CORONERS ACT, 2003

SOUTH  *AUSTRALIA*

FINDING OF INQUEST

An Inquest taken on behalf of our Sovereign Lady the Queen at Adelaide and Mount Gambier in the State of South Australia, on the 28th, 29th and 30th days of April 2009, the 8th and 11th days of May 2009 and the 24th day of June 2009, by the Coroner's Court of the said State, constituted of Anthony Ernest Schapel, Deputy State Coroner, into the death of Sienna Jools Linnell.

The said Court finds that Sienna Jools Linnell aged 7 hours, died at the Millicent and District General Hospital, Millicent, South Australia on the 17th day of October 2006 as a result of a Group B Streptococcus infection. The said Court finds that the circumstances of her death were as follows:

1. Introduction

1.1. Sienna Jools Linnell was born at the Millicent Hospital during the afternoon of Tuesday 17 October 2006 and died approximately 7 hours later. She was the first child of Amanda and Harley Linnell who were both residents of Millicent in the South East of the State. When Sienna was born she was an outwardly healthy baby. But she quickly succumbed to a debilitating infection that she had contracted during her mother's labour. There is no suggestion other than that clinical staff at the Millicent Hospital did all they could to save Sienna once the infection was detected.

1.2. A post-mortem examination was conducted in respect of Sienna by the State Perinatal Autopsy Service. The autopsy was conducted by Dr T Y Khong whose report,

verified by affidavit, was tendered at the Inquest as Exhibit C1a. Dr Khong's conclusions as to how Sienna died are as follows:

> 'The cause of death is ascribed to the Group B streptococcus infection. The clinical and pathological features are in keeping with early onset Group B streptococcus infection, which can present with sepsis with or without signs of respiratory distress and is usually characterised by fulminant pneumonia, septicaemia, shock and meningitis.'

In Sienna's case, Group B streptococcus (GBS) was identified within cultures taken from her liver, left lung, blood and stomach. Her lungs were congested, with histological confirmation of pneumonia and the GBS infection.

1.3. I find the cause of Sienna's death to have been Group B streptococcus infection.

1.4. The infection that took Sienna's life was undoubtedly contracted while she was still in her mother's womb and very likely contracted during the course of Mrs Linnell's labour. The GBS organism resides harmlessly and asymptomatically in the vagina in a certain percentage of women in the Australian community. The percentage has variously been described as 12-15%[1], 15-25%[2], and 20%[3]. If present during labour and delivery, in a small number of cases the organism can be passed from the mother to the baby and a resulting infection, known as an early onset GBS infection, might seriously compromise the health of the baby and on occasions fatally so. This is what happened to Sienna. The material before me as to the incidence in this country of early onset GBS infection and fatalities from the same was inconsistent and somewhat confusing. An article published in the Medical Journal of Australia in 2000[4] claimed that about 1-2% of infants born to women carrying GBS (12-15% of women) develop early onset GBS with about 6% of cases being fatal. Other statistics have been quoted. In any event, although it is apparent that fatalities occur infrequently, say one in thousands of births, they are preventable. For instance, Sienna's death was preventable as will be seen.

1.5. I will examine the details of Mrs Linnell's labour in due course, but suffice it to say at this point that Sienna was born approximately 43 hours after Mrs Linnell's

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[1] Exhibit C15, Tab 6, Page 1 and Tab 14, Page 1
[2] Exhibit C15, Tab 9, Page 1
[3] Exhibit C14, Page 4
[4] Exhibit C15, Tab 14, Page 2

membranes ruptured, commonly known as the breaking of the waters. In fact, although Mrs Linnell was at term, she had experienced a pre-labour rupture of the membranes (PROM), which in her case occurred between about 24 to 26 hours prior to the establishment of labour. The contraction of GBS by a foetus in-utero is a recognised risk during labour and the evidence is that the risk becomes greater where PROM has occurred and there is a prolonged period between PROM and commencement of labour and then birth. This risk factor is well recognised and is identified in all of the literature.

1.6. In order to minimise the period between PROM and the establishment of labour and birth, and to ameliorate the risk of the development of early onset GBS infection in the baby, many clinicians advocate induction of labour following PROM.

1.7. For several years now, in Australia and the USA, GBS screening tests have routinely been conducted shortly before the expected birth date. The test is usually conducted between 35 and 37 weeks gestation. It is designed to detect whether at the time of the examination the organism is present in the vagina of the pregnant woman. The examination involves the taking of a low vaginal swab. In some jurisdictions an anal swab is also taken. It is said that the taking of an anal swab marginally increases the detection rate. Because of the need to develop cultures, it takes a number of days for the result of a GBS screening test to be made available. For this reason, conducting the test closer to term (approximately 40 weeks) is generally avoided in case the mother enters labour before the test result becomes available.

1.8. On 11 October 2006 Mrs Linnell had undergone a GBS screening test that was administered by her general practitioner. In Mrs Linnell's case the result was reported as negative for GBS. The test can occasionally produce false negative results. The evidence as to the incidence of false negatives in percentage terms (variously estimated to be 10% or between 1% and 2%) was in my view unconvincing owing to the fact that some false negatives will never be detected. Suffice it to say, the incidence is not insignificant. In Mrs Linnell's case, her test result was either falsely negative or she was colonised with the organism after her test. To all intents and purposes it amounts to the same thing. In other words, at the time of her labour, she was GBS positive. In her case, the negative screening test result was misleading

insofar as any reliance could be placed upon it as an indicator of risk. But those responsible for Mrs Linnell's care were not to know that. All of this naturally brings into question the utility of a negative result as a risk management tool. The incidence of neo natal GBS fatalities where the mother had been screened and reported as negative for GBS, as in this case, would be regarded as a pertinent statistic. I have not seen that stat quoted anywhere in the mass of material before me. For all I know, it may not be known. However, while I am prepared to assume that it is not a frequent occurrence, it did happen in this case and it is fair to assume that it will happen again. I reiterate that the evidence will demonstrate that its occurrence is in any event preventable or at least that its incidence is capable of minimisation.

1.9. In order to minimise the risk of the foetus contracting GBS prior to delivery, in certain circumstances prophylactic antibiotic cover will be administered to the mother. It is now universally accepted that antibiotic cover is very effective in preventing early onset GBS in the baby. The acceptance of this proposition underpins all early onset GBS risk minimisation strategies. One such circumstance of administration is afforded by a positive GBS screening test in which case the giving of antibiotic cover is now routine. There are other circumstances in which antibiotic cover might be given on clinical grounds that do not depend on whether the GBS screening has been positive. They include the detection of a maternal temperature of, or greater than, 38ºC during the intrapartum period and prolonged rupture of the membranes of, or greater than, 18 hours where a GBS screening test has not taken place or its result is unknown. The relevant operative period is sometimes said to be 24 hours. Where the GBS result is negative, relevant guidelines and protocols suggest that antibiotic cover need not be given in prolonged rupture cases like Mrs Linnell's.

1.10. A number of objections are commonly voiced in respect of the indiscriminate administration of antibiotic prophylaxis. Firstly, the administration might expose the recipient to the risk, albeit small, of a fatal anaphylactic reaction. Secondly, there is a general objection to the unnecessary administration of antibiotics because of its tendency to engender resistance by the organism. Accordingly, there is a school of thought that antibiotic prophylaxis ought to be kept to a minimum. In the literature this notion is sometimes sought to be supported by an argument along the lines that

for every adverse outcome avoided by prophylactic administration, including a fatality, so many thousand women will needlessly be administered antibiotics.

1.11. Antibiotic cover was not given in Mrs Linnell's case. Her GBS examination was reported as negative and this appears to have been the underlying reason why antibiotic cover was not administered during her labour. This approach was in fact supported by the relevant South Australian Department of Health guidelines. I add here that there was no attempt to induce Mrs Linnell's labour or to hasten it by augmentation once it began. At one point she was offered a caesarean section delivery, but declined.

