Coroners Act 1996

[Section 26(1)]

Western  ***Australia***

RECORD OF INVESTIGATION OF DEATH

Ref No: 31/13

I, Barry Paul King, Coroner, having investigated the death of ***Hayley Bree Fisher*** *with an inquest held at the* ***Perth Coroner's Court, Court 51, CLC Building, 501 Hay Street, Perth,*** *on* ***15 to 17 July 2013****, find the identity of the deceased person was* ***Hayley Bree Fisher*** *and that death occurred* ***on 14 December 2009*** *at* ***King Edward Memorial Hospital*** *from* ***opiate toxicity*** *in the following circumstances:*

Counsel Appearing:

Marco Tedeschi assisting the Coroner
Stephanie Teoh appeared on behalf of King Edward Memorial Hospital and the Department of Health

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INTRODUCTION

1. Hayley Bree Fisher (**the deceased**) was a registered midwife employed at King Edward Memorial Hospital (**KEMH**) in Subiaco.

2. On 13 December 2009 the deceased worked night shift as usual.

3. At about 10.30pm she assisted another midwife to prepare and administer a patient-controlled intravenous analgesic device containing fentanyl solution to a patient who was in a bed in a single room. Fentanyl is a powerful opioid analgesic.

4. At about 12.30am, the deceased entered a staff toilet, locked the door and injected a fatal quantity of fentanyl into her arm.

5. At about 1.00am, colleagues of the deceased forced their way into the toilet and found her unresponsive. An emergency team attended but could not resuscitate her.

6. An inquest was held from 15 to 17 July 2013 into the deceased's death.[1] One area of particular inquiry was the means by which the deceased obtained the fentanyl in order to determine, if possible, how similar circumstances could be prevented in the future.

7. The evidence adduced at the inquest comprised an investigation brief[2] compiled by a police investigator, First Class Constable (now Senior Constable) Hayley Burke, together with statements and oral evidence from employees of KEMH and the Department of Health of Western Australia (**the Department**).

8. Winthrop Professor and Chair of Obstetric Anaesthesia at the University of Western Australia, Professor Michael Paech, also provided helpful evidence.

[1] The inquest was held together with an inquest into the death of Craig James Doherty.
[2] Exhibit 1

THE DECEASED

9. The deceased was born on 5 January 1982 in Western Australia and enjoyed a normal uneventful childhood. She excelled academically at school and went on to study nursing at university.

10. After graduating from university, the deceased completed a year of post-graduate study and then went on to study midwifery. She then began working at KEMH on a graduate program in January 2006.

11. In late 2007, the deceased had been providing care for a woman in labour when she misinterpreted a foetal heart pattern, which had an adverse result for the baby.

12. The deceased then underwent a performance review and was eventually cleared to return to work, but she was transferred from the stressful environment of the labour and birth area to neo-natal care in Ward 5. Her annual performance appraisals in 2008 and 2009 found that she was performing competently as a midwife.

13. The deceased lived primarily at home, but for a period of six months prior to her death she had been living with a friend of her sister's. She then moved back home, partly in order to save money while she undertook further study, including for an entrance exam to study medicine.

14. In December 2008 the deceased's mother died from cancer after a long illness. This had a significant effect on the deceased who had been very close to her mother and had been caring for her.

15. In November 2008 the deceased went to her doctor exhibiting symptoms of depression and anxiety. She had been using her mother's oxycodone and temazepam. She was prescribed an anti-depressant, Lexapro, and in January 2009 was offered counselling for her grief.

16. The deceased continued to abuse oxycodone and became dependent on her prescribed diazepam and panadeine forte. In March 2009, she presented at an emergency department with suicidal ideation.

17. In early April 2009, the deceased attempted to wean herself off oxycodone and diazepam with the help of her doctor and the use of panadeine forte as a substitute.

18. By May 2009, the deceased had stopped using oxycodone but continued to use diazepam and panadeine forte. She was prescribed a different anti-depressant, dothiepin. Her symptoms then fluctuated for some months.

19. In November the deceased saw a psychiatrist, Dr Daniel Morkell, who diagnosed her condition as a major depressive disorder with anxiety symptoms and the possibility of Bipolar II. He increased the deceased's dosage of dothiepin and prescribed a low dosage of Seroquel and, a little later, a low dosage of Clonazepam.

