

IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2018 5623

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2)
Section 67 of the Coroners Act 2008

Findings of:

Sarah Gebert, Coroner

Deceased:

Mrs L

Date of birth:

1966

Date of death:

31 October 2018

Cause of death:

1a) Neutropenic sepsis leading to multi-organ failure

1b) Rectal cancer T2N0M0 post neoadjuvant

chemotherapy and radiotherapy

Place of death:

Royal Melbourne Hospital, 300 Grattan Street,

Parkville, Victoria

Key Issues:

Capecitabine toxicity, progress in availability of

antidote in Australia

Introduction

- 1. Mrs L (referred to by her family as "") was a 52 year old woman who died at the Royal Melbourne Hospital (RMH) on 31 October 2018. At the time a Medical Certificate Cause of Death (MCCD) was completed. The cause of death was noted as:
 - 1 a) Neutropenic sepsis leading to multi-organ failure
 - 1 b) Rectal cancer T2N0M0 post neoadjuvant chemotherapy and radiotherapy.
- 2. Mrs L's husband, Mr L, communicated with the Coronial Admissions and Enquiries office prior to the funeral to raise concerns about her death. As the burial was about to proceed, the family elected to first conduct the burial and await a review of whether the death was reportable.
- 3. A reportable death under the *Coroners Act 2008* (Vic) (the Act) includes a death that appears to be unexpected, unnatural or violent, or to have resulted, directly or indirectly, from an accident or injury.
- 4. On 29 November 2018, following a review of material by the forensic pathologist, it was determined that the death was not reportable and the MCCD was reasonable.
- 5. On 3 December 2018, the investigating coroner decided to investigate the death on the basis that the treatment, rather than the cancer, was the cause of death and that the death was medically unexpected in view of Mrs L's age, general health and stage one cancer. In addition, that chemotherapy falls under the definition of a medical procedure and the death was the result of a rare toxic reaction rather than a progression of disease.

The coronial process

6. A coroner independently investigates 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. Coroners make findings on the balance of probabilities, not proof beyond reasonable doubt.²

Deputy State Coroner English.

² This is 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.

- 7. Coroners are also empowered to report to the Attorney-General on a death they have investigated. Coroners have the power to comment on any matter connected with the death, including matters relating to public health and safety or the administration of justice; and the power to make recommendations to any Minister, public statutory or entity on any matter connected with the death, including recommendations relating to public health and safety or the administration of justice.³ This is generally referred to as the prevention role of the coroner.
- 8. In this case both the medical cause of death and identity had already been determined.

Background

- 9. In August 2018 investigations revealed that Mrs L had rectal cancer. She had presented with rectal bleeding, change of bowel habit and weight loss. Following a colonoscopy in late August 2018, she was diagnosed with ano-rectal junction adenocarcinoma (**T2N0M0**). The T2N0M0 classification indicates the cancer has grown through the most superficial internal lining of the bowel (the mucosa) and into the next two layers of the bowel wall, that is the submucosa and muscularis propria (**T2**). It had not spread outside the bowel wall to lymph nodes (**N0**) or distant sites (**M0**). A PET scan showed the rectal primary tumour and no spread.
- 10. On 3 September 2018, a lower gastro-intestinal service multidisciplinary team meeting documented that Mrs L was diagnosed with rectal adenocarcinoma. Given how low the tumour was in the bowel there was a risk of inability to resect the tumour surgically. It was decided that Mrs L would have a long course of chemo and radiotherapy (LCCRT). Neoadjuvant chemo/radiotherapy⁴ was planned.
- 11. On 12 September 2018, Mrs L saw the colorectal surgeon Mr Jacob McCormick who advised surgery would likely occur post chemo/radiotherapy.
- 12. On 24 September 2018, the radiation oncology registrar reviewed Mrs L. She outlined the risks of radiotherapy to Mrs L.
- 13. On 25 September 2018, consultant medical oncologist Dr Jeanne Tie saw Mrs L and advised her of the planned chemotherapy. She informed her of the risk of severe toxicity

³ Sections 72(1), 72(2) and 67(3) of the Act regarding reports, recommendations and comments respectively.

⁴ Neoadjuvant therapy, in contrast to adjuvant therapy, is given before the main surgical treatment usually to shrink the size of the tumour to enable easier surgical **removal**.

from DPD deficiency⁵ from capecitabine and that there was no validated test to detect the enzyme deficiency. Mrs L was given the prescription on 3 October 2018 and advised to commence the capecitabine on the day radiotherapy commenced and to return every two weeks with blood tests for review.

