IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

Court Reference: COR 2007 004142

**FINDING INTO DEATH WITHOUT INQUEST**

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

I, PARESA ANTONIADIS SPANOS, Coroner,

having investigated the death of PAUL GARY LARMAN
without holding an inquest:
find that the identity of the deceased was PAUL GARY LARMAN
born on 13 June 1979,
and that the death occurred on 15 October 2007
at Frankston Hospital, 2 Hastings Road, Frankston Victoria 3199
**from:**

1 (a) OVERDOSE OF CLOZAPINE.

Pursuant to section 67(2) of the **Coroners Act 2008**, I make findings with respect to **the following circumstances**:

Background

1. Mr Larman was a 28 year-old man who was sharing a house in Seaford with a friend at the time of his death. Mr Larman had been involved with mental health services since 1999 and had many admissions to acute and residential mental health units in metropolitan Melbourne. He had a history of schizophrenia, borderline intellectual functioning and polysubstance abuse.

2. Between 2003 and 2005 Mr Larman was a psychiatric inpatient at the Warringa Secure Extended Car Unit at Southern Health Mental Health Service (SHMHS). He was released in 2005 and placed on a Community Treatment Order. In April 2007, Mr Larman was discharged from SHMHS with referral to the Peninsula Health Mental Health Service (PHMHS) for case management, after he moved house to his Seaford address. This meant that Mr Larman was now residing in the PHMHS area and was referred to this service for case management. PHMHS

provided case management with regular visits, which included assessment of Mr Larman's ability to fill his own medication dosette box, prior to his taking over responsibility for his own medication.

3. Clozapine was prescribed to Mr Larman from 19 August 2005 following ineffective responses to other antipsychotic medications that had been prescribed in varying combinations to treat his schizophrenia since 1999. Clozapine is used for the treatment of treatment-resistant schizophrenia and prescribed only where it is evident that a patient has not responded to other antipsychotic therapy or where other therapy produces intolerable adverse effects. Treatment of Mr Larman was complicated by periods of non-compliance with his medication and use of combinations of alcohol and illicit substances in moderate to high amounts.

4. Mr Larman was last visited by his case manager, Alison Shand, on 15 May 2007. Mr Larman had started using cannabis and either stopped or decreased his prescribed dose of Clozapine. This resulted in an exacerbation of his schizophrenia and he required admission as an inpatient at PHMHS for 32 days. Upon release, Mr Larman was unable to find suitable accommodation and went to live with his mother in Heatherton. With this move in residence, he needed to be transferred back to the care of SHMHS.

5. At this time, Mr Larman's care was being provided by the Crisis Assessment and Treatment (CAT) Team and consisted of weekly reviews and medication dispensing, associated with restarting Clozapine. The Clayton Community Health Service then treated Mr Larman. He was noted to be complying with his Clozapine treatment and was reviewed monthly by consultant psychiatrist Dr Sanghvi.

6. In September 2007, Mr Larman moved back to Seaford to share a flat with his friend. His last appointment with SHMHS was on 28 August 2007 where he received his usual four weeks supply of Clozapine from the Clayton Community Health Service. On 12 September 2007 Mr Larman was transferred to PHMHS, with the transfer documents stating that Mr Larman had four weeks supply of Clozapine, prescribed and dispensed on 28 August 2007 and that his monthly blood test was next due on 24 September 2007.[1]

7. Mr Larman's first appointment with PHMHS after transfer from SHMHS was on 25 September 2007 with a follow-up appointment arranged for 17 October 2010.

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[1] Registered Centre prescribing requirements of Clozapine are for pathology each week in the initial 18-week phase of treatment, every four weeks thereafter for the duration of treatment and one month after a patient stops taking Clozapine.

8. On 22 September 2007 at 3.20pm, Mr Larman presented to the Emergency Department (ED) at Frankston Hospital, requesting scripts for eight different medications. Records for that day note that Mr Larman had a psychiatric history with PHMHS. Dr Malik Majora was an ED doctor who provided Mr Larman with a script for Clozapine 25mg tablets x 28, the equivalent of less than two days supply, and Diazepam 5mg tablets x 50. There is no evidence available to determine whether this script was dispensed, and Dr Majora states he was not aware that he was not entitled to prescribe Clozapine.

