

IN THE CORONERS COURT  
OF VICTORIA  
AT MELBOURNE

Court Reference: COR 2009 1577

**FINDING INTO DEATH WITH INQUEST**

*Form 37 Rule 60(1)*

*Section 67 of the Coroners Act 2008*

**Inquest into the Death of: THELMA HOLT**

Delivered On: 13 August 2013

Delivered At: Coroners Court of Victoria  
Level 11, 222 Exhibition Street  
Melbourne 3000

Hearing Dates: 24-25 October 2011

Findings of: Jane Hendtlass, Coroner

**Representation:**

Mr C. Winneke appeared on behalf of Dr Marks and Dr Merrett.

Dr P. Halley appeared on behalf of Dr Prichard.

Ms F. Cockram appeared on behalf of Dr K. Bundy.

Police Coronial Support Unit Sergeant T. Weir was present to assist the Coroner.

I, JANE HENDTLASS, Coroner having investigated the death of THELMA KATHERINE HOLT

AND having held an inquest in relation to this death on 24, 25 October 2011

at MELBOURNE

find that the identity of the deceased was THELMA KATHERINE HOLT

born on 15 July 1929

and the death occurred 14 March 2009

at The Epworth Hospital, 89 Bridge Road, Richmond, Victoria 3121

from:

1 (a) PNEUMONIA IN A SETTING OF PERITONITIS (DUE TO PERFORATED STOMACH) (OPERATED).

in the following circumstances:

1. Thelma Katherine Holt was 79 years old when she died. She lived alone at 2/17 Central Avenue in Moorabbin. Mrs Holt was a widow and a former accountant.
2. Mrs Holt's medical history included cataracts, asthma, osteoporosis, gastroesophageal reflux disease and hiatus hernia treated with a Nissen fundoplication in 1995, hypothyroidism, hypertension, obesity, gout, chronic renal impairment, an aortic aneurysm repair in 1996, chronic low back pain as a consequence of degenerative spine and obstructive sleep apnoea. Her usual general practitioner was Dr Kay Bundy.
3. Mrs Holt also had a long history of obesity. Medical management of her attempts to lose weight included very low calorie diets, weight-loss medications, exercise programmes and referral to gastroenterologists and a respiratory physician.
4. Although she had some success prior to about 2000, these treatments failed to maintain Mrs Holt's weight reduction so that she became depressed and unable to go outside. She was prescribed Zoloft but Dr Bundy told the Court that she was not sure that Mrs Holt's mood was sufficient to warrant a diagnosis of clinical depression.
5. In 2004, Dr Richard Oei from South Road Family Clinic referred Mrs Holt to a new gastroenterologist, Dr Michael Merrett.

6. Before he considered physical intervention, Dr Merrett referred Mrs Holt to a consultant physician in clinical nutrition, Dr Sharon Marks, to try diet and pharmacological weight loss.
7. Mrs Holt did not lose enough weight using these medical procedures to change her diagnosis of obesity.
8. Therefore, on 29 March 2007, Dr Merrett performed an upper gastrointestinal endoscopy at Frankston Private Hospital. He placed an Enterics intragastric balloon in Mrs Holt's stomach and inflated it with 600mls saline. In the course of the procedure, Dr Merrett identified a moderate sized hiatus hernia (2-5cm).
9. Over the next five months, Mrs Holt lost 22 kilograms in weight.
10. However, on 6 August 2007, Mrs Holt was diagnosed with an abdominal incisional hernia that required surgical correction.
11. On 10 August 2007, Dr Merrett removed Mrs Holt's intragastric balloon at Frankston Private Hospital to enable surgery to correct her abdominal incisional hernia.
12. On 6 September 2007, Mr Paul Sitzler repaired Mrs Holt's abdominal incisional hernia at the Epworth Hospital. This surgery was associated with subsequent slow recovery, wound and site infection and exacerbation of Mrs Holt's respiratory disease.
13. On 20 March 2008, another surgeon, Mr John Leslie, noted that Mrs Holt had now been left with a recurrent hernia that would be better left to stabilise for a month or two.
14. Mr Leslie said he could not operate again until Mrs Holt lost a further 10-20kg. He recommended an abdominal binder to relieve Mrs Holt's discomfort.
15. On 11 September 2008, Dr Merrett placed a second intragastric balloon at Frankston Private Hospital to assist with Mrs Holt's weight loss before repair of her recurrent abdominal incisional hernia.
16. At 11.35am on 30 January 2009, Mrs Holt presented at the Emergency Department of the Epworth Hospital with symptoms consistent with significant small bowel obstruction. A Computed Tomography (CT) scan confirmed the diagnosis.

17. Dr Peter Prichard discussed Mrs Holt's condition with Dr Merrett. They agreed to admit her to the Epworth Hospital for the weekend and deflate the balloon at Frankston Private Hospital on 2 February 2009.
18. However, Mrs Holt's condition deteriorated. She was diagnosed with peritonitis and perforated stomach and transferred to the Intensive Care Unit at the Epworth Hospital.
19. At 1.45am on 2 February 2009, Associate Professor Peter Danne performed an emergency exploratory laparotomy. He corrected a gastric perforation and the outlet obstruction which he said was caused by Mrs Holt's intragastric balloon.
20. Mrs Holt recovered slowly after surgery and required admission to the Intensive Care Unit at the Epworth Hospital.
21. On 10 February 2009, Associate Professor Danne re-opened the laparotomy to close the abdominal wall and proceed with her bowel reconstruction.
22. However, Mrs Holt's condition continued to deteriorate and she underwent further abdominal surgery. Her abdomen became septic.
23. On 25 February 2009, Mrs Holt suffered symptoms consistent with a post-operative cerebrovascular accident (stroke).
24. Active treatment was withdrawn.
25. On 12 March 2009, a CT brain scan found no acute intracranial abnormality.
26. On 14 March 2009, Thelma Holt died at the Epworth Hospital in Richmond.
27. The forensic pathologist who inspected the body formed the opinion that Mrs Holt's cause of death was pneumonia in the setting of acute peritonitis (due to perforated stomach) (operated).
28. Accordingly, I find that Thelma Holt died of pneumonia in the setting of acute peritonitis due to perforated stomach.
29. This Finding will review in more detail Mrs Holt's background and the medical management of her obesity and her abdominal incisional hernia.

30. It will then comment and make recommendations intended to prevent other people dying for the reason that Mrs Holt died.

### **Background**

31. Thelma Holt had a long history of gastric reflux and obesity and related disorders. Her usual general practitioner was Dr Kay Bundy but she sometimes consulted other doctors in the South Road Family Clinic.
32. In 1995, Mrs Holt underwent a Nissen fundoplication to correct her reflux. However, she continued to gain weight.
33. Mrs Holt also suffered from persistent asthma, depression, lower back pain, chronic renal failure, hiatus hernia and significant vascular disease.
34. Dr Bundy also referred Mrs Holt to a respiratory physician, Dr Judith Morton. Dr Morton referred her to two gastroenterologists, Dr Gregory Taggart and Dr Henry Debinski, and a general physician with a special expertise in hypertension and vascular diseases, Dr Geoff Matthews.
35. Mrs Holt's out of pocket medical expenses were covered by the Department of Veterans' Affairs.
36. Dr Bundy attempted to assist Mrs Holt to lose weight using diet, exercise and weight-loss medications including Reductil (sibutramine) and Xenical (orlistat).
37. However, Mrs Holt did not lose weight.
38. On 6 April 2004, Dr Richard Oei from South Road Medical Practice referred Ms Holt to a new gastroenterologist, Dr Michael Merrett.
39. Dr Merrett is a consultant physician in gastroenterology. His practice included non-surgical management of weight loss using endoscopic placement of an intragastric balloon under neuroleptic anaesthesia. Mrs Holt instigated her referral to Dr Merrett because she had heard about intragatric balloons and was thinking she would like to try one.
40. An intragastric balloon is placed in the stomach and inflated with saline to reduce the capacity of the stomach.

41. Dr Merrett worked closely with and in the same practice as a consultant physician in clinical nutrition, Dr Sharon Marks.
42. Dr Marks is a general physician who specialises in clinical nutrition and metabolism. She has reported publicly on her experience with managing 73 obese patients with 92 water-filled intragastric balloons over 6 years. In the overall patient group, including eight patients whose balloons deflated, the mean weight loss was 10.5 kg. In the patients with intact balloons, mean weight loss was 11.0 kg.<sup>1</sup>
43. On about 27 April 2004, Dr Merrett saw Mrs Holt. Her Body Mass Index (BMI) was 44.1kg/m<sup>2</sup> so she would be classified as Obese Class III by the World Health Organisation.
44. However, Dr Merrett adopted his usual conservative practice and advised against immediate use of an intragastric balloon. Rather, on 4 May 2004, he referred Mrs Holt to Dr Marks for further management of her weight loss using exercise, diet and pharmacology.
45. Dr Marks replaced Mrs Holt's Reductil with Xenical and recommenced her Zoloft for depression. She also referred her to a dietician and encouraged her to use a food replacement product, Optifast. Dr Marks reviewed Mrs Holt every three months.
46. On or about 7 November 2004, Mrs Holt had a laparoscopic cholecystectomy at the Freemasons Day Procedure Centre. Her recovery was associated with ongoing nausea and reflux despite prescription of Nexium.
47. On 13 December 2004, Mrs Holt returned to consult Dr Marks.
48. Mrs Holt lost about 8kg over the next three years. She was still within the range for diagnosis as Obese Class III (BMI 41.8kg/m<sup>2</sup>).
49. From early 2006, Mrs Holt's oesophageal reflux and spasm returned. It did not respond to Nexium or Tazac or her weight loss.
50. On 6 December 2006, Dr Debinski noted that Mrs Holt had developed either a hiatus hernia or a dynamic oesophagus secondary to her Nissen fundoplication.

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<sup>1</sup> See for example: S. Marks, "Intragastric Balloons Safe and Effective Against Resistant Obesity" 21 May 2008, Abstract T2:PS:52.

