IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

COR 2018 000823

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2)

*Section 67 of the **Coroners Act 2008***

Findings of:	Coroner Leveasque Peterson
Deceased:	Ruth Ann McKenna
Date of birth:	28 December 1955
Date of death:	19 February 2018
Cause of death:	1(a) Hypovolaemic and cardiogenic shock (hysterectomy) in the context of cardiomegaly, cirrhosis and coagulopathy
Place of death:	Goulburn Valley Hospital, 2 Graham Street, Shepparton, Victoria, 3630
Key words:	Complications of surgery, Sentinel Event, Medical procedure investigation

INTRODUCTION

1. Ruth Ann McKenna was 62 years old at the time of her death and lived in Woolloongabba.

2. Ruth had a medical history of hypertension, cirrhosis, thrombocytopaenia, chronic kidney disease, chronic obstructive pulmonary disease and reduced exercise tolerance.

3. On 19 February 2018, Ruth died at Goulburn Valley Hospital on the operating table after undergoing an elective total laparoscopic hysterectomy (**TLH**) procedure.

THE CORONIAL INVESTIGATION

4. Ruth's death was reported to the Coroner as it fell within the definition of a reportable death in the *Coroners Act 2008* (the Act). Reportable deaths include a death that occurs during a medical procedure and a registered medical practitioner would not, immediately before the procedure was undertaken, have reasonably expected the death.[1]

5. The role of a coroner is to independently investigate reportable deaths to establish, if possible, identity, medical cause of death, and surrounding circumstances. Surrounding circumstances are limited to events which are sufficiently proximate and causally related to the death. The purpose of a coronial investigation is to establish the facts, not to cast blame or determine criminal or civil liability.

6. Under the Act, coroners also have the important functions of helping to prevent deaths and promoting public health and safety and the administration of justice through the making of comments or recommendations in appropriate cases about any matter connected to the death under investigation.

7. Upon review of the circumstances of Ruth's death, the Health and Medical Investigation Team of the Coroners Prevention Unit (**CPU**) were asked to review the appropriateness of Ruth's medical care and management. The CPU provided advice which has informed and guided my investigation.

8. This finding draws on the totality of the coronial investigation into the death of Ruth Ann McKenna including medical records, statements from treating practitioners, a Goulburn Valley Health (**GVH**) Root Cause Analysis (**RCA**), and an independent expert opinion from Dr Russell Dalton.

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[1] *Coroners Act 2008* (Vic), s 4(2)(b)(ii).

9. The court also received concerns of care from general surgeon Mr Roland Hunt. Whilst Mr Hunt's concerns were considered by the court, I have placed limited weight on this material in the discharge of my duties as Mr Hunt had no involvement, direct or otherwise, in Ruth's medical care or management.

10. In addition, the court received materials and findings from an investigation conducted by the Australian Health Practitioner Regulation Agency (**AHPRA**) into Dr Vasudha Iyengar's conduct, which included Dr Iyengar's treatment of Ruth. These materials included two expert opinions – an opinion obtained by AHPRA from obstetrician and gynaecologist Dr Stephen Lyons and an opinion obtained by Dr Iyengar from obstetrician and gynaecologist Dr Bernadette White. These opinions presented conflicting conclusions which were not able to be independently tested by the court. As such, whilst I have considered AHPRA's findings more generally, I have placed greater weight on the expert opinion obtained from Dr Dalton as this opinion was subject to thorough and independent assessment by the CPU.

11. After considering all the material obtained during the coronial investigation, I determined that I had sufficient information to complete my tasks as coroner and that further investigation was not required. Whilst I have reviewed all the material, I will only refer to that which is directly relevant to my findings or necessary for narrative clarity.

12. In the coronial jurisdiction, facts must be established on the balance of probabilities.[2] The strength of evidence necessary to prove relevant facts varies according to the nature of the facts and the circumstances in which they are sought to be proved.[3]

13. The standard of proof for coronial findings of fact is the civil standard of proof on the balance of probabilities, with the Briginshaw gloss or explications.[4] Adverse findings or comments against individuals in their professional capacity, or against institutions, are not to be made with the benefit of hindsight but only on the basis of what was known or should reasonably have been known or done at the time, and only where the evidence supports a finding that they

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[2] Subject to the principles enunciated in *Briginshaw v Briginshaw* (1938) 60 CLR 336. The effect of this and similar authorities is that coroners should not make adverse findings against, or comments about, individuals unless the evidence provides a comfortable level of satisfaction as to those matters taking into account the consequences of such findings or comments.

[3] *Qantas Airways Limited v Gama* (2008) 167 FCR 537, [139] per Branson J, noting that His Honour was referring to the correct approach to the standard of proof in a civil proceeding in the Federal court with reference to s. 140 of the *Evidence Act 1995* (Cth); *Neat Holdings Pty Ltd v Karajan Holdings Pty Ltd* (1992) 67 ALJR 170, 170-171 per Mason CJ, Brennan, Deane and Gaudron JJ

[4] *Briginshaw v Briginshaw* (1938) 60 CLR 336, pp 362-3 per Dixon J.

departed materially from the standards of their profession and, in so doing, caused or contributed to the death under investigation.

14. Proof of facts underpinning a finding that would, or may, have an extremely deleterious effect on a party's character, reputation or employment prospects demands a weight of evidence commensurate with the gravity of the facts sought to be proved.[5] Facts should not be considered to have been proven on the balance of probabilities by inexact proofs, indefinite testimony or indirect inferences. Rather, such proof should be the result of clear, cogent or strict proof in the context of a presumption of innocence.[6]

15. In considering the issues associated with this finding, I have also been mindful of Ruth's basic human rights to dignity and wellbeing, as espoused in the Charter of Human Rights and Responsibilities Act 2006, in particular sections 8, 9 and 10.

MATTERS IN RELATION TO WHICH A FINDING MUST, IF POSSIBLE, BE MADE

Circumstances in which the death occurred

16. The circumstances of Ruth's death are summarised below on the basis of a statement provided by Dr Vasudha Iyengar dated 27 March 2019, a statement provided by Dr Helen Roberts dated 30 January 2019, and the RCA conducted by GVH.

Referral for gynaecological evaluation

17. On 4 July 2017, Ruth was seen by specialist general physician, Dr Tunde Ibrahim who made a referral to obstetrician and gynaecologist Dr Iyengar[7] at GVH for gynaecological evaluation, intervention and management of a thickened endometrium identified on a computed tomography (**CT**) scan of Ruth's abdomen and pelvis.

18. On 16 August 2017, Dr Iyengar met with Ruth and discussed the results of the CT scan. Ruth disclosed that she did not have any vaginal bleeding, no family history of gynaecological malignancy and had had a normal pap smear five years prior. Dr Iyengar noted that Ruth was

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[5] Anderson v Blashki [1993] 2 VR 89, following *Briginshaw v Briginshaw* (1938) 60 CLR 336.

[6] *Briginshaw v Briginshaw* (1938) 60 CLR 336, pp 362-3 per Dixon J.

[7] Dr Iyengar stated that she has over 28 years of experience and became a fellow of the Royal Australian and New Zealand College of Obstetrics and Gynaecologists in 2001. She is a Fellow of the Royal College of the United Kingdom, and had completed Specialty Training in the United Kingdom. She has also been a continuous member of the Australian Endoscopic Gynaecological Surgeons' Society since 2003 and at the time of these events was a senior staff specialist obstetrician and gynaecologist with an advanced scope of surgical gynaecological practice including total laparoscopic hysterectomy by gynaecological laparoscopy and pelvic floor surgery.

62 years old, obese, and had been found to have a thickened endometrium which placed her at risk of endometrial cancer.

19. Dr Iyengar formulated a management plan to arrange an ultrasound scan with follow up in two weeks to look into her endometrial cancer risks.

20. On 28 August 2017, an ultrasound scan was performed which showed that the endometrial thickness was 8mm and there were few cystic areas in the endometrium. The thickness and cystic spaces seen were a concern.

21. On 30 August 2017, Ruth did not attend a scheduled follow up appointment with Dr Iyengar. Dr Iyengar followed up the matter by writing to Ruth to ask that she keep the appointment so they could progress the screening and treatment as necessary.

