IN THE CORONERS COURT

OF VICTORIA

AT MELBOURNE

Court Reference: COR 2013 2681

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 JOHN CHARLES PROHASKY

without holding an inquest:

find that the identity of the deceased was JOHN CHARLES PROHASKY

born 24 January 1947

and the death occurred on 20 June 2013

at 7 Maling Road Canterbury Victoria 3126

from:

1 (a) UNASCERTAINED

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

1. John Charles Prohasky was 66 years of age at the time of his death. He lived in Canterbury with his wife Helen and was retired. Mr Prohasky was diagnosed with insulin-dependent (type 1) diabetes mellitus[1] in 1979. His medical history also included sleep apnoea, depression, osteoporosis, a fractured pelvis as a result of a cycling accident in 2001, right knee replacement surgery in 2010, and atrial fibrillation[2] (AF), for which Mr Prohasky successfully underwent a

[1] An autoimmune disease that occurs when the pancreas cannot produce enough insulin because the cells that make the insulin have been destroyed by the body's own immune system.

[2] Atrial fibrillation is the most common cardiac arrhythmia, whereby disorganised, erratic and rapid electrical signals cause the atria heart chambers to contract irregularly. Symptoms can include palpitations, dizziness, shortness of breath, tiredness and low blood pressure.

pulmonary vein isolation (PVI) ablation[3] at The Avenue Hospital, Windsor, in November 2012. The ablation was performed due to the increasing frequency of Mr Prohasky's symptoms of dyspnoea[4] and weakness, which were determined to be related to his AF. A previous ablation in June 2011 successfully treated a refractory atrial flutter.

2. Mr Prohasky's last visit to his General Practitioner Dr Adrian Tang was on 27 May 2013, for review of urine voiding dysfunction, related to an enlarged prostate. Also noted by Dr Tang during this consultation was the result of Mr Prohasky's referral to Psychiatrist Dr Peter Drysdale on 1 February 2013 for mild cognitive impairment, where he wrote 'no further progression' (of the mild cognitive impairment), and 'memory has worsened'.

3. Mr Prohasky's diabetes was managed by Endocrinologist Dr Katherine Bate since 2008, and included self-injected insulin therapy, home glucose monitoring, regular blood tests for HbA1c[5] measurement, screening for diabetes complications and other autoimmune conditions, monitoring of other cardiovascular risk factors, and the prevention and management of hypoglycaemia[6]. Regular adjustments were made by Dr Bate to the insulin medications Mr Prohasky was prescribed, as improvements in insulin and regimens became available, and also in response to his disease progression. While increasing from single to multiple injections per day, as well as multiple types of insulin, Mr Prohasky fastidiously monitored and recorded his blood sugar levels (BSLs) and insulin administration.

4. On 6 June 2013, Mr Prohasky was admitted to Warringal Private Hospital, Heidelberg for commencement of a new insulin infusion pump, under the care of Dr Bate and Credentialled Diabetes Educator Ms Francine Brown. The insulin pump is worn on the waist, and a glucose sensor/insulin infusion line is placed in the abdomen, enabling 24 hour BSL monitoring, and continuous subcutaneous insulin infusion and bolus insulin administration as required. The planned overnight admission enabled the provision of six hours of comprehensive education relating to the new pump, as well as overnight monitoring of Mr Prohasky's ability to control his blood sugar levels using the new pump.

---

[3] An ablation is an invasive vascular procedure whereby radiofrequency energy is directed to destroy a small area of cardiac tissue, causing scar tissue to form. The resulting scar tissue blocks any abnormal or irregular electrical signals that are interfering with the normal electrical conduction pathway that regulates contractions of the cardiac chambers.

[4] Shortness of breath / difficulty breathing.

[5] Glycated haemoglobin (HbA1c) is a blood test that shows an average blood glucose level over the previous 10-12 week period. While the test does not replace the daily blood testing a person with diabetes will undertake to help manage their BSLs, it is a better indicator of glycaemic control.

[6] Low blood sugar levels.

5. Mr Prohasky was discharged home on 7 June 2013, and was in regular contact with Ms Brown, who was able to monitor the performance of the new pump as Mr Prohasky uploaded the data from his pump to his computer. Ms Brown's last contact with Mr Prohasky was a phone consultation on 19 June 2013.

