

Position Paper – Neonatal Unit Mortality

1.0 Executive Summary

The purpose of this paper is to provide the Executive Team with key mortality data and supplementary narrative to enable an assessment of the patient safety concerns identified by the neonatal clinicians relating to a perceived ~~apparent~~ increase in the number of neonatal deaths during financial years 2015/16 and 2016/17 (year to date). However for the purposes of data analysis, the preceding year's data also features

2.0 Background

The Trust provides a range of paediatric and neonatal services. The neonatal unit has 20 cots and provides critical care, high dependency care, special care and transitional care for newborn babies.

The Trust provides a Local Neonatal Unit service (Level 2 Care) providing short term ventilation. The Neonatal Unit provides care to 27/40 gestation; any baby born below this criterion is transferred to the nearest Level 3 unit. The critical care and high dependency care cots are interchangeable and can therefore flex according to the needs of the unit.

In June 2015, the Neonatal Unit identified 3 deaths during a 2 week window. These cases were subject to individual case review by the specialty. Due to these deaths occurring within short succession, and that no neonatal deaths had been reported by the Neonatal Unit during 2014/15, an additional Executive Serious Incident Panel was held on 3 July 2015. The summary of care provided to the 3 babies can be found in Appendix 1.

A comprehensive case review was undertaken in February 2016 following the deaths of 10 neonates (including one who died shortly following transfer). A Consultant from Liverpool Women's Hospital was present during this review (See Appendix 2).

2 of the neonatal deaths reported in 2015/16 occurred in February and March 2016 and are therefore missing from this comprehensive case review.

An action plan was drafted by the specialty. Within this, a further 'deep dive' was undertaken by the Neonatal Unit Manager to consider the nursing interventions prior to the neonatal death and included a further review of the health record, vital signs monitoring, feeding charts and blood gas results (See Appendix 3).

This nursing review led to further discussions regarding other possible, contributory factors including the medical devices used, infection control practices and staffing establishment and skill-mix. This review was discussed with the Medical Director and Director of Nursing & Quality in May 2016. Having reviewed the information presented, there were no obvious causes for concern and therefore a further meeting was agreed to take place in July 2016.

These reviews were not received at the Trust's Quality, Safety and Patient Experience Committee.

In June 2016, following the death of triplet 1 and 2, the specialty highlighted their concerns regarding an apparent increased mortality rate. Both babies appeared to have had a sudden deterioration in their condition and in respect of the clinicians view, were not expected to die. These have been subject to a case review; as an outcome from this, all x-rays undertaken are to undergo Radiology peer review.

3.0 Trust Review of the NNU

Following discussion between the relevant clinicians and members of the Executive Team a comprehensive review was undertaken to fully understand the Neonatal units mortality rates exploring potential contributing factors, this included the review of the following:

- Detailed neonatal mortality case reviews on babies who had died in 2015/16
- In addition to the above cases, review of cases since 2013 whereby baby's had deteriorated and were transferred to another hospital who then subsequently died – in total 32 cases were reviewed
- Staffing levels and skill mix on the NNU (nursing and medical)
- Actual staff on duty before and when babies deteriorated and died
- Levels of acuity, activity and external factors (eg changes in cot provision across the network, times the unit was closed)
- Security of the NNU
- Equipment review (previously reviewed in thematic review of 10 cases)
- Infection control review of cases above
- NNU staff training, appraisal, competency and potential HR issues

Using the data available from the 'Badgernet' database (national Neonatal database), the aim of the data analysis aimed to investigate the validity of these concerns.

The analysis had three aims:

1. To review the **significance** of any increase in mortality levels in the Neonatal Unit during 2015/16 and whether this represents normal variation or a significant change that breaks with long term trends.

2. To evaluate **activity** levels in the NNU during 2015/16 as a possible contributory factor. Was the unit under more pressure of work during the period?
3. To evaluate certain measures of **acuity** in NNU during 2015/16.
Was the condition of neonates admitted to the unit more acute than in previous years?

