IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2014 005032

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 60(2)
Section 67 of the ***Coroners Act 2008***

I, ROSEMARY CARLIN, Coroner having investigated the death of JOSIP DOBROVOLJSKI without holding an inquest:
find that the identity of the deceased was JOSIP DOBROVOLJSKI
born on 20 April 1952
and the death occurred on 1 October 2014
at Royal Melbourne Hospital, Carlton, Victoria

from:

1(a) GLOBAL CEREBRAL ISCHAEMIA

1(b) INTRA-OPERATIVE HYPOTENSION FOLLOWING THE ADMINISTRATION OF PROTAMINE

Pursuant to section 67(1) of the Coroners Act 2008 there is a public interest to be served in making findings with respect to the following circumstances:

1. Josip Dobrovoljski died on 1 October 2014 aged 62. He lived in North Melbourne and is survived by his daughter and other family members.
2. Mr Dobrovoljski had significant medical issues including ischaemic heart disease, type 2 diabetes mellitus, epilepsy, hypertension, high cholesterol, and depression. He was an ex-smoker.
3. In April 2014 Mr Dobrovoljski suffered an inferior acute myocardial infarction. A coronary angiogram performed on 30 April 2014 showed significant stenosis of the arteries supplying oxygen to the heart, indicating significant coronary artery disease.

4. On 21 August 2014 Mr Dobrovoljski presented to the Royal Melbourne Hospital (**RMH**) complaining of weight gain and shortness of breath. After review in the Cardiology Clinic he was admitted to hospital. He was assessed as having congestive cardiac failure in the context of his ischaemic heart disease.

5. On 26 August 2014 Mr Dobrovoljski had a coronary artery bypass graft. The anaesthetist was Dr Kluger. During the procedure the blood thinner heparin was administered to Mr Dobrovoljski to prevent blood clotting in the coronary bypass system. At the end of the procedure Dr Kluger proposed to administer protamine to reverse the effects of the heparin. Protamine is routinely used in cardiac surgery for this purpose.

6. In accordance with usual practice Dr Kluger gave Mr Dobrovoljski a 20mg *test* dose of the drug protamine. The test dose caused an immediate and significant drop in Mr Dobrovoljski's blood pressure (65 systolic). The problem was quickly identified and managed appropriately. A bolus of metaraminol was given which raised Mr Dobrovoljski's blood pressure to baseline level. Thereafter, protamine was administered extremely slowly with concurrent noradrenaline to maintain an adequate blood pressure. The operation otherwise proceeded without incident and afterwards Mr Dobrovoljski was electively admitted to the intensive care unit (**ICU**).

7. Mr Dobrovoljski's reaction to protamine was documented in the operation report by the cardiothoracic registrar, Dr Keenan, but was not documented on the anaesthetic chart.

8. On admission to the ICU following a verbal handover, Mr Dobrovoljski's nurse applied a red alert band to his wrist, updated his medication chart to reflect an allergy/reaction to protamine and documented the allergy/reaction on a patient alert form.

9. Over the next few days, Mr Dobrovoljski remained in ICU. He had multiple episodes of ventricular fibrillation (**VF**)[1] and cardiac arrests requiring cardiopulmonary resuscitation (**CPR**) with airway and inotrope support. He was connected to atrial-ventricular pacing wires to attempt to control his heart rate and rhythm. He regained consciousness following these episodes, but continued to have further episodes of VF.

10. On 30 August 2014, Mr Dobrovoljski had a transoesophageal echocardiogram (**TOE**), coronary angiography and insertion of an intra-aortic balloon pump (**IABP**) to assist with

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1 Abnormal heart rhythm that is pre-terminal, that is, it is usually followed by cardiac arrest. A VF rhythm cannot sustain adequate cardiac output maintain blood flow and thus oxygen supply to the rest of the body.

his cardiac function. During the procedure there was no evidence of pericardial effusions[2] or tamponade[3] and his grafts were patent.

11. Over the next 2 days Mr Dobrovoljski continued to have cardiac arrhythmias and poor cardiac function. His pacing wires were removed and he was weaned off the intra-aortic balloon pump (**IABP**). He was assessed as obeying commands, although intubated.

