Parliamentary and Health Service Ombudsman

Midwifery supervision and regulation:

recommendations for change

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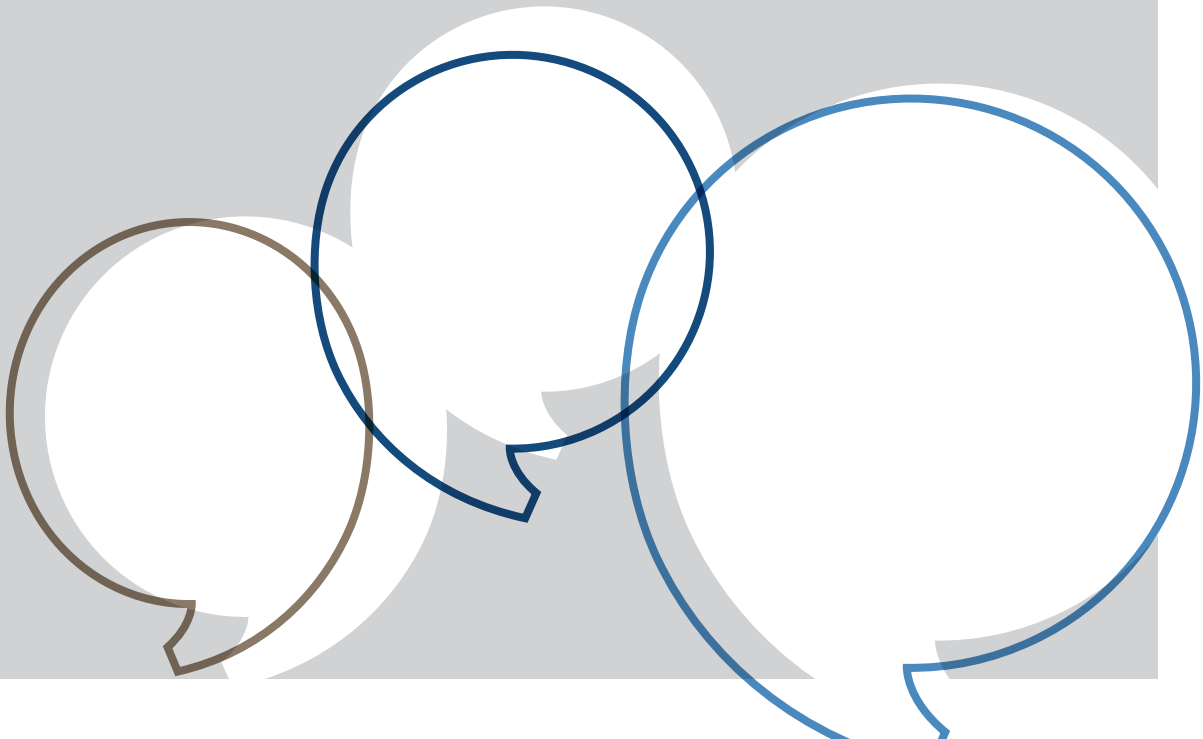


Foreword and summary

We are publishing this report following the completion of three investigations into complaints from three families, all of which related to local midwifery supervision and regulation.

In all three cases, the midwifery supervision and regulatory arrangements at the local level failed to identify poor midwifery practice at Morecambe Bay NHS Foundation Trust. We think these cases clearly illuminate a potential muddling of the supervisory and regulatory roles of Supervisors of Midwives.

Whilst we have found no direct evidence of a conflict of interest in these cases, we think they exemplify the weaknesses in the current regulatory arrangements at a local level. The cases we have seen have also highlighted that the current arrangements do not always allow information about poor care to be escalated effectively into hospital clinical governance or the regulatory system.

We think this means that the current system operates in a way that risks failure to learn from mistakes. This cannot be in the interests of the safety of mothers and babies, and must change.

We have worked with the Nursing and Midwifery Council (NMC), the Professional Standards Authority for Health and Social Care,

NHS England and the Department of Health. 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.

We recommend that these principles inform the future model of midwifery regulation.

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.

