced in the main kitchen, checked by the supervisor and then delivered on a red identifying tray directly to the patient rather than served from the ward pantry. Extra vigilance was recommended for patients with unstable asthma as this may contribute to a heightened risk of anaphylaxis. - This recommendation was implemented on 1 February 2016 as follows:*

   (i) *patients admitted to the paediatric unit with food allergies are managed by the food monitor for all meal selection;*

   (ii) *the meals are distributed on a separate trolley on red trays with the meal ticket with the patient's UR number and name;*

   (iii) *the meal is cross checked by the PSA, by confirming the patient's UR number and name with their red patient ID band; and*

   (iv) *training on the process has been undertaken with ward and menu monitor staff;*

f. *food presented to a patient requiring a special or allergen-free diet should be checked and signed off by the PSA and then co-signed by the nurse before being given to the patient. - This recommendation was implemented on 1 February 2016 as follows:*

   (i) *the PSA and nurse are responsible for delivering the meal to the patient;*

(ii) *the nurse will sign off on the tray ticket to confirm that the correct meal has been provided;*

(iii) *the signed tray ticket is then filed with the patient's notes; and*

(iv) *training on this process has been undertaken with the ward staff;*

g. *snacks should be provided as a snackbox prepared in the main kitchen and labelled with the patient's name, UR, ward and room number or appropriate portion pack biscuits such as rice crackers can be available on the ward stored in a separate airtight container.- This recommendation was implemented on 1 February 2016 as follows:*

(i) *snacks or midmeals for patients with food allergies will only be prepared and issued to the patient by the main kitchen;*

(ii) *a list of suitable snack items recommend by the paediatric team has been entered into the CBORD menu management system for compliance;*

(iii) *small red trays have been purchased for the paediatric ward to be used in the provision of snacks as an additional alert; and*

(iv) *any alternative products in the paediatric ward will be stored separately and labelled for patients with intolerances;*

h. *signage that clearly indicates 'special diet' be placed on the patient's bedside. - This recommendation was implemented on 19 February 2016 as follows:*

(i) *red ID bands are used to identify patients with allergies;*

(ii) *meals are crosschecked by nurses and PSAs; and*

(iii) *over-bed signage has been implemented in the paediatric ward and is the responsibility of clinical staff who enter the diet into the CBORD menu management system. Documentation and guidelines have been updated*

appropriately and training has been undertaken by ward staff, PSAs, menu monitors and nutrition staff;

i. *written documentation of training frequency, content and attendance be produced. Specific training on allergen management, cross contamination and special diet codes should be given by the clinical dieticians on a three monthly basis to all PSA and food service staff in addition to their usual food safety training modules. - This recommendation was implemented on 29 January 2016 as follows:*

   (i) *all staff now require log-on credentials so that they can access online training;*

   (ii) *FSAs and PSAs currently receive fully accredited training every three years;*

   (iii) *it is a condition of their employment that all food handlers have a current Food Handling Certificate;*

   (iv) *food safety refresher training is pursuant to a mandatory, annual training module; and*

   (v) *support services, speech pathology and nutrition deliver annual training to PSAs, to ensure the key aspects of allergen management, cross contamination and special diet codes are adequately covered. Training attendance is recorded for compliance;*

j) *a separate bain-marie or section for 'special products' be arranged to minimise the risk of cross-contamination or error. Alternatively, gluten free products should be placed in a single portion container that can be added to the meal separately. - This recommendation was implemented on 15 January 2016. All allergen-free meal components sit separately to the main meal choices at the point of service; and*

(k) *documentation and sign off for special diet meals or allergen free meals that state the recipe was followed verbatim and no product substitution was made during production. Alternatively, allergen-free meals can be purchased from an external supplier and*

reheated before serving. - This recommendation was implemented on 29 January 2016. A selection of meals which are free of all of the eight main food allergens have been purchased from Kingston Central Production Kitchen which is part of Monash Health. The meal items are entered in the CBORD menu management system for compliance and served to patients with allergies."

55. Dr Kerr also provided a copy of a Flow Chart for Management of Allergen Free Meals (Annexure A) in both the general and paediatric wards that flowed from the review, which is annexed to this finding.

56. Dr Kerr, in the final paragraph of his formal statement, provided a broad summary of the hospital's responses to the tragic circumstances surrounding Louis' death; he wrote (at paragraph 10) under the heading, "Additional changes implemented as a result of the reviews:"

> *"As well as responding to the recommendations outlined above arising from both the clinical and food handling reviews, Peninsula Health has continued to raise the awareness of anaphylaxis with all clinicians and highlighted the rising incidence of serious allergies in the Australian community with the Department of Health. Education of staff has been undertaken to increase the awareness of appropriate response/s to anaphylaxis. We are currently reviewing and updating out hospital guidelines to ensure that they are contemporary and accord with best practice."*

I am satisfied Peninsula Health's new policies, procedures and guidelines in this regard are thorough and appropriate. The recognition of the deficiencies in their systems, and the implementation of new practices, policies and guidelines, relieves me of the obligation to make formal recommendations on the issue.

CENTRAL ISSUES OF CONTENTION

57. I list below the matters upon which I am comfortably satisfied, and upon which there was virtual consensus of opinion by the experts, and then I will return to the central contentious issues:

    a) of the cause of Louis' anaphylactic reaction

    b) and the adequacy of medical management at "phase two"

I am satisfied:

- At 7am Louis' asthma exacerbation had all but resolved.

- Virtually immediately after the first mouthful of breakfast Louis experienced an allergic reaction.
- Dr Phillips and subsequently Dr Baillie attended upon Louis in a timely matter and within a reasonable timeframe Drs Phillips and Baillie concluded Louis' condition was likely an anaphylactic reaction to something in the breakfast provided.
- The decision to summon PIPER to transfer Louis to a tertiary hospital for treatment was appropriate and made in a timely manner.
- The decision to intubate Louis was appropriate.
- The medical management of Louis by Anaesthetist Dr Hales was reasonable and appropriate and the anaesthetic agents utilised to facilitate intubation were also appropriate;
- Louis suffered a reaction to an anaesthetic agent which resulted in malignant hyperthermia, an extremely rare condition, which could not reasonably have been foreseen.
- Subsequently Louis suffered a cardiac arrest from which, in spite of full resuscitation measures, he could not be revived.

THE CAUSE OF LOUIS' ANAPHYLAXIS

58. While I am comfortably satisfied Louis suffered an anaphylactic reaction to the breakfast provided, seeking to determine precisely what the allergen in the food was has been elusive. One of the principal reasons for my frustration is due to the fact I have been unable to satisfactorily determine whether the carton of milk delivered to VIFM for analysis was **the** carton from which Ms Fisher took the milk she delivered to Louis in a glass accompanying the Weetbix, or it was **a** carton of soy milk from the stock in the refrigerator in the paediatric kitchen.

59. It is to be recalled that earlier in the proceeding when Dr Halley made concessions as to food management, he specifically did <u>not</u> concede that the breakfast provided to Louis contained anything that it was known Louis was allergic to. (See paragraph 45 of Finding).

60. Initially, I, and I suspect Forensic Pathologist Baber, presumed it was **the** carton, but now, in spite of further eleventh hour enquiries, I am not sure it was.

61. Mr Winneke in his final submission, not surprisingly, was highly critical of the hospital in not "isolating the food that Louis had been given for the purposes of testing" (Transcript 21.12.17

on page 7). Even without knowledge that Louis would ultimately die, the fact that very shortly after commencing breakfast he suffered symptoms indicative of an allergic reaction, which attending doctors concluded quite quickly was very likely an anaphylactic episode, dictated that the foodstuff that may have contained the allergen should have been retrieved and secured, if for no other reason than for the purposes of internal investigation. I am somewhat frustrated by the fact that ultimately, although it is a possibility, I am unable to definitively determine whether Ms Fisher mistakenly provided cow's milk to Louis, rather than soy milk.

62. When one considers that Louis was only provided Weetbix and milk (whatever type it was), the potential source of the allergen is very much limited/restricted. Even more so when, shortly prior to the commencement of the inquest Professor Woodford facilitated further analysis which excluded the prospect that the allergic reaction Louis experienced was due to soy – the analysis undertaken at the Royal Children's Hospital shortly prior to commencement of the inquest demonstrated SIgE was negative to soy protein. That analysis laid to rest the prospect that Louis may have suffered a "new," previously unknown reaction to something in soy milk.

63. The submissions by counsel on the issue are interesting; Mr Winneke submitting that there is an "overwhelming inference" open to be drawn, that Louis was inadvertently given cow's milk, or the milk provided, if indeed it was soy, was in some way contaminated. On the other hand, Dr Halley maintained there was no good, primary evidence before me which demonstrated Louis was given cow's milk. Dr Halley conceded however that there was a "temporal connection" between the provision of breakfast and the onset of tingling in the mouth. He added:

> *"The admission is that that's a possible allergic reaction, but Your Honour has heard the totality of evidence."* (Transcript submission of page 58)

64. In answer to the third of the questions I formulated for consideration by the experts in conclave, in concurrent evidence I was advised there was consensus that Louis' deterioration was due to an "anaphylactic reaction in the setting of acute exacerbation of chronic asthma."