20. Dr Morkell saw the deceased on 8 December 2009 and noted that she seemed brighter. She told him that she was feeling significantly better. She did not have suicidal ideation, but she was grieving her mother, the anniversary of her mother's death having passed recently, and she was not looking forward to Christmas.

21. On 11 December 2009 the deceased went to a music concert with her father and really enjoyed it.

22. On the morning of 13 December 2009 the deceased went home after a full 12 hour night shift and stayed up to make a few notes. A page of the deceased's handwriting containing a list of things to do and notes of possible presents for friends and family was found by her father after her death.[3] She had planned a Christmas Eve celebration with her family at home.

23. The deceased had been on two overseas holidays with friends earlier in 2009 and had arranged to meet her cousin on 15 December 2009 in order to plan another holiday together.

[3] Exhibit 1, Tab 15

24. Before leaving for work on 13 December 2009, the deceased kissed her father goodbye and said 'See ya later.' She gave no indication of intentional self-harm.

THE NIGHT OF 13 DECEMBER 2009

25. The deceased commenced her 12 hour shift at 7.00pm on 13 December 2009. She was working with another registered midwife, Pramila Crasta, with whom she had worked for years. Ms Crasta considered the deceased to be a very good midwife who was a good team worker and always willing to help. Ms Crasta stated that the deceased provided good care to the patients.[4]

26. That night Ms Crasta had a patient who was in pain following a caesarean section. The patient was in a single private room. Ms Crasta had obtained an anaesthetist's prescription to provide the patient with a patient-controlled intravenous analgesia device, or a PCIA device[5], containing 2000mcg of fentanyl to control pain.

27. As fentanyl is a controlled drug under Schedule 8 of the *Poisons Act 1964*, KEMH had mandatory guidelines in place for its storage and handling. Those guidelines required that it be stored in a double locked cupboard and that the dispensing of any fentanyl from the cupboard and the administering of the fentanyl to a patient had to be done by two staff members working together, both of whom having to sign a drug register.

28. Each time a Schedule 8 drug such as fentanyl is dispensed from a cupboard, the stock levels in the cupboard are counted and reconciled with the register. The whole cupboard is counted at least twice a day by two staff members.

29. That night, Ms Crasta asked the deceased to check as Ms Crasta took four ampoules of fentanyl out of the locked cupboard, counted the remaining fentanyl in the cupboard and recorded in the relevant drug register the

[4] Exhibit 3 paragraph 9
[5] Also referred to as a patient-controlled analgesia device or PCA: Exhibit 7 paragraph 9

amounts of fentanyl taken and remaining. Both nurses then signed the register. Each ampoule contained 500mcg in a 10ml solution, making a total of 2000mcg of fentanyl in 40ml of solution.

30. Ms Crasta then used a syringe to extract all of the fentanyl from each of the ampoules and placed it into a 50ml syringe with 10ml of saline solution, making a total of 50ml.

31. The deceased did not handle the fentanyl at any time when Ms Crasta was preparing the PCIA. Her role was to check on Ms Crasta and then sign the register as confirmation that the fentanyl had been checked out and administered as prescribed.

32. After Ms Crasta set up the PCIA for her patient, the deceased left the room while Ms Crasta stayed with the patient for a while. Ms Crasta then checked on her patient every hour or so throughout the night. She kept a record of the readings on the PCIA, which indicates that she went in the room at 10.35pm, 11.00pm, 12.00pm, 1.15am the next morning and then hourly or so from then on.[6]

33. The record shows that the level of fentanyl solution in the PCIA did not decrease from 10.35pm to 11.00pm, decreased by 2ml from 11.00pm to 12.00pm, and did not decrease by from 12.00pm to 1.15am. On the face of the record, none of the solution had been removed apart from a small amount likely to have been used by the patient.

34. At some time between 11.00pm and 12.00pm, Ms Crasta took the patient into the bathroom for a shower and the deceased assisted to lift the patient from her bed. The PCIA went with the patient. The record indicates that when Ms Crasta checked on the patient at 12.00pm, the patient was sleeping.