6. At approximately 2.00pm on 20 June 2013, Mrs Prohasky came home and located Mr Prohasky on the floor of their study; he was cold and not breathing. That morning, Mrs Prohasky had left their home at 8.00am; at this time Mr Prohasky had just returned home after his golfing commitment had been cancelled due to frost. Mr Prohasky had told his wife he planned to change the vial in his insulin pump, which was a routine procedure. Upon finding her husband, Mrs Prohasky called emergency services and commenced cardiopulmonary resuscitation (CPR). Ambulance paramedics attended and briefly administered CPR, but Mr Prohasky was declared deceased shortly after their arrival.

INVESTIGATIONS

Forensic pathology investigation

7. Dr Paul Bedford, Forensic Pathologist at the Victorian Institute of Forensic Medicine (VIFM) performed a full post mortem examination upon the body of Mr Prohasky and referred to the Victoria Police Report of Death, Form 83.

8. Dr Bedford noted that the reported circumstances of Mr Prohasky's death, in which Mr Prohasky had changed the vial of his insulin pump that morning, raised the possibility of an abnormal introduction of insulin into the body in a man with relatively recent experience in using an insulin pump. This would result in very low levels of glucose; hypoglycaemia. Dr Bedford noted that basic interrogation of the insulin pump gave no indication that an unusual amount of insulin was delivered, and that review of the pump by the manufacturer Medtronic found no evidence of abnormal function or operation. Dr Bedford observed that while a low level of glucose (1.0mmol/L) was confirmed, it was difficult to interpret, as this is common in the post mortem setting. Also, while the specimen used in an assay test for insulin was haemolysed,[7] the level was not elevated (>2.0 milliunits per litre).

9. Dr Bedford noted Mr Prohasky's history of atrial fibrillation and opined that the clinical scenario, if not related to insulin issues, would suggest his death would most likely have

[7] Haemolysed connotes the breakdown of red blood cells in the test sample, leading to release of red blood cell by-products, which can potentially cause test result inaccuracy.

occurred due to an abnormal heart rhythm. Another possibility raised by Dr Bedford was abnormal heart rhythms as a consequence of diabetes related heart disease. However, there was no evidence of significant coronary artery or heart muscle disease.

10. Toxicological analysis of post mortem blood identified citalopram,[8] which Dr Bedford described as non-contributory.

11. Following full post mortem examination, and review by a second pathologist, Dr Bedford reported that the cause of Mr Prohasky's death was unascertained.

Victoria Police attendance

12. Upon attending the Canterbury premises after Mr Prohasky's death, Victoria Police did not find any signs of third party involvement.

Family Concerns

13. By way of telephone calls to the VIFM on 1 July 2013, Mrs Prohasky advised that she had received a letter stating that Mr Prohasky's Medtronic Paradigm insulin pump had been subject to a voluntary recall. Another family member also contacted the VIFM in relation to the testing of the device.

Coroners Prevention Unit investigation

14. After reviewing the available information, I asked the Coroners Prevention Unit (CPU)[9] to examine the circumstances surrounding Mr Prohasky's death and its proximity to the commencement of the portable insulin infusion pump. In the course of the review, the CPU sought and received statements made by Endocrinologist Dr Katherine Bate, Registered Nurse and Diabetes Educator Francine Brown, Director of Clinical Services at Warringal Private Hospital Suzanne Hall, Senior Supervisor of Product Reporting at Medtronic MiniMed Michele Franco and Medtronic Australasia Pty Ltd Legal Counsel Jessica Miller. Medical records from Mr Prohasky's General Practitioner Dr Adrian Tang, as well from the Avenue Hospital, Warringal Private Hospital, and Ambulance Victoria were also included in the review.

---

[8] Citalopram is a selective serotonin reuptake inhibitor with antidepressant activity.

[9] 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.

Medtronic Paradigm insulin pump - product recalls and safety advice

15. After reviewing both the Medtronic and Therapeutic Goods Administration websites, the CPU did not identify any information to suggest product recall of the Medtronic insulin pump itself. However, several safety advisories and product corrections were noted, as well as a product recall of a consumable attachment for the pump.

