

THE MORECAMBE BAY INVESTIGATION

University Hospitals of Morecambe Bay NHS Foundation Trust (UHMBT)
Maternity and Neonatal Services Investigation

Thursday, 12 June 2014

Held at:
Park Hotel (Council Building)
East Cliff, Preston, PR1 3EA

Before:

Dr Bill Kirkup CBE – Chair
Mr Julian Brookes – Expert Adviser, Governance
Ms Jacqui Featherstone – Expert Adviser, Midwifery
Professor Jonathan Montgomery – Expert Adviser, Ethics
Dr Geraldine Walters – Expert Adviser, Nursing

Ms Oonagh McIntosh – Secretary to the Investigation
Mr Nick Heaps – Deputy Secretary to the Investigation
Ms Hannah Knight - Analyst

PANEL MEETING

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1 [11.19 a.m.]

2 CHAIR: Hello, and welcome everybody. This is another meeting of the Morecambe Bay
3 Investigation. I think it is going to be a relatively brief meeting but it is important that
4 we do cover the items that are on here. We have apologies from Catherine, Stuart and
5 Jimmy; everybody else is here, thank you.

6 Matters arising from the last meeting.

7 MS MCINTOSH: The only matter that we discussed at the previous meeting that remains
8 ongoing is about the exchange you are having with the former Parliamentary Health
9 Service Ombudsman and her deputy, and you did say that you would keep your Panel
10 members updated on the progress.

11 CHAIR: Indeed.

12 MS MCINTOSH: So that is the commitment we've had.

13 CHAIR: We have made significant progress in the case in that we have had access to the
14 relevant internal documents. We are still involved in discussion with the previous
15 Ombudsman and her previous deputy about coming to talk to the Panel about the
16 events. That is not resolved yet. As soon as it is, I will let you know.

17 MS MCINTOSH: That was it.

18 CHAIR: Okay. Feedback from subgroup leads – shall I start on behalf of Stuart, who is not
19 here? I will just run through the state of progress on the clinical records reviews. We
20 had 31 that were included in the initial batch of files from Cumbria Constabulary, of
21 which 23 were relevant to the investigation. 21 one of those have now had full review,
22 so two outstanding. We had 23 responses altogether to the request for further people to
23 come forward. We determined that six of those would require a full review, which are
24 all outstanding. We also had information about 202 still births, and that is internal

1 deaths, of which 125 had been screened and 20 required a full review, one of which is
2 complete so 19 outstanding. So to do, to complete that process, we have 77 screenings
3 to complete, 27 full reviews and probably a further 10 or so full reviews that will be
4 generated by the 77 screenings. That is on the basis of the same sort of hit rate that we
5 have at the moment.

6 Stuart's view, and I agree, is that, if we set aside a further two day period, we
7 can do all of those and will have completed the clinical case note review part of the
8 Investigation. I am keen to do that as soon as we can because I would like that to be in
9 place and for the themes that have emerged to inform the interviews.

10 The themes that are emerging are, I think, reasonably clear at this stage but
11 obviously we shouldn't finalise them until they are quite clear. I don't think they will be
12 any great surprise: dysfunctional staff relationships; poor assessment of risk pre and
13 post-delivery; an issue about when people are transferred to another centre because
14 they're not a suitable risk level to be delivered in Barrow and to be kept in Barrow as
15 babies; and some evidence of failure to follow up clinical anomalies that are identified,
16 so, for example, raised blood pressure or people with questionable foetal heart rate
17 traces, where they've come in and had that done because they reported a reduced foetal
18 [inaudible]. We will complete the process hopefully within a couple of weeks and we
19 will formalise that and keep the Panel fully informed about it for the relevant clinical
20 interviews.

21 Any comments or questions on that one?

22 PROFESSOR MONTGOMERY: I am just wondering what format of feedback to the Panel
23 would be once those two days have happened and we're doing it. What's the way in
24 which we get our head around the implications of that for undertaking the interviews

1 that we need to do?

2 CHAIR: I think we do a formal record of that phase of the Investigation and the themes that
3 have emerged and begin to develop them into questions. Obviously it is for the
4 subgroup members to actually follow that through. I think we could give an indication,
5 but we'll have a proper discussion about that, and we can question the members of the
6 clinical subgroup.

7 MS MCINTOSH: We do have a Panel meeting on 10 July, I think. Obviously, the
8 conversation we had and are going to have about the interview programme, there may
9 some interviews scheduled, but, actually, if the Panel are all physically present on 10
10 July, that might be an ideal opportunity for the clinical subgroup to give feedback in the
11 Panel meeting to assist fellow subgroups. I think it is the 10th, I will check, so if that
12 assists you for further interviews.

13 PROFESSOR MONTGOMERY: I think that would be helpful because we don't want to miss
14 some questions that should be asked by not understanding the findings.

15 MS MCINTOSH: I will make sure that is a formal agenda item then and make sure Stuart is
16 prepared.

17 MR BROOKES: I am just going to raise this question as a general question: are we confident
18 that we have not found anything of a clinical nature in our reviews which require
19 immediate feedback to the Trust? I am saying that on the basis of some of the
20 conversations we have had coming out of the Fielding discussion and I'm just asking
21 that as a standard question. There's nothing in there that would raise serious safety
22 concerns that we feel are required to be fed back to the Trust at this stage?

23 CHAIR: I mean, my biggest concern I think was about the evidence of dysfunctional staff
24 relationships, but that was something we specifically went and tested at a very early

1 stage when visiting Barrow.