4.0 Key Issues/Gaps in Assurance

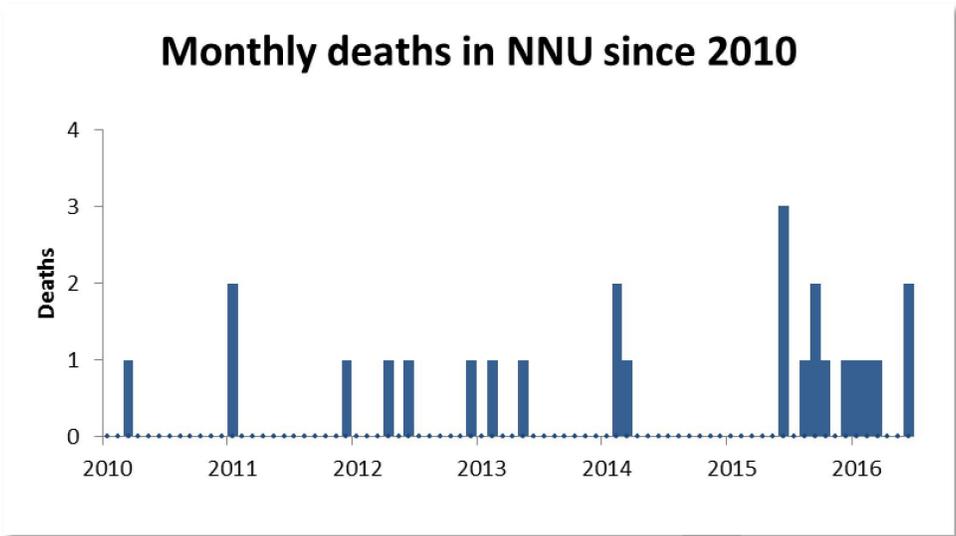
4.1 Mortality Data

Data discrepancies between the differing systems in place has led to a number of challenges in obtaining an accurate account of the Neonatal Unit activity over time. Having reviewed the outputs from Meditech, BadgerNet (neonatal specific electronic patient record), HED (Healthcare Evaluation Data) and that recorded within the Trust's Bereavement Office, the actual number of deaths occurring within the Neonatal Unit recorded from January 2010 up to and including June 2016 is as follows (calendar years):

Actual number of deaths in the Neonatal Unit:

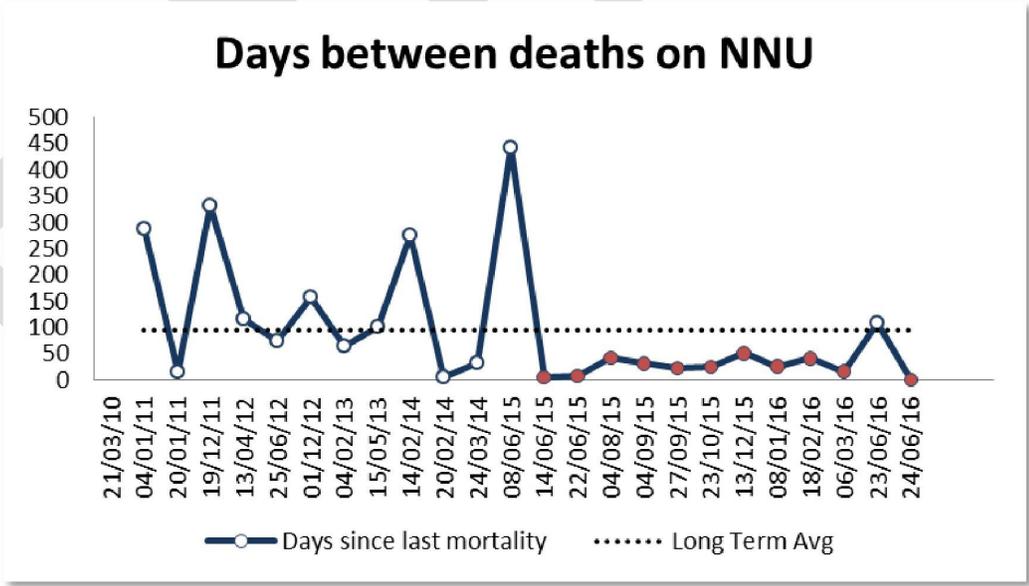
Year	Number of NNU Deaths
2010	1
2011	3
2012	3
2013	2
2014	3
2015	8
2016 YTD	5
Total	25

Since July 2015, there has been an increase in the number and frequency of mortalities on the Neonatal Unit which is visible in the clustering of deaths on the far right of the graph below as compared to the relatively sparse incidence of previous years.

