STATE CORONER'S COURT, SYDNEY

Inquest:	**Inquest into the death of Liam WOODCOCK**
File numbers:	1091/06
Hearing dates:	21-25 June 2010
Date of findings:	3 September 2010
Place of findings:	State Coroner's Court, Glebe
Findings of:	Deputy State Coroner H.C.B. Dillon
Findings:	I find that Liam Woodcock died on 29 June 2006 at the Royal Hospital for Women, Randwick, NSW due to myocardial failure resulting from excessive pulmonary blood flow and consequential loss of systemic blood flow upon a background of major congenital heart disease while receiving care and treatment in the neo-natal intensive care unit of the Royal Hospital for Women for his congenital heart disease.
Recommendations	**To the Minister for Health** 1. I recommend that the South Eastern Sydney and Illawarra Area Health Service and the Royal Hospital for Women Neo-natal Intensive Care Unit reconsider the Unit's protocol in relation to the use of propofol as an induction agent for infants suffering cyanotic congenital heart disease and settle that protocol in final form as a matter of urgency. The unit ought consider including a direction that propofol not be used in infants with compromised cardiac output and that, in any case, it be used only after senior intensivist or consultant review of the baby. 2. I recommend that the Area Health Service amend the Royal Hospital for Women's "Stillbirth, Fetal, Neonatal and Infant Deaths Documentation and Transport

Guideline" to insert a requirement that *if*:

(i) a death must be reported to the coroner in accordance with the hospital's coronial checklist *and*

(ii) a pulse oximeter permitting the downloading of data had been attached to the infant at the time of his or her death,

subject to any other clinical priorities for the use of that equipment, the data from the pulse oximeter ought be downloaded and retained as part of the infant's medical records.

3. I recommend that the Area Health Service consider whether the introduction of functional echo-cardiology training and technology in neonatal intensive care units within its jurisdiction is reasonably practicable, given its budgetary priorities and constraints, within the foreseeable future.

Representation:

Mr C. Hoy SC (Counsel Assisting) instructed by Ms L. Molloy, Crown Solicitor's Office

Mr N. Dawson instructed by Ms C. Doust (Nurses' Association) (for RN Mosey)

Mr R. Gambi instructed by Mr A Mineo, Avant Law (for Drs Cooper and Buist)

Ms G. Furness instructed by Mr Georgopoulos, Gild Insurance Litigation (for South-East Sydney and Illawarra Area Health Service and Drs Lui, Garvey, Smyth, Krishnan and Ooi)

Self-represented next of kin:

Mrs C Woodcock and Mr S Woodcock

Introduction

1. Liam Woodcock was a baby born to Claudia Woodcock and her husband Stephen on 30 May 2006. Liam was one of twins conceived by IVF. Unfortunately, to compound the loss suffered by Mr and Mrs Woodcock, Liam and his brother Riley developed Twin to Twin Transfusion Syndrome, a condition in which twins share their blood supply in the womb. An operation to correct this problem was performed but Riley survived only a short time afterwards and died at about 18 weeks gestation.

2. Shortly afterwards, at about 19 weeks gestation, Liam was diagnosed in utero with a severe cardiac problem, a pulmonary atresia, or blockage, with intact ventricular septum. He was born on 30 May 2006 at about 27-and-a-half weeks weighing approximately one kilogram.

3. A significantly premature baby with a serious congenital heart disorder has the odds very heavily weighted against him or her. It was initially thought that Liam was likely to survive only a short time after his birth and a plan was made for palliative care. To the surprise and pleasure of his parents and clinicians, however, Liam managed not only to live through his first few hours and days but to gain weight. Unfortunately, at about one month old, he began to decline. On 29 June 2006, he died in the Royal Hospital for Women, Randwick.

4. After his death, his parents raised a number of issues concerning his care and treatment in the hospital. An inquest is an independent judicial inquiry into the cause and manner of a person's death. One of the purposes an inquest may serve is to address questions that trouble the families of people who have died unexpectedly and to seek to allay fears and suspicions they and other members of the community may feel about such deaths.

Background

5. The facts in Liam's case are largely agreed. There were minor discrepancies between some witnesses' recollections of events but these were relatively inconsequential and came about, in my opinion, largely because of the lapse of time between the events in question and the making of statements. In some cases, witnesses did not have complete access to clinical records from which to refresh their memories. My impression was that

all the witnesses involved in Liam's care gave honest evidence to the best of their recollection. I did not detect any prevarication, much less any deliberate attempt to misrepresent the facts. Indeed, my strong impression was that the clinicians and nurses were upset by Liam's death and anxious to assist the court in finding the truth.

6. Liam's cardiac condition, pulmonary atresia and right ventricular hypoplasia, or underdevelopment of the right ventricle, was complicated by the fact that he was born extremely prematurely and therefore had very low birth weight (about one kilogram). His prognosis at birth was regarded as poor.

7. The blood supply to his respiratory system and the rest of his body was dependent at that stage on a patent or open ductus arteriosus which, in effect, enabled blood to flow around the blocked pulmonary valve in another direction, allowing it to be oxygenated in the lungs. The ductus in a normal newborn links the pulmonary artery and the aorta but at about the time of birth it closes, never to re-open. In a premature baby, however, the ductus remains patent for some time, gradually closing. That process of closing is not a linear progression. One witness, Dr Stephen Cooper, likened it to a sort of "winking", with variations in the degree of patency, but with a trend towards ultimate closure as the baby matures.

8. Without a repair of the atresia, Liam was, therefore, on borrowed time. He could only survive while the patency of his ductus arteriosus was maintained and it was gradually closing. He was unlikely to survive surgery on the atresia before he reached about 1.5 kg in weight. The patency of the ductus can be maintained by the use of prostaglandin, effectively slowing the natural process of closure, but this brings with it its own risks.

9. Among these is the risk of apnoea, or the cessation of spontaneous respiration. In short, the patient may cease to breathe. For this reason, the baby may need to be intubated and ventilated. These processes add further to an already very complicated and delicate clinical picture. One of the questions intubation raises is whether the baby ought be sedated and, if so, how and when. Almost invariably, except in emergencies, because of the great pain and discomfort that will be caused to babies being intubated, clinicians will seek to sedate them.