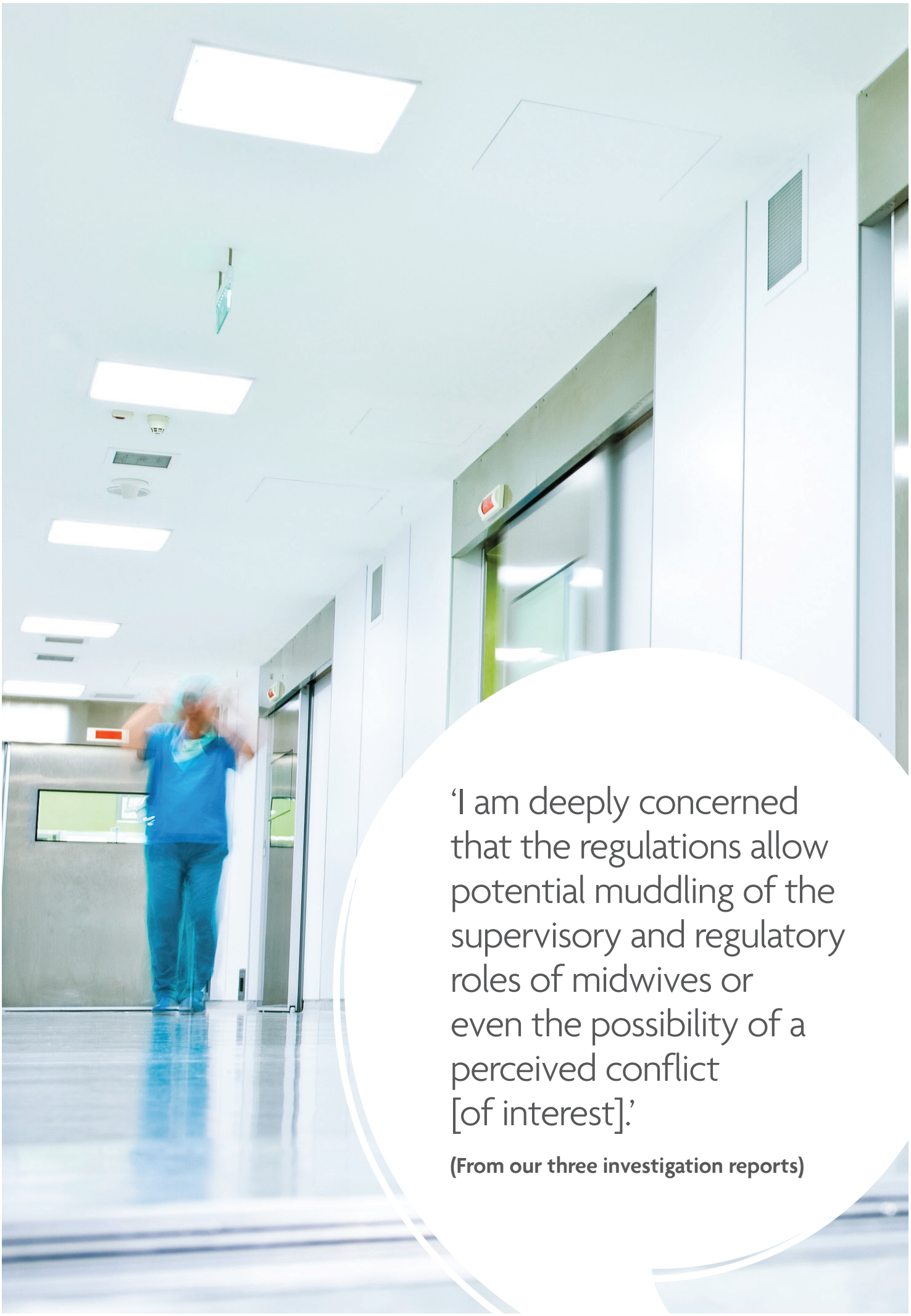
We recommend that the NMC works together with NHS England and the Department of Health to develop proposals to put these principles into effect. This will include developing and consulting on proportionate approaches to midwifery supervision and midwifery regulation. We recommend that this is done in 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.

Dame Julie Mellor, DBE

Health Service Ombudsman

December 2013

‘We think this means that the current system operates in a way that risks failure to learn from mistakes.’