[6] Exhibit 3, Annexure PWC4

14 DECEMBER 2009

35. The deceased's co-ordinator on the evening of 13 December 2009 was clinical nurse Reyney Booth. Ms Booth and the deceased had become close friends over the previous two years. That evening they spoke to each other several times about work and personal matters. The deceased told Ms Booth that she had been very manic and depressed on the morning of 13 December 2009.[7]

36. At round 12.30am on 14 December 2009, Ms Booth spoke to the deceased in the staff room on Ward 5 just before the deceased went on a half hour meal break. The deceased said that she had been feeling terrible since she started taking her new antidepressant medication. Ms Booth offered the deceased the opportunity to go home, but the deceased said that she felt better amongst her friends and being busy. The deceased then left the staff room.[8]

37. Ms Booth tried to gain access to the single staff toilet on Ward 5 about ten minutes later but found it locked from the inside. She went away and came back again at 12.50am and at 1.00am, but the staff toilet was locked each time. She went to the Ward 5 office and noted that all staff members were present except the deceased, so she obtained a screwdriver with which to override the lock on the toilet door. All the staff members went with her.[9]

38. When Ms Booth opened the staff toilet, she saw the deceased slumped kneeling on the floor with her head folded underneath her and her arms outstretched. On the floor beside her were two syringes with a winged infusion set, or cannula, attached to one syringe.[10]

39. The staff members began administering cardiopulmonary resuscitation and called the emergency medical team, but the deceased could not be resuscitated.

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[7] Exhibit 1, Tab 6
[8] ts.77
[9] Exhibit 1, Tab 6
[10] Exhibit 1, Tab 4

POST MORTEM AND TOXICOLOGY

40. On 15 December 2009 Chief Forensic Pathologist Dr C T Cooke and Anatomical Pathology Registrar Dr C Unwin made a post mortem examination of the deceased. They determined that the cause of death was opiate toxicity.

41. They had found puncture wounds to the front of both elbows and a toxicology analysis showed a high level of fentanyl as well as lower levels of codeine, morphine and antidepressants.[11]

42. The concentration of fentanyl was 6ug/L which was twice the average concentration of 3ug/L found in a series of deaths from fentanyl misuse.[12]

43. The syringes and the cannula found with the deceased were also subjected to a toxicology analysis. No drugs were detected on the syringes, but fentanyl was detected on the cannula.

FENTANYL

44. Fentanyl is a strong opioid analgesic, about 100 times more powerful than morphine. Due to its effectiveness, it is used in much smaller doses.

45. Fentanyl is widely used for acute and chronic pain relief from all different types of pain.

46. It can be used in an epidural during labour and delivery in childbirth, as part of an anaesthetic during an operation, and in recovery from an operation by a PCIA or a nurse controlled infusion. It is also used intravenously for acute pain in emergency medicine and can be delivered by transdermal patches to patients suffering chronic pain from, for example, cancer.

[11] Exhibit 1, Tab 17
[12] Exhibit 1, Tab 18

47. At KEMH fentanyl for intravenous use was available in 2ml vials and 10ml vials of 50mcg/ml concentration.[13]

THE PCIA DEVICE

48. Professor Paech demonstrated how a PCIA device is used to deliver an analgesic such as fentanyl to a patient.[14] The device comprises a syringe, in this case with a 60ml capacity, with a tube extending from the outlet to a fitting from which one tube extends to a push button pump and then to the patient and one tube provides access to the syringe to allow it to be filled. The latter tube has a removable cap. The syringe has a scale with a line for each millilitre.

49. The PCIA device demonstrated was identical to that used by Ms Crasta on her patient on 13 December 2009. It has a mechanical system controlled by the patient by using the pump which allows a set dose to be administered over a particular time. In this case, the pump provided a maximum of 0.5ml of fentanyl to be delivered every five minutes.

50. Mechanical PCIA devices are not secure because the medicine in them can be diverted. When patients are known to be unreliable with respect to drugs, a hospital can use a secure electronic PCIA instead if it has one available.

51. In the case of a mechanical PCIA containing fentanyl, it is possible for hospital staff to remove some of the drug solution and replace it with saline solution so that a reduction of the quantity of the fluid in the PCIA is not readily detected. Professor Paech demonstrated that such a procedure was simple and quick.

52. None of the witnesses from KEMH had been aware of a previous instance of anyone diverting a drug from a PCIA.[15]

[13] Exhibit 7 – Statement of Professor Paech
[14] Exhibit 8
[15] Eg. ts.87 per G. Boardley

HOW DID THE DECEASED OBTAIN THE FENTANYL?

53. Shortly after the deceased was found, the drug cupboards on Ward 5 at KEMH were checked by pharmacy staff but no discrepancies were found.[16]

54. The Director of Nursing – Midwifery, Margaret Davies, checked the drug registers and found no discrepancies. There were no notations in the drug registers by the deceased as far back as September 2009, so it is unlikely that she obtained fentanyl from KEMH prior to 13 December 2009.