9. On 25 September 2007 Mr Larman attended an appointment with PHMHS Continuing Care Team for initial assessment following the transfer. He was reviewed by Psychiatric Registrar Dr Sangeeta Raghav, Occupational Therapist and Team Leader Ms Judith Bakewell and Clozapine Coordinator Mr Guy Dobson. At the assessment, Dr Raghav recorded that Mr Larman was under the influence of a 'substance'. Mr Larman was unable to tell Dr Raghav what the signs and symptoms of his illness were when he was unwell, and reportedly denied any symptoms of psychosis. Mr Larman received a script for one month's supply of Clozapine and this was dispensed on the same day at Frankston Pharmacy.

10. There was no evidence available to indicate whether PHMHS was aware of Mr Larman's visit to the ED and the fact that he had been provided with a script for Clozapine on 22 September, and it appears that there was no further contact between PHMHS and Mr Larman up to the time of his death. The Continuing Care Team allocated Alison Shand as case manager on 11 October 2007.

Mr Larman's death

11. On 15 October 2007 at approximately 5.45am, Clare Henderson was driving along Halifax Street, Seaford and located Mr Larman lying unconscious on the footpath just outside his home. Ms Henderson called 000 and ambulance officers transported him to the ED at Frankston Hospital, believing that he may have overdosed on a substance. He was treated in the ED by Dr Schreve, however he died at approximately 7.45am on the same day.

12. An autopsy was performed by Pathologist Dr Paul Bedford from the Victorian Institute of Forensic Medicine (VIFM) who reviewed the circumstances as reported by the police to the coroner and provided a detailed written report of his findings. Dr Bedford attributed death to *overdose of Clozapine* and noted that toxicological analysis detected the presence of markedly increased levels of Clozapine (~21mg/L in blood), cannabis, as well as Lignocaine and Midazolam (consistent with substances which may have been administered to Mr Larman whilst in the ED on the date of his death). Dr Bedford stated that *elevated doses of Clozapine have been associated with a number of*

*factors which can lead to death. These include coma, hypotension, respiratory depression and seizures*. He did not identify any suspicious circumstances.

13. I find that the cause of death of Mr Larman is overdose of Clozapine. I note that he was deemed to be at risk of self-harm, however, on the basis of the evidence available, I am unable to determine whether he consumed the drugs with the intention of taking his own life.

Further investigation

14. Following consideration of the brief of evidence compiled by the police, I sought advice from the Mental Health Investigator within the Coroners Prevention Unit about Mr Larman's clinical management and care. Specifically, I was concerned about Mr Larman's ability to access sufficient Clozapine to enable successful overdose, and sought an assessment of the clinical management and care provided to him in the public mental health system, and the transfer between SHMHS and PHMHS. The assessment was in the following terms.

Clozapine prescribing

15. Clozapine is part of the Commonwealth Highly Specialised Drugs Program and should be prescribed only by registered centres and registered medical practitioners at registered centres. In addition, Clozapine carries five black box warnings;[2] agranulocytosis,[3] seizures, myocarditis, other adverse cardiovascular and respiratory effect and increased mortality in elderly patients with dementia.

16. There is ample evidence of the psychological benefits to patients who take the drug, however, the side effects are also many and range from mild to life-threatening. As such, metabolic monitoring is required prior to prescribing Clozapine.

17. The registered centre prescribing requirements include registering patients in a web-based database prior to commencement and the completion of additional safety checks, such as a prior history of adverse effects from previous Clozapine use. When prescribing and dispensing Clozapine, the following steps are required by the registered centre and pharmacy, all within a 48-hour period:

[2] A black box warning appears on the level of a prescription medication to alert patients and healthcare staff about any important safety concerns such as serious side effects or life-threatening risks. It is the sternest warning for medication.

[3] Agranulocytosis is an abnormally low white blood cell count. Since white blood cells are necessary to fight infections, this is a potentially fatal side effect.

- A white blood cell count, the results of which are reviewed before a prescription for a further 28 days supply is provided to the patient – this is to detect any signs of agranulocytosis.
- A registered pharmacist dispenses the prescription when it is accompanied by the results of the white blood cell count – a safety check to ensure the white cell count is within a safe range before the pharmacist gives the patient the 28 days supply of medication.
- The white blood cell count results are then entered into the database from which alerts are issued ranging from 'green' (normal) through to 'red' (abnormal). Each alert has a clearly outlined response required from the registered centre.