CIRCUMSTANCES IN WHICH THE DEATH OCCURRED

- 14. On 17 October 2018, Mrs L commenced LCCRT for treatment of her rectal cancer which included 1300mg oral capecitabine twice daily and radiotherapy. A statement from her family indicated that Mrs L had the chemotherapy and radiation treatment on 17, 18 and 19 October and began to develop mouth ulcers on 20 October 2018.
- 15. On 23 October 2018, Mrs L was seen at the RMH Emergency Department (**ED**) with throat tightness and voice change after use of Peter MacCallum Cancer Centre (**PMCC**) mouth wash for her symptoms of difficulty swallowing. She was admitted to the Short Stay Unit overnight.
- 16. On 24 October 2018, Mrs L was reviewed by the ear, nose and throat (ENT) registrar. Her mouth was noted to be ulcerated and the area near the vocal cords was swollen. Her condition was thought to be a reaction to the mouthwash and daily radiation continued. Mrs L and her husband continued to raise concerns that she was not feeling well.
- 17. On 26 October 2018, the radiation oncology registrar at the PMCC, Dr McMahon, reviewed Mrs L. He noted pain on swallowing since 21 October 2018, feeling dizzy and lethargic, an episode of vomiting and three episodes of diarrhoea. Mrs L's blood pressure was 90/65 mmHg (slightly decreased) and her heart rate varied between 115 and 137 beats per minute (bpm) (elevated). Mrs L was admitted to the PMCC with oral mucositis⁶ and poor oral intake in the setting of commencing capecitabine nine days prior. Capecitabine was withheld at that time.
- 18. On 27 October 2018, Mrs L was more unwell with diarrhoea and dehydration with a persistently elevated heart rate.
- 19. On 28 October 2018, diarrhoea and oral mucositis continued with increasing dehydration, electrolyte derangement, neutropenia⁷ and thrombocytopaenia, abdominal pain and hiccups.

⁵ Dihydropyrimidine dehydrogenase (DPD) deficiency is a condition in which the body cannot break down the nucleotides, thymine and uracil. DPD is required to break down capecitabine and the lack of the enzyme can cause severe toxicity to the drug.

⁶ Inflammation and subsequent shedding of mucous membranes that line the gastro-intestinal tract.

⁷ Low white cell count.

⁸ Low platelet count.

At 9.00pm a Medical Emergency Team (MET) call was made for a very low blood pressure of 54 mmHg systolic and heart rate of 126 bpm. Overwhelming infection was suspected; the sepsis pathway was commenced, intravenous fluids were continued, and antibiotics were administered.

- 20. At approximately 10.43pm, 28 October 2018, Mrs L was transferred to the intensive care unit (ICU) at the RMH. She continued to deteriorate. Medication to support blood pressure along with all ICU standard management were instituted. There were discussions with the surgical team overnight. A CT scan of Mrs L's abdomen indicated inflamed bowel that was considered most likely due to neutropenic enterocolitis. The surgeons reviewed Mrs L at 8.15am. Surgery was not required for the capecitabine induced inflammation as there was no ischaemia or perforation.
- 21. At 9.35am the medical oncology team from PMCC reviewed Mrs L. They diagnosed capecitabine toxicity causing pancytopaenia, enterocolitis and possible sepsis. The medical oncology team planned to commence Uridine Triacetate (Vistogard), the antidote to capecitabine. The family stated that this was sourced from another patient. The team also suggested the use of G-CSF.¹⁰
- 22. Mrs L was intubated due to further deterioration. Her surgeon reviewed her at 7.00pm and noted Vistogard had been commenced. On the night review, the following problems were noted: neutropenic sepsis, requiring high dose inotropic support, coagulopathy, low K +, bicytopaenia (low white cells and platelets) and metabolic acidosis. Mrs L was given blood products and vitamin K to reverse coagulation disturbance.
- 23. On 30 October 2018 the medical oncology team reviewed Mrs L and noted her problems of suspected capecitabine toxicity, neutropenic sepsis and hypotension, anaemia, coagulation disturbance and need for intubation. There was a meeting with Mr Lto inform him of Mrs L's serious condition.
- 24. Overnight on 30 to 31 October 2018 dialysis was commenced. At 5.15am, Mr L was urgently called due to his wife's further deterioration. Her heart rate slowed and cardiopulmonary resuscitation (CPR) was commenced. Full resuscitation was undertaken. At 5.55am, Mrs L had a return of circulation, then a further cardiac arrest. Despite some

¹⁰ Granulocyte-colony stimulating factor (G-CSF or GCSF), stimulates the bone marrow to produce granulocytes and stem cells and release them into the bloodstream.