51. On 18 December 2006, Dr Debinski performed a gastroscopy at Cabrini Medical Centre. He diagnosed Mrs Holt with another large hiatus hernia and a lax wrap from the original Nissen fundoplication. Dr Debinski attributed Mrs Holt's significant reflux to these conditions.
52. Further, on 22 February 2007, Mrs Holt's weight had increased slightly when she consulted Dr Marks and she was quite despondent. Dr Marks believed she would be suitable for insertion of an intragastric balloon.
53. Mrs Holt was attracted by the potential of an intragastric balloon to help her lose weight and accordingly reduce her reflux. Stomach banding was excluded because of her age.
54. On 1 March 2007, Dr Debinski wrote to Mrs Holt to arrange an opportunity to discuss alternative measures to reduce her weight.
55. Further, on 16 March 2007, Dr Debinski wrote to Dr Morton expressing concern that an intragastric balloon would exacerbate Mrs Holt's reflux and could potentially be dangerous. Dr Debinski also told Dr Morton that Mrs Holt had not been taking her Tazac (nizatidine) which could explain her poor control of the reflux. He copied this letter to Dr Bundy.
56. On 21 March 2007, Dr Marks and Dr Merrett discussed Mrs Holt's worsening oesophageal reflux and her co-morbidities with her and with Dr Debinski. At that stage, she was suffering painful oesophagitis associated with her reflux and she was unable to walk far because of her respiratory disease. However, there was no evidence of an abdominal incisional hernia.
57. Dr Merrett also wrote to Dr Bundy supporting a decision to insert an intragastric balloon. Contrary to Dr Marks' claims, he confirmed he had placed over 100 balloons with an average weight loss of about 20kg. He also confirmed that the balloon could worsen her reflux. Further, in about 5% of cases, the balloon has to be removed due to complications.
58. However, Mrs Holt was determined to proceed with an intragastric balloon.
59. Accordingly, Dr Marks referred Mrs Holt back to Dr Merrett.

### **Mrs Holt's first intragastric balloon**

60. On 29 March 2007, Dr. Merrett inserted Mrs Holt's first Inamed enterics intragastric balloon at Como Private Hospital. He filled it with 600ml saline.
61. Dr Merrett also noted a moderate sized hiatus hernia (2-5cm) with the gastroesophageal junction raised to 37cm from the incisors.
62. After this procedure, Dr Merrett referred Mrs Holt back to Dr Marks and the practice's dietician and psychologist.
63. By 10 May 2007, Mrs Holt had lost 10kg. She lost a further 12kg in the following two months.
64. On 9 July 2007, Dr Merrett reviewed Mrs Holt. She was now within Obese Category II (BMI 36.6 kg/m<sup>2</sup>).
65. Dr Merrett was very pleased. He wrote to Dr Bundy:

*"She feels much improved and interestingly has had no reflux symptoms since the balloon was placed."*

66. Dr Merrett's assessment of Mrs Holt's condition during the period that her first gastric balloon was in place differed from that of her other clinicians:
- Mrs Holt also consulted Dr Bundy on 14 occasions between 5 April and 7 July 2007. Dr Bundy told the Court:

*"I remembered after the first balloon how unwell she had been because she saw many times after the first balloon with all sorts of issues. "*

In particular, Dr Bundy reported on-going gastroesophageal reflux, pain, slight anaemia, rash and urinary tract infection as well as respiratory complications and gout. Dr Bundy prescribed Tazac, Prodiene, paracetamol, antibiotics, prednisolone, an inhaler and Spireva capsules, Xenical, Motilium and increased her Nexium.

- Further, Mrs Holt consulted Dr Marks on four occasions between 5 April and 7 June 2007. Dr Marks reported one episode of vomiting which was an expected side effect early in the placement of the intragastric balloon. However, she also reported on-going belching and



halitosis, one episode of reflux and muscle aches and pains that commenced when the intragastric balloon was inserted. Dr Marks prescribed charcoal as well as medication for gout. Dr Marks also reported severe inflammatory changes over Mrs Holt's abdomen and groin as well as evidence of iron deficiency.

67. On 18 July 2007, Mrs Holt consulted Dr Bundy about constipation, reflux and vomiting. Dr Bundy diagnosed a large incisional abdominal hernia that had become obvious since her last consultation on 7 July 2007. She referred Mrs Holt to a colorectal surgeon, Mr Paul Sitzler.
68. On 18 July 2007, Dr Marks also referred Mrs Holt back to Dr Merrett because of concern the balloon may have shifted. This referral was not activated.
69. On 23 July 2007, Dr Marks reported that there was a mass in Mrs Holt's abdomen. Dr Marks was unable to confirm whether or not it was a hernia.

#### **Mrs Holt's abdominal incisional hernia**

70. On 6 August 2007, Mr Sitzler reviewed Mrs Holt. He noted that she had suddenly developed a significant upper abdominal wall hernia and sent her for further radiological review.
71. A CT abdomen scan confirmed the diagnosis made by Mrs Holt, Dr Bundy and Mr Sitzler. The hernia included some small bowel and possible transverse colon.
72. Although her obesity placed her at risk, Mrs Holt had no known prior history of upper abdominal incisional hernia. Further, there had been no hernia detected in any of her medical examinations or radiology prior to 18 July 2007.
73. Accordingly, Mr Sitzler was unsure whether Mrs Holt's symptoms were attributable to her intragastric balloon or her abdominal hernia.
74. I accept the opinions of Mr Sitzler and Dr Bundy that there was no evidence of an incisional hernia prior to 18 July 2007.
75. Accordingly, I do not accept Dr Marks' alternative proposition that Mrs Holt's abdominal incisional hernia was unrelated to the balloon other than the fact that it became more visible and she became more conscious of it once she had lost weight.

76. Mrs Holt did not want to wait for surgery to correct her abdominal incisional hernia and Mr Sitzler was concerned about performing corrective surgery on Mrs Holt while the intragastric balloon was in place. He discussed the issue with Dr Merrett and they agreed that the balloon should be removed before surgery to correct the hernia.
77. On 8 August 2007, Mrs Holt consulted Dr Marks. Dr Marks referred her back to Dr Merrett for removal of her intragastric balloon and notified Dr Bundy.
78. Accordingly, on 10 August 2007, Dr Merrett performed a further upper gastrointestinal endoscopy at Frankston Private Hospital and removed Mrs Holt's first intragastric balloon.

#### **Repair of the abdominal incisional hernia**

79. On 6 September 2007, Mrs Holt was admitted to the Epworth Hospital. Mr Sitzler successfully performed a laparotomy to repair the ventral wall incisional abdominal hernia with mesh and divide the adhesions.
80. However, on 9 September 2007, Mrs Holt's respiratory condition declined, her blood pressure dropped and she developed acute renal failure, lung collapse, chronic obstructive pulmonary disease, and left ventricular fibrillation. She was transferred to the Intensive Care Unit. On 10 September, she was stable and returned to the ward.
81. On 14 September 2007, Mrs Holt was discharged to rehabilitation at Cedar Court, Epworth, Camberwell.
82. On or about 21 September 2007, Mrs Holt had a fall at Cedar Court and injured her back. She was diagnosed with soft tissue injury and discharged home because she could not undertake the appropriate exercises due to the pain from her fall. Pain persisted from her surgical site.
83. On 27 September 2007, Mrs Holt presented at the Epworth Hospital with discharge from her wound near the navel. Her treating doctor was unsure whether there was inflammation or a recurrence of the hernia. However, he prescribed antibiotics and indicated there was no sign of bowel obstruction.
84. On 3 October 2007, Mr Sitzler noted discharge from Mrs Holt's umbilicus and the distance between the discharge and the surgical wound. He formed the view that there must be some defect at the base of the umbilicus and referred her for an ultrasound.

85. On 5 October 2007, an ultrasound of the anterior abdominal wall allowed drainage of 70% of a collection anterior to the hernia mesh.
86. On 17 October 2007, Dr Morton noted continuing tenderness of Mrs Holt's lower thoracic spine and organised x-rays. There remained some weeping at the base of the hernia but it did not seem infected and "*was healing beautifully*".
87. On 18 October 2007, Mr Sitzler indicated that Mrs Holt was improving.
88. However, on 31 October 2007, Mr Sitzler diagnosed continuing persistent wound infection.
89. Accordingly, on 1 November 2007, a CT abdomen and pelvis detected a fluid collection within the anterior abdominal wall consistent with either a haematoma or an abscess. However, it failed to identify any evidence of a recurrent hernia and no intraperitoneal collections.
90. On 5 November 2007, Mr Sitzler arranged for Mrs Holt to be admitted to Lineacre Private Hospital for intravenous antibiotics to:  
  
*"knock this on it's head."*
91. On 7 November 2007, Mr Sitzler was concerned that Mrs Holt was still in pain but he believed the repair was sound.
92. On 22 December 2007, Mr Sitzler ordered a further CT abdomen and pelvis because Mrs Holt's pain persisted from her incisional hernia repair. This identified a further large collection within the subcutaneous tissues of the mid abdomen.
93. On 29 December 2007, Mrs Holt re-presented at the Epworth Hospital for an exploratory laparotomy. Mr Sitzler confirmed that mesh on her hernia wound had become infected so he drained, debrided and re-instated the mesh supporting the area and administered antibiotics.
94. On 4 January 2008, Mrs Holt was discharged home with support from Stanhope Nursing Service.
95. On 4 February 2008, Mrs Holt was re-admitted to Epworth hospital and Mr Sitzler performed surgery under general anaesthetic to further drain, debride and excise infected mesh on her hernia wound. Mr Sitzler was unsure whether Mrs Holt had a recurrent hernia.