10. A second great difficulty in the management of a patent ductus arteriosus with prostaglandin is that the flow of blood to the pulmonary system must be kept in delicate balance with the circulation to the rest of the body. If the ductus is enlarged too much

with prostaglandin, this may lead to excessive flow to the lungs and a consequent loss of blood pressure and flow in the systemic circulation, placing the baby in a downwards spiral from which it may be impossible to recover the baby.

11. As I noted before, following his birth on 30 May 2006, his prognosis was so poor that Liam was not admitted to intensive care but a decision was made to care for him palliatively. He confounded his doctors who, cautiously but with growing optimism, developed a tentative plan for surgical intervention if he continued to progress and gained sufficient weight, although no date for surgery was set at that stage.

12. In early June, Liam fed well and gained reasonable weight. On 6 June his patent ductus arteriosus was found to be 2.2mm, comfortingly large. His oxygen saturations on that day were recorded as being above 90 per cent in room air and this was maintained with Continuous Positive Airway Pressure. (The saturation readings at that stage are significant in interpreting his later collapse.)

13. Throughout June 2006, Liam continued to make good progress. The clinicians and surgeons kept closely in touch and a plan was made for surgery once his weight exceeded 1.5kg. On 26 June, Liam's weight was measured at 1.52kg and surgery was scheduled for 4 July.

14. Unfortunately, however, by this time the patent ductus arteriosus was closing. A trend that his oxygen saturations were dipping was noted. By 28 June, the saturations were generally in the mid-80 per cent range and the trend was downward. This indicated that the patent ductus arteriosus was reducing in size. On 29 June, it had diminished to 1.5mm. At that point, the clinical decision to introduce prostaglandin was made and intubation was discussed. These decisions will be further considered below.

15. Prostaglandin infusion commenced at about 1300 hours at a low dose of 5ng/kg/min. Liam's oxygen saturations were then at about 80 per cent with dips as low as 48 per cent and spikes as high as 90 per cent. At that stage, it was decided not to intubate and ventilate Liam. This too will be further discussed below. At about 1430 hours, the dosage was increased to 10ng/kg/min because there appeared to have been no improvement in the saturations at the lower dose. After this, the saturations rose gradually above the 90 per cent range. No apnoeas were noted. This decision will also be discussed further.

16. At about 1600 hours, Liam was noticed by a nurse and a senior doctor to be pale and lethargic and cool to the touch despite a normal temperature. He did not wake during his "cares". At that point, his saturations were in the low to mid-90 per cent range. A nurse also recalled that, although she had observed no apnoeas, Liam had some periods of shallow breathing.

17. Ward rounds, at which each patient was closely reviewed, commenced at about this time. Although a decision had been made during the morning rounds that Liam was "for intubation and prostaglandin"[1], it was not until about 1730 hours that a final decision to intubate was made. The actual procedure commenced at about 1800 hours.

18. At 1805 hours, propofol was given via Liam's foot and a junior doctor had a "first look" but was unable to complete the intubation. A senior doctor, without any significant delay, completed the process.

19. Immediately following his intubation, Liam's saturations rose to 98 per cent. Within minutes he "became mottled with reddish blotches on his chest. His perfusion was poor."[2] Liam's blood pressure was not able to be measured. Emergency resuscitation was then attempted by senior clinicians but Liam could not be revived and treatment ceased at about 1900 hours.

The issues

20. The *Coroners Act* requires me to seek to establish a number of formal particulars concerning Liam's death: his identity, the date and place of his death and the cause and manner of his death. There is no difficulty in establishing most of those matters. The only difficulties arise in determining the cause and manner of his death. In speaking of the "cause" I mean the physical mechanism as a result of which Liam's life was extinguished and by "manner" of death I mean the way he died or the circumstances surrounding and contributing to his death.

21. In coming to the formal findings I am required to make under the *Coroners Act*, it has been necessary to explore a number of factual issues relating to Liam's care and treatment in the Royal Hospital for Women and the aftermath of his death. They relate

[1] Clinical notes 29.06.10.
[2] Clinical notes 29.06.07 per RN Mosey.

to the ultimate questions of the cause and manner of Liam's death. Those issues may be expressed as the following questions:

- Was it necessary or appropriate to administer prostaglandin on 29 June 2006?
- Was the dose appropriate?
- Was Liam appropriately monitored during 29 June 2006?
- Ought Liam to have been intubated and, if so, when was the most appropriate time?
- Was there an excessive delay in intubating Liam on 29 June 2006?
- Was it appropriate to administer propofol for the purposes of intubation?
- Did the fact that a resident had the "first look" affect the process of intubation adversely?
- Was excessive oxygen administered during the intubation?
- Was there any shortcoming in the resuscitation effort?
- Ought data from the pulse oximeter to have been downloaded following Liam's death?
- Ought Liam's death to have been reported to the coroner immediately?
- What has been done at RHW as result of Liam's death?
- Should anything more be done?

The last two questions relate to the coroner's statutory power to make recommendations in relation to public health or safety. I will now deal with each of these issues.

Was it necessary or appropriate to administer prostaglandin on 29 June 2006?

22. The medical evidence is unanimous in demonstrating that it was both necessary and appropriate for prostaglandin to be administered on 29 June 2006.

23. Dr Stephen Cooper, a specialist paediatric cardiologist, had detected that Liam's patent ductus arteriosus was closing. This was inevitable and anticipated as Liam matured. The patent ductus arteriosus had reduced gradually in size from about 2.2 mm shortly after he was born to 1.8 mm a few days before the prostaglandin was commenced. On 29 June 2006, by an ultrasound examination, Dr Cooper found that it had reduced in size to 1.5 mm. This was consistent with the trend in his oxygen saturations which were dipping well below the satisfactory level in the mid-80 per cent range.

24. It was evident that action needed to be taken to maintain the patency of the ductus arteriosus until surgical intervention could provide an alternative shunt and, ultimately, repair his blocked pulmonary valve.

25. Following a discussion between Dr Cooper and Associate Professor Kei Lui, who was the consultant in charge of the neonatal unit and on call at the unit during 29 June, Professor Lui decided that the time had come to introduce prostaglandin. Dr John Smyth, a senior staff neonatologist, who had developed a close relationship with Mr and Mrs Woodcock, was also consulted.

Was the dose appropriate?