Neutropenic enterocolitis is an acute life-threatening condition classically characterized by transmural inflammation of the cecum, often with involvement of the ascending colon and ileum, in patients who are severely immunosuppressed.

intermittent return of circulation Mrs L died on 31 October 2018 whilst receiving maximal medical support.

The Coronial Investigation

- 25. As part of the coronial investigation, advice was sought from the Coroners Prevention Unit (CPU) regarding the medical management of Mrs L. The CPU is staffed by healthcare professionals, including practising physicians and nurses, who are not associated with the health professionals and institutions under consideration and are therefore able to give independent advice to coroners.
- 26. A review was conducted of medical records from both RMH and PMCC.
- 27. Mrs L's family wrote of their concerns regarding the initial diagnosis of an allergic reaction at the RMH, a lack of communication between RMH and PMCC as well as the quality of communication with family. They also queried whether the *antidote* had to be sourced from America but was then apparently sourced from another patient and whether earlier administration may have altered outcome. It is understood that there were meetings following Mrs L's death with the family, two at PMCC and one at RMH.
- 28. Statements were obtained including from Dr Richard Waller, Emergency Physician, RMH dated 11 July 2019, Dr Rohit D'Costa, Director, ICU, RMH dated 12 July 2018 and Dr Danny Rischin, Director of Medical Oncology, PMCC dated 11 July 2019 and 19 March 2020.
- 29. In addition, advice was obtained from the Medical Oncology Group of Australia (MOGA) regarding the PMCC recommendations. MOGA's advice was provided by Dr Prunella Blinman, Chair dated 1 October 2019.
- 30. Further, the proposed findings and recommendation were foreshadowed with all parties for their consideration and response.
- 31. As part of this process, the family continued to raise concerns about the communication with the both RMH and PMCC, which is addressed separately below.

Uridine Triacetate (Vistogard), the antidote to capecitabine

32. Enzymatic degradation of the fluoropyrimidine drugs, 5-fluorouracil (5FU) and capecitabine included, is mediated by the enzyme dihydropyrimidine dehydrogenase (DPD). Mutations in the DPYD gene that impair DPD activity can cause life-threatening toxicities from fluoropyrimidines. Uridine Triacetate (UT) is an FDA-approved antidote for use in 5-FU or

- capecitabine overdose within 96 hours of the last chemotherapy dose, but it is not available or readily accessible in Australia.¹¹
- 33. In the past, testing for the relative or complete enzyme deficiency was possible but complicated by the early tests being unreliable and difficult to interpret, slow turnaround time of results potentially delaying treatment, and cost. These factors have however changed over time and are discussed below.¹²

Statement from Mrs Caval's treating physicians

23 and 24 October 2018

- 34. A number of statements were obtained from Mrs L's treating doctors. Dr Richard Waller, Emergency Physician, RMH saw Mrs L in the RMH ED. Dr Waller stated that Mrs L presented to the ED one hour and 45 minutes after using the PMCC mouthwash having experienced throat tightness and voice change 30 minutes following its use. He was aware that Mrs L was taking capecitabine. She was admitted to the short stay unit and reviewed by the ENT team the following day. He did not consider Capecitabine toxicity. He did not contact PMCC as he believed she had been referred by PMCC and that she would be closely followed up there.
- 35. Dr Danny Rischin, Director of Medical Oncology, PMCC said that as far as he was aware there was no communication between RHM ED and PMCC staff following Mrs L's attendance at ED, and that RMH ED staff were aware when she was discharged that she had a review appointment with radiotherapy at Peter Mac on 25th October and that was their follow-up plan.

26 to 29 October 2018

36. Dr Rischin stated that the working diagnosis when Mrs L was admitted to PMCC on 26

October 2018 was capecitabine toxicity with mucositis and diarrhoea and associated

In a publication in 2017 the US National Institutes of Health found that about 275000 patients receive treatment with 5-FU and more than 1300 (0.5%) die from 5-FU toxicity every year in the US from life-threatening myelosuppression, gastrointestinal complications and neurotoxicity. Immunocompromised persons are at higher risk of developing toxicity. Recently, UT (Vistogard) has been approved by the Food and Drug Administration (FDA) as the only specific antidote available for 5-FU poisoning. In a clinical trial (n=135), 96% of patients with 5-FU toxicity recovered after treatment, whereas in a historical control group only 10% survived. Santos C, Morgan BW, Geller RJ. The successful treatment of 5-fluorouracil (5-FU) overdose in a patient with malignancy and HIV/AIDS with uriding triacetate. Am J Emerg Med. 2017 May;35(5):802.e7-802.c8. doi: 10.1016/j.ajem.2016.11.038. Epub 2016 Nov 15.

