

Midwifery supervision and regulation

A report by the Health Service Ombudsman of
an investigation into a complaint from Mr M
about the North West Strategic Health Authority

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of the Health Service Commissioners Act 1993

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Contents

Foreword	2
Summary	3
The complaint	4
Our decision	4
The Health Service Ombudsman’s jurisdiction and role	5
How we decided whether to uphold this complaint	5
What should have happened?	6
Background information	7
The investigation	10
Our clinical advice	15
Findings	17
Recommendations	20

Foreword

We are laying before Parliament, under section 14(4) of the *Health Service Commissioners Act 1993*, this report on an investigation into a complaint made to us as Health Service Ombudsman for England.

The report is being laid before Parliament to help others learn from the maladministration it describes.

The complaint is about the North West Strategic Health Authority (the SHA). Mr M complained to us that the SHA failed to carry out adequately its functions as the Local Supervising Authority (LSA) for midwives following the death of his wife and baby son at Furness General Hospital in July 2008.

This is one of three complaints we are publishing which deal with midwifery supervision and regulation under the SHA. All three cases are cited in *Midwifery supervision and regulation: recommendations for change*, which calls for changes in the interests of the safety of mothers and babies.

Dame Julie Mellor, DBE
Health Service Ombudsman

December 2013

Summary

Mrs M and Baby M

What happened

Mrs M went into Furness General Hospital in July 2008 for the birth of her son. Sadly, there were problems during her labour and she died after the birth, despite attempts to resuscitate her. Her son, Baby M, died the next day because he had been deprived of oxygen during the birth.

Two of the Local Supervising Authority's (LSA) Supervisors of Midwives, Midwife A and Midwife B, reviewed the records and decided that there were no midwifery concerns that would warrant a supervisory investigation. Mr M told us that, as a result of their decision not to investigate, he and his wife's family had not been able to mourn the deaths of mother and baby.

What we found

Midwife A should have identified a number of failings in the midwifery care provided for Mrs M, who was a high-risk mother because she had diabetes and was having her labour induced. Baby M's heart should have been monitored at regular intervals using continuous fetal heart monitoring from the moment Mrs M arrived in the delivery suite. The fact that this was not done should have prompted a decision to investigate.

The Strategic Health Authority (SHA) should have gone much further than they did in investigating the original decision by the Supervisor of Midwives not to undertake a supervisory investigation. As a result, they did not give Mr M an evidence-based explanation of that decision. They also said that the decision by the Supervisor of Midwives was sound when the evidence was clear that a supervisory investigation should have been carried out.

The complaint

1. We have investigated Mr M's complaint that the North West Strategic Health Authority¹ (the SHA) failed to carry out adequately its functions as the Local Supervising Authority² (LSA) for midwives in relation to open and effective supervisory investigations of midwives following the death of his wife and baby son at Furness General Hospital (part of University Hospitals of Morecambe Bay NHS Foundation Trust³) in July 2008.
2. We have also investigated Mr M's concerns that the SHA failed to deal with his complaint about this effectively.
3. Mr M said that he did not think the supervisory investigation process was followed by the SHA when they made the decision not to carry out a supervisory investigation. He said that, as a result, neither he nor his wife's family are able to mourn the death of Mrs M and their son, Baby M. Mr M said he would like to know who decided that an investigation was not necessary, the reason for this decision and whether all the appropriate information was considered. Mr M wanted the SHA to openly acknowledge any mistakes made, to improve processes and so improve public confidence.

Our decision

4. Having considered all the available evidence related to Mr M's complaint about the SHA, and having taken account of the clinical advice I received, I have reached a decision.
5. I have found that the SHA did not carry out its functions adequately as the LSA for midwives following the deaths of Mrs M and Baby M. I have concluded that this was so far below the relevant standards and established good practice that it was maladministration. I have also found maladministration in the SHA's response to Mr M's complaint about this.
6. I have found that an injustice arose to Mr M in consequence of this maladministration because, without an investigation into the midwifery care provided, or any acknowledgement that the original decision not to carry out an investigation was flawed, he has been unable to mourn the loss of his wife and baby son, in addition to having good reasons to doubt whether lessons have been learnt.
7. I therefore uphold Mr M's complaint about the SHA.

¹ At the time of the events complained about, the North West Strategic Health Authority was responsible for discharging the LSA function. Since 1 April 2013, SHAs no longer exist, and while LSA Midwifery Officers are to remain in place as before, the overall statutory responsibility for the LSA is now with NHS England.

² LSAs are impartial organisations responsible for ensuring statutory supervision of midwives is undertaken according to Nursing and Midwifery Council's (NMC) standards.

³ The actions taken by the University Hospitals of Morecambe Bay NHS Foundation Trust and the clinical care provided are not part of the scope of our investigation.

