

Independent Case Review

For

Jonnie Meek

Author

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Date

30th November 2015

Version 2

Final Report

Jonnie Meek
Born 09/08/2011
Died 11/08/2014

“Among competing hypotheses, the one with the least assumptions should be selected”
Ockham’s Razor

Introduction

I am Dr Martin Farrier MBBS MRCGP MRCPCH. I have been employed as a Consultant General Paediatrician at Wrightington, Wigan & Leigh NHS Trust since August 2001. I am currently Associate Medical Director and Chief Clinical Information Officer. I have 8 years of experience of reviewing deaths at Wrightington Wigan and Leigh.

I was approached by my colleague Dr Umesh Prabhu (Medical Director at Wrightington, Wigan & Leigh NHS Trust) and asked to take on a review of Jonnie’s case. Whilst I initially declined, I was persuaded that an independent overview would be helpful to all involved in reaching conclusions.

My purpose for accepting this role was the desire to bring a conclusion to all, but particularly for Jonnie’s family.

My review of this case was formally requested in October 2015 by Val Jones and Andrew Donald from Stafford CCG after they received communication from the Parents of Jonnie Meek. The communication expressed lack of satisfaction with the care given to their son and to the complaints process of the hospital (Mid Staffordshire NHS Foundation Trust). My involvement was sought as an independent expert to review the case and the subsequent responses.

I will at all times in this review attempt to use language that does not confuse.

I have received no payment for this report, and have no affiliation to any of the parties to which this reports.

I am not a pathologist, or an allergy specialist. My comments represent my view on the information presented. They reflect my experience over 14 years as a Consultant General Paediatrician.

Methods

This report was written having reviewed written evidence provided to me. It was then supplemented by interviews with people involved.

There are 2 sources of written information.

1) Stafford CCG

This information was provided to me and contains copies of the notes and charts from the 2 admissions along with a copy of the CDOP report and various letters and responses.

2) Jonnie's Family

This information was provided to me directly by Jonnie's Family. It is contained in 3 folders. The folders are systematically prepared and include information released through enquiry and Freedom of Information requests. There are copies of the notes from both admissions along with information relating to the CDOP report and complaints letters / responses.

There is no conflict between the 2 sources of information. There is more information available to me through the family than through the CCG. This is because the CCG provided formal documentation. The additional information from the family seems to include a range of less formal documentation (such as emails, forms submitted to CDOP and other information)

I separately sought information from those involved with the care of Jonnie. There were 2 days spent meeting and interviewing people. The first was with Jonnie's parents. The second was with healthcare professionals involved with Jonnie's care.

My review is based on an analysis of these documents alongside guideline / recommendation documents included in the appendix of this report. It has been added to and crosschecked by interviews with staff involved.

Jonnie's Story

Jonnie was born on 9th August 2011. Shortly after he was born he was noted to have problems, and later shown to have a rare genetic condition (De Grouchy Syndrome). The condition is linked with various physical problems and with significant learning difficulties.

During Jonnie's first 2 years of life the consequences of De Grouchy Syndrome become evident. He has feeding problems which result in him needing a Gastrostomy (feeding tube directly into the stomach). He takes very little food by mouth. His learning problems are severe. He is able to communicate by smile and indicate distress, but is not able to communicate using words. He is entirely dependent on his family for care. His movements are limited such that he is not independently mobile. He is prone to chest problems, not because of the De Grouchy Syndrome, but because of the swallowing problems and lack of movement. There are minor heart problems. He is also found to have a hormonal problem with steroid production. He doesn't make enough of the stress hormone Cortisol. He needs to be given this each day and if he becomes unwell, the dose needs increasing to help cope with the illness.

Jonnie was also thought to have allergy type problems These aren't necessarily related to the De Grouchy Syndrome. It's clear that he has eczma. He is treated for Asthma. He has had problems with feeds. These are given by tube and are all milk like fluid feeds. He has been tried on numerous feeds. In his early life he has been on Cow's Milk. After various changes he has been put on a specialist milk that treats Cow's Milk allergy. At the time of his admission in August 2014 there is a wish to change the milk feed that Jonnie is on. Jonnie's growth is poor. This is in part because of the De Grouchy Syndrome, but the team caring for him want to optimise his growth. He is being changed from a specialist milk feed which is used to treat Cow's Milk allergy, to a less specialist milk feed which is not used to treat Cow's Milk allergy, but is better for growth. The events that follow on August 14th are agonising and unexpected. Jonnie dies during a planned admission for introduction of a new feed.

De Grouchy Syndrome¹

This is an exceptionally rare condition. It is caused by a genetic error (a part of chromosome number 18 is missing). There is limited information available about the condition. What information there is indicates that children who have the condition will have a certain look to their facial features, and they will have learning difficulties. Their prospects for life are dependent on the severity of their learning difficulties. How long people will live with this condition again seems dependent on their disabilities rather than any specific feature of the condition.

Jonnie's genetic result (August 2012) in fact shows 18p trisomy (an extra bit of chromosome 18 was present) as well as the 18q deletion that is the cause of De Grouchy Syndrome. There is a bit of genetic tissue missing, and in its place is another piece. The bit that's missing is some of 18q. In its place is a replication of 18p. The problems present in Jonnie may therefore be more complex than would be expected from De Grouchy syndrome. 18p trisomy is reported in very few patients so the features are poorly established. Jonnie may have had a unique genetic anomaly taking the 18p trisomy with the 18q deletion.

The published experience of De Grouchy syndrome is that there is no specifically life limiting features. Patients' lives are limited by the severity of their problems. Thus children with severe learning difficulties tend to share a similar life expectancy. The

commonest cause of death will be recurrent respiratory illness typically in late childhood or early adulthood.

Jonnie had features much in keeping with those described in De Grouchy Syndrome.