55. Ms Crasta was sure that she withdrew all the fentanyl in the ampoules she had obtained from the locked cupboard on 13 December 2009 and that she placed the empty ampoules in a sharps container, so it appears that the deceased did not obtain fentanyl from those ampoules.

56. While there is evidence that the deceased had disclosed to her doctor that she had been obtaining oxycodone from friends, there is no evidence to suggest that she obtained fentanyl in the same way. The doctor's practice's consultation notes relating to the deceased contain no reference to fentanyl whatsoever. None of the deceased's colleagues were aware that she had been abusing drugs.

57. In these circumstances, it is most likely that the deceased went into Ms Crasta's patient's room while Ms Crasta was not there, possibly while the patient was asleep after 12.00pm, and removed some of the fentanyl solution from the PCIA device.

58. The deceased then took the fentanyl into the staff toilet in Ward 5 and injected it into one or both of her arms.

59. Professor Paech considered that the amount of the solution that the deceased would have taken and used in

[16] Exhibit 1 Tab 23 paragraph 67 per Patrick Yapp

order to have produced the concentration indicated by toxicology analysis would have been more than 10ml and possibly more than 20ml.

IMPROVED SECURITY OF SCHEDULE 8 DRUGS

60. As noted above, the storage, dispensing and administration of fentanyl at KEMH was strictly controlled. However, once it had been placed in a PCIA device and administered to a patient, it was no longer under the scrutiny of two nurses working together.

61. Evidence was adduced of the policies and procedures at KEMH and within the WA public health system generally regarding medicine management. In particular, Graeme Boardley, Executive Director of Midwifery Nursing and Patient Support Services of the Women and Newborn Health Service at KEMH, provided a comprehensive background of the procedures at KEMH with respect to Schedule 8 and Schedule 4 drugs[17], and Neil Keen, the Chief Pharmacist at the Department of Health, described the Department's role in directing the policies and procedures in public hospitals.

62. Mr Boardley noted that, over the last few years, KEMH has implemented a number of measures calculated to reduce the risk of drug discrepancies: pre-mixed syringes are used whenever possible to remove measurement errors, swipe cards are used for locked cupboards to allow tracking of staff who access drugs and 69 closed-circuit cameras have been installed in corridors.[18]

63. Mr Keen described the stringent procedural controls that have been in place in relation to Schedule 8 drugs since 2008 when the Department issued Operational Directive OD 014/08. Since then there have not been any substantial changes to the requirements related to storage and administration of Schedule 8 drugs,[19] but there is an improved system of reporting and investigating drug discrepancies implemented under

[17] Exhibit 4
[18] Exhibit 4; ts.86, 90
[19] ts.179

Operational Directive OD 0377/12. This new system has resulted in an increased number of discrepancies reported, possibly from an increased staff awareness and adherence to the directive. [20]

64. The Chief Pharmacist at KEMH, Patrick Yapp, also gave evidence consistent with that of Mr Boardley and Mr Keen. Mr Yapp expressed the view that the best way to reduce drug theft would be to implement a barcode system whereby every patient, medical chart and drug has its own barcode. He conceded, however, that the proposed system would not be foolproof because there would still be an opportunity for a nurse to misappropriate a drug at the point of administering it to a patient. He stated that at the end of the day it was up to the nurse's honesty. Having two nurses present for the whole process would be expensive.[21]

65. Shayne Sherman, the Assistant Director of the Ethical Standards Branch of the Department's Corporate Governance Directorate gave evidence about a number of departmental initiatives calculated to address misconduct by staff in relation to drugs, including ongoing staff training to raise awareness of the issue and the consequences of misconduct.[22]

66. When it comes to the question of how the use of PCIA devices can be controlled to remove the opportunity for a nurse to divert medicine when it is being administered to a patient, the evidence of Professor Paech provides one solution: the use of secure, electronically controlled devices. These devices have a locked Perspex box which can contain the drug reservoir bag.

67. His evidence did not include details of how the key to the box would be managed, but it seems to me that having two staff members check and sign for the locking of the box would not be much more onerous than the current system applying to the use of mechanical PCIAs.