1.12. In the event, the reported negative result of the GBS examination proved to be no bar to Sienna nevertheless contracting this rapidly debilitating and life threatening infection during the course of her mother's labour. It appears, therefore, that there is room for debate whether, notwithstanding the negativity of any earlier GBS test, prophylactic antibiotic cover ought nevertheless be administered in circumstances where a mother's labour becomes protracted and in particular where a long period of time has passed since the rupture of the membranes. There seems little doubt in this case that if antibiotic cover had been administered to her mother, Sienna would not have contracted the fatal infection. One cannot be completely sure about that, but the notion of Sienna's survivability is supported by expert evidence that was adduced in the Inquest and in my view it is more likely than not that Sienna would have survived. I so find.

1.13. The clinical guidelines that deal with the issue as to whether prophylactic antibiotic cover ought to be given in Mrs Linnell's circumstances would suggest on their face that there would be no need to give antibiotic cover, based for the most part upon the negativity of a GBS screening test. This, notwithstanding two important facts, firstly the fact that prolonged rupture of the membranes would otherwise be viewed clinically as a significant risk factor for the contraction of early onset GBS in the baby, and secondly falsely negative GBS screening results are not unheard of. Enmeshed in this issue is the question as to whether, in any event, Mrs Linnell's confinement had been allowed to progress for too long or whether her labour should have been induced or augmented, or even a caesarean section performed. Neither

strategy, namely antibiotic cover nor induction, had been adopted in Sienna's case and her delivery was an expectant natural vaginal delivery, as I say, after the passage of many hours since the rupture of her membranes.

1.14. The tragic irony of Sienna's death is that if Mrs Linnell had not had a GBS screening test, the risk of Sienna developing early onset GBS would have been managed on clinical grounds, namely the length of time since PROM, and antibiotic cover would have been given meaning that Sienna would have survived.

1.15. In the light of the events that we know occurred in this particular case, I examined whether or not some modification needs to be made in respect of the relevant guidelines. To this end, I heard evidence not only from the clinicians involved in Mrs Linnell's case but also from two obstetric experts, one from Victoria and another from South Australia. I also examined a great deal of literature on the subject that was tendered at the Inquest.

2. Background

2.1. Mrs Linnell's pregnancy was relatively uneventful and she went to full-term. Indeed, save and except for the length of time involved in her delivery, the labour was to all intents and purposes also uneventful. The only exception to this was that at one point in time there had been a deceleration in Sienna's heart rate, but this did not in the event prove to be of any significance and may simply have been reflective of an imperfection in the monitoring process.

2.2. Mrs Linnell's general practitioner was Dr Trevor Burchall who practised at Beachport Medical Services. It was Dr Burchall who had conducted the GBS test on 11 October 2006. Dr Burchall had a Diploma from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists. As such he had a busy practice that included obstetric and gynaecological matters and in that capacity he had seen Mrs Linnell. Dr Burchall was not, in the event, to have any involvement in the birth of Sienna except of a peripheral nature. Dr Stephan Van Eeden was also a general practitioner who practised in the South East but within Millicent itself. Dr Van Eeden originally came from South Africa. He obtained his original medical degrees in South Africa in 1993 and came to South Australia in 2002. Dr Van Eeden also had some

obstetric experience. He had conducted a number of caesarean sections under supervision of an obstetrics specialist. He had also administered other more conventional deliveries in his time at Millicent. Dr Van Eeden had also seen Mrs Linnell on three occasions during her pregnancy.

2.3. Both Dr Burchall and Dr Van Eeden had practising rights at the local Millicent Hospital. The Millicent Hospital was a maternity hospital having a number of registered midwives on its staff.

2.4. A local obstetric specialist, Dr George Olesnicky, resided in Mount Gambier. He had been an obstetrician gynaecologist for 25 years and treated both public and private patients. He also practised at the Mount Gambier and Millicent Hospitals. Dr Olesnicky supervised the caesarean section deliveries that had been administered by Dr Van Eeden in the three years preceding Mrs Linnell's delivery. Dr Olesnicky did not see Mrs Linnell during the course of her pregnancy but had a very minor role to play in the course of her labour and delivery. Suffice it to say Dr Olesnicky was not engaged in any consideration of whether antibiotics ought to be given to Mrs Linnell.

2.5. Mrs Linnell had compiled a birth plan. This plan set out her wishes and expectations in respect of her confinement and Sienna's delivery. This document was tendered in evidence[5]. There is nothing extraordinary about this birth plan. Mrs Linnell gave evidence before me and struck me as being a sensible individual who had been under no illusions about what her delivery of Sienna entailed. However, it was obvious to me that the one thing that she was keen to avoid was a caesarean section delivery unless it was absolutely necessary. On the whole Mrs Linnell appears to have been reasonably flexible. For example, her birth plan left open the possibility of epidural anaesthesia and in the event she had this. The birth plan, however, does not deal with the issue of induction should that have been recommended or indicated. It appeared to me during the course of Mrs Linnell's evidence and having examined her witness statement, that Mrs Linnell desired a natural childbirth with minimal intervention, but I did not gain any impression from her that she was averse to induction should it have come to that.

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[5] Exhibit C5, pages 5-7

3. Key events in Sienna's delivery

Date	Time	Event
15/10/06	10:30pm	Mrs Linnell's waters break at home (pre-labour rupture of membranes or PROM)
	10:45pm	Mrs Linnell telephones Millicent Hospital and advises nursing staff that her waters had broken Dr Burchall contacted re this - he advises Mrs Linnell may remain at home for the time being
16/10/06	8:30am	Mrs Linnell attends Millicent Hospital and is admitted Mrs Linnell has not gone into labour Mrs Linnell is examined vaginally, possibly by speculum
	≈ 11:00am	Mrs Linnell is discharged home Still not in labour
	≈ 5:00pm	Dr Van Eeden contacts Mrs Linnell at her home by telephone She advised if Mrs Linnell does not present during the night, that induction of birth will take place at 8am the following morning
	≈ 10:30pm	Mrs Linnell begins to experience regular strong contractions (approx 24 hours since PROM)
17/10/06	12:10am	Mr and Mrs Linnell present at Millicent Hospital Mrs Linnell is admitted. Labour is established. (nearly 26 hours since PROM)
	12:39am	Mrs Linnell is examined by Dr Van Eeden This is a manual vaginal examination Mrs Linnell is dilated approximately 2cm Sienna experiences one deceleration to 60 beats per minute but with good recovery Dr Van Eeden discusses the matter with Dr Olesnicky who advises Dr Van Eeden to apply a scalp electrode to Sienna to better monitor heart rate.
	1:43am	Dr Van Eeden applies scalp electrode at second attempt Sienna experiences a deceleration to approximately 60 beats per minute with head compression by Dr Van Eeden's fingers Accelerations present thereafter Mrs Linnell continues to contract
	2:45am	IV jelco inserted
	5:45am	Epidural anaesthesia inserted in Mrs Linnell with good effect Continues to contract
	7:45am	Vaginal examination conducted by Dr Van Eeden Mrs Linnell dilated to 5-6cm
	8:10am	Mrs Linnell reviewed by Dr Olesnicky Mrs Linnell continues to experience contractions

Date	Time	Event
	12:35pm	Vaginal examination conducted by Dr Van Eeden Mrs Linnell is dilated to 8cm Mrs Linnell observed to be exhausted and emotional Dr Van Eeden offers Mrs Linnell the option of a caesarean section and discusses the same with Dr Olesnicky Mrs Linnell declines a caesarean section intervention
17/10/06	1:30pm	Mrs Linnell indicates to a midwife, Ms Garner, that she wishes to continue labour as long as possible.
	3:20pm	Ms Garner manually conducts vaginal examination of Mrs Linnell Mrs Linnell's contractions are strong Mrs Linnell is fully dilated upon examination
	≈ 4:30pm	Dr Van Eeden vaginally examines Mrs Linnell who is confirmed as fully dilated Mrs Linnell continues to experience good contractions
	4:40pm	Mrs Linnell commences pushing with a view to vaginal delivery
	5:15pm	Ventouse suction applied
	5:25pm	Sienna is delivered per vaginam

It will be seen from this analysis that Mrs Linnell's membranes ruptured at term. Save for some intermittent contractions that occurred just before 10 hours since rupture, her labour was not established until about 26 hours after the rupture of her membranes. There was a manual vaginal examination at that time. Thereafter, there were manual vaginal examinations at 27 hours post rupture, at 33 hours post rupture, at 38 hours post rupture, at 41 hours post rupture and again at 42 hours post rupture. All of the manual vaginal examinations occurred during labour. It is said that the number and frequency of manual vaginal examinations during labour is one of the reasons that the risk of the baby contracting GBS is heightened. Sienna was born nearly 43 hours post rupture, or after nearly 17 hours of established labour.