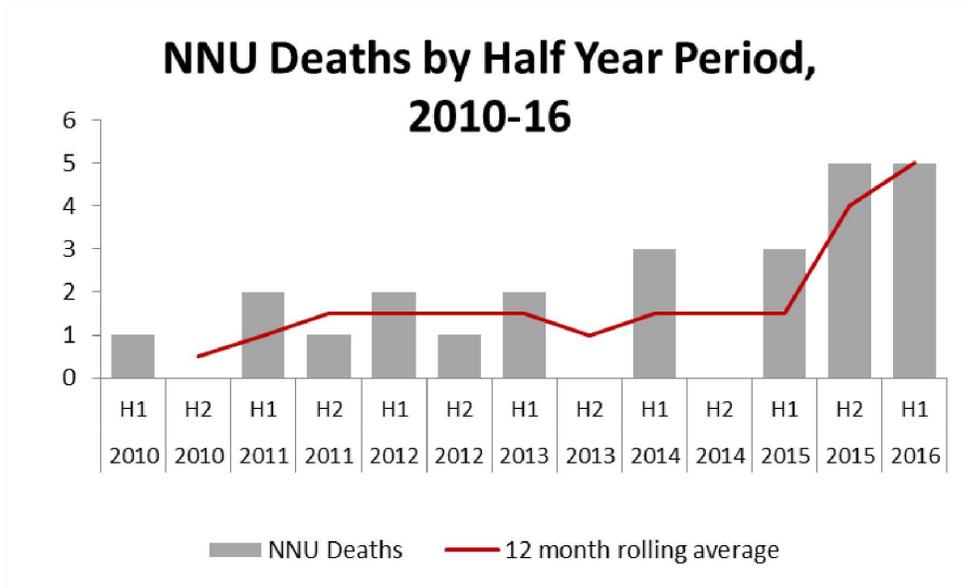


Another way to visualise the data is to plot the time between deaths on the Neonatal Unit. The key points of the graph below are:

- The long term average since March 2010 is a space of **94.8** days between deaths
- From June 2015, this fell to an average space of **31.3** days between deaths.
- 11 out of 12 deaths after 08/06/14 were below the long-term average number of 'days since last mortality'.



Finally, if deaths on the Neonatal Unit are analysed per half year period, there is a steady mortality rate until H2 2015. The 12 month rolling average shows a sudden increase at this point which continues into the first half of 2016.



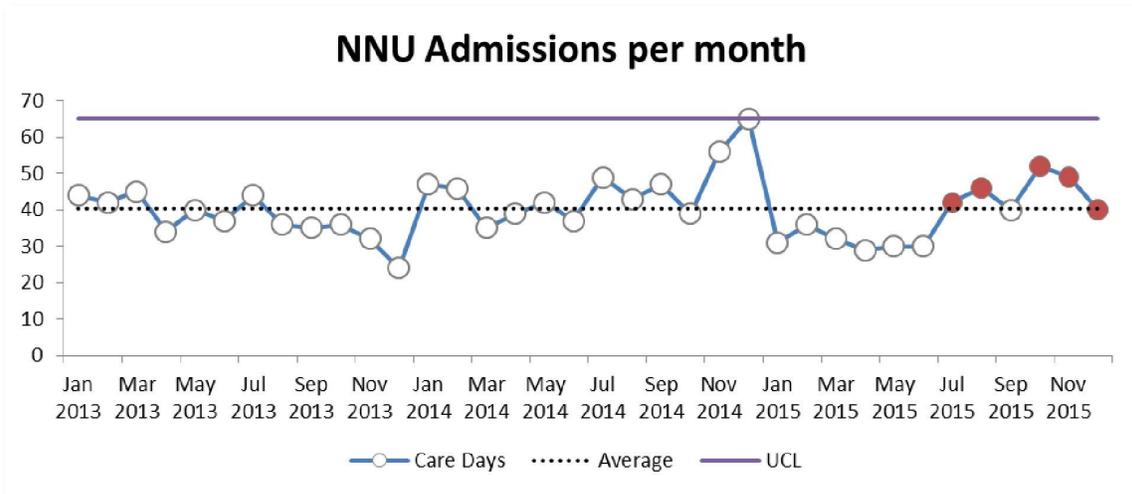
To give context to this apparent increase in the mortality rate reported on the Neonatal Unit, the unit's activity and acuity data has been obtained.

The number of admissions to the Neonatal Unit:

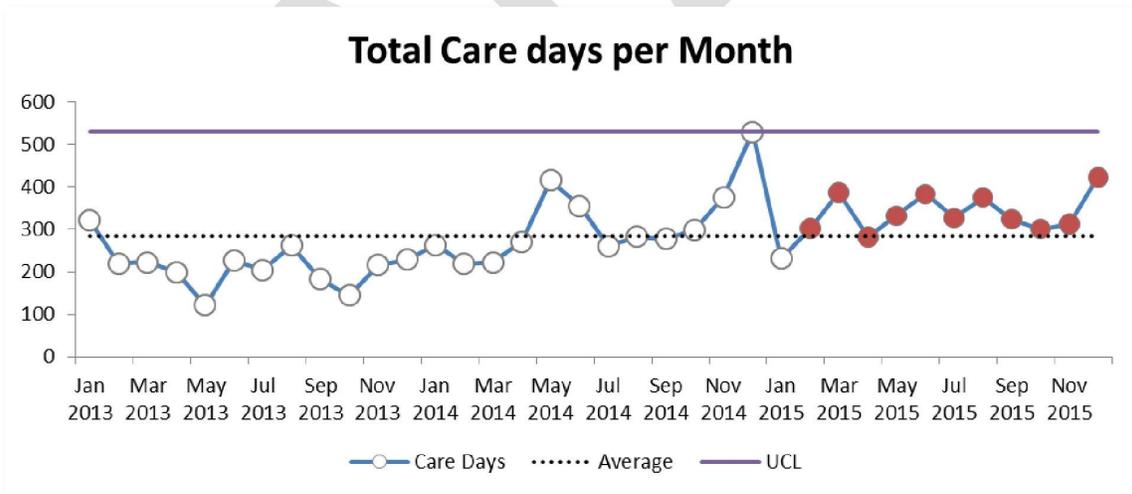
To what extent does the increase in mortality levels reflect a general increase in activity in the NNU? We can get a sense of the pressure of work by looking at monthly admission numbers and 'Total Care Days' per month.

