Original notes made by T/Chief Supt Nigel Wenham, recorded in ONE Note at the time and amended spelling and grammatical errors following the meeting.

Notes from meeting Paediatricians
15 May 2017
10:21

Dr Stephen Brearey - SB
Dr Susie Holt - SH
Dr Ravi JAYARAM - RJ
Paul Hughes - PH
Nigel Wenham - PH

NW welcome and outline purpose of the meeting
To review the contents of the report that was sent to NW last week, titled '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

- **Understand more about current operation of the ward**

7 Paediatric & neonatal (combined posts) Consultants employed by Countess of Chester NHS Foundation trust during time period. Business case approved in 01/2016 for 2 new consultants in keeping with national NHS recommendations. 8th consultant (Dr McGuigan) employed 01/2017 and interviews for 9th consultant took place on day of meeting. Dr Liz Newby in one of the Consultant posts until 03/2016 when left to work in Stepping Hill, succeeded by Dr Susie Holt
Funding of neonatal unit is split: Specialised commissioning through NHS England pay for care on the neonatal unit
Some care of newborn infants is funded by CCG,

NHS Improvement not involved
SB very keen from the start to involve the neonatal network
Part of network care across Cheshire/Mersey, there is some degree of accountability in the network, for example, mortality reviews

RJ – if you have concerns about Dr you would report to GMC; concerns about a Nurse to Nurse and midwifery council, if wider issue like this, escalate through the trust. Regarded as whistleblowing if you go outside. We have taken advice from our medical defence unions to do everything within the trust and deal that route
SH - guidance is available on line from the BMA & GMC
SB - there are invited college reviews, like the one from Sept, that was service review. They did recommend multi service review

SB - the case notes review by Dr Hawden did assess some cases, this was not what the Royal College of Paediatrics & Child health (RCPCH) review asked for. What happened was ONE neonatologist looked at cases notes, this was not multi discipline review that was suggested
Trust can have root cause analysis to invite professionals in to do review of whole case, these tend to be single case, not cohort reviews.

CQC have a responsibility for all NHS organisations and private, as clinicians very unusual for us to go direct, this would be more whistleblowing. We have not directly contacted the CQC, advice from legal reps exhaust all possibilities first

RJ, the JH review specifically mentioned forensic review, we can not conduct that level of review. The fact is these babies would not be the ones you would have expected, at the point they collapsed and they did not respond physiologically to the treatment as expected

- **Understand more detail of their concerns**

SB - of those 9 we reviewed initially, 6/9 collapsed between 000-0400, which was highly unusual. One of the action was to review the period prior and nothing was found (will share these reviewed) that review also noticed a significant number of collapses.

SB - following on from that thematic we discussed the nurse (Lucy) but no action taken. I shared the report with IH prior to the CQC inspection (Feb) at this time the nurse had been put on day shifts for mentoring reasons

Q - Confirm how many that Nurse has been present?

SB - the nurse was present in all but one of the deaths

RJ - the staffing review has looked at the notes, this has not necessarily been picked up What has not been looked at, this baby collapsed, who was where, what were you doing at the time. As consultants, it is very rare that consultants were present at time of collapse. At the point of the collapse, the nurse was present at that time in close proximity. This has not happened to other staff.

I can speak about one that did collapse, but survived, 27 weeks, was stable had breathing tube down, good ventilation, named nurse (ie nurse assigned to care for baby during that particular shift) had gone out of nursery, I went back in, the baby's oxygen levels had dropped, first thing to do disconnect baby from ventilator and bag. I noticed the breathing tube had been dislodged. The nurse (L) was present at the time.

RJ - there is perception that we are on campaign, this is not the case. Other (consultants & junior doctors) had come to the same view. It got to the point that when Nurse was on duty we feared something would happen.

RJ - we are not on a witch hunt, we have concerns that this nurse was present in far too many occasion

Provided example of baby that was being treated for low blood sugars, very erratic pattern of sugar level which changed with shift pattern no clinical explanation, consulted with Alder Hey, who agreed was unable to explain.

SB - we have looked hard, we cant find any explanation

- **Identify any specific evidence of any criminal or suspected criminal activity**

- **Clarify some aspects regarding the pathology and causes of death**

Q - 3 cases were certified by Dr's on wards, why?
SB - one baby 29 wks, felt that baby displaying typical signs of NEC, felt at time this was not suspicious. The baby had abdominal x ray an hour before death, there was no signs of NEC. The fact xray was normal is odd. As an isolated case, he would not have been considered suspicious, but assessed on the timeline, there are concerns

Q - questioned on the cause of deaths and pathology?

SB - this is what PM diagnosis is Neo is so hard. JH review identified those 4 cases, we also reviewed these and another 4, we felt there was unexpected or unexplained cause of death.

SB - there are several babies with clear genetic diagnosis, in some cases the PM does not explain why the babies suddenly collapsed and died.

Q - do you consult with the Pathologist regarding PM findings?

Outlined that this was not normal practice, communication would take place between the pathologist and coroner

Q - if third party involvement would you expect to see the same indicator?

SB - it is relatively easy to manipulate fluid, to administer drugs and or too block an airway

SB - there seems to be a theme with multiple births (triplets & twins) and the more stable infant being the one to collapse

SH - case of Baby I&S twins, 1 twin was on CPAP – but baby I&S (not needing any respiratory support) was the one that collapsed, from clinical perspective neither were anticipated to collapse but clinically the one on respiratory support was more vulnerable

RJ - concern we have is could something be done deliberately to harm them. We don't know, I don't know if this is something we just have to live with, we would rather there was some explanation, our concern is have enough questions been asked, can we be satisfied that we have done all we can to confirm if there is something more going on.

