IN THE CORONERS COURT

OF VICTORIA

AT MELBOURNE

Court Reference: COR 2017 0602

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)

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

I, AUDREY JAMIESON, Coroner having investigated the death of KEVIN PATRICK O'KEEFFE

without holding an inquest:

find that the identity of the deceased was KEVIN PATRICK O'KEEFFE

born 1 January 1935

and the death occurred on 5 February 2017

at Ballarat Base Hospital 1 Drummond Street North, Ballarat Central, Victoria 3350

from:

1 (a) CARDIOMEGALY, MYOCARDIAL FIBROSIS AND ISCHAEMIC CORONARY ARTERY DISEASE IN THE CONTEXT OF LARGE BOWEL RESECTION FOR ARGON PLASMA COAGULATION PERFORATIONS DURING A COLONOSCOPY

Pursuant to section 67(1) of the **Coroners Act 2008**, I make findings with respect to **the following circumstances**:

1. Kevin Patrick O'Keeffe was 82 years of age and resided in Scarsdale with his wife Gail O'Keeffe at the time of his death. He had no known allergies and was an ex-smoker.

2. Mr O'Keeffe had a medical history of: vitamin B12 deficiency, pulmonary hypertension,[1] pulmonary fibrosis,[2] asthma, hypertension,[3] chronic obstructive airways disease,[4] chronic renal failure,[5] bowel polyps,[6] paroxysmal atrial fibrillation,[7] diabetes, left subclavian stenosis[8] and bilateral carotid disease.[9]

3. Mrs O'Keeffe said that her husband had been increasingly unwell over the past three years. He was progressively more lethargic, less active, and less mobile around his home.

4. In January 2017, Mr O'Keeffe attended the cardiology outpatient unit of Ballarat Health Services (**BHS**). The cardiology clinic noted that his blood pressure and haemoglobin levels[10] were low. Mr O'Keeffe was transferred two units of packed red blood cells and admitted under the general medical team for investigations of ongoing anaemia.

5. On 31 January 2017, Mr O'Keeffe had a gastroscopy and no abnormalities were detected. Later that afternoon, he had a colonoscopy which revealed multiple large vascular malformations of the gut called angiodysplasia. These malformations had formed in Mr O'Keeffe's caecum and ascending colon and were actively bleeding.

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[1] An increase of blood pressure in the pulmonary artery, pulmonary vein, or pulmonary capillaries, together known as the lung vasculature, leading to shortness of breath, dizziness, fainting, leg swelling and other symptoms.

[2] Lung disease which occurs when a person's lungs are damaged and scarred and therefore restricted.

[3] High blood pressure.

[4] A collective name for lung diseases that block the flow of air in the lungs.

[5] Chronic renal failure since 2017 with a baseline creatinine level of 300 umol/L.

[6] Colonoscopy 2013. Mr O'Keeffe was diagnosed with iron deficiency anaemia.

[7] Mr O'Keeffe had been known to have chronic atrial fibrillation, diagnosed in 2011 however was not anticoagulated at the time of presentation on 25 January 2017.

[8] Narrowing of the left subclavian artery.

[9] A Carotid Doppler ultrasound was performed on 30 November 2016. Mr O'Keeffe's carotid stenosis was considered as less than 70 per cent. This occlusion was deemed not necessary for surgery and was considered in-line with Mr O'Keeffe's age and other atherosclerotic markers. Letter from A/Professor Robert McFadyen, Consultant cardiology in his letter to Dr Andrew Brommeyer (General Practitioner) on 5 December 2016.

[10] Haemoglobin is a protein of the red blood cell. It carries oxygen in the blood around the body.

6. The same day, Gastroenterologist Mr Mohammed Al Ansari treated the angiodysplasia with an argon plasma coagulation (**APC**). APC is a non-contact thermal method of haemostasis.[11]

7. The APC procedure was longer than normal and Mr O'Keeffe was becoming uncomfortable. Consequently, the procedure was stopped and a plan was made to repeat APC in two days' time. After the procedure, Mr O'Keeffe was hemodynamically stable and he was returned to the ward at 4.55pm.