Admissions

This review was instructed to consider 2 specific admissions during August 2014

Drugs at the time of these admissions:

Salbutamol inhaler as needed

Clenil Modulate 100mcg bd (for asthma)

Hydrocortisone (5mg/ml) 1ml / 1ml / 0.5mls (for steroid deficiency)

Domperidone 2mg (a treatment for oesophageal reflux)

Sytron 1ml daily (for iron deficiency)

Trimethoprim 4.2mls daily (200mg) – to prevent urine infection

Tarcrolymus eye ointment – because of corneal transplant

Omeprazole 4.5mg bd (antiacid treatment)

7th August 2014

This is an emergency attendance. Jonnie is not admitted. He is brought to hospital and arrives at 1.50am. He is seen at 2.30am by a doctor. There is a brief clerking. His observations note an increased breathing rate, and the Doctor's examination notes a wheeze. The doctor considers this to be asthma. Jonnie is previously considered to have asthma and is on Clenil Modulate (preventative steroid inhaler) and Salbutamol (acute treatment given as needed). He is given 4 puffs of his salbutamol inhaler (this is a relatively small dose in the context of an acute presentation – often a dose that is given at home). His breathing settles and he is allowed home. There is no long term change made to his medication.

11th August 2014

This is a planned admission. Jonnie is to be admitted to trial a new milk feed (Peptamen Junior Advance – Whey based / non-hydrolysed). He is being switched from Nutramigen AA (Casein based / hydrolysed). This switch has been tried before, but mum reported a reaction to the milk. There has been an agreement that this test feed will be done on the ward. Mum has expressed a wish for it to be in a safe environment. She has expressed a worry that he is reacting to the feed. The test feed has been arranged for a convenient time when Jonnie is well.

13.20pm

Jonnie is admitted to the ward. The clerking is appropriate and makes reference to ongoing issues. Of relevance is that Jonnie has had lots of secretions and choking episodes over the last 2 months. These are said to be getting worse. Observations at this time are normal. There are 4 sets of observations recorded during this admission prior to the arrest event. They all indicate no respiratory problem. Jonnie was in Air. His pulse rate and respiratory rate were steady. His temperature is normal. His saturations are being continuously monitored. He has a capillary refill time (this is a measure of how well skin is perfused and therefore an estimate of "how well" a child is) throughout the 4 observations recorded as less than 2 seconds (normal).

13.30

The nurse caring for Jonnie commences his new feed. There is some discrepancy as to the timing of the feed starting. It is documented as 13.30, and 15.10. However, Jonnie's parents still have the pump with the quantity of feed infused. There was 52mls infused at a rate of 25mls/h. They note that the feed was stopped for about 5 minutes whilst Jonnie is assessed by the medical staff around half way through the feed. The notes indicate it was stopped at 15.30 which is close to the time of the arrest. 2 hours prior to 15.30 is 13.30. These roughly line up.

15.00

Dose of Chlorpheniramine (commonly called Piriton and widely available for the treatment of allergies) given. According to the drug chart this is the only drug given between the time of arrival and the time of death. It is commonly given to treat an allergic reaction. It would seem to have been given at the request of the parents and probably because Jonnie has developed a rash. This was confirmed with Jonnie's parents who indicate that they had asked Jonnie's Nurse for that day if he could have a dose of Chlorpheniramine. They confirm that this was because he had a rash and looked agitated.

15.30

Precise timings for events are not available, but a clear sequence can be established. Jonnie has become less well. There is a rash, but its unclear how much the rash is due to Jonnie's severe eczma. It is likely that his Mum is more sensitive to subtle changes in Jonnie's eczma than the healthcare professionals. The discrepancy in views is likely to reflect this difference.

The saturation monitor (machine used for monitoring oxygen levels in Jonnie's blood) is alarming because it is either recording low saturations or it is not correctly reading. It is not possible to know the difference. The nurse caring for Jonnie might have been able to clarify this issue. However, Michelle Lyons tells me that the creams used for Jonnie's severe eczma regularly caused problems with saturation probes. I am aware of this difficulty in other children as well as the dilemma of saturation monitors having a poor trace (the picked up "pulse line" that is used as an indicator of the monitor functioning correctly) when skin perfusion is poor. The nurse caring for Jonnie seeks to resolve the issues with the saturation monitor which she considers to be misreading. Given how unlikely the events that follow would seem to be, checking the saturation monitor would seem to be a reasonable action.

There is a conversation between Jonnie's Mum and the nurse caring for Jonnie. Mum is becoming increasingly concerned.

Michelle Lyons arrives in Jonnie's room merely by chance at this time. She knows Jonnie and has cared for him in the community. She has an office on the ward, and just because she cares about Jonnie and his family has dropped in. She is immediately aware of the problems that are emerging and asks the nurse caring for Jonnie whether she wants help. They agree that a Doctor is needed and Michelle leaves to find one. In the time that she is out of the room the emergency buzzer is pressed. The nurse caring for Jonnie is on the wrong side of the bed to press the buzzer and so it is pressed by mum.

15.45

Gagging and frothing at the mouth are noted by the nurse caring for Jonnie. Saturations are reduced.

15.47

Chest compressions started.

Dr Oso and Dr Gupta respond to the emergency buzzer. They are both present on the ward. One because his office is on the ward, the other because he is doing some teaching on the ward. Their response times are consequently exceptionally rapid. They are joined by an Anaesthetist and other doctors and nurses. A very experienced team is established in a remarkably short time.

Resuscitation

Precise timings of the resuscitation are difficult. They are not a priority of the team caring for a child in this situation and there should be no inference drawn from the difficulty in recording precise times.

The sequence of events would seem to be:

- Initial choking
- Apnoea (or Gaspings irregular breathing as indicated by Dr Gupta during the interviews)
- Severe bradycardia (under 50 bpm as recorded by the Dr Gupta)
- Oxygen / Ventilation with an Ambu Bag
- Intubation (thick white mucous noted and no evidence of oedema, there is then a comment about “milky mucous”). There seems to be little difficulty with the intubation and air entry to the lungs is improved.
- Adrenaline 1ml 1;10,000 via the ET tube (there is no canula)
- Adrenaline 1ml 1;10,000 via the ET tube 2nd dose (there is no canula)
- Intraosseous Access
- Adrenaline 1ml 1;10,000 via the Intraosseous (large needle in the shin bone) line
- Reintubation by anaesthetist because of poor air entry (tube presumably became dislodged – a problem of chest compression and ET not being secured)
- 140mls 0.9% Saline (roughly 20mls / kg iv split as 3 separate boluses closely following each other)
- Adrenaline 3ml 1;10,000
- Asystole on the ECG trace

16.11

Resuscitation stopped. Resuscitation attempt lasted 25 minutes.