22. On 25 October 2017, Ruth attended the GVH Gynaecology Clinic where she was seen by registrar Dr Ayesha Akhter.[8] Dr Akhter discussed the results of the ultrasound with Ruth and conducted an examination.

23. On examination, Ruth's abdomen was soft and non-tender. Per speculum examination, the vaginal wall was atrophic and Ruth had a narrow vaginal opening. The cervix was visible but looked atrophic and Ruth was unable to tolerate internal speculum examination. Dr Akhtar wanted to perform an endometrial pipelle sampling, a less invasive outpatient procedure (performed while the patient is awake) to obtain a sample of the thickened endometrial lining, but Ruth was also unable to tolerate this procedure.

24. Dr Akhtar sought assistance from Dr Iyengar, who met with Ruth and discussed the treatment plan. Ruth completed a consent form for a hysteroscopy[9] and appropriate dilation and curettage[10] category 1, for the purpose of ruling out any possible endometrial malignancy. A pre-surgical clinic anaesthetic review was also requested.

Hysteroscopy Procedure

25. On 13 November 2017, Ruth was admitted to GVH for the hysteroscopy procedure which was performed under general anaesthetic by Dr Iyengar and senior registrar Dr Ibrahim Manu.

[8] This clinic was managed by Dr Iyengar.
[9] The insertion if a small endoscopic device into the uterus to directly visualise the interior.
[10] Obtaining samples of the lining of the uterus using a surgical instrument (curette) passed through the cervix into the cavity of the uterus.

Dilatation of the cervix was difficult and a 2mm hysteroscope was required to perform the saline hysteroscopy, rather than the regular 4mm hysteroscope.

26. The surgical team observed a polyp filling the whole cavity of the uterus on the theatre monitor. The cervix was too small to accommodate a polyp forceps to attempt to avulse off the polyp in toto, and in any case, it appeared that it would have had a sessile base or thick stalk which was out of the 2mm hysteroscope's view. As such, the hysteroscope was removed and a pipelle endometrial sample was obtained.

27. On 15 November 2017, the pathology report found that the limited endometrial sample was composed of two small, slightly polypoid fragments of glandular tissue, containing glands that were lined by ciliated or tubal type epithelium and showing slightly fibrous stroma with mildly prominent stromal vasculature. The glands were inactive and showed no atypia. The fragments could either be from the isthmic region, or may have possibly represented small benign polyps. There were no atypical features. Dr Iyengar arranged to follow up with Ruth in the clinic in two weeks.

Post Hysteroscopy Review

28. On 29 November 2017, Dr Iyengar had a clinic follow up appointment with Ruth and provided her with the histology from the limited sample. Dr Iyengar explained to Ruth that the photographs from the surgery showed a large polyp inside an atrophic menopausal uterus. The polyp looked benign, but it was required to be removed. The cervix was very stenosed, and it was not possible to take the polyp out through the cervix. Dr Iyengar explained that the small size of the cervix had caused access problems.

29. Dr Iyengar stated that she discussed with Ruth the potential treatment options available to her, namely:

    a) wait and monitor regularly, with a risk of a malignancy developing;

    b) perform a hysteroscopic endometrial recession which would involve inserting a 1cm operative hysteroscope into her cervix and then 'shaving off' the polyp. Glycine would be used in the procedure, which carries its own considerable metabolic and electrolyte imbalance risks. Dr Iyengar explained to Ruth her concern that her cervix may be too small for the 1cm scope to be inserted without trauma, perforation and other injurious complications, which could have further sequelae;

c) perform a TLH with higher than usual risks of conversion to a total abdominal hysterectomy (**TAH**). Dr Iyengar explained the risks of open laparotomy conversion because Ruth had previously had complicated septic laparotomies at an earlier age which had left her with a scarred abdomen; and

d) transfer Ruth to a tertiary hospital in Melbourne which may be able to provide her with some alternatives. However, Ruth indicated that she could not afford to travel to Melbourne for treatment and all that would be involved with such a plan, and so was very keen to have her treatment locally.

30. Dr Iyengar stated that she advised Ruth that she could have time to consider her options, but Ruth elected to proceed with having the laparoscopic hysterectomy at GVH.

31. Dr Iyengar stated that she discussed the material risks of the procedure with Ruth, as per her usual practice, and provided Ruth with information sheet from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists about TLH/TAH. Specifically, Dr Iyengar discussed the material risks of internal bleeding, bleeding/infection/hernias at incision sites, anaesthetic risks, risks of penetrative and spillage injury to other organs including ureter, large vessels and bowel, risks of sepsis and peritonitis and haemorrhagic bleeding at the time of surgery itself due to possible adhesions from her scars. Dr Iyengar also discussed the risk for Ruth of intra operative mortality due to her co-morbidities, and the higher open laparotomy conversion risk due to possible past scarring.

32. Dr Iyengar stated that she explained the procedure to Ruth, including after care and pre-operative and post operative surgical expectations, including the possibility that she may spend time in ICU due to her medical conditions. Dr Iyengar subsequently referred Ruth for a pre-surgical assessment by the pre-anaesthetic clinic.

Pre-Anaesthetic Clinic Review

33. On 23 January 2018, Ruth attended a pre-anaesthetic clinic (**PAC**) at GVH and was assessed by consultant anaesthetist, Dr Helen Roberts.[11]

34. Prior to meeting with Ruth, Dr Roberts stated that she appraised herself of Ruth's medical history by reviewing the initial referral to the gynaecological clinic and outpatient consultation

[11] Dr Roberts is a consultant specialist anaesthetist, predominantly trained in the United Kingdom but with pre and post Fellowship experience within the Australian public healthcare system in both metropolitan and regional settings. Dr Roberts is a Fellow of the Australian and New Zealand College of Anaesthetists (2014) and Fellow of Royal College of Anaesthetists, UK (2010) and obtained Certification of Completion of Training in Anaesthesia, UK in 2013.

letter by her general physician, the gynaecological clinic outpatient letter, blood test results, echocardiogram, nuclear medicine myocardial perfusion study, electrocardiogram, previous anaesthetic pre-assessment records, records of anaesthesia, health assessment questionnaire and blood pressure, heart rate and oxygen saturations.

35. During the consultation with Ruth, Dr Roberts took a relevant medical history which included alcoholic liver disease with portal hypertension with low albumin, renal disease, cardiomyopathy, chronic obstructive pulmonary disease, raised Body Mass Index (**BMI**) and thrombocytopenia. Dr Roberts also took a medication history and social history focused on alcohol intake. Dr Roberts advised Ruth to stop drinking alcohol. Dr Roberts assessed Ruth's functional capacity as low (3 metabolic equivalents) and her American Society of Anesthesiologists (**ASA**) score as correlating to severe systemic disease that affects function (grade 3).

36. Overall, Dr Roberts assessed Ruth as being a high risk patient for complex gynaecological surgery, due to her ASA grade and co-morbidities. It was considered that intensive care or high dependency unit admission would be required.

37. The management plan was to have repeat pathology testing to optimise haemoglobin if low, order one unit of platelets which were to be given if platelet results were below 50 and to omit her perindopril on the day of surgery. Subsequent investigations identified that the platelets were not ordered for Ruth despite the plan for this to occur.

38. Ruth was booked for 'homework' on 30 January 2018 to review the pre-operative bloods order. The homework review is usually completed by both the anaesthetist and PAC nurse. However, according to the RCA subsequently conducted by GVH, there was no documentation that the pre-operative bloods collected on 23 January 2018 were reviewed at the 'homework' or that Ruth was cleared to proceed to surgery.

<u>First Surgery</u>

39. On 19 February 2018, at about 7.10am, Ruth was admitted to GVH for the TLH as an elective patient through the Day Procedure Unit.

40. Dr Iyengar had been on leave for approximately two months, returning to work that day. Dr Iyengar did not know Ruth had been booked in for the TLH until she arrived at work that morning.

41. Dr Roberts stated that on the day of surgery she spoke with Ruth and confirmed there had been no major changes to her medical conditions or her functional capacity. Dr Roberts stated that repeat haemoglobin, platelet and INR testing conducted on the day of surgery confirmed there had been no significant reduction in her haemoglobin level, her platelet count was above 50 which was the lower limit of acceptability for elective surgery according to national guidelines, and her synthetic liver function was assessed as acceptable for elective surgery (INR below 1.5).

