



**CORONERS COURT
OF NEW SOUTH WALES**

Inquest:	Inquest into the death of Margaret Ann Pegum
Hearing dates:	3,4 and 5 April 2018
Date of findings:	26 April 2018
Place of findings:	NSW Coroners Court - Glebe
Findings of:	Magistrate Elizabeth Ryan, Deputy State Coroner
Catchwords:	CORONIAL LAW – death caused by perforation of stomach – bariatric procedure – intragastric balloon device with prior gastric surgery – adequacy of patient advice and post-procedure care – recommendations.
File number:	2015/198106
Representation:	Mr J Downing, Counsel Assisting, i/b the Crown Solicitor's Office. Mr R Royle for the Pegum family, i/b Carroll & O'Dea Ms P Dwyer of Counsel for Dr G Marinos and Dr C Eliades, i/b Avant Lawyers.

Findings:	<p>Identity of deceased: The person who died is Margaret Pegum, born 13 May 1947.</p> <p>Date of death: Margaret Pegum died on 6 July 2015.</p> <p>Place of death: Margaret Pegum died at Prince of Wales Hospital, Randwick NSW.</p> <p>Manner of death: Complications arising from a bariatric intragastric balloon procedure.</p> <p>Cause of death: Sepsis as a result of gastric perforation.</p>
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When an inquest is held section 81(1) of the *Coroners Act 2009 (NSW)* [the Act] the Coroner must record in writing his or her findings as to various aspects of the death.

These are the findings of an inquest into the circumstances of the death of Margaret Ann Pegum.

The role of the Coroner

An inquest is different to other types of court hearings. It is neither criminal nor civil in nature. It does not determine whether a person is guilty of an offence, and it does not make findings and orders that are binding on parties.

A Coroner presiding over an inquest is required to confirm that a particular death occurred and make findings as to:

- The identity of the person who died
- The date and place of the death
- The cause and manner of the death.

In addition, under section 82 of the Act a Coroner may make recommendations that are considered necessary or desirable in relation to any matter connected with the death, including in relation to health and safety.

Introduction

1. On 6 July 2015 Margaret Pegum aged 67 years died in Prince of Wales Hospital Randwick. She had been brought there on 24 June 2015 suffering very severe abdominal pain and vomiting. Doctors found a perforation in the wall of her stomach. Despite a series of repair surgeries over the following days, Ms Pegum's condition deteriorated and she suffered multiorgan failure. After consultation with her family, her life support was removed and she died on 6 July.
2. Ms Pegum's unexpected death deeply affected Stephen Pegum, her husband of 43 years, and their only surviving child, James. She was their much-loved wife and mother and her death came as a terrible blow.

Issues

3. Nine weeks before her death Ms Pegum had undergone a bariatric procedure involving placement of an intragastric balloon in her stomach.
4. This inquest has focused on the question of what caused the perforation in Ms Pegum's stomach, and whether her intragastric balloon procedure was appropriate in circumstances where she had had prior gastric surgery.

5. Obesity is recognised as a serious disease with substantial morbidity and mortality. In circumstances where bariatric procedures are increasingly being sought due to rising rates of obesity, this inquest has also considered whether sufficient information is available to clinicians and patients about the indications and contraindications for the procedure recommended for Ms Pegum.

Margot Pegum's life

6. Margaret Ann Pegum was known to her family and friends as Margot. She was born on 13 May 1947 and she grew up in the Bondi area of Sydney. When she finished her schooling she completed a secretarial course. She became a highly skilled legal secretary and spent some years working in New York and Europe for the United Nations' Office for Legal Affairs.
7. Shortly after Margot returned to Australia she met and married Stephen Pegum. Margot and Stephen had two children, Catherine born in 1975 and James born in 1978. Tragically Catherine was drowned on 1 January 1977 when she was only one year old.
8. In their 43 years of marriage Margot and Stephen shared a very close relationship and worked side by side in many businesses. These included hotels and guest houses in which Margot worked as a chef. Margot had an entrepreneurial spirit and in partnership with Stephen she developed other business enterprises, including the pioneering of gourmet muesli and a wedding catering business in Byron Bay.
9. At the close of the inquest's evidence James Pegum provided a vivid and moving tribute to his mother. He described a vibrant and generous woman with many creative and entrepreneurial talents. Friends fondly remembered her as a warm, gifted and stylish woman with a strong love of life and of people. James himself spoke of his deep sadness that his young children would never know their grandmother.
10. James suffered further sorrow when his father Stephen died in 2017 suffering, James believed, a broken heart at the loss of his wife.