16. A safety advisory regarding numerous Medtronic Paradigm insulin pump models was issued on 10 April 2013, nearly two months before Mr Prohasky commenced using the device[10]. The advisory related to three issues:

    - a possible fault with the drive support cap that holds the pump's motor if the pump hits a hard surface, which on one known occasion led to a user of the Paradigm insulin pump attempting to remedy the loose drive support cap and unintentionally delivering a bolus of insulin, causing severe hypoglycaemia;
    - a potential operational anomaly that could prevent the automatic resumption of the basal insulin infusion[11], leading to hyperglycaemia;[12] and
    - a reminder to avoid exposing the Paradigm insulin pump to water.

17. On 21 June 2013, a product correction advisory was issued with updated instructions for use of Medtronic Paradigm insulin infusion sets with the pump, in order to avoid the risk of fluid temporarily blocking vents that allow the pump to prime before use.[13] The advisory stipulated this issue was most likely to occur after the insulin reservoir was filled. Replacing the insulin vial in the pump is a routine procedure required to be performed by the wearer every two to three days. Each time a vial is replaced, the insulin reservoir is subsequently filled, and then the insulin infusion line is primed.

18. A product recall was issued on 16 July 2013, for the Medtronic MiniMed insulin reservoirs that are used with the Paradigm insulin pumps, due to increased risk of leaking, which could result in less insulin being delivered than intended.[14]

---

[10] https://www.tga.gov.au/alert/medtronic-paradigm-insulin-pump. Accessed 24 February 2015.

[11] A continual, minimal dose of insulin.

[12] Elevated BSLs.

[13] https://www.tga.gov.au/alert/medtronic-paradigm-insulin-infusion-sets. Accessed 3 March 2015.

[14] https://www.tga.gov.au/alert/medtronic-minimed-insulin-reservoirs-mmt-326a-and-mmt-332a-models. Accessed 24 February 2015.

19. A further safety advisory regarding risk of over-infusion of insulin was issued on 14 April 2014, due to Medtronic receiving a small number of reports of users accidentally programming the Paradigm insulin pump to deliver the maximum amount in bolus mode.[15] The advisory explained that this issue can occur when the user is programming the device's insulin dose settings. With the insulin amount set at 0.0 units, a single press of the down arrow changes the setting to the maximum insulin dose of 10.0 units. The advisory recommended that as accidental button pressing errors may occur, that users should always confirm the flashing insulin dose on the display is correct before confirming to commence insulin delivery.

Other specialist investigation

20. A report from Ms Michele Franco, Senior Supervisor of Product Reporting, Medtronic MiniMed dated 26 September 2013, provided to the VIFM, explained that Mr Prohasky's Medtronic MiniMed Paradigm Veo 5 Series CGMS and insulin pump (model number MMT-554CAL) was extensively tested to identify any performance anomalies that could be related to Mr Prohasky's death. The insulin pump passed all tests and no indication of abnormal operation was observed.

Review and assessment of contributing factors

21. Endocrinologist Dr Bate referred Mr Prohasky to Diabetes Educator Ms Brown prior to his Warringal Private Hospital (WPH) admission on 6 June 2013, to facilitate his transition from self-administered insulin injections to the Paradigm insulin pump therapy. In order to complete her statement, Dr Bate reviewed her records as well as the records of her colleague and Mr Prohasky's former Endocrinologist, Dr Jeffrey Zajac.

22. According to Dr Bate, Mr Prohasky's most significant and difficult complication of his diabetes was severe hypoglycaemia[16], which existed prior to 1990, and appeared frequently in his medical records. Dr Bate reviewed progress notes from 2002 that recorded Mr Prohasky had a significant lack of awareness of when he was experiencing his frequent hypoglycaemic episodes. Symptoms of hypoglycaemia vary, but may include weakness, trembling, shaking, sweating, light headedness, headache, dizziness, lack of concentration, behaviour change, tearfulness, irritability, hunger and numbness around lips and fingers. In 2003, Mr Prohasky was treated at Box Hill Hospital for severe hypoglycaemia complicated by a seizure. In 2006, Mr

[15] https://www.tga.gov.au/alert/medtronic-paradigm-insulin-pump-0. Accessed 24 February 2015.