The Health Service Ombudsman's jurisdiction and role

8. Our role is to look at complaints about the NHS in England.⁴ We can investigate complaints about NHS organisations such as trusts, strategic health authorities, family health service providers such as GPs, and independent persons (individuals or organisations) providing a service on behalf of the NHS.
9. Our approach when investigating is to consider whether there is evidence to show that maladministration or service failure has happened. We then look at whether that has led to an injustice or hardship that has not been put right. If we find an injustice that has not been put right, we will recommend that the NHS take action. Our recommendations may include asking the organisation to apologise, or to pay for any financial loss, inconvenience or worry caused. We may also recommend that the organisation takes action to stop the same mistakes happening again.

How we decided whether to uphold this complaint

10. When looking at a complaint, we generally begin by comparing what happened with what should have happened. So, as well as finding out the facts of the complaint, we look at what the organisation should have been doing at the time. We look at the general principles of good administration that we think all public organisations should follow. We also look at the relevant law and policy that the organisation should have used at the time.
11. Once we have found out what should have happened, we look at whether those things did happen or not. We look at whether the organisation's actions, or lack of them, were in line with what they should have been doing. If not, we decide whether that was so bad that it was maladministration or service failure.

⁴ Our role is formally set out in the *Health Service Commissioners Act 1993*.

What should have happened?

12. Our Principles of Good Administration, Principles of Good Complaint Handling and Principles for Remedy are broad statements of what public organisations should do to deliver good administration and customer service, and how to respond when things go wrong. The same six key Principles appear in each of the three documents. These six Principles are:
 - Getting it right
 - Being customer focused
 - Being open and accountable
 - Acting fairly and proportionately
 - Putting things right, and
 - Seeking continuous improvement.
13. The Principle of Good Administration particularly relevant to this complaint is:
 - *'Getting it right'* – which, among other things, means public organisations must act in accordance with recognised quality standards, established good practice or both.
14. Two of the Principles of Good Complaint Handling particularly relevant to this complaint are:
 - *'Being open and accountable'* – which includes public organisations providing honest, evidence-based explanations and giving reasons for decisions. They should keep full and accurate records; and
- *'Acting fairly and proportionately'* – which includes ensuring that complaints are investigated thoroughly and fairly to establish the facts of the case.
15. In addition to these principles, there are specific standards that were relevant to our investigation of this case.

Background information

16. Supervision is a statutory responsibility based on the Nursing and Midwifery Council's *Midwives rules and standards* (2004), which provides a mechanism for support and guidance to every midwife practising in the UK. The purpose of supervision of midwives is to protect women and babies by actively promoting a safe standard of midwifery practice. Supervision is a means of promoting excellence in midwifery care, by supporting midwives to practise with confidence, therefore preventing poor practice.⁵
17. Each Local Supervising Authority (LSA – in this case the SHA) is responsible for ensuring that statutory supervision of all midwives, as required in *The Nursing and Midwifery Order* (2001) and the Nursing and Midwifery Council's *Midwives rules and standards* (2004) is exercised to a satisfactory standard within its geographical boundary. LSA arrangements differ across the UK. In 2008, in England, the responsibility for the LSA function lay with the SHAs.
18. Each LSA appoints and employs a practising midwife to undertake the role of LSA Midwifery Officer (LSAMO) who has the responsibility of ensuring that the statutory supervision of midwives is carried out to a satisfactory standard.⁶ The LSAMO is based within the SHA. The LSAMO appoints Supervisors of Midwives, who operate locally (that is, they are employed by the relevant NHS organisation) and who are directly accountable to the LSA for all matters relating to the statutory supervision of midwives. Local frameworks

exist to support the statutory function. Every midwife will have her own named Supervisor of Midwives, with whom she will have regular contact (Rule 12).

19. When an incident occurs and a decision on whether a supervisory investigation is required, the Supervisors of Midwives will discuss and decide which Supervisor will carry out the initial investigation. This Supervisor cannot be the named Supervisor of the midwife or midwives who provided the care, nor can they be a Supervisor of Midwives who provided care during the incident.

The specific standards

The Local Authority Social Services and National Health Services and National Health Service Complaints (England) Regulations 2009

20. *The Local Authority Social Services and National Health Services and National Health Service Complaints (England) Regulations 2009* (the Regulations) say that NHS organisations must make arrangements for the handling of complaints. These arrangements must ensure that complaints are dealt with efficiently and are properly investigated. Complainants must receive a timely and appropriate response and be told the outcome of the investigation of their complaint. Necessary action must be taken by the organisation in the light of the outcome of a complaint.
21. The Regulations state that after completing the investigation, a report should be produced that explains how the complaint was considered and the conclusions

⁵ *Modern Supervision in Action* (August 2009 – NMC and LSAMO Forum UK).

⁶ LSAMOs are a point of contact for Supervisors of Midwives for advice on aspects of supervision, especially difficult or challenging situations.

reached in relation to the complaint. The response should confirm whether any remedial action is necessary following the complaint.