Margot's medical history

11. After the birth of her children Margot struggled to maintain a healthy weight. She developed other health problems including anxiety, hypertension and sleep apnoea. Problems with reflux also caused her considerable pain and discomfort.
12. In August 2012 while living in northern NSW Margot underwent a hernia repair operation to treat her reflux condition. The operation involved a reduction of her stomach and closure of the hernia. Margot's surgeon Dr Mark Smithers then performed a partial fundoplication, whereby the fundus or upper part of

the stomach was wrapped around the lower end of the oesophagus and stitched in place. Margot's fundoplication was a partial one, meaning that the fundus was wrapped 270 degrees around the oesophagus.

13. In 2013 Margot and Stephen moved back to Sydney to be closer to their son James. By 2015 Margot weighed 109 kilograms and had a BMI of 46, placing her in the category of Class III morbid obesity. The previous year she had suffered two seizures while sleeping which were thought to be related to her sleep apnoea, itself associated with her obesity. She began to seriously consider weight loss interventions, and on 22 January 2015 she consulted Dr Craig Taylor, a laparoscopic and obesity surgeon.
14. Dr Taylor discussed with Margot various forms of bariatric surgery including gastric banding, sleeve gastrectomy and gastric bypass. Dr Taylor explained that the latter two surgeries would require reversal of her fundoplication. He also explained that significant lifestyle and dietary change would be necessary for her to lose weight and not regain it. Margot did not return to see Dr Taylor, and he had the impression she was somewhat overwhelmed by the changes that he had explained would be needed. Stephen and James Pegum thought she wanted to investigate a less invasive weight loss intervention.

Margot's intragastric balloon procedure

15. Margot began to research a bariatric procedure known as an IntraGastric Balloon procedure [IGB]. This involves placing a soft saline filled balloon into the stomach via the mouth. The aim is for the balloon to promote weight loss by occupying a proportion of the stomach and creating a feeling of satiety, causing the patient to consume smaller portions of food. Depending on the model used, balloons must be removed after six or twelve months, after which the patient must entirely rely on behavioural and dietary changes to lose further weight or maintain weight loss.
16. On 18 February 2015 Margot attended a weight loss clinic Gastric Balloon Australia [GPA], now known as 'The BMI Clinic'. She had consultations with GBA's then primary care physician Dr Chris Eliades, and with GBA's specialist gastroenterologist Dr George Marinos.
17. Dr Marinos is an experienced gastroenterologist who has been performing IGB procedures since 2005. By 2015 he had personally performed more than 700 such procedures and as a supervisor and trainer in IGB insertion, had overseen more than 2,000. On 27 April 2015 Dr George Marinos placed an IGB into Margot's stomach by endoscopic procedure.
18. The type of balloon Dr Marinos used was a Spatz 3 version, which is able to remain in place for up to twelve months and to have its volume adjusted over that period by endoscopic procedure. The initial fill volume which Dr Marinos used was the relatively conservative amount of 450mls.