2 MR BROOKES: I'm hoping the answer is no, but I felt it was just important to raise that.

3 CHAIR: I think it's important that we have said that there's a process that will specifically
4 address that.

5 PROFESSOR MONTGOMERY: Yes.

6 CHAIR: Okay, Geraldine.

7 DR WALTERS: Not to a lot to update. We have not met for a while but just to sort of try to
8 set out the way we are thinking and this is sort of up for challenge. In terms of the
9 questions we tried to answer, I think, are: did the Trust know that there was a problem,
10 and, if they did, were they doing the right things about it? So I think what we need to
11 look at is, first: were there any reactive indicators which the Trust were receiving, so:
12 'You've got a problem'. I think from looking at the data which Hannah has showed so
13 far, I think the answer is probably a no. In some of the documents that I have looked at,
14 there are things like the local supervisor of midwives report; nothing of note there. The
15 patient survey through the years we have been looking at; nothing of note there, in fact
16 quite positive. The Deanery reports from the students; nothing of note there either.

17 Looking through some Trust board papers, which has not been terribly
18 systematic at the moment, they did have processes, they did an integrated governance
19 report. Whether it would allow you to be really sophisticated enough to look at trends, I
20 am not sure it would but then I don't think that's hugely different from what [inaudible]
21 reports that they have looked at. In terms of what information was hitting them in the
22 face, from what I've seen so far there wasn't very much of it, objective information.

23 I suppose the next bit is to look at: what sort of proactive processes did they
24 have to seek out whether things were okay or not? I think, because of the sort of mass

1 of documents, some of that will need to come through the interviews to ask them what
2 they did and what they looked at.

3 The other inquiry really was: how did they respond to sort of subjective
4 concerns, so things like complaints, was there whistleblowing going on and how did
5 they respond to that? So in their heads they may have been thinking, 'Right, we've got
6 a worried person here. Actually, all our data looks fine, so I think we've just got to try
7 and reassure that person.' But we haven't seen yet complaints responses and we
8 haven't seen the SUI reports to know how carefully they looked at some of the stuff that
9 you've been looking at.

10 I think in terms of just the general housekeeping and quality of governance
11 processes, I think we've got to be really mindful that if you scrutinise an organisation's
12 governance processes retrospectively and be very picky about it, you will always be
13 able to find a problem. I think we've got to be very careful that we are doing everybody
14 justice here.

15 Certainly, through looking at emails around how they were responding to the
16 gold command, they were taking it terribly seriously: private board reports discussing
17 various issues; they were actually very worried. I think what we need to know is: were
18 they actually doing anything that they were worried about? I think it would be really
19 helpful to look, when we hear the feedback from the clinical group, so that we get a
20 much better understanding of what the real themes were from that interrogation of the
21 records. I think then we have to make a decision about, if these were all big problems,
22 again, what we would have expected them to do and what we would have expected the
23 overarching organisation to do to help them? So, if there is a problem with scale, if
24 there is a problem with not being able to get the right amount of staff, if there is a

1 problem with not being able to recruit the right people, none of that is easily resolvable
2 from within an organisation in a very short timescale. I think they are some of the
3 things that we need to be talking to the interviewees about, and also seeing if we can we
4 target some of the documents to find some of those specific questions.

5 I would be very happy if anybody has got any points, or if you think we're
6 going down the wrong path or going to have problems.

7 CHAIR: Any views? Any comments? Sounds like the right track to me. Thank you.
8 Jonathan.

9 PROFESSOR MONTGOMERY: I am not sure there is much to report that you won't be
10 aware of, in that we now have four more boxes of legacy documents which we have
11 been through, of about six that are there, and there is material in that which I think is
12 going to be helpful to us, which is more than could be said for the first box, I think,
13 where there was a lot of material that was not helpful. We had set out to start by
14 interviewing the report authors and most of those are now in the schedule and we're
15 keen to get started, as people know. I think the experience from the first of those with
16 Dame Pauline Fielding was that, as one might expect, it threw out as many questions as
17 answers but they have been able to clarify questions about what we are seeking to find
18 out, so we have been able to focus the questions that we want to ask the other two
19 members of that panel much more precisely. I hope that will be the pattern as we go
20 through the other reports.

21 I think what is emerging from that for me is that there's a set of key themes
22 which we need to pick up. There are decisions at various stages around Terms of
23 Reference, which shape the history of what was understood to be the problem and what
24 wasn't understand to be the problem, some of which made clearer sense than others

1 from outside. I think that is a key set of questions which only became really apparent to
2 me, from the two interviews we have done so far, quite how important they were in the
3 process. I think there is a theme running through about clarifying points of decisions
4 about division of labour.

5 I think that then merges into a second theme, which is around coordination and
6 did anybody either have an overview of what was going on or feel responsible for
7 coordinating, because a number of assumptions seemed to be made about what other
8 people were doing. That does emerge around gold command, I think, in some sense,
9 coordination; it would be an interesting question to ask about what that looks like.

10 Then the third theme, I think, is around follow-up systems and their existence
11 or lack of. They all overlap, those questions. Julian and I are going to spend a bit of
12 time after this meeting and before the interview tomorrow perhaps trying to take stock
13 of where we have got to in a bit more detail, but I think that is a flavour of where we are
14 at at the moment.

15 CHAIR: Thank you, good progress all around. Item 5, data requirements.

16 MS KNIGHT: So, rather than data requirements, this is more like presenting some new
17 comparative and longitudinal analysis on the neonatal morbidity and also mortality at
18 the Trust between 2004 and 2012. This really completes the analysis of the hospital
19 episode statistics data that was commissioned through the Royal College of Surgeons,
20 or rather it completes the initial data analysis that was requested back at the beginning
21 of the year.

22 So the four things I am going to be presenting today, two morbidity measures,
23 firstly, a composite neonatal adverse outcome indicator, which I will talk about first.
24 Then I will present some data on unplanned neonatal readmission within 28 days and

1 then I will present some data done previously on stillbirth and neonatal death in a
2 risk-adjusted longitudinal format.

3 Firstly, a bit of a health warning about the completeness of this data. I've done
4 a case-ascertainment exercise looking at data in the HES compared with the births
5 registered in the ONS birth register. The blue bar here is ONS number of births and the
6 red bar is the raw HES data; the green bar is once I've taken out duplicate records and
7 cleaned up the HES data. You'll see that every year there is a gap which is about 4% of
8 all births not in HES that have occurred. That is largely accounted for, I suspect, by
9 home births and births not in NHS hospitals which will not be going into HES.