The Nursing and Midwifery Council *Standards for the supervised practice of midwives* (2007) (the NMC standards)

22. Standard 1.1 says that:

'Following an untoward event or the recognition of circumstances indicating lack of competence, a Supervisor of Midwives, independent of any management investigation, should undertake a full supervisory investigation of untoward incidents or circumstances. This should include where necessary a risk analysis and root cause analysis.'

23. Standard 1.2 says that:

'Supervisory investigations should take place as soon as possible after any untoward event or circumstances, and may be initiated by a Supervisor of Midwives regardless of any employment processes. The Local Supervising Authority should be informed that a supervisory investigation has commenced.'

24. In its explanatory notes to standard 1 (*'Investigating alleged lack of competence'*), the NMC Standards say that it is essential that a *'thorough and independent investigation of an untoward event or near miss be carried out by a Supervisor of Midwives to ensure that midwifery practice has been safe'*.

25. The NMC standards also say that the investigating Supervisor of Midwives should not have been involved in the original incident in order to reduce any potential conflict of interest. They say that it is *'in the interest of protection of the public that such investigations take place and are concluded promptly'* and that, in general, it *'would be reasonable for a 20-day investigation period for instance, following events or receipt of complaints'*.

North West Local Supervisory Authority *Guidance for Supervisors of Midwives 2005* (revised 2008)

26. The North West LSA *Guidance for Supervisors of Midwives, 2005* (revised 2008) provided guidance for midwifery supervision at the time of the episode complained about. This guidance incorporated parts of the Nursing and Midwifery Council's *Midwives rules and standards* (2004). In the section relating to *'reporting and monitoring of serious untoward incidents'* the guidance says that:

- a Supervisor of Midwives must be notified of all serious untoward incidents;
- if appropriate, a local untoward incident policy should be activated and an internal investigation initiated;
- the LSA should be notified of any maternal death;
- the LSA should be notified of all unexpected intrauterine or neonatal deaths.

27. In cases where there are any uncertainties, the LSA should be contacted for advice.

National Institute for Health and Clinical Excellence (NICE)⁷ guidelines on *Intrapartum care: care of healthy women and their babies during childbirth* (NICE guidelines – September 2007)

28. The NICE guidelines say that, in low-risk women, intermittent auscultation⁸ of the baby's heart should be changed to continuous fetal heart monitoring (using an electronic fetal heart monitor or cardiotocograph, CTG⁹) when an abnormal heart rate is detected in the baby, either because it is less than 110 beats per minute, or because it is greater than 160 beats per minute, or because it decelerates after the mother's contractions. CTG should also be considered in cases where the liquid is stained with meconium (the baby's first faeces, which have leaked into the uterus).
29. In women who have had more than one birth (parous women), the NICE guidelines state that birth would be expected to take place within two hours of the start of the active stage of labour¹⁰ in most women.

They say that a diagnosis of delay in the active second stage of labour should be made when it has lasted more than one hour, and the mother should be referred to a healthcare professional trained to undertake an operative vaginal birth¹¹ if birth is not imminent.

30. During the second stage of labour, intermittent auscultation of the fetal heart should occur after a contraction for at least one minute, at least every five minutes.
31. The NICE guidelines also set out certain risk factors that could indicate a pregnancy is at higher risk than normal. These include diabetes and having a labour induced.¹² Where these risk factors are present, a CTG should be offered and recommended throughout labour.

⁷ This organisation has recently changed its name, and is now known as the National Institute for Health and Care Excellence (NICE). Its functions are the same: to provide national guidance and advice to improve health and social care.

⁸ This is a systematic way of listening to the baby's heart by using an acoustical device (similar to a stethoscope) or hand-held ultrasound device. (This sends high frequency sound waves into the uterus and provides a reading based on the sound bouncing back.)

⁹ A CTG is a means of recording the baby's heart and the mother's uterine contractions.

¹⁰ The second stage of labour includes the part from the full dilatation of the cervix until the baby is completely out of the birth canal.

¹¹ An instrumental delivery (or operative delivery) is one carried out with the help of forceps, an instrument, similar to a large tong which encircles the baby's head and helps delivery. An instrumental delivery can also be carried out with a ventouse, which is a vacuum device used to assist delivery.

¹² Induction of labour means that labour is induced artificially, by inserting a gel (or pessary), or tablet into the vagina. Sometimes a hormone drip is also used.