65. Ultimately, due to an irresistible inference, I am comfortably satisfied Louis anaphylaxis was indeed due to an undetermined allergen contained in the breakfast provided. Whether it was mistakenly cow's milk in the glass, or some contamination due to dairy product, regrettably I am unable to determine.

MEDICAL MANAGEMENT - "PHASE TWO"

66. This is the area of more contention, and the area where the opinions of the experts are of necessity critical. Mr Winneke describing the medical management during the period prior to intubation as "ponderous," submitted that had the medical management been more "aggressive" the escalation of management, through to intubation, may have been avoided. He submitted:

> *"There is evidence that there were delays in the administration of the first line of treatment, being adrenaline and that the treatment was not sufficiently aggressive."*[9]

The basic thrust of the argument put on behalf of Louis' parents in relation to the medical management during what we have called "phase two" was, as I understood it, threefold:

- The Australian Society of Clinical Immunology and Allergy (ASCIA) guidelines in relation to the timing of administration of adrenaline were not followed.
- An adrenaline infusion (rather than intramuscular injections) should have been undertaken earlier.
- More senior medical staff (rather than paediatric resident and registrar) should have had more active, hands on involvement in Louis' treatment once there was a real prospect his deterioration was due to anaphylaxis, rather than an exacerbation of asthma or a mere food allergy.

67. I think it fair to say there is little contention surrounding the chronology of the actual actions, steps, treatments provided by Dr James Phillips the Paediatric Resident and Dr Cara Baillie, the Paediatric Registrar. However, whether their medical management of Louis was reasonable and appropriate is where the evidence of the experts is critical. I turn to that evidence.

68. The Court had, with considerable difficulty, commissioned independent expert opinions which were provided by Professor John Ziegler and Dr Andrew Numa, both of Sydney Children's Hospital.

69. In broad terms, in their initial reports, both the experts commissioned by Maurice Blackburn for the family, and those commissioned by Minter Ellison for Peninsula Health, supported the position taken by the respective parties (that is not in any way a criticism, merely a fact). That is, Drs Costello, Reeves and Daley opined that medical management was deficient in one way

[9] Submission Transcript page 10

or another; whereas Drs Jacobe and Ross opined the medical management afforded Louis was generally reasonable and appropriate.

70. I stress that purely because Dr Numa and Professor Ziegler were engaged by the Court does not necessarily mean their opinions will prevail. I am required to look at the whole body of expert evidence and seek to determine where the weight of evidence lies.

71. I have vacillated as to how, in this finding, I go about expressing the conclusions I have reached and the evidence I have relied upon to come to those conclusions.

72. Earlier in this finding (at para 33), I referred to the questions both I, and the parties, put to experts in conclave. Although I believed most of the specific questions put on behalf of the parties were encapsulated to a significant degree in the first eight of my questions, I thought it prudent for the experts to provide opinions in relation to all questions put. That was done and after the conclave, when the group of experts, (other than Drs Ross and Costello) gave concurrent evidence, my assistant, Mr King Taylor put each of the questions to Professor Woodford who relayed the experts' answers to the questions. Where there was contention, a divergence of opinion, the expert who held a contrary view to the others was given an opportunity to articulate his position. Furthermore Mr Winneke was able to explore with the witnesses their responses.

73. My dilemma lies in that that evidence is contained in some 27 pages of transcript. What I have sought to do, is carefully examine the transcript of the concurrent evidence and Mr Winneke's examination of various participants, and as best I can, address what I see as the critical issues by summarizing the responses to the questions posed. Of course the entire transcript of the proceeding (including final submissions some 610 pages) will form part of the public record of the proceedings.

74. I must say that to my surprise, there was a greater degree of consensus of opinion in the conclave than I had anticipated in relation to most of the issues raised.

75. The medical management of Louis in the period from when the anaphylactic event was recognised, through to intubation, ("phase two") was one of the two primary foci of my investigation and subsequent inquest hearing. It was the central issue addressed by the experts engaged by the Court, the family and the health service. The first "principal question" I had formulated for consideration in the conclave was – "was medical/nursing management of Louis appropriate and timely and in accordance with published guidelines?" As referred to earlier in this finding, the criteria to be applied when assessing the medical management of Louis anaphylaxis is, was it reasonable and appropriate in the circumstances.

76. Professor Woodford, in relaying the conclusions reached relating to my first, primary question indicated that although in broad terms, the opinion of the panel was that the medical management provided in phase two: was reasonable, *"notwithstanding things could've been done better"*, suggested that where there was some divergence of opinion, each expert could be invited to expand upon their view.

77. So as to ensure I do not misinterpret what was said by the various experts, and rather than me seeking to paraphrase their responses, I propose to include the relevant excerpts from the transcript.

78. Dr Reeves explained his position when I invited him to comment on the issue; he said:

> *"Yes, Your Honour. I do, do accept that hindsight is a marvellous thing and we are talking about some conflicting aspects in the notes. My, my reading of the record was that the time frame between the initial reporting of symptom and the subsequent administration was perhaps up to 25 minutes and so we would all agree that in hindsight, if anaphylaxis is recognised, that that is at the upper limit of normal range and, and perhaps that certainly falls within what my colleague says could've been handled better. And so I think -I think the feeling amongst some of our colleagues was that perhaps a more aggressive, more timely approach could have made a difference although we couldn't have confidently stated how much of a difference that would have made. That's very hard to quantify."*[10]

Dr Daly having earlier indicated he considered the intervals between the administration of the doses of adrenaline did not strictly conform with the guidelines, added:

> *"Yes, Your Honour. I agree in principle with what Dr Reeves was saying. The thing is the doctors in attendance were, as Dr Jacobe saying, empowered within the protocol to exercise their judgment. But in hindsight, and I understand that's a very powerful, I felt strongly that a more aggressive approach was warranted but I know the ultimate outcome, which of course invalidates that comment. But the practitioners who were exercising the judgment were those with the minimal medical qualification in setting of having worked all night as well, and I wonder whether the judgement might have been different with senior staff who were fresh."*[11]

79. On the other hand, Dr Numa, one of the experts engaged by the Court, expressed his opinion in the following terms:

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[10] Submission transcript page 490 – 491

[11] Submission transcript page 492

"Thank you, Your Honour. Look I believe that the time course of interventions from first recognition through to getting to the operating room for intubation was entirely reasonable. This is not a simple diagnosis to make, particularly in a child who's been admitted to hospital with an entirely different label and I actually think the junior medical staff did quite well to rapidly realise this was not an acute deterioration of asthma but in fact represented another illness altogether, and they responded I think appropriately. The guidelines allow for more frequent administration of adrenaline but the administration of any resuscitation drug is always titrated against the patient response. The patient should arrive in the operating theatre adequately oxygenated with a good cardiac output and were it not for the malignant hyperthermia, I'm absolutely certain that the outcome would have been positive. And in that setting, the role of the junior staff which is to stabilize the patient, get senior help, and get the patient to a safe place which in this case was or should have been the operating theatre in a decent condition, all of that was fulfilled."[12]

80. Professor Ziegler, also engaged by the Court, indicated he concurred with Dr Numa, adding:

"Your Honour, I don't really have anything to add to that. There's a variation in clinical response in any situation and I think it was in all within those constraints."[13]

Dr Jacobe, engaged by Peninsula Health addressing the particular issue of the timelines of the administration of intramuscular adrenaline, opined medical management was adequate, elaborating:

"Thank you, Your Honour. I believe that basically the treatment given by the nursing and medical staff were – was adequate and conformed with the guidelines insofar as the guidelines gives the treating medical staff some latitude to provide – or give further doses of adrenaline as required and according to the response of the doses given. I think the timeliness of the first does is – it's unclear in the medical literature about when too late is – or when adrenaline given is too late, usually within 30 minutes is currently what's in the medical literature. Obviously this is an area that can't be tested by empiric means."[14]

Dr Jacobe, responding to my query as to whether the timing of the administration of adrenaline was appropriate said:

[12] Transcript page 493
[13] Transcript page 493
[14] Transcript page 491
[15] Transcript page 492

"I think there was said to be improvement after each dose of adrenaline and then deterioration following that and I think the doctors used their judgement in terms of the administration of the adrenaline and I think that's reasonable in the circumstances."[15]

81. Mr Winneke broached with Dr Numa the subject of claimed failure to follow appropriate guidelines. I consider Dr Numa's responses in support of his opinion that the performance of Drs Phillips and Baillie was reasonable warrants inclusion. I include several excerpts from his evidence; he said:

> *"Look, guidelines are increasingly prevalent in medicine and definitely serve a role but in a starting point, they're not the definitive treatment...and the treatment of any patient is always based on the individual patient's circumstances. You cannot write a guideline that's entirely appropriate for all comers under all circumstances."*

He further added:

> *"The practitioners were attentive to Louis' condition and were observing and at intervals during that quite long period, more than an hour intermittently gave adrenaline injections when they felt it was clinically indicated. That's the sense I get from reading the notes. To say that guidelines says "thou shalt have five minute intervals" it's not really appropriate in the individual case. It's a broad based document, you know, it's an ASCIA national guideline to apply it verbatim to individual is not necessarily appropriate."*[16]

He concluded:

> *"Well, I would argue – as I said before, practitioners, we're at the bedside observing Louis' responses. And for a long period of time after that, I mean the point I made earlier was that he arrived in the operating theatres with – adequately oxygenated, with a cardiac output. After more than an hour of management at the bedside by the junior medical staff, to me that suggests the management was within the bounds of acceptable because they – he arrives in the anesthesia bay in a reasonable condition."*[17]

82. One of the questions I posed for consideration by the experts in conclave was – are the guidelines relating to individuals with both asthma and allergy consistent throughout the country and are they adequate? Professor Woodford advised that Dr Jacobe, who practices in

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[16] Transcript page 522 - 524
[17] Transcript page 528

NSW, considered the guidelines were reasonably consistent at least as far as Sydney is concerned. Professor Woodford indicated that Dr Reeves, who also practices in NSW, added that in his view the ASCIA guidelines suggest where asthma is a component of anaphylaxis, anaphylaxis should be treated first. The balance of experts concluded that the current guidelines are adequate. Later in this finding I propose to comment upon some of the issues surrounding the adequacy of present guidelines.