[16] Diabetes Australia defines hypoglycaemia as a BSL less than 4mmol/L, although this can vary between individuals.

Prohasky was exhibiting probable aggression-related hypoglycaemia, and in 2008, Mr Prohasky was involved in a car accident due to his hypoglycaemia.

23. Taking over his diabetes care in 2008, Dr Bate's major focus for Mr Prohasky's treatment was to prevent his severe hypoglycaemic episodes. Strategies included education, improved BSL monitoring, improving the insulin regimen, and setting higher BSL targets. Mr Prohasky was concerned about his unawareness of episodes of hypoglycaemia unawareness,[17] and was interested in the possible benefits of Continuous Glucose Monitoring Systems (CGMS),[18] which Dr Bate felt could be a very useful tool.

24. In 2008, Dr Bate found that despite Mr Prohasky diligently monitoring his BSL levels 7-8 times per day and recording his subsequent insulin dosing, Mr Prohasky was only sensing a low BSL when it dropped to 2.0-2.5 mmol/L. Diabetes Australia advises that a normal BSL range is between approximately 4-6 mmol/L when fasting[19], however ranges do vary between individuals, as do BSL targets for diabetes sufferers who self-manage their insulin requirements.

25. Mr Prohasky was commenced on a Medtronic Guardian CGMS in January 2009 with the assistance of Western General Hospital Diabetes Educator Ms Cheryl Steele. In August 2009, with frequent hypoglycaemic episodes still an issue, Dr Bate increased Mr Prohasky's pre-meal BSL target to 5-10mmol/L. Mr Prohasky's HbA1c level was 7.1 per cent, and although the usual goal for people with diabetes is an HbA1c level less than 7 per cent, Diabetes Australia advises that some individuals may require a higher level for optimum management.[20] Despite the increased risk of microvascular complications associated with a sustained elevated HbA1c, Mr Prohasky's hypoglycaemia episodes remained frequent and a greater immediate health risk. Dr Bate reported that Mr Prohasky was health screened regularly, and at this time, had no known microvascular health issues, such as diabetic nephropathy,[21] neuropathy,[22] and retinopathy.[23] Mr Prohasky told Dr Bate and Ms Steele that he was reluctant to raise his CGMS

---

[17] 'Hypoglycaemia unawareness' refers to a patient's lack of awareness of the hypoglycaemia symptoms they are experiencing, or that there are minimal or no symptoms that indicate a hypoglycaemic event. Consequently, the patient does not act to check their BSL and respond appropriately, such as by treating their hypoglycaemia with high-energy food, oral glucose supplements, or injectable glucose as appropriate.

[18] A wearable device with a glucose sensor inserted in the abdomen, that provides real-time BSL results for improved diabetes management. Alarms can be set to notify the wearer when their BSL is high or low.

[19] http://www.diabetesaustralia.com.au/Living-with-Diabetes/Type-1-Diabetes/Managing-Type-1-Diabetes/Blood-Glucose-Monitoring/#Glucose_Level_Targets. Accessed 18 February 2015.

[20] http://www.diabetesaustralia.com.au/Living-with-Diabetes/Type-1-Diabetes/Managing-Type-1-Diabetes/Blood Glucose-Monitoring/#Glucose Level Targets. Accessed 18 February 2015.

[21] Kidney impairment.

[22] Peripheral nerve impairment, that may result in altered sensation (burning, tingling, numbness), especially in the fingers and toes.

[23] Vision impairment.

'low glucose' alarm from 3.0mmol/L to 4.0mmol/L (as recommended by Ms Steele), and believed that recording a BSL of 3.0mmol/L was normal, as he experienced no symptoms of hypoglycaemia.

