

**FINDING INTO DEATH WITH INQUEST<sup>1</sup>**

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

**Inquest into the Death of ELSA HARRINGTON**

Direction Hearing Dates: 11 December 2006  
18 June 2008  
16 July 2008  
20 August 2008

Inquest Date: 17-20 November 2008

Held at: Coronial Services Centre, Southbank.

Appearances: Senior Constable Kelly Ramsey, SCAU<sup>2</sup> - Assisting the Coroner  
Mr D. P. Martin on behalf of the family of Mrs Harrington  
Mr J. P. Constable of Counsel - on behalf of Peninsula Health  
Mr S. P. Cash of Counsel on behalf of Mr Peter Evans  
Mr A. N. Murdoch of Counsel on behalf of Dorevitch Pathology

Findings of: AUDREY JAMIESON, Coroner

Delivered On: 2 March 2012

Delivered At: Level 11, 222 Exhibition Street  
Melbourne

<sup>1</sup>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 legal representatives/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.

<sup>2</sup> SCAU = State Coroners Assistant Unit and is now known as the Police Coronial Support Unit (PCSU)

I, AUDREY JAMIESON, Coroner having investigated the death of ELSA HARRINGTON

AND having held an inquest in relation to this death on 17 to 20 November 2008

at Southbank

find that the identity of the deceased was ELSA HARRINGTON

born on 27 November 1956

and the death occurred on 13 November 2002

at Austin Hospital, 145 Studley Road, Heidelberg 3084

from:

- 1a. MULTISYSTEM ORGAN FAILURE
- 1b. FULMINANT HEPATOCELLULAR NECROSIS
- 1c. EVIDENCE OF PARACETAMOL TOXICITY

**in the following summary of circumstances:**

1. Mrs Elsa Harrington was admitted to Frankston Hospital, Peninsula Health, on 31 October 2002, with abdominal pain. She underwent surgery for abdominal adhesions on 5 November 2002. In the following days her condition deteriorated. On 11 November 2002, Mrs Harrington was transferred to the Austin Hospital in preparation for a liver transplant but was deemed too unstable to undergo the surgery. She died on 13 November 2002.
2. The initial investigation into the death of Elsa Harrington identified an apparent failure by treating medical staff to respond to and treat abnormal liver function results.
3. An Inquest was held under section 17(2) *Coroners Act* 1985.

**JURISDICTION:**

4. At the time of Elsa Harrington's death, the *Coroners Act* 1985 (the Old Act) applied. From 1 November 2009, the *Coroners Act* 2008 (the new Act) has applied to the finalisation of investigations into deaths that occurred prior to the new Act commencement.<sup>3</sup>
5. In the preamble to the new Act, the role of the coronial system in Victoria is stated to involve the independent investigation of deaths for the purpose of finding the causes of those deaths and to contribute to the reduction of the number of preventable deaths and the promotion of public health and safety and the administration of justice. Reference to preventable deaths and public health and safety are referred to in other sections of the Act.<sup>4</sup>

<sup>3</sup> Section 119 and Schedule 1 - *Coroners Act* 2008.

<sup>4</sup> See for example, sections 67(3) & 72 (1) & (2)

6. Section 67 of the new Act describes the ambit of the coroner's findings in relation to a death investigation. A coroner is required to find, if possible, the identity of the deceased, the cause of death and, in some cases, the circumstances in which the death occurred.<sup>5</sup> The 'cause of death' generally relates to the *medical cause of death* and the 'circumstances' relates to the *context* in which the death occurred.

7. A coroner may also comment on any matter connected with the death, including matters relating to public health and safety and the administration of justice.<sup>6</sup> A coroner may also report to the Attorney General and may make recommendations to any Minister, public statutory authority or entity, on any matter connected with a death which the coroner has investigated including recommendations relating to public health and safety or the administration of justice.<sup>7</sup>

#### **BACKGROUND CIRCUMSTANCES:**

8. Mrs Elsa Harrington was 45 years of age at the time of her death. She lived at 56 Lindrum Road, Frankston. She had three children, Christina (DOB:25/05/74), Mariel (DOB:13/11/75) and a son Erwin (DOB: 6/04/77) who lived with her.

9. On 9 September 2002, Mrs Harrington underwent total abdominal hysterectomy for symptomatic uterine fibroids. She had previously been well.

10. Two weeks post operatively Mrs Harrington presented to her general medical practitioner, Dr Fairweather, with abdominal pains and vomiting. She was given an injection for her pain and sent home. She continued to experience pain and vomiting and on 15 October 2002, Erwin took her to Frankston Hospital where she was admitted and remained for a period of 3 days and was treated conservatively for an incomplete small bowel obstruction. At home she was occasionally taking Panadol<sup>8</sup> for ongoing pain.

#### **SURROUNDING CIRCUMSTANCES:**

11. On 31 October 2002, Mrs Harrington was readmitted to Frankston Hospital via the Emergency Department (ED) with subacute small bowel obstruction secondary to adhesions. She was admitted under Surgical Unit 3, which was receiving patients for that day. She had lost 10 kilograms in weight since her surgery on 9 September 2002, which was attributed to poor nutritional intake due to recurrent abdominal pain and intermittent vomiting. Initiation of conservative treatment in the form of intravenous fluids, potassium replacement<sup>9</sup> and nil by mouth, was unsuccessful. Liver function tests conducted on 4 November 2002, were within normal range.

