

IN THE CORONERS COURT OF VICTORIA AT MELBOURNE COR 2020 004409

FINDING INTO DEATH WITHOUT INQUEST

Form 38 Rule 63(2) Section 67 of the Coroners Act 2008

Findings of:	Coroner Dimitra Dubrow	
Deceased:	Amir Mohammad Iran	
Date of birth:	10 August 2020	
Date of death:	12 August 2020	
Cause of death:	1(a) hyaline membrane disease and pneumonia.2 pneumothorax	
Place of death:	The Royal Womens Hospital, 20 Flemington Road, Parkville, Victoria, 3052	

INTRODUCTION

- Amir Mohammad Iran was 2 days old when he died on 12 August 2020, at the Royal Women's Hospital (**RWH**). Amir was born at term and in good condition. He was well until about 11 hours of life before deteriorating and being admitted to the Neonatal Intensive Care Unit (**NICU**) with respiratory distress, desaturations (low oxygen) and a lung condition. Following his death, an autopsy identified that the cause of death was *hyaline membrane disease* and pneumonia (infection of the lungs).
- 2. Hyaline Membrane Disease (**HMD**), also known as Respiratory Distress Syndrome (**RDS**), is caused by a surfactant deficiency in the lungs. Surfactant decreases the surface tension in *alveoli*, the tiny air sacs at the end of branches of the lungs. Because alveoli are so small, without surfactant, surface tension causes alveoli to collapse in on themselves. This results in alveoli being underinflated and stiff and prevents oxygen from entering the body causing respiratory distress.
- 3. The associated damage to the lungs also causes accumulation of *hyaline membranes* which can be seen under the microscope.
- 4. Treatment is administration of surfactant (sometimes referred to exogenous surfactant) directly into the lungs until the baby's own cells can produce their own surfactant (endogenous surfactant). A single dose is usually sufficient but repeat doses may be necessary.
- 5. HMD usually occurs in premature babies as the cells that produce surfactant do not mature until very late in gestation; there is an inverse relationship in the incidence of HMD with gestation. However, while rare, HMD can still occur in term infants such as in this case.

THE CORONIAL INVESTIGATION

- 6. Amir'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.
- 7. 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.

- 8. 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.
- 9. As part of the investigation, the medical records including radiological imaging of the RWH were obtained as was a statement from the RWH in relation to its care and management and the RWH's own reviews into Amir's death. This statement was provided by Catherine Jones, Director of Quality and Safety dated 21 July 2022 together with the RWH's relevant guidelines policies and procedures.
- 10. Following referral to the Coroners Prevention Unit (CPU)¹, a report was obtained from Dr Janet Bronwyn Sharpe, an independent Consultant Neonatologist based at the Royal Brisbane and Women's Hospital commenting on the management and care provided and whether Amir's death was preventable.
- 11. This finding draws on the totality of the coronial investigation into the death of Amir Mohammad Iran including evidence contained in the coronial brief. Whilst 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.²

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

Birth of Amir

12. Amir was born on 10 August 2020 at 40 weeks and 5 days gestation. He was the fourth son to his parents Minsong Kang and Hossein Iran. His three older brothers were nine, seven and five years old at the time of Amir's birth. Amir was born at 3:50am in the emergency department soon after his mother arrived at the Hospital by ambulance.

¹ The CPU was established in 2008 to strengthen the coroners' prevention role and assist in formulating recommendations following a death. The CPU is comprised of health professionals and personnel with experience in a range of areas including medicine, nursing, mental health, public health, family violence and other generalist non-clinical matters. The unit may review the medical care and treatment in cases referred by the coroner, as well as assist with research related to public health and safety.

² 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.