Taking admission numbers first, the graph below shows that over the second half of 2015, the Neonatal Unit experience higher than average admissions for five out of six months.

Higher admissions may have been a contributing factor but it should be noted that 2014 saw higher admission numbers, including a significant peak in December, without a similar increase in the number of mortalities.

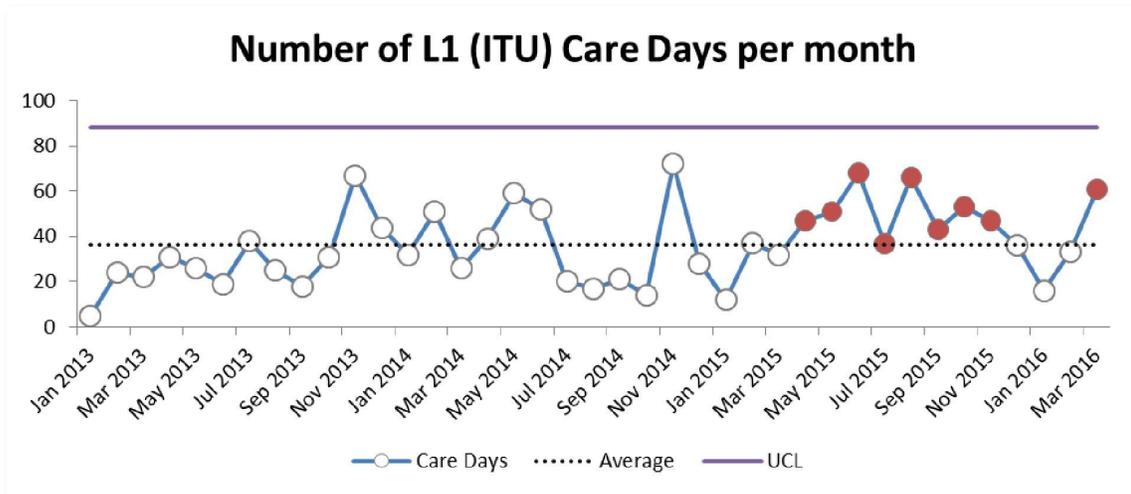


Another way to measure the overall level of work is to compare the number of patient care days per month in the NNU. Looking at the graph below, it is clear that every month since February 2015 has seen a greater number of care days than the long term average. This suggests that the NNU has been busier and workloads have been higher. Again, this needs to be qualified by the fact that there have been similar (and greater) peaks in 2014 without a corresponding increase in mortality levels.

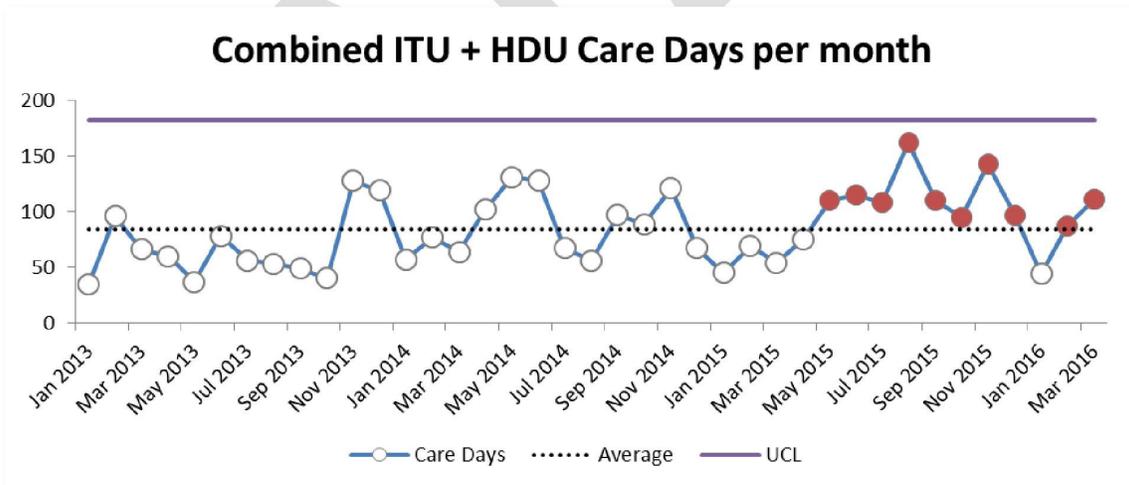


It is also possible that the increase in mortality numbers over the period may reflect increased levels of patient acuity. One measure of this is looking again at 'Total Care Days' but specifically at the highest levels of patient care: Level 1* representing intensive care 'Care Days' and Level 2 representing high dependency 'Care Days'. 2015/16 shows a sustained increase in the average number of care days at L1. Eight consecutive months are higher than average at L1.