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<sup>5</sup> Section 67(1)

<sup>6</sup> Section 67(3)

<sup>7</sup> Section 72(1) & (2)

<sup>8</sup> Paracetamol is a weak analgesic available over-the-counter as **Panadol** and many other commercial packs, usually 500 mg tablets or capsules. (Exhibit 6 - Report of professor Olaf Drummer)

<sup>9</sup> Admission potassium blood level was 3.3 mmol/L

12. On 5 November 2002, Mrs Harrington underwent a diagnostic laparoscopy followed by open division of adhesions, a loop of bowel was freed and an umbilical hernia repaired. Mr Peter Evans, Surgical Consultant, performed the surgery resulting in ongoing medical management being vested in Surgical Unit 1.<sup>10</sup> On 6 November 2002, Mrs Harrington was reviewed by Mr Evans and the surgical registrar. At this stage, her recovery was considered unremarkable.<sup>11</sup>

13. Mrs Harrington's post operative recovery was later perceived as slow. She continued to complain of abdominal pain and at this stage remained nil by mouth. She was prescribed Paracetamol 1 gram 4 times per day for this pain but her records reflect that she was given 1 gram only on 5 November and one gram, three times per day on each of the 6, 7, 8 and 9 November 2002.

14. On Friday 8 November 2002 (3 days post operatively) at around midday, Mrs Harrington experienced an episode of sudden onset of central chest pain associated with nausea and vomiting and shortness of breath. The Surgical Unit 1 intern, Dr Theodore Adraktas, was paged by nursing staff advising him of Mrs Harrington's complaints of chest pain. He was due to end his shift at 12:30 hours, but attended the ward straight away<sup>12</sup> and examined and reviewed Mrs Harrington. Dr Adraktas thought that her pain was cardiac in origin.<sup>13</sup> He contacted the surgical registrar to discuss and then referred Mrs Harrington to the cardiology registrar, Dr U. Dissanayke. Serial blood tests and electrocardiograms (ECG's) were ordered to rule out a cardiac cause and a number of blood tests, including serial Troponin I, the cardiac enzyme CPK, and other enzymes AST and LDH were ordered. She was treated with sublingual anginine with good effect, oxygen and analgesia as required. A number of other tests to exclude pulmonary embolism were organised. Once Mrs Harrington appeared stable, Dr Adraktas handed over to the covering surgical intern in order to follow-up the investigations as well as the appropriate referrals.<sup>14</sup>

15. At approximately 15:30 hours, Mrs Harrington was reviewed by the covering surgical intern, Dr Sivahamy Inpanathan, after she accessed the blood test/pathology results from a computer terminal. Mrs Harrington's enzymes LDH and AST<sup>15</sup> levels were abnormal/elevated. She was also noted to have ongoing hypokalaemia (2.1 mmol/L)<sup>16</sup>. ECG's were normal. Dr Inpanathan contacted the cardiology registrar, Dr Chris Hengel, because she was concerned about the abnormal enzyme results. Dr Hengel informed Dr Inpanathan that those particular abnormalities were more likely attributable to the recent surgery Mrs Harrington had undergone rather than being cardiac in origin. Dr Inpanathan followed up on the additional investigations including the Doppler ultrasound of the lower legs, chest X-ray and a CT pulmonary angiogram which ruled out the presence of deep vein thrombosis and pulmonary embolus. She received the remainder of the blood results and discussed them with her direct supervisor, surgical registrar, Dr Kenneth Wong. The plan was to follow up with the remaining serial

<sup>10</sup> Surgical Unit 1 is made up of three consultants

<sup>11</sup> Exhibit 8 - Statement of Mr Peter Evans

<sup>12</sup> Transcript of Proceedings (T) @ p 21

<sup>13</sup> T @ p 15

<sup>14</sup> Exhibit 1 - Statement of Theodore Adraktas dated 9 August 2005

<sup>15</sup> AST = Aspartate Aminotransferase, LD (or LDH) = Lactate Dehydrogenase - both not tissue specific enzymes - both occur in all forms of muscle and also in the liver (T @ p 214-215)

<sup>16</sup> Potassium reference range = 3.5-5.0 mmol/L

enzymes. At the end of her shift, at around 22:00 hours, Dr Inpanathan handed over to the night intern and asked that the remaining serial cardiac enzymes be followed up.<sup>17</sup>

16. Dr Adraktas was rostered to return to work on Saturday 9 November 2002, on a weekend cover shift for the hours 8:00 - 22:00 hours. On the Saturday, an intern would cover the three surgical units plus the vascular unit which was estimated to involve between 45-55 patients. A resident doctor - a doctor generally with 2-3 years experience, would cover the orthopaedics, thoracics and the specialities such as urology, ophthalmology and ENT. One general surgical registrar would cover the three surgical units, vascular and thoracic units plus calls from the ED and theatres.<sup>18</sup>

17. Late in his shift on the evening of Saturday 9 November 2002, Dr Adraktas was requested by nursing staff to see Mrs Harrington after she vomited approximately 500 mls of dark stained fluid. On examination she was noted to be absent of bowel sounds and looked unwell. Dr Adraktas' presumptive diagnosis<sup>19</sup> was of a further small bowel obstruction. He ordered that Mrs Harrington remain 'nil by mouth', ordered regular antiemetics and intravenous fluids and blood tests were ordered for full blood examination, urea and electrolytes. The blood was collected from Mrs Harrington at 20:26 hours. At the time of this examination of Mrs Harrington, Dr Adraktas was unaware of the results of the blood tests he had ordered the previous day. He was also unaware that nursing staff had recorded that Mrs Harrington was demonstrating signs of altered mentation in the Nursing Progress Notes including *unable to follow simple commands* and that she had been demonstrating other strange behaviour.<sup>20</sup> Dr Adraktas did not of himself note any signs of confusion or alteration to her mentation.<sup>21</sup> Dr Adraktas discussed Mrs Harrington's condition with the surgical registrar on duty<sup>22</sup> who in turn reviewed Mrs Harrington. Bloods were ordered for a full blood count and renal function tests. A repeat abdominal and chest X-ray were also ordered. Later that evening, there is a record of *scant* urine output and nausea and then that her urine output had been nil, blood pressure was 95/50 mmHg and a heart rate of 103 beats per minute (bpm).