10 CHAIR: I am slightly surprised that amount is almost 4%.

11 MS KNIGHT: There is probably about [inaudible] 3% based on the latest available figures
12 from the birthplace study, so there is a discrepancy about 1%. This is a national level.

13 The second thing I've been able to do is compare the number of births in HES
14 at the Trust with the number of births recorded in the Trust's own electronic maternity
15 information system. Again, we're finding a discrepancy. The information system was
16 introduced at the Trust in 2005, so I think by 2006 they were – they came to grips to
17 with it and were recording all births. Since that time, there has been a discrepancy of
18 about 150 births per year that are known to have taken place in the Trust but are not in
19 HES. I don't think that that is unusual; I think other Trusts will have the same, but there
20 may be a recommendation around that because what this means, if births are not finding
21 their way into our national database, we cannot follow up what is happening to those
22 babies.

23 CHAIR: Any suggestion that that systematically reports cases that we would be interested in?

24 MS KNIGHT: I will present in a moment – I know at least two of the index cases of interest

1 to this Investigation are not in HES because they have not been picked up when we
2 have linked HES with the death register, to look at neonatal death, so two of the high
3 profile index cases are not in HES.

4 DR WALTERS: Is that because they are stillbirths and not neonatal deaths?

5 MS KNIGHT: Stillbirths should be in HES as well.

6 CHAIR: There is a less sinister explanation, which is that, because they were going through
7 other processes like the root cause analysis and so on, the notes never got properly
8 processed.

9 MS KNIGHT: It is quite possible.

10 CHAIR: And there is a slightly more sinister explanation, which is they don't want it to go in
11 HES.

12 MS KNIGHT: I will start off with this composite indicator, looking at the range of adverse
13 outcomes. It is not something that I have just invented; it is based on work done in
14 Australia, which I've been able to replicate using the HES database. I will present the
15 individual components of the indicator in the next three slides. This is based on a
16 diagnosis or a procedure formed or made before the baby's first discharge home, so it is
17 including diagnosis, obviously, that has been made if baby is transferred to another
18 hospital, any procedure or diagnosis made before it was discharged home for the first
19 time.

20 DR WALTERS: Would that include just things like a bit of glucose?

21 MS KNIGHT: No, we are only looking at severe – so these are the specific diagnosis that I
22 have included: so we've got respiratory distress syndrome, seizures, TVH rates of two to
23 four, cerebral infarction, periventricular leukomalacia, birth trauma, hypoxic ischaemic
24 encephalopathy, necrotising enterocolitis and bronchopulmonary dysplasia. Here I

1 have, for the whole of England, the incidence of these diagnoses for two different
2 gestational age groups, and then here on the right is the incidence at the Trust. I have
3 highlighted in blue the incidence rates which look particularly low compared with the
4 national average and in red those that look particularly high, so it is double or more.

5 CHAIR: That is not a formal significance test?

6 MS KNIGHT: It is not a formal significance, it is just eyeballing the data. It is based on very
7 small numbers sometimes, particularly for this group, the 33 to 36-weekers.

8 PROFESSOR MONTGOMERY: Just a presentational point, if we're going to use any of this
9 in the Report, I'd find it a lot easier to do that if we have the gestational weeks together,
10 so you have the two columns right next to each other when we are comparing. It just
11 makes it easier to see.

12 CHAIR: Does that pick up babies who are delivered at Barrow but transferred?

13 MS KNIGHT: Yes, so, if a diagnosis was made after they were transferred, it would be
14 picked up, unless they were discharged at home and then readmitted somewhere else.

15 CHAIR: Sure.

16 PROFESSOR MONTGOMERY: A second question. There is one question about: was it any
17 different from elsewhere? There is another question about: was there any expectation
18 that it could have been picked up? Is there any way that this information would have
19 been known to the Trust without you having some work done on it?

20 MS KNIGHT: No, I don't think this sort of data would have been available to the Trust. This
21 is a retrospective analysis. They could not have been expected to necessarily know
22 particularly if a diagnosis was made elsewhere.

23 PROFESSOR MONTGOMERY: That is what I thought, because they are two separate
24 questions, I think.

1 MS KNIGHT: The things that stand out as being high, which I have highlighted in red, are
2 the IVH rate amongst the 33 to 36 weekers, and periventricular leukomalacia and
3 bronchopulmonary dysplasia. I would highlight that these are based on very small
4 numbers because very few of these have fallen into the gestation age range. Moving on
5 to some additional diagnoses, the sepsis rates are very much in line with the national
6 averages. The only things which stand out here are transient tachypnea, where there are
7 slightly higher rates at the Trust in both gestation age groups, and severe birth asphyxia,
8 which is of interest given some of the index cases that we have.

9 CHAIR: Yes.

10 MS KNIGHT: However, they have much, much lower rates of hypoxia in labour reported, so
11 I wonder if some of this could perhaps be explained by coding discrepancies with cases
12 of hypoxia being called asphyxia.

13 PROFESSOR MONTGOMERY: How many cases were in those two categories?

14 MS KNIGHT: I wouldn't like to guess. I would have to go and check the actual numbers, but
15 0.3% – this is an eight year period. I would have to go and check.

16 PROFESSOR MONTGOMERY: I am just wondering, if we say severe birth asphyxia is
17 twice as many as we expect, but if it's just one extra, that's very different.

18 CHAIR: It's got to be more than that, but we're trying to have a feel for it.

19 PROFESSOR MONTGOMERY: It may not be worth asking that question.

20 CHAIR: I'm not so likely to accept, without a bit more challenge, the explanation that this is
21 just coding and that they've stuck them down as severe birth asphyxia instead of
22 hypoxia. It seems to me that that is also compatible with under-diagnosis of foetal
23 distress in labour and being taken by surprise by distressed babies when they are born,
24 which is exactly compatible with some of the things that we have picked up in the

1 clinical reviews. We just have to bear that in mind, I think.