*For HRG purposes, intensive care is level 1, high dependency care is level 2 and special care is level 3



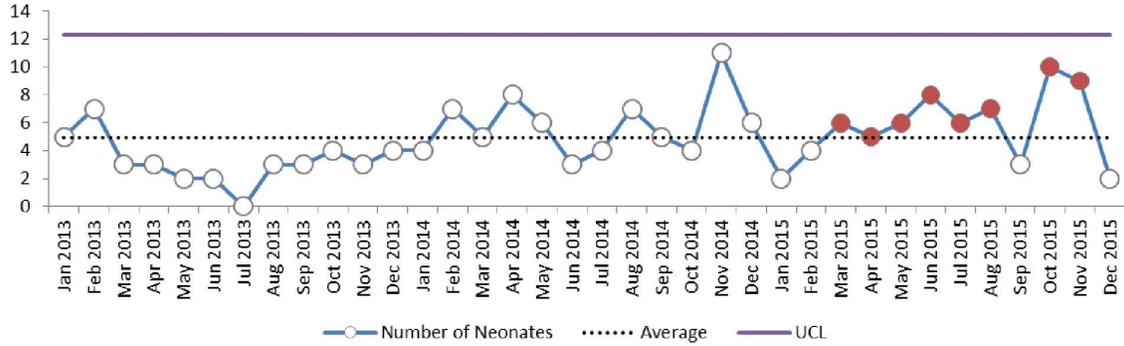
The increase in high acuity care days is evident when Level 1 (intensive care) and Level 2 (high dependency) care days are combined per month. Between May 2015 and March 2016, only one month shows a drop below the long term average. There have been two and three month fluctuations above the average in previous years, but nothing to match the sustained increase seen after May 2015. It is uncertain what changed in November 2014 in respect of activity.



Birthweight of neonates on admission to the Neonatal Unit:

Another measure of acuity is neonatal birth weight. Monthly figures show that between March and December 2015 there was a higher than average number of babies born in the lowest two categories of weight in all but two months. This would correlate with the increased demand for high level care over the same period.

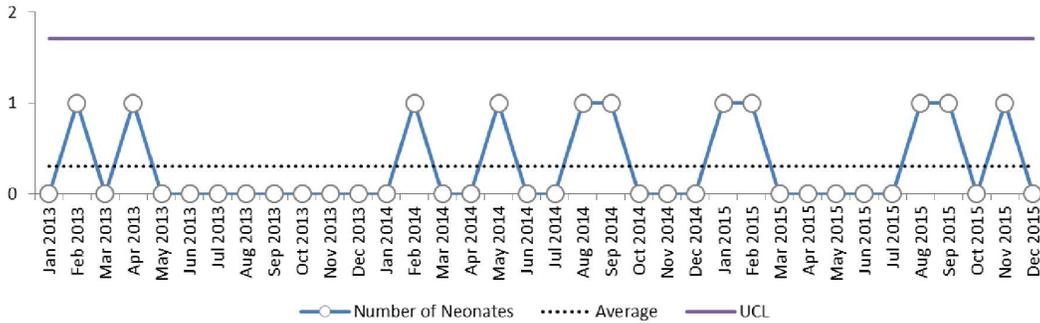
Neonates with Birth Weight < 2000



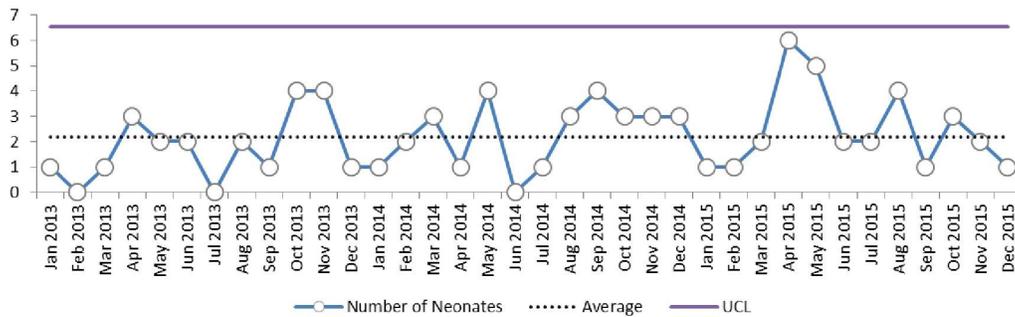
Gestation of neonates on admission to the Neonatal Unit:

Gestation periods were also analysed to assess whether there were greater levels of prematurity that coincided with the period of greater mortality levels seen in the second half of 2015. This does not seem to be the case for admissions in the most severely premature categories (below 26 weeks and between 26 and 30 weeks) but there was an eight month run of higher than average admissions at 31-36 weeks.