4. The evidence of Mrs Amanda Linnell

4.1. Mrs Amanda Linnell provided a statement to the investigating police officers in September 2008. That statement was tendered to the Inquest[6]. Mrs Linnell also gave evidence at the Inquest in Mount Gambier.

4.2. Mrs Linnell was 31 years of age at the time of Sienna's birth. Sienna was her first child. Mrs Linnell confirms that not long before her confinement Dr Burchall

[6] Exhibit C10

conducted a GBS screening test. Mrs Linnell says in her statement that she was not at any stage made aware of the result of that test. In the event, we know that the test was reported as negative. The test was taken by way of a low vaginal swab only.

4.3. I have already referred to Mrs Linnell's birth plan. Her statement makes it clear that Mrs Linnell was keen to experience a natural birth. However, her birth plan did not include any of her feelings about the possibility of the birth having to be induced. Having examined Mrs Linnell's statement, as well as the birth plan, and having seen Mrs Linnell give evidence, it occurred to me that Mrs Linnell was a pragmatic kind of person who would have been amenable to whatever intervention was considered to be necessary. She did not strike me as the kind of person who would reject compelling professional advice. That said, it was clear that during her confinement that she was quite unenthusiastic about the prospect of a caesarean section and, as seen, rejected that procedure when it was offered to her.

4.4. Although prior to Sienna's birth Mrs Linnell had heard of a GBS infection, she did not really have a complete understanding of it. She learnt of the possible infection, she believed, through a brochure. There is no evidence, for instance, that Mrs Linnell had any detailed appreciation of the risks involved in GBS infection, nor of the circumstances or clinical triggers behind such an infection. As a measure of this Mrs Linnell had not seen the need to find out what her GBS status was at any stage before or during her confinement.

4.5. As seen above, Mrs Linnell's waters broke some considerable time before she commenced labour and even longer prior to Sienna's delivery. Nobody had mentioned to Mrs Linnell at any time prior to delivery about the possibility of her requiring antibiotics to counter the contraction of a GBS infection in the baby. Indeed, during the entirety of the period following the rupture of her membranes, I understood that at no time was the question of antibiotic prophylaxis raised with her, nor was the issue of possible infection. A nurse employed at the hospital, Ms Cathie-Anne Williams whose statement verified by affidavit was tendered at the Inquest[7] discloses that she made a note in the clinical record as a reminder to consider the question of whether Mrs Linnell might need induction of labour or IV antibiotics at some point in time if labour did not establish or progress. The statement does not

[7] Exhibit C18

suggest that she discussed with Mrs Linnell the various clinical scenarios that might trigger the administration of antibiotics. It will be remembered that during the course of Mrs Linnell's labour she underwent a number of internal, manual vaginal examinations. There is no evidence that anyone raised with her the risk of infection posed to Sienna by virtue of these examinations.

4.6. In her evidence Mrs Linnell told me that although she did not know what the result of her GBS test had been, she had a general understanding that if the test had been positive she would have been given antibiotics during the course of her labour and possibly even before. She confirmed that she had not given any thought to whether or not the test had been positive or negative and only discovered the fact that it had been reported negative after Sienna had died. I think it fair to say, however, that if Mrs Linnell had an understanding that antibiotics would have been given if the tests had been positive, and given the fact that no antibiotics were given to her at all, that at some point she must have understood that the test had not been reported as positive. That said, I think it is also fair to observe that none of these thought processes entered her mind during the course of her labour[8].

4.7. Mrs Linnell told me that she was not aware of any allergy to antibiotics and had indeed taken antibiotics for tonsillitis. She was asked this question by Ms Kereru, counsel assisting:

> 'Q. If someone had spoken to you during your labour about antibiotics, what would your attitude have been to it.
>
> A. Didn't have a problem with it.' [9]

In fact Mrs Linnell had antibiotic cover when her second child was delivered.

4.8. Mrs Linnell told me during the course of her evidence that nothing had ever been said to her about any risk to her baby's health that might have been posed by a lack of antibiotic cover. Although one has to be careful about being wise after the event, Mrs Linnell told me that if anybody had explained to her that there was a risk of her baby contracting a GBS infection, she would definitely have gone ahead and had the antibiotics. Although this claim was made with the benefit of hindsight, it is clear to me that Mrs Linnell had no aversion to the administration of antibiotics. Her attitude

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[8] Transcript, page 33
[9] Transcript, pages 35-36

towards that seems to have been a pragmatic one that appears to be very much in keeping with her character. As well, there did not seem to me to be any reason why Mrs Linnell's own personal views about risk, and the administration of antibiotics to counter that risk, ought to have been accorded any less weight than any clinician's opinion on the subject. The difficulty of course is that nobody raised the subject with her at all. In this regard, Mrs Linnell accepted, in cross-examination by Mr Homburg, counsel for the Millicent Hospital, that it would have been appropriate for her to be advised of the possible adverse consequences of the administration of antibiotics as well as its possible benefits. However, Mr Homburg refrained from spelling out to Mrs Linnell what he had in mind as far as possible adverse consequences were concerned. For my part I cannot for a moment imagine the very remote risk of an anaphylactic reaction or the general subject of antibiotic resistance cutting much ice with Mrs Linnell. In this regard, some sections of the scientific community still appear to exhibit a rather paternalistic attitude by seeking to impose upon the rest of the community standards and viewpoints in respect of matters that the individual is quite able to make up his or her own mind about.

4.9. Mrs Linnell confirmed that there had been some discussion about the possibility of her being induced on the Tuesday morning. She had no difficulty with that proposal and it is safe to assume that had the issue of induction or augmentation of labour been raised at any time thereafter, she would not have had a difficulty at that time either. In the event we know that there was no further discussion about induction because the beginning of her labour overtook that consideration. Nor was there any further discussion of her labour being accelerated by way of augmentation. The only discussion about accelerating delivery was the discussion about a caesarean section which was rejected.

4.10. Although much of Mrs Linnell's pragmatism may owe itself to her experiences both with Sienna and her subsequent child's delivery, the following statement by her during the course of her evidence seems to sum up her attitude:

> 'I would say that antibiotics, if that's something that's going to fix or help like a baby or the mother, why wouldn't you? You'd have it done for - you know, people have antibiotics for earache.
>
> Why wouldn't you have antibiotics for - if you have the group B strep in you?'[10]

[10] Transcript, page 38

The rhetorical question posed by Mrs Linnell above to my mind is a good question and one that is quite capable of being answered by any properly informed woman in her situation.

5. Dr Van Eeden's involvement

5.1. Dr Van Eeden was the medical practitioner overseeing Sienna's delivery. He provided a statement to the police[11] and he also gave oral evidence.

5.2. Dr Van Eeden was not Mrs Linnell's usual general practitioner, although he had seen Mrs Linnell on two occasions during her early pregnancy. However, it fell to Dr Van Eeden to oversee Mrs Linnell's confinement at the Millicent Hospital.

5.3. Dr Van Eeden was a general practitioner who had some experience in obstetrics and gynaecology. His curriculum vitae was tendered to the Court[12]. Dr Van Eeden obtained his medical degrees in South Africa in 1993. He came to Australia and commenced practice in Millicent at that time. He practised both in South Africa in the United Kingdom before settling Australia in 2002. From July 2002 he practised in Millicent as a general practitioner obstetrician. Dr Van Eeden had admission rights at the Millicent Hospital to perform normal vaginal deliveries and instrumental deliveries when he was comfortable to do so and was in the process of gaining a sufficient level of expertise and experience to perform caesarean sections. Dr Van Eeden has a number of certificates in respect of obstetrics and, as well, he tendered to the Inquest letters from the Director of Obstetrics at both the Women's and Children's Hospital and The Queen Elizabeth Hospital that credentialed his ability to manage normal labour and deliveries that might require forceps or ventouse suction[13].