The investigation

32. We discussed with Mr M the nature of his complaint and how our investigation would proceed on 23 February 2012. We confirmed our understanding of the complaint in our letter of 12 March. On 10 July 2012 we interviewed one of the Supervisors of Midwives (referred to below as Midwife A) as part of our investigation. We also interviewed Mr M to discuss our investigation and his complaint.
33. During this investigation, we have considered relevant documents about Mr M's complaint, including documents relating to the attempts made by the SHA to resolve the complaint.
34. We obtained expert advice from one of our clinical advisers: a practising midwife and LSAMO (the Adviser). Our clinical advisers are experts in their field. In their role as advisers they are completely independent of the NHS.
35. In this report I have not referred to all the information examined in the course of the investigation, but I am satisfied that nothing significant to the complaint or my findings has been left out.
37. Two Supervisors of Midwives were involved in making the decision whether a supervisory investigation was required following the death of Mrs M and Baby M. For ease of reference, I will call them Midwife A and Midwife B in this report. Midwife A, who was also the Trust's maternity risk manager, notified the LSAMO about Mrs M's death by telephone on Monday 4 August 2008. The LSAMO responded in writing on 7 August to offer support if needed to the midwives involved in the care of Mrs M and Baby M.
38. A Supervisor of Midwives' meeting was held at the hospital on 17 September 2008. According to a note of the meeting, Midwife A and Midwife B attended. In a passage apparently related to Mrs M's death the note said:

'Recent maternal death; preliminary investigation suggests amniotic embolus.¹⁴ 2x Supervisor of Midwives', HOM [Head of Midwifery] and OCC [Occupational] Health involved with supporting staff at all levels. Supervisor of Midwives reminded that 1st contact forms to be sent to named Supervisor of Midwives if any concerns re MW/s practice.'

Key events

36. Mrs M attended Furness General Hospital in late July 2008, for the birth of her son, Baby M. Sadly, there were problems during her labour and Mrs M died after the birth of her son on Thursday 31 July 2008, despite attempts to resuscitate her. Her son, Baby M, died the next day as a consequence of being deprived of oxygen during the birthing process, which led to brain damage and ultimately his death.¹³
39. A second local Supervisor of Midwives' meeting was held on 22 October 2008. According to a note of the meeting, Midwife B attended, but Midwife A sent her apologies. In a section of the minutes titled *'Maternal death update'* it says:

'Provisional cause of death due to amniotic Eembolus. Root cause investigation of the case revealed a well managed, rare complication of pregnancy – no midwifery practice

¹³ This was the coroner's verdict.

¹⁴ Amniotic fluid embolism is a rare obstetric emergency in which it is postulated that amniotic fluid, fetal cells, hair, or other debris enters the maternal circulation, causing cardiorespiratory collapse.

issues identified. Midwives involved supported by group of supervisors and colleagues.'

40. The Trust's root cause analysis¹⁵ of Mrs M's and Baby M's deaths was completed in December 2008 (subsequently updated in June and August 2009). The root cause analysis included a chronology of Mrs M's care during pregnancy and summarised her care from when she was admitted until her death. No midwifery concerns were identified. Under a section titled 'Actions' it said that a debrief session was facilitated by the Head of Midwifery following Mrs M's death and was attended by both midwives and doctors involved in her care to discuss what was done well and what had been learnt. A later version of the root cause analysis included a summary of the coroner's inquest into Mrs M's death, which was held in July 2009.¹⁶

Local resolution

41. Mr M made a request for information from the SHA under the *Freedom of Information Act 2000* on 5 April 2011. He then made a formal complaint to the LSAMO on 14 April.

42. In his complaint, Mr M said that the SHA had recently answered his freedom of information request by confirming that the LSA had not undertaken a supervisory investigation. Mr M said that the LSA guidelines stipulate that such investigations should ideally be completed within 20 days of the incident occurring.

43. Mr M said that he understood the LSA processes were separate from those of the Trust and that this separation was an important principle of the midwifery supervisory system. He said that he was concerned that the LSA's decision not to undertake a supervisory investigation was based on the Trust's root cause analysis report rather than their independent assessment.

44. Mr M said that the LSA's refusal to undertake a supervisory investigation implied that the outcome for his wife and son was not influenced by midwifery care. He said that this view was in direct contrast with the latest Centre for Maternal and Child Health Enquiries (CMACE¹⁷) report *Saving mother's lives 2006-2008* (2011). Whilst the LSA had said that his wife's collapse was sudden and could not have been predicted as a result of amniotic fluid embolism, the CMACE report stated this condition should no longer be regarded as a condition with near universal maternal mortality. Mr M quoted the report as stating that amniotic fluid embolism should now be considered a treatable and survivable event in the majority of cases, particularly in a well-equipped unit.

45. Mr M said that given the fact that 62% of the maternal deaths covered in the CMACE report were found to have included some aspects of substandard care, he wanted the LSA to explain how they had reached their decision not to conduct a supervisory investigation into the deaths of his wife and son. Mr M said that '*other preventable*

¹⁵ Root cause analysis is a class of problem-solving methods aimed at identifying the root causes of problems or events. Root cause analysis is not a single, sharply-defined methodology; there are many different tools, processes, and philosophies for performing it.

¹⁶ The inquest said that Mrs M '*died from a very rare complication of pregnancy which was fatal and for which the cause is not yet understood by medical science.*'

¹⁷ CMACE is an independent charity with a mission to improve the health of mothers, babies and children by carrying out confidential enquiries and other related work on a UK-wide basis, and then widely disseminating the results.

deaths occurred in the [Trust's] maternity unit in 2008, which appeared to share common failures, such as dysfunctional teamwork. He questioned how the LSA could be learning lessons from these events when they did not investigate them.