12. It was decided to attempt to cure Mr Dobrovoljski's arrhythmias by performing a cardiac ablation procedure. As it was considered a medical emergency and the only known relative was overseas, the procedure was authorised by Dr Atkinson, the Director of Clinical Governance. It was performed by cardiologist Dr Morton on 3 September 2014 in the electrophysiology (**EP**) laboratory. Prior to the procedure, the anaesthetic nurse received a verbal handover from the ICU nurse, and the anaesthetist, Dr Iatrou, received a verbal handover from the treating intensivist. Mr Dobrovoljski's earlier reaction to protamine was not mentioned during either handover.

13. Normally, prior to any surgical procedure a team *Time Out* occurs whereby the theatre team stop to confirm the patient's identity, the procedure to be performed, whether consent has been obtained and whether the patient has any allergies. It did not occur on this occasion.

14. The ablation procedure appeared successful, however the sheath in the right femoral artery was found to have clotted. It was decided to remove the sheath and administer protamine to reverse the effect of previously administered heparin. Dr Iatrou, gave a 30mg *test* dose of protamine. Mr Dobrovoljski's blood pressure dropped significantly (50 systolic) and Dr Iatrou administered aramine and then adrenaline. Within minutes Mr Dobrovoljski suffered an asystolic cardiac arrest. CPR was instituted and an IABP was inserted. Blood pathology showed raised serum tryptase, a marker of anaphylaxis. Spontaneous circulation was restored. Dr Keenan, the surgical registrar on 26 August 2014, was called

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2 Pericardial effusion defines the presence of an abnormal amount and/or character of fluid in the pericardial space. It can be caused by a variety of local and systemic disorders, or it may be idiopathic. Pericardial effusions can be acute or chronic, and the time course of development has a great impact on the patient's symptoms.

3 A life-threatening situation in which there is such a large amount of fluid (usually blood) inside the pericardial sac around the heart that it interferes with the performance of the heart. The end result, if untreated, is low blood pressure, shock and death. The excess fluid in the pericardial sac acts to compress and constrict the heart.

to the EP laboratory and advised of her operative note and Mr Dobrovoljski's reaction to protamine on that day.

15. Once stable Mr Dobrovoljski was transferred back to the ICU. Over the next few days he was noted to have a slow neurological recovery. Antibiotics were administered due to the development of hospital acquired pneumonia. Investigations revealed abnormal brain function and areas of brain death.

16. Mr Dobrovoljski was reviewed by the neurology team who decided that he had sustained a severe neurological injury and had a poor prognosis. Following discussion with the family Mr Dobrovoljski was extubated and transferred to the care of the Palliative Care Team. He died on the morning of 30 September 2014.

17. Mr Dobrovoljski's death was reportable under the *Coroners Act 2008* as it appeared causally related to a medical procedure and was unexpected. The focus of my investigation was on the administration of protamine during the ablation procedure on 3 September 2014, given Mr Dobrovoljski's adverse reaction to protamine on 26 August 2014.

The Coronial Investigation

18. During my investigation I obtained RMH records, statements from Dr Malcolm Mohr, Medical Administrator at RMH, Dr Kluger (anaesthetist on 26 August 2014) and Dr Iatrou (anaesthetist on 3 September 2014). My assessment of the medical management of Mr Dobrovoljski was conducted with the assistance of independent medical professionals from the Coroners Prevention Unit (**CPU**).

Statement of Dr Kluger[4]

19. Dr Kluger stated that hypotension post protamine administration in cardiac surgery was very common, multifactorial in nature and frequently treated with vasopressor medication such as metaraminol. He noted that Mr Dobrovoljski's drop in blood pressure was not associated with other signs of an allergic reaction such as bronchospasm, tachycardia or rash. Given this, he and the cardiothoracic surgeon, Mr Antippa, believed the response was not an allergic reaction, but rather an expected side effect that was more pronounced in Mr Dobrovoljski's case as a result of his poor cardiac function. To prevent the need for

[4] Dated 9 January 2015.

protamine to be administered in ICU with a possible repeat of hypotension, Mr Antippa and Dr Kluger agreed that two extra doses of protamine should be given in theatre.

20. Dr Kluger stated that there was a verbal clinical handover to the intensive care doctors in which the pronounced hypotensive response to protamine was communicated, together with a warning to avoid giving subsequent doses of protamine unless there was a serious need.

RMH medical records

21. The 26 August 2014 anaesthetic record did not document Mr Dobrovoljski's protamine reaction during surgery. In particular, it did not document the change in blood pressure, the administration of metaraminol, the slow administration of protamine, the discussion of concerns with the surgeon and the rationale for further protamine whilst in theatre, nor the fact that these issues were handed over to the ICU team.