Drug dosages:

Adrenaline

Recommended IV dose 10mcg / kg (70mcg for Jonnie’s weight)

Actual dose given 100mcg Adrenaline via the intraosseous line then 300mcg via the intraosseous line.

Recommended ET dose not established, though 10 times dose has been suggested.

3mls of 1;10,000 is a dose of 300mcg (this is a large dose but not inappropriate and is in line with the dose recommended for anaphylaxis though there is no evidence the team considered they were treating anaphylaxis)

It is normal to use 1;10,000 Adrenaline when giving intravenously / intraosseously and this typically comes in prefilled syringes.

Guidance from Resus Council UK⁵ describes a stronger adrenaline solution (1:1000) but this is intended to be given Intramuscularly. The dose suggested is 150mcg for a child under 6 years. Dosages in this situation are imprecise.

The doses of Adrenaline given were reasonable. There is no reason to think that a smaller dose would have been better, and doses were at least that recommended.

Chlorpheniramine

Recommended IV dose 2.5mg

Actual dose given 1mg via the gastrostomy

The dose given is smaller than the recommended dose for anaphylaxis. This is not surprising as it was not given to treat anaphylaxis. It is given orally some 15 minutes before the arrest. It is not likely that significant amounts are absorbed, particularly if it is taken into consideration that Jonnie became very unwell around this time. It is unlikely this dose had any significant effect.

Answering Questions Raised In the Terms of Reference

1) The clinical reviewer will provide an opinion on the cause of death.

Cause of Death

The events of the 11th August 2014 were catastrophic and unexpected. Understandably that leaves many questions. They have clearly been difficult to answer, with much of Jonnie's families communication searching for answers as to how such an event could happen.

The mode of dying (this is the type of events leading to Jonnie's death) is significant. Children normally die because of breathing related problems. This is a respiratory mode of death. The other major alternative is a cardiac mode (the heart stops first). The evidence from the notes does not support a cardiac mode of death. The notes indicate a severe bradycardia (slow heart beat) when CPR is commenced on Jonnie. If his heart has not stopped, this effectively rules out heart rhythm problems at the time of Jonnie's death. The likely mode of death is respiratory, but that does not mean the problem was in the lungs.

In considering the cause of Jonnie's death it is reasonable to start by stating all possibilities. The possibilities can then be ordered in a rough level of likelihood. Jonnie's death was unexpected and there was no definitive cause found by the doctors involved with his care. The pathologist suggests a cause for death at Post Mortem, but this is at odds with the clinical history. Jonnie's death was therefore a very unlikely event. The causation will be equally unlikely. In this situation, it is reasonable to consider things which doctors will normally consider to have "never happened in my experience"

The events that I considered possible were:

- An event which only happens by chance during the admission (ie has no relationship to any of the reasons that Jonnie was admitted)
- A reaction to the Milk that Jonnie was given
- A reaction to a drug that Jonnie was given
- Aspiration of milk during feeding
- Pneumonia that was present at the time of admission and led to Jonnie's deterioration and death
- Failed resuscitation
- Malevolence (deliberate harm caused by an individual to Jonnie)

An event which only happens by chance during the admission (ie has no relationship to any of the reasons that Jonnie was admitted)

It is possible that the cause of Jonnie's death was nothing to do with his admission. In this situation Jonnie would have died at home at the same time from the same event whether admitted or not. Jonnie had significant long term conditions that increase his risk of death. However, his condition is not associated with sudden unexpected death and this would seem to be a profoundly unlikely explanation. It is worthy of note that Jonnie was on Domperidone at the time of his death. There have been alerts about sudden death associated with Domperidone, but these are thought to be associated with Cardiac Arrhythmia. The events of Jonnie's death don't indicate a cardiac arrhythmia, nor is it likely that this randomly occurring event would happen during the admission. All the same it is a possibility.

A reaction to the Milk that Jonnie was given^{6,7,8,9,10}

Jonnie was admitted for a trial of a new milk. He had previously had reactions to milks. Jonnie's parents and the dietician's notes indicate that there had been concerns. There had been 2 previous attempts to start this milk. They had been stopped because Jonnie became unwell.

At the time of admission he is well. This is evidenced by the family and by the actions of the medical staff. If they considered him unwell, they would not have proceeded. After the milk is started the family report a skin reaction. It is far from clear that this is an allergic milk reaction, but the nurse is summonsed and administers Chlorpheniramine, a treatment for an allergic reaction. Some 45 minutes later an arrest call is put out.

There can be little doubt that trial of a new milk was the reason for Jonnie's admission, and that he had a history of allergies. It also seems evident that the medical staff treated Jonnie for a reaction on this admission by giving Chlorpheniramine.

Jonnie was being started on a less hypoallergenic milk than he was currently on. The milk he was on prior to admission was a treatment for cow's milk allergy. The milk that he was being changed to was a higher energy feed, but is not specifically used to treat cow's milk allergy. It can cause reactions where there is cow's milk allergy.

This type of allergic response to milk is a reaction that "has never happened in my experience". A reaction to milk severe enough to cause death within 2 hours of starting the milk feed is then a very rare event.

Were it to happen this would be an anaphylactic reaction. There is little physical evidence to support the idea that there was an anaphylactic reaction. In this situation there would normally be breathing problems and the intubation would be difficult with a swollen airway. There were no post mortem findings to support there being an anaphylactic reaction. However, the team who resuscitated Jonnie did not consider this as a possible cause (they did not give iv Chlorpheniramine / steroids). Nor did the pathologist seem to specifically look for anaphylaxis according to the standards set out by the Royal College of Pathologists³. The same guidance and other articles^{2,3,4} indicate the findings at post mortem are inconsistent and may be entirely absent. Post mortem is therefore an unreliable method of diagnosing anaphylaxis.

Despite the lack of direct physical evidence, there is compelling situational evidence given the reason for admission and the previous reactions to milk. Situational evidence is though the normal way of reaching a diagnosis of anaphylaxis.

A reaction to a drug that Jonnie was given

Drug reactions are rare difficult to predict. The only drug that Jonnie was given on the ward was Chlorpheniramine. This is a widely used drug and is available without prescription. It is considered to be very safe. I do not have direct evidence of Jonnie's exposure to this drug in the past, but it is very likely given his problems. If there were a drug reaction it could be as an allergic anaphylactic reaction. That would be indistinguishable from an anaphylactic reaction to the milk. Previous exposure makes anaphylaxis less likely. Drugs could also cause heart rhythm problems, but Jonnie's Mode of dying does not indicate a heart rhythm problem.