[20] Exhibit 2, Volume 2, Tab 23 and Annexure NJK3
[21] Exhibit 1, Tab 23, paragraph 76
[22] Exhibit 2, Volume 2, Tab 23, Annexure SDS3.

68. Professor Paech estimated that the cost of obtaining and maintaining electronic PCIA's would be in the thousands of dollars per unit in contrast to the $30 or $40 that a mechanical PCIA costs.

COMMENT

69. Since the inquest, the Corruption and Crime Commission (**CCC**) has provided to this Court statistics of Schedule 8 drug discrepancies reported by the WA public health system to the CCC from March 2011 to December 2012 (**the statistics**). The majority of the discrepancies relate to oxycodone pills. Of the discrepancies that have been investigated and explained, only a small percentage of them have involved misconduct. However, the vast majority of discrepancies have remained unexplained.

70. Counsel for KEMH, Ms Teoh, responded to the statistics by submitting that fentanyl was not reported in the list of top 10 drug discrepancies and is less likely to go missing, so the evidence does not support the imposition of stricter controls on fentanyl.[23]

71. Ms Teoh also submitted that the amount of medication misplaced (or misappropriated) in light of the total number of transactions is minimal.

72. However, even using the figures provided from internal data from the Department, 20% of the loss reports in relation to tablets related to 5 tablets or more and 10% of the loss in relation to injectables related to four ampoules or more. While the figures may appear minimal in universal terms, when it is considered that four ampoules or less of fentanyl was sufficient to end the deceased's life, they take on a different significance.

73. Ms Teoh went on to submit that the low percentage of loss has been relatively stable since the introduction of Operational Directive 077/12, which suggests that there

[23] The submission also related to propofol, being relevant to the death of Craig James Doherty.

is a background level of discrepancy that cannot be prevented with current systems. It may be that this submission is directed to the inquest into the death of Craig James Doherty.

74. In any event, and whether or not it is an appropriate response to the potential dangers associated with unauthorised access to Schedule 8 drugs to accept a level of discrepancy, it may be that different systems may lead to a better outcome.

75. While it is worth remembering that statistics can be misleading, and while the Department and public hospitals are to be commended for improvements to drug security made recently, in my view the evidence suggests that there is a need for improved security with respect to the storage and management of Schedule 8 drugs in public hospitals.

76. It is clear that there is a gap of security that exists at the point of administration that needs to be addressed.

77. It may be, for example, that a mechanical PCIA can be devised with a secure container for the drug reservoir but, as Mr Boardley stated, opportunities would still exist for drugs to be drawn out of plastic drip infusions with syringes.

78. It may be, as Mr Keen suggests, that the only feasible approach is an iteration of the multi-pronged one currently in place, including the sort of staff training that has already been commenced.

79. However, there was insufficient evidence to allow me to recommend with any degree of confidence a step that would be effective and economically feasible to deal with that gap.

80. I therefore make the following comment.

> The Department of Health and public hospitals should continue to review and improve the means by which unauthorised

access to Schedule 8 drugs at hospitals is controlled, particularly at the point of the administration of the drugs to patients.

CAUSE OF DEATH

81. In accordance with the determination of Dr Cooke and Dr Unwin, I find that the cause of death was opiate toxicity.

MANNER OF DEATH

82. As the deceased was an experienced nurse, it might be presumed that she realised before using the fentanyl that the quantity she was about to use would be fatal and that she used it intending to cause her death.

83. However, the evidence as a whole has convinced me otherwise. As mentioned, it appears that the deceased had not used fentanyl herself previously, and the drug register checked by Ms Davies indicates that the deceased had not recently administered fentanyl to a patient. Any presumption that she was aware that the dose she was about to use herself was fatal is weak.

84. In addition, there was evidence from Ms Booth that the deceased was having mood swings and was feeling terrible, but there was no evidence of suicidal ideation. On the contrary, the evidence of her list of things to do, her plan to meet with her cousin to discuss a holiday trip, her plan to take an entrance exam to study medicine and her last interactions with her father all indicate that she was future orientated.

85. Importantly, when Dr Morkell saw the deceased on 8 December 2009, he conducted a safety assessment and found no suicidal ideation or psychotic symptoms.

86. In these circumstances, I find that the manner of death was accident.

CONCLUSION

87. I am satisfied that, while working as a midwife at KEMH, the deceased misappropriated a quantity of fentanyl which she injected into her arm and, due to the excessive amount of the drug, accidently caused her death.

B P KING
CORONER

5 September 2013