5.4. In the circumstances that prevailed in respect of Mrs Linnell's confinement, the then current guidelines promulgated by the South Australian Department of Health did not call for the administration of antibiotics. Mrs Linnell's GBS status was reported as negative. Her membranes had ruptured at term, that is to say not prematurely. A strict application of the South Australian guidelines meant that as far as antibiotic prophylaxis was concerned, *'no further special consideration'* was required in Mrs Linnell's case. In other words, the administration of antibiotic prophylaxis was not

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[11] Exhibit C12d
[12] Exhibit C12
[13] Exhibit C12a

recommended and indeed the guidelines suggested that it was simply not necessary, irrespective of the length of time since rupture of the membranes. As will be seen later in these findings, views differ about this issue and it is suggested that in circumstances such as Mrs Linnell's, where she had experienced a significant period of time post rupture of her membranes before going into labour, and then experienced many hours of labour, she should have been given antibiotic prophylaxis regardless of the fact that she had been reported as GBS negative.

5.5. In the event, Mrs Linnell was not given the antibiotic prophylaxis that would have offered Mrs Linnell and Sienna a high level of protection against early onset GBS. Although either the GBS negative status was a false negative or Mrs Linnell had picked up a GBS colonisation since her test, there was no reason for Dr Van Eeden to have questioned Mrs Linnell's negative GBS status at the time. There were no clinical signs of infection identified at any stage of Mrs Linnell's confinement. The only risk factor for GBS that existed in her case was the long period since PROM and the long labour, involving as it did a number of internal vaginal examinations. The relevant literature and guidelines suggested that this risk was, as it were, counterbalanced by the reported negative GBS status.

5.6. Despite what might be interpreted as criticism from an expert obstetrician gynaecologist who has overviewed this matter, and even having regard to the fact that, as we will see, other clinicians in the South East may on a practical level have viewed Mrs Linnell's circumstances and risk status differently, the fact of the matter was that Dr Van Eeden's management as far as the need to administer antibiotic prophylaxis was concerned was totally in accordance with the relevant South Australian Department of Health guidelines. Accordingly, it is difficult to see how he can be criticised.

5.7. That all begs the question of course as to whether the South Australian guidelines are in any sense appropriate or indeed effective.

5.8. As to the question of induction, Dr Van Eeden had resolved to induce Mrs Linnell at 8am on the Tuesday morning if she had not already gone into labour by then, but the issue was overtaken by the fact that Mrs Linnell went into labour overnight, albeit belatedly. When Mrs Linnell finally did go into labour and presented at the Millicent Hospital in the early hours of the Tuesday morning, Dr Van Eeden told me that he did

not think that any further intervention by way of hastening or augmentation of labour was necessary. He said that Mrs Linnell had gone into labour naturally and there was no reason to believe that she would be in labour for a long time. When it transpired that she was in labour for a long time, Dr Van Eeden offered Mrs Linnell a caesarean section and she declined. While with the benefit of hindsight it would have been appropriate for Mrs Linnell to have been induced during the day of Monday 16 October, in my view it is nevertheless difficult to see how any person can be said to have acted unreasonably at any stage.

6. The evidence of Professor Roger Pepperell

6.1. Professor Pepperell is a Professor Emeritus at the University of Melbourne. Professor Pepperell's Professorship is within the Department of Obstetrics and Gynaecology at that University. Professor Pepperell has medical degrees from the same University, a Doctorate of Medicine from the Monash University and he possesses Fellowships of both the British and Australasian Colleges of Obstetrics and Gynaecology. He is also an Honorary Fellow of the American College of Obstetrics and Gynaecology. Although Professor Pepperell is retired, he continues to undertake clinical work in obstetrics and, in particular, at the Royal Women's Hospital in Melbourne.

6.2. Professor Pepperell has been a practising obstetrician since the early 1970s and has held a Professorship at the University of Melbourne since 1978.

6.3. Professor Pepperell was invited by counsel assisting the Coroner to comment upon the management of Mrs Linnell from the time of the rupture of her membranes. He provided two reports to the Inquest[14] and gave oral evidence.

6.4. In his first report dated 5 June 2007 Professor Pepperell agreed that, given the recency of Mrs Linnell's GBS screening and the fact that it was negative, there was no absolute indication for antibiotic therapy to be given in labour. However, he expresses the view in this report that Mrs Linnell's labour should have been induced within 24 hours of her membranes rupturing and that antibiotics certainly should have been commenced within 24 hours of that time, meaning effectively when her labour commenced.

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[14] Exhibits C14 and C14a

6.5. Professor Pepperell explained that the risk of infection with organisms such as GBS within the vagina increases progressively with time and that antibiotic therapy is indicated 24 hours after membranes have ruptured, even in the absence of clinical infection. Even in the established absence of GBS organisms within the vagina as suggested by the negative screening test, in Professor Pepperell's view antibiotic therapy was indicated on the grounds of duration of membrane rupture alone.

6.6. In his report, Professor Pepperell emphasised that the GBS infection is devastating to many babies and is often not able to be recognised until it is severe, and even when antibiotic therapy is given in the presence of severe infection, at least half of the babies die in the same way that Sienna Linnell died. It is for this reason that between 36 to 38 weeks of gestation screening is now routinely performed. Professor Pepperell suggested that the screening test is positive in about 20% of apparently normal women. Where positive, the risk of infection occurring in the baby is about 50% and in 1% of these cases the babies contract severe infection if the mother does not receive the appropriate prophylactic antibiotic treatment in labour. Professor Pepperell stated that if penicillin is given in labour, infection in the baby almost never occurs.

6.7. Professor Pepperell maintained in his report that in a term pregnancy where the GBS screen test is reported as negative, as was the case with Mrs Linnell, routine penicillin antibiotics are not given in labour unless there is evidence of clinical infection or the duration of ruptured membranes exceeds 24 hours. It will be seen that this latter triggering event is not in accordance with the South Australian Department of Health guidelines.

6.8. Professor Pepperell pointed out that GBS screening in the mother does not have a 100% positive result even when the organism is present. It is most likely to be positive when the testing is done in the last 4 weeks of pregnancy but approximately 10% of patients who carry the organism are not detected at that time, even with screening. Other evidence suggested that the figure may not be as high as what Professor Pepperell suggested, but the evidence in the Inquest as a whole was clear that not all positive cases are detected by this method of screening and that a certain percentage of positive women will be incorrectly reported as negative. It appears that Mrs Linnell was probably one of those cases, or if not, she colonised at a time after

the test was conducted. Either way, as Professor Pepperell suggests, the screening test is not absolutely reliable.

6.9. In his second report dated 21 July 2008, Professor Pepperell suggested that Dr Van Eeden's approach that had involved not giving antibiotics because the GBS test had been negative and no other infection was identified, was erroneous and contrary to the standard teaching in relation to the administration of antibiotics when the membranes have been ruptured for more than 24 hours. This contention, as it transpired, proves to be a matter that is by no means free of debate and in any case is not supported as we have seen by the South Australian Department of Health guidelines.

6.10. Professor Pepperell gave oral evidence. In his evidence Professor Pepperell acknowledged that within Australia, South Australia being an example, certain groups deemed it unnecessary to give antibiotics where the woman has been screened as GBS negative, but that others adopt a policy and administer antibiotics on the grounds of duration of ruptured membranes alone. Professor Pepperell said that he is a person who subscribes to the latter practice. He pointed out that he has been a member of the Victorian Neonatal Mortality Committee for over 30 years and in that period many babies had been seen to die where antibiotics were not given.

6.11. Professor Pepperell elaborated on his report and upon the significance of the 24-hour period. He explained it in these terms, namely that if a woman ruptures her membranes at term, 90% of them would have laboured and delivered within the 24-hour period following rupture. If the woman has not laboured and delivered by that time then the risk of infection is increased. Such things as the number of internal pelvic examinations and, say, the administration of a scalp electrode to better monitor the baby's heart rate, as happened here, would all increase the risk of the baby contracting an infection. For Professor Pepperell, Sienna probably contracted the infection in the period following that first 24 hours since rupture given the level of aggression with which the infection ultimately took hold and took on fatal consequences.