18. Shortly after midnight on Sunday 10 November 2002, Mrs Harrington was reviewed by an intern for poor urine output and of the blood test results taken earlier in the night. Her haemoglobin had dropped to 10.4g/L, white cell count was markedly elevated and her creatinine was also elevated to 0.15 mmol/L. She was treated with a bolus (300mls) of intravenous fluid and a diuretic (frusemide 40mg). Intravenous fluids were ongoing and further blood tests ordered for the morning. At 0700 hours it was recorded that she had passed only 24 mls of urine since midnight. Traces of blood, protein and leucocytes were identified on full ward testing of her urine. Her urinary catheter was changed to exclude blockage and she was commenced on an antibiotic for possible urinary tract infection. Review of her abdominal X-ray excluded small bowel obstruction and review of her chest X-ray showed left lower lobe consolidation. A repeat FBE showed a further drop in her haemoglobin to 9.6 g/L and there was a further rise in her white cell count. Later that morning, Mrs Harrington was noted to be drowsy and

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<sup>17</sup> Exhibit 2 - Statement of Sivahamy Inpanathan dated 11 August 2005

<sup>18</sup> T @ pp 29-30

<sup>19</sup> T @ p 25

<sup>20</sup> Exhibit 1 - Statement of Theodore Adraktas dated 9 August 2005

<sup>21</sup> T @ p 22 & 36

<sup>22</sup> Dr Larabina was the surgical registrar for Unit 1 but he was not working as the covering registrar on the Saturday - T @ p 136

restless. She had no urine output and had vomited 200 ml of coffee ground vomitus. She was reviewed by the covering surgical registrar, Dr Justin Chee, at the request of the then covering surgical intern, Dr Nguyen, who had contacted Dr Chee with concerns about Mrs Harrington including her conscious state. Following his examination, Dr Chee in turn discussed Mrs Harrington's deterioration with Mr Peter Evans, surgical consultant. A plan was made for her transfer to the Intensive Care Unit (ICU) but before this occurred, Mrs Harrington was found unresponsive. She was discovered to be in metabolic acidosis (pH 7.22). At 14:20 hours a Medical Emergency Team (MET) call was made and she was transferred to ICU. En route to the ICU she underwent CT scan of the brain and abdomen.

19. Mrs Harrington was intubated, ventilated, transfused with blood products and given vitamin K to correct coagulopathy (INR > 11<sup>23</sup>) and was invasively monitored for fluid resuscitation. A paracetamol level ordered at 1750 hours was noted to be 238 µmol/L.<sup>24</sup> An intravenous infusion of *N*-acetylcysteine, a glutathione substrate used for the treatment of paracetamol induced liver toxicity, was commenced.

20. In the early hours of 11 November 2002, Mrs Harrington was transferred to the Austin Hospital for consideration of urgent liver transplant. On admission to the Austin Hospital liver function tests demonstrated abnormal results including an ALT<sup>25</sup> level of 2500 U/L, bilirubin of 44µmol/l and albumin of 28 g/L. Her creatinine was elevated and she was anaemic, had a high white cell count, marked coagulopathy and had an elevated lactate level. Repeated paracetamol levels on 8, 10 and 11 November 2002, demonstrated levels at ~30 mg/L, (analysed at the Victorian Institute of Forensic Medicine), 238 µmol/L (or 36 mg/L) and 185 µmol/L (or 28 mg/L) respectively.

21. Despite ongoing active treatment, Mrs Harrington continued to deteriorate. She developed multi-organ failure and evidence of brain death.

22. Elsa Harrington died on 13 November 2002.

## **POST MORTEM INVESTIGATIONS:**

23. The identity of Elsa Harrington was not in dispute and required no additional investigation.

### **The medical investigation:**

24. Dr Malcolm Dodd, Forensic Pathologist at the Victorian Institute of Forensic Medicine performed an autopsy and reviewed Mrs Harrington's medical records noting the elevated paracetamol level of 185 mg/L on admittance to the Austin and Repatriation Medical Centre. External examination showed extensive icterus (jaundice) and internal examination showed significant changes to the liver and changes to the brain in keeping with hypoxia. Histological examination showed florid panlobular hepatocellular necrosis, a finding, according to Dr Dodd, which is frequently seen in Paracetamol toxicity. He further commented that paracetamol is a potential hepatotoxin - the ingestion of ten or more tablets may result in fulminant hepatic failure resulting in death within five to seven days if unchecked. Dr Dodd attributed the primary cause of death to multisystem organ failure which he stated appears to have developed on a background of fulminant hepatocellular necrosis.