8. On 1 February 2017, a Medical Emergency Team (**MET**) call was made in response to Mr O'Keeffe's very high respiratory rate, respiratory distress and decreased blood pressure. A chest and abdominal x-ray identified that Mr O'Keeffe had air under his diaphragm and a hole in the wall of his gastrointestinal tract: a colonic perforation. He was transferred to the Intensive Care Unit (**ICU**).

9. At approximately 9.00am, Mr O'Keeffe was taken to an operating theatre for an emergency laparotomy.[12] The laparotomy revealed several injuries to Mr O'Keeffe's bowel. His injuries included a perforated caecum, right paracolic,[13] as well as right iliac fossa and pelvic faecal fluid contamination.

10. Surgeons used a salt water solution to washout the peritoneal cavity in Mr O'Keeffe's abdomen.[14] Surgeons then cut out a terminal part of Mr O'Keeffe's bowel and re-joined the remaining sections.[15] Subsequently, Mr O'Keeffe was returned to the ICU. He was intubated and required noradrenaline[16] for blood pressure support.

11. At approximately 8.20am on 2 February 2017, Mr O'Keeffe was extubated. At this stage, he was still unable to urinate[17] and was treated with increasing noradrenaline as well as frusemide.[18]

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[11] APC stems the flow of blood by using argon gas to deliver plasma of evenly distributed thermal energy to an area of tissue that is adjacent to the probe.

[12] A surgical incision in the abdominal cavity for diagnosis or in preparation for major surgery.

[13] Peritoneal recesses on the posterior abdominal wall alongside the ascending and descending colon.

[14] Peritoneal washout.

[15] Surgeons performed an open ileocolic resection with primary anastomosis.

[16] A hormone that can be used as a drug to raise blood pressure.

[17] Anuria.

[18] Frusemide is a drug used to treat fluid build-up due to various conditions or diseases.

12. On 3 February 2017, Mr O'Keeffe was taken to the radiology department for a CT scan. While he was in the department, Mr O'Keeffe's oxygen saturations dropped to 79 percent. Consequently, he was taken back to the ICU and continuous positive airway pressure (**CPAP**)[19] was applied.

13. Between 4 and 5 February 2017, BHS staff began to intravenously give Mr O'Keeffe milrinone; a short-term medication used to widen blood vessels and ease blood flow in veins and arteries. Milrinone also lowers blood pressure and its application increased Mr O'Keeffe's requirement for noradrenaline. He was commenced on vasopressin to increase his renal blood flow and oxygenation.

14. At this time, Mr O'Keeffe's oxygen levels were fluctuating and he required use of CPAP or high-flow nasal prongs. He was still unable to urinate. BHS staff contacted Mrs O'Keeffe and requested that she come to the hospital to discuss the potential of re-intubation and haemodialysis for her husband.

15. On 5 February 2017, Mr O'Keeffe's wife, daughter and sons came to a family meeting at the hospital. After a lengthy discussion concerning Mr O'Keeffe's medical history and potential for rehabilitation, Mr O'Keeffe's family and medical practitioners made a decision to withdraw active treatment and provide him with palliative care.

16. At 4.45pm on 5 February 2017, Mr O'Keeffe died in the Intensive Care Unit of BHS.

REPORTABLE DEATHS

17. A person's death is reportable to the Coroner if it is, or may be, causally related to a medical procedure and a registered medical practitioner would not reasonably expect the death prior to the procedure.[20]

18. On 5 February 2017, BHS reported Mr O'Keeffe's death to the Coroners Court of Victoria by an *E-Medical Deposition Form*. Treating staff believed the cause of Mr O'Keeffe's death may have been multi-organ failure and aspiration pneumonia.