6.12. Professor Pepperell also made mention of the fact that GBS was not the only difficulty and that there were other organisms that might be problematic and which are not screened for, such that antibiotic cover could be warranted on that basis as well.

6.13. Professor Pepperell pointed out that prior to the introduction of routine screening for GBS during the last few weeks of pregnancy, it was routine practice for antibiotics to be given when the duration of ruptured membranes exceeded 24 hours. However, owing to the prevalence of screening, the overall risk of infection is now less because screening identifies a high percentage of those who might be affected. However, there is still a difficulty created by the incidence of false negatives. Professor Pepperell was of the view that it was unlikely that colonisation would have occurred in the time interval between Mrs Linnell's test and her confinement given the fact that her test was conducted quite late in the piece and that it was, in his view, a truly false negative test.

6.14. Professor Pepperell acknowledged in his evidence that at the Women's Hospital in Melbourne there would be no absolute necessity to give antibiotics in the circumstances that prevailed in Mrs Linnell's case, but that when Professor Pepperell himself is on the labour ward, antibiotics would indeed be given by the clinical staff because Professor Pepperell's beliefs and practices in this regard were notorious.

6.15. It is fair to say that Professor Pepperell's opinions in respect of what should have taken place with respect to Mrs Linnell reflected a view that perhaps goes beyond what many of the clinical guidelines in existence require. In that regard, Professor Pepperell would advocate a more cautious approach in recognition of the fact that the time since rupture of membranes gives rise to a risk that still exists, notwithstanding the negativity of a screening test. Lest it be thought that Professor Pepperell's more conservative approach to the question of risk is idiosyncratic, other evidence adduced before me demonstrates that his view is widely shared within the medical community in spite of the guidelines. As we will see, that same approach seems to be adopted by other clinicians notwithstanding the guideline requirements that might be in existence. Suffice it to say at this point, Dr Van Eeden was not one of those clinicians, but a number of his colleagues in the South East are. More of that later.

6.16. As well as the question of antibiotics, Professor Pepperell expressed the view in his reports that Mrs Linnell should have been induced. He told me in his evidence that he would have advised her to have her labour induced at 24 hours post PROM. It will be noted that Mrs Linnell in fact did go into labour at, or not long after, the 24-hour period. Professor Pepperell conceded that one could wait longer, but the question

remains whether the antibiotics should be given. His view was that they should have been given[15].

6.17. Professor Pepperell did not believe that the risk of anaphylaxis was a relevant consideration. He acknowledged that the development of the organism to resistance to antibiotics had been identified as a reason for objection to the indiscriminate use of antibiotic therapy.

6.18. To those who might argue that in cases like Mrs Linnell's one would not administer antibiotics unless there was evidence of actual infection in the unborn baby, Professor Pepperell would argue that the severity of the infection, its devastating consequences and the fact that it might not be recognised until it was too late tends to override all other considerations[16].

6.19. Professor Pepperell pointed out that when antibiotics have been given, there have been virtually no cases in Melbourne where the baby has developed a severe GBS infection[17].

6.20. Professor Pepperell was asked to comment upon the South Australian Department of Health guideline. He said this:

> 'I think that guideline just indicates their belief that when the GBS test has been done and been shown to be negative, you don't need to worry about the alleged increase risk of infection, which I think is wrong.
>
> …
>
> I think the guideline needs to be changed and it needs to basically say that if in fact the patient is GBS negative, but the duration of membrane rupture is greater than 18 - or I would say 24 hours – then prophylactic antibiotic therapy should be recommended. That is what my belief is.' [18]

6.21. When giving evidence Professor Pepperell reiterated his opinion that Mrs Linnell's baby would have survived if Mrs Linnell had been given antibiotics.

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[15] Transcript, page 203
[16] Transcript, page 206
[17] Transcript, page 207
[18] Transcript, page 210

7. The evidence of Dr Geoffrey Matthews

7.1. Dr Matthews presented to the Court a differing point of view from that of Professor Pepperell. Dr Matthews is the current Director of Obstetrics at the Adelaide Women's and Children's Hospital. He obtained his original medical degrees from the Flinders Medical Centre in 1984 and obtained his Fellowship of the Royal Australian College of Obstetricians and Gynaecologists in 1996. He is also a Fellow of the UK equivalent having obtained that Fellowship in 2004.

7.2. Dr Matthews was of the view that there was no evidence base for the routine use of antibiotics as part of an expectant approach to the management of labour unless there was an actual clinical indication for it in the particular case. While there was a recognised necessity and practice to give prophylactic antibiotics to GBS positive women, Dr Matthews would question the justification for providing antibiotics in circumstances where the false negative rate was in his view very low. I have already referred to the fact that Professor Pepperell regarded the false negative rate as approximately 10%. Dr Matthews gave me to understand that the rate of false negativity was of the order of 1% or 2%, a figure that is reported in the literature and which he says statistically accords with the South Australian experience. Of course a detection rate of approximately 1% to 2% of false negatives would not necessarily reflect the actual false negative rate because false negative cases in which there is no clinical indication of infection and in which the baby is delivered without any adverse incident, would simply remain unidentified. It would seem that if the figure of 1% to 2% is based upon the incidence of detection, then the overall 10% rate advanced by Professor Pepperell might be real after all. However, it is as well perhaps for the purposes of these findings to proceed on the basis that for every 100 negative GBS test results obtained, between 1 and 2 are in fact positive. That in my view is not an insignificant incidence. Given the practice that all GBS positive women are routinely given antibiotics, it is difficult to resist the suggestion that women who are falsely negative should be regarded as at the same risk as those who are detected as positive. The difficulty in their case is that nobody knows they are falsely negative until it is too late.

7.3. Dr Matthews told me that general practitioners are encouraged to base their obstetric practices on the South Australian Department of Health guidelines. Dr Matthews recognised that the guidelines stipulate that the use of antibiotics is justified if the

woman is GBS positive, but that if they are GBS negative, antibiotics are not indicated unless there are specific criteria met that are clinical. For example, if the woman were to be brought in at 96 hours, or the morning after the 96th hour, then antibiotics would be used in that situation. It will be remembered that Mrs Linnell's confinement was well short of that figure.

7.4. Dr Matthews made what in my view are important observations:

1) The screening strategy whereby GBS positive women are given antibiotics and GBS negative women are not, unless there are clinical indications for the same, relies on accurate detection of GBS on screening. This to my mind was a concession of the obvious, but one that does recognise that as far as GBS negative women are concerned, much reliance is placed upon their negative status, even in circumstances where the membranes have been ruptured for a substantial period of time, a circumstance which would, but for the existence of routine screening nowadays, be regarded as a significant risk factor for the contraction of GBS and one that would attract antibiotic therapy;

2) Dr Matthews conceded that one would assume that 1% or 2% of the reportedly GBS negative women would have an infection;

3) The longer the baby is exposed to the process of labour the greater the risk of contracting an infection[19];

4) Vaginal intrusions and vaginal examinations during labour increase the risk of infection;

5) In his view Sienna acquired the infection from her mother during the birth process itself or during the course of labour;

6) That a certain percentage of even GBS positive mothers will have an infected baby[20];

7) That any morbidity associated with anaphylaxis is greatly offset by reduction in incidence of neonatal and maternal sepsis - in this regard Dr Matthews accepted that if a mother was properly informed of the risks of an adverse outcome from infection for the baby against the risks of herself having an anaphylactic reaction, then the woman is perfectly capable of making that decision herself.