2 PROFESSOR MONTGOMERY: I think that goes to the separation of the questions as to:
3 what would you expect someone monitoring it from outside to get flagged up, and what
4 does it tell us about what might be going on in clinical practice?

5 CHAIR: Yes, I think that is exactly right. To expect a board or a quality committee or
6 something to be monitoring this and picking it up might be too much.

7 [Crosstalk]

8 CHAIR: But, I think, as a signal of something which you are getting other signs of from
9 within the Trust, looking at complaints and incidents and all of that, then it is
10 interesting evidence.

11 MS KNIGHT: The final components of this indicator are procedures and we've got
12 resuscitation and ventilatory support, central venous and arterial catheter, transfusion of
13 blood or blood products, pneumothorax and then any body cavity search or procedure.
14 I haven't actually ended up including resuscitation in the final composite indicator
15 because there is definitely an issue with coding going on at the Trust, because I have
16 looked over time and the incidence of resuscitation is very much in line with the
17 national trend, and then in the last year and a half it goes way up like this, which cannot
18 really reflect clinical practice. There's something odd going on. So I have removed
19 that component.

20 DR WALTERS: Presumably babies can only go into one of these categories, can they?

21 MS KNIGHT: No, they can go into several.

22 DR WALTERS: Because the resuscitation, therefore, looks a bit too high compared with
23 what is in the other categories.

24 MS KNIGHT: That is why I have said there is definitely a coding problem going on with

1 resuscitation at the Trust so I have removed that component from the indicator.

2 CHAIR: Again, it is tempting to suppose that that reflects an anomaly, that the high level
3 reflects an anomaly later. We do just have to bear in mind that it is also compatible
4 with the underreporting of a high resuscitation rate earlier, which would fit with a
5 pattern of unexpectedly distressed infants being born with hypoxia.

6 MS KNIGHT: That's something I can certainly look into more and present to you.

7 MR BROOKES: They are all Trust wide.

8 MS KNIGHT: The whole Trust.

9 MR BROOKES: There's no way of indicating per hospital?

10 MS KNIGHT: I can look at a hospital level but the numbers would be small.

11 MR BROOKES: But there might be some – if there is a massive variation between sites, that
12 at least tells us something.

13 MS KNIGHT: This slide is about the validity of this indicator and of the testing. The graph
14 here shows the incidence by gestational age week, which fits in very much with what
15 the Australian group found and that one would expect. I've also followed up the infants
16 who have been flagged as having this indicator, and are 18 times more likely to die
17 before their first birthday and almost three times as likely to be readmitted to hospital
18 before their first birthday than babies who are not flagged as having this indicator, so I
19 think it is picking up sick babies reasonably well. However, as I said before, if the
20 baby's birth record is not entered into HES, there is no way that we can then pick up
21 these adverse outcomes.

22 DR WALTERS: So is that picture – that is a normal distribution of that, do you think, on the
23 previous slide?

24 MS KNIGHT: This previous slide?

1 DR WALTERS: No, sorry, next one.

2 MS KNIGHT: That is typical.

3 DR WALTERS: Would you expect to go into any organisation and see figures like that?

4 Because we were querying whether they had more problems in term babies, weren't we.

5 MS KNIGHT: In fact, for all of the analysis that I present from now on, I've done two

6 separate populations, one all babies and the second term babies more than 2,500g to see

7 whether they differ from the national average for that latter groups. These are trends

8 amongst all live born infants unadjusted for any case mix variables; in blue you have

9 the national average, in red is RLI – Royal Lancaster Infirmary – and, in green, FGH,

10 and, in purple, Westmoreland General. So there is nothing particularly unusual going

11 on. You would expect with small numbers for there to be considerable fluctuation from

12 year to year. Apart from this period here, it is below the national average.

13 CHAIR: What it shows clearly, though, is that the risk selection looks as if it is working at

14 Westmoreland, because you have a much lower level than expected.

15 MS KNIGHT: Yes, yes.

16 CHAIR: As would you expect from that kind of hospital. The question, I suppose, I have is:

17 should Barrow have been a low level as well, because they should also have been

18 selecting by risk.

19 PROFESSOR MONTGOMERY: It is probably [inaudible] but it would bounce around.

20 CHAIR: Sure.

21 DR WALTERS: Why would Barrow have been more selective?

22 CHAIR: If they were applying the checks.

23 MS KNIGHT: Prenatal assessments.

24 CHAIR: Applying a stricter risk assessment before expected date.

1 DR WALTERS: It's difficult though, isn't it, because it is supposed to an obstetric unit.

2 CHAIR: It is.

3 DR WALTERS: Serving a local population.

4 CHAIR: It is, but it does not have the paediatric resources.

5 DR WALTERS: Is that [inaudible] neonatal unit?

6 CHAIR: Yes.

7 MS KNIGHT: These are the trends, then, amongst the term babies more than 2.5kg
8 unadjusted. This time, the rates at Furness General do go a bit more than the national.
9 It is higher than that at Royal Lancaster at several points.

10 I have then risk adjusted the data, and I am presenting it using a new type of
11 chart, although it is just worth outlining what is this is all about. It is a recommended
12 technique now for monitoring cumulative occurrence of adverse outcomes. It's been
13 used retrospectively to look at Harold Shipman's outcomes, and it's been shown that if
14 it had been used at the time it would have picked up his much higher than average
15 mortality rate much, much earlier than was the case. Likewise for the Bristol cardiac
16 surgery.

17 CHAIR: They used it for the Oxford paediatric cardiac surgery as well.

18 MS KNIGHT: Yes. So here the test detects deviations from a benchmark value. I have used
19 the national mean for the following graphs. As measurements are taken, the difference
20 between each measurement and the benchmark value is calculated and it is
21 cumulatively summed up. Essentially, every time there is an adverse event, the line
22 will go up, and, every time there is not an adverse event, it will go down. Over time, if
23 it goes above thresholds, which I've set at 95% and 99.8% limits, it triggers an alert and
24 alarm. This just illustrates that, so, in the graph on the left there is... No, it doesn't

1 trigger the alert or the alarm [inaudible] above the benchmark, whereas on – and
2 eventually it does cross the dotted line on the bottom, which means there is not
3 necessarily anything to worry about. You can reject the alarm or you can accept a null
4 hypothesis.