26. The difficulty of this field of medicine and the fineness of the judgments to be made cannot be overstated so delicate is the circulatory balance in a tiny baby like Liam. The answer to this question is therefore highly problematical and must be approached with judicial modesty and caution. Nevertheless, with the benefit of hindsight, it appears more likely than not that the dosage may have been too high.

27. This is not to say that Dr Lui's decision to increase the dose from 5 ng/kg to 10 ng/kg was unreasonable. It appeared to Dr Lui that the 5ng/kg dose had not sufficiently reversed the tendency of the ductus to close and that to maintain or increase the patency of the ductus a small increase in dosage was called for. There can be no doubt that keeping the ductus open was Liam's one and only chance of survival at that stage and that, therefore, if the original dosage was not doing so, or did not appear to be doing so sufficiently, it was reasonable to increase the dose.

28. It must also be borne carefully in mind that the increase was not a large one. A dosage of 10ng/kg/min was, according to the medical evidence, a small one. One of the

unknowns and immeasurables in such cases is exactly how an individual patient may react even to a modest increase in dosage. For this reason, if clinicians perceive a need to step up the dosage of prostaglandin, the standard practice is to do so in small and gradual increments. The increase was from a very small amount to a slightly larger but still relatively small dosage.

29. It is noteworthy that one of the several difficulties of managing babies in such delicately balanced situations, however, is that controlling the effects of prostaglandin is extremely problematic: once the ductus begins to re-expand, there is no way to precisely fine-tune that effect. Good clinicians therefore proceed conservatively. There is nothing to suggest that Professor Lui's approach was anything other than careful and cautious but, while he was proceeding both with Liam's best interests in the forefront of his mind, he was also, because some things are simply unknown and unpredictable, unable to calculate the effect of the increase with precision.

30. With those provisos in mind, it may nonetheless be inferred from the fact that, after the dose was increased from 5 to 10ng/kg/min Liam's saturations rose from the low 80 per cent range to low-mid 90 per cent range, the increase in dosage had tipped the balance and had the effect of increasing the patency of the ductus, whereas a dose of 5ng/kg/min had apparently not been sufficient to do so.

31. This did not appear to Professor Lui at the time to be overly problematic as Liam's history to that time had apparently demonstrated a capacity to tolerate and cope reasonably well with saturations in that range. Nevertheless, it appears that, for reasons that are not clear, by the afternoon of 29 June 2006, his tolerance of such high saturations was not what it had been and that the increase from the low-mid 80 per cent range to the low-mid 90 per cent range tipped the balance toward the pulmonary system to the detriment of his systemic circulation and he began his downward spiral.

Was Liam appropriately monitored during 29 June 2006?

32. While Liam was closely monitored in various ways, such as his heart rate, oxygen saturations and respiratory rate, during his stay in the Intensive Care Unit, his blood pressures and blood gases were not monitored on 29 June 2006. The general consensus of the medical evidence, including that of Professor Lui, was that monitoring his blood

pressure and blood gases during the period after the administration of prostaglandin would have provided very useful and even critical information.

33. In a report of 17 June 2010, Dr Jonathon Egan, a senior staff specialist in paediatric intensive care at the Children's Hospital at Westmead, stated:

> A potential effect of [prostaglandin] is that the flow via the [patent ductus arteriosus] may increase excessively leading to congestive cardiac failure as well as systemic hypofusion. This needs to be monitored closely by examination for adequacy of systemic perfusion (clinically and via blood gases). Saturations which are greater than 90% or certainly 95% also suggest that shunt flow may be excessive or overly generous to the lungs and chest x-ray will provide further evidence of this in terms of heart size and lung vascularity.

34. Monitoring of blood pressure and gases should enable clinicians to detect when the balance between the pulmonary and systemic flows tips towards the pulmonary circulation. Similarly blood gas tests will show up increases in acidity indicating reduction in oxygen in the systemic flows.

35. I note that in his evidence, Professor Lui not only frankly conceded this point but informed the court that the practice now at the Royal Hospital for Women in cases like Liam's to closely monitor blood pressures and gases.

Ought Liam to have been intubated and, if so, when?

36. There is no clear consensus of medical opinion on this issue. There are respectable arguments for both the "old school" practice of intubating babies at the same time as prostaglandin is commenced and the more recent approach of delaying intubation until demonstrably indicated. Each approach has its pluses and minuses.

37. Both Professor Lui and Dr Krishnan, who was then a Senior Fellow at the hospital, consider that it is, on balance, preferable to intubate babies prophylactically when prostaglandin is commenced. The rationale for this approach is that a baby whose heart is congenitally defective and whose respiratory and cardiac systems are therefore under strain is supported and the risk of apnoea is obviated. Dr Stephen Cooper, a paediatric cardiologist at the Children's Hospital Westmead, also gave evidence that it may be preferable to commence intubation at the same time as prostaglandin but accepted that many specialists in neonatal intensive care hold the view that intubation ought not necessarily follow prostaglandin in tandem.

38. Intubation, however, is an added stressor for vulnerable and delicate babies already struggling. The medication(s) used to sedate babies being intubated, as with all powerful drugs, bring with them inherent risks (although they may in most cases be low). Intubation itself carries with it the risk of myocardial depression and loss of cardiac output. Intubation, no matter how or when it is done, no doubt increases discomfort for babies. For these reasons, many clinicians take the view that, unless there is a real indication of need or potential need, intubation should be delayed and the progress of the baby without artificial ventilation ought be observed before taking that step.

39. Dr John Smyth, a senior staff neonatologist at the Royal Hospital for Women, gave evidence that he would not ordinarily intubate when prostaglandin commenced but that intubation would more generally be used reactively depending on how the baby progressed. He cautioned that intubation can alter cardiac dynamics and can make things worse for a baby. The decision to intubate must therefore be a considered one.

40. Professor James Wilkinson of the Royal Children's Hospital, Melbourne, a consultant paediatric cardiologist, did not directly address the question of the timing of intubation in his report. It is implicit in his statement that "if a baby shows signs of having apnoeas [after prostaglandin is commenced] then intubation and ventilation would be the routine way of dealing with this" that he does not ordinarily require intubation when prostaglandin is commenced.