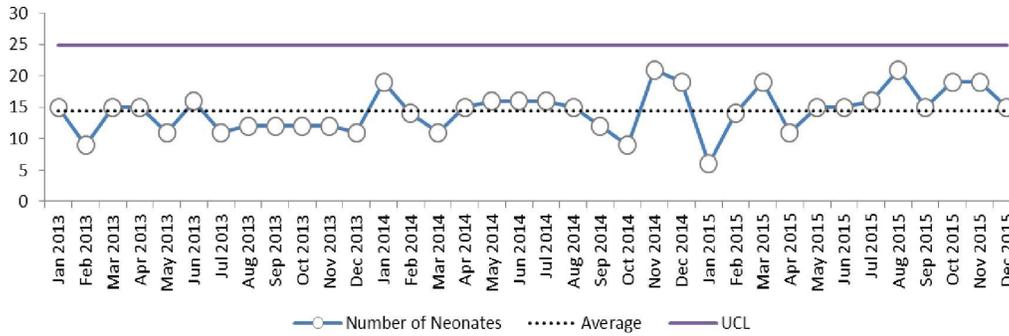
Neonates with gestation under 26 weeks



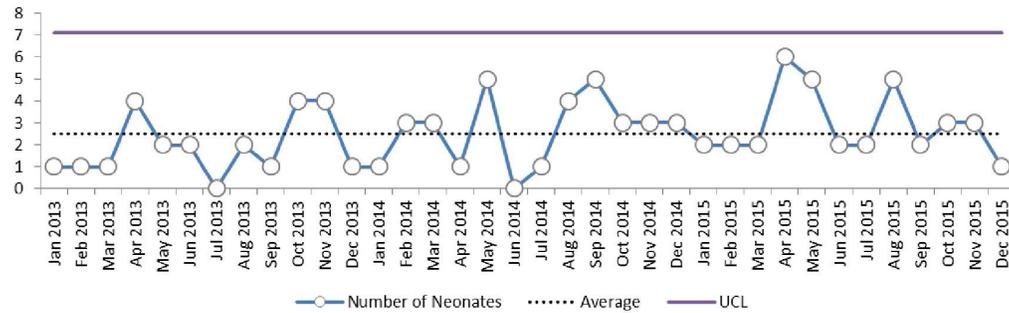
Neonates with gestation of 26 to 30 weeks



Neonates with gestation 31 to 36 weeks



Neonates with gestation over 36 weeks



4.2 Incident Reporting – Neonatal Deaths and Sudden Deterioration

Analysis of Datix for incidents reported confirms that there were incident reports logged regarding various aspects of care in 10 of the 11 neonatal deaths reported in 2015/16. The death of two babies (**Child D** and **I&S**) was subject to a NPSA Level 2 patient safety investigation and this included a review of the antenatal care and labour.

Of the 16 neonatal deaths identified during the 36 month period up to and including June 2016, 8 (50%) are from ‘out of area’ with 6 Mother’s being resident in **I&S** *.

Of the 16 neonatal deaths identified during the 36 month period up to and including June 2016, 5 (31%) are multiple pregnancies, predominantly of twins**.

(**The neonatal deaths include two neonates from a set of triplets from the same Mother, resident in **I&S**)

The specialty have identified that during 2015/16, a further 3 neonates died shortly after transfer to a Level 3 unit. These are **I&S** , **I&S** and **Child K** . The specialty have also identified a further 4 neonates who experienced a sudden deterioration in their condition during the period January – June 2016 (2015/16 = 1; 2016/17 = 3); none of these had been reported via the Datix incident reporting system and therefore these require further case review, these babies survived. These are **I&S** , **Child M** , **Child Q** and **Child N** .

As the specialty does not routinely capture these events, neonates transferred out of the Neonatal Unit to level 3 care have been considered within this review. This has identified that during the 36 month period up to and including June 2016, there were 4 neonates who experienced a sudden deterioration in their condition. These are **I&S**, **Child Q**, **I&S** and **Child H**.

Nurse and medical staffing has been matched to all 32 cases within this review, some staff do appear more frequently on the rota in respect of being allocated to those babies who deteriorated but there are no reported competency issues with nursing or medical staff and neonatal skill training is seen as a priority.

3.4 Patient Experience

Analysis of Datix for PALS contacts and formal complaints during the 36 month period up to and including June 2016 identifies no concerns raised.

3.5 Coroners Referrals & Inquests Opened

Analysis of Datix for Coroners inquests opened during the 36 month period up to and including June 2016 confirms 1 inquest (**I&S**) which the conclusion was death by misadventure following developing pulmonary haemorrhage during intubation for a neonatal network transfer. This death occurred on 24 March 2014 was subject to a NPSA Level 2 patient safety investigation.