42. At about 8.00am, Dr Iyengar spoke with anaesthetist Dr Roberts who informed her of the outcome of the PAC. A discussion was held related to the patient's platelet count of 51, recognised to be the lower limit of acceptability for surgery according to national guidelines. Dr Iyengar stated that she discussed with Dr Roberts whether they should cancel or postpone the surgery, but the decision was to proceed.

43. According to Dr Iyengar, Dr Roberts told her that Ruth was a high risk patient with a high BMI, but Dr Roberts was not alarmed and did not seek to cancel the surgery. She had assessed Ruth at the PAC and previously anaesthetised her for the hysteroscopy. According to Dr Iyengar, Dr Roberts has considerable experience and had anaesthetised patients of similar obesity and medical backgrounds, and it was not uncommon to treat obese and very obese patients at GVH due to the demographics of the Shepparton area.

44. As the platelets had not been ordered for the patient (despite the plan for this to occur following the PAC), a decision was made to delay the planned commencement time of the surgery in order to obtain the platelets, should they be needed peri-operatively. The platelets were expected to arrive on site at 11.00am.

45. Dr Iyengar and Dr Roberts met with Ruth in the preparatory 'day area'. They discussed the risks and asked Ruth if she was prepared to continue with the surgery. Ruth confirmed she wanted the surgery to take place. They also informed Ruth that there was a need to delay the surgery for a few hours to ensure there were platelets available on site at GVH, should they be needed perioperatively for Ruth.

46. An Intensive Care bed was requested, booked and available for post-operative care.

47. Dr Roberts also undertook peri-operative measures to mitigate the medical or anaesthetic risks posed to Ruth including two wide bore peripheral intravenous access cannulas, 18G in right wrist and 16G left antecubital fossa, to enable rapid infusion of fluid or blood products if needed, invasive arterial monitoring via the left radial artery to allow beat to beat blood

pressure measurements and active warming of Ruth using warmed intravenous fluids and a forced air warmer over her upper body. The routine "Time out" prior to commencing surgery was performed and so the theatre team were aware of Ruth's ASA status and the likely difficulties of surgery.

48. At about 9.15am, the TLH procedure commenced. The procedure was performed by Dr Iyengar who was assisted by gynaecological registrar Dr Akhter and her resident junior medical officer. Ruth's anaesthetic care was undertaken by Dr Roberts with the assistance of an anaesthetic registrar and an experienced anaesthetic nurse.

49. During the first part of the surgery, Ruth remained haemodynamically stable, requiring no pharmacological support.

50. Dr Iyengar made a 10mm vertical infraumbilical incision, followed by an uncomplicated Veres needle entry. She performed an uncomplicated abdominal insufflation. Through the visual entry, a camera port was inserted, and through the camera port, with the telescope, they observed an adhesion of omentum and bowel to the anterior abdominal wall. Operative vision was initially partially blocked due to these adhesions. Adhesiolysis was successfully accomplished improving vision, and access to the pelvis and lateral ports were inserted under vision and without complications.

51. According to Dr Iyengar, at this point it became obvious that Ruth had extensive pelvic adhesions between the bladder and the uterus and obliteration of the Pouch of Douglas posteriorly. In light of this, it was decided to change the surgical hysterectomy technique from the TLH to a laparoscopic assisted vaginal hysterectomy (**LAVH**). It was discussed and agreed that Dr Iyengar would take the tubal pedicles from above laparoscopically, because Dr Iyengar already had a routine and normal selection of ports inserted without complications into the abdominal cavity, and then move to completing the rest of the hysterectomy via a vaginal access method LAVH.

52. Dr Roberts stated that Dr Iyengar communicated to her and the rest of the theatre team that it was a difficult procedure. Dr Roberts did not have any concerns at this stage and there were no unexpected events or observations.

53. As Ruth had significant abdominal scarring, it was decided not to use a laparotomy or open approach at that conversion. The LAVH approach was considered the less risky option for Ruth as the ports were safely in and visibility was available. According to Dr Iyengar, these operative technique changes and decisions were made through collaboration, discussion and

agreement of all theatre staff including the anaesthetists, who were able to view the interior of the abdomen and pelvis on the laparoscopic visual operating monitors.

54. Dr Iyengar noted a complex adhesion at the right lateral pelvic wall and a post-menopausal right 'streaked' ovary with a paradoxically engorged ovarian venous plexus. When the adhesion was attempted to be released, bleeding was noted. Haemostasis was then achieved with Gyrus (bipolar) and the adhesion released. Gyrus was used to coagulate and cut the first and second tubo-ovarian pedicles bilaterally. The bladder was reflected off the anterior surface by appropriate laparoscopic dissection and the uterine arterial pedicles were taken bilaterally, with haemostasis achieved, using the Gyrus instruments.

55. Both fallopian tubes were then removed. The ovaries were embedded at the pelvic side wall areas and were not removed as they were noted to be streak remnant ovaries, inactive, and so it was safer to leave them in their densely buried state for eventual complete atrophy.

56. Subsequently, the ports were left in and the surgical team then moved down to the vaginal approach to continue the LAVH, as planned. Dr Roberts stated that after completion of the first laparoscopic part of the primary surgery, Ruth was returned to a supine position from a Trendelenburg position.[12] At this time, her blood pressure initially fell to approximately 90% of her pre-operative level. This was an expected event due to repositioning and a temporary loss of surgical stimulus and was treated with intravenous boluses of metaraminol (0.5mg x 3). Blood pressure returned to an acceptable level for 15 minutes when the vaginal part of the surgery began.

57. A vaginal approach was taken to remove the uterocervix. A circular incision around the cervix was made. Appropriate hydrodissection in tissue was undertaken prior to taking the pedicles. Cardinal ligaments were cut and clamped bilaterally with 0 vicryl. Regular lower pedicles were taken as per a regular vaginal hysterectomy technical approach and no injuries were noted to the other organs. The uterocervix was released and delivered. The vaginal vault was noted to be very high. However, the edges were grasped with Littlewoods all round and the vault was closed with 0 vicryl and haemostasis achieved. At that stage, the catheter had drained 500mls of clear urine intraoperatively.

[12] The Trendelenburg position is one where the patient is supine on the operating table, with the head tilted down. In the setting of gynaecologic surgery the legs are apart and the surgeon accesses the pelvic region between the patient's legs. In obese patients the abdominal wall and contents press up against the diaphragm, potentially compromising respirations.

58. Dr Roberts stated that upon commencing the vaginal part of the primary surgery, Ruth's blood pressure again fell to approximately 80% of her pre-operative level. She was unable to exclude hypovolaemia or heart failure at this point given the surgical difficulties and Ruth's known cardiomyopathy. Treatment was directed to augment circulating volume by means of a bolus of 1000ml of crystalloid to make a total of 2500ml infused by this time. Pharmacological treatment was given to support cardiovascular parameters; metaraminol boluses (0.5mg x 5) followed by infusion at 7.5mg/hr, ephedrine boluses (total 6mg x 2. Ruth's blood pressure was stable at between 80-90% of her pre-operative levels with these interventions for this part of the surgery.

59. The surgical team then had a second look into the abdomen using the pre-existing laproscopic access via the ports that had been left in, to ensure everything was okay. This was a routine second look laparoscopic 'finish up'. A few well-formed blood clots were seen, some were removed from the pelvis, and pedicle and vault haemostasis was achieved.

60. When the second look was undertaken, Pneumoperitoneum and Trendelenburg positioning was re-established. According to Dr Roberts, at this point Ruth's blood pressure again fell, this time to 70% of her pre-operative level. The same causes were deemed to be likely and were treated accordingly, with a bolus of 250ml crystalloid given and further boluses of ephedrine (6mg x 2) and metaraminol infusion continued. Ruth's blood pressure stopped falling but did not return to pre-operative levels with this intervention.

61. Dr Roberts stated that she informed Dr Iyengar that Ruth's blood pressure was low and she was attempting to support it with fluids and pharmacological agents. Dr Iyengar informed her that there were a few clots seen within the abdominal cavity, but there was no visible active bleeding, no visible organ damage and haemostasis had been achieved.