Jonnie was on a number of drugs given routinely by his parents. These will presumably have been given that morning by his parents. Reaction to one of those could also be considered possible. However, they more appropriately fit into the first group where consideration is given to an event that happens by chance during the admission.

Aspiration of milk during feeding

Jonnie was at risk of aspiration (food going into the lungs) because of his long term conditions. He was fed with a gastrostomy (tube directly into the stomach) and was being fed at the time of his death. The use of a gastrostomy reduces the risk of aspiration from swallowing. It does not stop food from coming back up from the stomach and going back down in to the lungs. Some children with Jonnie's problems have a fundoplication (operation to prevent food coming back up the oesophagus). This hadn't been done in Jonnie's case. The problems with milk refluxing hadn't been bad enough. However, the post mortem specifically addresses the issue of aspiration and did not find milk or food in the trachea / lung. Dr Gupta intubated Jonnie and confirms at interview that he did not see milk in the oropharynx. He refers to milky secretions, but in this reference he is merely referring to the white colour of the secretions and mucous. This is common. He did not consider there was evidence of Milk aspiration at the time of his intubation. It is most likely that at the time of Jonnie's deterioration there was vomiting. There are descriptions of Jonnie frothing at the mouth. It would be expected for there to be some secretions and possibly some stomach contents in Jonnie's mouth and throat at the time of the resuscitation. Clearing such fluid is typically needed whenever intubation is needed. Thus it is a likely consequence of deterioration rather than a cause of deterioration. Were this to be a cause of deterioration, it would be expected that there would have been a significant improvement in Jonnie's condition after clearing the airway and intubation. Massive aspiration should also be evident at the Post Mortem. There is then some evidence for aspiration / occlusion of Jonnie's breathing by food albeit limited to what might be expected during a resuscitation.

Pneumonia that was present at the time of admission and led to Jonnie's deterioration and death^{2,3,4}

Pneumonia was the cause of death given by the pathologist at Jonnie's Post Mortem. This is the "accepted" cause of death. Jonnie's death is a sudden catastrophic event. He is well at the time of admission as evidenced by parents and by the actions of medical staff. He has no respiratory problem. He is well assessed for a number of hours. His breathing is normal and he doesn't need oxygen. The findings at post mortem have no relationship to the events of Jonnie's death. There is no evidence in life of a pneumonia.

I review deaths at Wrightington, Wigan & Leigh NHS Trust each week and see this apparent anomaly frequently. Dying "with pneumonia" is very different to dying "from pneumonia".

It should not be surprising to consider that Jonnie's lungs had a chronic level of infection. He had a major disability. He will have had poor cough and did no "exercise" (a sort of natural physiotherapy for lungs). Secretions clear poorly and so there will be a level of chronic inflammation / infection. That this was evident on post mortem is not surprising. Rather, it would be surprising if there were no evidence of this.

The question that is raised is whether this was the cause of death, not whether it was present.

Failed resuscitation⁵

I am involved in reviewing deaths each week and there is a common perception that if the resuscitation had been run better the patient might have survived. On occasion that is true. Typically on such occasions there will be a delay in recognition of the deterioration and a failure to correct a simple anomaly. That is not apparent here. There is no evidence of delay in resuscitation, nor is there any simple anomaly which was not corrected. Jonnie's deterioration was catastrophic, and there is no reason to suspect that any action from the resuscitation team would have altered the outcome.

There are however issues with the resuscitation even if they are unlikely to have changed Jonnie's outcome. The treatment for anaphylaxis is a high dose of adrenaline and it would typically be given IM (intramuscularly) with the addition of steroids and chlorpheniramine (Resuscitation Council Guidance⁵). The steroids would take time (hours) to work and so are unlikely to have an effect. The Chlorpheniramine had already been given orally and so there is some level of conflict over what should be given intravenously. The dose of Chlorpheniramine intravenously would have been much larger though, and I would expect to have seen them give a dose. It is unlikely to have been life saving. The dose of Adrenaline given is in line with current guidance on anaphylaxis treatment. It was given initially down the ET (Endo tracheal tube – the tube put down to do the breathing for Jonnie) tube rather than IM (or intravenous / intraosseous). I don't consider however that it would have changed the outcome.

Jonnie's blood flow would have been dreadful and an IM injection would have been very unlikely to have greater absorption than the doses given into his lungs / into the intraosseous line. Further, it would not have prevented the initial event. The guidance is written in order to allow resuscitation in environments where there is no doctor able to intubate or place an intraosseous line. The IM nature of the Adrenaline allows the dose to be given by any attender.

What remains clear from the resuscitation is that the team did not consider anaphylaxis despite the admission for a test feed. The test feed is in case there is a reaction. I don't think that the addition of Chlorpheniramine and Steroids would have stopped Jonnie dying because of the very short time scales. I would however have expected them to be given.

Malevolence (deliberate harm caused by an individual to Jonnie)

This is an uncomfortable addition to the list. It should be considered however. It is not a comment on any individual and there is no evidence present in the notes to support it. We are aware however of incidents where family members or Healthcare Professionals have deliberately harmed children. Examples include physical injury and administration of medicines.

Hence, I would order the likelihood of these events as such

- A reaction to the Milk that Jonnie was given
- Aspiration of milk during feeding
- Pneumonia that was present at the time of admission and led to Jonnie's deterioration and death
- A reaction to a drug that Jonnie was given
- An event which only happens by chance during the admission (ie has no relationship to any of the reasons that Jonnie was admitted)
- Malevolence (deliberate harm caused by an individual to Jonnie)
- Failed resuscitation

It is important to reiterate that I do not consider any of these events to have been likely. They are all unlikely. I have merely ordered a sequence of unlikely events. It would be entirely incorrect to consider that I am certain Jonnie died from a reaction to a new Milk, only that from a list of unlikely events I think it is the most plausible.

"Among competing hypotheses, the one with the least assumptions should be selected"
Ockham's Razor

Jonnie was admitted so he could be monitored whilst a new feed was trialled. He was well at the time it was started. 2 hours later he has arrested. There is no evidence against this being a reaction to the new feed. It is the simplest explanation and has the least assumptions.