26. In 2010, Dr Bate found that implementation of the CGMS had resulted in improved BSL management for Mr Prohasky, with less overnight hypoglycaemic episodes, and no severe hypoglycaemic episodes. In 2011, Mr Prohasky attended a five-day diabetes training and education course called Dose Adjustment For Normal Eating (DAFNE),[24] where a diabetes educator also expressed concern to Dr Bate of Mr Prohasky's hypoglycaemia unawareness. In 2012 during his 12 month follow up review after the DAFNE course, Mr Prohasky expressed his frustration at his latest HbA1c result of 7.9%, which Dr Bate viewed as a much safer level to avoid episodes of hypoglycaemia. From their first meeting, Dr Bate recommended follow up consultations every three to four months due to his significant severe hypoglycaemic risk. However, Mr Prohasky was keen for six monthly appointments only.

27. At an October 2012 consultation, Dr Bate again noted Mr Prohasky's very poor hypoglycaemia awareness, having had two severe hypoglycaemic episodes in the preceding four weeks, with the two lowest BSL recordings in that period being 3.4mmol/L and 3.8mmol/L. Mr Prohasky had turned off the 'low glucose' alarm, as he found the CGMS alarm frustrating when he felt he was not having a hypoglycaemic episode. At this consultation, Dr Bate gave Mr Prohasky an insulin injecting 'pen' that recorded the previous 16 doses, allowing Mr Prohasky to check if he had already administered his insulin. This was due to Mr Prohasky possibly having given himself a double dose of insulin that may have been the precipitant of one of his recent hypoglycaemic episodes. At this time, Mr Prohasky's HbA1c target range was 8.0 per cent, and his BSL target range was 6-12mmol/L. In a December 2012 telephone consultation, Dr Bate determined that Mr Prohasky was managing his BSLs moderately well.

28. At Mr Prohasky's next scheduled appointment with Dr Bate in April 2013, he expressed his interest in changing his CGMS to one that also contained an insulin pump, as his Guardian CGMS had stopped working. Dr Bate supported this change, as she hoped it would further reduce the risks of Mr Prohasky experiencing a severe hypoglycaemic episode, in both duration and severity.[25] Additionally, a CGMS with an insulin pump had the added advantages of recording the insulin dosing and analysing the effect of the previous dose, reducing the risk of

[24] See: www.dafne.org.au

[25] Garg et al, Reduction in duration of hypoglycaemia by automatic suspension of insulin delivery: the in-clinic ASPIRE study. Diabetes Technology & Therapeutics, 2012, 14(3), pp. 205-209. http://www.ncbi.nlm.nih.gov/pubmed/22316089. Accessed online 18 February 2015.

overdosing or double dosing. At this consultation, Dr Bate noted that Mr Prohasky's HbA1c level was too low, at 7.1 per cent, and the current aim of a BSL target range from 6-12mmol/L was reiterated.

29. Dr Bate was confident Mr Prohasky could manage a dual function CGMS insulin pump due to his competent use of the Guardian CGMS, his meticulous and frequent BSL record-keeping, his recent completion of the DAFNE course, and his proficiency with modern technology devices such as mobile phones and computers. In 2011, Mr Prohasky had been commenced on an insulin dosing system that involved calculating and adjusting amounts of insulin to be administered based on variable factors such as current BSL, anticipated carbohydrate intake, and previous calculation of insulin sensitivity. Dr Bate explained that such an insulin therapy system is analogous to insulin dosing via the Medtronic Paradigm CGMS and insulin pump, and was an excellent preparation for the transition to using such a device. However, there are several significant differences between the two BSL treatment options, first and foremost being the use of quick-acting insulin as a continuous infusion rather than Mr Prohasky's long-standing insulin regimen that utilised slow-acting insulin medications.

30. Dr Bate was aware of Mr Prohasky's cognitive function assessment in early 2013, however she noted that Mr Prohasky's own concerns about his memory existed at least as early as 1994. Dr Drysdale's assessment ruled out any concerns of dementia, and Dr Bate referred to Mr Prohasky's high score on a mental acuity test at this consultation, concluding that Mr Prohasky should not have had any trouble learning how to operate the Paradigm insulin pump, especially in light of his previous experience with the Guardian CGMS.

31. Dr Bate referred Mr Prohasky to Diabetes Educator Ms Fran Brown for commencement on the Paradigm insulin pump. After her initial consultation with Mr Prohasky on 14 May 2013, Ms Brown also had no concerns about Mr Prohasky proficiently making the transition from the Guardian CGMS to the Paradigm insulin pump, and did not observe any behaviour that indicated a formal assessment of cognitive ability was required.