5 On the right, the graph shows that there is cause to continue monitoring
6 because it doesn't cross the bottom boundaries.

7 PROFESSOR MONTGOMERY: Just to be – go back. So, if I am looking at this without
8 understanding what it relates to, just trying to identify, what should I think about, you're
9 saying that, if it goes below the line, no immediate cause for anxiety, and the further
10 down it goes, the less anxiety. If it goes right down, I should think there is something
11 wrong with my data collection.

12 MS KNIGHT: Yes.

13 PROFESSOR MONTGOMERY: If I am just thinking, 'What's the shape?', I would like it to
14 be in this bit. Is it...?

15 MS KNIGHT: You would like it to be between the two inner dotted lines.

16 [Crosstalk]

17 MS KNIGHT: I have set the bar so that, if it hits the outer bottom line, it resets back to zero
18 so that you don't accrue credit as such.

19 CHAIR: Which disguises itself as a trend.

20 MS KNIGHT: Over a very long period of time it would just... So you will see that that is
21 linking back to what is happening here. Looking at the adverse outcomes, at the other
22 line, it almost hits the 0.05 limit in the very early part of 2004, but since then it is
23 consistently hitting the bottom line and resetting back to zero. It takes slightly longer to
24 do that in the period between the first resetting and the first –

1 MR BROOKES: Sorry, I don't understand why it's resetting when it hits the line.

2 MS KNIGHT: If we don't reset when it hits the bottom line, it will just continue to go down
3 and accrue –

4 MR BROOKES: Because it is cumulative.

5 MS KNIGHT: – positive credit, whereas, in fact, if you really want to detect –

6 PROFESSOR MONTGOMERY: So this is not cumulative in the sense that every bit of data
7 is continuing – it resets every time it hits the bottom.

8 MS KNIGHT: Yes, it resets every time it hits it. So that was at RLI.

9 At FGH, we do actually have an occasion where does hit the 0.05% limits
10 around January 2005. After that point, it does reset several times, but then it comes
11 close on a couple of occasions to hitting the 0.05%. It is certainly a cause for
12 continuous monitoring.

13 PROFESSOR MONTGOMERY: This is not a familiar type of job to me, but, presumably,
14 that means that, if it resets very often, this is less helpful in that you want to see a
15 cumulative trend and, if it keeps resetting, you only get a few months of data.

16 CHAIR: What you are looking for is the adverse outcome. So if it is heading upwards, then
17 you don't reset. If it starts to head upwards, you keep monitoring if it keeps heading
18 upwards or comes down.

19 MS KNIGHT: These graphs are designed to detect adverse outcomes.

20 PROFESSOR MONTGOMERY: So I would look at this and I might say I should have been
21 slightly anxious in December 2004 –

22 MS KNIGHT: Yes.

23 PROFESSOR MONTGOMERY: – but then it goes down.

24 [Crosstalk]

1 PROFESSOR MONTGOMERY: Well it doesn't trigger the alert.

2 MR BROOKES: It is a trend that you need to be aware of.

3 MS KNIGHT: This data has been adjusted for gestational age, birth weight, congenital
4 anomalies, year of birth, deprivation, ethnicity and sex of the baby, which are all the
5 risk factors that are available. That's not to say that there aren't other risk factors.

6 MR BROOKES: It's pretty important risk adjustment data.

7 MS KNIGHT: Having checked the risk adjustments, how the risk adjustments are falling, it is
8 quite a good model. It is about 0.8% for a C-statistic, which is generally a very decent
9 model. That was amongst all neonates, and then this is the same again for term infants
10 between nought and five at the RLI and then at Furness General, where you will see it
11 actually does hit the outer limits in that same period.

12 CHAIR: So it looks like there is a systematic problem in late 2005.

13 MS KNIGHT: Yes.

14 PROFESSOR MONTGOMERY: It also looks as though it sorted itself – or it went away after
15 whatever action was taken.

16 CHAIR: Yes.

17 MS KNIGHT: The next measure of morbidity we are able to look at is unplanned neonatal
18 readmission within 28 days of birth. I only looked at emergency readmissions which
19 resulted in an overnight stay to try and filter out those readmissions where they were
20 just called in for observation; these were severe readmissions. These are the unadjusted
21 trends for all live born infants and very much in line with the national mean at the two
22 larger units. Something happening at the Royal Lancaster towards the end of the period
23 we are looking at, but we unfortunately don't have the following year's data to be able to
24 see whether that has now come down or it was just a fluke. We need to get some more

1 numbers. That pattern very much similar for the term infants.

2 So the same types of graph, again, then adjusted for case notes, the first four
3 months, all births. Interestingly, we get a similar thing happening here in that period
4 2004-2005 as was happening with the other measure of morbidity.

5 CHAIR: That is at Lancaster.

6 MS KNIGHT: That is at Lancaster, similarly at Furness where it hits the 0.05% limit. Then,
7 when we restrict it to term babies, nought to five months, it is the same again. Greater
8 levels of readmission than we would expect in those two units in that period.

9 Now, for stillbirths, I have done some more case ascertainment looking at the
10 number reported in HES, on a national scale and in ONS, and there is definitely a
11 problem of under-ascertainment here, which also leads to lower estimated rates of
12 stillbirth derived from ONS data and HES, so there are definitely some warnings here
13 around this data. That is again reflected at the level of the Trust when looking at
14 stillbirths recorded in their electronic maternity system and what was going into HES.
15 Since 2008-09, there have been 52 stillbirths recorded in the Trust's electronic system
16 but only one has been recorded as being a stillbirth in HES. My conclusion was that
17 this data is completely unreliable.