- 13. Minsong's pregnancy and antenatal care had been provided by RWH. At 27 weeks, an ultrasound was performed following a concern about a fundal height measurement which suggested the baby was small for gestational dates. This fetal growth scan was reported as normal as was the baby's fundal height recorded throughout the remainder of the pregnancy.
- 14. At birth, Amir was well but had a low birth weight of 2670 grams making him Small For Gestational Age (**SGA**). Minsong and Amir were taken to the birth unit and monitored post-delivery. Amir was noted to be initially cold on arrival, with a temperature of 36.2 degrees, however, this normalized within one hour after skin-to skin contact, warm wraps, and heating under the radiant heater.
- 15. Amir's blood sugar was monitored as per SGA guidelines.
- 16. At 10:14am, Amir's blood glucose level (BGL) was low measuring 2.2mmol/L. In neonates less than 48 hours old, there is a lack of consensus on what constitutes normal BGL. However, there is consensus that a BGL <2.6mmol/L warrants immediate intervention.³ This was managed throughout the morning with oral glucose gel being provided along with attempts to feed including with expressed breastmilk and formula.
- 17. At 11:19am, Amir was seen by a neonatology fellow who was asked to review him in relation to asymmetrical ears. The doctor considered the issue to be cosmetic relating to his positioning in utero. A full newborn examination of Amir was also performed at this time which was normal.

Component	Value	Reference range
рН	7.21	7.30 - 7.46
pCO ₂	62	31 – 42 mmHg
Bicarbonate	24	20 – 26 mmol/L
Lactate	2.6	1.0 – 1.8 mmol/L
Glucose	2.7	3.6 – 5.4 mmol/L
Base excess	-5	-5 – 5 mmol/L

18. At 1:13pm, a capillary blood gas test was performed. It showed an improvement in BGL but also results suggesting decompensating respiratory condition:

³ Royal Children's Hospital Melbourne, Hypoglyaemia Clinic Practice Guideline

Deterioration and Transfer to Neonatal Intensive Care Unit

- 19. In a note made in the medical records the following day, Minsong reported that she had been concerned at around 2pm on 10 August 2020 because she had noticed that Amir's lips were blue, and his legs were purple. She said a midwife came in and checked the computer stating that she would return in a minute but did not return.
- 20. According to the medical records, a midwife came into the room at 2:45pm and let Minsong know she was going on a break. At that time, Amir was noted to be settled at the breast, alert and pink in colour, with no issues being observed.
- 21. Minsong reported that she attempted to feed Amir and then pressed the buzzer at around 3pm (the time recorded in the notes of the buzzer being pressed was 3:08pm).
- 22. A midwife answered the buzzer and found Amir to be cyanosed and called for help following which a Neonatal MET call was made. Amir was resuscitated. A neonatal team attended, and Amir was transferred to the NICU.
- 23. A chest x-ray showed *pneumonthoraces*, colloquially known as collapsed lung, in both lungs.From 4:45pm, Amir was intubated and ventilated, with bilateral intercostal drains draining the pneumothoraces. A transthoracic echocardiogram revealed no issues with his heart but mild persistent pulmonary hypertension of the newborn (**PPHN**).
- 24. PPHN is a sign of difficulties in transitioning from foetal circulation in the womb to normal newborn circulation supported by lungs breathing air. Central to this transition is a dramatic drop in pulmonary resistance. One important driver of this drop is lung inflation. As this is restricted in HMD, surfactant deficiency is associated with PPHN.
- 25. Nitric oxide helps reduce pulmonary vascular resistance by dilating the blood vessels in the lungs and is used in management of PPHN.
- 26. Amir was commenced on intravenous antibiotics (benzylpenicillin and gentamicin) to cover for possible sepsis as the underlying cause of his respiratory distress.
- 27. At 7:40pm, Amir's oxygen saturations dropped further necessitating increased oxygen back to 100%. This was revealed to be from reaccumulation of the left pneumothorax requiring aspiration of 300-400mL of air from the left drain. Amir was also commenced on nitric oxide for suspected PPHN.