83. In relation to the other aspect of Mr Winnekes' contention that treatment should, in the circumstances, have been more aggressive in that an adrenaline infusion should have been undertaken earlier, Dr Daley, as I understood him, accepted that his position on the issue may have been influenced by the fact that he, as a vastly experienced senior cardiothoracic anaesthetist in a renowned tertiary hospital, undertaking that procedure is in his "comfort zone."

84. In concurrent evidence, after the conclave, although there was some divergence of opinions as to the efficacy of medical management of "phase two," (the anaphylactic episode at approximately 7:20am), overall the conclave came to a consensus that in broad terms it was reasonable, albeit the experts engaged by Maurice Blackburn for the family maintained it was at the "upper end" of reasonable. I queried what was meant by the "upper end of reasonable," and was advised that those who held that view meant that treatment was just within what could be considered reasonable.

85. In reaching a conclusive view on this issue I have assiduously examined the relevant body of evidence. I think it fair to say Dr Reeves and Daly retreated to some degree from their initial opinions; by that, I mean although maintaining their views that aspects of medical management were what I will call sub-optimal, accepted that overall medical management was at the "upper end" of reasonable. Professor Ziegler, Dr Numa and Dr Jacobe all opined medical management was reasonable and appropriate.

86. Mr Winneke's client's contention was that had medical management been "more aggressive," including more "hands on" involvement by consultants Drs Pillay, Blair and Bowden, and had there been earlier administration of an adrenaline infusion, it would have significantly increased Louis chances of avoiding intubation. Mr Winneke conceded that was not the unanimous view of the conclave, adding that I was not bound by what the conclave concluded.

87. The consensus of opinion was that it was not necessary that any of the consultants actually undertake a "hands on" examination of Louis during the period he was being treated by Drs Phillips and Baillie.

88. The conclave considered this very question. When I examine the transcript of the concurrent evidence it seems there is some equivocation on this question. At page 48 of the transcript, the panel, addressing question 18 of the Maurice Blackburn questions concluded the issue was difficult, but it was thought that with more aggressive and timely treatment it was possible intubation could have been avoided, but on balance the conclusion was that it would not have altered the need for intubation.

89. Whereas, in response to question 15 posed by Minter Ellison, Professor Woodford, advised:

> *"The panel feel that it wasn't possible to say on a balance. But with the benefit of hindsight, more aggressive treatment might have made a difference to the outcome."* [18]

I do not have the luxury of considering the matter with the benefit of hindsight.

90. In reaching a concluded view on this significant issue I note Mr Winneke's final submission;

> *"It's accepted that Your Honour, on the evidence, the medical evidence could not find on the balance of probabilities that, had the aggressive treatment been provided, he would have avoided the requirement for intubation, but the evidence was that his prospects of avoiding it would have been significantly improved."*[19]

I conclude that even if Drs Blair Pillay or Bowden had a more direct involvement, the course of treatment would not have been materially different. Once the decision to transfer was made, and I am satisfied that decision was entirely appropriate, intubation necessarily followed.

91. Interestingly, during concurrent evidence Mr Winneke put questions to several of the experts seeking I believe to recover ground seemingly lost when, in spite of some reservations, they modified their opinions, accepting that aspects of medical management upon which they had been critical in their written reports was reasonable – the test of adequacy of performance - albeit at the "upper end" of reasonable.

92. On the other hand, Dr Halley, when he had the opportunity to examine the experts had no questions whatsoever. I concluded he considered his position secure and not requiring bolstering. I suggest the position taken by Dr Halley demonstrated where the weight of evidence lay.

93. While several participants in the conclave categorised the medical management of Louis during "phase two" as at the "upper end of reasonable," and that was the opinion relayed by Professor Woodford, I am satisfied the performance of Drs Phillip and Baillie was better than

[18] Transcript page 486
[19] Transcript of submissions page 10

that. In the final analysis, removing hindsight, I do not put the "upper end" caveat on their medical management of Louis which I concluded was well within the bounds of reasonable.

94. When I apply what I believe to be the appropriate standard of proof, I am comfortably satisfied there is no reasonable basis for an adverse finding about the overall medical management of Louis by medical staff who were involved in phase two of his treatment on the morning of 23 October 2015.

POST INTUBATION MANAGEMENT

95. At the second Mention/Direction hearing Mr Winneke indicated, as I understood him, that the medical management of Louis post intubation was not in issue. In indicating the scope and parameters for the formal inquest, I indicated I would not therefore be pursuing issues related to that period of medical management.

96. However, early in the inquest hearing, Mr Winneke indicated he did in fact wish to pursue several aspects of anaesthetist Dr Hales' management of Louis post intubation. Dr Halley indicated that if I permitted that area of examination, he would not formally oppose Mr Winneke broaching that issue, but may wish to review that position and seek to counter any criticism of Dr Hales' performance.

97. Mr Winneke went on to submit that aspects of Dr Hales' management of Louis post intubation were "unsatisfactory," in that a core temperature monitor was not utilised. However, in the initial outline of his submissions on this issue Mr Winneke conceded:

> *"Your Honour is not in a position, on the evidence available, to conclude that there was unreasonable delay in the diagnosis and management of the malignant hyperthermia."*[20]

98. Dr Halley, in his submissions, said:

> *"We say there is simply no evidence to make any criticism of the care post intubation."* [21]

Dr Halley submitted that Mr Winneke quite rightly conceded that Dr Hales found himself in a difficult situation.

99. The panel concluded that although Louis' end tidal carbon dioxide (ETCO2) was adequately monitored by Dr Hales, Louis' core temperature could have been more closely monitored with the use of a temperature probe, which may have resulted in an earlier recognition of

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[20] Submission Transcript page 11
[21] Submission Transcript page 60

Louis' deterioration and recognition of malignant hyperthermia. Professor Woodford, conveying the panel's opinion as to the anaesthetic management of Louis by Dr Hales, said:

> *"The answer was Dr Hales was the anaesthetist in charge of the case and had according to the notes gone through the possibilities so in the panel's opinion the course of action was appropriate."*[22]

100. In spite of the matters Mr Winneke suggested were "unsatisfactory," I am satisfied the medical management of Louis post intubation, including the method and timing of the administration of Dantrolene, was reasonable and appropriate in the circumstance. The fact is malignant hyperthermia is an extremely rare/complication following the administration of standard anaesthetic agents to facilitate intubation. Dr Hales was indeed in an unenviable situation.

WAS THE ANAPHYLACTIC EPISODE DUE TO BREAKFAST A CAUSAL FACTOR IN LOUIS' DEATH?

101. I turn to what I consider the principal question I am required to resolve - was the anaphylactic episode resulting from an undetermined allergen in the breakfast provided to Louis a causal factor in his death?

102. Having concluded Louis did indeed suffer anaphylaxis due to an undetermined allergen in the breakfast provided, I turn to what I consider the principal finding I am require to make.

103. In *Chief Commissioner of Police v Hallenstein* (1996) 2 VR 1, Hedigan J observed:

> *"The issues of causation and contribution have bedevilled philosophers for centuries and have attracted consideration by superior courts in all jurisdictions and places for more than a century."*[23]

I am sure His Honour was right, but irrespective, the issues of causation and contribution have certainly "bedevilled" me this last month as I penned this finding! The question I have anguished over is, although the anaphylactic episode that flowed from an allergen contained in the breakfast provided to Louis resulted in the need to intubate Louis to stabilize him for transfer to a tertiary hospital, was clearly a causal factor leading to the intubation, does the intervening event, a *novus actus interveniens*, the malignant hyperthermia event due to a reaction to the anaesthetic agent, break the chain of causation between the earlier anaphylactic

[22] Transcript page 480
[23] (1996) 2 VR 1 at page 14

episode and death, so that the provision of the breakfast containing the allergen cannot be seen as a causal factor in Louis' death?

104. When I consider the matters referred to earlier in paragraph 39 of this finding, I have asked myself, trying to apply a measure of common sense, is the connection between the initial breakfast anaphylactic episode and Louis' subsequent death logical, readily understandable and proximate; or illogical, strained, artificial? At first blush, looking at the circumstances, there is, I suggest, a logical attraction in the notion that there is a causal connection.