‘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 [of interest].’

(From our three investigation reports)

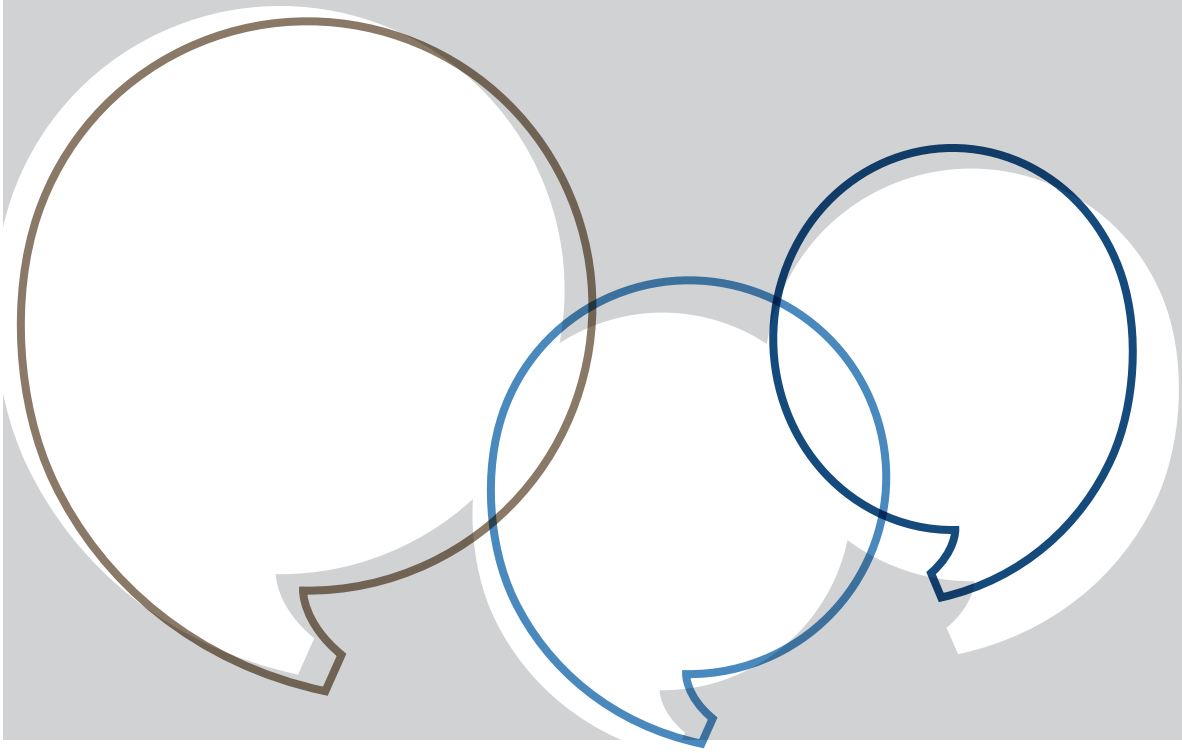
Our cases

We are highlighting three cases in which local statutory supervision of midwives failed. All three cases concern events that took place at Morecambe Bay NHS Foundation Trust (the Trust) and, specifically, how those events were investigated through midwifery supervision and regulation.

The families who complained to us could not mourn the loss of their loved ones properly because of the unanswered questions they had about the care provided during the births of their children. The fact that these questions were not addressed appropriately through the processes that are in place is a theme across each of the cases, as is the failure to learn from poor midwifery care, which could have resulted in future service users being put at unnecessary risk.

We have published the three cases in full and have laid them before Parliament.

You can see the reports on our website: **www.ombudsman.org.uk**. On the following pages, we have briefly summarised each case.



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.

‘As a result of their decision not to investigate, Mr M and his wife’s family had not been able to mourn the deaths of mother and baby.’

Baby Q

What happened

Ms Q went to Furness General Hospital in September 2008 and had her labour induced. There were complications during labour and, sadly, Baby Q was stillborn. The post mortem showed that Baby Q had not had enough oxygen during the birth.