- 28. Overnight, he was administered morphine. His ventilation requirements were high with peak inspiratory pressures (**PIP**s) at 35 to 37cm H2O. A urinary catheter was placed, as well as an arterial line. The supplemental oxygen was reduced to 30%, however required an increase at around 4:00am on 11 August 2020, with an associated re-accumulation of his left pneumothorax. It was documented in the medical notes that he was 'small for gestational age', with birth weight on the 7th centile.
- 29. At 8:30am on 11 August, Amir required needle aspiration on the left side for a recollection of his pneumothorax. At 10:30am, his oxygen was increased to 50% and by 12:40 pm this had further increased to 100%. At 1:57pm, a consultant neonatologist performed a "PPHN assessment" and noted persistent pulmonary hypertension and recommended consideration of noradrenaline and this was commenced.
- 30. At 2:05pm, Amir was given 240mg (2 x 120mg) of surfactant and following this Amir's saturations were 96% on 100% oxygen. Arterial blood gas testing at 3:30pm showed mild respiratory acidosis with hypoxaemia (low blood oxygen) and slowly worsening hyponatremia (low blood sodium, an electrolyte)
- 31. An indwelling catheter was attempted because of poor urine output at 7:33pm and there was a concern that the previous indwelling catheter had not been successfully inserted. A bladder scan was performed, and a catheter inserted at 7:52pm.
- 32. At 9:08pm, an umbilical vein catheter was inserted to administer medications. At 9:29pm, he was reviewed by a consultant neonatologist who noted that Amir's respiratory condition had deteriorated with him needing 100% oxygen and increased ventilator requirements with Peak Inspiratory Pressure at 38 and Mean Airway Pressure (MAP) at 16. A second left sided chest drain was placed at 10:10pm.
- 33. Amir's respiratory and cardiac status continued to deteriorate. Multiple inotropes (continuous medication infusions to increase blood pressure) were added, and their doses maximized. High frequency ventilation was trialled twice however this did not improve his respiratory status. Recurrent aspiration of air from his chest drains transiently improved his oxygen levels but did not have a lasting effect. His antibiotic cover was broadened to include cefotaxime. His potassium levels, another electrolyte, continued to rise and was treated with calcium gluconate.

- 34. Despite maximal cardiac and respiratory supports, over 6:30 to 8:00am on 12 August 2020, Amir's oxygen saturations and blood pressure continued to fall. Two NICU consultants discussed his prognosis with the family and the decision was made to withdraw active treatment.
- 35. Amir passed away at 11:05am on 12th August 2020.

Identity of the deceased

- 36. On 12 August 2020, Amir Mohammad Iran, was visually identified by his father, Hossein Iran at the RWH.
- 37. Identity is not in dispute and requires no further investigation.

Medical cause of death

- Forensic Pathologist, Dr Sarah Parsons from the Victorian Institute of Forensic Medicine (VIFM), conducted an autopsy 13 August 2020 and provided a written report of the findings. Dr Parsons also reviewed post-mortem CT scan.
- 39. Forensic Pathologist, Dr Linda Iles, also from VIFM, conducted a neuropathology examination of the brain on 18 August 2020 and provided a written report of the findings.
- 40. At autopsy, Dr Parsons found widespread hyaline membranes and pneumonia. Dr Parsons noted that HMD, also known as respiratory distress syndrome, is a deficiency of the molecule, surfactant. It is usually seen in babies born before 37 weeks and not usually in babies born at term. She considered the cause of HMD in this case to likely be due to neonatal infection, but that a genetic problem was also possible. Dr Parsons also noted the finding of pneumothoraces stating these were likely were due to pneumonia and hyaline membranes.
- 41. Toxicological analysis of post-mortem samples identified the presence of medications administered in hospital.
- 42. Dr Parsons provided an opinion that the medical cause of death was:
 - 1(a) Hyaline membrane disease and pneumonia
 - 2 Pneumothorax
- 43. I accept Dr Parsons's opinion.

FAMILY CONCERNS

- 44. Amir's mother expressed that she would like to know if Amir's death could have been prevented.
- 45. Prior to Amir's death and following his transfer to the NICU, Amir's mother expressed concerns about the impact of the baby's lips being blue for an hour before medical intervention. Minsong reported noticing that Amir's lips where blue and his legs were purple at around 2pm on 10 August 2024, and before the MET call was made.

ROYAL WOMEN'S HOSPITAL REVIEW OF CARE

- 46. Catherine Jones, the Director of Quality and Safety at the RWH, in a statement from 21 July 2022, outlined the course of Minsong's pregnancy and management and Amir's post birth care and addressed a number of matters as requested by the Court. Ms Jones provided to the Court copies of relevant RWH guidelines as follows:
 - a) Intergrowth chart fundal height;
 - b) Hypoglycemia Newborn management;
 - c) Antenatal Care Schedule;
 - d) Management of foetal growth restriction guideline;
 - e) Foetal growth restriction Improving the antenatal detection;
 - f) Respiratory support Surfactant Administration; and
 - g) Incident management guideline.
- 47. Ms Jones stated that the RWH adhered to the relevant hospital guidelines in relation to investigations for suspected foetal growth restriction during pregnancy and in relation to babies born with low birth weight for gestational age, as was the case with Amir.
- 48. Ms Jones noted that:
 - a) Amir was administered antibiotics once in NICU following his deterioration to cover potential early onset sepsis. She noted that antibiotics were not required prior to this time based on the early onset sepsis risk calculator.