[19] Transcript, page 284
[20] Transcript, pages 295-296

One would only add that it is not the kind of decision that should be made by a mother in extremis;

8) That the woman herself is in as good a position as anybody to evaluate whether the issue about the giving of antibiotics engendering a general resistance by bacteria ought to impact on her own personal circumstances;

9) That a false negative GBS test result and a positive GBS test result are one and the same;

10) In Mrs Linnell's case either the result of her GBS screening test was a false negative or she acquired GBS very late in pregnancy. I add here that for practical purposes they are the same in the sense that her negative screening status was, in the event, of no value and, if anything, misleading;

11) That it was a reasonable proposition that if Mrs Linnell had been given antibiotics prior to, or at the time of going into labour, Sienna would likely have survived;

12) That Mrs Linnell's case was not by any means an isolated one[21];

13) That even if unfortunate outcomes such as Sienna's occurred only once in several thousand, that if such a death were preventable then any statistical objections to the administration of antibiotic cover based on infrequency of adverse outcomes would be overcome[22] - I add here that to my mind the proposition that Sienna's death could have been prevented by antibiotic cover is unassailable. Dr Matthews added, however, that it was still a relevant concern to determine how many women would needlessly be given prophylactic antibiotics to prevent one death[23].

7.5. Dr Matthews also commented upon the desirability of inducing the woman's labour after rupture of the membranes. Dr Matthews, to my mind, had a very pragmatic approach to this issue. He suggested that the current view was that there is no benefit to be derived from waiting. For example, there was no convincing evidence to suggest that the incidence of caesarean section outcomes were avoided by expectant management in these circumstances. Dr Matthews gave me to believe that in circumstances such as Mrs Linnell's, it would be appropriate to offer her induction.

[21] Transcript, page 294
[22] Transcript, page 307
[23] Transcript, page 308

The observation can be made that if induction is embarked upon, then the time factor giving rise to risk of infection is somewhat ameliorated. Whether it would of necessity involve not giving antibiotics is another matter. In the event, this Inquest was less concerned with the situation involving possible induction than the question of the necessity of antibiotic cover when induction is not administered. The question of induction in Mrs Linnell's case was overtaken by the fact that she went into labour spontaneously in any event, albeit late after her membranes had ruptured. There was no induction or augmentation thereafter. The question was whether antibiotics should have been given in those circumstances and whether when those same circumstances are repeated in the future, antibiotic cover should be given.

7.6. Dr Matthews dealt with the question of the appropriate method of sample taking for the purpose of GBS screening. Dr Matthews acknowledged that in South Australia ano-rectal swabs are not routinely taken, as was the case with Mrs Linnell. He acknowledged that on a statistical basis there was a slight increase in the pick-up rate of GBS where an ano-rectal swab was taken. He told me that the feeling is that the pick-up rate is not sufficiently enhanced to really justify the routine taking of both anal and low vaginal swabs.

8. The views of other medical practitioners

8.1. Dr Trevor Burchall was Mrs Linnell's usual general practitioner. It was Dr Burchall who arranged for the GBS screening test of Mrs Linnell. Dr Burchall told me that one is entitled to work on the assumption that if the GBS screening test was undertaken at a late stage in the pregnancy, the negative status would be maintained. Dr Burchall would also tell his patient that if a test was negative then no further action needs to be taken. I took Dr Burchall to mean that one could justify that approach on the basis of the guidelines. However, looking at the matter from a practical viewpoint, Dr Burchall told me that in Mrs Linnell's case he personally would have instituted antibiotics and would have considered inducing Mrs Linnell's labour. He would have made those decisions in consultation with a specialist. Dr Burchall explained his own personal practice as follows:

> 'My general practice was to look seriously at giving antibiotics at 12 hours of ruptured membrane so that's rather conservative and it's more conservative than some of my peers, but that's been - that was my practice at the time and certainly if a woman hadn't come

into established labour within say 24 hours of ruptured membranes, then I would have been looking at getting advice on inducing labour.' [24]

8.2. Dr Burchall accepted that his practice in giving antibiotics was not supported by the guidelines that I have referred to and he also indicated that he did not believe that his practice necessarily accorded with that of his peers. In his evidence Dr Burchall expressed the view that the South Australian guidelines were '*not helpful for people practising*'[25]. Dr Burchall evinced a belief that the longer the time since rupture of the membranes, the greater likelihood of infection and that even with GBS negative women, the risk factors still had to be taken into consideration - such as the risk posed by the number of vaginal examinations that were undertaken during the course of labour as well as the fixation of a scalp electrode. He would administer antibiotics to a GBS negative woman after a period of 12 hours post rupture of the membranes, regardless.

8.3. Dr Olesnicky also provided a statement to the Inquest[26]. He is a specialist obstetrician and gynaecologist with his practice based in Mount Gambier. His statement suggests that if a woman ruptures her membranes at term, which happened in the case of Mrs Linnell, consideration should be given to the administration of antibiotics if delivery has not occurred within 24 hours thereafter.

8.4. Another specialist obstetrician and gynaecologist practising in the South East, Dr Colin Weatherill, also provided a statement to the Inquest[27]. Dr Weatherill says in his statement that that in a term pregnancy, it has always been his practice after a prolonged period since rupture of membranes (longer than 18 hours) to administer penicillin even when the GBS status is negative. It is to be noted that that scenario was that which pertained to Mrs Linnell. Dr Weatherill in his statement accepts that his practice is different from that envisaged in the South Australian guidelines. He opines that the guidelines are wrong insofar as they suggest that GBS negative women need no further special consideration even where PROM is greater than 18 hours.

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[24] Transcript, page 78
[25] Transcript, page 80
[26] Exhibit C9
[27] Exhibit C17a

8.5. Dr Weatherill also states that his current practice after PROM in a term pregnancy is to commence induction when convenient, and certainly within 24 hours.

8.6. Dr Weatherill's statement evinces a belief that the risk factors involved in clinical concerns, such as prolonged rupture of membranes and maternal fever in a GBS negative woman, in a sense equate to the risk factors posed by virtue of a positive screening test. Dr Weatherill's view is that it is not properly understood that risk factors remain risk factors even in a screening environment.

8.7. Two of the midwives who at one time or another were involved in this matter were called to give evidence. Ms Garner, who has practised as a midwife in both South Australia and Victoria, suggests that different medical practitioners had different practices where the woman is GBS negative and a prolonged period has transpired since term PROM. She suggested that in her experience practices in Victoria were more stringent and that women were given antibiotics in any event where women have gone 24 hours since PROM. On the other hand, Ms Cutting, another midwife said that she had not seen antibiotic cover given in circumstances where a GBS test had been negative. She suggested that antibiotics in Mrs Linnell's case were not indicated, and that of course would be so on a strict application of the South Australian guidelines.

8.8. I have already referred to the statement of Nurse Williams, also a Registered Midwife. Ms Williams states that it was her experience that once a woman's membranes had ruptured before labour was established, the question of induction of labour and/or antibiotic cover became possibilities that needed to be considered as time progressed. She was not aware of any blanket policy requiring antibiotics to be given at 18 hours or 24 hours after PROM. Her experience was that if a woman's GBS status is positive or unknown then antibiotics will be commenced once they are in established labour. If the GBS status is negative the introduction of antibiotics depends upon maternal observations, including regular temperature checks and the woman's informed choice of management in labour.

9. The literature

9.1. Literature concerning intrapartum antibiotic prophylaxis and a number of publications and written protocols were tendered at the Inquest. A bundle of this material was tendered and became Exhibit C15 that consists of nineteen such publications. As well, the United Kingdom Royal College of Obstetricians and Gynaecologists Guideline[28] was tendered. I have carefully read all of that material.

9.2. There does not appear to be any dispute in the literature that prolonged rupture of the membranes of equal to or greater than 18 hours is a risk factor for neonatal GBS and that antibiotic cover is an effective means of preventing early onset GBS. In any event, if there were any doubt that prolonged rupture gives rise to a risk factor, in my view this case would dispel that doubt. What appears to be contentious in the literature, or at least open to question, is whether it is necessary for antibiotic prophylaxis to be administered in cases where GBS screening has taken place and has been reported as negative. The bulk of the literature suggests that it is not necessary in those circumstances. Again, this case would suggest otherwise.

