



IN THE CORONERS COURT
OF VICTORIA
AT MELBOURNE

COR 2023 002444

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2)

Section 67 of the Coroners Act 2008

Findings of:	Coroner David Ryan
Deceased:	Frankie Skye Foulkes
Date of birth:	24 December 2022
Date of death:	8 May 2023
Cause of death:	1(a) Complications of spinal muscular atrophy
Place of death:	209 Yallambie Road, Yallambie, Victoria
Keywords:	Complex medical needs – Child car restraints – Lie-flat car restraints – Product safety regulations

INTRODUCTION

1. On 8 May 2023, Frankie Skye Foulkes was four months old when she passed away in Yallambie.
2. Frankie was born in Darwin on 24 December 2022 to parents Robert and Karine Foulkes. Shortly after her birth, Frankie was reviewed by a paediatrician as her parents observed that she was floppy and they were concerned about possible developmental delays. She was subsequently referred to the neurology team at the Royal Children's Hospital (**RCH**).
3. On 16 April 2023, Frankie was transferred from Darwin Hospital to RCH, where she was reviewed by the neuromuscular team and her primary neurologist, Dr Ian Woodcock. Following genetic testing, Frankie was diagnosed with spinal muscular atrophy (**SMA**) and a treatment plan was developed.
4. On 19 April 2023, Frankie received her first dose of nusinersen, delivered via lumbar puncture, which is designed specifically to treat SMA by increasing production of a protein known as 'survival motor neuron'.
5. On 21 April 2023, Frankie underwent an initial assessment for her safety to travel in a standard infant car seat, during which her breathing rate, heart rate and oxygen saturation levels were monitored. After 15 minutes in the car seat on the ward, she began to show signs of fatigue. During a subsequent test, she was able to tolerate 20 minutes.
6. On 23 April 2023, Frankie tolerated 60 minutes in a car seat with no changes in vital levels and was therefore deemed safe for short car journeys. Prior to Frankie's discharge, the treating team discussed with Mr and Ms Foulkes the conditions required for safe car travel, including the need for short journeys and an adult being seated in the back to supervise Frankie.
7. During her admission, Frankie was identified as having signs of bulbar dysfunction which impacted her ability to swallow. She subsequently underwent a nasogastric tube (**NGT**) insertion for long-term feeding with the assistance of a pump.
8. On 25 April 2023, Frankie was discharged to her parents' temporary address in Melbourne.
9. On 4 May 2023, Frankie received her second dose of nusinersen.

THE CORONIAL INVESTIGATION

10. Frankie's death was reported to the coroner as it fell within the definition of a reportable death in the *Coroners Act 2008* (**the Act**). Reportable deaths include deaths that are unexpected, unnatural or violent or result from accident or injury.
11. The role of a coroner is to independently investigate reportable deaths to establish, if possible, identity, medical cause of death, and surrounding circumstances. Surrounding circumstances are limited to events which are sufficiently proximate and causally related to the death. The purpose of a coronial investigation is to establish the facts, not to cast blame or determine criminal or civil liability.
12. Under the Act, coroners also have the important functions of helping to prevent deaths and promoting public health and safety and the administration of justice through the making of comments or recommendations in appropriate cases about any matter connected to the death under investigation.
13. This finding draws on the totality of the coronial investigation into Frankie's death including evidence contained in medical records from the RCH, a report from the forensic pathologist who examined Frankie, and advice received from Dr Woodcock. While I have reviewed all the material, I will only refer to that which is directly relevant to my findings or necessary for narrative clarity. In the coronial jurisdiction, facts must be established on the balance of probabilities.¹

MATTERS IN RELATION TO WHICH A FINDING MUST, IF POSSIBLE, BE MADE

Circumstances in which the death occurred

14. On the morning of 8 May 2023, Frankie attended a baby spa session with her parents. After the session, Frankie was placed in her car seat, which was positioned in the rear passenger compartment of her parents' vehicle, and she commenced a feed via her NGT and feeding pump.
15. While driving to inspect prospective rental properties in Yallambie, Mr and Ms Foulkes pulled over to check on Frankie as they had not heard any noise from her for approximately 10

¹ Subject to the principles enunciated in *Briginshaw v Briginshaw* (1938) 60 CLR 336. The effect of this and similar authorities is that coroners should not make adverse findings against, or comments about, individuals unless the evidence provides a comfortable level of satisfaction as to those matters taking into account the consequences of such findings or comments.

minutes. When they checked on her at approximately 11.10am, they found her unresponsive and not breathing, with her head slumped forward and foam forming at her mouth.

16. Mr Foulkes contacted emergency services and pulled into a nearby carpark to commence cardiopulmonary resuscitation (**CPR**) under instruction from the operator. Frankie vomited three times before emergency services arrived, but she remained unresponsive.
17. Ambulance Victoria paramedics and Fire Rescue Victoria arrived a short time later and Frankie was transferred to the ambulance to enable further CPR. Responding paramedics were sadly unable to revive Frankie and she was pronounced deceased at 11.38am.