32. Mr Prohasky attended WPH for the education day and Paradigm insulin pump commencement on 6 June 2013, and was reviewed by both Dr Bate and Ms Brown. It was noted that the six hour education day was comprehensive, covering all aspects of operating the Paradigm insulin pump, including programming, setting alarms, troubleshooting, replacing the insulin reservoir, when to suspend or reduce the pump, hypoglycaemic management plan, BSL targets and insulin use. The Paradigm insulin pump requires the user to input information regarding

carbohydrate intake and manual BSL calibrations. Also, the pump does not automatically deliver insulin without input from the user.

33. Although the Guardian CGMS and Paradigm insulin pump are similar menu-based electronic devices both manufactured by Medtronic, Ms Brown and Mr Prohasky jointly decided to initially only use the insulin pump function of the Paradigm insulin pump, and after several weeks of consolidated use, to combine this with the other features of the device, including the CGMS and the low-glucose suspend infusion function. Ms Brown felt that commencing use of all the features of the Paradigm insulin pump simultaneously would be unsafe, partly due to Mr Prohasky not having used his Guardian CGMS for several months as it had broken. All appropriate precautions for BSL targets were discussed with Mr Prohasky, and took into account his current HbA1c of 7.1 per cent. Mr Prohasky was reviewed again by Ms Brown before his discharge home on 7 June 2013. During this final inpatient review, Ms Brown supervised Mr Prohasky successfully perform a reservoir and line change. Ms Brown considered Mr Prohasky safe for discharge home. Mr Prohasky was provided Ms Brown's mobile phone number to assist with any troubleshooting issues for the new pump, and he also had the contact details of Dr Bate's consulting rooms, which provide 24 hour a day medical advice.

34. Mr Prohasky attended a routine follow up appointment with Ms Brown on 12 June 2013. In the first five days with the Paradigm insulin pump, Mr Prohasky's BSL average was slightly high at 12.0mmol/L, and he experienced two hypoglycaemic episodes (2.7mmol/L and 2.2mmol/L) on 9 and 10 June 2013 respectively. Both Ms Brown and Dr Bate stated that Mr Prohasky's BSLs were at an acceptable range in the early stage of his pump optimisation, and this was explained to Mr Prohasky. He had been checking his BSL an average of 11 times per day, above the recommended minimum of six times per day, and had also appropriately been entering carbohydrate intake information, bolusing insulin at correct amounts and times, and appropriately refilling the insulin supply for the pump. The higher than usual BSLs frustrated Mr Prohasky and had caused him to investigate how to bypass the suggested insulin bolus feature of the pump in order to give himself a higher dose of insulin than recommended by the pump. Overriding the suggested insulin bolus was not part of Mr Prohasky's education, and it was strongly discouraged, as besides the increased health risk, Dr Bate explained that over-riding the pump programming slows down the process of optimising the automatic settings. Ms Brown explained to Mr Prohasky that it would take some time to gradually work to bring his BSLs to an optimal range.

35. Ms Brown also identified that Mr Prohasky was not estimating his carbohydrate intake accurately, relying on a 'best guess' method, which could result in inaccurate insulin bolus calculations. Mr Prohasky was reminded to weigh his food, read nutrition panels on food packaging, and was encouraged to review the principles he learned on carbohydrate counting while attending the DAFNE course. Ms Brown also advised Mr Prohasky to review his carbohydrate counting skill with his daughter who, Mr Prohasky had informed Ms Brown, was a dietician. As Mr Prohasky had routinely practiced the skill of carbohydrate counting and calculating bolus insulin administration on a daily basis prior to commencement of the Paradigm insulin pump, a dietician review was deemed not necessary by Ms Brown during Mr Prohasky's WPH admission on 6 June 2013.

36. Ms Brown adjusted the pump settings at the 12 June 2013 consultation to aim for a slightly lower BSL, with a subsequent plan established for Mr Prohasky to upload his pump data weekly, so that Ms Brown could regularly remotely review the pump data and Mr Prohasky's ability to use the pump. A further appointment was scheduled in one month. As per her usual practice, Dr Bate's planned review of Mr Prohasky was six weeks after commencement of the Paradigm insulin pump. During Mr Prohasky's second week of using his new Paradigm insulin pump, he checked his BSL an average of nine times per day, and his average BSL improved to 10.2mmol/L.