- b) Intercostal catheters were inserted into both lungs to address Amir's bilateral pneumothoraces and to aspirate air to address Amir's deterioration with hypoxia.
- c) There was no evidence of HMD shown on chest x ray. It was noted that the x-ray taken at 9:28am on 11 August 2020 showed "bilateral airspace opacification seen patchily" which was interpreted as being atelectasis (collapse of the lung or part of the lung).
- d) Surfactant was administered at 2:05pm on 11 August 2020 but did not improve Amir's condition.
- e) Echocardiograms were performed at 6:00pm and 8:23pm on 10 August, 1:57pm on 11 August and at 1:17am on 12 August. These showed no issues with Amir's heart but showed that Amir was suffering from PPHN. Amir was administered nitric oxide to address this.
- 49. Ms Jones stated that Amir's death was the subject of two separate in depth case reviews at the RWH, a maternity services and a neonatal services in depth review, both of which concluded that the care and management provided to the mother and baby were appropriate and in accordance with best practice. The results of the in-depth case reviews were reported and endorsed by the RWH's Management Quality and Safety Committee in November 2020. As there were no identified issues relating to the care and management, no recommendations for improvements were made. Furthermore, a Root Cause Analysis (RCA) was not undertaken as it was considered that the incident did not fall within the criteria for an Incident Severity Rating (**ISR**) of 1 or 2.
- 50. ISR is the 4-tiered severity rating system for adverse events. The ISR is derived from the response to 3 questions related to:
 - level of harm (previously, 'degree of impact')
 - required level of care (previously, 'level of care')
 - level of treatment required (previously, 'treatment required').
- 51. ISR classification levels according to severity:
 - ISR 1 severe/death
 - ISR 2 moderate
 - ISR 3 mild

- ISR 4 no harm/near miss.⁴
- 52. Ms Jones stated:

This case was not assigned an ISR 1 or ISR 2 rating because while the outcome was serious, there were no contributing factors identified and medical management was found to be appropriate. In cases like these, the lessons are derived from what we did right, rather than what went wrong.

- 53. In Victoria, sentinel events are defined as an "unexpected and adverse event that occurs infrequently in a health service and results in the death of, or serious physical or psychological injury to, a patient as a result of system and process deficiencies at the health service entity".⁵
- 54. Health services are required to report sentinel events to Safer Care Victoria.⁶ Amir's death was not reported to Safer Care Victoria as a sentinel event as no 'adverse event' was identified.
- 55. Ms Jones referred to the Hospital's Incident Management Guideline for assigning of ISR and for responding and reviewing care which was said to be consistent with Safer Care Victoria's 2019 Sentinel Event Guide.

EXPERT OPINION

- 56. The CPU requested an independent opinion from consultant neonatologist, Dr Janet Sharpe of the Royal Brisbane and Women's Hospital.
- 57. In her report dated 10 February 2023, Dr Sharpe provided an opinion about the RWH's management and identified three areas of concern, being:
 - a) a lack of recognition and escalation of the abnormal blood gas results from 1:14 pm on 10 August 2020 which showed respiratory decompensation.
 - b) The lack of consideration of a possible diagnosis of HMD which in turn resulted in surfactant therapy, a treatment for HMD, not being considered.
 - c) The surfactant therapy which was administered was insufficient and there was no consideration of administering repeat doses.

⁴ Safer Care Victoria, Adverse Patient Safety Event Policy 2023

⁵ Health Services (Quality and Safety) Regulations 2020, r 3A.

⁶ Safer Care Victoria, Adverse Patient Safety Event Policy 2023

Abnormal blood gas results at 1:14 pm on 10 August 2020

- 58. Dr Sharpe identified that the full capillary blood gas performed at 1:14 pm showed a normal blood glucose reading but a mixed respiratory and metabolic acidosis which required intervention.
- 59. She stated:

This blood gas result is abnormal, particularly for an infant of 9 hours of age with no prior indication of illness and demonstrated an infant decompensating in respiratory condition [] and should have been escalated. At this stage, Baby Kang should have been reviewed by a medical officer and admitted to the nursery for cardiorespiratory monitoring and consideration of respiratory support.