For 2015/16, there are 2 inquests opened with no date yet scheduled. Both cases were subject to neonatal case review and were discussed at the Executive Serious Incident Panel meeting on 3 July 2015.

For the 36 month period up to and including June 2016, post-mortems were undertaken 14 of the 16 neonatal deaths reported, with 11 of these being a Home Office post-mortem.

3.6 National Neonatal Audit Programme (NNAP)

BadgerNet enables the Trust's real-time data (along with data from all neonatal units) to be analysed by the National Neonatal Research Database (NNRD) held at the Neonatal Data Analysis Unit (NDAU) in Oxford. NHS England and National Neonatal Audit Programme (NNAP) extract the data for their annual reports and dashboards etc.

The most recent NNAP report was published in November 2015 and captured data from 1 January – 31 December 2014 (see Appendix 4). Results from 10 audit questions are presented in the report. 515 babies and 538 care episodes from Chester NNU were included. Data entry was 100% complete. The specialty identified 2 actions from this report to be achieved by August 2016:

- Ensure good practice for central line (UVC, UAC and peripheral long lines) insertion. Continuing work with catheter care bundle.
- Continue to strive to improve support for parents wishing to breast feed their babies on NNU

The draft 2015 Quarter 2 NNAP data summary (1 January – 30 June 2015) was submitted to the Trust in October 2015 which demonstrated 0 central line infections and an increase from 56% to 64% of babies receiving Mother’s milk (exclusively or as part of their feeding).

3.7 Risk Register

The departmental risk register contains 15 risks, the oldest risk listed dates from November 2014. There are 4 risks scored as ‘high/red’ – these include a pseudomonas risk, availability of neonatal network transfer team and 2 risks associated with the availability of medical staff due to gaps in the junior doctors rotation

3.8 Staffing

The Neonatal Unit Ward Manager has stated that there have been no warnings to staff regarding capability (performance) or conduct (disciplinary).

ESR data for nursing staff on the Neonatal Unit shows compliance with training as follows:

Training	Compliance %
Individual Competencies	71.1%
Induction	50% (n=2)
Mandatory Training	100%
Appraisal	100%

Source: ESR June 2016

The Neonatal Unit began inputting nurse staffing and cot occupancy in BadgerNet in October 2014. The BadgerNet data for June 2015 – March 2016 has been utilised to assess compliance with the British Association of Perinatal Medicine (BAPM) standards i.e. 1:1 intensive care, 1:2 high dependency care and 1:4 special care. This review has identified that the Neonatal Unit nurse staffing numbers were below the BAPM recommendations (based upon neonatal acuity) at the time of 7 of the neonatal deaths (out of 11 deaths reported June 2015 – March 2016). BadgerNet has calculated the variation from the BAPM standards for these individual shifts as (minus) -0.6 to (minus) -2.6 from the recommended nursing establishment. Following on from this, BadgerNet demonstrates lower than recommended provision of ‘Qualified in Specialty’ (QIS) nurses. 11 incidents were reported by Neonatal Unit staff during the same period (for June 2015 – March 2016) regarding staffing/acuity concerns. 5 (45%) were in November 2015 and 4 (36%) in December 2015.

Staff reported an incident on 18/02/16 confirming that the Neonatal Unit had to close to admissions due to acuity; neonate I&S died the same day.

Neonatal nurse staffing is monitored monthly and reported through Unify to the Department of Health, this has on average been around 85% compliance against staff actually on duty, however according to the Unit, staffing is flexed to match acuity and occupancy. A formal review of nurse staffing was undertaken in 2015 which identified a gap in nursing in order to meet the BAPM standards –this case was being further reviewed by the Divisional team in respect of future service model and staff required.

The Department of Medical Education have stated that they are unaware of any concerns regarding capability (performance) or conduct (disciplinary) for doctors in training. The specialty college tutor has confirmed that there have been no significant performance concerns with any of the doctors in training over the period April 2014 to date.

With regard to substantive medical staff within the Neonatal Unit, ESR identifies 7 Consultant Paediatricians and 4 Community Paediatricians. The ESR data for these staff regarding compliance with training and appraisal has been requested.

3.0 Findings

Significance of change in mortality levels

There has been a step change in mortality levels in the Neonatal Unit since June 2015. The monthly average numbers and the frequency of mortality over time have increased.

Fluctuation due to common cause variation cannot account for the increased mortality seen in the Neonatal Unit.

Activity as a contributory factor

The number of admissions to the Neonatal Unit is recorded as higher than average for some months during 2015/16; the monthly 'total care days' also shows a sustained period of above average during this period.

Similar periods of increased activity recorded in previous years have not been associated with an increased mortality. Therefore activity levels alone cannot account for the increase but may be a contributory factor.

Acuity as a contributory factor

There is evidence of increased acuity within the second half of 2015 with high acuity 'care days' for both intensive care and high dependency care demonstrating a sustained run of above the average monthly figures over the period.