22. Despite the handover, there was no note made in the ICU admission note of these intraoperative issues. However, the ICU medication charts after 26 August 2014 did note in a red box at the top of the page an allergy/reaction to protamine (with hypotension as the documented reaction). Similarly, the daily Intravenous Orders charts after 26 August 2014 were generally marked in the same way, including on 3 September 2014[5].

23. The *Surgical Safety Checklist* for the procedure on 30 August 2014 recorded 'No' to the question 'DOES THE PATIENT HAVE A KNOWN ALLERGY?' and a *Surgical Safety Checklist* was not completed at all for the procedure on 3 September 2014.

24. The allergy/reaction section of the anaesthetic chart for each of the procedures on 30 August and 3 September 2014 was left blank.

Statement from Dr Iatrou[6]

25. Dr Iatrou stated that there is no known alternative to protamine and it was important to administer it to Mr Dobrovoljski to minimise bleeding complications at the puncture site. Prior to its administration he checked the previous anaesthetic chart and believes he also checked the drug chart. He found no evidence of an allergy or adverse reaction. Further, when he was requested by Dr Morton to administer protamine no-one in the laboratory

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[5] The box for 29 and 31 August 2014 was left blank.

[6] Dated 13 January 2015.

raised an alarm. He did not check the red alert bracelet as it was under the sterile surgical drapes.

26. Dr Iatrou said he administered an internationally acceptable test dose of protamine and other than hypotension, there was no other clinical evidence of an allergic reaction such as skin rash or wheeze.

27. Dr Iatrou considered Mr Dobrovoljski's reaction was within 'acceptable limits for a patient in his condition'[7].

RMH Internal Review – Dr Mohr's statement[8]

28. Dr Mohr indicated that the internal review conducted by RMH in the wake of Mr Dobrovoljski's death identified multiple problems with his care and made a number of recommendations as a result. The issues identified included that:

- There was inadequate communication and preparation of the patient in ICU (despite three hours notice) for the transfer to the EP laboratory on 3 September 2014. A *Surgical Safety Checklist* was not completed and consent was not obtained.
- There was inadequate medical and nursing handover from ICU staff to the EP laboratory receiving staff. The previous issues in respect of protamine were not communicated.
- The EP laboratory team did not initiate a *Surgical Safety Checklist* upon realising that one did not exist, nor conduct a *Time Out* prior to the procedure on 3 September 2014.
- The anaesthetic record on 26 August 2014 did not document the reaction to protamine administration and as the red alert bracelet was covered by the surgical drape it was not noticed.

29. As a result of the internal review and discussion at the RMH Anaesthetic Department Mortality and Morbidity Meeting a number of recommendations were made including:

- Improving handover processes for collecting a patient from the ICU, including notification of allergies/adverse drug reactions, a structured format for verbal clinical handover and a designated place for handover; hitherto the focus had been on the handover of patients brought to ICU.

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[7] Dr Iatrou's statement at [8].

[8] Dated 13 January 2015.

- The *Surgical Safety Checklist* must be completed by the transferring unit for all patients and included as part of the handover process.
- The clinicians directly involved in the patient care must be involved in the handover.
- A patient must not be accepted for transfer by the receiving team unless all relevant documentation has been completed and formally handed over (using ISBAR[9] minimum data set for clinical handover). EP laboratory nursing staff must check and sign off the *Surgical Safety Checklist* on acceptance of the patient to the laboratory.
- Further education to be provided to both ICU and EP laboratory medical and nursing staff on the importance of the completion of the *Surgical Safety Checklist* and conducting a *Time Out.*
- Improving documentation of protamine reactions on the anaesthetic chart:
  - including specifying the type of reaction, severity and treatment required; and
  - noting any allergy/sensitivity on the front of the anaesthetic chart "alert" section and preadmission "alert" section, if any - in addition to the established process of noting it on the computerised patient master index (iPM) and "alert" page on the case notes.
- The need for a review of indications for protamine use in non-cardiac theatre situations and the development of a policy considering:
  - the current clinical state of the patient (should a reaction occur); and
  - the presence, type and severity of previous protamine reactions and the necessity of protamine use in that situation.
- Education on protamine administration – indications and methods of administration.