18. The two main suppliers of Clozapine in Victoria are Hospira Pty Ltd, which markets Clozapine as Clopine, and Novartis Pharmaceuticals Australia Pty Ltd, which markets the drug as Clozaril. Each company has a protocol for its use. Peninsula Health is a registered centre with Hospira and prescribed Clopine to Mr Larman, whereas Southern Health is a registered centre with Novartis and prescribed Clozaril. With each transfer of care, the associated company's own web-based monitoring system had to be updated.

Transfer between Peninsula Health and Southern Health

19. In the seven months prior to his death and due mainly to accommodation needs, Mr Larman was cared for by SHMHS then transferred to PHMHS, transferred back to SHMHS and then again transferred back to PHMHS.

20. PHMHS provided care to Mr Larman from 14 September 2007 until the day of his death following transfer from SHMHS. At his initial assessment appointment, Ms Bakewell described him as 'sedated, poor attention, dishevelled, unshaven, malodorous, slow speech, being difficult to understand, had difficulty answering questions, unable to identify symptoms of illness'. In the context of this presentation, Dr Raghav prescribed one month's supply of Clozapine tablets.

21. Mr Larman's treatment plan stated that he was to be compliant with his medication, he was to explore his substance abuse issues, have monthly pathology tests, attend appointments and discuss with his case manager any other support needs.

22. In essence, Mr Larman was a new patient to the Peninsula Health Continuing Care Team when transferred from Southern Health. There are several clinical reasons, based on the evidence available, why a greater frequency of follow-up should have occurred following the 25 September appointment:

- Mr Larman's clinical presentation indicated use of substances and at least two other early warning signs.
- Mr Larman was in the recognised high-risk phase for patients following transfer of care and case manager.
- Clozapine was prescribed to Mr Larman.
- Mr Larman had a history of non-compliance and a recent history of an acute admission in the previous three months because of relapse of his schizophrenia.

Mr Larman's history of non-compliance

23. Mr Larman had a history of non-compliance with medications. His stay in the Wirringa Secure Extended Care Unit (2003-2005) and the Middle South Community Care Unit resulted in improvements in Mr Larman's presentation and ability to function in society, to the point of gaining employment and being discharged to independent living with community based case management. In both of these supported environments, with supervised medication and in the case of the Middle South Community Care Unit, a rehabilitation unit, Mr Larman used weekly dosettes with success.

24. On transfer from SHMHS to PHMHS in April 2007 a risk assessment of Mr Larman's ability to self-administer medication, with and without the use of weekly dosettes was completed. Any assessment of risk of non-compliance and capability to self-administer by PHMHS in the context of his presentation on 25 September 2007 does not appear to have occurred.

25. Prior admissions for Mr Larman to acute inpatient mental health units had taken place in the context of non-compliance with Clozapine combined with substance abuse. The clinical files indicate that on each of these occasions, the deterioration occurred over a period of 2-3 days of Mr Larman's failure to take his medication.

26. Even though PHMHS knew Mr Larman, in the context of his recent referral and transfer from SHMHS he was a new patient. It is therefore reasonable to expect a greater frequency of follow-up in his initial month, given his clinical presentation on 25 September 2007.

27. The making of an appointment in four weeks' time following the initial assessment on 25 September, appears to have been based on the Clozapine protocol process, rather than an individual assessment of the patient's needs. The early warning signs or *signs that I am becoming unwell* section of the Treatment Plan for Mr Larman dated 27 September 2007 lists the following: *Hearing voices, difficultly thinking clearly, poor self-care, increase in irritability or aggression, thoughts that others want to harm me, feeling restless, agitated.* Early warning signs are based on previous

illness processes and any or all of them can pre-empt a relapse. Throughout the clinical files at both PHMHS and SHMHS there is reference to Mr Larman being a suicide risk when he was unwell.

28. Review of patients stabilised on Clozapine is usually restricted to a monthly pathology test, followed by medical review with the prescribing of another 28 days supply of Clozapine if there are no abnormalities in the pathology results. In Mr Larman's case, he was also having case management and Alison Shand became his case manager on 11 September 2007. Ms Shand had also been Mr Larman's case manager prior to his admission on 18 May 2007. It is reasonable to presume Ms Shand would have made contact with Mr Larman, but it is not clear if this would have occurred prior to or at the 17 October 2007 appointment.