96. On 21 February 2008, CT abdomen and pelvis scans ordered by Mr Sitzler showed persistent but reducing collection within the subcutaneous tissues of the anterior abdominal wall and fat consistent with residual hernia.
97. On 13 March 2008, Dr Morton reviewed Mrs Holt. She found Mrs Holt's abdomen was:  
*"excruciatingly tender in the left iliac fossa along the inferior edge of the hernia."*
98. Dr Morton referred Mrs Holt immediately to Mr Sitzler because she was concerned that she had a recurrent incisional hernia.
99. On 13 March 2008, Mr Sitzler reviewed Mrs Holt. He told Dr Bundy that he did not believe clinically there was a recurrent hernia. However, he had difficulty judging Mrs Holt's abdomen and he sent her for a further CT abdomen.
100. On 17 March 2008, Mrs Holt asked Dr Bundy to refer her to another surgeon, Mr John Leslie, for a second opinion. Mrs Holt told Dr Bundy that she sought this referral:  
*"Because... she'd had so many problems after her last operation with Dr Sitzler, Mr Sitzler who'd repaired it and ... all that complications in hospital and then the wound infection so she wanted someone else."*
101. On 20 March 2008, Mr Leslie reviewed Mrs Holt. He noted that Mrs Holt had now been left with a recurrent abdominal incisional hernia that had developed when the gauze was removed and would be better left to stabilise for a month or two.
102. Mr Leslie also said that he required 10-20 kilograms weight loss before attempting to further surgically repair the hernia. He recommended an abdominal binder to support the hernia and reduce Mrs Holt's discomfort.
103. Dr Marks had also discussed an abdominal binder with Mrs Holt. Mrs Holt told Dr Marks that she would:  
*'rather be dead than wear an abdominal binder forever'.*
104. Mrs Holt told Dr Bundy that she was determined to proceed with the second intragastric balloon to achieve the required weight loss for surgery.

*"I'd asked her to delay the balloon she declined... she was keen to have the second balloon.... Because she'd had such good weight loss the first time."*

105. On 14 April 2008, Mr Leslie told Dr Bundy that Mrs Holt's incisional hernia continued to be tender at times:

*"...but it has not bothered her enough to remind her to get the binder she was going to obtain to see if she can control her symptoms this way."*

106. On 15 April 2008, Dr Bundy re-referred Mrs Holt to Mr Leslie.

107. On 21 May 2008, Dr Morton confirmed that Mrs Holt's respiratory condition was good despite the complications associated with her recurrent abdominal incisional hernia. She was waiting for an abdominal binder because Mr Leslie was hesitant about further surgery.

108. On 2 June 2008, Dr Marks wrote to Dr Bundy to say that Mrs Holt was keen to consider having a second intragastric balloon placed. This would have to occur either six months before or six months after the surgery contemplated by Mr Leslie.

109. On 23 June 2008, Mr Leslie commented that the abdominal hernia was annoying but Mrs Holt was rarely having anything more significant than that. It was not particularly tender and the binder was at least controlling the situation.

110. Accordingly, surgery was not urgent and she still needed to reduce her weight before Mr Leslie would perform the further surgery required to repair the hernia.

111. Mr Leslie also supported a decision in that regard. He told Dr Bundy in a letter:

*"I'd have no objection to her having a further intra gastric balloon if this was thought appropriate in the short term, though I agree that having one in situ during surgery would probably be inappropriate."*

112. On 28 July 2008, Dr Mark wrote to Dr Bundy to indicate she would facilitate Mrs Holt's referral for insertion of another intragastric balloon.

113. On or about 4 September 2008, Mrs Holt had a fall which caused lower back and knee pain. However, Mrs Holt refused to delay the insertion of her second gastric balloon while she was recovering from the fall.

### **Mrs Holt's second intragastric balloon**

114. On 11 September 2008, Dr Merrett admitted Mrs Holt to Como Private Hospital and inserted a second intragastric balloon to assist with her weight loss before further repair of her abdominal incisional hernia. He inflated the balloon with 600ml saline and advised it may be left *in situ* for six months.
115. On or about 14 September 2008, Mrs Holt was discharged home to support from Dr Bundy and Dr Marks.
116. Mrs Holt consulted Dr. Bundy 11 times between 16 September 2008 and 30 January 2009.
117. Through most of this period, Mrs Holt complained of nausea, constipation, urine infection, reflux, light-headedness, chest infection, low blood pressure, and finally severe abdominal pain. Pain also continued from her fall. She also required potassium and iron supplements.
118. On 10 October 2008, Mrs Holt consulted Mr Leslie. She felt ill all the time with painful indigestion. Mr Leslie manipulated her hernia which relieved her constipation.
119. By 12 November 2008, Mrs Holt had lost 13 kilograms in two months. This weight loss was slightly slower than she had achieved with her first intragastric balloon. However, she remained 23.5kg lighter than when she first consulted Dr Merrett in 2004 and she remained Obese Category II (BMI 35.9kg/m<sup>2</sup>).
120. On 15 December 2008, Mr Leslie reviewed Mrs Holt's abdominal wall hernia. He arranged a CT scan of the abdomen and pelvis due to soreness and swelling in the area. Mr Leslie arranged for copies of these CT scan results to go to Dr Bundy's practice.
121. The CT scan of Mrs Holt's abdomen and pelvis showed the intragastric balloon in her stomach but there was no abdominal aortic aneurism and no left upper quadrant mass lesion.
122. When Mrs Holt saw Dr Bundy on 6 January 2009, her respiratory infection had settled and she was feeling well but remained dizzy and lightheaded. Dr Bundy ceased Mrs Holt's diuretic medication
123. On 16 January 2009, Dr Marks advised a meal replacement programme to accelerate Mrs Holt's weight loss.

124. On 30 January 2009, Mrs Holt consulted Dr Bundy with a 24 hour history of severe upper abdominal pain and vomiting and a distended abdomen with a mass on the left side at the site of the hernia:

*"..she was brought in by a neighbour, she was too sick to drive and she'd been unwell since the previous day and she complained of constant upper abdominal pain, vomiting and everything she ate or drank and a lump in her abdomen"*

125. Dr Bundy was not sure whether it was the hernia or the balloon that was the problem. She tentatively diagnosed a bowel obstruction and referred Mrs Holt for transfer by ambulance to the Accident and Emergency Department at the Epworth Hospital.

### **The Epworth Hospital**

126. At 11:35am on Friday 30 January 2009, Mrs Holt presented at the Accident and Emergency Department at the Epworth Hospital. She was triaged Category 4.

127. At 12:15pm on 30 January 2009, an abdominal x-ray showed a possible pyloric outlet obstruction.

128. An x-ray is like a 'snapshot' in time and is taken from a particular perspective. Therefore, it cannot show dynamic changes in the position of the intragastric balloon relative to the pylorus. However, in the absence of any other identified body, I accept the implication that the balloon was in a position where it could be significantly obstructing the pyloric outlet.

129. At approximately 1:55pm, intravenous fluids commenced to rehydrate Mrs Holt after her vomiting and a nasogastric tube was inserted to drain fluid from Mrs Holt's stomach. Initially, the nasogastric tube drained a whitish fluid but it would not have been able to pass food residue.

130. A registrar from the Emergency Department at Epworth Hospital ordered a CT abdomen and pelvis scan.

131. Dr Peter Prichard, an experienced gastroenterologist and consultant physician at the Epworth Hospital and the Royal Melbourne Hospital, was one of the gastroenterologists on call when Mrs Holt presented at the Epworth Hospital.

132. At about 2:30pm on 30 January 2009, Dr Prichard was called by the gastroenterology registrar to review Mrs Holt and approve her admission.
133. Dr Prichard reviewed Mrs Holt and observed that she was feeling comfortable and was no longer vomiting. Then, he went personally to the radiology department and looked at the CT films and discussed them with the radiologist.
134. From this discussion, Dr Prichard and the radiologist formed the opinion that the intragastric balloon was properly inflated and in a position where it could be causing a significant pyloric obstruction. However, there was no excessive or gross distension of Mrs Holt's stomach.
135. Associate Professor Danne also saw food in Mrs Holt's stomach when he reviewed the CT film. Dr Prichard confirmed this impression. The radiologist also confirmed it verbally to Dr Prichard but did not include it in the report.
136. The subsequent written report of the CT abdomen and pelvis scan confirmed a 600ml fluid filled balloon impacted on the gastric outlet and obstructing the stomach. The small bowel seemed collapsed. It also showed a small aneurysm in her distal abdominal aorta with a large amount of thrombus. The nasogastric tube was appropriately *in situ*.
137. At 3.30pm, a registrar from the Emergency Department at Epworth Hospital contacted Dr Marks. He explained to Dr Marks that Mrs Holt had presented in an ambulance with vomiting, nausea and some slight abdominal pain.
138. Dr Marks suggested they transfer Mrs Holt that afternoon to the Frankston Private Hospital. However, the registrar advised that it was not possible to organise transport that afternoon.
139. Although Dr Prichard was aware of the issues raised by an intragastric balloon, he had never seen an intragastric balloon before. Further, he did not have the necessary training and the Epworth Hospital did not have the equipment to non-surgically remove the intragastric balloon. Dr Prichard consulted Dr Merrett.
140. Dr Prichard assured Dr Merrett that the CT scan confirmed a significant outlet obstruction but Dr Merrett expressed some doubt that the balloon would be causing any significant obstruction.



141. Dr Merrett explained to the Court:

*"all patients even if they're well and not vomiting will have distension of the stomach with food debris and it gives the appearance of obstruction but complete gastric outlet obstruction doesn't occur with balloons and hasn't been reported."*

142. Dr Merrett's discussion allayed Dr Prichard's concerns about the relationship between the intragastric balloon and the otherwise apparently significant obstruction.

143. After hearing Dr Merrett's evidence at the inquest, Dr Prichard confirmed that he *"would agree with (Dr Merrett) fully"* that the intragastric balloon was not causing the obstruction.

144. Dr Merrett offered to be available and was prepared to attend Mrs Holt at the Epworth Hospital with his equipment if she deteriorated. He also told the Court that:

*"Technically it would have been possible for the balloon to be removed on the day but there was no indication at that time that we needed to do that."*

145. At 7:20pm on 30 January 2009, Dr Prichard reviewed Mrs Holt's condition. He observed her to be stable and arranged for her admission over the weekend. Dr Prichard also ordered a gastroscopy but there is no evidence that this occurred.

146. However, at 9:20pm on 30 January 2009, Dr Prichard was contacted regarding Mrs Holt's increased blood pressure. Although, Dr Prichard prescribed a Glyceryl Trinitrate (GTN) patch at 9:30pm, he was not concerned by the increased blood pressure due to Mrs Holt's other medical problems, which included hypertension.