105. In submissions, Mr Winneke said:

> "*...If he'd gone home prior to being given his breakfast, he would have survived. But the unfortunate circumstance in this case is that he was given a breakfast which contained a substance that he was highly allergic to, and ultimately that was the significant cause of his death or the circumstances that led to the malignant hyperthermia.*" (my emphasis) [24]

106. Dr Halley submitted:

> *"That brings me to a point that is an important causation point, Your Honour, and it's this that we say in relation to the medical management, Your Honour, can't make a finding that the medical management was causally related to the outcome."* [25]

107. As I stated earlier in this finding, there is a logical attraction in the notion that the anaphylactic episode I have found was due to an allergen unintentionally contained in the breakfast provided to Louis, ultimately irrespective of the efficacy of initial medical management, led to intubation and thereafter due to the reaction to the anaesthetic used to facilitate intubation led to malignant hyperthermia and Louis' death.

108. In concurrent evidence, Mr Winneke put the following proposition to Professor Woodford:

> *"In view of the fact that there's general agreement that anaphylaxis was the material cause of death, surely it would not be referred to in the report of the pathologist as being a significant contributing factor or one of the cause of death?"*[26]

I think the proposition put by Mr Winneke is not properly reflected in the transcript. I believe the proposition put was – as an anaphylactic event occurred surely should it not be referred to in the autopsy report? Professor Woodford understood what was being put and answered the question on the latter basis. Professor Woodford responded:

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[24] Submission Transcript page 56
[25] Submission Transcript page 61
[26] Transcript page 494

"Well, this was specifically raised with the panel. I should say that when Dr Baber was formulating this report, she didn't have the benefit of all the information our panel had, but I specifically put that question to the panel. It might be worth restating it but the panel's view was that the cause of death as stated was reasonable. It does mention food allergy as a contributing factor. My understanding in the circumstances is that it was the acute respiratory deterioration that was – that prompted the need for consideration of intubation."[27]

Pursuing the issue further, Mr Winneke suggested:

"Well I understand that. Obviously, if the view is taken that without the anaphylaxis – there's no doubt as I understand it that anaphylaxis was material contributing to the conditions which led to intubation. If the view is taken that the intubation leads to death, surely it would be the case would it not that the anaphylaxis was a relevant and contributing factor?"[28]

That proposition led me to put the following question to Professor Woodford:

"Dr Woodford, if I were formulating a cause of death in these proceedings, bearing in mind your experience as a senior forensic pathologist, would you anticipate that I'd make some reference as a contributing factor at the very least to an anaphylactic reaction?"[29]

He replied:

"Yes Your Honour."[30]

109. I concluded Mr Winneke's examination on this issue was likely founded upon a view that the cause of death as formulated by Dr Baber in her autopsy report did not adequately reflect the position that the sequence of events, through to death resulted initially from an anaphylactic reaction to the breakfast provided to Louis. The conclusions reached by Dr Baber in formulating a cause of death were no doubt influenced by the fact that the analyses[31] of the soy milk provided by the hospital and the stomach and small bowel material did not demonstrate milk allergen contamination or cow's milk protein.

110. What Professor Woodford said in response to Mr Winneke's proposition – is when Dr Baber formulated the cause of death in her report, she did not have the benefit of all the subsequent

[27] Transcript page 494 - 495
[28] Transcript page 495

[29] Transcript page 496
[30] Transcript page 496
[31] National Measurement Institute – Reports nos RN1098258 and 10982584

information the panel had access to. That was so, further significant information came to light during the course of my investigation which ultimately led me to the view Louis did suffer an anaphylactic event.

111. While this is one of the saddest cases I have dealt with over the decades, and I cannot start to imagine the grief the death of Louis visited upon Ms Catan and Mr Tate, I must endeavour to be completely dispassionate and objective in assessing the performance of those who treated Louis on the morning of 23 October 2015.

112. I accept that the principles relating to causation in the context of civil proceedings for negligence are applicable to considerations concerned with causal factors in a death under coronial investigation, (Hedigan J. in *Chief Commissioner of Police v Hallenstein*). The evidence, from several quarters, suggests that the prospect of such a reaction occurring leading to malignant hyperthermia is approximately 1 in 250,000 to 300,000 cases; an extraordinarily rare occurrence and one that could not be reasonably anticipated.

113. In evidence, Dr Bowden maintained that it was his absolute expectation that once Louis was intubated and stable he would have been transferred to ICU, monitored for 24-48 hours and discharged.

114. In his expert report (at paragraph 35 (d)) Professor Zeigler said:

> *"It can be confidently concluded that had malignant hyperthermia not occurred Louis would not have died on 23/10/2015."*

115. One of the questions I formulated for the panel's consideration was:

> *"Had Louis not been intubated, is it more likely than not he would have survived?"*

For reasons primarily related to the issue of causation, I considered this an important issue. Professor Woodford advised that the conclave preferred another form of words, namely:

> *"Had Louis not required intubation is it more likely than not he would have survived?"*

I was more than happy with that alternative phraseology. The panel concluded, unanimously that had Louis not required intubation he would have survived.

116. Consequently, the evidence establishes to my satisfaction that save for the intervening event, the reaction to the anaesthetic agent resulting in malignant hyperthermia, Louis would have survived and been discharged home well; therein lies the cruellest irony.

117. The incontrovertible fact in this matter is that the prospect of Louis suffering malignant hyperthermia due to a reaction to the anaesthetic agents used to facilitate intubation could not have been predicted and broke the chain of causation.

118. Ironically, the weight of evidence, as stated earlier, led me to the view that the medical management of Louis' anaphylactic episode was, even if not optimal, reasonable and appropriate in the circumstances, so that adopting what I refer to as the "Callaway dichotomy" the medical management could not have been seen as a causal or contributing factor in any event.

FINDING/CONCLUSION

119. I conclude Louis Oliver Tate died at Frankston Hospital on the 23 October 2015 due to:

> **I (a) Malignant hyperthermia due to a reaction to an anaesthetic agent administered to facilitate intubation.**
>
> **Contributing factors:**
> **Anaphylaxis resulting from an undetermined allergen in breakfast provided to Louis which necessitated intubation.**

COMMENTS

120. Pursuant to section 67 (3) of the Act I make the following comments:

121. At the first Mention/Directions Hearing, through Clayton Utz solicitors, Allergy and Anaphylaxis Australia (A&AA) sought input into my investigation. I declined to accept A&AA as a formal "interested party" within the meaning of the Act, but indicated that in due course I may well invite input in relation to issues relating generally to relevant guidelines, their adequacy, and uniformity, and whether Peninsula Health's current Anaphylaxis Management Guidelines are appropriate.

122. A&AA accepted my invitation and provided a submission which I have found most helpful. I propose to annex the entire submission to this finding, but will also make reference to some matters contained therein.

123. Significantly, A&AA advise that there is no uniform standard for the management of anaphylaxis in Australia. At paragraph 9 of the submission is a table of "ten key guidelines for the treatment and management of anaphylaxis," together with a commentary regarding their adequacy. I found that part of the submission interesting. I do not know whether other entities involved in this area hold precisely the same views.

124. As well as annexing the entire submission to my finding, I include in the body of the finding several excerpts from the conclusions to the submission. It is submitted:

"There are no Government (National, State or Territory) acute anaphylaxis management guidelines/protocols for the recognition and emergency treatment of anaphylaxis that have all the information contained in the ASCIA Acute Management of Anaphylaxis Guidelines.

A&AA submits that current national and state guidelines, including those listed above, are inadequate because they fail to provide a uniform, national clinical care standard for recognition and emergency treatment of anaphylaxis."

125. A&AA submit that a mandatory Clinical Care Standard for Anaphylaxis be developed for application Australia wide. It is suggested that the Australian Commission for Quality and Safety in Healthcare are presently looking at the issue, apparently with a view to developing, and presumably promulgating, an appropriate/comprehensive standard. A&AA have suggested that this proposal be accelerated. Although I appreciate there are no doubt complex issues that require thorough consideration with the alarming increase in the numbers of children diagnosed with allergies I merely support their plea.

126. In the final paragraph of the A&AA submission, it was suggested that where a patient with an ASCIA Action Plan for anaphylaxis and in possession of an EpiPen presents at a paediatric unit or other high risk unit within a healthcare facility including a hospital, that EpiPen should be available for use. During the running of this matter it became apparent that presently there is a prohibition upon a patients personal EpiPen being utilised, at least by registered nurses. I went back to A&AA and invited the organization to expand on the issue.

127. In further correspondence under the hand of the A&AA CEO, Ms Maria Said, it was indicated the organization strongly supported health professionals being permitted to utilise an individual patients EpiPen. The position advocated by A&AA is encapsulated in the following excerpt from Ms Said's letter; she wrote:

"In conclusion, adrenaline autoinjectors are designed for prompt administration of a lifesaving medication, by lay people in the community setting. If available, there should be no barrier to health professionals administering an adrenaline autoinjector in any setting. It is nonsensical that an off duty health professional can administer an adrenaline autoinjector that is stored in a first aid kit at a football stadium, for example, but cannot administer an individual's own device when working in a hospital setting if it is not specifically ordered by a doctor."

Having given the matter thought, although it has a logical attraction, I decided to merely annex Ms Said's supplementary correspondence to my finding as a comment, rather than a formal recommendation. I decided to proceed on that basis primarily because I am not fully cognizant

of the precise rationale behind the prohibition, nor did I flag it to the parties during the inquest, and in any event considerations such as this are better determined in a specialist forum.