2) The clinical reviewer will provide an opinion on whether there is sufficient evidence to recommend that there should be a second inquest

Inquest

I consider that the most likely cause of death was anaphylaxis, though this cannot be considered a definitive conclusion. The findings at Post Mortem were not consistent with Jonnie's condition on the ward. I would recommend a second inquest.

3) The clinical reviewer will comment as to whether or not the care provided in last two episodes of care was in line with recognised best practice

I have outlined the care given to Jonnie during the 2 episodes I have been asked to consider.

Some aspects of his care should be commended.

Response

This was an entirely unexpected event. The response of the team was rapid. The 2 Consultants who respond did so because they were on the ward rather than they were specifically called. There is a large team of capable doctors and nurses established rapidly. They proceed in a logical way with Jonnie's resuscitation.

There are areas that warrant comment.

Documentation

In broad terms the documentation is adequate. It breaks down around the time of Jonnie's final deterioration. This is not unreasonable. There are omissions /conflicts from the notes in terms of timings and sequence of events. They are not serious. There are details from Jonnie's case missing, but given the teams close knowledge of Jonnie's case these are understandable. I have reviewed large numbers of case notes and these are comparatively complete. With almost all case notes, there is room for improvement.

Adequacy of supervision / Planning the admission

Jonnie was brought in for a change of feed. The purpose was to improve his growth. The fact that the milk was less hypoallergenic seems to have been given little consideration. In a child with severe eczma this perhaps should have been more of an issue. After 2 failed introductions at home, more so. If there was a moment to alter the events of 11th August it would have been in the planning and in the early stages of starting the new feed.

The new feed was started at a relatively fast rate and there doesn't seem to have been anticipation that there could be an extreme reaction despite the reason for admission. When there is a potential reaction, the feed is stopped. Aspirating the stomach contents might have been wise. Administering a small amount of feed (as we would with a food tolerance test) would seem to be more sensible than merely starting a feed. When Jonnie deteriorates it does not seem that the team consider Anaphylaxis despite the reason for admission.

Escalation

When a child dies in sudden and unexpected circumstances there are inevitable questions about the response of those around. In particular there is a question about the recognition of deterioration. The question is whether earlier detection of the deterioration could have changed the outcome. It is impossible to precisely identify the time of Jonnie's deterioration. After about an hour the feed is stopped for Jonnie to be reviewed. It would be unreasonable to consider this to be the moment of deterioration as he is reviewed and a decision to restart the feed is taken. He may well have had some reaction at this time but he is not in a collapsed state. When the saturation monitor is "not reading" (possibly clogged with creams, or possibly not working accurately because of Jonnie's deteriorated state) would seem the most likely point of deterioration. It is not long before the alarm is raised and the response is almost instantaneous. If there had been a correctable cause, it is very likely that the

response is in time to correct the problem. Jonnie still has a slow heart beat and some gasps. I can find no reason to consider the escalation was excessively slow. The team that responds to the arrest acts appropriately. They do not seem to treat anaphylaxis. This is an error, but an inconsequential one. There is no life saving treatment that is missed. It does however indicate that they were not anticipating a reaction to feeds despite the reason for admission.

Post Mortem

I am a paediatrician and not a pathologist. There is a limit to my ability to comment on a post mortem. The finding of lung infection does not reasonably explain Jonnie's sudden unexpected death. It is not clear whether the post mortem fully considers the possibility of a reaction to milk. I am unable to find evidence of a Mast Cell Tryptase test having been sent, or bloods for specific antibodies being considered.

The correlation between findings in life and findings after death seems to have been absent. In my experience this is not an isolated example. Rather it is the norm. It is rare for there to be any communication between clinicians and pathologists around post mortems. In my experience many post mortems are at odds with the clinical findings. There seems to be a loss of opportunity for learning.

Malevolence

In a similar way to the question of anaphylaxis comes the question of malevolence. Whilst I find no evidence whatsoever to support this cause of death, it is relevant. Jonnie's death has no simple, obviously correct causation. It was unexpected. In these situations we should consider unlikely events. It is possible for toxicology bloods to be sent. The purpose of these is to look for deliberate poisoning. I have no reason to believe these would have been helpful, but unless they are sent in these situations such malevolent events will never be found. I would have expected that the Coroner and the Pathologist would have routinely processed bloods to examine this possibility.

Answering Jonnie's family's questions

Jonnie's family asked for answers to specific questions:

1. *In Dr Gupta's recordings he describes during resuscitation he removed thick milky mucus from Jonnie's oral and nasal cavity reaching as far as his larynx, requiring several attempts to remove with +++ suction . As Jonnie was nil by mouth and had been for 12 months previously why was the thick mucus present? Was it a signal as in previous trials that the milk did not agree with him. As on other recorded milk trials he had vomited 1 to 1.5 hours into trial, as he had done on this occasion.*
2. *Now we are aware of what Dr Gupta had to remove, to allow air entry to Jonnie, would have it have improved his chance of survival if Dr Gupta or emergency help been summoned earlier?*
3. *Jonnie was reviewed by Dr Sharmine at 14.00hrs and appears to say that Jonnie was clinically well at this point. She recorded the following:*
 - *No significant respiratory distress*
 - *Pink in colour*
 - *No need for U+E's or ABX*

At 15.10 Staff Nurse Nicholls recorded that Jonnie had had a dusky episode due to secretions, now saturating at 94% in air.

At 15.30 in food chart a choking episode is recorded

At 15.40, Dr Gupta responded to the emergency call and found Jonnie with no respiratory effort, poor short gasps, central cyanosis, with no pulse, severe bradycardia, no high sounds, flat lines, asystole. He removed thick milky mucus requiring +++ suction, describing it as no small amount and it reached as far as his laryngeal opening.

Is it not possible that the blockage that Dr Gupta removed blocked Jonnie's airway and he choked on the substance that Dr Gupta removed, instead of dying of pneumonia as stated on his death certificate?