<sup>23</sup> INR = international normalised ratio. Reference range = 0.9-1.2

<sup>24</sup> Therapeutic range = 66-132 µmol/L or 20-40 mg/L

<sup>25</sup> ALT = Alanine Aminotransferase (Reference range <55U/L)

25. In a supplementary report, Dr Dodd provided clarification to the units of measure cited in his original report. He stated that in a toxicology report dated 18 November 2002, the paracetamol level was 185 µmol/L with a therapeutic range of 60 to 120 and again commented that *this level is exceedingly high and certainly sufficient to cause acute chemical hepatitis*.

26. The Clinical Liaison Service (CLS)<sup>26</sup> was requested to review the medical management of Mrs Harrington on behalf of the Coroner. An initial Case Review meeting occurred on 9 July 2003 at which time the CLS identified a need for a more extensive investigation as it appeared that clinicians had continued to prescribe paracetamol to Mrs Harrington despite significantly abnormal liver function tests over a period of at least 24 hours. Subsequent Case Review meetings occurred on 11 May 2005, 8 June 2006 and April 2008 following receipt of expert opinion reports.

### THE INQUEST:

27. *Viva voce* evidence was obtained from:

- Dr Theodore ADRAKTAS, Surgical Intern
- Dr Sivahamy INPANATHAN (previously Dr Sivahamy SIVASUBRAMANIAM) - Surgical Intern
- Ms Jennifer COUPER - Laboratory Manager, Dorevitch Pathology
- Dr Justin Beng Lin CHEE - general surgical registrar
- Professor Olaf DRUMMER - Victorian Institute of Forensic Medicine
- Dr Ian CARNEY - Clinical Director of Medicine - Frankston Hospital
- Mr Peter EVANS - Visiting Surgical Consultant
- Dr Phillip CARRILLO - Cardiologist
- Dr Clive WELLINGTON - Medical Director of Patient Safety and Medico-Legal Services, Peninsula Health
- Professor Frances DUDLEY - Co-Director Medical Specialities, The Alfred Hospital-
- Professor George BRAITBERG - Emergency Physician and Toxicologist

<sup>26</sup> The role of the CLS was to assist the Coroner's investigation into the nature and extent of deaths, which occurred during the provision of healthcare, and identify potential system factors in healthcare related deaths. CLS personnel were comprised of practising Physicians and Clinical Research Nurses who drew on their medical, nursing and research experiences, skills and knowledge to independently evaluate clinical evidence for the investigation of reportable and reported healthcare deaths and to assist in identifying remediable factors that may assist in prevention and risk management in health services settings. The CLS was replaced with the Health and Medical Investigation Team (HMIT) in 2010. HMIT sits within the Coroners Prevention Unit, which was established in 2008 to strengthen the prevention role of the coroner. The unit assists the coroner in relation to the formulation of prevention recommendations, as well as assisting in monitoring and evaluating the effectiveness of the recommendations.

## FINDINGS and COMMENTS<sup>27</sup> :

### Communication between health professionals:

28. The accepted lines of communication between medical personnel was extensively covered through witnesses. Mrs Harrington's death highlighted a systemic problem within Frankston Hospital (which may be applicable in other public hospitals) of the accepted lines of communication between intern, registrar and Consultant. The intern does not believe it is his/her position to communicate directly with the Consultant in the normal course of patient management but to communicate with the unit registrar who has the responsibility to communicate with the Consultant. This becomes a problem if there are concerns about a patient that the intern has communicated to the registrar but the registrar does not communicate this to the Consultant. Mr Evans supports the hierarchy of communication but also said it was at times appropriate to escalate concerns about a patient directly to the Consultant for example, if a registrar does not give an intern an answer to a problem or during times when the registrar is not available to assess and sort out a problem. Mr Evans assumes that interns know that they could go to a Consultant straight away.<sup>28</sup> The risk of communication failure appears to increase once the after-hours roster commences particularly in relation to a weekend where the hierarchy of communication between intern and registrar continues but is between covering doctors and not necessarily those who are a part of the patient's treating Unit or indeed the same Unit.

29. On the weekends at Frankston Hospital the surgical registrar works a 24 hour shift from 08:00 hours on Saturday morning until 08:00 hours on Sunday morning. During the shift the surgical registrar is responsible for the three surgical units and the vascular unit and may be required to see patients in the ED and attend/assist in the operating theatres.<sup>29</sup> Unit 1 Surgical Registrar, Dr Larabina was Dr Adraktas' immediate supervisor. His whereabouts on Friday 8 November 2002, was not able to be established.

30. Dr Adraktas ordered bloods to be taken on Mrs Harrington shortly before going on an afternoon off on Friday 8 November 2002, after he had seen her in relation to complaints of chest pain. He has communicated with a surgical registrar and handed over to covering intern Dr Inpanathan who obtained the results and communicated them to the cardiology registrar.

