Witness Name: Nigel Wenham

Statement No.: One (1)

Exhibits: NW/1 – NW/40

[redacted]

THIRLWALL INQUIRY

EXHIBIT NW / 16 - Summary Report on Neonatal Deaths and Collapses, Final Version 10.05.2017

WITNESS STATEMENT OF NIGEL WENHAM

Reasons for concerns regarding a possible criminal cause for increased neonatal mortality at the Countess of Chester Hospital NHS Foundation Trust, June 2015 – July 2016

Contents

Summary

The historical annual number of deaths on the neonatal unit at the hospital has been between 1 and 3. From June 2015 there were 13 deaths in the 13 months. The probability of this increase in mortality occurring by chance alone is very low. Many of the babies who died were born at gestations where death is statistically very unlikely (Appendix 1).

Of the babies who died, most deteriorated unexpectedly without explanation at the time or subsequently. It is very unusual not to see any clinical evidence of a baby becoming unwell e.g. you might expect to see their heart beating faster or the level of oxygen in their blood changing. In some of these cases there was no recovery to adequate resuscitation measures. For this to occur in such a large number of babies is highly unusual and could be considered as suspicious.

There is an association with a member of staff who was present during the majority of instances when the babies unexpectedly deteriorated. When this member of staff was put onto day shifts for 3 months, no sudden collapses occurred during the night. Previous to this change in her work pattern, in 6 out of 9 deaths, the arrests occurred between 0000 and 0400. When this member of staff was no longer working on the unit (July 2016-present), there have been no neonatal deaths on the unit and no unexpected or unexplained sudden deteriorations. This member of staff was present on the unit during the deterioration of the babies who died Child A Child C Child E I&S I&S Child I I&S I&S and Child F

The gestation at birth of the babies who died was between 27 weeks and 40 weeks. 6 babies were >32 weeks gestation. The redesignation of the unit from July 2016 (only permitted to

care for babies >32 weeks gestation) cannot therefore be the only reason why there have been no deaths or sudden unexplained deteriorations of babies on the unit since July 2016.

An external neonatologist from London has identified 4 babies [redacted] who require further forensic review. Further to her report, a consensus between 3 CoCH paediatricians and an external neonatologist from the Liverpool Women's Hospital (LWH) have identified a further 4 babies [redacted] for whom the cause of death is still unexplained.

An unexplained rash was observed for at least 3 babies. This was initially thought to be due to infection by the clinical teams. However, the rashes resolved spontaneously despite the babies being very ill. This is highly unusual and may indicate a possible unnatural cause of death.

The increase in neonatal mortality did not coincide with any significant changes in acuity or staffing levels in 2015 and 2016. Nursing staffing in Chester NNU was above the national average. The percentage of shifts staffed to BAPM standards was higher than other LNUs in the network and higher than the national average. High dependency and intensive care days did not change appreciably in 2015 and 2016 compared to previous years.

In addition to the babies who died, there were also a significant number of babies who suffered an unexpected collapse or deterioration. The cause for the deteriorations is unknown and the member of staff mentioned above was present on the Neonatal Unit (NNU) for the majority of these cases.

The investigations undertaken by the Trust to date do not appear to have included a comprehensive analysis of staffing at the time of all the collapses and deaths. Senior medical staff, trainee doctors and nursing staff involved with the cases listed below have not been interviewed in relation to the care given around the time of the events listed below. The babies who were transferred from the unit and subsequently died and the babies who collapsed unexpectedly and survived do not seem to have been adequately investigated by the Trust to date. In addition to the concerns listed below, some clinical staff (consultants and trainee doctors) had specific concerns regarding aspects of care of some of these babies but have not had an opportunity to share these concerns with an investigative team.

In summary:

- The number of neonatal deaths in this time period is highly unusual.
- The number of unexpected and unexplained collapses is highly unusual.
- Cause of death is still uncertain for 8 babies.
- Many of the babies who died did not respond to adequate resuscitation as would normally be expected.

- One member of staff has been present during the collapse and/or deaths of an unusually high proportion of the babies involved. The likelihood of this occurring by chance alone is very low.
- Investigations and reviews to date have not identified any other potential cause for the increased mortality or been able to exclude an unnatural cause of the deaths and collapses.

Mortality cases

Child A

31 week gestation twin born in good condition. Sudden unexpected arrest on day PD. PM and inquest failed to identify cause of death.

External London neonatologist has recommended further forensic review, yet to be undertaken.

Consensus of CoCH paediatricians and external Liverpool neonatologist that the cause of sudden deterioration and the cause of death are still unexplained.