19. BHS also notified Victoria Police of Mr O'Keeffe's death. Police officers attended the hospital and completed a *Victoria Police Report of Death for the Coroner* (**Form 83**).

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[19] CPAP is a continuous positive airway pressure mode used during non-invasive pressure ventilation.

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

20. Mr O'Keeffe's body was transported to the Victorian Institute of Forensic Medicine (**VIFM**) after the Coroners Court received the notifications of his death.

INVESTIGATIONS

Forensic pathology investigation

21. On 8 February 2017, VIFM Forensic Pathologist Dr Malcolm Dodd performed an autopsy upon the body of Kevin Patrick O'Keeffe. Dr Dodd reviewed a post mortem computed tomography (**CT**) scan and referred to the Form 83 as well as the *E-Medical Deposition Form*. Dr Dodd completed a Medical Examiners Report (**MER**) for the Coroner after completing his post-mortem examinations.

22. In the MER, Dr Dodd commented that the autopsy revealed Mr O'Keeffe had significant cardiovascular disease. His heart was enlarged and showed a degree of biventricular dilation. Examination of Mr O'Keeffe's heart muscle identified variable degrees of dense fibrosis. Dr Dodd identified that Mr O'Keeffe had triple vessel ischaemic coronary artery disease.

23. Dr Dodd examined Mr O'Keeffe's abdominal organs and commented that the resection appeared healthy and sound; there was no evidence of active peritonitis. He also commented that there was no remaining evidence of the diathermy or any other injuries to the abdominal organs attributable to the APC procedure.

24. Dr Dodd found no evidence of aspiration pneumonia.

25. Toxicological analysis detected medication associated with Mr O'Keeffe's treatment and care at BHS; analysis did not detect drugs attributable to his death.

26. Dr Dodd formulated the medical cause of Mr O'Keeffe's death as cardiomegaly, myocardial fibrosis and ischaemic coronary artery disease in the context of large bowel resection for argon plasma coagulation perforations during a colonoscopy.

Coroners Prevention Unit investigation[21]

27. In light of the circumstances of Mr O'Keeffe's death, I held a meeting with the Health and Medical Investigations Team (**HMIT**) of the Coroners Prevention Unit (**CPU**). I requested that the HMIT review statements from BHS addressing their investigations into why the APC procedure caused burns to Mr O'Keeffe's bowel during his colonoscopy.

28. At my request, the CPU reviewed the following:

    a. a statement from BHS Deputy Chief Medical Officer Dr Linda Danvers;

    b. a statement from BHS Head of Gastroenterology Mr Mohammed Al Ansari;

    c. a letter from CONMED[22] ANZ Director of Quality & Regulatory Kevin Samuels; and

    d. Mr O'Keeffe's medical records.

CONMED Australia

29. The CONMED CE200 Beamer Electrosurgical System ('the machine') was used during Mr O'Keeffe's APC procedure. BHS provided a letter from Mr Samuels to the Coroners Court; it was originally sent to BHS and was dated 5 April 2017.

30. In his letter, Mr Samuels stated that the machine was returned to the service and repair facility in Sydney, where it was evaluated by a qualified repair technician, in conjunction with the manufacturer in Germany. The probe was not sent for review. In Mr Samuels' statement he said:

> *The devices and associated cables passed all tests. No fault was found and following consultation with the manufacturer in Germany, it was agreed no further tests were necessary.*

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[21] The Coroners Prevention Unit (CPU) was established in 2008 to strengthen the prevention role of the Coroner. The unit assists the Coroner with research in matters related to public health and safety and in relation to the formulation of prevention recommendations, as well as assisting in monitoring and evaluating the effectiveness of the recommendations. The CPU comprises a team with training in medicine, nursing, law, public health and the social sciences.

[22] CONMED Corporation is a global medical technology company.