31. On Saturday 9 November 2002, Dr Adraktas is then the weekend covering intern for 3 units. He did not follow-up on the bloods he ordered or on Mrs Harrington *per se* despite his concerns the previous day and he did not follow-up on the blood results when he is called to see her that evening with vomiting. Dr Adraktas did not look at Mrs Harrington's file for other entries but did make his own extensive notes of his examination. He did not see the nursing entry on the previous page, noting altered mental state. Dr Adraktas could not recall if he did follow-up on the results of the bloods he had ordered on 8 November 2002 - he did not think he had. He did not follow his own practice of continuum of care.<sup>30</sup>

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<sup>27</sup> Pursuant to section 67(3)

<sup>28</sup> T @ p 151-152

<sup>29</sup> T @ p 149

<sup>30</sup> T @ p 34



32. Dr Justin Chee was the surgical registrar covering Frankston Hospital from 08:00 hours on Sunday 10 November 2002 to 08:00 hours on Monday 11 November 2002 as part of the after hours roster.<sup>31</sup> His duties were to assess patients in the emergency department and patients in the wards other doctors had concerns about.<sup>32</sup> He did not receive a handover specific to Mrs Harrington when he commenced his shift. He reflected that it was general practice to handover at the change of shifts information of a patient who was unwell or whose *recovery had been less than expected* so the patient could be reviewed by the registrar coming on duty. When Dr Chee did review Mrs Harrington's file he noted that she had *abnormal liver function tests that were very elevated*, and that there had been an episode of chest pain and discussion with the cardiology registrar and that in the previous two days she *was not well really already, and she was deteriorating*.<sup>33</sup>

33. Mr Peter Evans last saw Mrs Harrington on Wednesday 6 November 2002. He was not contacted about Mrs Harrington's changed and deteriorating condition until he received the call from Dr Chee on Sunday 10 November 2002. He had not been told about her episode of chest pain "during normal hours" on Friday 8 November 2002. He operated at Frankston Hospital on Tuesdays and would see postoperative patients and any new patients in the morning on the Wednesdays prior to consulting in his rooms in Frankston from approximately 11:00 hours. Thereafter, the normal practice would be for patient follow-up to be performed by the surgical registrar who was expected to telephone Dr Evans on a daily basis.<sup>34</sup> He had a pager which he carries with him at all times.<sup>35</sup> Mr Evans felt he should have been notified of Mrs Harrington's condition earlier because:

*..it was clear there was a patient who was deteriorating over a two day period and a specific cause had not yet been found. So I would have thought it would be appropriate for me to be called and notified of that so that I can be involved in helping sort out the cause of the deterioration and the management of that.*<sup>36</sup>

34. Between 8 November 2002 and 10 November 2002 no one has looked at the results and investigations in the context of Mrs Harrington's complaints, no or little oral intake and continued use of Panadol. No one has turned their mind to the possibility hepatic toxicity.

#### **Paracetamol toxicity:**

35. Paracetamol is widely prescribed for postoperative pain relief. Mr Evans stated that it is *part of a multi management of pain relief for post operative patients*.<sup>37</sup>

<sup>31</sup> Exhibit 5 - Statement of Justin Beng Lin Chee dated 15 December 2005.

<sup>32</sup> T @ p 81

<sup>33</sup> T @ p 76

<sup>34</sup> T @ pp 137-138, 140

<sup>35</sup> T @ p 146

<sup>36</sup> T @ p 139

<sup>37</sup> T @ p 157

36. I am satisfied that there is no evidence that Mrs Harrington was consuming excessive amounts of paracetamol at home prior to her admission on 31 October 2002 or that she was taking paracetamol whilst an in-patient other than in accordance with what was prescribed by her medical team and provided to her by nursing staff. I also accept that Mrs Harrington only received normal therapeutic doses of Paracetamol during this, her last admission.

37. Professor Olaf Drummer, in his expert report to the Court<sup>38</sup>, stated that:

*Paracetamol can cause liver damage if taken to excess. The dose and concentration capable of causing this is variable and is dependent on both dose and time, and the sensitivity of the liver to paracetamol ingestion.*

38. Professor Drummer agreed that paracetamol was an analgesic that had been around for a very long time but that it is *a quite safe drug, if used appropriately*.<sup>39</sup> He stated that it is commonly used in the post operative stage for minor pain and thus taken in the absence of any nutrition but is still *clearly safe in the great majority of people*.<sup>40</sup> Most cases of paracetamol toxicity that he was aware of, were associated with circumstances where an individual had taken around 20-30 tablets at once which made the potential associated risks more easily identifiable for the health care professionals to treat. Earlier recognition leads to the earlier implementation of treatment because *the longer you leave the drug causing damage, the less likely you are able to reverse the liver (sic) damage and then prevent further damage*.<sup>41</sup> Professor Drummer agreed with the proposition that receipt of abnormal liver function tests should prompt a response of removing any medication from the patient's regime that are known to have toxic effects to the liver. He stated:

*That would be a cautious - prudent approach.*<sup>42</sup>

39. Dr Carney however stated that ceasing paracetamol may depend on obtaining a clear diagnosis of paracetamol toxicity in the presence of abnormal liver function tests otherwise it was more likely and common that the dose of paracetamol would only be modified/reduced.<sup>43</sup>

40. Consultant intensive care specialist, Dr Ian Carney, was on duty at the time Mrs Harrington was admitted to the ICU. He stated that it was apparent that Mrs Harrington had acute liver failure. She had very abnormal liver function - her enzymes were elevated, her blood clotting was abnormal and she was unconscious. On review of Mrs Harrington's notes Dr Carney considered paracetamol toxicity as a possible cause of her precarious state. She had been receiving paracetamol and he could not identify *any other obvious drugs which were likely to be causing the liver impairment*.<sup>44</sup> He stated:

<sup>38</sup> Exhibit 6 - Expert Opinion of Professor Olaf Drummer dated 12 February 2004