147. At around midday or early afternoon on 31 January 2009, Dr Prichard reviewed Mrs Holt. He found her to be stable and comfortable. In particular, there was no evidence of gross distension of Mrs Holt's stomach.

148. Dr Prichard ordered capping of the nasogastric tube and gentle fluids commenced orally because he noted minimal drainage (16mls). Dr Prichard advised nursing staff to cease fluids and recommence gastric drainage if Mrs Holt did not tolerate the capping and oral fluids.

149. Four litres of saline had been administered by 12:15pm on 31 January 2009 and a further litre by 4:35pm. There is no record of urinary output. However, it is unlikely that the minimal noted by Dr Prichard drainage reflected a small volume of fluid in the stomach.
150. By 11:00pm on 31 January 2009, Mrs Holt was nauseous and experiencing pain. Nursing staff administered anti-nausea medication and morphine and attempted to contact Dr Prichard but he did not respond.
151. By 12:05am on 1 February 2009, Mrs Holt's symptoms had settled and she was considered stable. Dr Prichard ordered 1 milligram of Kytril if Mrs Holt's nausea returned. This was not administered because there was no evidence that the distension was of a severe nature and the clinical assessment of the patient was that the stomach was not gross or distending further.
152. Further, Dr Prichard was not convinced that Mrs Holt's symptoms were masked by her analgesia because she only required a low dose of morphine and only on two occasions. He told the Court:
- "Ongoing requirement for that sort of narcotic analgesia would be definitely of concern but that was not the situation."*
153. However, at 8:35pm on 1 February 2009, Mrs Holt's condition had deteriorated. Her blood pressure was 200/100mmHg, she was sweating, nauseous and complaining of pain.
154. Although Mrs Holt's condition initially responded to Maxalon and morphine, by 12:00am on 2 February 2009, the pain was ongoing and she was referred to the Intensive Care Unit with a differential diagnosis of gastric perforation.
155. Dr Prichard was of the view that this change in Mrs Holt's condition would have occurred within about 30 minutes of the perforation occurring, that is at about 8.30pm on 1 February 2009.
156. The Intensive Care Fellow, Dr David Chirovski, confirmed the diagnosis of gastric perforation and sought assistance from the on-call surgeon, Associate Professor Peter Danne.

157. At 1:45am on 2 February 2009, Associate Professor Danne performed an emergency laparotomy.

158. The laparotomy revealed:

- a large perforation of the gastric wall high up on the lesser curve due to gross distension of the stomach with ischaemia and/or or mechanical splitting at that point;
- contamination of the gastric contents (a large amount of food and fluid) into the peritoneal cavity and obvious peritonitis; and
- balloon obstruction of the gastric outlet.

159. Associate Professor Danne surgically removed the intragastric balloon, performed a peritoneal toilet and partial gastrectomy, closing the perforation and the ischaemic part of the lesser curve of the stomach. He closed Mrs Holt's abdomen with a VAC dressing.<sup>2</sup>

160. Associate Professor Danne told the Court:

*"This is my first contact with an intragastric balloon. I have to say, and it's not a device that, when I talk around with my colleagues that many of them have had contact with. It's not a commonly used device. Certainly here anyway. I think there are parts of the world where it is commonly used but, ah, so I've never before or after had contact with one."*

161. Mrs Holt returned to the Intensive Care Unit. Associate Professor Danne was happy with her progress.

162. On 4 February 2009, Associate Professor Danne performed a second laparotomy to review Mrs Holt's surgical site. He found that the stomach was healing well. However, the right colon had infarcted and there were signs of ischaemia in the small bowel.

163. Accordingly, rather than closing the surgical site, Associate Professor Danne maintained her VAC dressing to allow continuing review.

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<sup>2</sup> A VAC dressing promotes wound healing by applying a vacuum through a special sealed dressing and foam which acts as the wound contact material and fills the wound. The continued vacuum draws out fluid from the wound and increases blood flow to the area. The VAC dressing allows management of an open abdomen wound, which was required for Mrs Holt's expected further laparotomy inspections.

164. Mrs Holt returned to surgery seven more times. Her wound healing was excellent but her overall condition failed to improve:

- Ischaemia and/or infarction continued to develop in the gastrointestinal tract requiring resection and anastomosis of the right colon, sigmoid colon and small bowel;
- Her cardiovascular system became unstable but then recovered;
- Her respiratory status became compromised but improved as her infection came under control; and
- Her central nervous system declined so that she lost all movement in her right hand and became aphasic.

165. On 4 February 2009, Mrs Holt's caecum (right colon) was found to be necrotic and a right hemicolectomy (surgical resection of the large intestine) was performed.

166. Associate Professor Danne told the Court that this series of events was a cascade of recurring episodes of ischemia that, in his opinion, were directly caused by the obstruction by the balloon.

167. Associate Professor Danne was also firm that the nasogastric tube did not perforate the stomach:

*"the nasogastric tube was in her stomach, it was sitting in its correct position. It's almost unheard of for a nasogastric tube to perforate the stomach at its end."*

He also said:

*"there is absolutely no doubt that this stomach perforated because of the intragastric balloon."*

168. On 10 February 2009, Mrs Holt's abdomen was closed.

169. However, on 13 February 2009, the surgical registrar noted that Mrs Holt was lacidotic which indicated possible further infarction of a segment of the gastrointestinal tract. Her thyroxin levels were low. Her creatinine was elevated. She had intermittent atrial fibrillation. She had no bowel sounds. Her blood pressure was low. She was hypokalaemic.

170. At 8:00pm, Associate Professor Danne performed a further laparotomy. This revealed an infarcted sigmoid colon. A Hartmann's resectosigmoidectomy was performed and a further VAC dressing applied.
171. Mrs Holt did not respond positively after this time. By 17 February 2009, she was in renal failure, her albumin levels were low, she still had intermittent atrial fibrillation and she was not sleeping. She remained on Continuous Positive Airway Pressure (CPAP) oxygen.
172. On 18 February 2009, the VAC dressing was changed. On 19 February, further lactic acidosis and clinical peritonitis necessitated further surgery for a jejunum (small intestine) resection.
173. On 25 February 2009, Mrs Holt's abdomen was closed with mesh closure and a VAC dressing over the mesh. Shortly after this final surgery, tests indicated that Mrs Holt had no movement in her right hand and was aphasic.
174. Mrs Holt was also differentially diagnosed with having suffered a cerebrovascular accident (stroke).
175. At 11:30am on 5 March 2009, after consultation with Mrs Holt's family, Mrs Holt was extubated and, on 6 March, active treatment was withdrawn. Mrs Holt was moved to a ward with Intensive Care support.
176. Over the following week, Mrs Holt showed no neurological improvement. Further, on 12 March 2009, a CT brain scan found no acute intracranial abnormality.
177. At 1:35am on 14 March 2009, Thelma Holt died.

#### **COMMENTS**

Pursuant to section 67(3) of the Coroners Act 2008, I make the following comment(s) connected with the death:

1. Thelma Katherine Holt was 79 years old when she died. She lived alone at 2/17 Central Avenue in Moorabbin.
2. Mrs Holt had a long history of obesity and other co-morbidities. Her usual general practitioner was Dr Kay Bundy but she sometimes consulted other doctors in the South Road Medical Practice.

3. Dr Bundy assisted Mrs Holt to manage her weight including very low calorie diets and weight-loss medications. However, she did not lose weight and she developed further weight-related complications including emphysema and hypertension.
4. In 1995, Mrs Holt underwent Nissen fundoplication surgery to correct her gastroesophageal reflux and her hiatus hernia. During fundoplication surgery, the upper curve of the stomach (the fundus) is wrapped around the oesophagus and sewn into place so that the lower portion of the oesophagus passes through a small tunnel of stomach muscle.
5. Therefore, the Nissen fundoplication reduced the volume of Mrs Holt's stomach by removing access to the fundus.
6. However, in 2003, Mrs Holt's gastroesophageal reflux and her hiatus hernia returned. She also gained about 13 kg in weight. She was within the Body Mass Index (BMI) range for diagnosis as World Health Organisation Obese Class III.
7. Mrs Holt asked Dr Richard Oei from South Road Medical Practice to refer her to Dr Michael Merrett. In December 2003, Dr Oei made the referral.
8. Dr Merrett was a gastroenterologist. His practice included non-surgical management of weight loss using endoscopic placement of an intragastric balloon under neuroleptic anaesthesia.
9. Dr Merrett worked closely with and in the same practice as a consultant physician in clinical nutrition, Dr Sharon Marks.
10. Dr Merrett advised against immediate use of an intragastric balloon. Rather, on 4 May 2004, he referred Mrs Holt to Dr Marks for further attempts to lose weight using diet and pharmacology.
11. Mrs Holt lost about 10 kg over the next three years. She remained obese. She was still troubled by gastroesophageal reflux and her hiatus hernia. She was still keen to try the intragastric balloon.
12. On 29 March 2007, Dr Michael Merrett performed a gastrointestinal endoscopy and placed an intragastric balloon in Mrs Holt's stomach.

13. Mrs Holt lost 22 kilograms in five months. Her level of obesity improved from Obese Class III to Obese Class II.
14. However, on 6 August 2007, Mrs Holt was diagnosed with a serious incisional abdominal hernia that had developed over a period of less than three weeks.
15. Despite her predisposition to incisional hernia because of her weight, Mrs Holt had no prior history of incisional hernia.
16. Mrs Holt's surgeon, Mr Paul Sitzler, was appropriately concerned about performing a laparotomy to repair the incisional hernia while the intragastric balloon remained in place.
17. Accordingly, Dr Merritt removed her intragastric balloon and, subsequently, Mr Sitzler repaired the hernia.
18. Mrs Holt did not respond well to surgery. She was admitted to the Intensive Care Unit for a day to stabilise her respiratory function. Further, her wound remained infected and she was admitted to hospital on three occasions before November 2007.
19. Mrs Holt also began to regain weight and her abdominal incisional hernia recurred.
20. Dr Bundy referred Mrs Holt to another surgeon, Mr John Leslie. He would not operate until she lost 10-20kg.
21. Mrs Holt rejected the use of a binder to support her hernia. Against the advice of her general practitioner, her respiratory physician and her original gastroenterologist, she asked for and was administered a second intragastric balloon.
22. Mrs Holt was supported in this decision by Dr Merrett and her new surgeon, Mr Leslie.
23. Mrs Holt was never comfortable with her second intragastric balloon. She complained of nausea, gastroesophageal reflux, pain, slight anaemia, rash and urinary tract infection as well as respiratory complications and gout.
24. On 30 January 2009, Dr Bundy tentatively diagnosed a gastro-intestinal obstruction. She referred Mrs Holt for transfer by ambulance to the Accident and Emergency Department at the Epworth Hospital.