31. In his letter, Mr Samuels wrote that there were two series of activations recorded on 31 January 2017. The break in-between each series indicates a different patient and procedure. He wrote that the record of these activations identify that:

    a. There were no error messages

    b. The mode used on both occasions was '*Argon Fast 30W*'.

32. In his letter, Mr Samuels wrote that '*Argon Fast 30W*' is an acceptable setting for use in the caecum.

33. The second activation series was between 3.57pm and 4.11pm. According to his medical record, this series of activation was for Mr O'Keeffe's procedure. In Mr Samuels' letter, he states:

    Activation ranged up to 29 seconds and the overall activation time was 3.5 minutes. Whilst the first 66 activations were typical, subsequent activations are untypical (long) in the final third of the procedure. If this was the result for surgery in the rectum it may be acceptable...but again would be untypical of usage expected in the right colon.

34. On 6 February 2017, Dr Al Ansari contacted a CONMED representative to discuss the argon program settings on the machine. On 9 February 2017, the representative and the CONMED ANZ National Product Manager met with Dr Al Ansari to discuss the program settings and argon therapy principles.

BHS Statements

35. ICU Consultant Dr Silvester raised concerns that the machine failed to function correctly. He queried whether the wattage was set higher than recommended for the procedure, causing the full thickness burns and consequent perforations to Mr O'Keeffe's bowel.

36. In Mr O'Keeffe's medical record, Dr Al Ansari has clearly documented a concern related to the machine and another patient who had a similar event:

usually we adjust it manually to 10 watt in the right colon...we found the default setting of the device for the right side is 30 watt and possibly that contributed to the perforation.[23]

37. In his statement, Dr Al Ansari said:

There was a lot of bleeding from these lesions when we were cauterizing them. This made the bleeding control more difficult and took longer time (sic)*...The periods of long activations referred to in this report were necessary to control excessive bleeding during this procedure...We did not see any perforation at the time of the procedure.*

38. In her statement, Dr Danvers said that the machine replaced a 15 year-old unit. It was first used in November 2016. She stated that the machine was subsequently used on four occasions without issue. However, Dr Danvers said that:

On 31/01/2017, another patient was treated with the machine, prior to Mr O'Keeffe's treatment...this patient was also treated for angiodysplasia of the right colon...This patient had been treated with argon coagulation for this condition previously across many areas of the gastrointestinal system without incident. On this particular occasion, the patient re-presented on the day following the surgery complaining of abdominal pain. A CT scan of the abdomen was performed and showed significant signs of inflammation around the cautery site with no perforation. The patient was admitted to hospital, treated conservatively and she responded well and was discharged.

BHS Clinical Investigation Report

39. The BHS Governance and Risk Management Unit undertook a clinical investigation to determine what caused burns and intestinal perforations during these APC procedures. The Unit consulted Kevin Samuels and BHS Health Practitioners: Clinical Director of Surgical Services & Surgeon General Mr Matthew Hadfield, Clinical Director of Internal Medicine Services Dr Brett Knight, and Chief Medical Officer Dr Jaycen Cruickshank.

[23] Documented in Mr O'Keeffe's Ballarat Health Services progress notes, found on disc (page 421/866). In her statement Dr Linda Danvers, Deputy Chief Medical Officer stated that Dr Al Ansari's credentialing and scope of practice had been approved for continuation at the BHS in December 2016. The scope of practice included endoscopic haemostasis including APC. Dr Al Ansari had been using the equipment over the five years he has been working at Ballarat Health Service.

40. BHS provided pages three to six of the clinical investigation report to the Coroner's Court. This included conclusions, recommendations and actions taken by BHS subsequent to Mr O'Keeffe's death.