46. The SHA provided a response dated 23 May 2010 (clearly meant to read 2011). They said that the LSA function was the statutory responsibility of the SHA. They could comment only on the areas of Mr M's complaint that fell within the remit of the LSA. They said any comments relating to the overall care and treatment of Mrs M should be addressed to the Trust.
47. The SHA said that there is no requirement to undertake a supervisory investigation unless there is some indication of a lack of competence on the part of a midwife, or of poor midwifery practice. These decisions are made independently of the Trust's decision about any disciplinary action. This did not mean that the Trust and Supervisor of Midwives had to work independently of each other when reviewing the root cause analysis following a serious untoward incident.¹⁸ The SHA said that at the time of Mrs M's and Baby M's deaths it was normal practice for a trust's root cause analysis to inform the supervisory decisions about whether or not there were any fitness to practice issues.
48. The SHA said that the statutory supervision process required the Supervisor of Midwives to inform the LSAMO when there was a maternal death; and for a referral to be made to CMACE. Although a maternal death had to be notified to the LSAMO, he or she does not personally become involved in the local supervisory review as this is the responsibility of the local Supervisor of Midwives. The SHA said that the role of the LSAMO was to ensure that the local Supervisor of Midwives was working with the Trust's root cause analysis process to determine whether a supervisory investigation was required.
49. The SHA said that the Trust's chronology of events and root cause analysis did not raise any concerns about the fitness to practise of the midwives involved in Mrs M's care.
50. The SHA said that the decision not to hold a local supervisory investigation did not imply that there were no lessons to be learnt from either Mrs M's or Baby M's deaths. It did indicate, however, *'that the initial consideration of events did not identify any concerns about the midwives fitness to practise'*.
51. The SHA concluded by stating that:

'the local Supervisor of Midwives followed the process in place at the time, did take into account the outcome of the root cause analysis to inform the decision of whether there should be a separate supervisory investigation and did conclude that this was not appropriate as fitness to practice issues were not identified.'
52. In an email exchange of 13 September 2011, following Mr M's complaint to us, the LSAMO asked Midwife A for *'any evidence – if you have it – of the decision not to undertake a SOM [Supervisor of Midwives] investigation re Mrs M'*. Midwife A said:

'I undertook the root cause analysis as Risk Manager and did not identify any midwifery practice issues. [Midwife B]

¹⁸ The National Patient Safety Agency defines a serious untoward incident as one which results, amongst other things, in unexpected or avoidable death (of patients, staff, visitors or other members of the public) or serious or permanent harm, or reduction in life expectancy.

and I then reviewed the case as Supervisor of Midwives and agreed there were no practice issues. We then agreed this at the October 2008 meeting ... there were five Supervisors [of Midwives] present at the maternity risk management meeting when the case was discussed.’¹⁹

Initial complaint to the Ombudsman

53. Mr M remained dissatisfied with the Trust’s response to his complaint and complained to the Ombudsman in July 2011. We initially agreed to investigate the SHA’s response to Mr M’s complaint.

SHA response to our proposal to investigate Mr M’s complaint

54. The SHA said, in their letter of 1 March 2012, that they had reviewed all their evidence. They provided what they said was a summary of their findings about the local decision making and the steps they had taken to improve their process.

55. The SHA said that under the guidance in place at the time of Mrs M’s death, the Supervisor of Midwives would have been expected to inform the LSAMO of all maternal deaths. The SHA said this had happened.

56. According to the SHA, the local Supervisor of Midwives would have been expected to review the incident and decide whether there were any midwifery practice concerns to investigate. The SHA said that:

‘the Maternity Risk Manager confirmed (when asked by the Local Supervisory Authority Midwifery Officer in

September 2011) that she had done a root cause analysis as the risk manager and had not identified any midwifery practice issues. She then reviewed the case as a Supervisor of Midwives with another Supervisor of Midwives and agreed there were no midwifery practice issues. At this time the guidance supported the dual role of a risk manager acting as a Supervisor of Midwives in the same case as good co-ordinated practice. The decision was subsequently agreed with five other Supervisors of Midwives in their October 2008 meeting.’

57. The SHA said that if the ‘investigation’ had found a case to answer then the Supervisor of Midwives would submit a formal report and recommendations to the LSAMO. Midwife A had ‘confirmed there were no midwifery practice issues, therefore there was no need to undertake a supervisory investigation and submit a formal report’.

58. According to the SHA, as part of their investigation, the LSAMO reviewed the root cause analysis report, the timeline and the outcome of the coroner’s inquest. She has confirmed that, based on the information available:

‘the midwife acted within the Nursing and Midwifery Council Midwives rules and standards (2004) as she escalated as soon as she noted that a deviation from the norm has occurred (Rule 6 – Sphere of Practice). This midwife acted within the Nursing and Midwifery Code (2008) in that she acted in the best interests of her client.’

