

EXTRA-ORDINARY BOARD OF DIRECTORS (PRIVATE)

MINUTES OF THE MEETING HELD ON THURSDAY,
14TH JULY 2016 at 12.30PM
BOARDROOM
SPC/CER FINAL VERSION

		Attendance	
Chairman	Sir D Nichol	<input checked="" type="checkbox"/>	
Non Executive Director	Mr A Higgins		<input checked="" type="checkbox"/>
Non Executive Director	Mr J Wilkie	<input checked="" type="checkbox"/>	
Non Executive Director	Mr E Oliver		<input checked="" type="checkbox"/>
Non Executive Director	Mrs R Hopwood	<input checked="" type="checkbox"/>	
Non Executive Director	Ms R Fallon	<input checked="" type="checkbox"/>	
Chief Executive	Mr T Chambers	<input checked="" type="checkbox"/>	
Medical Director	Mr I Harvey	<input checked="" type="checkbox"/>	
Interim Chief Finance Officer	Mr S Holden	<input checked="" type="checkbox"/>	
Director of Nursing & Quality	Mrs A Kelly	<input checked="" type="checkbox"/>	
Director of People and Organisational Development	Mrs S Hodgkinson		<input checked="" type="checkbox"/>
Director of Corporate & Legal Services	Mr S P Cross	<input checked="" type="checkbox"/>	
Director of Operations	Ms L Burnett	<input checked="" type="checkbox"/>	

In attendance:

Mrs C Raggett – Secretary to the Board
 Dr Steve Brearey, Consultant
 Dr Ravi Jayaram, Consultant

FORMAL BUSINESS

1. WELCOME AND APOLOGIES

Apologies were received from Mrs Hodgkinson, Mr Higgins and Mr Oliver.

2. To review and consider the position with regard to the Neonatal Unit

Mr Chambers reported that the Trust has noticed a change in mortality rates in the neonatal unit. This rise could not be explained and following on from concerns raised by the clinical team, the Trust is sufficiently motivated to do an in-depth review into the deaths. Mr Brearey, lead for the neonatal unit, had asked for a peer review from colleagues in Liverpool into the cases to see if anything had been

missed. This review had proved inconclusive. Mr Brearey and the team decided that there was a need to escalate further to understand what had changed, what this meant in terms of staffing, to understand the clinical context of all the baby deaths over a longer period and to also commission an independent review on the neonatal services.

The Trust has taken the decision to change the admission criteria for the unit so that the unit would no longer admit babies who require intensive care. The neonatal unit team have supported the Trust in this decision. The Trust has prepared a statement which will be released to the Press. A deep dive has been undertaken on the data and the Trust is keeping an open mind as to the causes of the increased mortality rates. A meeting has been held with the clinicians; Mr Harvey will review the data and also the agreement of the scope and terms of reference for the external review. Mr Harvey reported that there has been a huge amount of work undertaken into the neonatal deaths data including a query around the place of death, i.e. the labour suite or neonatal unit, and to understand the numbers. This information will feature in the more detailed report. There are further areas to be looked into after this review. A lot of work has been done in a short amount of time with some staff working all weekend and consultant and specialist nurses reviewing case notes. Mr Brearey has done a lot of work on independent case reviews which he has shared with me and Mrs Kelly.

Mr Harvey stated that there is a need to be careful on language as there is not a significant number; it is small numbers in neonatal mortality figures. Mr Brearey and I have found higher than expected mortality rates for our unit and some babies were classified as not expected deaths. The Trust needs to understand how busy the unit was and how this compares on a local and national basis. The Trust's neonatal unit closes on a regular basis to admissions. In 2010 the Unit had 1-3 deaths per calendar year then in 2015-16 there was an apparent step change. The data is around 6 months behind, the Trust does not have the most current data but it was felt there could be a longer timeframe. The total number of care days on the unit is an upward trend with more care days on the unit. If this is matched in terms of intensity this shows that these babies needed higher care and this trend is over the average.