41. Associate Professor Nadia Badawi, medical director of the neonatology unit at the Children's Hospital Westmead, expressed a similar view in a report of 26 September 2006 to the Director of Clinical Services at the Royal Hospital for Women. She said:

> While it is not mandatory to intubate a baby who is on low dose [prostaglandin], there would have been a low threshold to do so in the event of him becoming apnoeic, becoming clinically unwell or developing abnormal blood gases or high lactates. Having high saturations above 90 would also have been concerning although I hasten to add that most neonatologists would not realize that very high saturations could be a danger in Liam because of his older age and lower pulmonary vascular resistance. This danger is apparent mainly in hindsight.

42. Dr Egan agreed that Liam ought to have been intubated on 29 June. He made the point, however, that "such activities are typically done best early in the day and utilising the most senior personnel available."

43. Even in retrospect, the question whether it would have been desirable to intubate Liam earlier in the day, possibly following the morning ward rounds when Professor Lui first

indicated an intention to commence prostaglandin and commence intubation seems to me to remain an open one. There can be a real risk in prematurely intubating a baby. Highly experienced neonatologists, weighing the costs and benefits of both approaches, have not been able to reach a consensus because there is no "one-size-fits-all" answer to the question because patients do not come in "one size". Even with the benefit of hindsight, it is very difficult to say whether earlier intubation would have made any significant difference for Liam. It is at least possible that it may have brought on a crisis at an earlier time in the day.

Was there an excessive delay in intubating Liam on 29 June 2006?

44. Once it became obvious at about 1600 hours that Liam was lethargic and unwell, it is difficult to understand why it took until 1805 for the intubation to commence. Perhaps the explanation is that the ward rounds were being conducted. A number of clinicians had taken a close interest in Liam and his parents were also very closely engaged in his care and treatment. Almost every significant decision concerning Liam's treatment appears to have been the subject of discussion and consultation between clinicians, such as Dr Smyth, and Mr and Mrs Woodcock. It may be that this generally commendable process of inclusion and consultation, which had developed since Liam's birth a month or so previously, had the unintended consequence of slowing the decision-making process at a time when it was desirable that decisions be made more quickly.

45. Commonsense suggests that with Liam obviously in serious difficulties at 1600 hours the sooner he was stabilised and treated the better. That said, there is no clear evidence that intubation at, say, 1600 hours rather than two hours later, would have made a significant difference to the ultimate outcome. Because of the complexity and delicacy of Liam's condition, however, it can only be a matter of speculation whether earlier intubation would have saved him or given him a better chance of survival.

Was it appropriate to administer propofol for the purposes of intubation?

46. Liam's family raised the question was whether propofol was an appropriate pre-medication agent for intubation for Liam given its possible side-effects.

47. Pre-medication of patients about to be intubated is a routine part of the process except in emergencies because intubation without it is painful and stressful. Propofol had been used at the neonatal unit at the Royal Hospital for Women since 2003. Prior to that, the unit had used the combination regimen of morphine, atropine and suxamethonium. According to Professor Lui, in 2006 both regimes were available.

48. Propofol had three major advantages over the combination of drugs. First, it was given in a single dose and thus reduced the possibility of error in drawing up the drug. Second, it did not require the elaborate checks that are required for Schedule 8 drugs such as morphine and therefore could be drawn up more quickly and efficiently. Third, propofol is a hypnotic agent that allows the patient to breathe spontaneously and therefore reduces the risk of hypoexemia that comes with the use of paralytic agents such as suxamethonium.

49. Professor Lui stated:

> When intubating adults and children, the use of rapid induction medications is a standard practice because it is a very painful and invasive procedure. Premedication for neonatal endotracheal intubation is now considered as essential and appropriate practice. Very few neonatal units (if any) in Australia would not use a pre-medication prior to an elective endotracheal intubation. We have previously shown in a randomised control trial that the use of a rapid induction regimen (3 medications in combination, including a muscle relaxant - paralysing the baby) would facilitate intubation with less failure and trauma compared with awake intubation without any premedication (Oei et al, Journal of Paediatrics and Child Health 2002 - Ref 16). Many other authors have shown the harm of the painful awake intubation. Our second clinical trial of medications for elective intubation in babies conducted in 2004 to 2005 has shown propofol performed better than our previous rapid induction regimen of 3 medications ... The intubation success rate was higher with quicker time of intubation and less oxygen desaturation. Blood pressure showed a trend to be better maintained. In contrast to other neonatal intubation regimens that include muscle paralytic agents, propofol allows spontaneous breathing and therefore there was less oxygen desaturation. It is of note that hypotension during intubation is a fairly common event...
>
> The propofol used in Liam's case was for the purpose of brief hypnosis and sedation for the painful procedure of endotracheal intubation. It was not used as an anaesthetic agent.

50. Professor Lui made the point that all medications carry risks with them and that there were very few data in relation to other pre-medications. In his view, propofol was a very useful preparation for the purpose of intubation because it was short-lasting and fast-acting and therefore likely to give more stability than other drugs.

51. In his report of 4 June 2008, Professor Lui stated that "we have used propofol to intubate infants with congenital heart disease but not specifically for a baby with pulmonary atresia." In answer to the proposition that Drs Egan and Baines would not use propofol for children in Liam's condition, however, Professor Lui said that he might

not use it in future himself, not for a scientific reason but because of the emotional strain the controversy of this case had placed on him and other members of the unit.

52. Dr Smyth stated:

> The policy in our unit is to use either propofol or suxamethonium, atropine and morphine for premedication for intubation. This includes babies with cardiac conditions. Our unit has published two randomised control trials comparing the use and efficacy of different premedications for intubation including propofol. Propofol has been widely used as a premedication for intubation of children over the past 20 years and has the distinct advantage of the child being able to breathe throughout the process. Administration of propofol or suxamethonium atropine and morphine and their effects are monitored very closely in our unit.
>
> It is currently difficult to assess precisely the safety of intubation using these two different methods of premedication as the numbers are not large enough. Premedication of babies receiving intubation by neonatologists is now considered routine practice throughout the world in neonatal intensive care units in western countries. All treatments are associated with a risk of side effects and the reported side effects of propofol are not greater than other drugs that have been used.

53. A study by clinicians from the Royal Hospital for Women, published in 2007, compared the efficacy of propofol and the combination of drugs.[3] It concluded:

> ...propofol is superior to the MASux as an induction agent to facilitate [endotracheal intubation]. Propofol also offered additional advantages, such as the maintenance of spontaneous respiration, less profound hypoxemia, and less procedure-related trauma compared with MASux. Faster recovery could also be an advantage in a compromised infant or in a case of difficult intubation.[4]

54. It is notable, however, that infants with major congenital abnormalities were excluded from that study.

55. Dr Krishnan's evidence was that she had not considered another alternative to propofol as the unit had switched away from the combination regime.