18 MR BROOKES: I can't think of any reason why you wouldn't put it on. It is just bad practice,
19 isn't it?

20 MS KNIGHT: It is quite hard to know whether the babies themselves are not in HES or
21 whether they are in HES but the stillbirth box has not been ticked, so to speak. Either
22 way it is obviously unsatisfactory and does not allow us to draw any conclusions about
23 whether the stillbirth rate at the Trust was higher than expected or not. We also cannot
24 distinguish between intrapartum and antepartum stillbirths satisfactorily because that

1 data item is missing in so many cases, and that is not just in the Trust; that is a national
2 problem. I did wonder whether perhaps there was something going on in the recording
3 of stillbirths and that they were being mislabelled as prenatal births or vice versa, so I
4 have looked at all perinatal deaths.

5 CHAIR: Just before we go on, Oonagh wants to –

6 MS MCINTOSH: Could I just ask, Jacqui, what normally would happen in the Trust? How
7 does the recording happen and how would you get anomalies like that?

8 MS FEATHERSTONE: I have no idea. Any delivery automatically goes into the computer,
9 whether it is a live birth or a stillbirth, so I don't understand. It would be interesting to
10 see their normal – you know, is there anomalies with their normal data? Why are they
11 not recorded? I don't understand that; it is no different at all. The outcome and
12 obviously what you do after is different, but the actual recording is no different.

13 CHAIR: There is something happening at the coding for HES stage rather than the ward
14 completion of records stage.

15 DR WALTERS: Who is that done by?

16 CHAIR: It varies.

17 MS FEATHERSTONE: Whether they're hanging on to the notes for a certain amount of time
18 and they are not going to coding appropriately.

19 PROFESSOR MONTGOMERY: Do we know whether the total numbers add up? If you look
20 at the births comparison between the Trust data and what is submitted to HES and you
21 add to that stillbirth, whether the totals add up.

22 MS KNIGHT: There is a discrepancy of 150 per year in the total number of births, and there
23 are approximately – well, there are 15 stillbirths in 2008-09, and slightly fewer – so it
24 may be that all of these were just not being entered as births, but it doesn't account for

1 the entire discrepancy.

2 PROFESSOR MONTGOMERY: In 2006 and 2007, there are more stillbirths gone in, and
3 then they almost disappear. It looks like incompetent data collection as opposed to a
4 standing conspiracy, doesn't it?

5 MS KNIGHT: Whereas in 2005 and 2006 there is a very close match.

6 DR WALTERS: Would it be anyone's responsibility at the Trust to be checking data? Was
7 there any quality control on the inputting or the coding?

8 MS FEATHERSTONE: The internal audit should do it.

9 MR BROOKES: Not just that, but the coding and the IT function – the heads of function in
10 the Trust should be doing that.

11 DR WALTERS: So somebody should have looked and thought, 'That's a bit odd.'

12 PROFESSOR MONTGOMERY: The standard reporting that we went through from the audit
13 commission was called KLOE, and I can't remember what the KLOE stands for, but
14 that picked up the quality of reporting and it always showed that the quality of reporting
15 was poor. Whether there is much variation, I don't know. I don't know how useful it is
16 for us to ask that question.

17 CHAIR: It is an irritating problem but I don't think it's central to the story.

18 PROFESSOR MONTGOMERY: No.

19 MR BROOKES: In my mind, clearly, if you don't do this well, then you ain't going to pick up
20 the signs that might be there. It's that kind of message, so you need get your systems in
21 place to ensure you have the best chance to spot trends when they are there.

22 CHAIR: I would have to say there wasn't a trend.

23 [Crosstalk]

24 CHAIR: I think there are two separate issues. I think Julian is absolutely right; you have to

1 have systems so that you could. But the second question is: would it have picked up
2 anything here? Probably not, I think. That is not the mechanism that they should have
3 been relying on for this.

4 DR WALTERS: When did their maternity system go?

5 MS KNIGHT: Sorry?

6 DR WALTERS: When did their maternity system go?

7 MS KNIGHT: 2005.

8 PROFESSOR MONTGOMERY: They are enthusiastic in the first year, 2005, and then they
9 drop away.

10 MS KNIGHT: They have put in a new system now, called Lorenzo, which I think will lead to
11 a direct data transfer between the Trust and HES rather than having to code it
12 beforehand.

13 CHAIR: Okay.

14 MS KNIGHT: So the final case to present on neonatal deaths. Again, on the case
15 ascertainment looking at, ONS is the gold standard. Here, there is again a discrepancy
16 in the total number but that does not affect the estimated rates from either data sources.
17 Here, this is amongst all live born infants; national mean in blue. There's something
18 odd at the Royal Lancaster before about 2005-06 and I can't explain what is happening
19 there. It is based on small numbers.

20 DR WALTERS: They did have quite a lot in that first two years.

21 PROFESSOR MONTGOMERY: They did.

22 DR WALTERS: Far more than in Furness. When I say a lot, I think something like eight,
23 that sort of number.

24 MS KNIGHT: As we expect, the majority of those were early neonatal deaths, within the first

1 seven days.

2 CHAIR: But they presumably had [REDACTED]

3 MS KNIGHT: Yes, that is one neonatal death at Westmoreland and it causes a spike that size,
4 because it's very small numbers. So there is a spike in the neonatal death rate among
5 term infants weighting more than 2500g at Furness in 2007-08, and there were four
6 deaths recorded in HES and linked to the ONS death register. It is quite interesting that
7 there were no deaths recorded in 2008-09, which is where we have got two of our index
8 cases. So obviously those births are not in HES but they would have been in ONS, but
9 it is not possible to link to ONS if it's not in HES, I'm afraid.

10 DR WALTERS: Was that because they died somewhere else?

11 MS KNIGHT: That shouldn't matter because you can link wherever. That's amongst term
12 infants. The sequential probability ratio test chart again detects a problem in this period
13 between 2004 and 2006 where you say you were aware that there were a high number
14 of deaths at the RLI, but, since then, it resets quite near the end of the period.