Identity of the deceased

18. On 8 May 2023, Frankie Skye Foulkes, born 24 December 2022, was visually identified by her father, Robert Foulkes.
19. Identity is not in dispute and requires no further investigation.

Medical cause of death

20. Senior Forensic Pathologist Dr Matthew Lynch from the Victorian Institute of Forensic Medicine conducted an examination on 9 May 2023 and provided a written report of his findings dated 19 October 2023.
21. Dr Lynch reviewed a post-mortem computed tomography (**CT**) scan, which revealed small volume muscle mass, consistent with Frankie's medical history. He did not observe any evidence of unexpected skeletal trauma.
22. Toxicological analysis of post-mortem samples did not detect any common drugs or poisons. Post-mortem biochemistry did not detect any abnormalities in renal function or elevated inflammatory markers.
23. While Dr Lynch was unable to identify an unequivocal cause of death, he noted that SMA in infants (Werdnig-Hoffman disease) is often fatal within the first year of life.
24. Having regard to Frankie's well-documented condition, Dr Lynch provided an opinion that the medical cause of death was 1(a) Complications of spinal muscular atrophy. Dr Lynch considered that Frankie's death was from natural causes.

25. I accept Dr Lynch's opinion.

FURTHER INVESTIGATION

26. During the course of the investigation, Dr Woodcock, was asked to elaborate on concerns he expressed to emergency services regarding the type of car seats available in Victoria to infants diagnosed with SMA. Dr Woodcock expressed an opinion that the circumstances of Frankie's death involved a number of contributing factors, including her diagnosis of SMA type 1 and the expected delay in experiencing the benefits of her nusinersen treatment; her fatigue following the spa session; and the use of a standard car seat in the absence of an appropriate alternative.
27. Dr Woodcock noted that a significant concern for babies with SMA is their positioning within the car seat, as their vulnerability and reduced muscle strength increases the risk of airway compromise. He explained that for vulnerable infants such as Frankie, the upright or semi-reclined position in a standard car seat can cause their heads to flex forwards towards their chest, potentially compressing their airways. While healthy babies have stronger muscles and can more easily adjust their position in a car seat, weaker infants may struggle to move their head or take bigger breaths due to respiratory muscle weakness, leading to rapid fatigue and increased risk of adverse events.²
28. Dr Woodcock advised that for longer distances, the only alternative transport RCH can recommend to families is non-emergency patient transport, whereby an infant patient with SMA is held by a parent seated on an adult stretcher, or the infant would be strapped to the stretcher with a single abdominal belt restraint. Unfortunately, there are limited alternatives for transporting infants who are not assessed as suitable for standard car seats, often leading to isolation for these families as they are generally restricted to travelling to locations within walking distance with the use of a lie-flat prams.

² Davis, N. L., & Shah, N. (2018). Use of lie-flat car restraints for infant travel: a review of the literature. *J Perinatol*, 38(10), 1287-1294. doi:10.1038/s41372-018-0195-7

29. While there are specialist lie-flat car restraints available in the United States and Europe that allow for infants to lie-flat during transport by car, such restraints are not available nor licensed for use in Australia. Dr Woodcock advised that the RCH Occupational Therapy department has meticulously researched the issues and concerns surrounding car seats for vulnerable infants. To that end, RCH has developed guidelines for assessment and prescription of two lie-flat car restraints now available at the hospital, for which RCH intends to launch a pilot program for children with conditions like SMA who are unable to be safely transported with a standard car seat.
30. Dr Woodcock highlighted several complexities associated with the regulation of safe transport in Australia for children with complex medical needs. With respect to safety standards for child restraints used in motor vehicles, the Australian Competition and Consumer Commission (ACCC) by Consumer Protection Notice requires all car restraints to comply with the relevant Australian/New Zealand Standard (AS/NZS 1754:2013).³ Notably, the Notice specifically excludes motor vehicle child restraints designed for children with a disability.
31. For treating clinicians, Dr Woodcock advised that AS/NZS 4370:2013 offers guidance in assessing a vulnerable child's needs for vehicle restraint and recommending the most suitable option. Standard 4370 specifies that a 'special purpose restraint' for children is: (1) designed to be used for children with a disability or medical conditions; and (2) is compliant with at least one of the following standards relating to child restraint systems in motor vehicles:
- (i) AS/NZS 1754:2013;
 - (ii) Canadian Motor Vehicle Safety Standard 213;
 - (iii) US Federal Motor Vehicle Safety Standard 213; or
 - (iv) Economic Commission for Europe Regulation 44.
32. Dr Woodcock advised that the lie-flat car restraints for the proposed RCH pilot, the Hope car bed and the Jane Matrix lie-flat car restraint, are compliant with relevant international standards⁴ and suitable for a variety of ages and medical conditions. The Jane Matrix lie-flat car restraint, however, is not specifically designed as suitable for use by a child with a

³ ACCC Consumer Protection Notice No 3 of 2014, Safety Standard: Child restraint systems for use in motor vehicles.

⁴ US Federal Motor Vehicle Safety Standard 213 and Economic Commission for Europe Regulations 44, respectively.

disability or medical condition and therefore does not meet the criteria for ‘special purpose restraint’ in AS/NZS 4370:2013.