62. An intra abdominal drain was inserted into the suprapubic area port on the left side. Dr Iyengar stated she inserted this drain using the available port wound as she had thought the vaginal operation had been 'oozy' at the circumcervical incision area. Dr Iyengar stated she was aware she had properly secured all the pedicles and vault angles and was sure she had taken the vault edges well. However, as a precautionary measure, Dr Iyengar placed the drain through an available port site aperture without making another incision, given Ruth's known decreased platelets. The drain was stitched in situ and immediately drained approximately 250mls of collected blood and clots from the vault area when suction was applied. The drainage slowed right down thereafter. All of the ports were removed under vision. The port sites and skin were closed with vicril and 3-0 monocryl.

63. During the first surgery, there was an estimated total blood loss of 800mls from all parts of the surgery noted. The indwelling urinary catheter drained 5-10mls of clear urine at the end of the procedure in the catheter itself, but 600mls clear urine was found in total in the catheter bag. Ruth was administered approximately 3000ml of crystalloid during the primary operation.

64. Point of care haemoglobin estimation was performed in theatre using a HemoCue and a level of 115 was read at the end of the primary operation. This was below the pre-operative level of 140 and in the context of cardiovascular instability, Dr Roberts decided to send formal laboratory samples for haemoglobin, platelet and coagulation assessment, and to transfuse packed red blood cells.

Second Surgery

65. At the end of the primary operation, Dr Roberts advised Dr Iyengar that Ruth's blood pressure had been labile during the vaginal part of the procedure and remained so post-surgery, and so she required small boluses of adrenaline intravenously and a 10mg/hr metaraminol infusion. A central venous line was inserted into her right internal jugular vein at this time. The anaesthetic agents were ceased and Ruth opened her eyes, and responded to voice command, but remained cardio vascularly unstable.

66. Dr Roberts advised Dr Iyengar that Ruth was not stable enough to be transferred from the operating table to her bed due to cardiovascular instability. Despite ongoing fluid resuscitation and the use of metaraminol, adrenaline and noradrenaline, cardiovascular stability could not be maintained. Point of care haemoglobin estimation and subsequent laboratory testing revealed low haemoglobin, raising the possibility of a source of concealed surgical bleeding.

67. According to Dr Iyengar, she remained in theatre and advised that she would be happy to reopen to exclude any possible surgical bleeding intraperitoneally, if the anaesthetist agreed to do so. However, it was decided by the anaesthetic team to give Ruth more time.

68. A second point of care haemoglobin estimation using HemoCue was performed (approximately 50 minutes after the first point of care haemoglobin estimation) and read at a level of 85. At this point, a major haemorrhage was declared in accordance with GVH protocol and packed red blood cells, fresh frozen plasma and platelets were requested from the blood bank and transfused. According to Dr Roberts, the formal laboratory blood samples supported this treatment as a low haemoglobin of 90, a low platelet count of 26 and slightly raised prothrombin time of 17s were reported.

69. Subsequently, Dr Iyengar and Dr Roberts agreed to re-anaesthetise and proceed with a laparotomy to exclude bleeding or another surgical issue as a cause of the ongoing hypotension.

70. Additional gynaecology surgical and anaesthetic staff were called to assist. Dr Iyengar called for her colleague Dr Tihomir Djorjic to attend theatre and asked him to perform the laparotomy as "a second surgeon's fresh eyes and hands were, in [her] view, required." Dr Djordjic was assisted by Dr Iyengar and Dr Akhter, the registrar.

71. Dr Djordic and Dr Iyengar reopened the vaginal vault by vaginal access by cutting out the sutures. About 400mls of dark venous blood came through the top of the vault per vaginum plus a couple of small clots. They notified Dr Roberts.

72. Dr Djordjic then commenced a midline laparotomy incision with the assistance of Dr Iyengar, which was easily performed. There was no evidence of fresh blood spillage from the cavity on entry and no evidence of spurting or fresh intra peritoneal 'welling' haemoperitoneum. There was no large or visible retroperitoneal bleeding or haematoma. They noted there was a pelvic collection in the area of the top of the vaginal vault of around 250mls of dark clots and venous ooze which was cleared. They packed the abdominal bowel with saline soaked abdominal packs to better expose the pelvic area of surgery.

73. According to Dr Iyengar, the left ureter was traced and appeared to run its normal course anatomically on inspection and palpation. The right side was being tracked and they picked up the vaginal vault by the right edge. It was noted there was no bleed higher up from either adnexae/adnexal pedicles or from the abdomen above the pelvis. Some minor ooze was visible from the right re-opened vaginal angle.

74. At about this time, general surgeon Dr Ruwangi Udayasiri, came into theatre from her adjoining operating suite and was asked to assist. Dr Udayasiri assisted in placing retractors in, and then explored the abdomen and examined the pelvis. According to Dr Iyengar, Dr Udayasiri agreed that there was no major vascular breach, ongoing fresh bleeding or organ injury within the abdomen, pelvis or in the abdominal wall.

75. At this point, 1000mls of dark blood had been suctioned (400mls from the vaginal vault area after reopening the vaginal suture line, and 600mls within the laparotomy, where the reopened vaginal vault was contributing to the ooze). In her statement, Dr Iyengar noted that there would have been some saline mixed into the sucker with these measurements, as saline was used to soak the bowel packs and irrigate at laparotomy.

76. The collection and ooze were noted to be clotted and 'old' venous blood. There were no spurting blood vessels in the area and no evidence of fresh and heavy blood loss. Dr Roberts was notified. Dr Udaysiri recommended closing all open sites as she had not found bowel or visceral injuries or vascular breaches.

77. Dr Roberts informed the surgical team that Ruth was having a cardiac arrest. They stopped handling the surgical site, stood back, and cardiopulmonary resuscitation was commenced. The cardiac arrest occurred approximately 20-25 minutes after they commenced the laparotomy surgery and occurred over several minutes.

78. Dr Iyengar noted that blood did not spill over the wound edges and did not well up filling the peritoneal cavity, but the prolonged cardiac thumping did cause some re-oozing into the re-opened vault area in the pelvis.

79. After additional theatre staff members came into the theatre, the surgical team resumed with intent to close all open sites expeditiously. A further 500mls of dark venous blood, mixed with fluid used to irrigate and soak bowel packs, was found to have collected within the pelvis during the prolonged cardiac resuscitation and was sucked through the sucker from the pelvis. The surgical team again conducted a thorough, repetitive check for any fresh, ongoing bleeds, slipped pedicles and spurting vessels but there were none visible.

80. As the surgical team was about the close the open vaginal vault and abdomen, Dr Roberts identified that Ruth had developed ventricular tachycardia and synchronised cardioversion was attempted three times in the form of 'stacked shocks' according to advanced life support (**ALS**) algorithms, to no success. The third attempted Direct Current Cardioversion (**DCR**) shock was not able to be delivered due to equipment failure. DCR pharmacological agent amiodarone was then administered to control ventricular tachycardia. Despite these actions, Ruth deteriorated to cardiac arrest.

81. A 'code blue' cardiac arrest was initiated as per GVH policy. An additional defibrillator machine was sourced promptly, and additional staff attended theatre to assist, including additional nursing staff, GVH Code Blue team, and anaesthetists Dr Juan Rodriguez, Dr JC Kruger and Dr Nigel Dunk.

82. Dr Roberts stated that the ALS standard of care was continued and cardiopulmonary resuscitation (**CPR**) was commenced immediately. Ruth was treated as per the documented resuscitation record with reversible causes of cardiac arrest considered. Likely pathology was treated or excluded as appropriate. Possibility of hypovolaemia was treated with crystalloid

and packed red blood cells. Hyperkalaemia identified on arterial blood analysis was treated with calcium gluconate and an actrapid insulin infusion. The possibility of coagulopathy was treated with blood products (fresh frozen plasma and platelets) and a bolus of tranexamic acid. Intralipid was also given as per international guidelines as Ruth had received an intraoperative infusion of lignocaine as part of the anaesthetic technique.

83. After 46 minutes of resuscitative efforts, it was agreed by all present that continuing was futile and resuscitation efforts were ceased. Ruth was pronounced deceased at 2.46pm.