25. Although the CT abdomen scan confirmed a significant gastric obstruction, her treating gastroenterology consultant accepted Dr Merrett's advice that the intragastric balloon was unlikely to be causing the obstruction.
26. The plan was for Mrs Holt's transfer to Frankston Private Hospital on Monday 2 February 2009 so that Dr Merrett could remove the intragastric balloon.
27. However, on 31 January 2009, Mrs Holt's condition deteriorated. The obstruction remained. Her stomach had perforated.
28. Associate Professor Peter Danne performed emergency surgery. He confirmed that the intragastric balloon was obstructing the gastric outlet and Mrs Holt's stomach had perforated.
29. Despite extensive efforts by Associate Professor Danne and Epworth Hospital Intensive Care Unit staff, Mrs Holt continued to deteriorate.
30. On 14 March 2009, Thelma Holt died of pneumonia in the setting of acute peritonitis due to perforated stomach (operated).
31. This review will discuss the circumstances in which Mrs Holt died including:
  - Intragastric balloons as part of a weight loss program;
  - Mrs Holt's first intragastric balloon;
  - Mrs Holt's incisional hernia;
  - Mrs Holt's second intragastric balloon; and
  - Mrs Holt's significant gastric outlet obstruction.
32. It will then make recommendations intended to prevent further deaths occurring for the reasons that Mrs Holt died.



### **Intra-gastric balloon as part of a weight loss program**

33. Obesity is an important public health issue in our community. The World Health Organisation has developed a simple means of determining the level of risk associated with particular height and weight ratios: the Body Mass Index (BMI).<sup>3</sup>
34. Individuals with a BMI greater than 30kg/m<sup>2</sup> have statistically heightened risk of chronic non-communicable disease including cardiovascular disease and hypertension, Type II diabetes, pulmonary disease, osteoporosis and gout, and psychological effects including eating disorders.
35. Individuals with a BMI greater than 40kg/m<sup>2</sup> are diagnosed in the highest category as Obese Class-III.
36. Endoscopically placed intra-gastric balloons are one of several space-occupying devices available to obese patients and their medical advisors who seek rapid weight loss in order to improve their co-morbid symptoms such as gastroesophageal reflux and hiatus hernia or to perform surgery.<sup>4</sup>
37. As well as effectively reducing stomach volume, one of the most important features of the intra-gastric balloon is that the volume is large enough to create pressure on the wall of the stomach to make the patient feel that they have eaten sufficient. This pressure on the stomach wall also changes the level of a specific hormone called ghrelin which is responsible for satiety so it reduces the drive and the desire to eat.
38. Dr Marks told the Court that the intra-gastric balloon also works by causing dilatation of the fundus and in this situation was a risk for Mrs Holt because of her other co-morbidities. In the absence of a functional fundus, it is unclear how this side effect would play out on the rest of the stomach.
39. A double blind study performed in Italy has shown that three month placement of a Bioenterics intra-gastric balloon in 32 patients (mean age: 36.2±5.6 years, range 25–50 years; mean BMI 43.7±1.5 kg/m<sup>2</sup>, range 40–45 kg/m<sup>2</sup>) in association with restricted diet was

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<sup>3</sup> For example, World Health Organisation, "Obesity: Preventing and Managing the Global Epidemic", WHO technical Report Series 894, Geneva 2000.

<sup>4</sup> Department of Human Services "Surgery for morbid obesity: Framework for bariatric surgery in Victoria's public hospitals" (2009).

associated with statistically significant weight reduction when compared to sham procedure plus diet.<sup>5</sup>

40. Further, review of 2515 Italian patients with Bioenterics intragastric balloons (mean age: 38.9±5.6 years, range 12–71 years; mean BMI 44.4±7.8 kg/m<sup>2</sup>, range 28.0–79.1 kg/m<sup>2</sup>) placed for six months demonstrated satisfactory weight loss and improvement in co-morbidities.<sup>6</sup>
41. Another review of 44 mild or moderately obese patients in Saudi Arabia (mean age: 31 years; mean BMI 45 kg/m<sup>2</sup>) found use of Bioenterics intragastric balloons was associated with an average of 13kg weight loss over six months.<sup>7</sup>
42. The Victorian Government has developed guidelines for bariatric surgery in public hospitals including use of intragastric balloons. These specify the following appropriate selection criteria for prioritising of patients for bariatric interventions:
  - a BMI of more than 40 or a BMI of more than 35 with medically important co-morbid obesity-related conditions;
  - aged between 18 and 65 years;
  - have tried but failed to achieve or maintain clinically beneficial weight loss using non-surgical measures;
  - have the motivation and capacity to make the dietary and lifestyle changes needed for a successful long-term outcome from the surgery;
  - have a realistic understanding of the risks and benefits of the surgery;
  - do not have significant medical contraindications to surgery; and
  - do not have psychiatric, behavioural or cognitive conditions that impair their capacity to give informed consent or commit to post-operative care plans.<sup>8</sup>

<sup>5</sup> A. Genco *et al.*, "BioEnterics® Intragastric Balloon (BIB®): a short-term, double-blind, randomised, controlled, crossover study on weight reduction in morbidly obese patients" (2006) 30 International J. Obesity 129.

<sup>6</sup> A. Genco *et al.*, "Bioenterics intragastric balloon: The Italian Experience with 2515 patients", (2005) 15 Obesity Surgery 1161.

<sup>7</sup> Abdulhameed Al-Momen & Ibrahim El-Mogy, "Intragastric balloon for obesity: A retrospective evaluation of tolerance and efficacy" (2005) 15 Obesity Surgery 101.

43. However, after considering the safety and clinical effectiveness of intragastric balloons for the temporary management of morbid obesity, the Medical Services Advisory Committee of the Federal Government found that intragastric balloons pose additional risks to patients and do not provide additional clinical benefits when compared to the standard treatment for morbid obesity. They recommended against public funding for this procedure.
44. The Minister for Health and Ageing endorsed the Medical Services Committee recommendation on 20 May 2008. Accordingly, treatment with an intragastric balloon is not covered by Medicare.<sup>9</sup>
45. In 2007, a Cochrane Collaboration advised that:
- “Despite the evidence for little additional benefit of the intragastric balloon in the loss of weight, its cost should be considered against a program of eating and behavioural modification.”*<sup>10</sup>
46. Further, as late as 2011, Canadian gastroenterologists noted that a commercially available intragastric balloon was the most commonly used space-occupying device for weight loss. They also concluded that new endoscopic methods for weight loss may be valuable in the treatment of obesity. However, they said that more clinical experience and technical improvements were necessary before implementing their widespread use.<sup>11</sup>
47. Mr Mohammed Ballal is associate professor of surgery at the University of Western Australia and works in a Fremantle Hospital as a consultant surgeon and with specialist interest in upper gastrointestinal and hepatic biliary pancreatic surgery. He was invited to provide independent expert evidence in this coronial investigation.
48. Associate Professor Ballal had never seen an intragastric balloon but he worked with a colleague who has had training and experience in using this device.

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<sup>8</sup> Department of Human Services “Surgery for morbid obesity: Framework for bariatric surgery in Victoria’s public hospitals” (2009).

<sup>9</sup> Medical Services Advisory Committee, “Intragastric balloons for the temporary management of morbid obesity”, March 2008.

<sup>10</sup> M. Fernandez *et al*, “Intragastric balloon for obesity”, The Cochrane database of Systematic Reviews 2007 Issue 1. Art.No. CD004931. DOI: 10.1002/14651858.CD004931.pub2.

<sup>11</sup> A.Swidnicka-Siergiejko, E.Wróblewski, & D.Andrzej, “Endoscopic treatment of obesity”, Can J Gastroenterol, 25 (2011) 627-33.

49. Associate Professor Peter Danne is an experienced gastrointestinal and general surgeon in Melbourne. He had never seen an intragastric balloon before. He told the court that none of his colleagues had seen one either.
50. Associate Professor Ballal and Dr Oleg Svanidze, Senior Medical Director of Allergan (the intragastric balloon manufacturer), agreed that placement of an intragastric balloon is absolutely contraindicated in patients with previous gastric surgery and/or a hiatus hernia larger than 5cm.<sup>12</sup>
51. Therefore, although Mrs Holt's weight placed her within the range for diagnosis as Obese Class III, she was also in the category of patients for whom intragastric balloons are strongly contra-indicated:
- She was 73 years old when she first asked Dr Merrett to insert an intragastric balloon;
  - As well as obesity, she suffered from a number of relevant co-morbidities including hiatus hernia, gastroesophageal reflux and vascular disease;
  - She had a 5cm hiatus hernia; and
  - She had previously undergone a fundoplication which reduced her stomach capacity and probably changed the dilatation response to an intragastric balloon.
52. Therefore, in 2004, Mrs Holt's medical advisers were consistent and appropriate in advising her to continue with alternative diet and medication approaches to weight loss.
53. Accordingly, Dr Merrett referred Mrs Holt to Dr Marks for nutritional and pharmaceutical weight loss management.
54. Mrs Holt gained 7kg over three years using alternative diet and medication as advised by Dr Marks. She remained Obese Class III. However, she still suffered from hiatus hernia, gastroesophageal reflux and vascular disease. She was still keen to try the intragastric balloon. She was still in the category of patients for whom an intra-gastric balloon was contra-indicated.

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<sup>12</sup> See also: A. Genco *et al*, "Bioenterics intragastric balloon: The Italian Experience with 2515 patients", (2005) 15 Obesity Surgery 1161.