The abnormalities within this blood gas result appear unrecognised. There is no documentation of recognition in the progress notes, nor any escalation or requests for review.

Earlier recognition and escalation of care may have contributed to preventing the severity of Baby Kang's deterioration and subsequent critical condition.

Consideration of diagnosis and investigation of differential diagnoses including HMD

- 60. Dr Sharpe considered that the resuscitation of Amir when he was in respiratory distress with severe hypoxemia was timely and in keeping with best practice. He was intubated and ventilated. Bilateral pneumothoraces were identified and were aspirated followed by insertion of intercostal pigtail catheters to continue to drain air leaks. Early onset sepsis was considered and tested for, and Amir was given intravenous antibiotics. An echocardiogram was performed to check the anatomical structure of the heart and assess function which showed evidence of pulmonary hypertension and decreased cardiac contractility or filling requiring medical intervention. At this time, pneumothoraces with PPHN were appropriately identified.
- 61. However, Dr Sharpe was of the opinion that the underlying cause of the bilateral pneumothoraces and pneumomediastinum (air in the space between the lungs) were never fully considered. Given that the baby's deterioration occurred later than the immediate birth, at 10 or 11 hours of life and the air leaks were in both lungs, this would tend to indicate underlying lung pathology. Dr Sharpe considered that the pneumothoraces were likely to be

present at the time of Amir's deterioration and cyanosis and contributed to his presentation rather than being caused by the resuscitation efforts.

- 62. The potential underlying causes of Amir's lung pathology included a number of conditions, one of which was HMD, but there were only two occasions where this may have been considered a potential differential diagnosis.
- 63. The first occasion was when respiratory distress syndrome (RDS), another term for HMD, was listed in the notes at 11:45pm on 10 October 2020 but no discussion about treating the potential RDS with exogenous surfactant.
- 64. The second occasion suggesting that the diagnosis may have been considered, though not specifically referred to, was at 2:05pm on 11 August 2020 when Amir was administered surfactant to treat possible surfactant deficiency and, while such deficiency may be due to a number of reasons, the most common considered in NICU is HMD.
- 65. Dr Sharpe acknowledged that Amir's presentation was not usual for HMD. She noted that it is seen more typically in premature babies. Furthermore, Amir's clinical presentation was also unusual. Premature babies will often show signs of respiratory distress in the first few minutes of life. However, for more mature babies the signs have a more gradual onset starting over the first hours of life with poor feeding, worsening work of breathing and tachypnoea.
- 66. Dr Sharpe noted that there is no test to diagnose HMD. The diagnosis is made on the basis of clinical history and presentation with worsening signs of respiratory distress and changes shown on chest x-ray, referred to as reticulogranular ground glass opacities with air bronchograms.
- 67. Dr Sharpe considered that following Amir's deterioration, there were some clinical features that suggested HMD that did not appear to be appreciated. A number of chest x-rays were performed and according to Dr Sharpe 'the presence of reticulogranular ground glass opacities with contrasting air bronchograms in the lung fields, demonstrating alveolar atelectasis, is suggestive of the diagnosis'.
- 68. Dr Sharp acknowledged that her interpretation of the chest x-rays was made with 'the benefit of hindsight and diagnostic knowledge' but noted that the x-ray features did not appear to have been appreciated. Interpretation of the lung fields was only referred to occasionally in the radiology reports of the chest x-rays and not referred to in the medical notes at all by the medical staff.

- 69. In addition, Dr Sharpe noted that issues with ventilation raise the possibility of HMD. Amir's ventilator-generated Peak Inspiratory Pressure (PIP) and subsequent mean airway pressure (MAP) were high and though they improved and lowered for a time, they increased again from 11 August 2020. This would suggest an underlying condition with poor lung compliance including HMD.
- 70. Dr Sharpe concluded:

On review of baby Kang's case, he had three concurrent pulmonary conditions, which were interrelated; bilateral pneumothoraces, persistent pulmonary hypertension of the newborn and [HMD]. When reviewing the size of baby Kang's pneumothoraces, these are easily appreciable on chest x-ray. The identification and management of these in baby Kang's case was rapid, and ongoing re accumulations appeared to also be well identified and managed. Similarly, the presence of PPHN was assessed and identified in a timely manner by echocardiogram (with regular ongoing monitoring of echocardiogram) and again, appropriately managed with inhaled nitric oxide and inotropic support. These two conditions are certainly more commonly seen in term neonates presenting with acute deterioration, like in baby Kang's case.