¹² Coroner Spanos investigated the death of Graeme H Griffiths (COR 20154937) from capecitabine toxicity and made recommendations which included a request that the Medical Oncologist Group of Australia reconsider whether testing for DPD deficiency should be standard care for patients proposed to be commenced on 5-FU chemotherapy treatment but given the barriers at the time was not recommended as routine care.

dehydration due to poor oral intake. In response to the Court's question as to whether the use of Vistogard was considered on 26, 27 or 28 October 2018 and whether there were any barriers to prescribing it, Dr Rischin stated that the use of Vistogard was not considered until 28 October 2018 noting that there was some initial lack of familiarity by the covering doctor about the process for accessing the drug, but that doctor was able to obtain relevant information after consulting others and checking hospital policy. The drug was accessed through some unused Vistogard from another patient while they waited the full course of treatment to arrive from the US.

- 37. Dr Rischin was asked whether any progress had been made regarding PMCC becoming a repository for Vistogard. He wrote that despite numerous attempts to contact Wellstat, ¹³ there had been no success.
- 38. I note that the Court also attempted to contact Wellstat by email and by phone without success. From previous inquiries, the Therapeutic Goods Administration (**TGA**) cannot approve the drug for use in Australia unless Wellstat approaches them. Currently, the drug remains available only via a Special Access Scheme (**SAS**) where it is supplied on an urgent case by case basis. However, PMCC has now approached the TGA about whether PMCC may become a sponsor of an unapproved therapeutic good in order to be able to directly import the drug.
- 39. With respect to DPD testing Dr Rischin indicated several advances have been made. The test has become more reliable, less expensive (\$99) and that studies on feasibility and cost analysis have shown DPD testing to be readily able to be embedded into routine clinical practice. There are no Australian recommendations yet and the test is not covered by Medicare.
- 40. Dr Rischin also provided information regarding the medical record system and ability to communicate across the RMH and PMCC. Both facilities share and can see each others' medical records and there was to be a new electronic medical record (EPIC), across these two hospitals and the Royal Women's Hospital. The transition was to be completed by May 2020, but due to the COVID-19 pandemic this roll out has been delayed.
- 41. The Court was advised that Mrs L's case was reviewed at both the PMCC Department of Medical Oncology morbidity and mortality meeting and the PMCC Adverse Events Committee. The following issues were identified:
 - Difficulty in recognising early toxicity of this class of drug.

¹³ The US manufacturer of Vistogard.

- Lack of awareness by after-hours staff of how to access Vistogard.
- No clear guidelines on pre-emptive testing for DPD deficiency.
- 42. The following recommendations were made:
 - Patient alert card to be developed for patients receiving the fluoropyrimidines –
 delivered.
 - Pathway and policy for early recognition of toxicity –nurse led clinic to contact all patients receiving the drug within the first week of treatment.
 - PMCC pharmacy to stock uridine triacetate –as yet unable to set up a formal arrangement with Wellstat or the TGA but PMCC has maintained some limited stock and Mrs L was treated with onsite stock.
 - Development of an education program for all tumour streams using fluoropyrimidines and also for RMH and ICU staff.
 - The PMCC Pharmacy and Therapeutic Advisory Committee (PTAC) will have commenced testing all patients prescribed fluoropyrimidines in the next three months.
- 43. Dr Rischin noted that meetings were held with family on 4 and 24 December 2018 and that,

 Problems with communication were acknowledged including the need for improvement in

 this area and an apology was made.