41. BHS' clinical investigation report made the following conclusions:

    a. Dr Al Ansari had extensive experience in the use of APC;

    b. CONMED provided training to Dr Al Ansari in the use of the machine;

    c. technique was not part of the training provided by CONMED;

    d. the right colon setting[24] on the machine was in an acceptable range;

    e. the intervals of use were reasonable for the first two thirds of the procedure;

    f. the intervals were long in the final third of Mr O'Keeffe's procedure; and

    g. Mr O'Keeffe's bowel injuries probably occurred due to the prolonged intervals of use in the final third of his procedure.

42. The Governance and Risk Management Unit made a number of recommendations as a result of the conclusions of the clinical investigation report:

    a. a clinical protocol for use of the machine should be developed and should include the advice for use provided by CONMED

        i. the protocol must address treatment of angiodysplasia

        ii. the protocol must endorse the "spotwise" technique for larger areas of angiodysplasia

        iii. the protocol must mandate the treatment of only one or two lesions during a complex procedure, including if a patient presents with extensive angiodysplasia

        iv. the protocol must state that a patient should be referred for surgical management if they are experiencing bleeding that is difficult to control

[24] The right colon setting was 30 watts.

v. the protocol must dictate training and competency requirements

vi. the protocol must require Key Performance Indicators (**KPIs**);

b. BHS should undertake a target six monthly audit of endoscopy patient medical records, including APC procedure patient records, which identifies complications and monitors KPIs;

c. BHS should create a regular, formalised process to discuss complex or high risk patients prior to treatment occurring, such as a multidisciplinary meeting between gastroenterologists and surgeons;

d. BHS Medical Credentialing and Advisory Committee should discuss whether uncommon procedural techniques ought to be included in the Advanced Scope of Practice Procedure; and

e. a BHS gastroenterologist representative should attend the surgical mortality and morbidity meeting quarterly to present and discuss audit results, KPIs and complications.

CORONIAL JURISDICTION

43. It is not the role of the Coroner to lay or apportion blame, but to establish the facts.[25] It is not the Coroner's role to determine criminal or civil liability arising from the death under investigation, or to determine disciplinary matters.

44. The jurisdiction of the Coroners Court of Victoria is inquisitorial.[26] A Coroner must independently investigate a reportable death to ascertain, if possible, the identity of the deceased person, the cause of death and the circumstances in which death occurred.

45. The broader purpose of Coronial investigations is to contribute to a reduction in the number of preventable deaths, both through the observations made in the investigation findings and by the making of recommendations by coroners. This is generally referred to as the Court's "*prevention*" role.

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[25] *Keown v Khan* (1999) 1 VR 69.

[26] *Coroners Act 2008* (Vic) 84(4).

COMMENTS

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

1. The evidence before me indicates Mr O'Keeffe's bowel injuries occurred due to the prolonged activation intervals of the machine during the final third of his APC procedure. Mr O'Keeffe's death occurred in the context of emergency surgery which was required because of these injuries.

2. BHS has undertaken its own clinical investigation into Mr O'Keeffe's death. The service has identified that Gastroenterologist Dr Al Ansari was experienced in the provision of APC. The investigation also identified that CONMED provided training to Dr Al Ansari in the use of the machine however that training did not involve "technique".

3. In this instance, I have understood "technique" to include application of the APC. For example, training concerning "technique" would include the method by which APC should be applied to a large area of angiodysplasia: the "spotwise technique".

4. In their clinical investigation report, BHS informed me that another patient had experienced an adverse reaction to APC applied to angiodysplasia in the right colon. That patient had previously undergone APC through the service with no apparent issues. BHS reported that the patient re-presented after their procedure due to abdominal pain. She responded well to treatment and was subsequently discharged.

5. The Governance and Risk Management Unit's clinical investigation report contains several recommendations, which I have listed in the body of this Finding.

6. The recommendations are directed, *inter alia*, to improvement in education, training and application in relation to the APC procedure. In particular, the Governance and Risk Management Unit has recommended that BHS implement a clinical protocol for the use of APC. Additionally, BHS Governance and Risk Management Unit recommended that the service undertake an audit of endoscopy patient medical records, including APC.