The underlying HMD in baby Kang's case does not appear to have been considered early in his course, likely due to the significantly atypical presentation, and the presence of two other explanatory (and proven) diagnosis, which appeared to create a degree of "diagnosis-fixed" which limited the consideration of other associated conditions. This was furthermore confounded by his lack of response to the exogenous surfactant administration. However, identified factors suggesting the potential for HMD as an associated diagnosis were not appreciated.

Administration of Surfactant, dose and repeat administration

71. Dr Sharpe noted that there was a discrepancy in the medical notes as to the amount of exogenous surfactant given to Amir with one note suggesting an amount equalling 90mg/kg per kg and another that 100mg/kg was administered. Dr Sharpe noted that either amount fell short of the Hospital's own guideline, 'Respiratory Support – Surfactant Administration' which recommended doses of 100mg/kg to 150mg/kg for babies weighing 3.6kg to 2.4kg (as Amir weighed 2.7kg at birth his dose should have been closer to 150mg/kg when applying the guidelines)

- 72. While the Hospital's guideline was consistent with other Victorian surfactant guidelines, being the Paediatric Infant Perinatal Emergency Retrieval (PIPER) and Safer Care Victorian (SCV) Surfactant replacement therapy for neonates guideline, Dr Sharpe noted they were inconsistent with the user guide of the manufacturer of the Surfactant product, Curosurf.
- 73. The manufacturer recommends an initial dose of 200mg/kg with up to 2 repeat dosages of 100mg/kg. The Victorian guidelines were also not consistent with interstate guidelines which also support a higher initial dose of 200mg/kg. This higher dose is also consistent with European Consensus Guidelines on the Management of Respiratory Distress Syndrome.
- 74. Dr Sharpe noted that the Victorian guidelines refer to recommended doses "to minimise waste and unnecessary use of additional vials..." and that:

The RWH dosing schedule (as well as the PIPER and Safer Care Victoria dosing schedule) with the reduced initial dosages (by giving full vials for weight cohorts), purely as a means to 'minimise waste' (and hence cost) is not consistent with latest available evidence, manufacturer's guidance, nor when benchmarked against similar Australian services or international consensus guidelines. Review of the dosage guidelines should be considered.

- 75. Dr Sharpe also commented in relation to the timing of Surfactant being given noting that surfactant replacement therapy is to be considered when a baby is intubated and requiring supplemental oxygen over 40% (normal air is 21% oxygen) and that the Hospital's own guidelines "emphasize the practice of early consideration of surfactant for neonates of any gestation with severe respiratory distress (marked by need for intubation and ongoing high oxygen requirement)".
- 76. Dr Sharpe expressed the view that earlier administration of surfactant "would likely to have been more beneficial, and may have prevented further reaccumulations of air leaks, and the progressive cycle of worsening of PPHN and respiratory function, with resultant cardiac dysfunction and renal failure".
- 77. Finally, Dr Sharpe noted that repeat dosing is recommended at 6 to 12 hours but there is no indication that this was considered for Amir.
- 78. Dr Sharpe expressed the view that "earlier identification of baby Kang's respiratory compromise (through recognition of the abnormal blood gas result) and earlier administration

of appropriate dose surfactant may have provided opportunities to reverse the ongoing deterioration."