19. On 22 June 2015 Dr Marinos performed an inflation of Margot's IGB. Again he proceeded with caution, inflating only a further 180mls. However when she got home that evening Margot became extremely unwell with severe abdominal pain, vomiting and retching. This persisted over the next day and night.
20. On the morning of 24 June James Pegum became alarmed and took his mother to Prince of Wales Hospital, where Dr Marinos performed an emergency removal of her IGB. In doing so he found a 5cm linear perforation in the lesser curve of her stomach wall. This was repaired, but soon afterwards it was found that irreversible ischaemia was affecting her bowel and colon. Despite further surgery over the next few days, multiorgan failure developed. After consultation with Margot's family, on 6 July her life support was removed and she died.
21. An autopsy was not conducted. Deputy State Coroner Dillon issued a Coroner's Certificate which gave the cause of Margot's death as sepsis with antecedent causes of gastric perforation and obesity. Margot's fundoplication for hiatus hernia was identified as a significant contributing condition.
22. In addressing the issues raised in this inquest the Court was assisted by expert evidence from the following medical specialists:
 - Dr Anthony Greenberg, general and gastrointestinal surgeon.
 - Associate Professor Michael Talbot, upper gastrointestianl and bariatric surgeon, and consultant surgeon at St George Private Hospital.
 - Dr Craig Taylor, laparoscopic and obesity surgeon.
 - Dr David Links, upper gastrointestinal surgeon and Visiting Medical Officer at Prince of Wales Hospital Randwick.

Was Margot an appropriate candidate for IGB placement?

23. This issue focuses upon whether Margot, as a patient who had previously undergone a form of gastric surgery, should have been implanted with an IGB device.
24. The Court heard evidence that for some years the only IGB system available in Australia was the version known as the Orbera fixed device. The company which manufactures it publishes directions to instruct clinicians about its patient risks and benefits. In 2012 an alternative was introduced, known as the Spatz adjustable device. This was the type which Dr Marinos used in Margot's case. At the time, the Spatz manufacturer did not publish directions for its use, advising clinicians to rely on those relating to the Orbera device.
25. The Orbera directions current as at April 2015 specified that one of the contraindications for its use was '*prior gastrointestinal or bariatric surgery*'.
26. Peer-reviewed research which was available then, as now, likewise listed prior gastric surgery as a contraindication, with the Position Statement of the

American Society for Gastrointestinal Endoscopy identifying previous gastric surgery as '*an absolute contraindication*' and counselling clinicians as to the importance of careful patient selection on this account. The Court was provided with a number of medical journal articles which similarly warned against the use of IGBs in cases of previous gastric surgery.

27. The reason why prior gastric surgery, including hiatus hernia repair and fundoplication is contraindicated for IGB use is because it elevates the patient's risk of a stomach perforation following the IGB placement and/or reinflation. Associate Professor Talbot and Dr Greenberg explained to the Court that fundoplication alters aspects of gastric function, in particular the ability of the person to expel gas from the stomach by way of belching. Belching is a very important mechanism for patients to relieve gastric distension. Associate Professor Talbot, with whom Dr Greenberg agreed, stated that: '*A patient who develops an obstruction in their stomach or gut who cannot belch is in danger of developing acute gastric dilatation which ...can cause significant haemodynamic instability, abdominal pain and the risk of gastric necrosis and perforation*'.
28. It should be noted that for the average patient the risk of stomach perforation with IGB use is extremely low. Although there is unanimity of medical opinion that prior gastric surgery elevates this risk, the degree to which it is elevated is unknown.
29. Thus there is no controversy about the status of prior gastric surgery as a contraindication to IGB therapy, and indeed as an experienced gastroenterological specialist Dr Marinos was well aware of this fact. Consistent with all literature and guidance on the subject however, he was unable to quantify the extent to which it elevated the risk.

Dr Marinos' risk assessment

30. Dr Marinos had never previously performed an IGB procedure on a patient who had had a partial or full fundoplication.
31. In his statements and oral evidence to the inquest Dr Marinos explained the reasons why he had reached the conclusion that in Margot's case he could proceed to use an IGB device, notwithstanding her previous gastric surgery. His reasoning was as follows.
32. Before making any decisions he had taken steps to inform himself about the nature of Margot's previous surgery. He had sought and obtained a copy of Dr Smithers' operation report. This confirmed that a hernia repair and 270 degree fundoplication wrap had been performed without complication. In Dr Marinos' opinion, Margot's risk of perforation was reduced by reason of the fact that her fundoplication was a partial and not a full one.
33. Further, in two consultations with Margot on 11 March and 8 April 2015, Dr Marinos had established that she did not experience problems with bloating or

being unable to belch. This he said reassured him that she would be able to expel gas and fluid to relieve any gastric distension following placement of the IGB.