A sustained increase in low birth weight admissions (<2000g) also corresponded with the increase in mortality levels. There were no notable trends in prematurity the second half of 2015, with the exception of a small increase in the rate of admissions at 31-36/40 gestation.

Therefore an increased and sustained acuity level may be a contributory factor. There does not appear to be an escalation process in place between obstetrics and the neonatal unit to highlight when the unit is struggling to cope. The unit is 'closed' on numerous occasions each month due to capacity and acuity levels being high (Appendix

Nurse Staffing Levels as a contributory factor

There is evidence that the Neonatal Unit does not consistently meet the BAPM recommended nurse staffing levels or the recommended provision of 'Qualified in Specialty' nurses.

4.0 Recommendations

The Executive Team is asked to note the challenges to the analysis undertaken and the findings of this mortality review.

Alison Kelly, Director of Nursing & Quality

Ruth Millward, Head of Risk & Patient Safety

July 2016

Title: Compilation of Action Plans for the review 2016
NEONATAL MANAGER: Eirian Lloyd Powell

ACTION PLAN: July 2016

Areas for Review	Recommendation/ Action	Lead Person	Target Date for completion	Progress of Actions	Date for next Review	Date of Completion
Staffing Resource	Meeting Divisional Director and Head of Nursing every two weeks to review staffing establishment (initial meeting 22.07.16)	Eirian Powell	On-going	Collate pertinent information to ensure that we have sufficient staff to deliver safe Level 1 care during this transitional time frame (check against the Level 1 service specification)	August 2016	
	Training - Maintaining clinical Competency – Nursing staff	Yvonne Farmer/Eirian Powell		Devising a programme that can be integral in the neonatal mandatory training of all staff Integrating a programme with the Operational Delivery Network (ODN)		
	Clinical competency for Medical staff			Discussion with Medical Director		
Babies requiring IV antibiotics on labour ward	Meeting to be arranged with DDON, HOM, HON Urgent Care, Neonatal Manager and Lead Nurse for Paediatrics	Sian Williams	September 2016			
Staff wellbeing	Access to occupational health team	Eirian Powell	14/07/16	The OH team have been visiting the unit on a regular basis and have seen relevant staff already.		

Areas for Review	Recommendation/ Action	Lead Person	Target Date for completion	Progress of Actions	Date for next Review	Date of Completion
Unit Capacity	Outline the number and level of cots to be reduced to take to the Medical, Executive Team & the Network	Eirian Powell	14/07/16	Completed and sent on the 14/07/16	NA	14/07/16
	Escalation beyond agreed number of cots	Eirian Powell	On-going	Process agreed Escalation to be sought via Director of Nursing and Medical Director – out of hours via On-call Manager	NA	July 2016
Additional Support	Daily NNU visit	Karen Rees	Daily	Head of Nursing to attend NNU each morning to review staffing, position and identify any key issues	NA	July 2016
Security	Installation of CCTV – already met with Tim Lister prior to meeting regarding the installation of cameras	Eirian Powell	ASAP	Meeting with security with regards to security access – swipe card to the back door and CCTV within the unit		
	Communication with parents regarding the use of CCTV on the NNU	SH				
IT	The additional supply of laptops/tablets to be used within the nurseries to ensure timely documentation	Eirian Powell	ASAP	Contacted IT with regards to arranging a meeting with TR on the NNU for the installation of the IT products		

Areas for Review	Recommendation/ Action	Lead Person	Target Date for completion	Progress of Actions	Date for next Review	Date of Completion
Standards	Compilation of action plans that include all the relevant standards pertinent to Neonatal Care	Eirian Powell	22/07/16	<ul style="list-style-type: none"> • The Rag ratings on these particular standards are predominantly green. • The areas that remain amber/red are due to the building/staffing issues which have been highlighted on the risk register and within the business case & staff overview. There are some areas which needs addressing are out of our control. • Other areas include: Security of parents belongings – this is currently being addressed with the introduction of swipe doors/CCTV • We have no neonatal outreach service – however we do provide a follow up neonatal clinic after the neonate has been discharged. • We do not provide financial support – however we do provide food/accommodation/transport on BH's • The Neonatal Network Transport service do not currently provide an acceptable service due to the fact that they do not have a designated ambulance 		

Areas for Review	Recommendation/ Action	Lead Person	Target Date for completion	Progress of Actions	Date for next Review	Date of Completion
CQC Action Plan	As per embedded document  CQC AP CYP July 2016.docx			Monthly update via Head of Nursing and action plan to be received as part of monthly Divisional Governance meeting. Quarterly update at QSPEC	August 2017	
External Review	To undertake a full review of the recent increase in mortality for NNU	RCPCH		Data packs are being collated		

Name of Lead for Action Plan:

Eirian Lloyd Powell

Date July 2016