¹⁹ We have not seen any minutes or evidence of the maternity risk management meeting. The SHA have confirmed that they do not have the minutes or a copy of them.

59. The SHA said that they had concluded that the process followed was consistent with the relevant guidance. They said, however, that they were aware that their process needed to be improved by *'introducing more rigour and opportunities for scrutiny and challenge'*. A supervisory investigation toolkit had now been introduced to: (a) aid decision making when deciding to carry out a supervisory investigation; and (b) guide the assessment that a Supervisor of Midwives needs to make before a formal supervisory investigation. If a Supervisor of Midwives is concerned about a midwife's ability to practice safely and effectively, the Supervisor of Midwives needs to justify whether or not a formal investigation is appropriate. The SHA said *'it is this justification and documentation of the decision taken that is the key difference between the process in 2008 and process in 2012'*.
60. The SHA said that if a formal supervisory investigation is undertaken, the documentation must be sent to the LSAMO. If an investigation is not required, the documentation can be kept with the serious untoward incident report.

Interview with Midwife A

61. On 10 July 2012 we interviewed Midwife A. She explained that she was the Trust's maternity risk manager and a Supervisor of Midwives for the LSA. She told us that the deaths of Mrs M and her son, Baby M, triggered her review of the midwifery care that had been provided. She said she had reviewed the clinical records and compared them with the appropriate standards. She said that she did not identify any concerns with the midwifery care provided. When asked about the CTG, Midwife A said that it appeared sound before Mrs M's transfer to the labour ward (this occurred at 4.15pm on 31 July 2008). She said that after Mrs M's transfer to the labour ward, the CTG was not started. Midwife A confirmed that she felt confident that there were no shortcomings in the midwifery care at the time.
62. She said that she was a *'runner'* in Mrs M's case. In other words, she was not directly involved in the care provided but obtained supplies as required.

Our clinical advice

63. The Adviser said that the Supervisor of Midwives should consider whether to begin an investigation when a trigger event occurred. At the relevant time, the SHA had guidance that specifically set out the circumstances in which a Supervisor of Midwives should be notified of an untoward incident, and when the LSA should be notified. The deaths of Mr M's wife and child should have been reported both to a Supervisor of Midwives and to the LSA.
64. The Adviser said that Midwife A should have started by reviewing the midwifery records to see if the midwifery care was appropriate and in line with NMC standards. She should have reviewed the maternal and neonatal records to see if there were any concerns. If she found any, she should have made further enquiries of the midwife and, if she had any doubts about whether to begin a supervisory investigation, she should have asked for advice from the LSAMO.
65. The Adviser explained that Supervisors of Midwives are the 'eyes' of the LSA in their role of ensuring that the midwifery care provided is in line with current midwifery standards, as set out by the NMC. This means that there is an expectation that a Supervisor of Midwives will intervene and investigate when there are low or unacceptable standards of care.
66. The Adviser said that if at any point Midwife A identified low standards of care or poor conduct issues, then an investigation should have been started. She said that the LSAMO would offer advice, support and guidance in these circumstances.
67. There was no guidance in place in 2008 about whether it was appropriate to base a decision on the local root cause analysis. However, the Adviser has told me that in 2008 a chronology of events and root cause analysis would have been sufficient in terms of written evidence to support a decision about whether a supervisory investigation was necessary.

The midwifery care

68. The Adviser said that the initial review of the records should have identified a number of concerns about the midwifery care provided to Mrs M and her son. The Adviser said that Mrs M was a high-risk mother because she had diabetes and was having her labour induced. This meant that she should have had continuous fetal heart monitoring with a CTG from the time her labour became established, at approximately 3.15pm. The Adviser said that Mrs M's transfer to the labour ward would have interrupted this, but the CTG should have been started again as soon as she arrived at the delivery suite at approximately 4.15pm.
69. The Adviser explained that the purpose of continuously monitoring the baby's heart would have been to monitor for signs that the baby might not be getting enough oxygen (hypoxia). Mrs M began to feel unwell at approximately 5.54pm. The Adviser said that there was enough time between 4.15pm and 5.54pm for the midwife to set up the CTG, yet this was not done. The Adviser noted that when the midwife listened to the baby's heart, she could have set up a CTG but she did not do so. In any event, the Adviser also said that the baby's heart was not listened to often enough. She said that in a low-risk pregnancy the baby's heart should be listened to at least every 15 minutes

in the first stage of labour, and every five minutes during the second stage of labour. Even this basic level of care was not given to Mrs M.