CAUSE OF DEATH

30. A normal level of serum tryptase is considered to be < 12 µg/L. After the administration of protamine on 3 September 2014 Mr Dobrovoljski's level was 14.1 µg/L. Dr Mohr noted that 14.1 µg/L was only marginally raised and was possibly affected by CPR and cardiac disease.

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9 Standardised communication tool recognised by the National Safety and Quality Health Service Safety Standards. Is an acronym standing for Identify, Situation, Background, Assessment and Recommendation.

31. Both Dr Kruger and Iatrou remarked that there was no clinical evidence of an allergic reaction to the protamine they administered, such as a skin rash or wheeze. Both doctors claimed there was no adverse reaction beyond what could be expected in a patient in Mr Dobrovoljski's condition. On the other hand the symptoms of anaphylaxis are variable and often there is no rash. Further, the significant amounts of inotropes, including adrenaline, administered to Mr Dobrovoljski after his reaction, may have masked symptoms of anaphylaxis, including ventilatory difficulties and rash.

32. Dr Iatrou noted that Mr Dobrovoljski had several cardiac arrests in ICU leading up to his procedure on 3 September 2014 and one after the anaesthetic and before the protamine was administered. He postulated that Mr Dobrovoljski's death was the result of his numerous cardiac arrests due to his gross underlying cardiac pathology.

33. Forensic Pathologist Dr Sarah Parsons conducted an external examination and reviewed the results of a post mortem CT scan and RMH medical records and deposition. She noted that the rise in serum tryptase level after protamine administration was consistent with anaphylaxis. However, having regard to all the circumstances, including clinical observations, she could not be satisfied that Mr Dobrovoljski necessarily had an anaphylactic reaction to protamine. She formulated the cause of death as:

    1a. Global cerebral ischaemia

    1b. Intra-operative hypotension following the administration of protamine.

I accept and adopt that cause of death.

CONCLUSIONS AS TO CIRCUMSTANCES OF DEATH

34. Dr Iatrou stated:

> *Mr Dobrovoljski was in a perilous medical condition and, indeed, he was having a highly risky procedure as a last effort to save his life...Caring for Mr Dobrovoljski at this time was very difficult and challenging.*

I accept that to be the case.

35. RMH's internal review identified a number of areas of concern in the treatment of Mr Dobrovolkski. Likewise, I am satisfied there were a number of areas in which the care for Mr Dobrovoljski could have been improved. Of particular significance are the following:

- The anaesthetic chart on 26 August 2014 should have recorded Mr Dobrovoljski's significant adverse reaction to protamine and how it was handled (whether or not it was classed as an allergic reaction), including the initial fall in blood pressure, the administration of metaraminol, the slowing down of the protamine infusion, the discussion between the surgical and anaesthetic teams, and the handover of the issues to the ICU team.
- The ICU admission record on 26 August 2014 should have detailed the protamine reaction in theatre.
- The previous adverse reaction to protamine should have been communicated during handover from ICU to the EP team.
- A *Surgical Safety Checklist* should have been completed and a team *Time Out* conducted prior to the procedure on 3 September 2014. If nothing else, both of these things would have prompted a review of the alert bracelet prior to the patient being draped.

36. Improved documentation and handover would have alerted the treating team on 3 September 2014 to the potential problem in relation to the administration of protamine. More definitive inquisition by Dr Iatrou and Dr Morton as to the presence or absence of a drug reaction or allergy should also have alerted them to the problem.

37. Understandably, Dr Iatrou relied heavily on the previous anaesthetic chart for information regarding possible adverse reaction to protamine and found nothing. However, Dr Iatrou also stated that '[t]o the best of [his] recollection' and in accordance with his 'usual practice' he also checked the drug chart and there was no note of a protamine adverse reaction'. As noted above, the adverse reaction is in fact clearly documented on ICU medication and Intravenous Order charts after 26 August 2014, including specifically 1 to 3 September 2014. It was also documented on a patient alert form and the red alert bracelet.

38. Dr Iatrou commented that several days after Mr Dobrovoljski's death he checked the medication chart and patient history (patient alert form and alert stickers) and observed

that they had been amended[10] to record the allergy/reaction to protamine. He believed they were amended after death.