Identity of the deceased

84. On 20 February 2018, Ruth Ann McKenna, born 28 December 1955, was visually identified by her sister, Leah Cotterell.

85. Identity is not in dispute and requires no further investigation.

Medical cause of death

Autopsy Report

86. On 22 February 2018, Forensic Pathologist Dr Malcolm Dodd from the Victorian Institute of Forensic Medicine (**VIFM**) conducted an autopsy on the body of Ruth Ann McKenna and provided a written report of his findings dated 15 May 2018.

87. The post-mortem examination revealed gynaecological surgical intervention. The operative site showed areas of suturing at the level of the vaginal vault, which appeared sound with no evidence of breakdown. The abdomen showed adherent blood clot masses on the mesentery and omentum and approximately 400ml of liquid blood was identified in the anatomical region of the hepatic flexure.

88. The post-mortem examination also revealed significant enlargement of the heart and a thickened right ventricular wall showing fatty infiltration and focal myofiber disarray, although the level of disarray was of no significance.

89. The post-mortem examination also showed cirrhosis of the liver.

90. Examination of the bone marrow showed a normocellular population. However, the megakaryocytes appeared decreased in number.

91. Toxicological analysis of ante-mortem samples identified the presence of fentanyl, temazepam, metoclopramide, propranolol, promethazine, ondasetron, lignocaine and bupivacaine consistent with medical treatment. Dr Dodd considered these were essentially non-contributory to Ruth's death.

92. Dr Dodd commented that it appeared Ruth suffered a cardiac arrest in the context of blood loss, cirrhosis (which would lead to a coagulopathy) and reduced megakaryocytes in the bone marrow (leading to reduced circulating platelets), again compounding the state of coagulopathy. He considered that the immediate cause of death appeared to be one of hypovolaemic and cardiogenic shock in a woman who had undergone a laparoscopic hysterectomy in the context of multiple comorbidities, including cardiomegaly, cirrhosis and apparent coagulopathy.

93. Dr Dodd noted that Ruth's comorbidities constituted a significant surgical risk and that in the presence of intraoperative blood loss, a state of disseminated intravascular coagulation (**DIC**) can often develop.

94. Dr Dodd provided an opinion that the medical cause of death was '1(a) Hypovolaemic and cardiogenic shock (hysterectomy) in the context of cardiomegaly, cirrhosis and coagulopathy'.

Alternative formulation of cause of death

95. Dr Iyengar disagreed with the cause of death as formulated by Dr Dodds and submitted that the cause of death would be more appropriately formulated as *'right ventricular hypertrophy and complex cardio-pulmonary -hepatic disease*'.

96. Dr Iyengar stated that:

> *I have been advised and believe that during the operation, this patient with significant cardiac disease decompensated when challenged by the expected (if higher than usual) range of blood loss due to complex surgery with positive pressure ventilation. This combination led to increasing pulmonary hypertension in Ms McKenna who had pre-existing probable pulmonary hypertension combined with reduced left ventricular filling and subsequent hypotension despite adequate fluid replacement. The RVH is arrhythmogenic and in the setting of myocardial hypoperfusion and inotropic support, Ms*

McKenna developed ventricular tachycardia that failed to respond to the usual resuscitative measures.

This is consistent with the pathologist's findings that Ms McKenna had a significantly enlarged heart measurements and muscle thickening at post mortem examination and that the right ventricular wall was much thickened.

97. Dr Iyengar referred to the RCA conducted by GVH (discussed below), which she stated had determined that Ruth had right ventricular hypertrophy (**RVH**) and probable pulmonary hypertension that had not been recognised during the pre-anaesthetic evaluation.

98. Dr Iyengar further referred to the Addendum to the RCA (discussed below), which determined that Ruth's RVH produced more lethal arrhythmia, and that her cardiac condition was of such complexity that it would likely have been overlooked by even a general cardiologist and only appreciated by an anaesthetist who worked predominantly in Liver Transplants Units.

99. Dr Roberts stated that she was unable to state the cause of Ruth's cardiac arrest, and in subsequent telephone contact with Ruth's next of kin confirmed she was unable to state a definitive cause of death.

100. Dr Dalton considered that the cause of death was:

one of an under appreciated cardiac condition, probably right ventricular hypertrophy with pulmonary hypertension, which caused the patient to have limited and poor response to intraoperative blood loss, resulting in arrhythmia and cardiac arrest.

Whilst the bleeding during the operation was contributory and much more than would normally be expected, the blood loss occurred over 4 hours in total. This rate of blood loss would have been easily managed with fluid replacement, and likely without detriment, had Ruth's cardiac function been less compromised.

Conclusion

101. I have carefully considered the submissions made by Dr Iyengar, in conjunction with the medical and expert opinions obtained through this investigation. Having considered these materials, I am satisfied that the cause of death was hypovolaemic and cardiogenic shock that arose in a hysterectomy procedure, in the context of cardiomegaly, cirrhosis and coagulopathy.

102. Whilst the evidence indicates Ruth had an under appreciated cardiac condition, most likely right ventricular hypertrophy with pulmonary hypertension which compromised her cardiac function, I am satisfied on the evidence before me that Ruth's death was ultimately caused by intraoperative blood loss which resulted in arrhythmia and cardiac arrest.

103. Accordingly, I accept and adopt the medical cause of death as formulated by Dr Dodd.

REVIEW OF CARE

Goulburn Valley Health's Root Cause Analysis

104. Goulburn Valley Health (**GVH**) appropriately identified Ruth's death as a sentinel event and conducted an internal RCA of Ruth's case under the Safer Care Victoria Sentinel Event Program.

105. The Sentinel Event Program (**program**) is designed to ensure sentinel events are investigated to identify deficiencies in healthcare systems and processes and that actions to prevent recurrence and reduce patient harm are implemented. The program aims to share, across the sector, lessons learned from sentinel events and subsequent innovations to improve patient safety.

106. The RCA investigation team was led by the Professor of Obstetrics and Gynaecology, assisted by the Professor and Chair of Anaesthesia, the Manager of Elective Admissions and the Patient Safety Officer. The RCA was completed on 24 April 2018.

107. Safer Care Victoria did not independently review Ruth's case but was provided with a copy of GVH's RCA report.

108. The RCA identified the root cause of the event as underestimation of Ruth's medical complexity, particularly the possibility of pulmonary hypertension, in the context of complex gynaecological surgery. Notably:

    a) There was no hepatology specialist review or pre-operative work up to determine the severity of Ruth's liver disease. In particular, Ruth remained on a hepatology wait list without escalation of this review and no tertiary hepatology review or opinion was sought;

    b) There was no cardiology specialist review or work up undertaken pre-operatively. There was a lack of collaboration between Ruth's general physician, surgeon, anaesthetic

clinician and specialist cardiology services, with no local or tertiary cardiology review or specialist opinion sought; and

c) Ruth's wishes were respected with the decision to perform the surgery at the local hospital. Ruth requested to have the procedure performed, understanding the alternative treatment and options. Ruth did not have the logistical support (funds, transport) to travel for tertiary specialist review, and had no desire to seek tertiary opinion of her condition.

109. In an addendum to the RCA Report dated 20 April 2018, it was further noted that the patient's complexities exceeded the level of expertise available in rural and regional hospitals. While Ruth's medical complexities may have been identified by an anaesthetist who worked predominantly in Liver Transplant Units, it was not expected that they should have been identified by a generally trained gynaecologist or anaesthetist in the context of a regional hospital.

110. Overall, the RCA concluded that no clinical practice performance issues were identified, that there was no misconduct or major transgression in practice, and that in no way was the standard of care negligent. Further, the RCA commended:

> *The maturity of the collegial management approach including collaborative clinical discussions, early escalation and seeking advice/second opinions of all staff involved in particular the anaesthetic and gynaecology surgical practitioners involved. It was evident during the investigation process that all staff were working together to optimise the best patient outcome possible despite the ultimate resultant demise of the patient.*

111. However, the RCA noted the specific difficulties experienced by Ruth in accessing planned tertiary medical assessments (particularly hepatology) due to the problems of cost and convenience. It found that it was "arguable" that:

a) the cost of these medical assessments should have been met by the Health Department; and

b) the surgery should not have taken place until these assessments had approved major surgery in a non-tertiary setting for this patient.