Child C

30 week gestation baby, birth weight 800g. Died on day PD of life despite stable observations 24 hours prior to deterioration – clinically this death would not have been anticipated. Primary cause of death given on PM as widespread hypoxic damage to heart. However, this was likely to have been caused following the decision to withdraw intensive care. As part of the dying process this baby had several hours of very slow heart rate and occasional respiratory gasps. During this time the heart would not have received adequate oxygen and therefore caused the changes seen at PM. The PM finding of hypoxic heart damage does not explain his sudden deterioration following normal observations beforehand.

Consensus of CoCH paediatricians and external Liverpool neonatologist that the cause of sudden deterioration and the cause of death are still unexplained.

Child D

37 week gestation baby admitted to NNU at PD of age with congenital pneumonia. Subsequently she improved clinically. On Day PD of life she became mottled and developed dark brown/black tracking lesions across her trunk. 2 "bruises" noted on abdomen thought at the time to represent infection but as the baby improved the areas of discolouration completely disappeared. Areas of discolouration then reappeared prior to sudden deterioration. No response to resuscitation efforts. Awaiting an inquest. PM states primary cause of death is pneumonia with acute lung injury. However, the baby was on CPAP and

had no oxygen requirement immediately prior to deterioration. Clinically therefore this makes acute lung injury as a cause of the deterioration and subsequent death very unlikely. The transient rash is also unexplained.

Consensus of CoCH paediatricians and external Liverpool neonatologist that the cause of sudden deterioration and the cause of death are still unexplained.

Child E

29 week gestation twin, 1327g. Died on day PD Blood stained and bile stained aspirates prior to cardiorespiratory arrest. No PM agreed with coroner and cause of death given as necrotising enterocolitis (NEC) and prematurity. However, abdominal X ray taken less than 1 hour before death showed no signs of NEC, therefore clinically it would not be anticipated that this baby would have deteriorated and died in such a short time frame.

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Child I

27 week gestation infant born at LWH and transferred to CoCH on day PD Transferred back to LWH 3 weeks later due to distended abdomen, desaturations and bradycardia. Improved at LWH and returned to CoCH 1 week later. 1 month later, found blue and apnoeic in cot at 0336, responded to resuscitation. Treated for suspected NEC and/or infection. Following day at 0500, further arrest and distended abdomen. Responded to resuscitation and

improved. Following day at 0400, further arrest and resuscitation. Presumed abdominal pathology. Transferred to Arrowe Park Hospital (APH) – improved and no further deteriorations so transferred back to CoCH 3 days later. 6 days later, further arrests overnight and resuscitation discontinued at 0230. No evidence of abdominal pathology on PM. PM cause of death given as hypoxic ischaemic damage of brain and chronic lung disease of prematurity. There is no clinical explanation for the repeated sudden deteriorations at CoCH and periods of stability and improvement elsewhere and it is highly suspicious.

External London neonatologist has recommended further forensic review, yet to be undertaken.

Consensus of CoCH paediatricians and external Liverpool neonatologist that the cause of sudden deterioration and the cause of death are still unexplained.

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Child O

Triplet born at 33 weeks gestation. Generally well and stable - clinically evident as on optiflow and NGT feeds. On day PD he suddenly deteriorated with inadequate breathing, a very slow heart rate and abdominal distension. Did not respond to resuscitation. Subsequent PM showed a ruptured sub-capsular haematoma of liver which may have occurred during attempts to resuscitate the baby and is unlikely to be the cause of his sudden deterioration. Had a discoloured abdomen at one stage which resolved later. Awaiting inquest.

External London neonatologist has recommended further forensic review, yet to be undertaken.

Consensus of CoCH paediatricians and external Liverpool neonatologist that the cause of sudden deterioration and the cause of death are still unexplained.

Child P

Triplet born at 33 weeks gestation. Generally well and stable - clinically evident as on optiflow and NGT feeds. On day PD he suddenly deteriorated with inadequate breathing, a very slow heart and abdominal distension. Did not respond to resuscitation. Had been started on antibiotics and had a thorough consultant review after sibling's death and no concerns raised. Clinically very surprising that subsequently arrested. No cause for death identified on PM.

External London neonatologist has recommended further forensic review, yet to be undertaken.

Consensus of CoCH paediatricians and external Liverpool neonatologist that the cause of sudden deterioration and the cause of death are still unexplained.

Babies who had an unexplained deterioration and survived or died outside CoCH

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Child B

31 week gestation twin (sister of Child, who arrested on Day PD of life). Day PD at 0030 suddenly became cyanosed, limp, apnoeic and bradycardic with purple blotches on skin. Successfully resuscitated and intubated. Nurse L present. No cause for respiratory arrest identified.