33. Pursuant to rule 267(3)(a) of the *Victorian Road Safety Rules 2017*, an RCH clinician may authorise a child with a medical condition, like SMA, to use an unapproved child restraint if their disability or medical condition renders it “*impracticable, undesirable or inexpedient*” to do so. In circumstances where the authorisation does not then extend to the use of an alternative restraint, the requirements outlined above for Standard 4370 continue to apply to any special purpose child restraint, such as a lie-flat restraint.
34. In relation to the low level of availability of special purpose car restraints, Dr Woodcock posited that the relatively small market and complex regulatory environment in Australia may operate as a deterrent to manufacturers for submitting their lie-flat car restraints for testing in accordance with AS/NZS 1754:2013. Dr Woodcock explained that the RCH pilot also required the hospital to assume a degree of risk for the installation of lie-flat car restraints and TAC third-party recovery claims associated with vehicles involved in an accident.
35. Notwithstanding, Dr Woodcock expressed the view on behalf of RCH that the risks associated with the pilot program are far outweighed by the risks associated with not providing a safe alternative to families for transporting vulnerable infants with complex medical needs.
36. I am grateful to Dr Woodcock for his committed advocacy and insight in the development of safe transport options to support vulnerable children with special needs and their families.

FINDINGS AND CONCLUSION

37. Pursuant to section 67(1) of the Act, I make the following findings:
 - (i) the identity of the deceased was Frankie Skye Foulkes, born 24 December 2022;
 - (ii) the death occurred on 8 May 2023 at 209 Yallambie Road, Yallambie, Victoria, from complications of spinal muscular atrophy; and
 - (iii) the death occurred in the circumstances described above.

COMMENTS

38. I acknowledge the need for the strict regulation of car restraints to ensure the safety and wellbeing of all children in motor vehicles. It is equally important, however, to recognise that a degree of flexibility and adaptability within this otherwise rigid framework is required to enable innovation in creating safer and more accessible transportation options for children with disabilities or medical conditions.
39. It is clear that progress in this space will require collaboration between key stakeholders, such as health services, consumer protection and product safety regulators, policymakers, insurers, road safety and accessibility advocates, and Standards Australia as the organisation responsible for the development and publication of standards.
40. The ACCC, through its Product Safety Consultative Committee, illustrates such a unified approach whereby it may initiate a consultation process with relevant stakeholders in proposing or reviewing product safety regulations. While the review and revision of mandatory safety standards is one of its core product safety functions, the ACCC has also consistently prioritised consumer product safety issues for young children, including taking appropriate regulatory and enforcement action.⁵
41. I therefore consider the ACCC product safety consultation process to be an appropriate mechanism for a consultative review of regulations pertaining to child car restraints, which will assist in addressing the barriers to safe transport of children with specialist needs.

RECOMMENDATIONS

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

- (i) That the Victorian Government consider amending the *Road Safety Road Rules 2017* to include a specific authorisation within rule 267 for the use of an alternative restraint in circumstances where, by virtue of a disability or medical condition, a child is exempted from wearing a seatbelt or being placed in an approved child restraint or booster seat.

⁵ Australian Competition & Consumer Commission, Product Safety Priorities for [2022-23](#) and [2023-24](#).

- (ii) That Standards Australia consider granting an exemption to AS/NZS 4370:2013 to the Royal Children's Hospital for the use of the Jane Matrix lie-flat car restraint in its lie-flat car restraint pilot.
- (iii) That the Australian Competition and Consumer Commission commence a review of mandatory standards regarding child restraint systems for use in motor vehicles, in consultation with relevant expert stakeholders such as Mobility and Accessibility for Children in Australia Ltd, the Royal Children's Hospital, Transport Accident Commission (TAC), the Department of Transport and Planning, and interstate equivalents, for the purpose of:
 - a. developing standards that ensure the adequate testing and safety of special purpose car restraints; and
 - b. revising existing standards to facilitate the availability of a broader range of car restraints in Australia which meet the needs of children with complex medical conditions and/or disability.

I extend my heartfelt condolences to Frankie's parents for their loss.

Pursuant to section 73(1B) of the Act, I order that this finding be published on the Coroners Court of Victoria website in accordance with the rules.

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

Robert and Karine Foulkes, Senior Next of Kin

The Royal Children's Hospital

Australian Competition and Consumer Commission

Consumer Affairs Victoria

Department of Transport and Planning

Mobility and Accessibility for Children in Australia Ltd

Standards Australia

Traffic Accident Commission

First Constable Sean Pascoe, Coroner's Investigator

Signature:



Coroner David Ryan

Date : 18 July 2024

NOTE: Under section 83 of the *Coroners Act 2008* ('the Act'), a person with sufficient interest in an investigation may appeal to the Trial Division of the Supreme Court against the findings of a coroner in respect of a death after an investigation. An appeal must be made within 6 months after the day on which the determination is made, unless the Supreme Court grants leave to appeal out of time under section 86 of the Act.