DISTRIBUTION OF FINDING

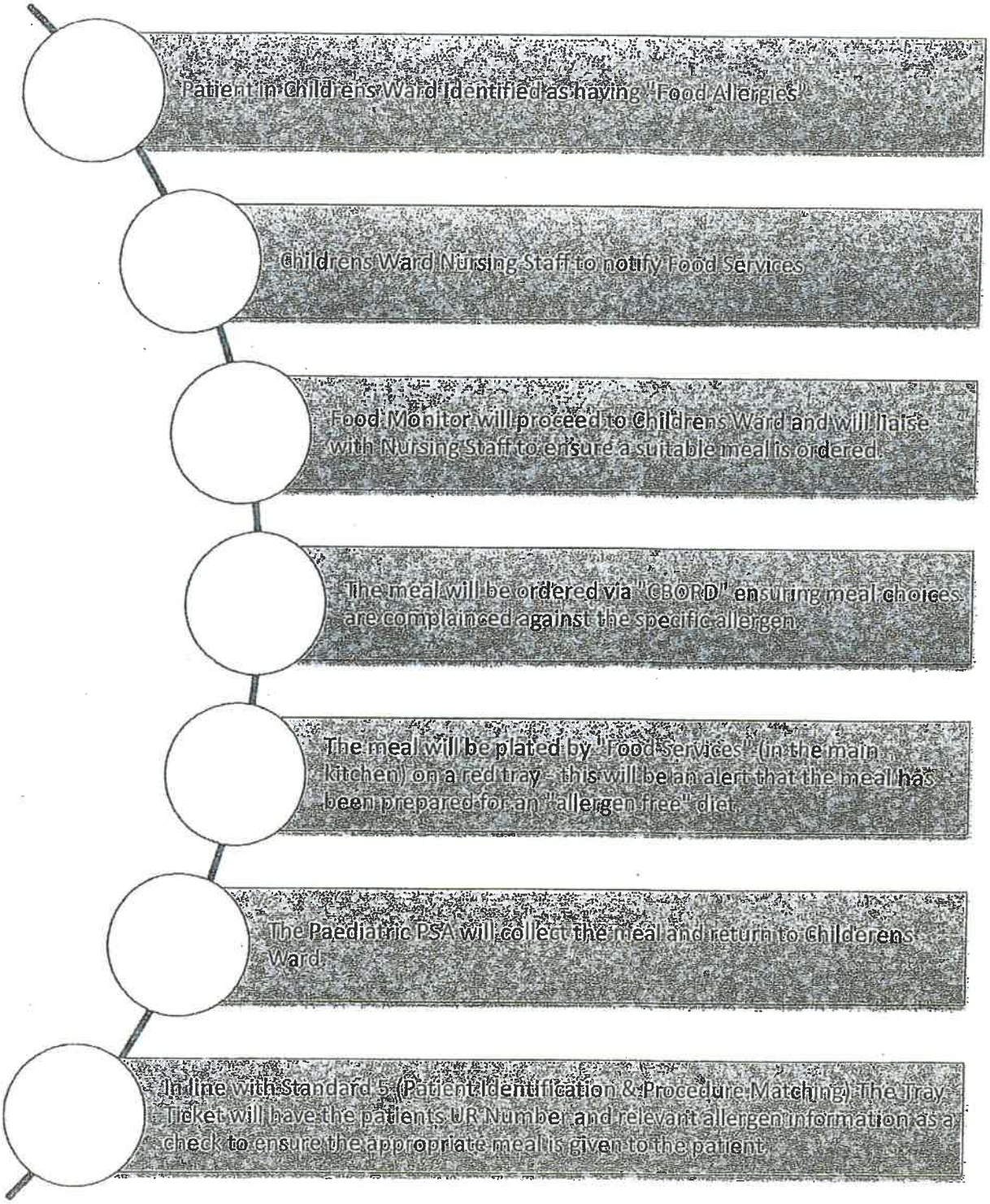
128. I direct that a copy of this finding be provided to the following:

- Maurice Blackburn, Solicitors for Ms Catan and Mr Tate;
- Minter Ellison, Solicitors for Peninsula Health;
- Safer Care Victoria;
- Australasian Society of Clinical Immunology and Allergy (ASCIA);
- Department of Health and Human Services;
- Allergy and Anaphylaxis Australia (A&AA); and
- Australian Commission on Safety and Quality in Healthcare.

Signature:

PHILLIP BYRNE
CORONER
Date: 13 April 2018

FLOW CHART FOR SERVING ALLERGEN FREE MEALS (Children's Ward)



COR 2015 5382

IN THE CORONER'S COURT OF VICTORIA
AT MELBOURNE

INQUEST INTO THE DEATH OF LOUIS TATE

Submissions filed by Allergy & Anaphylaxis Australia on 12 December 2017

Allergy & Anaphylaxis Australia (A&AA)

1. A&AA is a national charity supporting Australians with allergic disease. The organisation is recognised as a Peak Health Advisory Body and receives funding from the federal government. The A&AA Board and Medical Advisory Board include experts in the management of allergic disease, food policy and legislation, national policy and government, finance and consumers who live with allergic disease. More detailed information on Board and Medical Advisory Board members can be found at www.allergyfacts.org.au.

2. In 2014, the Australasian Society of Clinical Immunology and Allergy (**ASCIA**) and A&AA partnered to progress the National Allergy Strategy (**NAS**).[1] An Allergy Summit was held in 2014 and the NAS was launched in August 2015. This 53 page document contains 5 goals - namely, Standards of Care; Access to Care; Information, Education & Training; Research; and Prioritised Chronic Disease - and continues to drive best practice. The unique relationship between a medical and consumer peak body continues to drive the NAS.

Role in coronial inquest

3. His Honour Coroner Byrne has requested submissions from A&AA regarding the adequacy of:

   (a) current guidelines for the treatment of anaphylaxis at a state level;

   (b) current guidelines for the treatment of anaphylaxis at a national level;

   (c) current Peninsula Health Anaphylaxis Management Guidelines (**Peninsula Health Guidelines**).

4. A&AA's submissions are based on its knowledge and experience of severe allergy treatment, published data and ongoing management by health professionals. The submissions are not specific to the circumstances of Louis Tate.

[1] www.nationalallergystrategy.org.au/download

Executive summary

5. Currently there is no uniform standard for the management of anaphylaxis in Australia. Rather, there are hundreds of guidelines/protocols that have been published by various stakeholders including various healthcare providers at every level, national and state based medical colleges, individual medical practices (primary, secondary and tertiary), immunisation clinics and the like. With one qualification regarding adrenaline (epinephrine) auto-injectors (i.e. EpiPen®), A&AA submits that the ASCIA Guidelines which include the ASCIA Action Plan, are adequate. The other guidelines incorporate some, but not all, information required to recognise and manage anaphylaxis using available best practice national ASCIA Guidelines.

6. Due to the vast number of guidelines available, A&AA has focussed on ten key guidelines in these Submissions. These guidelines are detailed below and, along with the other guidelines that have not been specifically outlined in these Submissions, are mostly inadequate because they do not list/detail important evidence-based aspects of the ASCIA Guidelines.

7. A&AA submits that consistent guidelines for the recognition and emergency treatment of anaphylaxis will improve clinical outcomes for both patients and health professionals. The increase in food, insect and medication allergies in both adults and children means healthcare providers need to be educated on recognition and emergency treatment of anaphylaxis so they are prepared when they are faced with an allergic reaction. The increased prevalence of anaphylaxis means that all healthcare professionals, not just those working in areas such as food challenge clinics,[2] immunisation clinics, operating theatres, emergency departments and radiology units, need to be aware of the risk of anaphylaxis. Regular anaphylaxis training must be a component of every health professional's regular professional development (in the same way as cardiopulmonary resuscitation (CPR) and fire safety are currently).

8. One set of evidence-based guidelines that includes all required information should be introduced and mandated. This will assist healthcare professionals and patients in obtaining the best possible outcomes.

[2] Clinics where a food is given to an individual to see if they are at risk of anaphylaxis or have in fact outgrown their allergy.

Key guidelines

9. The following table lists ten key guidelines for the treatment and management of anaphylaxis and includes A&AA's submissions regarding the adequacy of each guideline.