Mr Brearey added that during 2014/15 there had been a drop in the admission rate from November to January. Mr Harvey stated that this related to the classifying of babies prescribed with antibiotics. Mr Brearey also added that the Trust had included babies that received antibiotics i.e. infection in pregnancy, the baby would be screened and have antibiotics within 36 hours, the babies would then go on to the unit. These babies had been included in the admission figures however other Trusts were not including these admissions so it was agreed that COCH would not include these babies either.

Mr Harvey stated that the Trust had looked at gestational age and birthweight, there had been no strong trend in gestational age and an increase in babies less than 2000g. There is no basis for that at this stage and the obstetricians cannot see why Dr Jayaram stated that there had clearly been a rise over time but there is a

difference from 2013 to 2014.

Mr Harvey stated that the staffing had been cross referenced however the staffing is post Francis so there is not a lot of back data. Mrs Kelly added that staffing is in-line with the Department of Health standard however it is more complicated in the neonatal unit as there is a specific measure and that comes with specialist training. The overarching view was that staffing compliance was reducing so the gap was wider.

Mr Harvey stated that there had been a more detailed review into each of the cases including those babies that were out of area. [redacted] I&S [redacted] I&S [redacted] This carries through and in 2016 2 of the babies relate to triplets who had been under the Trust's care for the whole of their pregnancy. There seems to be an increase in patients from [redacted] I&S [redacted] that needs to be understood. Mr Harvey has met with the obstetricians and they are not aware of any issues. There is also a need to look into babies who have suddenly deteriorated.

Mr Harvey reported that the activity on the unit, staffing levels from June 2015 and cross referenced to the numbers on ITU, HDU and the specialist care babies. There are normally 14 cots with some flexibility between 3 classifications. From 2015, the unit has seen 17, 18 and at one point 19 cots in use against that some of the staffing levels did not match up as more at night than in the day.

Mr Harvey highlighted an issue around the rota allocation of medical and nursing staff on shifts before and when babies deteriorate. There are a number of staff who appear more frequently and one member of staff in particular. This member of staff is one of the unit's highest trained staff. The unit is working over and above, some babies are due to transfer but we are still taking babies but this is being managed. The Trust is in a position to take the next steps to ensure the unit is safe now and in the future.

Dr Jayaram stated that the nature of neonatal babies is that they are premature babies and by definition at higher risk. Within the context of that when things happen, they happen for a reason, so can see any trends. The concerns we had was not only the numbers of deaths rising but that these babies were not the ones we were expecting to die. These babies may have been premature but were stable, there was no reason to explain the collapse and then when they didn't respond to what was an entirely timely and correct intervention, this as well as the numbers made us worry. The data presented by Mr Harvey is helpful and backs what we say. The unit is busier and there is a strong strain on staffing and this is what we have been saying. This is not unusual across the region, neonatal cots are reducing, hard to recruit staff, lower staffing and higher intensity will lead to more risk, that said when look at these babies no direct effect on each patient.

Mr Harvey stated that Dr Jayaram was not referring to all babies. Dr Jayaram replied no, some baby deaths were anticipated as the babies were very poorly with abnormalities.

Mr Brearey stated that even if abnormalities were the cause of death, babies were stable before collapse.

In some ways post mortems are not always helpful and added that everyone had done a lot of work on the data. The clinicians had not seen the data until yesterday and it had no input from neonatal specialist or context with workloads at COCH compared to other units in the network. The network report had been discussed yesterday and if one looked at the activity in HDU, ITU and Special Care with others this is comparable. If one looked at nursing standards, the average amount of time compliant is 50% compared to the national average which is 64%. Some units such as Warrington only have 20% compliance. There are strains in the system and as the neonatal lead, Mr Brearey could not see that any of the apparent changes in acuity, or staffing levels can account for the increased mortality.

Mr Harvey said that he was not saying this would be the end as there are factors to be considered.

Dr Jayaram stated that what he was to say next was confidential and not to be minuted.

Mr Chambers reported that the Trust has seen an increase in harm and acuity which is probably greater than originally thought. The Trust has seen pressures on staffing, there is a proportion of part time staff on the unit. This has been discussed with the clinicians. Mr Chambers sought assurance that the board felt the Trust are taking this seriously. The Board agreed that the Trust was taking these issues seriously and agreed that the proposed actions were proportionate.