34. Dr Marinos was aware that if Margot were to undergo an IGB procedure there was a heightened need to minimise the expected post-procedure vomiting and retching. This was for two reasons.
35. The first was that possible changes to her stomach's anatomy and functioning due to her previous surgery meant that she would be at higher risk of perforation in the event of persistent vomiting and retching. As with most patients, in Margot's case it was not known to what extent such alterations had occurred, although as noted Dr Marinos felt confident she did not experience difficulties belching. Nevertheless he was alive to the importance of reducing her post-procedure vomiting as much as possible.
36. The second reason arose from Margot's anti-seizure medication. Margot was most anxious to ensure that vomiting and dehydration were minimised, so as not to increase her vulnerability to seizures. She also needed to be able to keep down her anti-seizure medication.
37. In weighing up the risks and benefits Dr Marinos also took into account Margot's strong need for a weight loss intervention. Margot was well aware of this too. With a classification of Class III obesity she faced a reduced life expectancy. Further, in addition to her diminished quality of life she was very concerned about the risk of further seizures arising from her severe sleep apnoea, itself a co-morbidity of her obesity. She had achieved little with attempts over the years to change her diet and lifestyle. She had explored surgical possibilities and was concerned about their safety. Dr Marinos was aware she was very keen to undertake the IGB procedure.
38. In view of Margot's heightened risk of perforation Dr Marinos considered that using a Spatz 3 device would be preferable to an Orbera one. The Orbera device could not remain in the stomach for more than six months, meaning that to achieve significant weight loss the fill volume needed to be large, usually between 650 and 700mls. This caused patients to suffer higher levels of post-procedure cramping and vomiting. In Dr Marinos' opinion the Spatz 3 device would be likely to have milder side effects. It is able to be implanted with an initial volume of as little as 400mls, and is designed to be able to be incrementally filled to higher volumes over the six to twelve months it remains in the stomach.
39. Dr Marinos' evidence was that having considered all the above, while there were acknowledged risks in Margot's case of using a Spatz IGB, he believed these were not such as to conclude that it was too dangerous to proceed. He determined to further mitigate the risks by commencing with a relatively low fill volume, and providing a reinflation two months later of only 180 mls.

Was Dr Marinos' decision appropriate?

40. The evidence establishes that Dr Marinos' assumptions regarding risk mitigation were not supported by evidence which was available to him at the time.
41. In stating that prior gastrointestinal surgery was a contraindication for IGB procedures, IGB manufacturers did not qualify this in any way by indicating that a distinction could be made between partial and full fundoplication; or by suggesting that the risk could be mitigated by use of a Spatz device rather than an Orbera one.
42. Similarly, peer-reviewed research literature available at the time stated without qualification that prior gastrointestinal surgery was a contraindication for IGB procedures, likewise making no distinction between partial and full fundoplication, or between Spatz and Orbera devices. In their evidence to the inquest Associate Professor Talbot and Dr Greenberg confirmed the unanimous state of expert opinion on these points. This was also acknowledged by Dr Marinos.
43. Associate Professor Talbot and Dr Greenberg conceded that Dr Marinos faced a difficult decision, given the unknown magnitude of Margot's elevated risk and her pressing clinical need for weight reduction. They acknowledged too that Dr Marinos had taken certain steps to assess Margot's risk, informing himself about the nature of her previous surgery and ascertaining that she retained the capacity to expel gas by belching.
44. Nevertheless both experts concluded it was unwise of Dr Marinos to have proceeded, given what was known of Margot's clinical history and the unanimity of opinion in relevant literature.
45. Neither expert was willing to state that there were absolutely no circumstances in which it might be safe and appropriate to provide IGB treatment to a patient with a history of previous gastric surgery. However both stated they would not have offered IGB treatment in Margot's case. Associate Professor Talbot stated that if after advising Margot against the procedure she still wanted it he would have referred her to another gastroenterologist.
46. I accept that as an experienced gastroenterologist Dr Marinos took steps to better understand the degree of Margot's risk. I also accept that the decision he faced in 2015 was not an easy one and that he approached it with Margot's best interests at heart.
47. Nevertheless the above evidence compels the finding that Dr Marinos' decision to proceed represented a significant error of judgement. No peer-reviewed literature or guidelines supported his conclusion that it was safe to proceed because Margot's risk was mitigated by the fact that her previous surgery was a partial fundoplication only, and that it could be further mitigated by conservative use of a Spatz device. It could not be assumed that her risks were any less on account of these factors.