9.1 Current Peninsula Health Anaphylaxis Management Guidelines (Victoria) - **pages 4-6**

9.2 Acute Management of Anaphylaxis Guidelines published by ASCIA (Federal) - **pages 6-8**

9.3 Australian and New Zealand College of Anaesthetists, Perioperative Anaphylaxis Management Guidelines (Federal) - **page 10**

9.4 Australian Immunisation Handbook (Federal) - **pages 11-12**

9.5 Australian Resuscitation Council Guidelines (Federal) - **pages 12-13**

9.6 Queensland Ambulance Service (Queensland) - **page 13**

9.7 Ambulance Victoria Clinical Practice Guidelines (Victoria) - **pages 13-14**

9.8 Royal Flying Doctor Service Guidelines (Western Operations) - **pages 14-15**

9.9 Sydney Children's Hospital Network Clinical Policy (NSW) - **page 15**

9.10 Royal Children's Hospital Anaphylaxis Clinical Practice Guidelines (Victoria) - **page 15**

Name of anaphylaxis guideline	National / State	Adequate or inadequate? (if so, why?)
9.1 Current Peninsula Health Anaphylaxis Management Guidelines **(Peninsula Health Guidelines)**	VIC	A&AA submits that the current Peninsula Health Guidelines are inadequate for the following reasons: ***(a) Inconsistent signs and symptoms*** The Peninsula Health Guidelines refer to tongue swelling, stridor, hoarse voice, bronchospasm, hypotension +/- rash/ urticaria. They do not mention wheeze, persistent cough, difficulty talking, swelling/tightness in the throat, difficult/noisy breathing, persistent dizziness, collapse or pale and floppy (young children) which are included in the ASCIA guidelines and ASCIA Action Plans.[3] The absence of these signs and symptoms in the Peninsula Health Guidelines makes it less likely that an anaphylactic reaction will be treated sooner rather than later by health professionals working at Peninsula Health. ***(b) Information regarding posture is incorrect and insufficiently emphasised*** The Peninsula Health Guidelines only refer to posture (positioning of the patient) in Appendix 1, pages 4 and 6 and the information is related only to patients who are considered hypotensive. ASCIA clearly states that any patient displaying signs or symptoms of anaphylaxis/severe allergic reaction should be laid down and no such patient should stand or walk when experiencing anaphylaxis. The ASCIA Guidelines and ASCIA Action Plan identify posture measures as the first emergency management step for anaphylaxis whether the patient is hypotensive or not. ***(c) Lack of information regarding asthma*** The current Peninsula Health Guidelines do not reference asthma. ASCIA has had specific information about asthma and anaphylaxis on the ASCIA Guidelines and ASCIA Action Plan since 2012. This important information is not included in the Peninsula Health

[3] The ASCIA Action Plan can be found at www.allergy.org.au/health-professionals/ascia-plans-action-and-treatment

Name of anaphylaxis guideline	National / State	Adequate or inadequate? (if so, why?)
		Guidelines. Many people with food allergy also have asthma. Asthma is a known risk factor for fatal anaphylaxis.[4] However, there is often uncertainty and confusion surrounding the interaction between asthma and anaphylaxis and most people suffering a severe food allergic reaction present with respiratory symptoms that can mimic asthma. Unfortunately, even health care professionals mistake anaphylaxis for asthma or treat anaphylaxis with nebulised Salbutamol (Ventolin), antihistamines and corticosteroids rather than adrenaline which has long been recognised as first line treatment for anaphylaxis. This statement is supported by recent Australian research indicating sub-optimal management of anaphylaxis presentations to eight different hospital emergency departments.[5] Guidelines need to include information about the relationship between asthma and anaphylaxis to prevent confusion and ensure appropriate treatment is provided. ***(d) Medical Observation*** The Peninsula Health Guidelines make no reference to how long the patient experiencing anaphylaxis should be observed. ASCIA states that the patient should be observed for a minimum of 4 hours after the last dose of adrenaline. Biphasic reactions can and do occur in up to 20% of cases,[6] hence the requirement to monitor and observe for recurrence of anaphylaxis once the patient appears to be in recovery phase.

[4] Pumphrey, R. Anaphylaxis: can we tell who is at risk of a fatal reaction? Current Opinion in Allergy & Clinical Immunology.2004; 4 (4): 285-290; Bock SA. Fatal anaphylaxis. UpToDate. 2015 www.uptodate.com/contents/fatal-anaphylaxis Last accessed July 2015.

[5] Brown SGA et al. Anaphylaxis: Clinical patterns, mediator release, and severity. JACI. 2013; 132 (5): 1141.; Murad A, Katelaris C. Anaphylaxis audit in a busy metropolitan emergency department: a review of real life management compared to best practice. Asia Pacific Allergy. 2016; 6: 29-34.

[6] Tole JW, Lieberman P. Biphasic anaphylaxis: review of incidence, clinical predictors, and observation recommendations. Immunol Allergy Clin North Am. 2007 May;27(2):309-26, viii. DOI: 10.1016/j.iac.2007.03.011; Seiro Oya, Tomoki Nakamori, and Hirohisa Kinoshita. Incidence and characteristics of biphasic and protracted anaphylaxis: evaluation of 114 inpatients. Acute Medicine & Surgery 2014; 1: 228–233. doi: 10.1002/ams2.48 http://onlinelibrary.wiley.com/doi/10.1002/ams2.48/pdf.

Name of anaphylaxis guideline	National / State	Adequate or inadequate? (if so, why?)
		A&AA submits that the above issues require correction in order to adequately provide guidance on the management of anaphylaxis.
9.2 Acute Management of Anaphylaxis Guidelines published by ASCIA (ASCIA Guidelines)[7]	National	The Australasian Society of Clinical Immunology and Allergy (ASCIA – peak professional medical body) has had an ASCIA Action Plan for Anaphylaxis and an ASCIA Action Plan for Allergic Reactions (for those not prescribed an adrenaline (epinephrine) autoinjector) available to individuals since 2003. With one qualification regarding adrenaline auto-injectors (i.e. EpiPen®), A&AA submits that the ASCIA Guidelines are adequate for the following reasons: ***a) ASCIA Action Plan*** ASCIA Guidelines refer to the ASCIA Action Plan which is a medical document listing signs, symptoms and actions to be taken in the case of medical emergencies arising from allergic reactions. It is completed and signed by the individual's medical practitioner. It is important to note that Australia is the only country globally that has ONE nationally recognised emergency response plan that is completed and signed by a doctor and given to the individual with the prescription for an adrenaline autoinjector (EpiPen®). ***b) Evidence based information*** ASCIA guidelines reflect global evidence-based information that has been collected from publications and coronial inquests and information from families and healthcare professionals when near misses or fatalities have occurred. ***c) Contains required information*** Where guidelines/protocols/policies on anaphylaxis emergency treatment exist, it is critical that information and advice on the below is included alongside other existing accurate and critical information (as it is in the ASCIA Guidelines):

[7] https://www.allergy.org.au/health-professionals/papers/acute-management-of-anaphylaxis-guidelines; note that ASCIA Guidelines are based on international guidelines, namely, International Liaison Committee on Resuscitation and Australian and New Zealand Committee on Resuscitation guidelines, American Academy of Allergy, Asthma and Immunology anaphylaxis parameter and World Allergy Organisation anaphylaxis guidelines.

Name of anaphylaxis guideline	National / State	Adequate or inadequate? (if so, why?)
		• signs and symptoms of mild/moderate reaction (noting that signs of a mild to moderate allergic reaction (including skin signs) may/may not be present when someone is having an anaphylaxis[8] • signs and symptoms of anaphylaxis • posture and positioning including "do not stand or walk" • removal of trigger if present • give adrenaline intramuscular (IM) • dosages of adrenaline and protocol for intravenous adrenaline infusion by health professional with specialised training in adrenaline infusions • observations to be performed e.g. pulse rate, pulse oximetry; blood pressure, conscious state, cardiac monitoring, respirations • intravenous cannula insertion • call for help. Do not leave patient. • if in doubt, give adrenaline • always give adrenaline first and then asthma reliever medication if someone with known asthma and allergy to food, insects or medication has sudden breathing difficulty (including wheeze, persistent cough or hoarse voice) even if no skin symptoms are present • if no response to first IM dose of adrenaline, give another dose after five minutes. If no response, continue to give doses of IM adrenaline every five minutes until someone with expertise in intravenous adrenaline infusions is in attendance. • antihistamines have no place in the emergency treatment of anaphylaxis. However, if they are used in the recovery phase, a non-sedating antihistamine should be used. Promethazine (Phenergan) is not to be used in anaphylaxis emergency treatment because it causes drowsiness and given IM or IV it can further decrease blood pressure and cause muscle necrosis.

[8] Simon G A Brown, Raymond J Mullins and Michael S Gold. Anaphylaxis: diagnosis and management Med J Aust 2006; 185 (5): 283-289; Sampson HA, Munoz-Furlong A, Campbell RL, et al. Second symposium on the definition and management of anaphylaxis: summary report — second National Institute of Allergy and Infectious Disease/Food Allergy and Anaphylaxis Network symposium. J Allergy Clin Immunol 2006; 117: 391-397

Name of anaphylaxis guideline	National / State	Adequate or inadequate? (if so, why?)
		• at least 4 hours of close medical observation after last dose of adrenaline is required because of the possibility of biphasic/rebound anaphylaxis • Commence CPR if person is unresponsive and not breathing normally. ***d) Inconsistency in application of ASCIA Guidelines*** A&AA notes that the ASCIA Guidelines (through school and childcare specific free e-training for staff) and ASCIA Action Plan are well-utilised in schools and childcare. While the ASCIA Action Plan is mandatory in schools and childcare (as all school and childcare legislation/policy/procedures and guidelines include a statement clearly stipulating that any person who is prescribed an adrenaline auto-injector must have an ASCIA Action Plan), the use of an ASCIA Action Plan by health professionals, including paramedics, is almost non-existent. This variation puts individuals at risk of anaphylaxis at an even greater risk because of doubt, confusion and inconsistency in the way the various guidelines are written and applied. Therefore, while the ASCIA Guidelines, including the ASCIA Action Plan, are adequate, the way in which they are applied is not. ***e) EpiPen®*** A&AA submits there is one shortcoming of the ASCIA Guidelines; that is, the failure to provide guidance on health professionals' use of the patients' adrenaline auto-injector (i.e. EpiPen®) when available. Health professionals need to have clear instruction on what happens with a patient's EpiPen® once a patient arrives in hospital (e.g. storage, access, and whether it is written onto the medication chart as a PRN medication), and its use in an emergency. In relation to EpiPens®, A&AA submits: • **What should Healthcare Professionals do upon arrival at hospital of a person with an EpiPen?** Health professionals need clear guidance. When a person who has a prescribed adrenaline auto-injector is admitted to hospital, the EpiPen should be included as a PRN (administer as required) medication on their medication chart. This will serve as a reminder to all staff that the person is at risk of anaphylaxis and importantly, create a pathway for administration of the EpiPen® in accordance with