<sup>39</sup> T @ p 92

<sup>40</sup> T @ p 100

<sup>41</sup> T @ p 94

<sup>42</sup> T @ p 95

<sup>43</sup> T @ pp124-125

<sup>44</sup> T @ p 104

*In hospital drug reactions are probably the most common cause of liver impairment and paracetamol is probably not the most common cause that I would see, usually it's due to antibiotics, particularly Flucloxacillin which she had not received and a number of other agents which are much more commonly associated with abnormal liver function. But paracetamol is the most common cause of severe acute liver failure, so someone who developed this degree of impairment, paracetamol becomes much more likely. So drug reactions due to relatively minor changes in liver function can be due to a very wide number of causes, severe liver failure to this extent makes paracetamol more likely.*<sup>45</sup>

41. Dr Carney stated that it was established that it was 8 November 2002, when the first changes in liver function tests were apparent but as there are a number of causes of changes to the liver's enzymes in the postoperative stage, it was not clear that Mrs Harrington had liver failure at that stage. Observations of Mrs Harrington's increase in confusion on 9 November 2002, probably represented the onset of liver failure and encephalopathy.<sup>46</sup> Professor Dudley expressed the same opinion.<sup>47</sup> Dr Carney was not however prepared to categorically state that the outcome would have been different for Mrs Harrington even if her liver failure had been realised on 9 November 2002.

#### **Treatment of abnormal liver function :**

42. Associate Professor (A/P) Paul Desmond, in an expert opinion obtained by the Court, also stated that:

*There are numerous causes of abnormal liver function tests in the post operative situation and paracetamol toxicity is relatively rare. It would not necessarily be recognised in the first instance. Abnormal liver enzymes can be due to infections, drug reactions and ischemia.*<sup>48</sup>

43. A/P Desmond opined that if a diagnosis of paracetamol toxicity had been made 24-48 hours earlier it may have been possible to treat Mrs Harrington with *N*-Acetylcysteine *although it is not definite that this would have altered the clinical outcome necessarily.*

44. Dr Carney and Professor Braitberg agreed as did Professor Dudley who stated that it was debateable whether the administration of *N*-acetylcysteine was effective after a patient had developed signs of acute liver failure.<sup>49</sup>

45. Professor Dudley stated that *the concept of hepatotoxicity at therapeutic doses, recommended therapeutic doses is not well recognised by the community*<sup>50</sup> even today. The information produced by the pharmaceutical companies and the prescriber information contained within MIMS does not mention any risks at therapeutic levels. The lack of knowledge within the medical profession at large that

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<sup>45</sup> T @ p 105

<sup>46</sup> T @ p 109

<sup>47</sup> T @ p 215

<sup>48</sup> Report of A/P Paul Desmond dated 20 March 2008 - contained within Exhibit 14 - Balance of the Brief

<sup>49</sup> T @ p 218

<sup>50</sup> T @ p213

therapeutic doses of paracetamol could be responsible for acute liver failure, particularly at the time of Mrs Harrington's death is explicable and highlighted by the fact that it was not until 2007, that an article appeared in the Medical Journal of Australia (MJA)<sup>51</sup>

### **The role of pathology services:**

46. An interrogation of the role Dorevitch Pathology at Frankston Hospital played in the communication of blood test results was undertaken by Ms Jennifer Couper, Laboratory Manager. In 2002, the normal practice was for medical staff to complete a request slip identifying the type of testing required. The specimens would be received in the laboratory, processed and the results electronically validated by a scientist in the laboratory. Normal results will auto-validate by the computer and other results viewed by the scientist who would accept and enter as okay to be released.<sup>52</sup> Once validated, results were available to ward staff on the Frankston Hospital Vital Computer or in the Intensive Care Unit via Dorevitch Pathology terminal. Abnormal results would generally be telephoned through to the ward and a record of the call manually made in the "Phoning Book". There is no such entry in the "Phoning Book" for the abnormal cardiac enzymes identified in the first sample of serial enzymes taken on 8 November 2002, and validated at 15:19 hours.<sup>53</sup>

47. At the time of giving her *viva voce* evidence, Ms Couper advised that the system at Frankston Hospital had since changed in that a paper "Phoning Book" was no longer maintained. Results telephoned through to the ward were recorded into the tracking system in the computer. Hard copies of such results were and still are printed and delivered to the ward where the patient is located. The system notes that the results report has been printed. The reliance on the hard copy appeared to have lessened since 2002 due to increased computer usage by the doctors.<sup>54</sup> The Pathology service also has a Abnormal Results Training Protocol which formalises the practice of ringing through abnormal results to the ward or to the doctor ordering the tests if specifically requested.

48. Dr Wellington gave evidence that the pathology test results on Dorevitch's computers are electronically linked via the Orion Concerto Software, to the hospital's computers and are more or less instantly available. This upgrade to the hospital's software not only allows access by staff to information on tests, imaging from the imaging specialists and pathology tests from the pathology specialists but unlike in 2002:

*you can also make records, such as the synoptics that are used in the rounds now at the times patient handovers are occurring.*<sup>55</sup>

49. The identified shortcoming in the communication of the abnormal cardiac enzymes from the laboratory to the ward and/or a doctor had no bearing on the outcome in Mrs Harrington's case. Whether actually telephoned from the laboratory to the ward, communicated to Dr Inpanathan by ward

<sup>51</sup> "Accidental Paracetamol Poisoning", John S Lubel *et al*, MJA 2007; 186 (7) 371-372

<sup>52</sup> T @ p 54

<sup>53</sup> Exhibits 3 & 4 - Statements (and attachments) of Jennifer Couper

<sup>54</sup> T @ p 66

<sup>55</sup> T @ p 188

staff or accessed by Dr Inpanathan herself from the computer system as she suspects, those first abnormal results were known to a doctor in a timely manner and were acted upon. Dr Inpanathan reported the abnormal results to two of her more senior doctors, the cardiology registrar and the surgical registrar, Dr Wang. She also made appropriate entries in the medical file of her involvement with Mrs Harrington and gave a handover to the next covering doctor coming on duty.