112. The learnings identified as a result of the RCA investigation were that:

a) The organisational culture reflects the absolute appropriateness of the theatre complex staff to initiate a 'code blue' response providing additional support for crisis management situations. This would be enhanced by all clinical staff having current Basic Life Support (**BLS**) certification and options for all medical staff to have ALS training with reinforcement of training by regular multidisciplinary simulation sessions.

b) The investigation during this case review demonstrated that the patient was booked for PAC homework and discharged from PAC homework without documentation of any outcome of homework review. Therefore, it was suggested to formalise the component of the PAC homework review to ensure consistent documentation of the review and outcome for patient safe to proceed to surgery.

c) The organisation should explore if the option of utilising Victorian Patient Transport Assistance Scheme (**VPTAS**) and other forms of funding are advocated when patients indicate financial restraints impact the accessibility of tertiary services.

113. Six recommendations were identified to address the root cause and learnings identified during the investigation, namely to:

a) Implement a model of care to further enhance coordination of complex patients in the pre-admission pathway and pre-anaesthetic clinics ensuring a robust multidisciplinary specialist approach;

b) Implement formal memorandum of understanding relationships with specialist tertiary centres for cardiology and hepatology disciplines in the context of patient selection for capacity for the organisation to perform elective surgical procedures for patients with medical comorbidities;

c) Implement a system to ensure all patients with substantive liver disease have an appropriate medical hepatology review prior to elective surgical intervention to determine the nature, severity and optimal management. Importantly, this referral is not primarily asking the hepatologist whether to proceed, or not, with surgery. That is a multidisciplinary decision;

d) Purchase equipment and implement bedside pathology testing facilities including the minimum data set of blood gas and haemoglobin testing in a central location within the organisation ensuring access for utilisation for intensive care and the operating theatre;

e) Review massive transfusion policy to ensure processes for activation and product release meet best practice for the organisational requirements; and

f) Review and implement increased organisational platelet stock availability to ensure supply is equal to the operational demand of the organisation (i.e. trauma, obstetric and surgical workload).

114. The plan for sharing the recommendations and learnings from this event was for the sentinel event report to be presented to the clinical senate committee for clinical governance of recommendation progress and distributed to the executive management committee for completion of risk reduction action plan. The recommendations and learnings were also to be distributed to divisional morbidity and mortality forums and learnings included in the biannual patient safety communique.

115. A progress report dated November 2018 indicated that GVH had completed actions in response to each of the six recommendations above. Specifically, in relation to each recommendation listed above:

a) A process of mapping was undertaken to identify gaps in the existing pre-admission and pre-anaesthetic clinic processes. A gap was identified with regard to escalation processes and timely response to referrals from anaesthetic clinic to other specialties, and changes to the referral form were actioned accordingly.

b) It was noted that GVH no longer uses Memorandums of Understanding for these types of services. However, contractual arrangements are in place with tertiary centres for cardiology and hepatology. GVH noted that as part of the model of care development, service delivery frameworks would be developed to support these specialist services.

c) Pre-admission clinic criteria were developed as part of the specialist hepatology review for elective surgical patients.

d) A briefing paper analysing the options for point of care testing in the hospital was tabled at the Clinical Operations Directorate Committee. However, it was determined that a review of relevant pathology test results that were needed to inform Ruth's care was performed as quickly as a point of care testing machine and reported in a timely manner.

e) A working group was formed and conducted a review the massive transfusion policy, including an evaluation of the use of particular products (fresh frozen plasma, platelets, packed cells). Gaps were identified and a recommendation was made to implement massive exsanguination packs (**MEPs**) which are configured to issue a pre-defined ratio of red cells. fresh frozen plasma, and platelets to a clinical area during a critical bleeding episode. Work was ongoing to bring the clinical practice guidelines in line with best practice, with oversight of the Blood Management Committee.

f) A briefing paper was tabled at the Clinical Operations Directorate Committee and Blood Committee with regard to the current platelet stock system and demand from the past 12 months to determine whether increased stock is required. It was noted that platelet base-line stock levels for the Shepparton site were recently doubled to two bags and are regularly reviewed, with replacement stock ordered where necessary to ensure that base-line unassigned stocks are maintained, while minimising wastage.

AHPRA Review

116. The Australian Health Practitioner Regulation Agency (**AHPRA**) conducted an investigation into Dr Iyengar's treatment of Ruth. The investigation considered whether Dr Iyengar appropriately assessed and managed the care of Ruth between November 2017 and February 2018, including whether she obtained full and informed consent and appropriately managed the post-operative review of Ruth's death.

117. As part of their investigation, AHPRA obtained an expert opinion from obstetrician and gynaecologist Dr Stephen Lyon. Dr Lyon was critical of the decision to perform a TLH on Ruth, given her co-morbidities. Dr Lyon also formed the view that the consent process adopted by Dr Iyengar was below the reasonably expected standard.

118. Dr Iyengar denied this and made submissions that conservative approaches were discussed with Ruth but that she opted for surgery.

119. Dr Iyengar also provided an expert opinion from Dr Bernadette White which concluded that Dr Iyengar's overall care of Ruth was appropriate. In Dr White's opinion, the hysterectomy was a reasonable option assuming that Ruth was assessed by an anaesthetist as being fit to undergo a major gynaecological procedure.

120. On 3 December 2020, AHPRA determined not to take any further action in relation to the care provided by Dr Iyengar to Ms McKenna. This was on the basis that it was unable to form the

view that Dr Iyengar's performance was below the standard reasonably expected of her in the management of Ruth, taking into account the differing expert opinions, the findings of the RCA that there were no major transgressions in practice, and the fact that the procedure was managed by a multi-disciplinary team of surgeons and anaesthetists.

121. As noted above, whilst I have considered AHPRA's findings, and I accept that there is a number of divergent opinions, I have placed greater weight on the advice provided by the CPU, including in relation to the independently obtained expert opinion obtained from Dr Dalton, as outlined below.

CPU Review

122. Ruth's case was also reviewed by the Coroners Prevention Unit (**CPU**). The role of the CPU is to assist coroners investigating deaths, particularly deaths which occur in a healthcare setting. The CPU is staffed by healthcare professionals and institutions under consideration. The CPU professionals draw on their medical, nursing and research experience to evaluate the clinical management and care provided in particular cases by reviewing the medical records, autopsy report and any particular concerns which have been raised.

123. Due to the specialist and technical aspects of this case, at my direction, the CPU commissioned an expert report from Dr Russell Dalton, a Consultant Obstetrician Gynaecologist with Ballarat Health Services and practices in regional areas.[13]

124. Dr Dalton was asked to provide an expert opinion as to:

    a) risks posed by, and options for investigating and treating, the endometrial polyp;

    b) risks posed by Ruth's co-morbidities, past surgical history and general health status;

    c) appropriateness of conducting the procedure at a regional health service;

    d) consent process;

    e) preparation and planning for the hysterectomy procedure;

    f) surgical procedure, operative technique and intra-operative surgical decisions;

[13] Dr Dalton is a Consultant Obstetrician and Gynaecologist with over 25 years experience, performing over 1500 laparoscopic procedures per year and more than 1000 laparoscopic hysterectomy procedures during his career.

g) cause of death (discussed above);

h) contributing factors; and

i) opportunities for systems improvement to prevent similar deaths.

Risks posed by, and options for investigating and treating, the endometrial polyp

125. Dr Dalton explained that the risk posed by an endometrial polyp found incidentally, without any associated symptoms, such as bleeding is relatively small. The numerical risk of malignancy increases in the menopausal state to about 5%, but in the absence of associated bleeding, the risk of malignancy is around 2%.

126. Whilst these risks are relatively small, standard gynaecological practice suggest that polyps, even if detected coincidentally should either be removed in the short term, or be subject to a brief interval of surveillance before removal. The reason for this approach is that removal via hysteroscopy is usually a straightforward procedure associated with minimal surgical related risk. There was a low to moderate degree of urgency to remove the polyp.