28 and 29 October 2018

- 44. Dr D'Costa, Director, ICU, RMH outlined the management in ICU from late on 28 October 2018. He stated that the differential diagnoses were an abdominal surgical problem or neutropenic enterocolitis.
- 45. Capecitabine toxicity was raised by the medical oncology team with the ICU team on the morning of 29 October 2018 and Vistogard was obtained via the PMCC pharmacy and was first administered at 12.00pm on 29 October 2018, three and a half hours after it was suggested by the oncology team. It was supplied rapidly by the PMCC pharmacy.
- 46. Mrs Ls death was discussed at the ICU mortality meeting and the ICU team also contributed to the PMCC multidisciplinary clinical incident review. The ICU audit found that there were no prevention opportunities as Mrs L had presented to the ICU in severe shock and had not responded to full resuscitative measures.
- 47. The team acknowledged the educational opportunity as capecitabine toxicity is rarely seen in ICU.

Outcome of CPU Review

- 48. The CPU noted that the doctors at PMCC recognised the condition (capecitabine toxicity) as a possible working diagnosis on 26 October 2018 but the *antidote* was not considered by PMCC until 28 October 2018, noting that there was some initial lack of familiarity by the covering doctor about the process for accessing the drug.
- 49. The doctors at PMCC did not convey their concerns to the RMH ICU team who were not aware of the condition and therefore, the possibility of administering the antidote prior to 12.00pm on 29 October 2018 was not considered by them. The CPU considered that the RMH ED diagnosis and management was reasonable in these circumstances.
- 50. The CPU considered that at the time of ICU admission, administration of the antidote appears to have been warranted and there was a <u>delay</u> to its administration of at least 12 hours, possibly longer. Ideally the drug should be administered within 96 hours of cessation of the capecitabine. The drug was ceased on admission on 26 October and the uridine triacetate administered on 29 October 2018.
- 51. I note that PMCC conceded that there was a delay in the diagnosis of DPD deficiency and in the administration of the antidote by their staff over the weekend, with Mrs Caval's admission having occurred late on 26 October 2018 with the uridine triacetate not administered until 29 October 2018.
- 52. The CPU noted that the lack of availability of a universally accessible, reliable, inexpensive test for DPD deficiency was responsible for non-testing of Australian patients until this point.
- Factors contributing to Mrs L's death included the relative rarity of her condition and the lack of familiarity with it for some of the clinical staff.
- 54. Earlier administration of the drug would have no doubt improved Mrs L's chances of survival, and the earlier this took place further likely to have increased her opportunity for survival.

COMMENTS

- 55. I make the following comments connected with the death under section 67(3) of the Act.
- Mrs L died of toxicity to the chemotherapy agent capecitabine. Similar investigations into deaths from this drug have identified an absence of a test for the deficiency of the

- enzyme required to metabolise the drug and unavailability of the antidote in Australia. The investigation into Mrs L 's death has revealed significant progress in both these issues.
- 57. Mrs L's family should be commended for their courage in reporting her death to the Coroners Court and facilitating this further investigation of capecitabine toxicity.
- 58. Dr Rischin has indicated major improvements in the areas contributing to Mrs L's death.

 They have recognised the rarity of the condition and addressed this by education, patient alert cards to alert any treating clinician of the possibility of this reaction and a clinic specifically responsible for following up all patients commenced on the drug to check for early symptoms.

 PMCC continues to address the difficulties with obtaining access to uridine triacetate and are currently in discussion with the TGA regarding importing the drug. PMCC has introduced DPD deficiency screening in all patients commencing this class of drug.
- 59. It is apparent that major changes have occurred in this area, such that medical oncologists (at PMCC) have moved from a position where there was no way of testing for the condition, so that some people would develop the condition and be managed to the best of their ability, to now actively being able to test and treat, the commencement of routine testing and continued attempts to establish an Australian repository for Vistogard.
- 60. Dr Prunella Blinman, chair, MOGA, advised the Court that the PMCC changes were consistent with expected best practice and directly address the issues that surround the case.
- Dr Blinman did however consider that despite emerging evidence on DPD testing, major practical barriers remain that preclude routine DPD testing in Australia. She noted that genetic testing is difficult to interpret (however PMCC are now using enzymatic testing). Dr Blinman indicted that the test is currently difficult to access for some oncologists, is slow (10 days) and may significantly compromise outcomes by causing substantive delays and is expensive (at \$200). Therefore, MOGA was of the view that mandated DPD testing for all patients cannot be currently recommended as routine care.
- 62. The Court sought a further response from PMCC, who indicated by correspondence dated 19 March 2020 that since July 2019 they had implemented their DPYD gene testing program. We have tested over 1 00 patients. The test turnaround time has been 5 business days, so patients in general have not been delayed by more than 7 days. The consensus of our medical oncologists is that this is definitely clinically acceptable for the great majority of patients. Whilst we have not yet conducted a formal evaluation of the program, the

consensus is that the testing program is feasible and has not been difficult to incorporate into our clinical program.