48. In short there was no evidence to support the proposition that an IGB device for a patient in Margaret's circumstances was safe or appropriate.
49. In his evidence Dr Marinos accepted that his decision to proceed with IGB in Margot's case was unwise. He acknowledged the lack of evidence that it was safe and appropriate to do so. He expressed sincere and genuine regret for her death, describing how he had liked and admired her as a person and a patient.
50. Dr Marinos has since introduced some important changes to his patient selection procedures which will be described below. The most significant is that his practice no longer offers IGB procedures for patients who have had any kind of fundoplication, whether partial or full.

Was it likely Margot would have gained long term benefit from the IGB?

51. All medical witnesses who assisted this inquest agreed that weight loss procedures carry the risk of weight regain. Maintaining weight loss depends to a large degree on whether a person achieves long term dietary and behavioural change.
52. The Court heard evidence in relation to this issue from Dr Craig Taylor, the surgeon whom Margot consulted in February 2015. For a period in 2010 Dr Taylor performed IGB procedures but ceased doing so. In his view they were rarely clinically effective because most patients lost weight only while the IGB was in place, and regained it when it was removed. He acknowledged an IGB procedure may be justified where the patient was only mildly obese, making the inherent risks of surgery less justifiable. It might also be of benefit where a patient was severely morbidly obese and needed to lose some weight in order to reduce the risks inherent in subsequent bariatric surgery. In all such cases the patient needed to be fully informed, among other things, of the very real risk of weight gain once the IGB was removed.
53. Associate Professor Talbot has current experience in using IGB procedures. His evidence was they delivered a median weight loss of 10% body weight but that according to research, after 24 months only one in four patients managed to maintain clinically significant weight loss. He and Dr Greenberg agreed the critical factor was the degree to which patients had managed to incorporate positive changes to their diet and lifestyle. It is to be noted that Dr Marinos' clinic provides its bariatric patients with the ongoing services of a dietitian.
54. I accept the submissions on behalf of Counsel for Dr Marinos, that it is not possible to determine whether or not Margot would have achieved sustained weight loss benefits from her IGB procedure. While the odds of long term weight loss through use of IGB do not appear to be very favourable, it is simply not possible to determine whether Margot would have fallen within that percentage of people who do manage to maintain their weight loss.

Was Margot given adequate information about the IGB placement and inflation?

55. Margot's husband Stephen accompanied her to her consultations with Dr Eliades and Dr Marinos. Unfortunately due to his death in 2017 his evidence about what advice she received at the GBA clinic is not available.
56. Nor is the Court assisted by Dr Marinos' patient notes of his two meetings with Margot on 11 March and 8 April 2015. These are wholly inadequate, consisting in each case of little more than a few scrawled lines. These indicate Dr Marinos' awareness of Margot's previous fundoplication, and record a decision to '*go very slowly with insertion and inflation*', but otherwise contain no reference to advice given to her about the risks and benefits of an IGB procedure.
57. In his supplementary statement made on 11 July 2017 Dr Marinos said that at both consultations he advised Margot of an increased risk of perforation due to her previous gastric surgery. He says further that at the second meeting he told her he was unable to quantify the exact risk of perforation as there was not enough data available; and he told her of the strategies he could use to try to minimise her adverse effects.
58. Despite the absence of clinical notes to corroborate Dr Marinos' evidence about his advice to Margot, there is independent evidence he was concerned about her heightened risk of perforation. As noted he informed himself about the nature of her previous surgery and made clinical decisions aimed at minimising her risk of post-procedure vomiting and retching. It is reasonable to assume therefore that he provided Margot with advice along the lines indicated in his statement.
59. However Dr Marinos admitted that at no time did he inform Margot that manufacturer instructions and research literature contraindicated use of IGB for patients with prior gastric surgery. There can be no doubt Margot was entitled to know this.
60. Further, it does not appear Margot was informed that a high proportion of IGB patients do not manage to maintain their weight loss. Margot's initial consultation at GBA was with its then director and general care physician, Dr Chris Eliades, on 18 February 2015. Dr Eliades' records generally corroborate his evidence that he discussed with Margot some of her bariatric options, and the side effects commonly experienced after IGB implantation including nausea and vomiting. Although he advised her of the importance of lifestyle changes after the procedure, he agreed he had not told her that weight loss was not maintained in the majority of IGB cases.
61. It cannot be known whether Margot's decision concerning an IGB procedure would have been different had she been advised that it was contraindicated in her case, and that it had relatively low prospects of providing sustained weight loss. Given her reported enthusiasm for the procedure, it is possible her