Seven months later, one of the LSA's Supervisors of Midwives (Midwife B) reported on her investigation into the care provided by the two midwives at the birth. She concluded that both midwives needed more training on monitoring a baby during labour. There was then a second investigation by the Trust into 11 cases in which one of the midwives had provided care. The report of this investigation recommended that the midwife should undergo supervised practice for at least 150 hours.

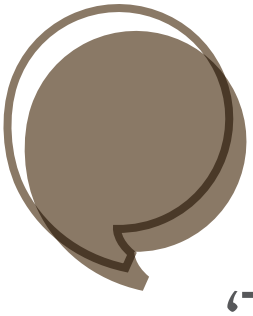
Ms Q and Mr R complained to us that the LSA had failed to carry out an open and effective investigation into the death of Baby Q and that the SHA had not dealt with their complaint about this effectively. This added to the distress they felt as a result of their loss.

What we found

The supervisory investigation should have taken place in 20 days. It was seven months before it was started. The investigation was not independent and subsequent reports were not thorough. This meant that they did not identify that care fell short of relevant guidelines and good practice.

Midwife B did not identify all the failings in midwifery care given to Ms Q, and she did not establish why some actions were not carried out, for example, why the midwife had not started electronic monitoring of Baby Q's heart when it was beating faster than normal. Midwife B also did not explore in enough detail an earlier failure by one of the midwives to start electronic fetal heart monitoring. The LSA Midwifery Officer had an opportunity to explore some of the issues that had arisen from the supervisory investigations and raised a query about whether midwives were comfortable in contacting consultants, but did not follow this up. Overall, the LSA failed to carry out its functions adequately.

When Ms Q complained to us about the SHA, they said they would investigate. They tried to be open and accountable in their review but Ms Q had to wait more than a year for their response. This meant that the reassurance she might have had from their report was diluted by the delay.



‘The reassurance Ms Q might have had from their report was diluted by the delay.’

Baby L

What happened

Mrs L went to Furness General Hospital in October 2008 when her waters broke. She explained that she had been poorly for a few days, but after two sets of observations she was told she could go home and return the next day. Two days later she started to have contractions and Baby L was born. Mrs L was given antibiotics because she felt unwell, but no antibiotics were given to Baby L, who was only seen by a paediatrician 24 hours later. Baby L's condition deteriorated and he was transferred to two different trusts for intensive treatment. Sadly, he died from pneumococcal septicaemia in another hospital early in November.

The Trust commissioned an external review of Baby L's care but this was difficult because Baby L's observation chart went missing around the time he was transferred to another hospital. The external report said that '*the care received by* [Baby L] *was not acceptable*' and that '*as a direct consequence, he lost his fight for life*'.

After the external inquiry, the LSA issued their report. This report did not agree with all of the findings of the external report, and Mr L felt it was fundamentally flawed. The SHA agreed to commission an external review of the report and then, following Mr L's complaint about this first review, a second review, jointly with the Nursing and Midwifery Council (NMC).

What we found

The LSA did not carry out its duty to perform open and effective supervisory investigations in line with relevant standards and established good practice. The supervisory investigation should have been completed in 20 days but it was delayed until after the Trust's external investigation. This meant that events were no longer fresh in the midwives' minds, which was particularly important without the observation chart. The report was of poor quality, and was based on assumptions. It did not establish why Baby L was put on a cot warmer on more than one occasion, why the midwives had not asked for paediatric support and whether they would do so in future.

When Mr L provided fresh information about Baby L's temperature, which was accepted by the midwives, this meant that the original report was unsound. But the LSA Midwifery Officer did not tell the NMC about the new information and so failed to take an opportunity to put things right.

The first review commissioned by the SHA took six months and it did not consider the actual midwifery care provided to mother and baby. As a result, these six months were wasted. The second review was open and accountable and correctly identified many of the issues.