127. The options for investigation and treating Ruth's endometrial polyp were:

a) observation at two to three monthly intervals with ultrasound and review of symptoms, with a plan for surgical intervention if Ruth developed symptoms or the polyp was enlarging. This option carried a risk of delaying removal of a malignant polyp but needed to be balanced against the risks of surgical intervention;

b) hysteroscopy, uterine cavity curettage and removal of the polyp;

c) hysteroscopy and resection of the polyp using a resectoscope; or

d) where the polyp was unable to be removed, a hysterectomy.

128. Dr Dalton considered that given Ruth's co-morbidities and ASA status, the preferred initial treatment was a low level intervention – hysteroscopy and curettage – as was performed on Ruth in November 2017.

129. Dr Dalton explained that where there is a level of difficulty in removing a polyp, or accessing the endometrial cavity during the first hysteroscopy, a further option is to use a vaginal misoprostol to soften the cervix in a subsequent procedure. This usually allows the cervix to be dilated more easily, permitting a successful hysteroscopic removal of the polyp.

130. However, based on the difficulty faced in attempting to remove the polyp at the hysteroscopic procedure, Dr Dalton considered it was reasonable to advise Ruth to have a hysterectomy as the next step.

Risks posed by Ruth's co-morbidities, past surgical history and general health status

131. Ruth had a number of significant co-morbidities, namely chronic thrombocytopenia, compensated cardiac failure, alcoholic liver disease, chronic obstructive airways disease, elevated BMI and a history of previous surgery, one related to post appendicectomy abscess formation. She had also had a caesarean section in the past.

132. Dr Dalton noted that these co-morbidities posed a significant risk of excessive bleeding and a poor and limited cardiovascular response to haemodynamic challenges such as blood loss, reduced capacity to generate and produce blood clotting factors, respiratory compromise when in Trendelenburg position, reduced access to the peritoneal cavity and possible extensive peritoneal and pelvic adhesive disease.

133. Dr Dalton also noted that chronic liver disease may contribute to more rapid development of a coagulopathy in the situation of heavy bleeding due to reduced rates of coagulation factor production.

134. Dr Dalton considered that Dr Iyengar was aware of, and addressed, Ruth's co-morbidities before the operation during the consent process and by way of referral for pre-anaesthetic assessment.

Appropriateness of conducting the procedure at a regional health service

135. Dr Dalton considered that it was a matter for the clinical team involved in Ruth's care to decide whether the clinical scenario was one they were happy to deal with given the comorbidities that had been identified pre-operatively.

136. Dr Dalton explained that if the risks associated with the procedure made it inappropriate to perform the procedure at GVH, Ruth could be referred for surgery in a tertiary centre or to a colleague in another regional centre who had the requisite expertise.

137. Overall, he considered that it was reasonable to perform the procedure at GVH provided that the doctors were comfortable in managing the surgical risks.

138. However, Dr Dalton considered there were gaps in the planning process to manage intraoperative complications, such as the omission of review of investigations during the "homework session" on 30 January 2018, one week after Ruth's PAC appointment, and the lack of organising platelets to be available for use on the day of surgery.

Consent process

139. Dr Dalton considered the consent process undertaken by Dr Iyengar was adequate. The medical records confirmed that Dr Iyengar had explained the risks of the procedure and the risk of conversion to an abdominal procedure to Ruth.

Preparation and planning for the hysterectomy procedure

140. Dr Dalton noted that Ruth's significant co-morbidities were documented and identified. He considered that Ruth had appropriate pre-operative medical assessment, including in relation to her cardiac condition and thrombocytopenia.

141. In relation to Ruth's cardiac condition, Dr Dalton noted that her management was acceptable, and that planning included optimising her haemoglobin before the operation and withholding antihypertensive on the day of operation. However, he considered that given Ruth's low exercise tolerance, a contemporary echocardiogram to ascertain Ruth's current cardiac function would have been beneficial.

142. In relation to Ruth's thrombocytopenia, Dr Dalton noted that overall the planning and focus was acceptable, although a plan to cross much blood prior to surgery would have been beneficial.

143. Dr Dalton also considered that the preparation and planning on the day of surgery was adequate, except for the decision to commence surgery without having immediate access to platelets to manage the previously identified thrombocytopenia. Whilst the baseline count of 50 was just within the acceptable range for straightforward surgery, the other components of the clinical picture and identified risks were significant. Consideration of these could have led to a decision between the surgeon and the anaesthetist to cancel or delay the operation until platelets were available for administration. If this decision had been made, it would have likely reduced the amount of bleeding that occurred during the hysterectomy.

144. Dr Dalton considered that Dr Iyengar clearly anticipated an increased degree of difficulty in the processes involved to perform the operation, reflected in her decision to allocate an entire

operating list to perform the procedure, and correspondence to Ruth's General Practitioner on 29 November 2017 which noted the high risk of conversion.

145. Noting the anticipated difficulty, Dr Dalton considered that further steps could have been undertaken to prepare for intraoperative complications, namely:

    a) insistence on Ruth getting a further opinion from a complex gynaecological surgery specialist such as a gynaecological oncologist and having surgery in a tertiary centre;

    b) planning to undertake the procedure with a local specialist colleague from the outset;

    c) performing the procedure as an open operation from the beginning of the procedure; and

    d) advising a non surgical approach to management of the polyp, at least in the short term.

Surgical procedure, operative technique, and intra-operative surgical decisions

146. Dr Dalton reviewed Dr Iyengar's operative technique and surgical choices. He considered the patient positioning was standard practice. The placement of additional access ports for the laparoscope and instruments was not standard, but he noted this possibly reflected a requirement to place additional ports to manage access to the operative field due to adhesions.

147. Dr Dalton noted that Dr Iyengar was unable to place the 'Rumi vaginal manipulator' instrument prior to commencing the procedure. This device (and other cervicovaginal delineator devices) facilitates the safe dissection (ie. careful separation without damage) of the bladder from the anterior cervix, particularly in situations where there is a caesarean scar, as was the case here. This instrument is also essential to dissect the bowel from the posterior cervix. Dr Dalton commented that it is virtually impossible to perform a laparoscopic hysterectomy without the instrument in place and recourse to an open abdominal hysterectomy would have been a safer option.

148. Dr Dalton considered the decision to perform a vaginal hysterectomy and the surgical steps taken and choices made were acceptable. However, with the benefit of hindsight, the completion of the procedure would have been better managed by conversion to a laparotomy (ie. opening the abdomen). Dr Dalton explained that in his personal experience, he would not plan to perform a laparoscopic hysterectomy without a cervicovaginal delineator in place as there is a major increase in the risk of injuring the bladder during mobilising of it from the anterior cervix, and it would be very difficult to know where to divide the uterine arteries.

149. Dr Dalton estimated that the blood loss during the procedure was 2000-2500mls. He explained that normally 150-200mls of blood loss would be anticipated from the procedure. Dr Dalton considered that Dr Iyengar's response to the bleeding was generally appropriate, but the bleeding, which he considered was predominantly from the vaginal component of the operation, was not adequately controlled.

150. Given that the bleeding occurred over four hours, Dr Dalton considered that the resuscitation was adequate.

151. Dr Dalton considered it was sensible to keep Ruth on the operating table whilst she was unstable. Dr Dalton also considered the steps undertaken following the decision to re-anaesthetise Ruth were standard and reasonable, including requesting additional assistance from colleagues and re-exploring the surgical site and ongoing bleeding.

152. In all of the circumstances, Dr Dalton considered the surgical steps taken and choices made were acceptable. However, considering that the procedure was anticipated to be difficult, the complexity of the surgical findings and the fact that there was bleeding in excess of usual for a laparoscopic hysterectomy, a very high level of surgical skill was required.

153. Dr Dalton observed it is up to the individual surgeon to determine whether they have the requisite skills when assessing a surgical scenario and to make reasonable decisions about the management steps. These steps could include ceasing the procedure and replanning the operation with a colleague who has additional, or specific, skills.

Contributing factors

154. Dr Dalton considered that the cause of death was one of an under appreciated cardiac condition, probably right ventricular hypertrophy with pulmonary hypertension, which caused Ruth to have a limited and poor response to intraoperative blood loss, resulting in an arrhythmia and cardiac arrest. Whilst the bleeding during the operation was contributory, and much more than would normally be expected, the blood loss occurred over four hours in total. This rate of blood loss would have been easily managed with fluid replacement, and likely without detriment, had Ruth's cardiac function been less compromised.