55. Despite all these arguments against managing Mrs Holt's obesity with an intragastric balloon, Dr Marks referred Mrs Holt back to Dr Merrett for its placement.

#### **Mrs Holt's first intragastric balloon**

56. On 29 March 2007, Dr Michael Merrett performed a gastrointestinal endoscopy and placed an intragastric balloon in Mrs Holt's stomach.
57. At that time, Dr Merrett was the only gastroenterologist in Melbourne using intragastric balloons for treatment of obesity. However, he had already been using them for about seven years.
58. Accordingly, although Mrs Holt was always a high risk patient for use of an intragastric balloon, it is concerning that Dr Merrett told the Court:
- "the presence of a hiatus hernia isn't an absolute contraindication...  
it's a relative contraindication, something I'd prefer not to be there but we've still had good results in patients who've had hernias. If the patient had a large hiatus hernia I wouldn't place a gastric balloon."*
59. Dr Merrett also told the Court
- "...we were aware the patient had a fundoplication but it was difficult to see whether she'd had a fundoplication or not because that area where the fundoplication would be looked fairly normal so that it was fairly wide open at the time. (The fundoplication was) no contraindication to placement of the balloon."*
60. Dr Merrett explained that his opinion was instructed by the fact that neither procedure involves surgical incision and consequent suturing of the stomach wall because these procedures would increase the risk of perforation.
61. On the other hand, neither Dr Merrett nor Dr Marks told Mrs Holt about the possibility of gastric perforation because it was very rare, they had no experience of it and it was not documented in the training manuals.
62. Dr Merrett's two explanations for placing the intragastric balloon without fully informing Mrs Holt about the risk of gastric perforation are mutually inconsistent in the way in which

they reflect Dr Merrett's knowledge of the risks associated with insertion of a gastric balloon in a person with Mrs Holt's characteristics.

63. Further, gastric obstruction and gastric perforation were and remain known but rare complications of intragastric balloon placement.

- Swiss research indicates that 0.2% of patients suffer gastric perforation associated with gastric obstruction.<sup>13</sup>
- The Italians treated 19 gastric obstructions in the first week of placement of the balloon. In all these cases, the balloon was removed. They also had a gastric perforation rate of 0.19% or five out of 2515 patients.<sup>14</sup> Four had undergone previous gastric surgery. Two of these patients died and two were successfully treated by laparoscopic repair after balloon removal.
- Saudi Arabian clinicians had one gastric perforation in 44 patients.<sup>15</sup>
- It was recognised by Allergan who manufactured the intragastric balloon in their advice to remove the intragastric balloon as a matter of emergency if it is causing gastric obstruction.

64. Therefore, Dr Merrett was or should have been aware of the possibility that gastric obstruction was a known complication of placement of an intragastric balloon. His inability to articulate this knowledge consistently in Court and failure to discuss it with his patients is a matter of real concern.

65. In the circumstances of managing Mrs Holt's obesity, it seems to me that Dr Merrett was acting in isolation from his gastroenterology peers. In particular:

- Dr Merrett was the only person in Victoria using this form of obesity management in 2007 and 2009;

<sup>13</sup> J-M Dumonceau, "Evidence-based Review of the Bioenterics Intragastric Balloons for Weight Loss" (2008) 18 Obesity Surgery 1611.

<sup>14</sup> A. Genco *et al*, "Bioenterics intragastric balloon: The Italian Experience with 2515 patients", (2005) 15 Obesity Surgery 1161.

<sup>15</sup> Abdulhameed Al-Momen & Ibrahim El-Mogy, "Intragastric balloon for obesity: A retrospective Evaluation of tolerance and efficacy" (2005) 15 Obesity Surgery 101.

- Although Dr Merrett had been inserting intra-gastric balloons for seven years and had been involved in Mrs Holt's treatment in 2009, he told the Court that he had only started a dialogue with bariatric surgeons in Sydney who also use intragastric balloons in 2011;
- None of the other experienced and well qualified gastroenterologists giving evidence in this Court had any experience with intragastric balloons;
- Dr Merrett was certain that Dr Prichard was a much more experienced gastroenterologist than he was and would not advise him on how to manage a potentially significant gastric obstruction; and
- Dr Merrett and Dr Marks were friends with Dr Prichard but they said they would not discuss work with him in a social context.

66. From this evidence, I have formed the view that Dr Merrett was providing patients with intragastric balloons without any or sufficient professional peer support or critique of his work.

67. Accordingly, I have formed the opinion that the Royal Australasian College of Physicians and the Gastroenterological Society of Australia should introduce a mentoring service for members who practice in bariatric gastroenterology using intragastric balloons.

**Recommendation 1.**

#### **Mrs Holt's incisional hernia**

68. Throughout the five months that Mrs Holt hosted her first intragastric balloon, she experienced continuing gastroesophageal reflux and pain.

69. Further, on 6 August 2007, Mrs Holt was diagnosed with a serious abdominal incisional hernia that had developed over a period of less than three weeks.

70. Although her obesity and other co-morbidities placed Mrs Holt at risk of developing an abdominal incisional hernia, there is no evidence that this had occurred before.

71. I am unable to say whether or to what degree Mrs Holt's gastric balloon and/or her rapid weight loss over four months influenced the breach of her upper abdominal wall and consequent development of her incisional hernia.

72. However, Dr Merrett inflated the balloon with 600mls saline in Mrs Holt's stomach. This volume was within the inflation volume recommended and used in Europe:
- Allergan advise inflating the balloon with at least 400ml saline to reduce the risk of obstruction and/or stomach perforation as well as to maximise its effectiveness.
  - Further, the Italian, Swiss and Saudi Arabian investigators used 500-700mls saline in their patients.
73. However, in Court, Dr Marks produced an exhibit that was filled with 500mls saline. It was quite pliable but she pointed out that a balloon with 600mls saline would be less distensible. It takes quite a bit of pressure to add the extra 100mls.
74. Further, Mrs Holt had undergone a Nissen fundoplication so that the operational volume of her stomach was less than it would otherwise have been.
75. The coincidence of these factors raises the possibility that Mrs Holt's intragastric balloon and her rapid weight loss contributed to development of her first abdominal incisional hernia in late July 2007.
76. The particular practical issues that influence my raising this possibility include:
- Mrs Holt's balloon had been inflated to 600mls so that it was large and quite inflexible in her stomach;
  - Mrs Holt had lost 22kg in five months including 12kg between 10 May and 12 July 2007;
  - Mrs Holt's abdominal wall would be less resistant to pressure than before her weight loss because of the loss of fat; and
  - Mrs Holt's vascular disease placed her at extra risk of developing an incisional hernia.
77. Dr Merrett would have been able to remove the intragastric balloon if, in Mrs Holt's circumstances, he perceived that there was risk of an incisional hernia caused by or related to the device.



78. However, Dr Merrett reviewed Mrs Holt once after insertion of her first intragastric balloon. He was impressed by her weight loss but he did not acknowledge the effect it had on her health. Therefore, he does not know whether or to what degree the intragastric balloon influenced development of Mrs Holt's abdominal incisional hernia.
79. Accordingly, I have formed the view that gastroenterologists who are responsible for placing intragastric balloons should regularly monitor their patients for abdominal hernia while the balloon is in place and particularly during periods of rapid weight loss. **Recommendation 2.**
80. On 6 September 2007, Mr Paul Sitzler successfully performed a laparotomy to repair Mrs Holt's ventral wall abdominal incisional hernia with mesh and divide the adhesions.
81. Mrs Holt's surgery was associated with slow recovery, wound and site infection and exacerbation of Mrs Holt's respiratory disease.
82. On 13 March 2008, Mrs Holt's abdomen remained:  
*"excruciatingly tender in the left iliac fossa along the inferior edge of the hernia."*
83. On 20 March 2008, another surgeon, Mr John Leslie, noted that Mrs Holt had now been left with a recurrent hernia that would be better left to stabilise for a month or two.
84. Mr Leslie said he could not operate again until Mrs Holt lost a further 10-20kg. He recommended an abdominal binder to relieve Mrs Holt's discomfort from the abdominal incisional hernia.
85. However, Mrs Holt was unable to lose this weight. Further, she refused to use a binder to relieve her discomfort.
86. Mrs Holt was very determined to have a second intragastric balloon. She was supported by Dr Marks and Mr Leslie.
87. As Dr Marks told the Court:  
*"She was very, very determined to lose enough weight to have that hernia repair."*
88. However, Dr Marks also conceded:

*"she can't insist on a balloon if we don't agree to do it. The balloon was done for Thelma to help her as best we could and I believed at the time that she needed that help."*

89. This refusal was not outside the contemplation of Mrs Holt, Dr Merrett or Dr Marks because Dr Merrett had refused to place an intragastric balloon in Mrs Holt's stomach in 2004.

90. Further, Dr Bundy, Dr Morton and Dr Debinski all advised her against using an intragastric balloon.

91. In 2007, Dr Merrett had placed the first intragastric balloon at Mrs Holt's insistence when she failed to lose weight after over two years of management by Dr Marks.

92. Dr Merrett knew that, since then:

- She was now 79 years old;
- She had developed an abdominal incisional hernia while the first intragastric balloon was in place;
- She had experienced a complicated recovery from surgery to correct her abdominal incisional hernia including acute renal failure, lung collapse, chronic obstructive pulmonary disease, and left ventricular fibrillation as well as persistent peritoneal infection and pain;
- She recently experienced a fall;
- Her respiratory and vascular disease remained real issues for her; and
- Although she did not want to use a binder, that option was open to her to manage her abdominal incisional hernia.

93. He also knew or should have known about the risk of significant gastric obstruction and stomach perforation associated with an intragastric balloon.