7. The clinical investigation, report, and recommendations represent significant preventative measures taken by BHS in relation to public health and safety.

8. CONMED is an international corporation which develops and supplies medical devices and technology.

9. The Therapeutic Goods Administration (**TGA**) regulates, *inter alia*, the supply of medical devices in Australia. The TGA's regulation of medical devices includes assessing compliance of the device with a set of internationally agreed Essential Principles for quality, safety and performance.[27]

10. The Australian Essential Principles[28] requires the design and construction of safety materials to conform to safety principles. A medical device must not compromise the clinical condition or safety of a patient where the device is used on a patient in the conditions and manner intended by the manufacturer.[29] Additionally, it must not compromise the clinical condition or safety of a patient where the user has appropriate technical knowledge, experience, education or training.[30] Any risks associated with the use of a medical device must be acceptable when weighed against the intended benefit to the patient and meet a high level of protection for health and safety.[31]

11. In adopting these principles, a manufacturer must:

    a. *first, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; and*

    b. *second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and*

    c. *third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and*

    d. *fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted.*[32]

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[27] *Therapeutic Goods Administration Act 1989* (Cth) s 41C.

[28] *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) schedule 1.

[29] Ibid.

[30] Ibid.

[31] Ibid.

[32] Ibid.

FINDINGS

The investigation into the death of Mr O'Keeffe identified that he underwent Argon Plasma Coagulation by a CONMED CE200 Beamer Electrosurgical System for treatment of angiodysplasia in his gastrointestinal tract. Mr O'Keeffe sustained full thickness burns and colonic perforations due to prolonged application of Argon Plasma Coagulation in the final third of his procedure.

The investigation also identified that the Gastroenterologist who applied Argon Plasma Coagulation during Mr O'Keeffe's procedure was appropriately experienced and had received education and training in the use of the CONMED CE200 Beamer Electrosurgical System. However, that training did not include techniques.

I find that the technique adopted during the procedure directly contributed to the complications experienced by Mr O'Keeffe, a man already compromised by a number of pre-existing medical conditions.

I accept and adopt the medical cause of death as ascribed by Dr Malcolm Dodd and I find that Kevin Patrick O'Keeffe died from cardiomegaly, myocardial fibrosis and ischaemic coronary artery disease in the context of large bowel resection for argon plasma coagulation perforations during a colonoscopy.

And I further find that BHS has responded appropriately to the death of Kevin Patrick O'Keeffe by its investigation and has implemented restorative and preventative measures with the aim of preventing like complications and like deaths.

RECOMMENDATIONS

Pursuant to section 72(2) of the **Coroners Act 2008**, I make the following recommendations:

1. With a view to reducing harm to others and preventing like deaths, **I recommend** that the Therapeutic Goods Administration review the circumstances of Mr O'Keeffe's death.

2. With a view to reducing harm to others and preventing like deaths, **I recommend** that the Therapeutic Goods Administration review the Ballarat Health Services Governance and Risk Management Unit Investigation Report conclusions and recommendations.

3. With a view to reducing harm to others and preventing like deaths, **I recommend** that the Therapeutic Goods Administration consider whether the manufacturer has met the relevant Australian Essential Principles in relation to the CONMED CE200 Beamer Electrosurgical System.

Pursuant to sections 72(5) and 73(1) of the Coroners Act 2008 (Vic), I direct that these Findings be published on the internet.

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

Mrs Gail O'Keeffe
Deputy Chief Medical Officer Dr Linda Danvers of Ballarat Health Services
Head of Gastroenterology Mr Mohammed Al Ansari of Ballarat Health Services
CONMED ANZ Director of Quality & Regulatory Kevin Samuels
Department of Health and Human Services
Therapeutic Goods Administration

Signature:

AUDREY JAMIESON
CORONER
Date: **28 May 2018**