15 PROFESSOR MONTGOMERY: But that is the first one where we're seeing a systemic
16 spike, isn't it?

17 MS KNIGHT: Yes.

18 PROFESSOR MONTGOMERY: The others have tended to come down quite quickly,
19 whereas that has stayed high. It is high, above the alert, and it is over a year long
20 period. I am just trying to think what: might I have done as an executive director. I
21 might have looked at that and said, 'There is something I need to understand there',
22 whereas, for previous ones, I would have just probably accepted that it was a blip,
23 because it looked as though it was a blip and came down.

24 MS KNIGHT: Yes.

1 CHAIR: By the time you looked at it, it had come down again.

2 MR BROOKES: It is at a lower level, but there are others of a similar length. It is just not
3 quite hitting the top of alter, but put them together –

4 MS KNIGHT: We don't see that at Furness General but, as I said, at least two –

5 CHAIR: The two cases, yes.

6 MS KNIGHT: – are missing, so I am not sure that's very reliable. When we restrict it to the
7 term babies, neither the RLI nor Furness hit the alert. So those are the four measures.

8 THE CHAIRMAN: Thank you.

9 PROFESSOR MONTGOMERY: Can I ask how...? This is not related to that presentation,
10 but as we looked through the, I think it was the PCT papers relating to the gold
11 command, we found a table, and I showed it to you at the time, but it looks as though
12 someone had been asking similar questions to the ones that you had asked. I don't
13 know if you remember. I think you took a photocopy of it. It was just a table in the
14 papers that looked as though someone had been asking questions around the
15 monitoring. I just wondered whether you had any reflections on it.

16 MS KNIGHT: No, I'm sorry. I haven't had a chance to look at that again.

17 PROFESSOR MONTGOMERY: Okay. The reason I think it's interesting is that that's the
18 first evidence that I've seen –

19 CHAIR: Of anyone being systematic –

20 PROFESSOR MONTGOMERY: – that anyone was hunting to get to the bottom of: was there
21 a systematic logistical problem here? I think it could be quite helpful. All it was was a
22 sheet. It didn't say where it had come from. It looked similar to the sort of stuff you
23 have. It would be useful to know what you think.

24 DR WALTERS: We have actually invited that individual analyst for interview, so we can

1 share that in the interview.

2 PROFESSOR MONTGOMERY: I think it would be quite useful before that interview to
3 know what animated that piece of paper.

4 CHAIR: Yes.

5 PROFESSOR MONTGOMERY: – so that we would know what questions to ask, because, as
6 I've explained already, I am not in a position to understand what lies behind this.

7 MR BROOKES: It's the reasonableness question – what could be seen as reasonable.

8 PROFESSOR MONTGOMERY: Yes. Firstly, to know if they had it, but, if it was used in
9 some way, it is useful to be able to ask about that.

10 CHAIR: Thank you. Any other questions or comments?

11 MR BROOKES: No, just thank you, that is really helpful.

12 CHAIR: Yes. Good.

13 DR WALTERS: I suppose, in terms of the conclusion from that, I suppose we are saying it
14 may prompt a few more questions but it still doesn't give us anything conclusive.

15 PROFESSOR MONTGOMERY: I think my take from what I've heard of these questions is
16 that there is an issue about whether it corroborates some of the conclusions that might
17 be emerging from the clinical group. But, on the governance side, it seems to me to say
18 there is nothing that I have seen that from that that would have led me to be really
19 worried about it, even if I had seen it, other than that one point where it didn't just look
20 like a spike; it stayed high for a bit. If we can only find that out by this sort of work, I
21 don't think I would criticise the Trust for not knowing about that underlying problem
22 from the statistical analysis.

23 CHAIR: With the slight proviso that you are aware of some of the cases.

24 MR BROOKES: I was going to say, with the recommendation about data quality, because

1 there are some issues there.

2 PROFESSOR MONTGOMERY: And the fact that they ought also to be alerted by
3 complaints and other things, which we're looking at separately.

4 CHAIR: And incidents and people writing letters.

5 PROFESSOR MONTGOMERY: If we are asking was there a statistical variation, I think you
6 have worked really hard to try and ask that question, and the answer has come back that
7 it probably wasn't detectible by that sort of analysis.

8 MS KNIGHT: Would it be useful to me to...? I have presented quite a lot over the last sort
9 of six months, and I am going to compile everything I have done into one pack with
10 tabs by different themes. I wonder how you would like that organised. This is mainly a
11 conversation we can have then we are upstairs but I need to request stationery in order
12 to get this all into a pack with, perhaps, tabs – one for workforce, one for neonatal
13 outcomes, one for maternal outcomes. Does the panel have any preference about how
14 this is done?

15 CHAIR: I think, as far as you can, if you anticipate the different sorts of people who we will
16 be asking the questions of, so all of the clinical stuff together for when we are talking to
17 midwives and doctors and so on, all the workforce stuff together for we are talking to
18 nurse managers and so on. It is difficult to be more specific at the minute.

19 MS KNIGHT: Would you like to have everything for these two different groups – so for all
20 babies and then the term babies and broken down into the two hospitals – the main two
21 hospitals?

22 CHAIR: Definitely into the two hospitals.

23 MS KNIGHT: With Westmoreland as well?

24 CHAIR: I don't think we're particularly concerned with Westmoreland. I cannot see that we

1 will be asking many questions about Westmoreland.

2 PROFESSOR MONTGOMERY: There's the birth rate one, though, that has emerged as a
3 possible variation. The pattern might lie in the term babies rather than early babies so
4 we probably do need to keep that separate.

5 CHAIR: Given that, in a sense, all the findings are negative with the exception of the
6 incomplete data recording, we are not going to go into the minutiae of it.

7 PROFESSOR MONTGOMERY: That is true.

8 CHAIR: So I don't think we need to do that, but I certainly think it would be useful to have
9 the hospitals out separately. The other comment that I wanted to make is that we have
10 got somebody who has raised concerns about overall hospital mortality figures as well,
11 so we need to do some work on just understanding the different ways of calculating
12 hospital mortality rates and the different approaches that different people have taken.
13 He has been in correspondence with Professor Jardin[?], so we need to look at that.
14 Anything else on that one?