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Glossary of terms

APH – Arrowe Park Hospital, also known as Wirral University NHS Foundation Trust

Apnoeic – pauses in breathing which are a sign of illness in neonates.

Arrest/collapse - Respiratory arrest is defined by the absence of spontaneous respiration (breathing) or a severe respiratory insufficiency (not breathing effectively to sustain life) that require respiratory assistance. Cardiac arrest is defined as the absence of central arterial pulse or signs of circulation (movement, cough or normal breathing) or the presence of a central pulse less than 60 beat per minute in a child who does not respond, not breath and with poor perfusion (i.e. the heart has stopped beating or is beating so weakly/slowly as to be ineffective). The two are closely linked (i.e. heart is dependent on lungs and vice versa) but in children (including neonates) the most likely cause of an arrest is due to oxygen insufficiency leading to a respiratory arrest.

Aspirate – babies have a naso gastric tube (NGT) that allows them to be fed as they have not yet developed the suck reflex and/or are unable to feed normally due to illness. Prior to feeding, the nurses will connect a syringe and suck the contents of the stomach to ensure the NGT is in the correct position. This is the aspirate.

BAPM – British Association of Perinatal Medicine is an organisation that aims to improve the standard of care delivered to unwell, newborn infants by improving standards of hospital care, clinical guidance and supporting ongoing education. The BAPM standards is an aspirational document outlining how hospitals should aim to deliver neonatal care including physical factors e.g. the environment, space around beds and human factors e.g. ratios of nurses to infants etc.

Bilious – bile from the intestines is seen in the secretions taken from the stomach. This is a concerning feature in neonates. See NEC

Bradycardia – pathologically slow heart rate

CoCH - Countess of Chester Hospital NHS Foundation Trust

Congenital – present from time of birth

Desaturations – a fall in the oxygen level detected in the blood (routinely measured on neonatal unit)

Gestation – period from conception to birth which is typically 40 weeks. Newborn infants are categorized according to when they were born. A baby born 8 weeks early is born at 32 weeks gestation. The World Health Organisation gives the following definitions for the different stages of preterm birth:

- extremely preterm: before 28 weeks
- very preterm: from 28 to 32 weeks
- moderate to late preterm: from 32 to 37 weeks.

Hypoglycaemia – low blood sugar level

Hypoxic – due to insufficient oxygenation.

Ischaemic – insufficient oxygen to living tissue causing it to die

LNU – local neonatal unit

LWH – Liverpool Womens' Hospital

Meconium – this is first stool passed by infants. There is controversy around the clinical implication if meconium is present at the time of delivery and it may be linked to foetal compromise (meaning that the foetus may have not got sufficient oxygen via umbilical cord) during the labour & delivery but must be interpreted alongside other clinical signs & symptoms.

Mortality – number of deaths

Neonatologist - on the General Medical Council specialist register for neonatal medicine or equivalent and have primary duties on a neonatal unit alone i.e. paediatricians who have undertaken specialist training in neonatal medicine

Necrotizing enterocolitis (NEC) - is the most common gastrointestinal emergency occurring in neonates. Prematurity and low birth weight are the most important risk factors. The disease is not well understood but affected infants will not tolerate their feeds, and have progressive symptoms including aspirates (milk from the stomach after a feed as not being digested), abdominal distension, pain and other evidence of compromise.

NNU – neonatal unit, ward in hospital where newborn infants are cared for if they become unwell.

Pathology/pathological – linked to disease

PM – post mortem. Some infants had post-mortem examinations but none of them were home office post mortems.

Pneumonia – medical term for chest infection.

Resuscitation – this is a skill learnt by all doctors and some nurses. It follows set guidance from the resuscitation council which promotes team work and improves outcomes. There are logarithms that are learnt and followed if a child is recognised to have arrested (for whatever reason).

Term – babies born at or around expected due date (37-42 weeks gestation).

Ventilatory support – if unable to breathe adequately, ventilatory support may be required. This is a complex area.

- Invasive ventilatory support is when a breathing tube is placed in big airways of the lung and 'breaths' are given by a ventilator.
- CPAP or BiPAP is non-invasive ventilatory support. A tight fitting mask is applied to the nose &/or mouth and a ventilator produces intermittent pressure so the effort of breathing is less (but patient is spontaneously breathing). It is less intensive than above.
- Optiflow is a way of delivery warm and humidified oxygen at different flow rates. It is less intensive than either of the above.

Appendix 1

Survival – graph below taken from Office for National Statistics: Pregnancy and ethnic factors influencing births and infant mortality: 2013