9.3. The literature distinguishes between what are referred to as two discrete GBS prevention strategies. One of them is referred to as a culture based or screening based strategy and the other is termed a risk based strategy. The screening based strategy is predicated on routine culture screening for GBS during the latter stages of pregnancy. The risk based strategy assumes that screening has not taken place and relies upon the identification of risk factors for neonatal GBS in a particular case. The risk factors relevantly include an elevated maternal temperature intrapartum and prolonged rupture of the membranes equal to or greater than 18 hours. The Australian sourced literature for the most part embraces the culture based strategy and recommends that all pregnant women be screened at 35-37 weeks gestation for ano-genital GBS colonisation via a low vaginal and rectal swab. I note that the rectal swab does not form part of any recommendation within South Australia. The culture based approach would see intrapartum antibiotic prophylaxis being administered where the mother has registered a positive GBS culture taken at 35-37 weeks gestation or where the culture result is unknown at the time of labour and the membranes are ruptured for equal to or greater than 18 hours prior to delivery or where a maternal temperature of

[28] Exhibit C6b

equal to or greater than 38ºC during labour is present. The culture based approach was utilised in Mrs Linnell's case because reliance was placed on her negative GBS screening result as a reason for not administering antibiotics in spite of the length of time since PROM. Clearly the South Australian guidelines that I have referred to are predicated on the culture based approach. The Operational Circular dated 28 October 2004 promulgated by the Western Australia Department of Health affords another example of this approach. There are other documents in c15 that advocate the same approach, except that in some cases the figure of 24 hours supplants 18 hours since PROM as the triggering time frame. Some documentation specifically stipulates that, as far as a culture based strategy is concerned, no intrapartum prophylaxis is needed where the GBS culture is negative. This recommendation seems to apply irrespective of the amount of time that has elapsed since PROM. The South Australian guideline is an example. A document promulgated by the King Edward Memorial Hospital in Western Australia[29], which purports to have been revised in May 2007, is another guideline that spells out in terms that no intrapartum antibiotic cover is needed where the culture is negative. In this context, it argues that one would need to treat 600 women with the risk factor created by prolonged rupture to prevent one case of early onset GBS infection and treat 10,400 women to prevent one death. Much of the other documentation that was tendered also speaks in terms of the number of women needed to be prophylactically treated, usually quoted in the thousands, before one adverse outcome could be prevented.

9.4. The guideline or protocol promulgated by the Royal Women's Hospital in Victoria, which is copyrighted in 2006, basically confirms what Professor Pepperell told me, namely that at this hospital, although the practice is not his personal practice, GBS negative women with PROM greater than 24 hours will be commenced on antibiotics '**only** if indicated (eg. temperature greater than 38ºC)' (the emphasis on the word 'only' is part of the original text).

9.5. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists College Statement[30] dated July 2007 identifies clinical risk factors for early onset GBS as including rupture of membranes greater than 18 hours. The document recognises that guidelines for the prevention of early onset neonatal GBS have recommended

[29] Exhibit C15, document 4
[30] Exhibit C15, document 9

either a risk based or screening based approach to identify pregnant women for intrapartum antibiotic prophylaxis. It does not appear to advocate a preference for either strategy, although it points out that the Centre for Disease Control in the United States of America has concluded that the culture based strategy is superior. The document goes on to say, however, that where it is impractical or inappropriate to collect swabs for assessment of GBS colonisation, it is recommended that the obstetric risk factor strategy be adopted. That would, of course, see the giving of antibiotic prophylaxis where the rupture of the membranes has occurred equal to or greater than 18 hours.

9.6. I should finally refer to the three Cochrane reviews that were tendered in evidence[31]. The Cochrane Collaboration, as I understand it, is an entity set up to review and evaluate clinical trials. The first two Cochrane publications before me are both entitled 'Antibiotics for pre-labour rupture of membranes at or near term'. The first review purports to have first been published in July of 2002. The second review appears to an updated version of the first taking into account trials conducted since the first. The stated objective of both reviews was to assess the effects of antibiotics administered prophylactically to women with term PROM on maternal, foetal and neonatal outcomes. It is apparent that both reviews accept the basic premises that term PROM increases the risk of infection for the woman and her baby and that the routine use of antibiotics for women at the time of term PROM may reduce this risk. However, both reviews state that the review of trials found that routine antibiotics for term PROM reduce the risk of infection for the pregnant woman, but there is not enough strong evidence about other outcomes including infections and complications for the baby. The conclusion reached by both reviews is that there is not sufficient evidence to justify the routine use of antibiotics prior to the onset of labour for women with term PROM. I make two comments about this. Firstly, the premise that intrapartum antibiotics prevent early onset GBS in the baby has overwhelmingly been accepted by the medical community and government health entities around the world for many years. Secondly, the reviews do not really address the same issues at stake here. We are not concerned with the issue as to whether antibiotics ought necessarily to have been administered to Mrs Linnell before her labour was established. The evidence is clear that Sienna contracted GBS during labour and the issue is whether

[31] Exhibit C15, Tabs 10-12

Mrs Linnell should have been given antibiotics at 18 hours or 24 hours after PROM or at the latest at the commencement of labour.

9.7. Interestingly, both Cochrane reviews, like Dr Matthews, advocate induction of labour as a strategy to reduce infectious morbidity associated with term PROM, thereby obviating the necessity of administering the administration of antibiotics in any event. The third Cochrane review apparently published for the first time in 2005 and which deals with the whole issue of induction versus expectant management in term PROM cases, concludes that concerns that induction may result in more caesarean sections and instrumental births were not supported by the review.

9.8. I do not need to refer to all of the documentation. It is clear that it is accepted that the use of intrapartum prophylaxis with antibiotics (penicillin) given to women at risk of transmission of GBS to their newborns prevents early onset sepsis and is cost effective and that in Australia it has led to a decline in the incidence of GBS disease in the past decade[32]. Australia favours the culture or screening based approach. The same for the USA, although it appears from the literature that the risk based approach is still the preferred approach in the United Kingdom.

9.9. It is difficult to know what ought to be taken from this documentation when examined as a whole beyond the fact that there are two possible approaches to the question of antibiotic prophylaxis, both of which have legitimacy, but that in Australia routine screening appears to have well and truly taken over as the preferred strategy. This has meant that in cases of term PROM like Mrs Linnell's, where the woman has been screened in reportedly negative terms, antibiotic prophylaxis will not be given unless the views of clinicians such as Professor Pepperell hold sway over the guidelines in an individual case. Although one can accept the assertions in the literature that the culture based strategy is more effective in preventing GBS disease than the risk based strategy, it also has to be observed that if the risk based strategy had been adopted in Mrs Linnell's case, and she had not been screened, she would undoubtedly have been given antibiotic prophylactic cover during her labour. This would have seen Sienna's birth and immediate postpartum period being an uncomplicated one and the chances of her survival would have been excellent. Thus it is that with the culture based approach, there will inevitably be cases like Sienna Linnell's falling through the

[32] Royal Australian and New Zealand College of Obstetricians and Gynaecologists College Statement July 2007, Exhibit C15, Tab 9, Paragraph 2

cracks, whereas with the risk based approach Sienna's case would always be identified as a case at risk and be treated accordingly.

9.10. The other irony of all of this is that it is apparent from the literature that the culture or screening approach has in Australia resulted in a significantly greater frequency of administration of antibiotic prophylactic cover than would otherwise have been the case if it was given purely on clinical grounds such as those that existed in the Linnell case[33]. The argument that the widespread use of antibiotics contributes to the development of resistant organisms, and that for this reason its use should be limited even in cases such as the Linnell case, is somewhat diminished by this revelation.

9.11. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists have taken a common sense approach to the question of possible anaphylactic reactions from the administration of antibiotic cover in labour. In their College Statement on Screening and Treatment for GBS in Pregnancy dated July 2007[34] they assert that mortality from an anaphylactic reaction to penicillin is rare in a fully medically staffed hospital setting and that in any event any morbidity associated with anaphylaxis is greatly offset by reduction in incidence of neonatal and maternal sepsis.

10. Conclusions

10.1. On 11 October 2006 Mrs Linnell underwent a GBS screening test that consisted of the taking of a low vaginal swab. The result of the test was reported as negative for GBS.

10.2. On the night of Sunday 15 October 2006 Mrs Linnell experienced a term pre-labour rupture of her membranes (term PROM).