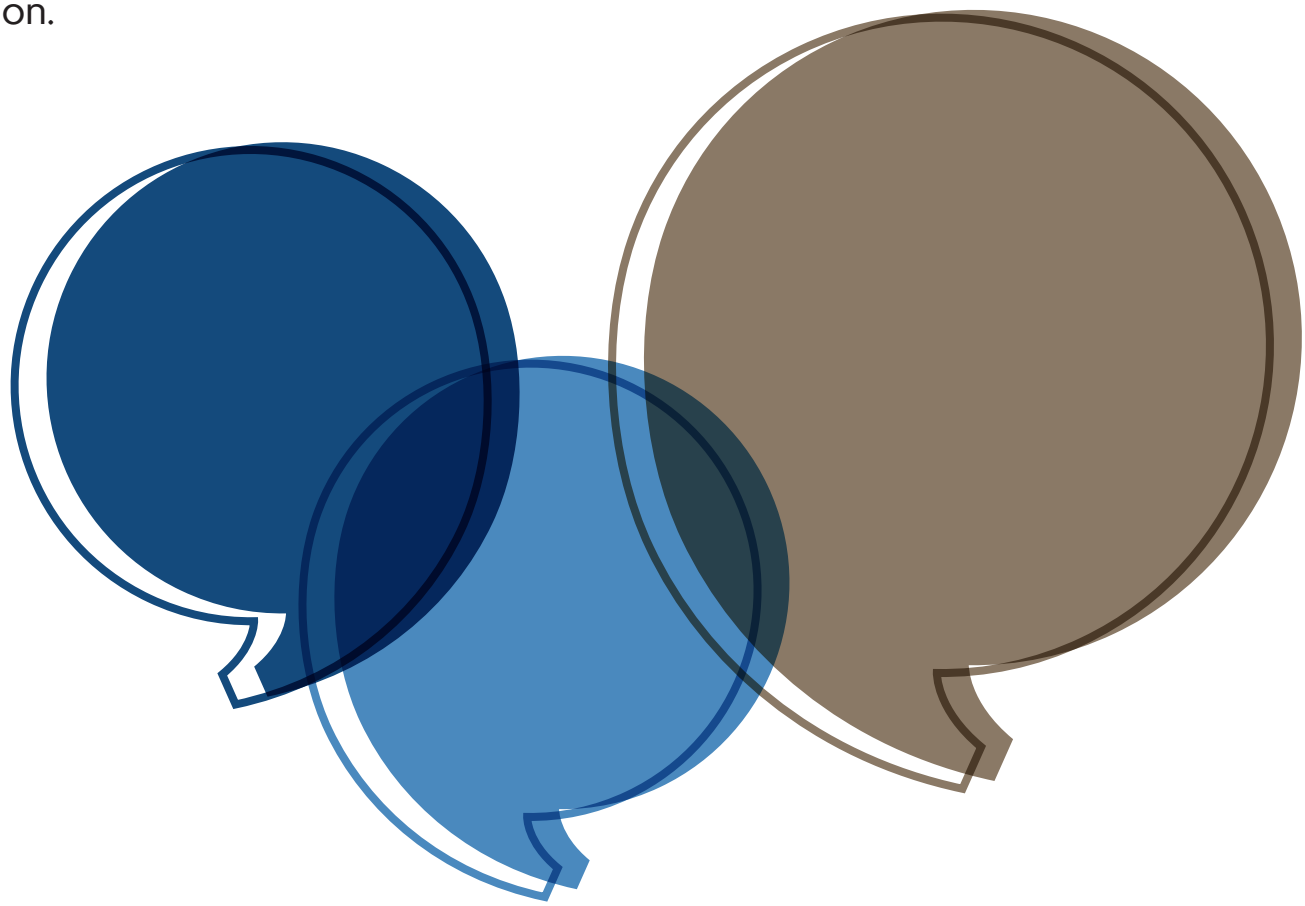
‘The LSA Midwifery Officer did not tell the NMC about the new information and so failed to take an opportunity to put things right. ’

Current midwifery supervision and regulation – the Nursing and Midwifery Council's role

The Nursing and Midwifery Council (NMC) is the independent statutory regulator of nurses and midwives in the UK. The NMC is required by the *Nursing and Midwifery Order 2001* (the Order) to establish and maintain a register of all qualified nurses and midwives eligible to practise in the UK, to set standards for their education, practice and conduct, and to take action when those standards are called into question.