29. Mr Larman had other historical and known behaviours that might have enabled his access to large numbers of Clozapine tablets, such as his non-compliance and habit of reducing the dose taken. He would usually reduce from four to two tablets of Clozapine 100mg, especially if he was feeling sedated or was late home at night. This reducing or skipping of doses would have increased the number of Clozapine tablets available to Mr Larman.

30. Mr Larman's history of missed and reduced dosing combined with the likely ability to stockpile his own supply potentially resulted in his having access to a significant number of Clozapine tablets at the time of his death. This is without considering the possibility that the prescription supplied through his visit to the Frankston Hospital ED was filled.

31. Further, in the context of Mr Larman's clinical presentation on 25 September and his history of an increased suicide risk when unwell, it was reasonable to have expected staff to assess the safety of dispensing a one-month supply of Clozapine.

Presentation at Frankston Hospital ED

32. On 22 September 2007 Mr Larman presented to the ED at Frankston Hospital requesting scripts for eight different medications, and the ED record noted that he had a psychiatric history with PHMHS. Dr Majora provided Mr Larman with a script for less than two-day's supply of Clozapine and Diazepam 5 mg tablets x 50. Dr Majora did not record any attempts to refer to the PHMHS, even though it is clear from his notes that he was aware of Mr Larman's relationship with them. He also is clear in describing Mr Larman as "psychotic" and of recording his requests for at least four psychoactive medications.

33. With all of this information, Dr Majora prescribed a controlled antipsychotic Clozapine medication and Diazepam, a benzodiazepine and a drug subject to 'doctor shopping'. Based on the

evidence available, Dr Majora did so without contacting the PHMHS either while Mr Larman was in the ED for over two hours, or at any stage during discharge planning or following his discharge.

34. The omission of any mention of Mr Larman's visit in the assessment documentation completed by Ms Bakewell and Dr Raghav on 25 September indicates they were unaware of his ED presentation three days prior. There is also no evidence of a discharge summary or other communication made to Mr Larman's General Practitioner who, according to his notes, Dr Majora was aware he had recently visited. It appears from the notes that neither the ED triage, nursing or administration staff nor Dr Majora asked Mr Larman the name of his General Practitioner.

35. Associate Professor Jespersen of Peninsula Health, states in his statement that *[d]octors who do not work in the mental health service do not receive any formal training regarding the Clopine Connect Protocol. As they are not registered as Clozapine prescribers this is not necessary. However, it is appropriate that all doctors at Peninsula Health should have a basic knowledge of the Clopine Connect system and this should be incorporated into their orientation or education program.* It is not clear if this has occurred or if, as part of that training, medical officers in the Frankston Hospital ED are also trained regarding the problems associated with prescribing patients with large amounts of benzodiazepines.

36. A patient presenting to any hospital ED with a mental health history, the symptoms of a mental illness, or requesting psychiatric medications should be referred to the mental health service. It is not clear why this did not occur in Mr Larman's case in 2007, but in the context of the Victoria Mental Health Triage Scale Project,[4] referral direct to the mental health service should now be occurring at the point of initial contact and triage.

**RECOMMENDATION**

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

1. In order to improve the safety of patients and their continuity of access to Clozapine, I recommend that SHMHS and PHMHS review their existing policies and procedures related to Clozapine to address what is required in relation to patients' own supplies of medications at the point of transfer, and the change from one brand of Clozapine to another.

[4] Department of Health Mental Health and Drugs Division. Mental Health Triage Project: http://www.health.vic.gov.au/mentalhealth/triage/triage-guidelines-0510.pdf

2. In order to improve the safety of all patients, I recommend that Peninsula Health includes information on the restrictions of Clozapine prescribing in the training and/or orientation of all medical officers, to decrease the risk of inappropriate and unsafe patient access to Clozapine.

3. In order to improve the safety of patients who are prescribed Clozapine, I recommend that PHMHS reviews its guideline to increase frequency of review of such patients in the initial weeks following transfer from another mental health service on the basis that this is a recognised high-risk period.

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

The family of Mr Larman
Senior Constable Robert Colcott, Carrum Downs Police Station.
General Counsel, Southern Health
General Counsel, Peninsula Health
Dr Mark Browne, Chief Psychiatrist

Signature:


**PARESA ANTONIADIS SPANOS**
CORONER
Date: **10 September 2013**