56. Dr Cooper, a senior specialist paediatric cardiologist, although not offering an opinion on whether propofol was appropriately administered, stated that propofol is widely used by anaesthetists involved in cardiac care.

57. The disadvantageous side-effect of most concern for a patient like Liam is that, as Dr Egan noted, it "has important effects upon the myocardium [heart wall] – reducing its contractility and also dilating the system circulation", both of which can lead to reduced

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[3] Ghanta, S et al "Propofol compared with the morphine, atropine and suxamethonium regimen as induction agents for neonatal endotracheal intubation: a randomized, controlled trial" *Paediatrics* vol 119, No 6, June 2007 e1248-e1255.

[4] Ibid at p. e1255.

systemic blood pressure. For this reason, Dr Egan stated that propofol "would certainly not have been my first choice in this instance."

58. Dr Egan explained that he would not use propofol in a patient with an impaired heart because "the critical thing is the pump". The heart is trying to pump blood to two circulations and propofol reduces or may reduce pump function. He conceded that he had not used propofol much but thought that it did not have a role in relation to critically ill children.

59. One of the reasons why he thought it ought not be used is that propofol has a sedative rather than analgesic effect and that, therefore, to have a pain-reductive effect, a larger dose would be required. This in turn heightened the risk of reducing myocardial function. He conceded that the Royal Hospital for Women's study suggested that there are, in fact, significant benefits and that few disadvantages had been identified. He emphasised that the study had specifically excluded cardiac patients.

60. He suggested that propofol only be used after senior intensivist or consultant review and that, in any event, it not be used in babies with compromised cardiac output.

61. In his opinion, a more appropriate regime for children with impaired circulation is to use ketamine instead of propofol because ketamine maintains or even tends to increase blood pressure.

62. Dr Baines noted that "there is little in the literature on which to draw support for, or indeed to criticise, the use of propofol in this age group." He was cautious in his opinions about the use of propofol. He concluded:

> I consider that it is possible (not probable) that the dose of propofol used might have contributed to Liam's deterioration. However, we do not know what would have happened if another drug was used, or if no medication was used at all. It is possible, given Liam's precarious state, that the same outcome would have occurred. Nevertheless, in retrospect, a smaller dose of propofol might have been prudent.

63. Endotracheal intubation of newborns is a common procedure. The best conditions in which to intubate a newborn are to have the baby's jaw relaxed, open with immobile vocal cords and suppressed reflex responses to the introduction of the tube. For these reasons, and to prevent unnecessary pain, there can be no criticism of the decision to pre-medicate Liam before he was intubated.

64. It appears that there are at present significant gaps in medical knowledge regarding the practice of pre-medication for elective intubation. It is evident that the optimal regime has not yet been identified, perhaps because the optimal agent has not yet been developed by the pharmaceutical industry. It is also evident that this area of medical practice, because of the delicacy of some patients, is inherently difficult and to some degree risky. Significant benefits in one regime bring with them significant potential disadvantages. The management of those benefits and risks in the circumstances of particular patients is no easy task.

65. The evidence presented in this case, including the Royal Hospital for Women study, indicates, first, that there are significant potential risks in intubating a newborn with any of the available agents. So far, although intubation does not appear generally to be a high-risk procedure, all risk has not been eliminated. It must be doubted that all risk will ever be eliminated. Second, the Royal Hospital for Women study suggests that propofol in many cases is highly effective and generally safe. Third, there is no clear evidence that the use of propofol caused Liam's death or significantly contributed to it. Fourth, nevertheless, because propofol may reduce cardiac output and lower systemic blood pressure by reducing the contractility of the myocardium and dilating the system circulation, that possibility is not speculative or remote and has not been and cannot be eliminated. Fifth, with the benefit of hindsight there appears to be cogent circumstantial evidence that, despite Liam's apparent stability and capacity to tolerate high saturation levels, the balance between his pulmonary and systemic flows was very close to tipping point. Finally, for these reasons, the use of propofol as a pre-medication agent may well have been inappropriate in Liam's case.

66. Absent a full study including children with severe cardiac conditions – a study that presumably would have severe ethical constraints – it is difficult, in the current state of medical knowledge and research, to draw a more powerful conclusion.

Did the fact that a resident had the "first look" affect the process of intubation adversely?

67. Dr Ju-Lee Ooi, now an ophthalmology registrar, in June 2006 was a junior doctor doing her first term of paediatrics at the Royal Hospital for Women. She was working under the supervision of Dr Krishnan in the unit when the intubation was commenced. As part

of her training, she was invited to attempt to intubate Liam. She made one attempt. This involved trying to sight Liam's vocal cords with her laryngoscope but she was unable to do so. Dr Krishnan took over immediately and completed the intubation.

68. Since Liam's death, the Royal Hospital for Women has taken the approach that very sick infants ought only be intubated by skilled and experienced senior doctors. The independent experts, however, were not generally critical of the Royal Hospital for Women for allowing Dr Ooi to take the "first look".

69. As noted above, Dr Egan, for example, suggested that it is generally preferable to do intubations during daytime when more resources, especially senior clinical staff, are available in the event of something going wrong. Although he took the view that it was unlikely that any harm was done to Liam, Dr Egan suggested that by 1730 hours the intubation should have been carried out not by a junior doctor but by a senior doctor because "the intubation needed to occur as slickly as possible." He thought it would have been appropriate at, say 1300 hours, for Dr Ooi to attempt the intubation but at 1730 hours, with Liam breathing erratically and real concerns about his circulation having arisen, this was not the time for training.

70. Dr Baines also thought that a junior doctor ought not to have attempted the intubation but thought that there had been no harm done.

71. In my view, as the Royal Hospital for Women is a teaching hospital, it is generally reasonable and appropriate to offer junior doctors the training opportunity of having "the first look". An emergency, however, is almost certainly not the appropriate time for such an exercise. That said, Dr Ooi was closely supervised and Liam's care and treatment was not compromised. In this case, Dr Krishnan quickly took over and had no problem intubating Liam. Professor Lui, although not on duty, was in his office and, when the emergency developed, came immediately to assist. Nevertheless, given the delicacy of Liam's situation, it would have been preferable for Dr Krishnan to carry out the intubation first time around.