For historical reasons, midwifery has an additional framework of statutory supervision. When midwifery was provided outside the health sector, additional safeguards were deemed necessary. Today, the overwhelming majority of midwives work in the health service, where there is clinical governance, appraisal and performance management.

The Order gives the NMC powers to set rules for the regulation of the practice of midwifery (article 42). The Order requires the establishment of a Local Supervising Authority (LSA) for Midwifery in every area and requires midwives in that area to give notice of their intention to practise.



Each LSA must ensure supervision of midwives in their area and investigate any concerns about midwives' practice.

The Order also requires the NMC to set rules and standards for midwives and the LSAs who are responsible for the statutory supervision of midwives. These are contained in *Midwives rules and standards 2012*.

Statutory supervision

For midwifery, supervision is a statutory responsibility which provides a mechanism for support and guidance to every midwife practising in the UK. The stated purpose of supervision of midwives is to protect women and babies by actively promoting a safe standard of midwifery practice.

Roles and responsibilities

With the abolition of SHAs in April 2013, responsibility for the LSA moved from SHAs to the NHS Commissioning Board (now NHS England). Previously, SHAs were responsible for discharging the role of the LSA, ensuring that statutory supervision of all midwives was exercised to a satisfactory standard within its geographical boundary.

The LSA

The functions of the LSA include:

- providing a framework of support for supervisory and midwifery practice;
- receiving intention to practise data for every midwife practising in that LSA;
- ensuring that each midwife meets the statutory requirements for practice;
- assessing initial and continuing education and training for Supervisors;
- leading the development of standards and audit of supervision;
- determining whether to suspend a midwife from practice;
- being available to women if they wish to discuss any aspect of their midwifery care that they do not feel has been addressed through other channels; and
- investigating cases of alleged misconduct or lack of competence.

These duties are discharged through an appointed LSA Midwifery Officer.

LSA Midwifery Officer (Midwifery Officer)

The Midwifery Officer carries out the functions of the LSA and develops and audits standards of supervision within the LSA boundary. Each Midwifery Officer is a practising midwife with experience in statutory supervision, and provides a focus for issues relating to midwifery practice within each area. The Midwifery Officer does not represent the interests of either the commissioners or providers of NHS maternity services. The Midwifery Officer reports to the statutory regulatory body, the NMC. Although the Midwifery Officer is selected and employed by the LSA, the person specification and role criteria are specified by the NMC.

Supervisor of Midwives (Supervisor)

The Supervisor provides support and advice to midwives to ensure their practice is consistent with the regulatory framework. Supervisors are accountable to, and appointed by, the Midwifery Officer. They are practising midwives, with at least three years' experience. Each midwife within the LSA's geographical boundary must have a named Supervisor, selected from those appointed as Supervisors by the Midwifery Officer. Supervisors must meet with each midwife for whom they are a named Supervisor at least once a year. Midwives must have 24-hour access to a Supervisor.

How supervision works following a serious untoward incident

The role of the Supervisor is to monitor and support the practice of each midwife for whom they are responsible, including development needs, whilst at the same time discharging their own duties as practising midwives. Their role is also to investigate untoward or serious incidents and determine whether action is required. This might include recommendations for how the relevant midwife might improve their practice (for example, through further training), or whether his or her fitness to practise should be called into question. The Midwifery Officer must be notified when an investigation is being carried out and the Supervisor must notify the Midwifery Officer what action is required (if any) upon completion of their investigation and seek further advice. In fulfilling this role, Supervisors are independent of their employers.

How it works in other areas of clinical practice

The difference between the LSA process for investigating incidents and how this works in other areas of clinical practice, is that the clinical governance process is dependent on the organisation's own procedures for investigating serious untoward incidents. This means that, generally, the practitioner's employer will be responsible for deciding to

We have identified two principles:

- that midwifery supervision and regulation should be separated;
- that the NMC should be in direct control of regulatory activity.

investigate, carrying out the investigation, and ensuring that actions are taken to improve the practitioner's practice, or refer him/her to external organisations if there are serious concerns about his/her fitness to practice. A decision on whether an investigation is required will not be taken by the practitioner's peer – in other words, there is no equivalent supervisor for doctors. Instead, the decision will likely be taken by a clinical director, or be mandated by a policy or procedure which the specific organisation has in place, for example, to investigate all elective surgery deaths. Furthermore, there are also additional legal requirements which might mean that certain incidents (such as deaths) need to be reported to a coroner independently of the Trust's internal process.