In response:

1. There are a number of parts to this question.
 - a. The first issue is to consider why there was "milky mucous" present. This may represent white mucous with no milk, or thick milk which looks like mucous. Dr Gupta has clarified the intent of his comment. He meant that there was white mucous with no milk.
 - b. The family ask whether this could be evidence of there being a reaction to the milk. If there were milk present, it would not be evidence of a reaction to the milk, only of reflux of milk from the stomach. However, it is not evidence of the lack of reaction either. It does not lend any evidence to the question of whether there was a reaction to the milk.
2. The emergency response of the team to Jonnie's deterioration is as quick as I would expect from any unit. Jonnie's family are suggesting that the mucous removed from Jonnie's airway might have been responsible for stopping his breathing and so being the cause of his death. This is not an unreasonable consideration. I would however have expected that if this were the only thing that had led to Jonnie's deterioration that the removal of the obstruction and subsequent intubation (the tube being put in Jonnie's throat to take over his

breathing) would correct this. Jonnie should have recovered, or at least stabilised for a time. At the time Dr Gupta arrived Jonnie was bradycardic. Reversal of hypoxia (poor breathing) will typically lead to improvement in this situation where the cause is removed.

3. There are some inaccuracies in the question (bradycardia and asystole cannot go together) but I understand very well what is being asked. It is closely linked to the second question. Jonnie's family consider that there may have been a blockage to Jonnie's breathing. As with my response to the second question, I would consider this to be a possibility too. However, the obstruction alone seems unlikely to explain the events that follow after Dr Gupta intubates Jonnie. A better explanation would be that the obstruction was caused by refluxed milk and that the milk was then aspirated into the lungs. There was no evidence of aspiration at post mortem though. Overall I find this explanation less likely than Jonnie having had an anaphylactic reaction.

In broad terms, Jonnie's family wonder if the resuscitation was appropriate and if the response had been faster whether Jonnie would have survived. I can see little to suggest this is true. Jonnie's deterioration is dramatic and unexpected. The response to the deterioration is appropriate and were there to be a simple, correctable problem I think that Jonnie would have recovered. What is more difficult is to explain why he deteriorated and did not respond to appropriate resuscitation. That indicates that the cause of his deterioration was more complex and more severe than a simple obstruction. Anaphylaxis to milk or aspiration of milk become the most compelling explanations. The lack of post mortem evidence of either is a conundrum. Evidence in anaphylaxis² indicates that no findings at post mortem is in fact common for anaphylaxis. Hence, I consider this the most likely explanation for Jonnie's death.

Answering Concerns about the Child Death Overview Panel (CDOP)

There are a large number of documents that were made available to Jonnie's family originating from the CDOP panel. They are confusing in the format that they were provided.

Jonnie's family found these documents difficult and I too was confused by the documents. Despite having an understanding of our local CDOP group I concluded incorrectly what forms related to which event. The documents led to Jonnie's parents concluding that the CDOP was provided with incorrect information.

I was assisted in interpreting the documents by meeting with Mark Dean, Chair of Staffordshire and Stoke-on-Trent Child Death Overview Panel, and John Wood, Independent Chair of Staffordshire Safeguarding Children Board.

The documents had been provided to Mid Staffs Trust who had then copied and re-ordered the documents. The Trust had released the documents without further explanation.

There are redacted (blacked out) parts to the documents. I was shown the documents without the redactions, and was able to confirm the appropriateness of the redactions. Despite the documents being for CDOP, the information within them is entered electronically by other agencies. The forms are standard across the country.

Form A

This is a notification of death completed from the Police system to CDOP. It looks to have been transcribed directly from another document (very similar details are present in the Guardian System which would have been completed initially).

Form B

This is an information collection form. It is completed by other agencies and submitted to CDOP. One of the forms includes an apparent statement from Lauren Tew. It seems to be completed by someone who has spoken with Ms Tew about events rather than Ms Tew herself. The author of this document is recorded electronically as Staffordshire Social Care Children and Families Independent Futures.

This apparent statement from Ms Tew caused significant confusion, and added to Jonnie's Parents view that incorrect information was being provided to the CDOP.

Form C

This is the only document that is seen by the CDOP committee. It is a summary of the information gathered for the CDOP process. None of the information that Jonnie's family considered contentious appears on this document.

I found nothing to indicate that incorrect information reached CDOP.

Guardian System

This is a Police system that gathers information as an enquiry is opened. In the documents provided this system have a title "Action Enquiry Log". It is a confusing set of pages that were unhelpfully incorrectly ordered and have multiple redactions (blacked out areas). With explanation it is possible to understand the documents. They run as a sequence of entries by Police Officers. The authors identity and time / date are recorded. They commenced as soon as notification of Jonnie's death is received by the Police. The initial entries are inaccurate and poorly written. However, they are intended merely as a simple note pending further information which will be available later.

It is the Guardian System which is the source of a number of Jonnie's Family's concerns. The entries incorrectly refer to Jonnie having "had previous cardiac arrests and has been

resuscitated in the past 2 – 3 times”. Whilst this is inaccurate, it seems to be innocently inaccurate. The information is entered after a brief telephone conversation by a person who has no involvement with the case and no knowledge of the case. The entry carries no significance for later enquiries.

CDOP

The outcome of the CDOP is recorded as a document which contains other discussions and business. There is only brief record of Jonnie’s case. The output of the CDOP group includes the submission of data to the Department of Health.

“Minutes of Final Case Discussion for Jonnie Meek”

This document was included as part of the documentation for CDOP. I incorrectly had assumed it made up part of the discussion process for CDOP. Jonnie’s parents had viewed the document similarly.

Mark Dean explained that this was not part of CDOP process. It was in fact a meeting that Mid Staffs Trust had arranged for their own purposes. It did not form part of the CDOP process.

Panel

Dr Manzoor – Designated Doctor For Unexpected Death (Chair)

Rebecca Sage – Nurse Practitioner for CDOP

Kim Wooliscroft – Head of Paediatrics (Advanced Nurse Practitioner)

Dr Oso – Consultant Paediatrician (present during the resuscitation)

Dr Melville – Consultant Paediatrician (General Paediatrician with interest in Allergy)

Lucy Preston – Dietician (who had arranged the trial of new milk)

Michelle Lyons – Community Nurse (present during the resuscitation)

Jonnie’s GP and the Pathologist did not attend

This document is clearly written. It summarises the discussion held at a meeting. The document records there was no rash, though that seems to be a difficult conclusion given conflicting accounts.