37. Mr Prohasky emailed Ms Brown on 18 June 2013, informing her that he had achieved better BSL control in his second week, though had again recorded two further hypoglycaemic episodes on 15 and 16 June 2013, measuring 2.3mmol/L and 2.8mmol/L respectively. Both episodes were associated with exercise. Mr Prohasky informed Ms Brown he had not made any adjustments to the pump.

38. In a telephone consultation discussing pump settings with Ms Brown on 19 June 2013, Mr Prohasky reported that his BSLs were low in the morning. Ms Brown recommended Mr Prohasky reduce his overnight basal insulin infusion rate, and talked Mr Prohasky through making this adjustment on the pump himself. Ms Brown also reminded Mr Prohasky that he should set the pump to infuse insulin at a temporarily lower than normal infusion rate during and after exercise to avoid hypoglycaemia. Mr Prohasky died the following day.

39. WPH Director of Clinical Services Suzanne Hall stated that Mr Prohasky's death was discussed at the quarterly meeting of the WPH Patient Care Review Committee on 25 February 2014. The inpatient care and post discharge follow up of Mr Prohasky were deemed appropriate by the

Committee, except for identifying that the 'Procedure / Reason for Admission' consent form – whilst signed by Mr Prohasky – had not been completed or signed by the Visiting Medical Officer. WPH educated medical and nursing staff of the requirement for this form to be completed for all patients undergoing procedures outside the perioperative environment. A follow up audit[26] of the 2014-15 WPH admissions for insulin pump insertions resulted in 100 per cent compliance for completing the consent form.

Review of the operation of the Medtronic Paradigm insulin pump

40. The review noted forensic pathologist Dr Bedford's comment that a basic interrogation of Mr Prohasky's pump gave no indication that an unusual amount of insulin was delivered. Nonetheless, the review attempted to formally assess all available pump data. In a second statement, Ms Brown explained that the uploading of pump data on a monthly basis is encouraged, however she had requested Mr Prohasky upload the data from his pump weekly so she could initially review it more regularly. After the last data upload by Mr Prohasky on 16 June 2013, no additional data beyond this date was available for review. Mr Prohasky was scheduled to next upload his pump's data on 25 June 2013.

41. Medtronic Australasia were contacted to investigate whether they had uploaded Mr Prohasky's missing pump data from 17 to 20 June 2013, during their testing of the pump function. Ms Jessica Miller, Legal Counsel for Medtronic Australasia, advised by letter dated 31 March 2015 that there was no data available for this period as a result of the Paradigm insulin pump having been without a battery for a prolonged period of time, corrupting the historical data stored on the pump.

42. With Dr Bedford's initial pump interrogation not revealing any unusual insulin administration, and no pump data available from 17 to 20 June 2013 for review, the review concluded that there was no evidence of pump program malfunction or improper pump program operation by Mr Prohasky.

---

26 Of the 43 admissions to WPH for insulin pump insertions during this period, 20 were audited.

COMMENTS

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

1. Mr Prohasky appears to have demonstrated reluctance to abide by some of the recommendations provided by various diabetes specialists, however, the evidence indicates his BSL control improved and his overall diabetes management was adequately supervised by Dr Bate. Mr Prohasky was an appropriate candidate for the CGMS and Paradigm insulin pump, and Dr Bate was aware of his mild cognitive impairment, but reasonably believed that it would not interfere with his ability to operate the devices.

2. I note that the functioning of the Paradigm insulin pump was extensively tested by Medtronic, with no observation of abnormal operation. However, this testing does not exclude the possibility of Mr Prohasky's death being related to the 10 April 2013 safety advisory regarding a possible fault with the Paradigm insulin pump's drive support cap coming loose, which subsequently on one known occasion, resulted in an unintentional delivery of an insulin bolus to a user, causing severe hypoglycaemia. I also note that another safety advisory regarding a risk of over-infusion of insulin issued on 14 April 2014 related to users accidentally programming the Paradigm insulin pump to deliver the maximum amount in bolus mode.