39. Analysis of the ICU medication charts, fluid balance sheets and Intravenous orders prior to 3 September 2014 and the Patient Alert Form, does not support Dr Iatrou's belief as the 'alerts' on these documents were completed (including signed and dated) by many different individuals. There is no reason not to accept them at face value and I am satisfied they have not been retrospectively altered. The operation report from 26 August 2014 also documented the protamine reaction. I am therefore satisfied that despite significant inadequacies in hospital documentation, Mr Dobrovoljski's adverse reaction to protamine was apparent upon a perusal of the hospital records.

40. According to Dr Iatrou there is no alternative to protamine and it was important to administer it to Mr Dobrovoljski to minimise bleeding complications. Nevertheless, he administered it ignorant of Mr Dobrovoljski's previous reaction. If he and Dr Morton had been aware of the extent of cardiovascular compromise following protamine administration on 26 August 2014, they would have been better prepared for the procedure on 3 September 2014. Such knowledge may have prompted a reconsideration of the necessity for protamine and/or the manner in which it was administered on 3 September 2014, particularly given the perilous condition of Mr Dobrovoljski's cardiac condition.

FINDINGS

41. I find that Josip Dobrovoljski died on 30 September 2014 and that his cause of death was:

    1a. Global cerebral ischaemia

    1b. Intra-operative hypotension following the administration of protamine.

42. I find that there were a number of stages at which his care could have been improved including better documentation of his initial reaction to protamine, better preparation and handover at critical transfer points between theatre, ICU and the EP laboratory, and more definitive inquisition by the treating proceduralist and anaesthetist regarding the presence or absence of a drug allergy or reaction prior to the fatal administration of protamine.

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[10] He said the medical history 'had been amended extensively (alert stickers and patient alert form) to refer to a protamine reaction'.

43. It is possible that optimal care and in particular, knowledge by Dr Iatrou or Dr Morton of Mr Dobrovoljski's previous protamine reaction, would have prevented his death from protamine administration, as there may have been a decision not to administer it or to administer it in a different manner on 3 September 2014. However, given the complexities involved and the parlous medical condition of Mr Dobrovoljski, I am not satisfied that there would necessarily have been any different treatment, nor that the outcome would have been different in any event.

COMMENTS

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

1. This case highlights the importance of communication between medical teams and the documentation of relevant clinical information in ensuring medical staff are optimally prepared for complex procedures in critically unwell patients. In such patients, room for error is minimal and errors can have catastrophic results.
2. The RMH internal review addressed the major issues arising from this case and provided a list of considered and reasonable recommendations to improve these areas in the hope of preventing similar future incidents.
3. I am concerned however that the review only identified the need for a review of indications for protamine use in non-cardiac theatre situations. Dr Iatrou was a cardiac anaesthetist of 16 years' experience and indicated he had given thousands of doses of protamine and that there was no known alternative. Given the risks of protamine administration in a patient with perilous cardiac function, a general review of the use of protamine and the development of guidelines for all locations is justified, not just outside of the cardiac theatre.
4. Further, the review recommended improved documentation of protamine reactions on anaesthetic chart. There is no reason to limit such documentation to protamine. There should be education of relevant staff as to the importance of accurately detailing any adverse reaction on the anaesthetic chart.
5. Finally, given there was some controversy in this case as to whether Mr Dobrovoljski had an anaphylactic reaction or simply a pronounced adverse reaction to protamine, the *Surgical Safety Checklist* should be amended so that it accords with the alert

stickers and asks the question 'DOES PATIENT HAVE A KNOWN ALLERGY OR ADVERSE DRUG REACTION?' and not simply 'DOES PATIENT HAVE A KNOWN ALLERGY?'.

RECOMMENDATIONS

Pursuant to section 72(2) of the *Coroners Act 2008*, I make the following recommendation(s) connected with the death:

1. That Royal Melbourne Hospital develop a general guideline for the use of protamine, outlining indications, high-risk patients, potential complications and management options for high risk situations.
2. That Royal Melbourne Hospital educate anaesthetists as to the need to document any significant intraoperative event and the medications administered.
3. That Royal Melbourne Hospital amend its *Surgical Safety Checklist* document to include adverse drug reactions as well as known allergies.

I direct that this finding be published on the internet and that it be distributed to the following persons or institutions:

The family of Mr Dobrovoljski;

The Investigating member;

Dr Malcolm Mohr;

Chairman, Victorian Consultative Council on Anaesthetic Mortality and Morbidity;

The Australian and New Zealand College of Anaesthetists; and

Interested parties.

Signature:

ROSEMARY CARLIN
CORONER
Date: 19 May 2016