94. Therefore, the decision to insert Mrs Holt's second intragastric balloon lay squarely with Dr Merrett.

95. In my opinion, no gastroenterologist should place a second intragastric balloon in a patient with Mrs Holt's characteristics and co-morbidities. **Recommendation 3**

### **Mrs Holt's second intragastric balloon**

96. On 11 September 2008, Dr Merrett inserted a second intragastric balloon to assist Mrs Holt with her weight loss before further repair of her continuing abdominal incisional hernia.
97. As before, Dr Merrett inflated the balloon with 600ml saline and advised it may be left *in situ* for six months.
98. Mrs Holt consulted Dr Bundy 11 times between 16 September 2008 and 30 January 2009. Again, she complained of nausea, constipation, urine infection, reflux, light-headedness, chest infection and low blood pressure. Pain continued from her fall. She also required potassium and iron supplements during this period.
99. In about 4 ½ months, Mrs Holt lost 10kg. She remained Obese Class II.
100. On 30 January 2009, Dr Bundy called an ambulance when Mrs Holt presented with severe abdominal pain consistent with gastric obstruction.

### **Mrs Holt's significant gastric outlet obstruction**

101. At 11:35am on Friday 30 January 2009, Mrs Holt presented at the Accident and Emergency Department at the Epworth Hospital with symptoms consistent with gastric obstruction.
102. At 12:15pm, an x-ray confirmed the presence of the intragastric balloon and distension of the stomach suggested a pyloric obstruction.
103. In the absence of any alternative body capable of obstructing the pylorus and in the context of Mrs Holt's symptoms, I accept that the intragastric balloon appeared to be in a position where it could significantly obstruct the pylorus.
104. At about 2:30pm on 30 January 2009, the gastroenterology registrar called Dr Peter Prichard to review Mrs Holt. He formed the opinion that the intragastric balloon was causing a significant obstruction.
105. Dr Prichard is an experienced gastroenterologist and consultant physician at the Epworth Hospital and the Royal Melbourne Hospital. He was one of the consultant gastroenterologists on call when Mrs Holt presented at the Epworth Hospital.

106. Dr Prichard had no practical experience with intragastric balloons. However, he had presented a paper to endoscopy colleagues at a national meeting on complications that endoscopists may encounter in bariatric surgery. Part of that presentation included intragastric balloons.
107. Dr Prichard also discussed the CT abdomen scan with the radiologist. Together, they formed the opinion that Mrs Holt's intragastric balloon was fully inflated, it was impacted at the gastric outlet and it was significantly obstructing the stomach. I note that the small bowel had also collapsed.
108. In the absence of the x-ray and the CT scans, I cannot make a retrospective assessment about whether the intragastric balloon had moved between 12:15pm and 2:30pm on 30 January 2009 when the x-ray and CT scans were performed.
109. However, at that time, Dr Prichard interpreted the CT abdomen scan to show that the intragastric balloon remained in a position where it was still causing a significant obstruction of the gastric outlet.
110. At about 3:45pm on 30 January 2009, Dr Prichard discussed Mrs Holt's condition with Dr Merrett.
111. Contrary to Dr Prichard's opinion and that of the radiologist, Dr Merrett told Dr Prichard that it was most unlikely that the intragastric balloon was significantly obstructing the pyloric outlet of Mrs Holt's stomach.
112. Dr Merrett also told the Court:

*"I can't find reference to balloons causing complete mechanical obstruction. There are no reference on where a balloon ever producing that. They do produce stasis as shown outlined which give the CT scan appearance of obstruction but an obstruction is actually a dynamic event, it's not at a single point in time. "*

113. I have no doubt that Dr Merrett's advice strongly influenced Dr Prichard's management of Mrs Holt's symptoms because:

- Dr Prichard was a personal and professional friend of Dr Merrett and Dr Marks;

- Dr Prichard was experienced in managing gastric obstructions but he had no experience with intragastric balloons;
- Dr Prichard approached his conversation with Dr Merrett with the opinion that the intragastric balloon was fully inflated, it was impacted at the gastric outlet and was obstructing the stomach;
- Dr Merrett's explanation of the way in which an intragastric balloon looks on a CT scan is a plausible explanation of Mrs Holt's symptoms, particularly when she was medicated and before Dr Prichard ordered capping of her nasogastric tube.
- Dr Prichard told the Court:

*"Dr Merrett was able to reassure me that he felt that it was not obstructed. And having heard further evidence I would agree with him fully."*

114. Medical practitioners, including the registrar and Dr Prichard, are well aware that distension arising from unmanaged gastric obstruction causes gastric rupture with associated peritoneal infections and other serious complications.

115. Further, Mrs Holt's particular risk of gastric perforation associated with the gastric distension was accepted by all medical practitioners involved in her management whether or not they accepted that it was caused by obstruction:

- Mrs Holt was 79 years old. As Associate Professor Danne said:

*"people in that age group who have cardiovascular disease can end up with poor blood supply to certain areas which, when other pathological factors operate, can then facilitate more easy rupture."*

- Mrs Holt had a previous Nissen fundoplication. Four of five patients with reported gastric perforations associated with the BioEnterics intragastric balloons had previous gastric surgery.<sup>16</sup>
- Mrs Holt's presenting symptoms were consistent with gastric obstruction.

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<sup>16</sup> A. Genci *et al*, "BioEnterics Intragastric Balloon: The Italian Experience with 2,515 patients" (2005) 15 Obesity Surgery 1163.

- The radiology was consistent with gastric obstruction and collapse of the small bowel.
116. Alternatively, even if the gastric outlet was not physically obstructed, Dr Merrett conceded that the intragastric balloon would create stasis and reduce the rate of drainage from the stomach.
  117. Therefore, despite Dr Merrett's advice, Dr Prichard was ill-advised in deciding to treat Mrs Holt's symptoms conservatively rather than proceed with surgery on 30 or 31 January 2009 to remove the intragastric balloon and relieve the gastric distension.
  118. Further, on 31 January 2009, four litres of saline were administered completing at 12:15pm and a further litre by 4:35pm.
  119. At 8:35pm on 31 January 2009, Dr Prichard reviewed Mrs Holt and noted minimal drainage (16ml) from the nasogastric tube. He ordered the tube be capped and gentle fluids commenced orally. Dr Prichard advised nursing staff to cease fluids and recommence gastric drainage if Mrs Holt did not tolerate the capping and oral fluids.
  120. There is no record of Mrs Holt's urinary output during this period but, in the context of the large volume of fluid administered, it is unlikely that minimal drainage from the intragastric tube reflected a small volume of fluid in the stomach. This extra fluid would contribute to distension in the stomach, whether or not the pylorus was physically obstructed.
  121. At 11:00pm on 31 January 2009, Mrs Holt became nauseous and had abdominal pain.
  122. However, when nursing staff contacted Dr Prichard at 12:05am on 1 February 2009, Mrs Holt's symptoms had settled following administration of anti-nausea medication and morphine as ordered by the medical fellow on duty. Mrs Holt was considered stable.
  123. No attempt was made to replace Mrs Holt's nasogastric tube.
  124. As Associate Professor Danne pointed out to the Court, minimal drainage from a nasogastric tube in circumstances where there is also food in the stomach can also indicate the tube is blocked.
  125. However, the CT report did not refer to the food contents that Associate Professor Danne and Dr Prichard identified when they looked at the films.

126. Further, there is no evidence that anyone tried to manipulate the nasogastric tube or use a larger bore tube which would reduce the risk of blockage.
127. It is also unclear why the nursing staff and the medical fellow chose not to implement Dr Prichard's earlier order to cease fluids and recommence gastric drainage if Mrs Holt did not tolerate capping of her nasogastric tube and oral fluids.
128. Associate Professor Danne told the Court that, having diagnosed an obstruction:
- "If my first attempt to relieve the obstruction with a simple nasogastric tube doesn't work, then I would be doing something else and that something else would be surgery."*
129. On the other hand, Associate Professor Ballal told the Court he would try to wait until after the weekend before commencing a laparotomy:
- "she's very, very high risk and I wouldn't want to embark on anything like that on a weekend when there's less expertise around. I would rather wait until a Monday when there is a very large number of expertise around in case things do not go as planned."*
130. However, even with that proviso, Associate Professor Ballal also agreed that, if the nasogastric tube was not draining so the stomach was becoming more distended, any upper gastrointestinal surgeon would know that perforation was a real risk and would do whatever they could to minimise that risk even if they did not have the expertise to extract the balloon endoscopically.
131. Accordingly, I am unable to understand why an experienced gastroenterologist like Dr Prichard did not check that Mrs Holt's nasogastric tube was operating correctly or make alternative arrangements to address the potential consequences of failure to drain fluid from the naso-gastric tube.
132. Associate Professor Danne and Dr Prichard agreed that the stomach perforation occurred on the afternoon of Sunday 1 February 2009.
133. Accordingly, I find that ineffective use of the nasogastric tube in conjunction with administration of large amounts of fluid and failure to monitor fluid output could have contributed to perforation of Mrs Holt's stomach.

134. Therefore, Dr Prichard's decision to cap the nasogastric tube on 31 January rather than check whether it was patent and operational may have contributed to Mrs Holt's death.
135. In the absence of evidence about what Dr Prichard would have done and how Mrs Holt would have responded if the nasogastric tube had been reinstated, I am unable to say whether or to what degree the nursing staff's failure to comply with the consultant gastroenterologist's direction influenced Mrs Holt's death. **Recommendation 3**
136. At 8:35pm on 1 February 2009, Mrs Holt's condition had deteriorated. Her blood pressure was 200/100mmHg, she was sweating, nauseous and complaining of pain.
137. Mrs Holt initially responded to Maxalon and morphine but, by 12:00am on 2 February 2009, the pain was ongoing and she was referred to the Intensive Care Unit with a differential diagnosis of gastric perforation.
138. The Intensive Care Fellow confirmed the diagnosis of gastric perforation and sought assistance from the on-call surgeon, Associate Professor Peter Danne.
139. At 1:45am on 2 February 2009, Associate Professor Danne performed an emergency laparotomy.
140. The laparotomy revealed:
- a large perforation of the gastric wall high up on the lesser curve due to gross distension of the stomach with ischaemia and/or or mechanical splitting at that point;
  - contamination of the gastric contents (a large amount of food and fluid) into the peritoneal cavity and obvious peritonitis; and
  - balloon obstruction of the gastric outlet.
141. On the evening of 1 February 2009, Dr Prichard did not anticipate Mrs Holt's perforation. He told the court that he would have had no hesitation in contacting Dr Merrett if her condition had deteriorated sufficiently to justify removal of her intragastric balloon.
142. Further, Dr Prichard remained unconvinced that Mrs Holt's perforation occurred because of gross distension of her stomach on the evening of 1 February 2009.
143. Dr Prichard supported his opinion by indicating that Mrs Holt's stomach was never grossly distended. Further, he said there was no evidence of pressure necrosis related to the balloon



and the perforation was anatomically well removed from the site of the intragastric balloon and the alleged blockage.