decision would not have changed. Nevertheless it was information she and any other patient in her situation was entitled to know.

After the adjustment was Margot's post-procedure advice and care adequate?

62. The inquest heard evidence about another aspect of Margot's care which in my view had the potential to have impacted her outcome. It concerns what Margot was told about the circumstances in which she should contact Dr Marinos after her IGB was adjusted on 22 June.

63. On 8 April in accordance with usual practice it is likely Margot was given an information form prepared by GBA, containing pre and post procedure instructions. The form included the following advice:

In case of emergencies:

If, after two days, you are experiencing any severe nausea or vomiting (after insertion or adjustment of the balloon), you must contact Dr Marinos on [phone number redacted] or Lorraine on [phone number redacted].

64. The natural interpretation one would give to the above is that there was no need to contact Dr Marinos or his staff if severe vomiting was experienced in the first 48 hours following implantation or inflation.

65. In his supplementary statement of 19 February 2018 Dr Marinos stated that when Margot was in recovery immediately following the inflation, he emphasised to her that she should call him '*at the earliest possible time*' if she had protracted vomiting, pain or nausea. There is therefore a conflict in the advice given to Margot about the circumstances in which she should contact Dr Marinos after the inflation.

66. On the evidence it seems likely Margot's understanding was she should contact Dr Marinos only if her severe vomiting persisted after 48 hours. James Pegum described visiting his mother on the morning of 23 June and feeling concerned about her persistent vomiting and dry retching. When he asked if she had contacted Dr Marinos she replied she had not, as she understood these symptoms were to be expected. On the basis of this evidence it seems likely Margot relied on her written instructions. It is entirely feasible that in her recovery condition she had not absorbed Dr Marinos' verbal advice.

67. There is basis to conclude that this lack of clarity had the potential to affect Margot's outcome. In his statement Associate Professor Talbot commented that in the 24 hours following the inflation procedure Margot likely developed severe dehydration such that by the time she reached hospital on 24 June she was in a state of circulatory compromise. In his view: '*...it seems likely that if she'd presented 24 hours earlier this unfortunate circumstance of events may well have been preventable ...*'