50. I acknowledge the system improvements implemented by Dorevitch Pathology since the death of Mrs Harrington.

#### **Other changes implemented at the hospital since Mrs Harrington's death:**

51. The circumstances surrounding Mrs Harrington's death was and still is, extremely unusual according to Dr Carney and, as such, it is more difficult to raise awareness in the medical profession about the potential toxic effects of paracetamol. He cited the Medical Journal of Australia (MJA) as being the most widely read Australian journal by the medical community and as such it could be considered an appropriate method for educating them. In 2008, Peninsula Health adopted the paracetamol treatment guidelines that had recently been promulgated in the MJA.

52. Dr Carney outlined a number of changes that had occurred at the hospital since Mrs Harrington's death, although he could not say if they were specifically related to her death or from reviews of a number of matters where shortfalls in patient care had been identified.

53. There has been a change to the criteria that enables nursing and medical staff to make a MET call. Urine output parameters<sup>56</sup> has been added to the enabling criteria and if in place at the time of Mrs Harrington's admission, could have resulted in a MET call being made because of her low urine output on the Saturday night or at the latest on the Sunday morning.

54. Loss of consciousness was and remains the most common reason that a MET call is made and was the basis of the call in Mrs Harrington's circumstances. The changes of confusion/delirium noted by nursing staff on 9 November 2002, are not identified as MET call criteria particularly in the post operative patient.<sup>57</sup>

55. There has also been an associated education campaign to increase awareness of the MET system.<sup>58</sup> A ready reference card that is provided to all medical and nursing staff, setting out the MET call parameters has also been amended to include the addition of urine output levels. The card can be carried by staff in their identification tags.

56. Other innovations adopted by Frankston Hospital include the creation of an Intensive Care Liaison Nurse who is available to provide education on the wards and attend any ward to make assessments and give patient treatment advice.

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<sup>56</sup> Urine output of less than 50ml over 4 hours

<sup>57</sup> T @ pp 120-121

<sup>58</sup> T @ p 115

57. Dr Wellington, who has been the Medical Director of Patient Safety at Peninsula Health since May 2007, also outlined changes implemented at Peninsula Health since Mrs Harrington's death. His statement<sup>59</sup> was in response to the recommendations contained in the expert opinion report of Professor Braitberg<sup>60</sup> and in his *viva voce* evidence he outlined that the change, albeit minor, to the criteria for "Mandatory Contact with Specialist" complemented the change to the MET call criteria specific to the inclusion of low urine output. The effect being that if the urine output is less than 50 mls over 4 hours that the specialist should be contacted and/or a MET call is made.<sup>61</sup> The "Clinical Escalation Procedure" document reinforced with staff that the organisation endorses escalation of concerns about clinical management by junior staff through acknowledging that the hierarchial system can be intimidating for them to take such an approach.

58. At the time of Mrs Harrington's admission, Dr Wellington stated that the initial clinical management of her complaint of chest pain was appropriate. The investigations to exclude a cardiac origin and/or blood clot included appropriate consultation with the cardiology registrar but more could have been done. Dr Wellington stated that the intern could have sought further advice about the significance of the elevated enzymes with either another medical registrar or the surgical registrar. He also stated that the supervising consultant should have been contacted *on the Friday or certainly the Saturday*.<sup>62</sup> He conceded that the *communication processes were clearly inadequate*.<sup>63</sup> He said that *we could have had better communication (sic) and we might have been led to an earlier escalation of attempts to try to salvage the situation*.<sup>64</sup> He could not however say whether this would have changed the outcome.

59. Dr Wellington also stated that another initiative taken after Mrs Harrington's death, albeit several years later, was a review of the literature on the risks of Paracetamol by the Director of Pharmacy at Frankston Hospital. This review was summarised and published and sent to all clinical users, all nurses and doctors and allied health professionals with the aim of raising awareness particularly in relation to some types/group of patients who are at increased risk of adverse outcome from its use. Dr Wellington also acknowledged the hospital's sorrow to Mrs Harrington's family along with apologising for the hospital's poor communication to the family about the deterioration in her condition with the onset of chest pain as well as on the Sunday when she had become increasingly confused.<sup>65</sup> Dr Wellington also stated that at the time of Mrs Harrington's death rigorous processes of investigation of critical events was in its embryonic stages.<sup>66</sup> Such processes are now more timely and with the aim to *determine what could be done to remediate faults and inadequacies in their processes*.<sup>67</sup>

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<sup>59</sup> Exhibit 10 - Statement of Dr Clive Wellington dated 15 August 2008

<sup>60</sup> Exhibit 12 - Expert Opinion Report of Professor George Braitberg dated 27 December 2007

<sup>61</sup> T @ pp 175-176

<sup>62</sup> T @ p 189

<sup>63</sup> T @ p 197

<sup>64</sup> T @ p 205

<sup>65</sup> T @ p 209 & 210

<sup>66</sup> The Root Cause Analysis (RCA) process implemented by the Department of Human Services mandating public hospital reporting and inquiry into serious adverse events commenced in 2001. T @ p 193

<sup>67</sup> T @ p 181 & 204

## CONCLUDING FINDINGS AND COMMENTS:

60. I accept and find that Mrs Harrington's clinical deterioration was not readily identifiable as having any relationship to the ingestion of Paracetamol for pain relief in the post operative period. I accept that accidental paracetamol poisoning is rare particularly, in a patient within the hospital setting. Even in the presence of limited nutritional intake there was a consensus of opinion/expectation that Mrs Harrington would have been able to tolerate the levels of paracetamol she was administered.