'The purpose of supervision of midwives is to protect women and babies by actively promoting a safe standard of midwifery practice.'

Changes to statutory supervision

The NMC undertook extraordinary reviews of the Morecambe Bay NHS Foundation Trust in 2011 and 2012. In response to the learning from events at Morecambe Bay and other failings of care, it revised its *Midwives rules and standards* in 2012. These changes might be described as moves to mitigate any risks inherent in the Supervisors' dual role for support and regulation. In particular, a new rule strengthened the requirements on the LSA for investigating, reporting and information sharing about adverse incidents and complaints. The changes were designed to reduce the possibility of poor handling of cases because of confusion or a lack of awareness between the LSA and the employer/service provider.

What we can learn from other professions – the Professional Standards Authority's view

The Professional Standards Authority for Health and Social Care (the Authority) is an independent body, accountable to the UK Parliament, which promotes the health, safety and wellbeing of patients, service users and the public by overseeing and reviewing the work of the nine statutory bodies that regulate health professionals in the UK.

There are few parallels or similarities to the supervisory arrangements for midwifery in the regulation of other professions. Perhaps the closest example is the role of the Responsible Officer within medical regulation, although this is a much more recent development for a different regulatory purpose. However there are important differences between the Responsible Officer role, which was established to help deliver revalidation, and the Supervisor of Midwives, not least that the Responsible Officer does not have a role in investigating untoward incidents on behalf of the General Medical Council (GMC).

The Authority raised concerns about the role of the Responsible Officer in revalidating doctors and the challenges this role presents to meeting its expectations of good regulation in response to the 2010 GMC consultation on revalidation, for example:

- The Authority believed the concept introduced a conflict of interest – as medical directors, Responsible Officers might be considered to have a vested interest in having their doctors deemed fit for revalidation;
- Lack of independence from the profession – whilst the decision whether to revalidate rests with the GMC, this is based on the Responsible Officer's assessment. The role of assessing whether a doctor is fit to practise essentially remains with the profession; and
- Opportunity for inconsistency – there is scope for considerable variation in the type, amount and strength of evidence submitted, and subjectivity in its interpretation. In addition, the number of Responsible Officers, the periods over which assessments are made and the resources required, added to potential weaknesses in the evidence, present a challenge to obtaining accurate and consistent judgments.

As has already been noted, these difficulties also arise in the Supervisor of Midwives' role, although to a greater extent, given the wider regulatory function that the Supervisor role is intended to fulfil.

Other regulated professions do not have this confusion of roles or the potential for a conflict of interest with respect to investigating incidents on behalf of the regulator. The absence of clear comparators from other professions suggests that there may be difficulties in sustaining these supervision arrangements in their current form in the future. This position is supported if we examine the rationale for the regulatory reforms that arose following the Shipman Inquiry. These sought to change the balance of power and influence which professionals and non-professionals had in regulation. The White Paper *Trust, Assurance and Safety* (2007) described the reason for these reforms:

> *'... patients, the public and health professionals need to be able to take it for granted that the councils act dispassionately and without undue regard to any one particular interest, pressure or influence. This will ensure that the regulators are not only independent in their actions, but, just as critically, that they are seen to be independent in their actions. Doubts based on perceived partiality have threatened to undermine patient, public and professional trust in a number of regulators over many decades.' (paragraph 1.3)*

The most significant change in this respect was to create the General Pharmaceutical Council and establish a clear separation between the regulatory and professional leadership roles previously fulfilled by a single organisation (the Royal Pharmaceutical Society of Great Britain). Across other regulators, including the NMC, elections of professional representatives to regulatory councils were abolished and replaced by appointment of members based on evidence of merit and competence. Councils were reconstituted to give parity of lay and professional membership. These two steps removed the direct influence of the profession over their regulation, moving away from self-regulation to a shared approach that clearly prioritised the interests of patients and the public.