3. I also note that while there were four recorded hypoglycaemic episodes between the commencement of the Paradigm insulin pump on 6 June 2013 and the last data upload on 16 June 2013, Dr Bate and Ms Brown were both satisfied with Mr Prohasky's use of the pump and BSL monitoring. It is disappointing and somewhat concerning that Medtronic's parent company was unable to provide the data for the period 17 to 20 June 2013, due to the insulin pump having been without a battery for a prolonged period, corrupting the historical data. In these circumstances, I remain unclear as to whether Mr Prohasky's history of hypoglycaemia unawareness contributed to his death.

4. In addition, it was reported to attending police that Mr Prohasky had planned to change the vial in his Paradigm insulin pump on the morning of his death. I also note that Mr Prohasky had mild cognitive impairment. While there is a lack of evidence of pump program malfunction or improper program operation by Mr Prohasky, and no concerns noted by Dr Bedford after initial interrogation of the pump, the possibility remains that something has happened in relation to the

Medtronic Paradigm insulin pump on 20 June 2013, be it a machine malfunction or operator error.

5. Mr Prohasky's routine inpatient stay at Warringal Private Hospital for the commencement of the Paradigm insulin pump was unremarkable, and Ms Brown reasonably staggered the commencement of the features of the pump due to a concern of lack of recent practice, as Mr Prohasky had broken his CGMS several months earlier. Ms Brown's routine follow up and phone consultations with Mr Prohasky were all adequate, and it was during one of these follow up consultations that Ms Brown learned that Mr Prohasky was not accurately estimating his carbohydrate intake. While appropriately prompting and re-educating Mr Prohasky on his carbohydrate counting skills, Ms Brown's advice that Mr Prohasky consult his dietician daughter for further advice was not ideal. During Mr Prohasky's overnight admission to WPH on 6 June 2013 when the Paradigm insulin pump was commenced, it would have been ideal if Ms Brown had considered a dietician review necessary, rather than assuming Mr Prohasky's carbohydrate counting skills were adequate as he routinely undertook this as well as calculating insulin requirements every day.

RECOMMENDATIONS

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

1. With the aim of improving the provision of treatment to diabetic patients at Warringal Private Hospital, **I recommend** that all patients admitted to Warringal Private Hospital for commencement of an insulin pump are more thoroughly screened, possibly through referral to a dietician's assessment, for their ability to appropriately perform the tasks of carbohydrate counting and insulin calculating, both vital skills for the effective ongoing management of such a device.

2. With the aim of maintaining important data records, **I recommend** that Medtronic Australia Pty Ltd, in consultation with its parent company, install additional data retention technology to its Paradigm insulin pump, or implement a policy whereby the historic data contained in any insulin pump devices under review is salvaged as a matter of priority, to prevent the possibility of it becoming corrupted.

FINDINGS

The investigation has failed to elucidate the circumstances of Mr Prohasky's death. There was insufficient evidence to support a finding that the Medtronic Paradigm insulin pump malfunctioned, however I do note pump data from between 17 and 20 June 2013 was not available for interrogation. In circumstances where there is no evidence to suggest Mr Prohasky improperly operated the Medtronic Paradigm insulin pump on 20 June 2013, and where I remain unclear as to whether hypoglycaemia unawareness contributed to his death, I am unable to make specific findings about causal or contributing factors to his death.

In the circumstances, I accept and adopt Dr Paul Beford's forensic pathology report and find that the cause of John Charles Prohasky's death is unascertained.

Pursuant to section 73(1A) of the *Coroners Act 2008,* I order that this Finding be published on the internet.

I direct that a copy of this finding be provided to the following:
Mrs Helen Prohasky
Ms Elizabeth Berriman, Warringal Private Hospital
Mrs Francine Brown, Greensborough Consulting Rooms
Dr Adrian Tang, Blackburn Clinic
Ms Jessica Miller, Medtronic Australasia Pty Ltd
Therapeutic Goods Administration
Leading Senior Constable Ruth Habel

Signature:

AUDREY JAMIESON
CORONER

Date: **23 June 2016**