61. I also accept and find that complications associated with therapeutic doses of paracetamol were not widely known within the medical profession, other known cases were few and the literature scant. Mrs Harrington's death has highlighted the need to improve awareness about this widely used analgesic.

62. Nevertheless, Mrs Harrington's overall clinical state did change on Friday 8 November 2002, and I find that more could have been done to identify the cause of this change and deterioration. The delivery of appropriate treatment depends greatly on accurate diagnosis. Obtaining an accurate diagnosis is often achieved through a process of elimination of other differential diagnoses. In Mrs Harrington's situation I find that the process of elimination was appropriately commenced with the investigations into her chest pain but stalled upon receipt of the elevated enzyme results once they were considered not to be cardiac in origin. The failure to continue with the process of elimination that is, to identify with some greater clarity a cause for these abnormal results and her continuing deteriorating state, denied Mrs Harrington an opportunity for the cessation of Panadol and the implementation of specific treatment, such as with *N*-acetylcysteine. Other opportunities for further interrogation arose as Mrs Harrington continued to deteriorate over the weekend including the change in her mentation - now known to be attributable to cerebral odema caused by liver failure; and her reduced urine output. In isolation, the raised LD and AST, the vomiting, decreased urine output, could have been attributed to the general post-operative complications/problems but when examined holistically or indeed in conjunction with her changed mentation, we know that her clinical condition was indeed dire. The lack of an holistic approach to Mrs Harrington's clinical state is in part attributable to the involvement of a number of doctors involved in her care whilst covering the weekend shifts and which required them to work long hours and perform a wide range of duties as well as deliver and administer medical attention to a large number of patients, not only within their own Unit but for three other Units. Missing in the equation and which has been acknowledged by the hospital, was a review of blood results, handover at the registrar level and escalation of Mrs Harrington's changed condition to consultant status - all matters which fall within the umbrella of effective communication - either documented or handed over and includes communication escalation. Through Dr Wellington, the hospital has made a clear acknowledgment of their shortcomings in this regard.

63. However, having considered all the evidence including that of the expert senior physicians and the opinions expressed by A/P Desmond in his report, I am unable to definitively find that the outcome for Mrs Harrington would have been different, that her death could have been prevented, even if the seriousness of her decline had been realised and effectively communicated earlier.

64. I accept the acknowledgments of the hospital as a true expression of a commitment to address the identified shortcomings and similarly accept that the hospital has put into place a number of changes to address them.

65. I accept the opinion of Professor Braitberg that the identified shortcomings in Mrs Harrington's medical management are attributable to systemic issues and not individuals involved in her care - some of whom were thorough, enquiring, escalated their concerns and documented their involvement with Mrs Harrington appropriately. The comments I have made about failures to follow-up should be interpreted as failures within the system and I make no adverse findings in respect of individuals involved in Mrs Harrington's care.

66. I accept and adopt the medical cause of death as identified by Dr Malcolm Dodd and find that Elsa Harrington died from multisystem organ failure secondary to acute liver failure associated with paracetamol toxicity.

### RECOMMENDATIONS

Pursuant to section 72(2) of the **Coroners Act 2008**, I make the following recommendation(s) connected with the death:

1. I commend the work of Dr John Lubel and his colleagues who through their article in the MJA highlighted to the medical profession the little known risk of accidental paracetamol poisoning. Of note, he stated:

*..in Australia, severe life-threatening liver injury from accidental paracetamol poisoning appears to be quite uncommon. Nevertheless, this is a readily preventable syndrome of which both patients and the medical profession should be made more aware. In particular, clinicians should be cautious about prescribing regular doses of paracetamol for pain control in malnourished or fasting patients, and need to appropriately counsel patients who are regular users of the drug.<sup>68</sup>*

2. Having regard to the passage of time since Mrs Harrington's death, the culmination of evidence obtained in the course of the investigation and the benefits of periodic reminders on matters of public health and safety, **I recommend** that the Australian Medical Association (AMA Victoria), and the College of General Practitioners collaborate for the purposes of implementing a medical profession and public awareness raising program regarding the risks of accidental paracetamol poisoning as identified by Dr John Lubel.

3. **AND** I further recommend that the Therapeutic Goods Administration (TGA) update their bulletins and alerts on the risks associated with accidental paracetamol poisoning on the same grounds and that consideration be given to mandating improvements to consumer information to address the risks as identified in this investigation albeit that it is acknowledged the risk is small.

<sup>68</sup> "Accidental Paracetamol Poisoning", John S Lubel *et al* MJA 2007;186 (7) : 371-372



Pursuant to section 73 of the *Coroners Act 2008*, this Finding will be published on the internet.

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

The family of Mrs Harrington  
The Chief Medical Officer - Peninsula Health  
Australian Medical Association (AMA Victoria)  
College of General Practitioners  
Dr John Lubel  
Therapeutic Goods Administration.

Signature:



AUDREY JAMIESON  
CORONER

Date: 2 March 2012