10.3. Mrs Linnell's labour was not established until approximately 26 hours after PROM. No attempt was made to induce Mrs Linnell's labour at any time.

10.4. Sienna Linnell was born approximately 17 hours after established labour. She was delivered expectantly per vaginam. During the course of Mrs Linnell's labour she experienced six internal vaginal examinations that were all manual examinations.

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[33] Exhibit C15, Tab 4, Page 2 and Tab 13, Page 199
[34] Exhibit C15, Tab 9, Paragraph 3

10.5. At no time after Mrs Linnell's rupture of membranes was she advised in respect of the need, or otherwise, for prophylactic antibiotic cover specifically to guard against early onset GBS in her baby. In the event she was neither offered nor administered the same.

10.6. The fact that Mrs Linnell experienced PROM many hours before the establishment of labour, and the fact that there were many hours of labour involving a number of internal vaginal examinations, amounted to a well understood and recognised risk factor for the development of early onset GBS in her baby. However, her negative GBS screening result meant that, according to the South Australian Department of Health guidelines for the management of intrapartum antibiotic prophylaxis and treatment, 'no further special consideration' was required in her case, meaning that there was no perceived necessity to administer antibiotics.

10.7. Mrs Linnell had no other clinical or other recognised risk factors for the development of early onset GBS.

10.8. Notwithstanding the negative result of Mrs Linnell's screening test, Sienna Linnell nevertheless contracted early onset GBS from her mother. I find that Sienna contracted the GBS infection at some time after Mrs Linnell went into labour.

10.9. Sienna died approximately 7 hours after her birth and the cause of her death was Group B Streptococcus infection.

10.10. Mrs Linnell's reported negative GBS screening test result was falsely negative in the sense that either a colonisation of GBS in Mrs Linnell at the time of her test was not detected by that test, or she was colonised with GBS after her test. To my mind the implications of either scenario were the same in the sense that by the time of her labour, Mrs Linnell was in fact GBS positive.

10.11. If Mrs Linnell had been detected as GBS positive before the commencement of her labour, she would have been administered antibiotic prophylactic cover in accordance with the South Australian Department of Health guidelines to which I have referred. If Mrs Linnell's prolonged post PROM period had been regarded as a risk factor for the development of early onset GBS notwithstanding her negative screening result, it is likely that antibiotic prophylactic cover would have been given to her.

10.12. If Mrs Linnell had been given antibiotic prophylactic cover at the appropriate time, in my opinion it is more probable than not that Sienna would not have contracted early onset GBS and she would have survived. In my view, Sienna's death was preventable.

10.13. It would have been appropriate for Mrs Linnell to have undergone induction of labour at a time before her delayed onset of labour nearly 26 hours after pre-labour rupture of membranes. This strategy would also have reduced the risk of Sienna developing early onset GBS.

10.14. Clinicians in Australia favour a culture or screening based approach to the administration of antibiotic prophylactic cover in cases of PROM. An alternative approach is to administer antibiotics simply on the basis of identified risk factors in the individual case. This is known as the risk based strategy. If Mrs Linnell had been managed by way of a risk based strategy, then in my view she would have been given the appropriate antibiotic cover and Sienna probably would have survived.

11. Recommendations

11.1. Pursuant to section 25(2) of the Coroner's Act 2003 I am empowered to make recommendations that in the opinion of the Court might prevent, or reduce the likelihood of, a recurrence of an event similar to the event that was the subject of the Inquest.

11.2. To my mind this Inquest has demonstrated that given the shift in Australia towards an approach based on GBS screening during pregnancy, and if the South Australian Department of Health guidelines were to be adhered to without question, cases such as Sienna Linnell's will, sooner or later, inevitably recur. If the argument that the prevention of one adverse outcome such as this will result in the needless administration of antibiotics to several thousand women were to prevail, this would see cases such as Sienna's being regarded as little more than a statistical curiosity. That unfortunate notion would also be fuelled, perhaps, by the fact that deaths such as Sienna's, particularly where a GBS screening result has been reported as negative, are uncommon. But to view the issue in that way would be to entirely miss the point. The point demonstrated in this Inquest is that deaths such as Sienna's, notwithstanding their rarity, are preventable.

11.3. In my opinion there is much validity in the notion, as expressed by Professor Pepperell and Dr Weatherill, that risk factors remain risk factors even in a screening environment. In other words, the contention is that Mrs Linnell's circumstances ought still be regarded as giving rise to a recognised risk factor, notwithstanding the negativity of her GBS test. It is still a risk factor, for the most part because of the not insignificant incidence of false negative tests. No one in this Inquest has advocated the indiscriminate administration of antibiotics in all cases involving term PROM. The risk factor in PROM is generated by the length of time since PROM. If one were to draw any analogy from the existing guidelines it seems to me that cases such as Mrs Linnell's ought to be regarded in the same manner as cases where the mother has either not been screened or her screening result is unknown. In which case antibiotics are regularly administered where PROM is equal to or greater than 18 hours.

11.4. The other matter worthy of consideration is whether mothers in Mrs Linnell's circumstances ought to be allowed to make their own decisions. In my view a fully informed woman, and indeed her partner, are perfectly able themselves to make sensible decisions as to whether or not the woman should be administered antibiotics based upon the known risk factors in her individual case. At least they ought to be told of the existence of a particular risk factor in their case.

11.5. There is also the question of improving GBS screening. There are two aspects to this. Firstly, should there be both low vaginal and anal swabs taken? There is material to suggest that the benefits of this are marginal only and might in any case be offset by its inhibiting effects to the point where women might elect not to undergo the test at all. Secondly, are there ways and means of testing for GBS intrapartum? In relation to the latter question, in the Royal Australian and New Zealand College of Obstetricians and Gynaecologists College Statement it is said:

> 'Recently, the FDA approved a rapid real-time polymerase chain reaction (RT-PCR) IDI-Strep B assay as a non-culture molecular test (high sensitivity and specificity) with one-hour turnaround time. However, it is not yet available in routine practice in Australia and would require a 24-hour, 7-day week operating molecular biology service.' [35]

I do not know how progressed this particular matter is, but it occurs to me that much of the uncertainty surrounding GBS screening would be mitigated by rapid screening

[35] Exhibit C15, Tab 9, Page 2, Paragraph 8

intrapartum. All I can recommend is that the authorities continue to pursue the development of such a screening strategy.

11.6. I make the following recommendations:

1) That the South Australian Minister for Health, the South Australian Department of Health and the Medical Board of South Australia bring to the attention of the medical profession the findings in this particular case, and in particular to draw attention to the incidence of false negative GBS screening test results and to the possible adverse consequences of implicit reliance upon reported negative screening test results in determining whether to administer antibiotic prophylactic cover after PROM;

2) That the South Australian Department of Health amend the guidelines in respect of the 'Management of intrapartum antibiotic prophylaxis and treatment' in the following ways; (a) to recommend that women at term who are reportedly GBS negative and who have prolonged rupture of membranes greater than 18 hours, or 24 hours if considered more appropriate, be administered antibiotic prophylactic cover notwithstanding the reported negativity of their test and the absence of any other clinical factors, (b) to include within the relevant guidelines reference to the incidence of false negative GBS screening test results, (c) to include within the relevant guidelines reference to the suggestion that clinicians should consider advising induction in cases of term PROM and (d) to encourage clinicians to involve the woman and her partner in any decision making process in relation to (a) and (c) above;

3) That the South Australian Department of Health consider the question as to whether GBS screening examinations should involve the taking of an anal swab as well as a low vaginal swab;

4) That the South Australian Department of Health participate in and continue to monitor the development of more accurate screening methods for GBS, and in particular methods that involve the rapid intrapartum testing of women for GBS status.

11.7 I wish to express my acknowledgment of the excellence of the work of Ms Naomi Kereru of Counsel Assisting and of Mr John Homburg who was counsel for various entities including the Millicent and District Hospital and Health Service Incorporated.

Key Words: Group B Streptococcus; Pregnancy and Birthing

In witness whereof the said Coroner has hereunto set and subscribed his hand and Seal the 24th day of June, 2009.

Deputy State Coroner

Inquest Number 9/2009 (1548/2006)