Seen in this context, the Authority's view is that these supervision arrangements are a clear candidate for reform, as they demonstrate a local manifestation of an older model of professional regulation – one that uneasily combines important regulatory and professional leadership roles. This combination of functions in one role creates circumstances that have the potential to undermine confidence in regulation. It would be far more appropriate, and it would better reflect the realities of current midwifery practice, and the role of professional regulation, if the Supervisor did not have such regulatory responsibilities. In essence, the regulatory responsibilities of an employer-based supervisory role should be adequately captured by the core standards for the profession issued by the regulator.

If it is decided that a local professional leadership role in midwifery remains important, the new role could be developed by learning from supervision and clinical leadership in other professional groups such as social workers and psychotherapists.

Conclusions and recommendations

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.

The strengths of statutory supervision for midwives include:

- It provides support for midwives through 24-hour access to a Supervisor;
- The independence of the LSA **should** ensure that the LSA's Midwifery Officer and Supervisors of Midwives can comment freely on the safety and quality of midwifery services, which could be said to be in the public interest.
- The LSA can protect the public by taking immediate action to suspend a midwife pending referral to the NMC.
- Midwives' entitlement to supervision and support is protected by its statutory framework.

- Where investigations are conducted well by Supervisors, this makes for a more effective and cost-effective investigation stage on the part of the NMC following a referral.

The weaknesses of statutory supervision include:

- The dual role of a Supervisor, providing support but also a regulatory function, allows for an inherent conflict of interest.
- The fact that the Supervisor can be a peer allows for a further conflict, because of a natural desire to support and protect a colleague while at the same time fulfilling an important regulatory role.
- The confidentiality of the Supervisor of Midwives' role can impede hospital investigations and can prevent potentially valuable information coming to light. This can be particularly problematic in root cause analysis because it can stop issues to do with team effectiveness coming to light, as it focuses on the role and actions of midwives.
- Midwifery Officers are appointed locally rather than by the NMC. This means the NMC has limited control over the quality of the Midwifery Officers.
- There is a risk that the presence of supervision allows the employer/provider to have less control over the quality of maternity services and staff performance than they do for other services. This is not in the public interest because the public has a right to expect the provider to be responsible for quality and safety.
- The NMC is not a system regulator and therefore it is in the uncomfortable position of setting requirements, and receiving information, relating to systems (such as ratios) without powers of enforcement.
- There is a weak evidence base in terms of risk for the continuation of an additional tier of regulation for midwives.

In conclusion, we can see that midwifery supervision may have real merits in the support it provides for midwives across the country on a daily basis. However, those strengths do not extend to the regulatory role of supervision. In fact, any value added by supervision **as a mechanism for regulation** is outweighed by its weaknesses for regulatory purposes. It does not achieve desired safety objectives and the continuation of statutory supervision begs the following questions:

- Is this the most effective and cost-effective regulatory model for this profession?
- If statutory supervision did not exist, would it be proposed, just for this group of health professionals?

Health and care professionals are subject to a number of mechanisms to ensure safe practice, from frameworks put in place by employers or service providers, to professional regulation. The case for an **additional** tier of regulation for midwives is not clear. Moreover, other health and care professions benefit from supervision without it being a statutory right, or an aspect of their professional regulation.

We cannot tell from the evidence in these cases what the emotions and motivation of the individuals involved were. We also found no direct evidence of a conflict of interest in these cases. However, the cases do clearly illuminate a potential muddling of the supervisory and regulatory roles of midwives. We think this exemplifies the weaknesses in the current regulation arrangements at a local level.

The conflicts of interest we can see may or may not have been the reasons behind the failures we have observed – we simply cannot say. However, they do mean that the current arrangements are not in the interests of, and potentially pose a risk to, the safety of mothers and babies.

This is sufficient reason for change.

Principles for the future of regulation and supervision

We have worked with the NMC, the Professional Standards Authority, NHS England and the Department of Health. We have identified two key principles that will form the basis of proposals to change the system of midwifery regulation.

The two principles are:

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Parliamentary and Health Service Ombudsman

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