72. The weight of evidence nevertheless indicates that there was no significant delay and that it is unlikely that the short time involved led, of itself, to any harm to Liam.

Was excessive oxygen administered during the intubation?

73. Because it was critical to maintain the balance between pulmonary and systemic circulation, a fact that was well understood by all relevant staff at the Royal Hospital for Women, a post-it note was placed on the ventilator saying "NO O^2 FOR LIAM".

74. Immediately after intubation, Liam's saturations spiked to 98 per cent. This was the undisputed evidence of RN Mosey who made her notes at about 1930 hours, after Liam had died. That sudden surge in saturations raised the question whether Liam had been over-oxygenated via the ventilator during his intubation. Unfortunately, there are no records available from the oximeter or any other machine. Clinical notes, perhaps understandably, were not a priority during the period when clinicians and nurses were attempting to intubate him and, shortly afterwards, to resuscitate Liam.

75. Given the passage of time, as well as the fact that between the intubation and Liam's death the drama of the attempted resuscitation had taken place, it was very difficult for the witnesses to recall with great clarity what had occurred during the intubation. Dr Ooi was unable to recall whether Liam was on air or added oxygen during the intubation. RN Mosey knew that Liam was "not for O^2" and thought that the ventilator setting had not been shifted during the intubation. As far as Dr Krishnan could recall, Liam did not need added oxygen during his intubation. Professor Lui, who was not present, stated that " the ventilator oxygen concentration might have been turned up to high oxygen for the intubation process and turned down after intubation".

76. Because of the difficulties of witnesses in recalling the events with clarity, and the lack of documentation, this evidence must be treated cautiously. Nevertheless, this was not at the time regarded as an emergency intubation in which it might be expected that the oxygen would be turned up high to counter a drop in saturations. The staff knew that during an intubation saturations generally drop for a short period but also that Liam was "not for O^2".

77. In those circumstances, while it is possible that oxygen was added to counter the anticipated drop in saturations, it seems unlikely that this was done both because Liam's saturations had already been high during the afternoon (in the 90 per cent range) and because of the warning against giving him added oxygen.

Were there any shortcomings in the resuscitation effort?

78. Mr and Mrs Woodcock were naturally concerned to know whether more could have been done to save Liam once the emergency was recognised. The overwhelming weight of independent evidence concerning the resuscitation effort suggests that there were no shortcomings in it. It was a case of "all hands to the pumps". RN Mosey, when she had observed the mottling of Liam's skin, immediately recognised that he was "crashing" and called doctors. Drs Krishnan and Ooi attended immediately and Professor Lui was called from his office.

79. Very unfortunately, Liam was not able to be saved.

Ought data from the pulse oximeter to have been downloaded following Liam's death?

80. After Liam's death, Mr Woodcock requested that the relevant data from the pulse oximeter be downloaded. This was not done because, soon after Liam's death, the machine was reset and used for another patient.

81. It was agreed by all concerned that the data ought ideally to have been captured. This would not only have provided the family with information but would have assisted the clinicians to understand what had happened to Liam, a matter of significant interest and concern to them.

82. Professor Lui agreed that it would have been desirable to download the data before the machine was used for another patient but explained that there was a limited number of machines for the unit. Since Liam's death, work has been done by his unit to enable data to be captured from oximeters. This will be discussed further below.

Ought Liam's death to have been reported to the coroner immediately?

83. Under s 13(1(f) of the 1980 Coroners Act the hospital was obliged to notify the coroner of any death which occurred within 24 hours of the administration of an anaesthetic. Propofol, generally used as an anaesthetic agent, was used in the Royal Hospital for Women neonatal unit for the purpose of sedating babies being intubated. This raised the

question of whether, for the purposes of s 13(1)(f), Liam's death was required to be reported. Professor Lui initially took the view that it was not because the key issue was not whether the agent was an anaesthetic or not but whether the baby had been anaesthetised. (An argument could be made that the death was reportable also under s 13(1)(b) as "a sudden death the cause of which [was] not known" but this was not considered at the time.)

84. Had Liam's death been reported, there would almost certainly have been an autopsy conducted at the order of the coroner. Because the initial view taken at the Royal Hospital for Women was that Liam's death was not a coroner's case, and because his parents objected to a hospital autopsy, a full physical investigation into Liam's pulmonary and cardiac state at the time of his death was not conducted.

85. When the issue of notifying the coroner was raised by Liam's parents, however, this was done immediately. Professor Lui stated, and I accept his word, that he simply had not thought of Liam's death as a coroner's case until then. There is no suggestion that Professor Lui or the Royal Hospital for Women was in any way involved in a cover up. In my view, he and all the witnesses from the Royal Hospital for Women who gave evidence were frank and open and anxious to assist the court and the Woodcock family to find the answers to the troubling questions Liam's death raised. The clinicians were keen for an autopsy to be conducted and, had this been recognised straight away as a coroner's case, no doubt would have welcomed the chance to learn from a post mortem examination.

86. The 2009 Coroners Act, which commenced on 1 January 2010, has eliminated the requirement to notify in relation to anaesthetic deaths and has replaced that requirement with one obliging doctors to report deaths which are the unexpected outcomes of health-related procedures: ss 6 & 35. In my view, had the new provision applied at the time of Liam's death, it would have required a report to the coroner.

The cause and manner of Liam's death

87. The ultimate cause of Liam's death was that he was born with a pulmonary atresia or a defective heart that failed. This summary, however, does not provide a satisfactory answer to the question of why Liam died on 29 June 2006. Nevertheless, Liam's

congenital heart disease and the complications it brought with it are the critical background against which I must answer the question. Opinions were sought from a number of experts.

88. Dr Cooper stated in his report:

> Liam had a very major cardiac lesion which even in full term babies carries a guarded prognosis. The fact that he was born around 1 kg in weight and at 27 weeks gestation certainly carries a grave prognosis in combination with the cardiac disease... [His] management was complicated by extremely low birth weight and prematurity... The catastrophically low systemic cardiac output that followed the start of prostaglandin was most likely related to excessive pulmonary flow and low systemic cardiac output... [The] cardiac prognosis was always very poor and I do not feel that different perinatal management would have altered this to any significant degree.