68. Professor Talbot explained that had Margot been able to receive fluids and medication intravenously following her inflation, this would have reduced the severe and protracted vomiting which led to her circulatory collapse.
69. Dr Marinos himself expressed deep regret that there had not been any clinical contact with Margot on 23 June. Had there been, he said he could have taken immediate steps to alleviate her symptoms by reducing the balloon's volume. His expectation had been that on 23 June she would have received a follow up call from the Day Hospital at which he had performed the inflation. This did not occur. He agreed that in the circumstances of her being a higher risk patient, it would have been appropriate for himself or someone from his clinic to make contact with her on 23 June.
70. I should note that in Dr Greenberg's opinion the availability of intravenous fluids on 23 June was unlikely to have made much difference in Margot's case, as he believed her perforation occurred sometime that day or even the previous night. This contrasted with Professor Talbot's opinion that it was likely to have occurred shortly before her presentation to hospital on the morning of 24 June. He based this on his experience that following perforation, patients very quickly develop acute and unequivocal abdominal pain.
71. In this case the evidence does not enable me, nor is it necessary to the discharge of the coronial function, to make a finding that Margot's death would have been prevented had she understood she needed to contact Dr Marinos on 23 June.
72. However the evidence is sufficient to conclude, and it is appropriate to do so, that had Margot received medical attention on 23 June her chances of surviving would likely have been enhanced, either by way of reducing her risk of perforation through rehydration, or earlier detection of the perforation. I find that her post-procedural care following the inflation was deficient in that:
- The instructions she received about contacting Dr Marinos following the inflation lacked clarity, resulting in her not doing so on 23 June.
 - Her status as a higher risk patient warranted Dr Marinos or a member of his clinical team contacting her on 23 June.
73. In both these respects Dr Marinos has since introduced changes to his practice, as follows:
- The practice now employs two full-time registered nurses, to enable all patients following implantation or adjustment of their balloon to receive follow up calls during the first 48 hours.
 - There is a 24 hour/365 days a year '1300' number for patients to contact a clinical member of the practice at any time.

- After IGB implantation all patients must attend the practice's Infusion Clinic for intravenous fluids and medications. This enables them to remain fasted for 48 hours after the procedure, allowing the stomach to rest and reducing the severity of post-procedure vomiting. Selected patients are required to attend the Infusion Clinic after inflation as well.

What caused the gastric perforation Margot suffered?

74. As to what was the most likely cause or causes for the perforation of Margot's stomach, there was general consensus among the expert witnesses. In the opinion of Professor Talbot, with which Dr Greenberg agreed, there were two main factors:

- After the inflation Margot's severe vomiting and dry retching increased intragastric pressure. Vomiting was described as a compressive action on the stomach whereby powerful contractions caused the abdomen to push the lower part of the stomach upwards while the diaphragm pushed down on it. This pressure made her stomach more vulnerable to perforation.
- The presence of the balloon itself further reduced space in Margot's stomach and exacerbated her vomiting. Professor Talbot thought the balloon had likely become compressed against Margot's stomach wall as a result of the contractions induced by her vomiting, leading to perforation at that site.

75. Dr Marinos was in strong agreement with these two factors as the cause of perforation, as was Dr Links.

76. Dr Greenberg and Dr Links both postulated a third contributing cause related to Margot's history of prior gastric surgery.

77. Dr Greenberg thought it possible Margot's previous fundoplication had altered the structure and function of her stomach making it more difficult for her to regurgitate wind, leading to gastric distension and perforation. Dr Links was also of this view. However Professor Talbot considered this less likely, for the reason that any such distension would be more likely to perforate the thin wall of the stomach's fundus rather than the part of the wall which did perforate, being the relatively thicker tissue of the stomach's lesser curve.

78. Dr Links also considered it possible that scar tissue and adhesions resulting from Margot's previous surgery had provided a fixed point against which the contractions caused by her vomiting impacted, leading to perforation. Dr Links conceded he could not recall seeing any such scarring when he performed Margot's emergency surgery, but he commented that it can be difficult to access the relevant areas where a patient is obese. Professor Talbot and Dr Greenberg agreed such scarring may have played a role in the perforation.

79. On the basis of the evidence I am able to conclude on the balance of probabilities that the perforation which caused Margot's death was the result

of two main factors: the pressure created within her stomach by the compressive action of severe and protracted vomiting and retching; and the exacerbation of such pressure by the presence of the intragastric balloon. It remains a possibility that Margot's previous gastric surgery also played a role in the perforation, in the manners suggested by Dr Greenberg and Dr Links.