155. Dr Dalton considered that Ruth clearly had significant comorbidities which were underestimated and the complexity of the surgery appeared to be on the boundary of Dr Iyengar's skill base. Dr Dalton noted that the GVH RCA considered that staff knowledge/skills were not a contributing factor. If this was the case, this would mean that

Ruth's demise was inevitable in anyone's hands, and in any clinical workup scenario. In Dr Dalton's opinion, this was not a correct assumption.

156. Dr Dalton also considered that in the context of a recognised complex case, the scheduling of two consultants to operate together from the outset, and/or a request for assistance from a colleague early on in the procedure would have greatly improved the team structure. Dr Dalton considered that the subsequent request for, and attendance of, other colleagues at the time of the second operation was commendable and appropriate.

157. With the benefit of hindsight, Dr Dalton considered there were two decisions that may have changed the outcome: the decision to commence the operation prior to Ruth receiving the platelet infusion; and the decision to continue the operation, and a laparoscopic approach in particular, when the findings upon entering the peritoneal cavity were so complex.

158. Dr Dalton noted that Ruth received the platelet infusion as part of resuscitative manoeuvres at 2.23pm. Had the platelet infusion been administered before or at the time of commencement of the surgery, Dr Dalton considered that it is reasonable to assume that the amount of, or tendency for, bleeding, would have been reduced.

159. Dr Dalton explained that there are many scenarios when, upon accessing the peritoneal cavity and assessing the findings, a surgeon would assess the situation as being out of capability. The assessment of capability not only relates to personal surgical skill, but should encompass other clinical factors such as comorbidities, location of the proposed operation, team structure and access to remedial resources if a complex situation were to arise. In this case, despite complex findings upon entering the peritoneal cavity, Dr Iyengar determined to continue the surgery.

<u>Opportunities for systems improvement</u>

160. Dr Dalton agreed with the root causes, learnings and recommendations outlined in the GVH RCA and specifically commended GVA's commitment to enhance coordination of care for complex patients at the pre-admission stage and develop relationships with tertiary specialist services for patients with hepatology and cardiology co-morbidities.

161. Dr Dalton made further suggestions that:

    a) patients should not be placed on the waiting list for surgery until final sign off of all investigations requested during the pre-anaesthetic consultation. In this case, review of

investigations would have provided a further opportunity to assess and quantify the degree and number of co-morbidities; and

b) patients with reduced exercise tolerance and possible underlying cardiac problems should also be given streamlined access to echocardiography services in specialist tertiary centres.

162. I agree with Dr Dalton's comments and have made recommendations in line with this.

Conclusions

163. Dr Dalton concluded that Ruth's tragic death occurred in the context of all clinicians trying to do their best for her, but that it raised some opportunities for health authorities to consider as they work towards better, and consistent, outcomes for people who choose to undergo laparoscopic surgery, and in particular, laparoscopic hysterectomy.

Further opportunities for improvement

164. In her statement to the court, Dr Iyengar explained that following this incident she had confirmed that she did not receive any correspondence from the PAC regarding Ruth whilst she was on leave, and no telephone messages were left for her.

165. Dr Iyengar noted that at GVH, surgeons were rarely formally advised about the outcome of the PAC unless they wanted to cancel the surgery or transfer the case. If the PAC did contact the surgeon, it would be in writing, which she noted would often be received late, or surgeons would find out about PAC decisions by initiating a discussion with the anaesthetists or by receiving a call from a nurse in the pre-operative booking suite.

166. Dr Iyengar identified that there could be a better system of communication between the PAC and surgical team.

167. I agree with Dr Iyengar's comments, which align with the GVH RCA recommendation to implement a model of care to further enhance coordination of complex patients in the pre-admission pathway and pre-anaesthetic clinics ensuring a robust multidisciplinary specialist approach. I have made recommendations accordingly.

FINDINGS AND CONCLUSION

168. I express my sincere condolences to Ruth's family for their loss. I also wish to acknowledge the distress the prolonged coronial process has caused them.

169. Pursuant to section 67(1) of the *Coroners Act 2008* I make the following findings:

    a) the identity of the deceased was Ruth Ann McKenna, born 28 December 1955;

    b) the death occurred on 19 February 2018 at Goulburn Valley Hospital, 2 Graham Street, Shepparton, Victoria, 3630, from hypovolaemic and cardiogenic shock (hysterectomy) in the context of cardiomegaly, cirrhosis and coagulopathy; and

    c) the death occurred in the circumstances described above.

170. In the interests of procedural fairness, draft findings were provided to Dr Iyengar, GVH, and Dr Dalton for response. Extensive comments were provided on behalf of Dr Iyengar which were carefully considered in finalising this matter. No further comments were provided by Dr Dalton, while GVH raised two factual inaccuracies which were subsequently clarified.

COMMENTS

Pursuant to section 67(3) of the Act, I make the following comments connected with the death.

171. In his concluding remarks, Dr Dalton noted that the circumstances of Ruth's death presented an opportunity for health authorities to consider how they might work towards better, and consistent outcomes for women who choose to undergo laparoscopic surgery, and in particular, laparoscopic hysterectomy.

172. Dr Dalton noted that, in general terms, there can be a disconnect between clinician and service capability and the complexity of the clinical case.

173. In order to enhance quality and accountability in laparoscopic gynaecological surgery, Dr Dalton advocated for the establishment of a laparoscopic surgery database within Victoria (and ideally, Australia), to enable health authorities such as RANZCOG and the Department of Health to access live outcome data, provide feedback to clinicians, target training, or make recommendations to clinicians and services regarding service capability.

174. Dr Dalton also suggested that all gynaecologists applying for credentialling for advanced laparoscopy should present logged outcome data from preceptorship training, and have increasing levels of credentialling over time to allow for increasing clinical complexity, based on their patients' outcome data.

175. The circumstances of Ruth's death highlight the complexity of laparoscopic hysterectomy procedures, particularly in the setting of multiple co-morbidities. Noting these complexities

and having regard to my function of promoting public health and safety, I have made a recommendation in line with this.

RECOMMENDATIONS

Pursuant to section 72(2) of the Act, I make the following recommendations:

1. I recommend that Goulburn Valley Health:

    a. Considers a review of its policies and procedures to ensure that patients are not placed on the waiting list for surgery until final sign off of all investigations requested during the pre-anaesthetic consultation;

    b. work with echocardiography services to streamline assessments for patients with reduced exercise tolerance and possible underlying cardiac problems; and

    c. review the system of communication between the pre-anaesthetic clinic and surgical teams to ensure surgeons are apprised of the outcome of PAC review, management plans and (where necessary) requests for further investigations and the outcome of same, in advance of the surgery date.

2. I recommend that the Royal Australian and New Zealand College of Obstetricians and Gynaecologists liaise with the Department of Health to explore the possibility and feasibility of developing a laparoscopic surgery database within Victoria to enhance quality and accountability in laparoscopic gynaecological surgery. Such a database could enable health authorities to access live outcome data, provide feedback to clinicians, target training, and make recommendations to clinicians and services regarding service capability.

ORDERS AND DIRECTIONS

Pursuant to section 73(1A) of the Act, I order that this finding be published on the Coroners Court of Victoria website in accordance with the rules.

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

Ms Leah Cotterell, Senior Next of Kin

Associate Professor Vasudha Iyengar c/ Ms Madhavi Ligam, Avant Law

Dr Helen Roberts

Dr John Elcock, Goulburn Valley Health

Mr Roland Hunt

Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Professor Euan Wallace, Secretary of the Department of Health (Vic)

Australian Health Practitioner Regulation Agency

Signature:

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Coroner Leveasque Peterson

Date : 19 August 2022

NOTE: Under section 83 of the ***Coroners Act 2008*** ('the Act'), a person with sufficient interest in an investigation may appeal to the Trial Division of the Supreme Court against the findings of a coroner in respect of a death after an investigation. An appeal must be made within 6 months after the day on which the determination is made, unless the Supreme Court grants leave to appeal out of time under section 86 of the Act.