89. Dr Badawi was of a similar view. She said in her report of 26 September 2006:

> In our experience [at the Children's Hospital Westmead], most babies who are born at very early gestations and who are very low birth weight with congenital heart disease (excluding persistent ductus arteriosus) either do not survive or are left with severe disability... We continue to look after premature babies with congenital heart disease in the hope that they will do well but usually we and the parents are ultimately disappointed.

90. Associate Professor David Baines, in his report of 29 December 2009, stated:

> I think the cause of death, especially without a post mortem, remains open to conjecture, but most likely was myocardial failure in the presence of major congenital heart disease and prematurity. The myocardial failure would have occurred as a result of the need for the left ventricle to pump blood to both the systemic and pulmonary circulations – always a risk in "duct dependent" circulation as Liam had. This may, or may not, have been compounded acutely by the use of a significant dose of propofol, which could have exacerbated the myocardial depression and possibly by excess oxygenation at the time of intubation... It is not clear as to why he had deteriorated significantly prior to the intubation process. The narrowing of the foramen ovale... might have been more significant than realised and this restriction of flow of blood returning to the left side of the heart might also have contributed to his demise by limiting his cardiac output even more.

91. Dr Egan, in his report dated 29 September 2009, stated that the most likely cause of death was "an acute unbalancing of his circulation as a result of generous ventilation and possible oxygenation during intubation, together with Propofol, which has been shown to maximise saturations in neonatal intubation and is a vasodilator and myocardial depressant."

92. In a report dated 17 June 2010, prepared after he had viewed chest and abdomen x-rays taken of Liam on 29 June 2006, Dr Egan revised his opinion somewhat. He stated that in the chest x-ray there was "impressive cardiomegaly, the size of the heart is increased and the relative proportion within the thorax is increased. The pulmonary vascularity is increased, there are no effusions." This indicated to him that, following the commencement of prostaglandin, "the circulation overbalanced and pulmonary flow

became excessive... Additionally ventilating or bagging the child in inspired oxygen would have further exacerbated the left to right shunt via the [patent ductus arteriosus] and additionally loaded the heart."

93. In my view, Dr Egan's second report, which indicates that Liam's heart probably became very enlarged after prostaglandin was commenced, enables me to find that on the balance of probabilities Liam's death was due to myocardial failure resulting from excessive pulmonary blood flow and consequential loss of systemic blood flow on a background of major congenital heart disease. A number of factors almost certainly contributed to his death: prematurity, low birth weight, pulmonary atresia combined with right ventricular hypoplasia and the administration of prostaglandin to the treat the closing ductus arteriosus. The administration of propofol may have contributed also but the evidence of that is inconclusive.

94. As to the manner of Liam's death, it is obvious that he died while undergoing receiving care and treatment in the neo-natal intensive care unit of the Royal Hospital for Women for his congenital heart disease.

What has been done at RHW as result of Liam's death?

95. Since Liam's death, the Royal Hospital for Women has introduced a number of significant changes. First, a new form of laryngoscope fitted with fibre-optics has been purchased to assist with intubation and the training of junior medical staff in the skills of intubation.

96. Second, as noted above, junior doctors are not permitted to attempt intubation of very sick children.

97. Third, immediately after Liam's incident, the unit obtained the software to enable it to download data from its pulse oximeters and has now purchased six oximeters with extended memory capacity so that relevant data may be captured after a significant event.

98. Fourth, it developed a clinical guideline for Neonatal ICU Blood Pressure Management and Monitoring to supplement ongoing education and training for medical and nursing staff.

99. Fifth, a new coronial checklist was introduced in 2009 to ensure that coroners' cases were recognised as such and promptly notified.

100. Sixth, the unit also developed a checklist or guideline relating to stillbirths, neonatal and infant deaths which operates in conjunction with other checklists such as the coronial checklist.

101. Seventh, Professor Lui made the point that, following Liam's death, the unit had adopted a policy of leaving critical decisions in the hands of the on-call consultant. At the inquest, Professor Lui expressed an opinion that the difficulties of managing Liam had been further complicated by the more consultative process that had operated in 2006. Although in some respects the practice of including consultants who were not on call and who therefore did not have the immediate care of intensive care patients in decisions was advantageous, it obviously can have the disadvantage of slowing the decision-making process and possibly leading to decision by committee when that may not be appropriate. Although a significant degree of flexibility is built into the process, and the on-call consultant has the discretion to sound out others, the decision-making responsibility will reside with him or her.

102. Finally, and very significantly, the intubation protocol as it relates to the use of propofol is under review. Dr Smyth is conducting research in this area but his study had not been completed at the time the evidence was taken in this inquest. I understand that the unit has delayed finalising it because it wishes to consider the evidence and conclusions of this inquest. Two documents were produced at the inquest each on its face appearing to be the current protocol. This caused some confusion. Most importantly, however, both documents state that hypotension, myocardial depression and bradycardia are possible adverse effects and one of them that cyonitic congenital heart disease is a contraindication for the use of propofol.

103. As I understand the current practice, notwithstanding Professor Lui's comments concerning his own reluctance to use propofol in some cases, it is still used by the Royal Hospital for Women to intubate babies with impaired hearts but the initial dose is now only 1.5mg/kg/dose. Most significantly, whenever propofol is used, the neonatal unit now monitors blood pressures continuously and takes regular blood gases.

Should anything more be done?

104. Coroners have power under s.82 of the *Coroners Act 2009* to make recommendations relating to the death in question.

105. I acknowledge that since Liam's death, the neo-natal unit at the Royal Hospital for Women has given a great deal of time and thought to improving its performance for the benefit of the infants in its care. The unit is obviously staffed by caring and highly professional people. As the previous section of this decision shows, they have not been idle in the time that has passed and that is a credit to them. Nevertheless, no human organisation is ever incapable of improvement. The following ideas are offered not as criticisms of individuals but with a view to assisting the Royal Hospital for Women and the Area Health Service in their endeavours to maintain and improve the excellence of the neo-natal unit's practice.

106. One of the principal issues considered during the course of this inquest has been the question of the use of propofol as an induction agent for endotracheal intubation. It is evident that it would be highly advantageous for more research to be done on this question. Research in the field of neonatal care, as I apprehend it, consists largely in the collation and analysis of large number of case studies and reflection upon clinical practice in the light of that quantitative and qualitative exercise.