15 MR BROOKES: That is mortality across the hospital?

16 CHAIR: Yes. Okay, thanks very much. Interview programme, Nick, progress report, please.

17 MR HEAPS: Since the last panel meeting, we have continued to chase the authors of the
18 other reports and are making progress there. We are in contact with all the concerned
19 organisations and have a number of interviews set up, particularly with the CQC and
20 other authors of the Fielding report. We are working well with the others to arrange
21 dates. In the last seven or eight days, we have issued invitations to a further 90 people
22 to interview and we already have 11 responses from that, 10 of those from people
23 employed at the Trust. We expect those to roll in over the coming days, so we will start
24 to put those in the interview calendar, aiming to fill up slots in June and July.

1 CHAIR: Realistically, probably July is going to be the busier month by the time people have
2 had the chance to respond.

3 MR HEAPS: It is. There is a week at the end of June that you indicate is available and we
4 will try to get some of those in there. But, yeah, July is likely to be a busier month.

5 CHAIR: Any questions or comments? Thanks, Nick, that is very helpful. Where are we at
6 with Paul?

7 MS MCINTOSH: He has not appeared, and I think the reason he has not appeared is that over
8 the last few weeks lots of evidence has come in.

9 [Crosstalk]

10 MS MCINTOSH: Well, ploughing through it, I think. Over the last week in particular, the
11 investigation has received a significant volume of additional material as a result of the
12 chase-ups and the work that the Panel did in clarifying what they wanted, and also the
13 new requests had been made. I know Paul would appreciate speaking to some of the
14 panel members separately after this meeting. The information, a lot of it is from the
15 department, which Jonathan has referred to earlier, relates to the gold command report,
16 which would be helpful because I know that Nick has been working with the report
17 authors and has got a date in the diary for you to see them. There is also material that
18 has come in from the CQC and some additional material from NHS England, so I think
19 it will be quite helpful for Paul to point you in the direction of that.

20 MR BROOKES: Certainly, yes.

21 MS MCINTOSH: Yes, that would be really helpful. It is just to let you know that the
22 chase-ups have been working. We haven't got everything yet, and a matter of concern
23 to Julian is – and we have been chasing this doggedly – is that we haven't got all –

24 MR BROOKES: We've got some, but –

1 MS MCINTOSH: – we've got some but not all of the board meeting papers that we actually
2 imagined it would be quite straightforward to obtain, so it is quite interesting that some
3 of the material that you expect to get is the last to arrive. What we are now getting is,
4 for example, in relation to the Foundation Trust application, that we actually got from
5 the department. We are getting material or rather we've got material from the Trust.
6 We are still looking at material from the PCTs and SHA and you might find that in your
7 trawl over the next 24 hours. Actually, you can actually build up the conversations that
8 have happened and who saw what material when, which will help because Nick is
9 working with those report authors. It is taking a long time, Chairman, but it is coming
10 together.

11 I think the other thing Paul wants to draw to your attention is the volume of
12 material. I know that he has asked subgroup leads for their advice on a sensible way
13 forward. It has been very helpful to get an input of how that might be prioritised. He
14 would like to talk to you about that later.

15 CHAIR: Good. Thank you. Anything else on that one? Any other business; I have none.

16 [*Responses in the negative*] Okay, in that case, the date of the next meeting is...?

17 DR WALTERS: 10 July.

18 [Crosstalk]

19 CHAIR: Okay, thanks very much. We can close the meeting.

20
21 [The meeting concluded at 12.20 p.m.]

Report from the Clinical Sub-Group for Panel Meeting on 12 June 2014

The main work of the Clinical Sub-Group has been to undertake a clinical practice review of Maternity and Neonatal Services within UHMBT Trust.

The aims of the clinical practice review are:

- 1) To assess the quality of maternity and neonatal care provision for identified cases.
- 2) To identify areas of sub-optimal care.
- 3) To review whether the Trust was following national and network guidelines / pathways in relation to the selected cases.
- 4) To identify any recurring themes for potential improvement in relation to maternity and neonatal care provided by the Trust.

Sources of cases include:

- a) An overarching dataset of all cases of maternal, perinatal and neonatal deaths within UHMBT during the period of the Inquiry – January 2004-June 2013.
- b) The cases relating the families who attended meetings with the Inquiry Panel
- c) Additional cases that were investigated by Cumbria Police
- d) Cases who responded to a request by the Inquiry Panel in the local media for further information.

Progress to date:

- I. In the original file from Cumbria Constabulary there were 31 cases. Of these 4 cases were not pursued by the police, and 4 cases are out with the scope of the Inquiry. Of the remaining 23, 21 cases have had a full review and 2 cases are awaiting review.
- II. 23 families responded to the advertisement in the local media for further information on concerns regarding maternity and neonatal care. All of these cases have been screened and 6 have been identified for a full review.
- III. 202 maternity, perinatal and neonatal deaths were reported to have occurred in the Trust between January 2004 and June 2013, 125 cases have now been screened and 20 have been identified as requiring a full review. One full review undertaken, leaving 19 outstanding.
- IV. The details of the 27 cases that are currently awaiting full review are available on Huddle under the Clinical Sub-Group Workspace, there also details of a further 7 cases where the full review has been undertaken but further information has been requested.

Ongoing work

1. Continue to screen cases, approximately 18-20% of cases are being selected for a full review, therefore a further 10 reviews may be required.
2. From both the screening and the full reviews there are several themes already emerging which relate to clinical practice, clinical risk management, communication and network working.
3. A two day meeting of the Clinical Sub-Group is proposed. The purpose of the meeting will be a) to undertake outstanding full reviews b) to review key questions for interviews c) in discussion with secretariat clarify information requirements that relate to key questions.

4. Prior to interviews with clinicians and managers from the Trust there needs to be an opportunity for the three Sub-Groups to exchange and corroborate information.

Stewart Forsyth