The decision not to investigate

70. The Adviser said that there was a lack of documentation about the decision not to carry out a supervisory investigation.²⁰ The Adviser said that the failure to monitor Mrs M's baby with a CTG was a poor standard of midwifery care and not in line with NICE guidelines. She said that this should have prompted a decision to investigate, in order to ensure that the midwives involved in Mrs M's care were safe and competent practitioners.
71. In addition, the Adviser said that it is not clear from the records whether a CTG was started or not, because there is no mention of this or of any readings. It was only when asked, during our investigation, that Midwife A confirmed that the CTG was not started. The Supervisors of Midwives should have identified this gap in the records and established, before making their decision, whether a CTG was started or not.
72. The Adviser said that, although Midwife A and Midwife B were present during Mrs M's labour, they were mainly in a supporting role. She said that it was therefore acceptable for them to have made the decision about whether a supervisory investigation was required. She also said that this decision was reviewed at a supervisors' meeting on 17 September 2008, with six other supervisors present. She said that there was agreement at this meeting that an

investigation was not required, although it was not clear from the notes of the meeting whether all the Supervisors of Midwives who were present had actually reviewed the clinical records. She said that if anyone had concerns about the care provided by midwives, they should have raised them at this meeting.

73. The Adviser said that this team of Supervisors of Midwives reviewed the decision again on 22 October 2008, although Midwife A was not present. The written note from the minutes of this meeting says that:

'the provisional cause of death was due to amniotic fluid embolus. The root cause investigation revealed a well-managed, rare complication of pregnancy – no midwifery practice issues identified. Midwives involved supported by a group of supervisors and colleagues.'

74. The Adviser said that the fact that Mrs M did not have continuous fetal heart monitoring was a poor standard of care, which should have prompted a decision to investigate. She said that it was not clear from the records whether CTG fetal heart monitoring had been carried out and this should have been established before a decision that a supervisory investigation was not required, because this was clearly not in line with the relevant midwifery standards. The Adviser said that she was very critical of the Supervisors of Midwives for not identifying that electronic fetal heart monitoring had not been started.

²⁰ The Adviser said that in 2008 across the UK, standard practice would not have included clearly recording a decision not to investigate. However, she said that another Supervisor of Midwives should be able to read the same clinical notes and come to the same view around the midwifery care provided.

Findings

The decision not to carry out a supervisory investigation

75. In order for the SHA to ‘get it right’ and adequately carry out its duty to perform open and effective supervisory investigations of midwives, the SHA should have acted in accordance with the relevant standards and with established good practice (as described by the Adviser). This means that when the Supervisor of Midwives reviewed Mrs M’s records, she should have identified any areas of midwifery care that were not in line with national guidance or NMC standards. If any such concerns were identified, she should have informed the LSAMO, and a supervisory investigation should have been started in order to establish the reasons behind midwifery practice issues; and what action was necessary in order to safeguard the public and ensure the midwife was practicing to an acceptable standard.
76. I have been advised that Mrs M was a high-risk mother and that her baby’s heart rate should have been monitored electronically from the moment she arrived in the delivery suite at 4.15pm. This did not happen, even though there was time to start the CTG. Even if Mrs M had not been identified as a high-risk mother, her baby’s heart should have been listened to more frequently than it was. Baby M’s heart was listened to only four times between 4.15pm and 5.50pm, when it should have been checked a minimum of six times. With a high-risk mother, Baby M’s heart rate should have been checked 19 times.
77. It was not against the then guidance for Midwife A to make the decision about whether a supervisory investigation was

required, and I have not seen any evidence that a conflict of interest influenced her decision in Mr M’s case. Nonetheless I can quite understand why the possibility of such a conflict would be a worry for any parent finding themselves in this position. For that reason, I am deeply concerned that the regulations allow potential muddling of the supervisory and regulatory roles of midwives, or even the possibility of a perceived conflict. That cannot be in the interests of the safety of mothers and babies. And it is inherently unfair to service users and to midwives themselves.

78. Putting aside the question of any perceived conflict of interest, when making her decision that an investigation by the LSA was not required, Midwife A did not identify the failings in midwifery care. She did not realise that continuous fetal heart monitoring was not started, and she did not realise that the baby’s heart was not listened to as frequently as it should have been. The records show that, even for a low-risk pregnancy, Baby M’s heart was not listened to frequently enough, yet this did not prompt either Midwife A or Midwife B to ask more questions. I believe that if these concerns had been raised with an LSAMO, an investigation should have been started in order to determine whether the relevant midwife had the knowledge and skills to be a competent practitioner.
79. The SHA says on their website that the purpose of the LSA is:

‘to ensure that statutory supervision of midwives in the North West is carried out to a satisfactory standard and thus ensure safe midwifery care and protection of the public within its boundaries.’

It is clear that this did not occur in Mrs M’s case.

80. Having considered all the evidence and the advice I have received, I conclude that the decision taken by Midwife A fell so far below the applicable standards and established good practice that it was maladministration. When she made this decision, Midwife A was acting on behalf of the LSA and it therefore follows that, by not carrying out a supervisory investigation when one was clearly required, the SHA did not adequately discharge its functions as the LSA for midwives.