Dr Melvin (presumably Dr Melville) indicates that Jonnie has been very unwell previously. 2 – 3 months previously he is said to have been critically unwell with pseudomonas and had iv antibiotics for 3 weeks. Jonnie’s parents found this to be a misleading statement. It probably overstates the severity of Jonnie’s illness at that time. However, Michelle Lyons in interview confirmed that there had been a wish to discuss an Advanced Care Plan during this admission and is in keeping with a view that he had a limited life expectancy.

The document concludes that there was nothing to indicate Jonnie had aspirated, and nothing to indicate he had an allergic reaction. It fails to address the post mortem finding of Pneumonia (this does not seem to have been discussed). The document would only seem to be concerned with what didn’t cause Jonnie to die, rather than what did.

Conclusions

- The documents provided as a record of CDOP are misleading in the format that they were provided. They needed some level of explanation. Jonnie’s family

reasonably concluded that the information provided to CDOP was inaccurate. The information in fact seems to have been accurate, however some of the early parts of information collection are inaccurate. There is no conflict for CDOP as the early information is recognised as inaccurate and not provided to the committee. Because of the way that the information was provided to Jonnie's family this was not clear to them. Until it was explained, it wasn't clear to me either.

- CDOP is an overview panel with statutory responsibilities. It must provide data about cause of death according to strict criteria. It meets, reviews and reports only at the end of the process of reviewing children's deaths. The coroner's hearing will be concluded before CDOP review the case, as will the Acute Trusts internal review processes. CDOP will therefore receive information that it will be poorly positioned to challenge. The group will inevitably conclude what it is "told". The family's view (or arguably "the voice of the child") is not heard in this process. There is nothing unusual or unique about the process in Stafford. It is likely to be the same for all CDOP groups. In Jonnie's case the CDOP group recorded only what had been already concluded. They missed an opportunity to resolve a conflict. They were adequately powered, but only arrived at the finish. There is an opportunity for CDOPs to develop a greater role in the overview of child deaths. In order for them to achieve this, they need to be actively involved from an earlier stage, and they need to hear the voice of the family. If they had, then they could have been a powerful advocate for Jonnie's family's concerns.

Responses to Complaints

My conclusions to this report are at odds with the responses made to Jonnie's family by Mid Staffordshire NHS Trust.

Jonnie's Family offered the Trust an opportunity to rethink what had happened and review the care that had been given. They pointed out some omissions in the considerations that had been given to Jonnie's case. At the core of their complaint was the belief that Jonnie had died because of a reaction to the milk that he had been given as a test feed. They felt that this was the most obvious explanation for the events leading to his deterioration. It was an entirely logical case. It deserved consideration. Had that consideration been given I would not be writing this report and the organisation would have learnt important lessons. It is self evident from the conclusions of my report that I consider the complaints process to have failed.

I have the letters and transcript from a meeting with the Trust. I do not consider that responding to each point in turn is a helpful process. I would prefer to make a few short comments.

- The Complaints Process failed to give adequate consideration to Jonnie's parents' concerns.
- There seems to be little if any independent scrutiny given.
- There is a failure to consider the broader points that Jonnie's parents are making
- The letters are long and impersonal.

Interviews

21st October 2015 - Parents

We met at Jonnie's parents house to discuss the preliminary report and the conclusions to that point in time. We clarified some remaining concerns.

The following Professionals were contacted for interview

Dr Oso and Dr Gupta Consultants present at resuscitation and who knew Jonnie from previous care.

Michelle Lyons - community nurse who was part of the initial response to Jonnie's deterioration in the hospital and had cared for Jonnie at times prior to this.

Amanda Nicholls - Nurse caring for Jonnie in his last illness

Lauren Tew - HCA who was present on the ward as Jonnie's Freedom Support Worker

23rd November – Healthcare Professionals

Interviews were conducted with Dr Oso, Dr Gupta and Michelle Lyons. These were held at Stafford CCG.

I was not able to meet with Lauren Tew or Amanda Nicholls on this day.

30th November – Lauren Tew

I was able to talk with Ms Tew on 30th November 2015. We spoke on the phone. Ms Tew was pleased to be contacted. She found it odd that no-one had previously made contact with her about Jonnie's case. She remembered events clearly. She knew Jonnie and his family well and cared very much for them. We discussed events of the 11th August 2014. Lauren's memory of events was very similar to Michelle Lyons' recollection. Lauren had been present at the start of the admission however. She considered that Jonnie had been well at the start. She was aware of how anxious mum was. She remembered the saturation monitor having caused problems right from the beginning of the admission. She confirmed the review that happened after about an hour of Jonnie having the new feed. She remembered him becoming less well and needing oxygen which she had held over Jonnie. This was unusual from her viewpoint. He didn't normally need oxygen. She remembered Michelle Lyons visiting and the final call for help using the emergency buzzer. The team arrived very quickly and she was then moved out of the room. There were lots of people.

Lauren confirmed that she had never given a statement to the CDOP panel. I read the entry in the CDOP form to her. She didn't consider that it was a reasonable reflection of her memory of events. She didn't consider that April had been holding Jonnie, or specifically that he went rigid. I explained that we had now electronically tracked the document to Staffordshire Social Care Children's and families Independent Futures. Lauren told me that they had not taken a statement from her, but she had discussed Jonnie's case with her manager.

Amanda Nicholls – Ms Nicholls now works for another NHS Acute Trust. Stafford CCG worked hard to identify her whereabouts and make contact. The interviews had been booked for 23rd November. Ms Nicholls was contacted in the week prior. She indicated that she didn't expect to be able to attend, and we confirmed that a telephone conversation would suffice. On the 23rd November contact was made, but the Trust told us that Ms Nicholls would not be available to speak to us. They told us that she had

spoken with her Union rep and with her manager. They had advised her not to talk with me.

On the day of the interviews I called the Trust to confirm that there hadn't been a misunderstanding. I explained that we had no criticism of Ms Nicholls and simply wanted to confirm an understanding of events. I was interested to ask about rashes and saturation monitors. I was told that if I had no criticism of her, that "I had no need to speak to her anyway".

We were emailed instruction that we would need to give Ms Nicholls "formal request in writing". The Trust also expressed that they would not release her during working hours.