ROYAL WOMEN'S HOSPITAL RESPONSE TO EXPERT OPINION

- 79. On 2 October 2024, the Royal Women's Hospital was provided with a copy of the report of Dr Sharpe and provided with the opportunity to comment generally and particularly in relation to the three identified issues: the blood gas results from 1:14pm on 10 August 2020, the consideration of the possibility of HMD, the reporting of the chest x-rays and the administration of surfactant.
- 80. In a response from 7 November 2024, the RWH acknowledged that the blood gas results from 1:14pm were abnormal and did not appear to be recognised as it would be expected that this would be documented in the medical records. Had the abnormality been recognised, this would have resulted in a medical review of the baby and repeat blood gas test within the next hour.
- 81. The RWH highlighted that HMD would not be suggested in a term baby with normal breathing as in the case of Amir and the typical conical features were not present. Amir presented with two other overt diagnosis; bilateral pneumothoraces and likely secondary persistent PPHN.
- 82. Furthermore, having reviewed the three initial chest x-rays taken on the afternoon and evening of 10 August 2020, "the typical features of RDS (ground-glass appearance/atelectasis) are not obviously present". The first x-ray to suggest that there may be evidence of RDS is the x-ray from the morning of 11 August 2020 which was reported on by the radiologist at 1:34pm and following this surfactant was administered. The RWH asserted that given the administration of surfactant shortly thereafter, "…the diagnosis of surfactant deficiency (by whatever cause) was considered…"
- 83. The RWH explained that the likely reasoning behind the lower dose of surfactant was that 20% of a further vial would have been used to achieve the prescribed dose resulting in waste of the remainder.
- 84. The RWH noted that dosing information usually relates to preterm babies and, as to dosing for a term baby, noted that:

Off-label use of surfactant is common despite a paucity of good quality evidence for use in other gestations, thus extrapolating treatment criteria from the surfactant-deficient preterm cohort to the term infant with RDS is contentious. There are still no evidencebased recommendation for surfactant use in term infants with RDS and the thresholds for decision making are variable.

85. In relation to administering a second dose, the RWH noted that this may have been considered but may not have been given as there was minimal improvement with the first dose. The RWH indicated that they did not consider the surfactant therapy administered was insufficient based on the available data in term infants but agreed "...that documentation should be more robust".

FINDINGS AND CONCLUSION

- 86. Pursuant to section 67(1) of the Act I make the following findings:
 - a) the identity of the deceased was Amir Mohammad Iran, born on 10 August 2020;
 - b) the death occurred on 12 August 2020 at the Royal Womens Hospital, 20 Flemington Road, Parkville, Victoria, 3052, from hyaline membrane disease and pneumonia in the setting of pneumothorax; and
 - c) the death occurred in the circumstances described above.
- 87. Having considered all of the evidence, I am satisfied that:
 - a) There was a delay in recognising and acting on blood gas abnormalities at 1:14pm on 10 August 2020. Earlier recognition and response may have prevented Amir's further deterioration.
 - b) The underlying cause of Amir's pneumothoraces required further investigation and features suggestive of HMD were not appreciated such as Amir's ventilation issues with high PIP and MAP levels. This was compounded by the reporting and interpretation of the chest x-rays. Had an underlying lung condition such as HMD been considered, this may had led to earlier administration of surfactant and repeat dosing.
 - c) The dose of surfactant administered was insufficient by reference to the RWH's own guidelines which, in turn are below the recommendations of the manufacturer and other interstate and international guidelines.
- 88. It is not possible to conclude that diagnosis and treatment of HMD would have prevented Amir's death, but I do consider that such treatment, including earlier administration of dose

appropriate surfactant and repeat doses may have reversed Amir's deteriorating condition and prevented his ultimate death.

COMMENTS

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

- 1. The RWH confirmed that the doses of surfactant were influenced by considerations of wasted vials. While waste and associated cost should be a relevant consideration in the delivery of healthcare, optimal dosing of medication for a sick newborn should be paramount consideration.
- 2. The recommendation I have made below in relation to surfactant dosing guidelines may present an opportunity to introduce flexibility in administration volume to ensure optimal dosing while minimising waste.
- 3. While HMD is uncommon in term babies, this matter serves as a reminder that HMD should be considered in cases of a newborn presenting with deteriorating lung conditions even in the presence of other diagnoses and that related conditions can co-exist.

RECOMMENDATIONS

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

- (i) That the Royal Women's Hospital, PIPER and Safer Care Victoria review their guidelines relating to surfactant to ensure prompt administration to newborns who require intubation for respiratory distress and that initial and repeat doses accord with the latest available evidence bearing in mind interstate and European guidelines and the manufacturer's user guide.
- (ii) That parents of newborns be informed of the importance of and encouraged to notify carers in relation to any changes in colour or breathing, supported by visual signs to aid education.

I convey my sincere condolences to Amir's family for their loss.

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

Minsong Kang & Hossein Iran, Senior Next of Kin Royal Women's Hospital PIPER

Safer Care Victoria

Signature:

2____



Coroner Dimitra Dubrow

Date: 29 January 2025

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.