Mr Chambers reported that supported practice and increased supervision would be discussed with staff and put in place. There will also be increased security arrangements not only access and egress but also CCTV. The Trust needs to understand the data more and this will start quickly whilst continuing the investigation. This is supported by Dr John Gibbs, Senior Paediatrician. There will be more investigation around still births and transfers. The terms of reference for the external review with the scale and scope will include an investigation of the competence of all staff.

Mr Chambers stated that the unanimous view from the clinicians is that the actions are proportionate and balanced and is the right course of action.

Mr Brearey referred to the competence and stated that 'MBRACE' data for 14 babies (perinatal review) showed that COCH was between 0-10; less than the national average, coding can vary across Trusts however the Trust was below the national average in these 14 cases. Neonatal nursing staff are highly trained outside of the Trust for their qualifications and there is a double checking procedure on the neonatal unit. There was a thematic review undertaken in February 2016 which noted deaths occurred between 12am and 4am and there was an action to go back and look at the proceeding 12 hour period of collapse and a secondary review was

undertaken up to January 2016 but we could not identify any changes in observations, blood gas or blood results that would have indicated that we should have acted sooner. There is a high likelihood of being picked up by other staff as this had not been the case so in terms of competence he felt there were no issues.

Dr Jayaram added that there was no wrong or right thing, the actions proposed are very much around safety. The unit has downgraded so the babies that are admitted are lower risk.

Dr Jayaram stated that the paediatricians think the actions are proportionate so far and felt that the holding measure to reduce risk as far as possible pending the investigations into the data and the external review. The worry is that at the end of the review there is no conclusion or idea as to what is going on. He knew this could not be answered until after the review but he felt that this could ultimately be a delay however he accepted that this needed to be explored further.

Mr Harvey said that there are too many uncertainties and that he has approached the Royal College of Paediatric and Child Health to undertake the external review. They are quickly pulling a team together and will start the review on the 18th August 2016. If they have any areas of concern they will highlight them straight away.

There will be 4 in the review team including a neonatal specialist, paediatrician, nurse lead for neonatal palliative care and lay member barrister, who has previously chaired the NMC Fitness to Practice Board. Mr Harvey felt this was a very good team. It is important that we ensure that the unit is safe now, explore the data and assess any other issues. This is not easy and is incredibly difficult. He said we haven't slept for a couple of weeks and we do need to check we are not setting someone up to fail and need to make sure not due to stress.

Mr Wilkie stated that he accepted that no evidence to say is due to an individual but there is no evidence to say the contrary, his question is what has been changed since the last conversations. He understands the stakes here and in previous discussion there was considerable disquiet about an individual. We are saying there is something wrong here as we are now supervising that person. Mr Wilkie stated that he wanted to better understand what are the critical issues that mean it is not appropriate to engage the police as he could see disquiet. Mr Brearey replied that this had been discussed after the last meeting with Mr Harvey, there is a considerable amount of discomfort regarding the member of staff, it was felt that this was dragging on and that this would not solve the problem. There is a fantastic team and morale is very low, they will see a member of staff being closely supervised for no apparent reason, people do have anxiety about that and there is definitely discomfort.

Mrs Fallon stated that there is a point in time where a change in data can be seen, and asked in terms of that member of staff, how long they have been on the unit. Mr Brearey stated there are nurses on the unit that have had concerns about clinical practice and that this staff member was off sick. There have been no clinical practice

concerns raised about the individual referred to previously in the meeting. The individual has been praised by a transport consultant during a resuscitation. It is inconceivable to have a year like we have had and if there had been a competence issue this would have been flagged up.

Mr Brearey added that a full day has been spent on reviewing each of these incidents.

Mrs Hopwood asked how practical it was for the staff member to work under supervision. Mr Brearey said that the sister did talk to the staff member for a 3 month period, I have met with Mr Harvey and Mrs Kelly and in that 3 month period there were no unexplained collapses on nights when the individual was on days. When the recent deaths triggered where we are now, we came to execs with the background of increased mortality and concern around the member of staff. We then looked at the data when the individual was on leave however we have not seen the data for staffing so as a body we have not had the full information before making any decisions.