107. Given that Sydney has a number of excellent teaching hospitals with neonatal intensive care units in different Area Health Services, from an outsider's point of view it appears somewhat strange at first blush that there can be such a wide divergence of views about the use of propofol as an induction agent in infants with compromised hearts. On the other hand, it might be argued that progress is generated by different researchers tackling problems in different places in different ways and ultimately sharing the fruits of their research through scientific literature.

108. This raises the question, however, whether it would be appropriate for some form of meta-study of the use of propofol, ketamine and other induction agents used for infants with congenital heart defects to be conducted. This would require researchers to be willing and available to undertake the research and funding, perhaps through the Australian Research Council. I do not propose a formal recommendation because, as this question was not explored during the inquest, I am not in a position to assess whether it would be a practical suggestion. Nevertheless, Liam's case has prompted

much thought and consideration in neonatal circles in NSW and perhaps will act as a spur to further research.

109. More immediately, however, there are further things that can be done. First, in the light of the evidence that the Royal Hospital for Women's protocol for the use of propofol remains in draft or preliminary form still subject to final approval, and in the light of the evidence that came out of this inquest, there appears to be an urgent need for the Royal Hospital for Women to reconsider the question whether propofol ought be used in babies with cyanotic congenital heart disease and to settle its protocol in final form.

110. Dr Egan proposed that if propofol is to be used it not be used in infants with compromised cardiac output and that, in any case, it be used only after senior intensivist or consultant review of the baby. In my view, both those suggestions recommend themselves.

111. Second, it was agreed by the Royal Hospital for Women consultants that, if a baby died in the unit, it would be very useful to be able to download the data from the pulse oximeter. I understand that this is now the practice when it is practicable to do so. A checklist for use in coronial cases was placed in evidence. It makes no reference to the downloading of that data (although I understand that it is the practice to do so whenever a suitable oximeter was in use for that patient). I propose to recommend that the neonatal death checklist be amended to require that to be done if the data are available and other clinical priorities do not take precedence.

112. Third, in the course of his evidence, Dr Smyth said that, after the prostaglandin had been administered to Liam, it would have been helpful if the unit had had functional echo-cardiology equipment and expertise available. He said that some neonatologists are now training in the use of ultra-sound technology to enable them to monitor cardiac issues in infants with greater immediacy than other means allow. One of the difficulties in monitoring infants like Liam with ultra-sound is that experts (cardiologists) are not always available when it would be useful to have them. He therefore thought that greater use of functional echo-cardiology technology by trained neonatologists would be improve the monitoring of infants with compromised cardiac output.

113. In relation to the third point, I appreciate that Area Health Service and hospitals have budgets and many calls on their finances. Whether the introduction of the equipment and training that Dr Smyth envisages is reasonably practicable in the current financial

climate I do not know. Nor do I know where such a program would stand in order of priority given the many competing needs of patients and clinicians. I will, however, recommend that the Area Health Service consider whether the introduction of such training and technology is reasonably practicable within the foreseeable future.

Conclusion

114. Mr and Mrs Woodcock had desperately wanted to create a family. The deaths of their twins were, naturally, a very hard blow for them. The loss of Liam was perhaps especially difficult because, contrary to their expectations, he had shown that he was a tenacious little fighter with a strong will to live, despite his condition.

115. One of the important functions an inquest may serve is to take seriously and to seek answers to questions that trouble grieving families. We also have a communal interest in seeking answers to difficult questions about the lives and deaths of our fellow citizens. Associate Professor Nadia Badawi, medical director of the neonatology unit at the Children's Hospital Westmead, remarked in a letter that "Liam's clinical course is particularly unusual in that he appeared well during the first few weeks of life and then required [prostaglandin] administration. This is a situation most Neonatologists would never have encountered."[5] As painful as it has been for the family, Liam's death has not been in vain because it has prompted much careful reflection on, and some important changes in, the care of infants with serious heart disease at the Royal Hospital for Women.

116. The desire to create and nurture life is a profound instinct in human beings. Mr and Mrs Woodcock have honoured Liam by pursuing questions relating to his death in hope of ensuring that his life and their suffering were not in vain but will help other babies to survive. I hope that they may now find some peace and satisfaction in knowing that they have now done all they can do for Liam and will honour him more not by forgetting him but by nurturing their son Joshua and giving him the freedom to grow.

117. I now turn to the formal findings I am required to make under the Coroners Act and my recommendations.

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[5] Letter dated 26.09.06 to the Director of Clinical Services, Royal Hospital for Women

Findings under s 81 Coroners Act 2009

118. I find that Liam Woodcock died on 29 June 2006 at the Royal Hospital for Women, Randwick, NSW due to myocardial failure resulting from excessive pulmonary blood flow and consequential loss of systemic blood flow upon a background of major congenital heart disease while receiving care and treatment in the neo-natal intensive care unit of the Royal Hospital for Women for his congenital heart disease.

Recommendations under s 82 Coroners Act 2009

119. I make the following recommendations:

To the Minister for Health

1. I recommend that the South Eastern Sydney and Illawarra Area Health Service and the Royal Hospital for Women Neo-natal Intensive Care Unit reconsider the Unit's protocol in relation to the use of propofol as an induction agent for infants suffering cyanotic congenital heart disease and settle that protocol in final form as a matter of urgency. The unit ought consider including a direction that propofol not be used in infants with compromised cardiac output and that, in any case, it be used only after senior intensivist or consultant review of the baby.

2. I recommend that the Area Health Service amend the Royal Hospital for Women's "Stillbirth, Fetal, Neonatal and Infant Deaths Documentation and Transport Guideline" to insert a requirement that *if*:

   (i) a death must be reported to the coroner in accordance with the hospital's coronial checklist *and*

   (ii) a pulse oximeter permitting the downloading of data had been attached to the infant at the time of his or her death,

   subject to any other clinical priorities for the use of that equipment, the data from the pulse oximeter ought be downloaded and retained as part of the infant's medical records.

3. I recommend that the Area Health Service consider whether the introduction of functional echo-cardiology training and technology in neonatal intensive care units within its jurisdiction is reasonably practicable, given its budgetary priorities and constraints, within the foreseeable future.

Magistrate Hugh Dillon
Deputy State Coroner