Mr M's complaint

81. When responding to Mr M's complaint, the SHA should have been 'open and accountable'. It should have taken responsibility for the actions of its staff (or those acting on behalf of the LSA) by ensuring that the decision made by Midwife A, acting in her capacity as supervising midwife on behalf of the LSAMO, was made in accordance with recognised quality standards and established good practice. It also should have provided evidence-based explanations and given reasons for their decisions. It should have acted fairly and proportionately by ensuring that Mr M's complaint was investigated thoroughly and fairly to establish the facts.

82. The SHA said that a Supervisor of Midwives was notified immediately after Mrs M's death, when the Trust started an internal investigation which included a root cause analysis. The LSA were also informed about the deaths. The SHA told Mr M that the decision not to conduct a supervisory investigation was based on the chronology of events and root cause analysis of the care Mrs M received. While I am critical of the substance of that decision, it was not unreasonable for the Supervisors of Midwives to have used the

root cause analysis to help them arrive at their decision. Nor was it unreasonable for them to rely on the root cause analysis completed by Midwife A, who was also the Trust's maternity risk manager. At the time it was not contrary to the applicable standard or established good practice for the same person to hold both roles. The SHA's response to both of these points was therefore accurate.

83. However, in responding to Mr M's complaint, the SHA should have gone much further than it did. The SHA did not carry out a thorough investigation of the original decision not to carry out a supervisory investigation. Confining itself to procedural questions meant that it did not investigate whether there were any deficiencies in the substance of the original decision. It did not identify that basic levels of care were not provided and, worse still, it did not identify that Midwife A had not identified them. The failings were readily apparent from the clinical records. At the very least, the absence of any mention of the CTG from 4.15pm should have prompted the SHA to consider it as a concern.

84. It took an investigation by the Ombudsman to establish that CTG monitoring was never actually started. The SHA was in a position to do this at the time, and this information would have been crucial in responding to Mr M's complaint.

85. In order to fulfil the role of LSA, some reliance is placed on the relevant Supervisors of Midwives determining, locally, whether a serious incident has been caused by midwifery practice issues. However, in order to safeguard against poor decisions being made locally, the SHA should have ensured that complaints about decisions made by Supervisors of Midwives

not to investigate were addressed thoroughly and fairly. In Mr M's case, I have found that this did not happen.

86. Having considered the evidence and the advice I have received, I find that the SHA was not open and accountable and did not act fairly and proportionately. It did not carry out a thorough investigation of the decision made by Midwife A and Midwife B, and consequently, did not provide Mr M with an evidence-based explanation of that decision. Finally, it also did not 'get it right', because although it maintained that the decision taken by the Supervisor of Midwives was sound, the evidence is clear that in fact a supervisory investigation should have been carried out. I find that the SHA's actions in responding to Mr M's complaint amounted to maladministration.

Injustice

87. Without an investigation into the midwifery care provided, or a thorough evidence-based response to his complaint about the absence of such an investigation, and in particular, without any acknowledgement that the original decision was flawed, I can understand why Mr M has been unable to mourn the loss of his wife and his baby son. I can also see that Mr M has good reason to doubt whether lessons have been learnt as a result of his wife's and his son's deaths. That can only have made things worse for him and his wife's family. I find that this is an injustice to Mr M which has arisen in consequence of the maladministration I have identified.

Recommendations

88. This is one of three complaints we have investigated which deal with midwifery supervision and regulation under the SHA. In all three cases, the midwifery supervision and regulatory arrangements at the local level failed to identify poor midwifery practice. As we have said, we think these cases clearly illuminate a potential muddling of the supervisory and regulatory roles of Supervisors of Midwives.
89. We brought together leaders in the field of midwifery and regulation to discuss the strengths and weaknesses of the current system and what needs to change to enhance the safety of mothers and babies.
90. We have worked with the NMC, the Professional Standards Authority for Health and Social Care, NHS England and the Department of Health. In our publication *Midwifery supervision and regulation: recommendations for change*, we have identified two key principles that will form the basis of proposals to change the system of midwifery regulation.

The two principles are:

- that midwifery supervision and regulation should be separated;
 - that the NMC should be in direct control of regulatory activity.
91. We recommend that these principles inform the future model of midwifery regulation.

92. We recognise that the regulatory framework for midwifery is a UK-wide framework and changes need to be negotiated with stakeholders across the UK. We undertake to share our conclusions and reasoning with the other UK ombudsmen and we look to the Department of Health to convey these recommendations to its counterparts in Northern Ireland, Scotland and Wales.
93. We recommend that the NMC works together with NHS England and the Department of Health to develop proposals to put these principles into effect. This will include developing and consulting on proportionate approaches to midwifery supervision and midwifery regulation. We recommend that this is done in the context of the anticipated Bill on the future of healthcare regulation. We also recommend that the Professional Standards Authority advises and reports on progress.

Parliamentary and Health Service Ombudsman

Millbank Tower
Millbank
London SW1P 4QP

Tel: 0345 015 4033

Fax: 0300 061 4000

Email: phso.enquiries@ombudsman.org.uk

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