Sir Duncan stated that following the deep dive, the situation is that on the back of the staffing and the acuity this does not link to the mortality rates. What still needs to be informed is the rotas, competencies and situation all to be combined. This next stage is not a holding measure but it is understood that the proposed actions are a proportionate response while the deep dive continues.

Dr Jayaram agreed that the actions are to reduce risk and improve patient safety. He added that he did not mean to be an insult but thinking ahead, we would want to find something as we worry about the unit's well-being.

Dr Brearey stated that from the clinical lead point of view, the unit was high performing in the past and think it is now low performing that we will find something else and then come back to clinical concerns, however the clinicians are open to the external review.

Mr Chambers stated that the external review was totally necessary as we cannot say conclusively if there is a statistical blip and the advantage of the review was that it would look at the data, people, context and environment. The Trust is keeping an open mind, our values are safe, kind and effective and we need to do what is right for babies, families and staff. If the Trust felt conclusively about one issue then we would take absolute action however as we cannot determine that harm is happening by competence, we do think it is proportionate to take the proposed approach of supervised practice, ongoing review of data and an external review. The Trust has found things to question such as the antenatal pathway for patients. The Trust has to take an objective view. We are taking this personally and I understand that emotions are high but by putting babies, families and staff first there is a balance and this is in line with the problem we are facing as we cannot see what is causing the issues.

Dr Jayaram stated that the majority view is yes the measures proposed are proportionate and appropriate.

Mr Wilkie said that as a lay person he did not know how effective the measures will be and asked how confident the Trust were that we are removing all risk. Mr Chambers replied that there will be weekly monitoring on neonatal services at the Executive Directors Group.

Mr Wilkie said that this was about the member of staff. Mrs Kelly reported that the Deputy Director of Nursing, Sian Williams and the Unit Manager had an extremely difficult conversation with the individual who is devastated. It was a very sensitively worded conversation and the staff members understood about the review. The individual knew about the review, there are a lot of upset staff on the unit. The individual's stress levels, competency and competency in the round were discussed; Mrs Kelly added that if a staff member does an ITU course they do not get tested again so there is a need to update everyone's competencies and to do skill drills. This does not currently happen on the neonatal unit, everyone is kept up to speed on clinical skills and we are looking at doing in a difference way. There was the option given that the staff members may feel too stressful then they would be moved to a non-clinical area. However the individual did not want to do so and wants to go to a clinical area, where the individual's clinical skills and competencies will be monitored.

Mr Wilkie asked if that would abate any possibility of further issues. Dr Brearey replied not completely. Ms Burnett added that there will be no ITU babies on the unit and will only be 10 babies on the unit. Mrs Fallon asked if the individual would have access without being supervised. Mr Chambers said that if we believe that this is the only explanation, then we phone the police. The most plausible option is competency and when the individual has interaction with babies they will be supervised. We will look at everything as we need to make sure all areas are covered. He added that the neonatal network was not functioning well.

Mrs Hopwood referred to the low mortality in the unit and the reference made to the Warrington unit only having had 1 death. She asked what the historic data was. Mr Harvey replied that from 2010 to 2015 there was between 1 to 3 deaths per year, which increased to 8 in 2015. Dr Brearey added that there were 8 in the second half of 2015 and 5 in the first half of 2016. He added that the mortality numbers for the Ormskirk unit were 2, Warrington unit was 1, Whiston unit was 2 and then COCH had 10.

Sir Duncan stated that there is a major future exercise to look at everything and noted that the Trust is committed to do this. In the meantime, the previously expressed concerns about the individual, actions are being taken and it is agreed that these are reasonable as we cannot see a single hypothesis. We have to move forward in this way if the majority agrees, in the meantime there are no guarantees however this is what we would do in these circumstances or are there any alternative propositions. Dr Jayaram replied the only alternative is to go straight to

the police and that they would want hard evidence.

Mr Cross outlined his understanding of what action the police would take if they were called in to investigate this matter.