Name of anaphylaxis guideline	National / State	Adequate or inadequate? (if so, why?)
		instruction on the ASCIA Action Plan which SHOULD be attached to the patients medication chart. • Currently, ASCIA resources do not include information on EpiPen management and placement when a person with a diagnosed severe allergy is hospitalised or attends a healthcare setting. Although ASCIA resources say the individual must always have their adrenaline autoinjector with them, they currently do not give advice on management/placement etc in a hospital or other healthcare setting. This is an identified gap which needs addressing. A&AA has advice for individuals at risk of anaphylaxis when in hospital. A **Hospital Stay Help Sheet** and **Checklists** have been developed. These resources can be found at https://allergyfacts.org.au/resources/help-sheets • **Training of Healthcare professionals.** Healthcare professionals should be trained in how to administer an EpiPen® so it can be used in an emergency whilst waiting for the resuscitation team and others are drawing up next dose of adrenaline/observing vital signs etc. • **Few guidelines refer to administration of EpiPen® by healthcare professionals.** A&AA is aware of very few state or national anaphylaxis guidelines that make mention of health professionals administering an EpiPen®, as opposed to adrenaline via needle and syringe, in an emergency. A&AA notes the *Australian Immunisation Handbook* and the *Royal Children's Hospital Guidelines* do refer to health professionals administering an EpiPen® if one is available. Therefore, it is an inadequacy across almost all guidelines at state and national levels. Clear instructions on EpiPen® use following instructions on the ASCIA Action Plan, even in a healthcare setting by health professionals (including nursing staff), needs to be included as an appropriate first step in an emergency. Without this clarity and clear instruction in guidelines, EpiPen®s are unlikely to be administered by healthcare staff. A&AA submits that an ASCIA Action Plan completed and signed by a doctor should be sufficient documentation for emergency administration of the EpiPen® even if it is not written on the hospital medication chart. Importantly, healthcare professionals need to understand that, although a person (an older child, teen or adult) is prescribed an adrenaline auto-injector, they may not be able to self-administer it in an emergency. This may be due to the sudden deterioration of their condition. Healthcare staff need to recognise signs and symptoms and be able to administer an adrenaline auto-

Name of anaphylaxis guideline	National / State	Adequate or inadequate? (if so, why?)
		injector according to instructions on the ASCIA Action Plan.
9.3 Australian and New Zealand College of Anaesthetists, Perioperative Anaphylaxis Management Guidelines **(PAMG)**[9]	National	A&AA submits that the PAMG are inadequate for the following reasons: ***a) Inconsistent signs and symptoms*** The PAMG refer to hypotension, tachycardia, bradycardia, skin symptoms and bronchospasm as symptoms of anaphylaxis. They do not mention swelling of the tongue, wheeze, persistent cough, difficulty talking and/or hoarse voice, swelling/tightness in the throat, difficult/noisy breathing, persistent dizziness, collapse or pale and floppy (young children) which are included in the ASCIA Guidelines and ASCIA Action Plans. ***b) Use of antihistamine*** Guideline 4.2 encourages administration of antihistamine but does not specify non-sedating antihistamine. ASCIA Guidelines clearly state sedating antihistamines should not be used as they could delay recognition or deterioration of anaphylaxis. ***c) Lack of information regarding asthma*** Whilst bronchospasm is clearly documented as a sign of anaphylaxis in the PAMG there is no statement similar to: 'Always give adrenaline first and then asthma reliever medication to someone with known asthma and allergies if they are having sudden breathing difficulty (including wheeze, persistent cough or hoarse voice) even if no skin symptoms are present.' This statement should be included.

[9] PAMG can be found at http://www.anzca.edu.au/resources/endorsed-guidelines

Name of anaphylaxis guideline	National / State	Adequate or inadequate? (if so, why?)
9.4 Australian Immunisation Handbook **(AIH)**[10]	National	A&AA submits that the guidelines for recognition and emergency treatment of anaphylaxis within AIH are inadequate for the following reasons: ***a) Signs and symptoms of an allergic reaction, including anaphylaxis*** The AIH states that, *"Early signs* [of anaphylaxis] *include involvement of the skin (e.g. generalised erythema, urticaria and/or angioedema) and/or gastrointestinal tract (e.g. diarrhoea, vomiting)"*. This is incorrect as early signs including skin and/or gut involvement do not always occur before someone has an anaphylactic reaction.[11] ***b) Conflicting advice on administration site of adrenaline*** Initial doses of adrenaline should be given by intramuscular injection (IM). The AIH handbook refers to adrenaline being administered in both upper, outer thigh muscle and mid, outer thigh muscle on pages 90 and 91. This conflicting information could waste precious time in an emergency. ***c) Signs and symptoms of anaphylaxis*** There is no information exclusively outlining the signs and symptoms of a mild/moderate allergic reaction and the signs and symptoms of anaphylaxis. The information refers to early signs of anaphylaxis rather than signs and symptoms of a mild/moderate or severe allergic reaction/anaphylaxis. There is no mention of the possibility that mild/moderate signs of an allergic reaction may be absent or transient and that someone can suddenly present with anaphylaxis without skin and gastrointestinal symptoms i.e. signs and symptoms related to the respiratory system and/or the cardiovascular system. A mild or moderate allergic reaction is not anaphylaxis. There is a table that sets out the difference between vasovagal (fainting) and anaphylaxis. Anaphylaxis is life-threatening whereas vasovagal is not. Putting information regarding the signs and symptoms of anaphylaxis and vasovagal could contribute to doubt and, possibly, a delay in the provision of appropriate emergency care.

[10] AIH can be found at http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home

[11] See ASCIA Guidelines and ASCIA Action Plan https://www.allergy.org.au/health-professionals/anaphylaxis-resources

Name of anaphylaxis guideline	National / State	Adequate or inadequate? (if so, why?)
		If someone having a vaccine has no tongue/throat swelling/skin signs/breathing difficulty and the table is followed, it is likely the patient will be managed for a vasovagal and adrenaline would not be administered promptly. Additionally, the symptoms the table does list are insufficient. For example, asthma-like symptoms as a possible sign of anaphylaxis is not mentioned. There is also no mention of dizziness and/or collapse in relation to anaphylaxis. These are clearly documented in the ASCIA Guidelines and ASCIA Action Plan. The table also states that lip swelling is a sign of anaphylaxis which it is not (it is a sign of a mild/moderate reaction but alone, without respiratory or cardiovascular symptoms, it is not an anaphylaxis). *d) An adequacy* A&AA acknowledges and commends the inclusion of the following statements in the AIH: • "If a patient who carries an autoinjector device develops anaphylaxis post vaccination, it is appropriate to use their autoinjector to administer adrenaline"; • "No serious or permanent harm is likely to occur from mistakenly administering adrenaline to an individual who is not experiencing anaphylaxis"; and A&AA also supports the information included about who can administer an adrenaline autoinjector and the fact that instructions on how to administer an adrenaline auto-injector are on the device.
9.5 Australian Resuscitation Council Guidelines **(ARCG)**[12]	National	A&AA submits that the current ARCG are inadequate for the following reasons: ***a) Inadequate information about asthma*** The ARCG guidelines do not mention of the possibility that anaphylaxis can easily be mistaken for asthma in an emergency. Information on giving adrenaline first and then giving asthma reliever medication if someone with known food, insect or medication allergy has sudden breathing difficulty needs to be added.