144. However, without seeing Mrs Holt, Dr Merrett accepted that distension of Mrs Holt's stomach preceded and caused the perforation but he still did not accept that the distension was caused by obstruction by the intragastric balloon.

145. Dr Merrett also accepted that stasis was a normal response to the intragastric balloon. This would have slowed drainage of the stomach whether or not the gastric outlet was also significantly blocked:

*"...my presumption is that the stomach was distended and in the presence of other factors, perhaps vascular insufficiency that was enough to produce an ischemic perforation. I think that's a likely reason."*

146. Accordingly, Dr Merrett told the Court that he would now consider vascular disease as a contra-indication to placement of an intragastric balloon:

*"I would consider it more carefully than I have in the past. I know for surgical weight loss and patients having lap-banding and various bypass type procedures, vascular disease would be a major contraindication. Because placement of balloon is an endoscopic procedure, vascular disease wouldn't have seemed to be such an important issue but I think given that gastric distension occurs, it's possible that we'll consider it more as a contraindication in the future."*

147. Having considered all these opinions, I have formed the view that the perforation of Mrs Holt's stomach would not necessarily, or probably, have been caused directly by the intragastric balloon pressing on the stomach wall. Therefore, it would not necessarily be physically related to the position of the balloon.

148. Rather, perforation of Mrs Holt's stomach resulted from distension caused by the increasing volume of the stomach content. This volume in the stomach would reflect fluid accumulation which was unable to redistribute through the gastrointestinal system because of either capping or blockage of the intragastric tube and/or significant obstruction of the pyloric outlet by the balloon and/or stasis caused by the balloon and/or, possibly, small bowel effects caused by the abdominal incisional hernia.

149. Further, in the context of Mrs Holt's known co-morbidities and circumstances including her intragastric balloon, vomiting, vascular disease, and abdominal incisional hernia with recent difficult recovery from surgery, I have formed the opinion that the pressure required to breach the stomach wall at its weakest point was probably less than would otherwise have been the case. The weakest point could be determined by existing or developing ischaemia of the stomach wall and/or physical pressure points from the fluid or the balloon that would reflect gravity and Mrs Holt's position in bed.
150. Dr Prichard's management of Mrs Holt was independently reviewed by Associate Professor Paul Desmond, Director of the Department of Gastroenterology at St Vincents Hospital.
151. In the opinion of Associate Professor Desmond, Dr Prichard's management of Mrs Holt was:
- "appropriate and would be widely accepted by the majority of Gastroenterologists practising in Australia."*
152. Associate Professor Desmond explained his opinion by referring to Dr Prichard's lack of personal experience with intragastric balloons and Mrs Holt's stable condition when Dr Prichard reviewed her on 30 & 31 January and 1 February 2009. He also says that ischaemic gastric perforation was an unforeseeable complication of Mrs Holt's presentation during this period.
153. On its face, Associate Professor Desmond's opinion applies the civil standards required to determine whether or not Dr Prichard was negligent in his management of Mrs Holt. These standards are only of peripheral relevance to the coronial investigation of Mrs Holt's death.
154. From a systems perspective and in fulfilling my prevention role, Associate Professor Desmond's opinion raises further wider issues about the way in which gastroenterologists respond to unusual circumstances and assess the advice of their colleagues.
155. In particular, in forming the opinion that it was appropriate for Dr Prichard to cap Mrs Holt's nasogastric tube, Associate Professor Desmond stated that it was normal practice to allow free drainage without suction from the nasogastric tube. Associate Professor Desmond also acknowledged that it was possible that the slow drainage reflected a blocked

or kinked tube rather than an empty stomach. However, in these circumstances, the patient would usually vomit and would definitely be nauseated.

156. I note that Mrs Holt became nauseous and had abdominal pain at 11:00pm on 31 January 2009, that is three hours after the nasogastric tube was capped. In that sense, Associate Professor Desmond supports my opinion that Dr Prichard's capping of Mrs Holt's nasogastric tube and failure to review its effects was one of a number of factors that contributed to Mrs Holt's death.

157. Having investigated the circumstances of Mrs Holt's death, I have formed the opinion that, despite and because of her Obesity Class III, Mrs Holt was always an unsuitable candidate for an intragastric balloon because:

- Mrs Holt was 77 years old;
- Mrs Holt's co-morbidities included chronic cardiovascular, respiratory and vascular disease; and
- Mrs Holt had previous Nissen fundoplication and cholecystectomy.

158. Further, even if Mrs Holt's first intragastric balloon was justified, Dr Merrett should never have agreed to place her second intragastric balloon because he knew or should have known that:

- Mrs Holt was now 79 years old;
- Mrs Holt's prior co-morbidities continued;
- Mrs Holt was now Obesity Class II;
- Mrs Holt had a recurrent abdominal incisional hernia;
- Mrs Holt refused to adopt alternative measures to manage her discomfort from recurrent abdominal incisional hernia; and
- Mrs Holt would be expected to have on-going peritoneal issues arising from surgery to correct her incisional hernia.

159. Therefore, patients who seek insertion of an intragastric balloon must be carefully screened and rejected if they do not otherwise meet the guidelines determined by the gastroenterology profession and the manufacturer of the device. **Recommendation 4**
160. Mrs Holt did not recover from perforation of her stomach. Peritonitis is the usual consequence of perforation. Associated ischaemia was always a possibility in a woman with her co-morbidities.
161. Associate Professor Danne told the Court that the cascade of recurring episodes of ischemia that required further surgery was, in his opinion, directly caused by the obstruction by the balloon.
162. However, this is too simplistic. In my opinion, a series of systems failures led to Mrs Holt's stomach perforation and her failure to respond to intense management of the consequences.
163. These systems failures included:
- Mrs Holt's insistence on having a intragastric balloon as a 'one stop' solution to her obesity issues;
  - Mrs Holt's rapid weight loss and its possible association with development of her first abdominal incisional hernia;
  - Mrs Holt's slow recovery from surgery to correct the abdominal incisional hernia which resulted in on-going infection and a recurrent hernia;
  - Mrs Holt's weight gain while she recovered from surgery to correct the abdominal incisional hernia;
  - Dr Merrett's expressed belief that significant gastric obstruction was not a known side effect of intragastric balloons;
  - Dr Merrett's insertion of a second intragastric balloon against the advice of Mrs Holt's general practitioner, her respiratory physician and her usual gastroenterologist;
  - Development of significant gastric obstruction and/or stasis associated with stomach distension on a Friday;

- Mrs Holt's transfer by ambulance to the Epworth Hospital rather than Frankston Hospital on 30 January 2009;
- Dr Prichard's acceptance of Dr Merrett's advice that it was unlikely that the intragastric balloon would significantly obstruct Mrs Holt's pyloric outlet and she should be stabilised and hydrated over the weekend;
- Dr Prichard's failure to check the intragastric tube for blockage prior to capping it on 31 January 2009;
- Administration of five litres of intravenous fluids on 31 January 2009 without measuring fluid outputs or continuing to use the intragastric tube for drainage;
- Failure of Epworth medical and nursing staff to notify Dr Prichard that Mrs Holt was not tolerating capping of her intragastric tube;
- Dr Prichard's failure to recognise that degree of distension that could result in perforation of Mrs Holt's stomach and/or further consult with Dr Merrett or seek his assistance to remove the intragastric balloon and/or find another way to relieve the significant apparent obstruction;
- Mrs Holt's short term response to Maxalon and morphine so that suspicion of perforation was allayed on the evening of 1 February 2009.

164. Many of these systems issues arose because Dr Merrett was the sole provider of services to place intragastric balloons in Victoria and Dr Prichard was inexperienced with intragastric balloons.

165. Correction of any one of these systems failures may have prevented Mrs Holt's gastric perforation and/or changed the circumstances of Mrs Holt's death.

## **RECOMMENDATIONS**

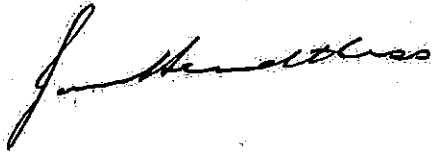
Pursuant to section 72(2) of the Coroners Act 2008, I make the following recommendation(s) connected with the death:

1. That the Royal Australasian College of Physicians and the Gastroenterological Society of Australia facilitate a training and mentoring service and a recording mechanism for adverse events for members who practice in bariatric gastroenterology using intragastric balloons.
2. That the Royal Australasian College of Physicians and the Gastroenterological Society of Australia develop a clinical update and/or media release advising gastroenterologists responsible for placing intragastric balloons to regularly monitor their patients for abdominal hernia while the balloon is in place and particularly during periods of rapid weight loss.
3. That the Royal Australasian College of Physicians and the Gastroenterological Society of Australia develop a clinical update and/or media release advising gastroenterologists not to place a second intragastric balloon in a patient with Mrs Holt's characteristics and comorbidities.
4. That the Epworth Hospital ensures nursing staff and hospital medical staff follow the directions of consultant physicians and, where they choose not to follow those directions that the reason for not doing so is communicated back to the consultant physician.
5. That the Royal Australasian College of Physicians and the Gastroenterological Society of Australia develop a clinical update and/or media release advising gastroenterologists that patients who seek insertion of an intragastric balloon should be carefully screened and rejected if they do not otherwise meet the guidelines determined by the gastroenterology profession and the manufacturer of the device.

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

President, Gastroenterological Society of Australia  
President, Royal Australasian College of Physicians  
Group Chief Executive, Epworth Healthcare

Signature:



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DR JANE HENDTLASS  
CORONER

Date: 13 August 2013