Nobody has talked to junior Dr's who have been involved. We appreciate that a lot of time has passed since these. We at end of the day are responsible for patient safety on the ward, the buck stops with us.

SB- to put in perspective consultant who joined us from Crewe, he has never experienced anything like this in 5 years as consultant

RJ - we all have concerns, nothing significant changed over the years to explain the deaths e.g. the changes in patient numbers, staffing, do not explain the number of deaths or collapses.

RJ – We do not dispute the findings from the RCPCH report and it has made useful suggestions for our service, but feel these are background factors

RJ - the pathology report may attribute a likely cause of death, but this does not explain timing nor what caused the collapse that ultimately led to death

Agreed not challenging the pathology findings, but the fact is the cause of collapse leading to death has not been identified

SB - survival rate for babies over 32 is nearly 100%, for 6 of our babies to have died who were over 32 weeks, to die is not right.

- **Review the key statements outlined in the report**

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.

SB - did thematic review in Jan 2016, looking at the 9. senior nursing staff from Liverpool Woman's Hospital, looking at themes trends. Staffing was included in that report, staffing on shift, designated nurse, consultant on duty, name of junior Dr;s present. Could not find link with consultant or Dr's.

RJ - all collapses and deaths would involved wide range of professionals

NW - at what point was concerns raised?

SB - from December, I raises some concerns. The first discussion took place in June 2015, when we had 3 deaths within few weeks, this was highly unusual, we met with IH and head of risk at that time, we reviewed all three cases. Could not identify any issues regarding clinical practice. At that time the unit manager noticed that Lucy Letby (The nurse) was present at all three. That was first conversation.

All three reported to coroner and had PM's

RAVI was clinician for [redacted], he attended inquest, cause of death unascertained

SB - [redacted] collapsed unexpectedly and died. His twin [redacted] Child A and Child B, collapsed but recovered. This was unexpected and unusual, now looking back we think this was suspicious. She had unusual rash.

SB - baby [redacted], improved after intervention being brought into the unit & started on treatment, then collapsed and died on day PD. All blood markers did not indicate worsening infection. PM still spots inflammation in the lungs, but this does not explain the improvement in the baby health and then collapse.

Explain collapse?

SB - baby do not have cardiac arrest like adults do, collapse on unit would be inadequate breathing, babies stop to breathe, may stop breathing, dropped oxygen levels, breathing stops and oxygen level for period, heart slows down, this requires cardiac massage. These babies had apnoea, stopped breathing. Increased number result in desaturation. These babies just stopped out of the blue.

How do we know that?
RJ - they are on monitors, however monitors don't keep digital record of numbers. Nurses document observations from monitors hourly on observation charts.

SB - most babies were at gestation would not expect these sort of things happening.

RJ - these babies simply did not respond as expected, interventions did not result in expected results. The baby [redacted], interventions were put in place, there was evidenced electrical activity of the heart, but he did not have output (no pulse). Not many things can cause this, he had adrenalin, he did not respond, half hour without output. (Child A)

SH - there is big difference adult and neonatal practice, with intervention we would expect to see some response and statistics support this

What was thought process with no response?

RJ - in one off, there could be explanation.
SB - we would expect the PM to find evidence to support cause of death. The pick up rate from pathology has not informed us as to why the babies have collapsed.

RJ - we accept in medicine some uncertainty, we accept cognitive bias, but we cant see explanation. Is it people, practice, building, accommodation, it is big leap of faith to suggest these all lined up and led to the deaths. All of these factors (acuity of unit, medical & nursing staff levels) are there and common to other neonatal units in the country

SB - PM for [redacted] was done urgently

RJ - if any concerns we would escalate to the coroner, would discuss and agree process

SB - all neonatal deaths are discussed with the coroner

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 Children who died Child A, C, D, E, I&S, I&S, Child I, I&S, I&S, Child O and Child P

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 **Child A, I, O and P** 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 Child C, D, I&S and I&S 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.

RJ - did some reading and found that situation called air embolism, small amounts of free air in circulation can obstruct flow of blood into the lungs, free oxygen can be picked up. There is a rash associated with these diagnosis

SH - explained that we associated infection with rashes, this was not the case here, not a recognisable rash outside these collection of babies.

RJ - air embolism can happen deliberately or accidently, for example, cannula administering drugs, what could happen, there could be error in how the cannula is managed

Babies I&S Child D and one survived Child B

RJ - my understanding is that unless the PM is done very soon, there will not be any evidence on the PM

Closing comments:

RJ - we are used to dealing with uncertainty, this is what we do. We have said we want enough done to rule out foul play. IH has suggested getting another neonatal review. JH refers to forensic, but what this means

SB - we were very worried, the triplets (twins who died) there was no explanation, she was named nurse, other nurses have gone off work with stress, she didn't' Duty exec was happy for nurse to remain on duty at that time. When expressed our concerns, we don't think the executives have understood our concerns.

In jan, we met with Chief exec, all seven of us, we were told we have spoken to family, don't cross the line, we are dealing with it.

Every Paediatrician were worried about her going back to work and none of us were happy with her returning back to work, we don't feel this is acceptable. This has not been investigated properly.

RJ - I don't want the obvious fractious relationship between us and the executive, this is not why we want you here. We are not sure the process, reports have asked the right questions, we want to exclude is there anyone who is deliberately harming these babies.

At a meeting in Jan executive read out letter from the nurse that stated she was exonerated by reviews to date.

RJ - we fully understand the impact of investigation, damaging to the trust, the neonatal unit and staff and the impact on the families of the babies. At the end of it you may ask what was the point. Speaking for myself, we are not comfortable as worried about safety of our patients.