[12] ARCG can be found at https://resus.org.au/glossary/anaphylaxis-guideline-9-2-7/

Name of anaphylaxis guideline	National / State	Adequate or inadequate? (if so, why?)
9.6 Queensland Ambulance Service (QAS)[13]	QLD	***b) Inadequate instructions regarding hospital stay*** Whilst the ARCG guidelines state that an ambulance must be called, they do not state that an individual that has received adrenaline must be taken to hospital and hospitalised for at least 4 hours. A&AA submits that the current QAS guidelines for management of anaphylaxis are inadequate for the following reason: ***a) Inadequate information about asthma*** Although there is a statement about asthma and anaphylaxis, the guidelines advise to administer adrenaline first only if uncertain about whether it is anaphylaxis or asthma. If personnel are confident that a patient with previous history of anaphylaxis is experiencing asthma, the wording in the QAS guidelines does not allow for administration of adrenaline according to ASCIA Guidelines (i.e. that adrenaline should always be administered first if someone with known asthma and allergy to food, insects or medication has sudden breathing difficulty, even if there are no skin symptoms). The ASCIA Guidelines, including the ASCIA Action Plan, appropriately remove discretion about whether the patient is experiencing anaphylaxis or asthma.
9.7 Ambulance Victoria Clinical Practice Guidelines (AVCPG)[14]	VIC	A&AA submits that the AVCPG Guidelines for recognition and emergency treatment of anaphylaxis are inadequate for the following reasons: ***a) Posture*** Posture of the patient is not mentioned in the guidelines. This is despite Ambulance Victoria being a member of the 2016/17 Victorian Paediatric Clinical Network which facilitated the Anaphylaxis Expert Working Group (AEWG). The AEWG released a report in April

[13] QAS can be found at www.ambulance.qld.gov.au/CPGtable.html

Name of anaphylaxis guideline	National / State	Adequate or inadequate? (if so, why?)
		2017 which discussed how to better manage anaphylaxis in Victoria. The report clearly shows posture of the patient as an important evidence-based consideration in a severe allergic reaction/anaphylaxis. ***b) Adrenaline auto-injector:*** These guidelines discourage use of an adrenaline auto-injector if at the scene. ***c) Inconsistent signs and symptoms:*** Signs and symptoms of anaphylaxis are inconsistent with those contained in ASCIA Guidelines and ASCIA Action Plan. In addition, signs and symptoms of a mild/moderate reaction are listed together with signs and symptoms of a severe allergic reaction/anaphylaxis. This can lead to confusion. ***d) Inadequate information about asthma:*** The AVCPG suggest nebulised adrenaline for asthma symptoms without acknowledging that IM adrenaline should be given first.
9.8 Royal Flying Doctor Service Guidelines, Western Operations **(RFDS Guidelines)**[15]	WA	A&AA submits that the RFDS Guidelines for recognition and emergency treatment of anaphylaxis are inadequate for the following reasons: ***a) Posture*** There is no mention of posture of the patient. ***b) Antihistamine use*** The RFDS Guidelines encourage use of the sedating antihistamine, promethazine (Phenergan). This antihistamine is contraindicated because it causes drowsiness and may therefore mask deterioration of the patient's condition and, importantly, it can also cause further

[14] The AVCPG is available from: https://www.ambulance.vic.gov.au/paramedics/clinical-practice-guidelines/
[15] Available at https://www.flyingdoctor.org.au/assets/magazine/file/Part_1_-_Clinical_Manual_-_January_2018_-_Version_8.0_-_FINAL.pdf

Name of anaphylaxis guideline	National / State	Adequate or inadequate? (if so, why?)
		hypotension and muscle necrosis when given IV or IM. ***c) Inadequate information about asthma*** There is no mention of advice to always give adrenaline first and then asthma reliever medication if someone with known asthma and allergy to food, insects or medication has sudden breathing difficulty, even if there are no skin symptoms.
9.9 Sydney Children's Hospital Network Clinical Policy **(SCHNCP)**[16]	NSW	A&AA submits that the SCHNCP for recognition and emergency treatment of anaphylaxis is inadequate for the following reasons: ***a) Asthma versus anaphylaxis*** There is no mention of advice to always give adrenaline first and then asthma reliever medication if someone with known asthma and allergy to food, insects or medication has sudden breathing difficulty, even if there are no skin symptoms. ***b) Posture*** The SCHNCP clearly states that the patient is to lay down but does not specifically say that the patient should not stand or walk.
9.10 Royal Children's Hospital Anaphylaxis Clinical Practice Guidelines **(RCHACPG)**[17]	VIC	A&AA submits that the RCHACPG are inadequate for the following reason: ***a) Asthma versus anaphylaxis*** There is no mention of advice to always give adrenaline first and then asthma reliever medication if someone with known asthma and allergy to food, insects or medication has sudden breathing difficulty, even if there are no skin symptoms.

[16] The SCHNCP is available from: http://www.schn.health.nsw.gov.au/our-policies/index/clinical
[17] The RCHACPG are available from: www.rch.org.au/clinicalguide/guideline_index/Anaphylaxis/

Conclusion

10. There are no Government (national, state or territory) acute anaphylaxis management guidelines/protocols for the recognition and emergency treatment of anaphylaxis that have all the information contained in the ASCIA Acute Management of Anaphylaxis Guidelines.

11. A&AA submits that current national and state guidelines, including those listed above, are inadequate because they fail to provide a uniform, national clinical care standard for recognition and emergency treatment of anaphylaxis.

12. One of the 5 main goals detailed in the National Allergy Strategy (**see paragraph 2 above**) is to develop standards of care to improve the health and quality of life of people with allergic diseases. One of the stated priority objectives relating to this issue is to develop and implement a national standardised framework for the prevention, diagnosis and management of allergic diseases to improve consistency and accuracy of information. This includes facilitating communication across all Australian regions at every level to adopt standardised guidelines for acute management of anaphylaxis in all hospital emergency departments.[18]

13. A&AA submits that a mandatory Clinical Care Standard for Anaphylaxis (**CCSA**) is required to reduce the variation in emergency care at primary, secondary and tertiary health level and give people the best chance of recovery. A&AA, through the NAS, has met with the Australian Commission for Quality and Safety in Healthcare (the **Commission**) and discussed the critical need for a CCSA. NAS co-chairs, Associate Professor Richard Loh and A&AA's CEO Maria Said, are confident the development of a CCSA will be part of the Commission's work plan for 2019-2020 but urge that it be actioned sooner.

14. A&AA also submits that all guidelines/policies/protocols need to include information on:

    (a) health professional training and clear consistent process for the storage and administration of an adrenaline auto-injector and its use in the healthcare setting when available; and

    (b) the importance of promptly administering adrenaline according to the ASCIA Guidelines/ASCIA Action Plan (regarding, in particular, when the patient with a history of anaphylaxis presents with symptoms that are consistent with sudden onset of breathing difficulty often mistaken as asthma).

15. Finally, A&AA submits that adrenaline auto-injectors (EpiPen®) stored with an ASCIA Action Plan should be available for use in paediatric units, and other high risk units, of healthcare facilities including hospitals.

Signed by Maria Said
Chief Executive Officer, Allergy & Anaphylaxis Australia
12 December 2017

[18] https://www.nationalallergystrategy.org.au/images/doc/NAS_Document_Final_WEB.pdf (page 12)

Allergy & Anaphylaxis Australia

15th January 2018

Coroners Court of Victoria
Attention: Coroner Byrne
65 Kavanagh St
Southbank VIC 3006

Dear Coroner Byrne

Investigation into the death of Louis Tate

Court ref: COR 2015 5382

Thank you for your correspondence dated 20th December 2017 requesting Allergy & Anaphylaxis Australia's (A&AA) opinion on health professional administration of an adrenaline autoinjector (EpiPen®) belonging to a patient in a healthcare setting.

A&AA strongly supports health professionals administering an individual's adrenaline autoinjector in any healthcare setting including but not limited to paediatric units, general medical and surgical units, rehabilitation units and hospital cafeterias.

An individual with an adrenaline autoinjector must also have an ASCIA Action Plan for Anaphylaxis. This is a Pharmaceutical Benefits Scheme prescription requirement.

The individual's ASCIA Action Plan (which is completed and signed by the individual's general practitioner or allergy specialist) is a medical document that is to be followed if someone shows signs of an allergic reaction no matter what setting they are in. When a patient with a severe allergy brings their adrenaline autoinjector to a hospital, medical staff looking after the patient should know how to, and have permission to, administer it using the patients ASCIA Action Plan to guide them. Whilst we encourage the adrenaline autoinjector to be prescribed on the patients PRN medication chart, if it is not, this should not be an obstacle to administration as the patient has the ASCIA Action Plan which will have been completed and signed by a doctor.

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Individuals are advised to always have their medical kit containing their ASCIA Action Plan, their adrenaline autoinjector and other medications (such as antihistamines and asthma reliever puffer) with them and easily accessible (not in a locked cupboard). When an individual displays signs and symptoms of an allergic reaction, the individual or their carer/friend should review the ASCIA Action Plan to guide them on next steps.

A&AA's advice to patients is clearly communicated on our Hospital Stay Help Sheet and our Hospital Checklist which can be found at https://allergyfacts.org.au/resources/help-sheets.

We take this opportunity to inform Your Honour, that some healthcare facilities take the individual's adrenaline autoinjector and place it in a locked cupboard or an unknown location during the individual's stay in hospital. This is done for the purported safety of other patients. A&AA submits that children and adults should have their adrenaline autoinjector easily accessible at all times and it should not be taken from them when in a hospital setting. For an individual with food allergy, the healthcare environment is high risk and is no different to a restaurant. There may even be a greater risk in hospital settings because often, there is no direct communication with whoever prepared the meals provided. Children have had their adrenaline autoinjector and ASCIA Action Plan with them at school, either on their person or in their classroom/other central location since the early 1990s. Therefore, the concern around safety of surrounding persons should not be an obstacle to individuals having their emergency medication with them at all times in healthcare settings.

In conclusion, adrenaline autoinjectors are designed for prompt administration of a lifesaving medication, by lay people in the community setting. If available, there should be no barrier to health professionals administering an adrenaline autoinjector in any setting. It is nonsensical that an off duty health professional can administer an adrenaline autoinjector that is stored in a first aid kit at a football stadium, for example, but cannot administer an individual's own device when working in a hospital setting if it is not specifically ordered by a doctor.

If you have any further queries or need further clarification please do not hesitate to contact me via email (msaid@allergyfacts.org.au), phone (0409 609 831) or post.

Yours sincerely,

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