I was already aware that Ms Nicholls was fearful. There is enough information from the interaction with the coroner. I had hoped to ask some questions for clarification. I had also hoped to tell her that Jonnie's parents don't blame her or feel that she let Jonnie down (they had expressed this when we met). My concerns about Jonnie's case does not include concerns about the resuscitation. To my knowledge, concerns have not been expressed about the resuscitation at any point. I am unaware of any criticism of Ms Nicholls.

It is possible to understand the response from Ms Nicholls. It is very difficult to understand the response from her new employing Trust, or the advice that she has been given.

My reason for including this story is because of its resonance with Jonnie's parents' story as a whole. They had sought reasonable clarification and been met by a closed, unhelpful response. They resorted to complaining only when their questions weren't answered. Ultimately they were given a response that gives an impression of there being something that needs to be hidden.

My contact with a different Acute Trust met the same closed, unhelpful response. It is difficult to see why the organisation would consider it unreasonable to talk to Ms Nicholls on the telephone. Even more it is difficult to understand what is gained by a "formal request in writing" other than delay. Again it gives an impression of there being something that needs to be hidden.

Two different Trusts. Two different times. Neither Trust had a reason to hide. Both responded in the same closed unhelpful manner.

The NHS has been widely criticised for this behaviour. There has been much talk of Duty of Candour. I found myself in the same position as Jonnie's parents. On the outside, unable to find a way in to ask simple questions. Blocked by fear.

A Sort of Ending

This report starts with Jonnie's Story. All stories should have endings. So far, this story has failed to reach an ending. I doubt that this report will represent an ending in itself, but I hope that it will allow Jonnie's family to reach an ending which makes sense to them.

The responses to Jonnie's family's complaints are the final steps in the story that I am to summarise. Throughout the story there are 2 competing narratives, that of Jonnie's Parents and that of the Professionals involved in Jonnie's care. I am aware that Jonnie's family fear there may have been a conspiracy. I understand that they consider that there may have been people who colluded together to cover up events. I can see no evidence that this is true.

However, throughout the story there is another narrative. It is one of convenience. The finding of pneumonia by the pathologist was convenient. It meant the professionals involved not needing to consider other issues. It was accepted by all those involved other than Jonnie's family.

Conclusions and Recommendations

1. The trial of “whey based” milk in a child managed with “hypoallergenic” milk was inadequately supervised and the deterioration was not managed in an expectant way. Management of resuscitation did not consider the possibility of anaphylaxis.
 - I recommend that advice should be sought from allergy experts and a pathway for care of children being reintroduced to Cow’s Milk (and other non hypoallergenic milks) should be considered.
2. The failure to give adequate consideration to an anaphylactic reaction as a potential cause of death is surprising. It is the most obvious cause for deterioration given Jonnie’s reason for admission. Reporting the cause of death as Pneumonia is at odds with the clinical information and this contradiction should have been noted. There should have been at least an expression of uncertainty.
 - It is my opinion that there should be a further inquest into the cause of Jonnie’s death where the information available during Jonnie’s life is given greater consideration.
3. The Child Death Overview Panel (CDOP) failed to notice any discrepancy between the cause of death and the information available during life despite Jonnie’s parents’ concerns. There is an opportunity missed by CDOP to provide an impartial overview. The system is designed such that CDOP is the final step. If it were to maintain a view throughout the process and hear the voice of the child through their parents, then its role could be greater than it currently is. There is no reason to consider that this is an issue specific to an individual CDOP.
 - I consider that CDOP processes should be reviewed. There are opportunities for the Panel to give an independent view and act as an “ombudsman” for families that are not currently taken.
4. The opportunity to learn from Post Mortem is limited by the lack of clinical correlation. There is little or no link between the clinical team and the Pathologist. From my experience this is not a problem isolated to this case. The unexpected nature of Jonnie’s death should have led to the exploration of “all possible causes” including malevolent ones.
 - I consider that it should be routine for pathologists and clinicians to discuss cases both before and after the post mortem particularly where there is an unexpected death of a child.
 - Where there is an unexpected death of a child there should be routine investigation for malevolent causation.
5. The response of Mid Staffordshire NHS Foundation Trust to the complaints of Jonnie’s family was poor. There is little evidence of the open culture that is aspired to by the NHS. Our contact with a separate NHS Trust during the review suggests this is not isolated.

- I consider that problems of a closed culture within the NHS continue to exist. Expectation of blame leads to defensive behaviours. There should be an expectation within NHS organisations that they will openly co-operate with reviews of care performed within the NHS.

It would be wise for the CCG to seek opinions from specialists in the areas that are questioned. Specifically, an allergy specialist and a pathologist.

Addendum

Nutramigen AA (a hypoallergenic milk suitable) – extensively hydrolysed casein based formula. This is intended for use with cow's milk allergic children. Reaction to this milk is exceptionally unlikely.

Peptamen Junior Advance (a less hypoallergenic milk) – This is a whey based protein feed. It is intended for use with gastrostomies. It is not one of the extensively hydrolysed formulae. Proteins are broken down to a lesser extent. Reaction to this milk is less likely than to a normal casein (cows milk) based formula, but more likely than to an extensively hydrolysed formula normally used for cow's milk allergy.

Appendix

Document log

Terms of Reference

Hospital Records

Parents' Complaints

Initial Complaint Response

CDOP Report and associated FOI release documents

Post Mortem / Pathology Report

Coroner's inquest notes

Notes of meetings between parents and NHS Stafford and Surrounds CCG

MSHFT / UHNM Complaints Response

References/ Sources

1. Orphanet 18 p deletion syndrome (De Grouchy Syndrome)
2. Pumphrey R et al, Post mortem findings after fatal anaphylactic reactions. JClinPath 2000, 53 273-276
3. RCP anaphylaxis recommendations for Post Mortem
4. Guidelines on Autopsy Practice : Autopsy for suspected acute anaphylaxis RCP 2012
5. Resuscitation Council (UK) Anaphylaxis Algorithm
6. RCPCH Pathways: Allergy Care 2011
7. NICE Guidance for Food Allergies in Children (Clinical Guideline 116)
8. NICE Guidance for anaphylaxis (Clinical Guideline 134)
9. Data Card for Nutramigen AA
10. Data Card for Peptamen Junior Advance