Question of recommendations: GBA Clinic

80. After Margot's death the GBA clinic undertook a review of its safety and monitoring procedures. This resulted in a number of changes, perhaps the most important being that the clinic no longer offers IGB therapy to any patient who has had a fundoplication, whether partial or full.
81. Other changes have been described above which are aimed at improved contact arrangements and post-procedure care.
82. The Court heard that the clinic has also reviewed its patient information documents. A revised 'Informed Consent' document is now used, providing greater detail about the risks associated with IGB. Importantly, patients are directed to contact the clinic '*immediately*' to report '*any significant symptoms (including vomiting) to ensure these are managed appropriately*'.
83. I accept the submission of Counsel Assisting that all these changes are relevant and appropriate. They are the result of genuine reflection by Dr Marinos and his team on the circumstances of a tragic death and how it could be prevented in future cases. It should be noted that Dr Marinos provided full co-operation to this inquest. He expressed sincere regret for Margot's death and evinced a genuine desire to make any further changes thought necessary to ensure such an outcome was not repeated.
84. I have commented on the poor quality of Dr Marinos' patient notes in relation to his treatment of Margot, a matter which Dr Marinos acknowledged in his evidence. I am confident it is an aspect of his practice which will be rectified.
85. For the above reasons I do not see the necessity to make any recommendations in relation to Dr Marinos or the GBA Clinic (now the BMI Clinic). I did not receive any submissions that any such recommendations should be made.

Question of broader recommendations

86. I accept the submissions of all parties that as a result of the matters examined in this inquest there is scope for making recommendations of a broader nature.
87. The prevalence of obesity is rising each year resulting in serious health issues and reduction in quality of life for those who suffer it. There is also an increasing burden on the public health budget. For these reasons it is likely

that performance of bariatric procedures as an area of medical practice will continue to evolve and grow. As with all medical procedures it is reasonable to assume that such interventions will be performed by clinicians with varying degrees of individual expertise and experience.

88. The inquest heard evidence that there would be utility in a suitable professional body preparing guidelines concerning IGB procedures covering patient selection and exclusion criteria, indications and contraindications, risks, and appropriate follow up care and advice. Indeed the inquest heard that preparation of such guidelines is already under consideration by the Australian and New Zealand Metabolic and Obesity Surgery Society [ANZMOSS]. ANZMOSS is a professional body formed to encourage research, education and communication in the surgical specialties of obesity surgery and procedures.
89. In addition there was consensus among the witnesses who gave expert medical evidence to this inquest that there would be value in developing a data registry with details and outcomes for all bariatric patients. The aim would be to provide clinicians and prospective patients with evidence-based information to guide decisions about the various bariatric options. In addition to the obvious information benefits such data would provide, Professor Talbot added it would benefit the public interest for obesity clinicians to be aware that the outcomes of their procedures were being monitored.
90. I accept that the above recommendations are necessary and desirable, and I propose to make them.

Conclusion

91. Ms Pegum's death was a very sad one, and continues to deep affect her family. I hope this inquest has answered some of their questions about how they came to lose their much-loved mother and grandmother. I hope too that the Pegum family will accept the sincere sympathy of all of us here at the Coroner's Court.
92. I thank all who have assisted in this inquest, including the Pegum family, the witnesses, and the Officer in Charge of the investigation. I thanks also the legal representatives – in particular Counsel Assisting Mr Jason Downing and instructing solicitor Ms Jessica Murty of the Crown Solicitor's Office.

Findings required by s81(1)

As a result of considering all of the documentary evidence and the oral evidence heard at the inquest, I am able to confirm that the death occurred and make the following findings in relation to it.

The identity of the deceased

The person who died is Margaret Ann Pegum born 13 May 1947.

Date of death

Margaret Pegum died on 6 July 2015.

Place of death

Margaret Pegum died at Prince of Wales Hospital, Randwick NSW.

Cause of death

Margaret Pegum died from sepsis as a result of gastric perforation.

Manner of death

Margaret Pegum's death occurred in the context of complications from a bariatric intragastric balloon procedure.

Recommendations

To the Australian and New Zealand Metabolic and Obesity Surgery Society:

1. That consideration be given to developing guidelines concerning intragastric balloon procedures covering patient selection and exclusion criteria, indications and contraindications, risks, and appropriate follow up care and advice.
2. That consideration be given to compiling a data registry with details and outcomes for all bariatric patients, aimed at providing clinicians and prospective patients with evidence-based information to guide decisions about the various bariatric options.

I close this inquest.

E Ryan

Deputy State Coroner
Glebe

Date 26 April 2018