With regard to Dr Blinman's specific comments on behalf of MOGA, Dr Rischin said that they do not feel that genetic testing is difficult to interpret. He noted that the test is now less difficult to access, with at least 4 pathology laboratories in Australia providing the test, and that they did not feel that a delay of one week would not compromise outcomes. It was agreed that cost may be the major barrier but that the exact cost could be negotiated with the pathology laboratories, but it is unlikely to be used widely if it is not on the MBS or funded by another mechanism. Feasibility and cost effectiveness need to be established in the Australian environment. In evaluating cost effectiveness it is important to note that the antidote, uridine triacetate (Vistogard), is available but costs \$125,000 and is no longer available on a compassionate access program and is not on the PBS.

64. Dr Rischin further noted,

We agree with MOGA that a submission to the Medical Services Advisory Committee would be appropriate, and at this time it would be difficult to mandate DYPD testing for all patients prior to commencement of fluoropyrimidines in Australia. Finding a way to fund the test and the support required to implement a DYPD testing program would remove the major barrier to testing and assist in providing oncologists and patients the choice to undertake DYPD testing when clinically indicated.

Communication

- 65. Mrs L's family consistently raised concerns about communication with health professionals and noted that as a result of the *general lack of accurate communication* from medical staff, they were not aware of Mrs L's condition which meant that a number of family members were not present during Mrs L's final stages and were unable to say goodbye.

 This has been the source of deep distress for the family members during an already difficult time.¹⁴
- 66. The RMH indicated that the ICU staff made every effort to keep Mrs L's family informed of her rapid deterioration and her condition and prognosis but acknowledged the, *unfortunate* nature of her rapid deterioration and the fact that some members of her family were not able to see her before she died.

¹⁴ Letter dated 3 August 2020 from Adviceline Injury Lawyers on behalf of Mr L.

- We acknowledge the distress experienced by Mrs L'sfamily. 15
- 67. PMCC noted that patients in ICU are primarily looked after by ICU staff but still remain under the medical oncology bed card and that communication with the family when in ICU is a joint responsibility of ICU and Medical Oncology. PMCC reiterated, we regret that the communication needs of the family were not met and have taken steps to improve both inter-hospital communication and communication with families. ¹⁶
- 68. Mrs L's death was not reported to the Coroners Court by her treating clinicians, instead the family made the report. In communications with the Court it was apparent that they had many unanswered questions regarding the circumstances leading to Mrs L's death. It is hoped that the further investigations and responses provided by her treating clinicians have provided some answers regarding these circumstances and also validated their original concerns regarding Mrs L's deteriorating health around the 23 October 2018.
- 69. It should also be noted their actions are likely to have contributed to the prevention of deaths in similar circumstances in future as well as reinforced the importance of effective communication with patients, family members and treating medical staff including across medical facilities.

RECOMMENDATION

70. I make the following recommendation connected with the death under section 72(2) of the Act:

That the PMCC and MOGA make a submission to the Medical Services Advisory Committee to consider the feasibility of funding DYPD testing for all patients prior to commencement of fluoropyrimidines in Australia and to determine the support required to implement a DPYD testing program to remove the major barrier of cost to testing and provide oncologists and patients the choice to undertake DYPD testing when clinically indicated.

¹⁵ Letter dated 6 October 2020 from Dr Susan Sdrinis, Locum, Director of Medical Services, RMH.

¹⁶ Email dated 27 October 2020 from Ms Elizabeth Kennedy, General Counsel & Corporate Secretary.

FINDINGS

- 71. Having investigated the death, without holding an inquest, I find pursuant to section 67(1) of the Act that Mrs L, born 1966, died on 31 October 2018 at the Royal Melbourne Hospital, 300 Grattan Street, Parkville, Victoria, from *I a) Neutropenic sepsis leading to multi-organ failure*, *I b) Rectal cancer T2N0M0 post neoadjuvant chemotherapy and radiotherapy*, in the circumstances described above.
- 72. I convey my sincere condolences to Mrs L's family for their loss.
- 73. I direct that a copy of this finding be provided to the following:

Mr L, senior next of kin

Adviceline Injury Lawyers

Royal Melbourne Hospital

Peter MacCallum Cancer Centre

Medical Oncology Group of Australia

Signature:

SARAH/GEBERT

CORONER

Date: 28 January 2021



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.