Dr Jayaram stated there was a need to be clear on the terms of reference for the external review. Mr Harvey replied that he had draft terms of references ready for review by Mr Cross.

Mr Harvey referred to the data and that the fact that this is now on one spreadsheet was massive as this was done in a 2 week time limit. We had to make a decision in 2 weeks but there is still more to do. Dr Gibbs has reviewed cases where babies collapsed and survived but we need to look at these as well. There are more stones to be turned over which is why we are where we are, does sound like a limited disclosure but we will know more next week. Mr Wilkie asked about the timescale. Mr Harvey replied that most of it would be completed in the next week.

Mr Chambers reported that the external review in August 2016 will feedback any concerns immediately. The Trust will continue to drill down into our data with the whole data pack and review being undertaken in August 2016.

Mr Wilkies stated so the results would be available by mid-September.

Mrs Fallon asked if the external review would look at staffing. Mr Harvey replied that the process was a bit like the CQC visit, the reviewers will be given a list of documentation and data, they will meet the Medical Director, Director of Nursing and the Chief Executive. They will then provide a list of those staff they want to interview either individually or as a group. The Longhouse Conference rooms have been cleared for the reviewers. The reviewers will bring their own administration team. Mr Harvey will provide the reviewers with whatever information they need.

Mrs Fallon asked if there was a direct correlation, would they uncover this. Mr Harvey replied that as part of the process any issues will be outed and we will advise them of the supervision of staff as it will be the part of the measures we have undertaken.

My Harvey gave details of the draft terms of reference for the review which included points from the RCPCH and the Trust.

Mrs Fallon asked about the individual and how many of those babies involved had the individual been on shift for. Mr Harvey relied that the individual had been on shift for 10 out of the 13 babies involved.

It was noted that the individual was a full time member of staff who also did overtime. Mrs Kelly had queried how staff were allocated overtime and it is allocated on the skills of the individual, as the individual in question was full time they would have been well skilled.

Mr Harvey said are we doing this on probabilities or the balance of doubt.

Dr Jayaram said that 2 days was not long for a review. Mr Harvey replied that the review will have all the data before they arrive so they will be fully prepared. If they need more time they will advise us.

Dr Brearey made a request that there is a neonatal specialist involved as it is a minor speciality.

Mr Brearey added that where we are we know most about this subject, there was a discussion about the plan to improve including reducing the number of band 4 nurses and to employ other nurses. Morale on the unit is rock bottom and many nurses have done extra shifts at the expense of families. Mrs Kelly said that it was not about getting rid of band 4s, it was about converting post to band 5s as the band 4s leave. There are a few nurses coming up for retirement that will be replaced with a band 5.

Sir Duncan said that in light of the data, if we take the basis that it was proportionate to call the police, we would. We recommend to the Board that we would explore the data and that if the individual returns to duty, this would be under supervision, Sir Duncan asked if the Board agreed.

Dr Brearey said that operationally that would take more staff away and we will have to reduce transitional care to allow nurses just on the neonatal unit. Mrs Kelly said that this was being looked into.

Sir Duncan said the review is important and asked whether the review team will be briefed on the explicit concerns. Mr Harvey said that they would be and this will be discussed as part of the review and interviews.

Mr Harvey confirmed that he would discuss the concerns regarding the individual during his interview with the review team.

Mrs Hopwood asked how the on-going discussions and fact finding would be brought to the Board. Mr Chambers stated that the dashboard will give a clear oversight of the current position, decisions on the unit and will be monitored at the weekly executive meeting. Mr Cross added that as soon as the Board needs to be updated they will be. Mr Chambers said that the Trust will be proactive on communications for all staff and the media.

Sir Duncan stated that Mrs Hopwood made a reasonable point and that he, along with Mr Higgins as Chair of QSPEC, will be in very close contact with the review.

Mrs Hopwood stated that she felt this was fine but that another Board meeting be held post review as a minimum unless there is a need to get together sooner.

Sir Duncan stated that nobody doubts the trauma of this, we need to support each other and those on the unit.

Sir Duncan would like to register thanks to the Risk Team and Dr Gibbs and team for their hard work in preparing the data and information.

Unapproved