

## Council

### Review of midwifery regulation

**Action:** For decision.

**Issue:** The Council has an opportunity to respond to the recommendations of the review of midwifery regulation which it commissioned from the King's Fund.

**Core regulatory function:** All.

**Corporate objectives:** Corporate objective 2: "We will set evidence-based and accessible standards of education and practice. We will assure the quality of education programmes for nurses and midwives and the quality of supervision for midwives, so that we can be sure everyone on our register is fit to practise".

Corporate objective 4: "We will maintain open and effective regulatory relationships with patients and the public, other regulators, employers, parliamentarians and the professions".

**Decision required:** The Council is recommended to:

- Accept the recommendation of the King's Fund as its position on the future of midwifery regulation;
- Call upon the government to provide an opportunity to amend the NMC's legislation accordingly;
- Authorise the preparation of amendments to the standards component of the Midwives Rules and Standards for consultation.

**Further information:** If you require clarification about any point in the paper or would like further information please contact the author or the director named below.

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- Background:**
- 1 In December 2013, the Parliamentary and Health Service Ombudsman (PHSO) in England published a thematic report into midwifery regulation. She had been prompted to scrutinise the unique arrangements that apply to midwifery as a consequence of investigating cases at Morecambe Bay, but was clear that the thematic report was not about Morecambe Bay, but about what she described as 'structural flaws' in the framework from the perspective of public protection.
  - 2 The Ombudsman set out two principles that should apply to a future model for midwifery:
    - 2.1 That midwifery supervision and regulation should be separated;
    - 2.2 That the NMC should be in direct control of regulatory activity.
  - 3 The Ombudsman has shared her recommendations with her counterparts in the other countries of the UK and kept them up to date with developments since her report.
  - 4 In January 2014, the Council discussed the Ombudsman's report. It concluded that it was a very serious matter for another regulator, tasked with upholding public protection, to raise questions about the fitness for purpose of an aspect of our regulatory framework.
  - 5 The Council also noted the view expressed by the Professional Standards Authority in the Ombudsman's report, 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.*
  - 6 The Council accepted the Ombudsman's judgement that midwifery regulation was 'structurally flawed' and commissioned an independent review, not to go behind the Ombudsman's findings but to make recommendations for a future model of midwifery regulation that addressed the concerns raised.
  - 7 The NMC's terms of reference required the King's Fund to make recommendations having regard to:
    - Public protection;
    - Proportionality;
    - Public confidence in the regulatory model which, post-Shipman, includes the expectation that regulatory decisions are not taken by professionals in isolation;

- The PSA's standards of good regulation;
  - Public assurance about the responsibility and accountability of service providers for the quality of maternity services;
  - Fairness to midwives whose fitness to practise is called into question.
- 8 The King's Fund was selected to undertake this work and report back to the NMC at the end of 2014. Its report attached as **annexe 1**.
- 9 The methodology employed by the King's Fund is set out in the report, but in summary, the work consisted of a literature review, focus group work and two rounds of engagement with key stakeholders. The second round of engagement involved the use of future scenarios which were appraised against the principles set out in the terms of reference
- 10 The Midwifery Committee has been asked, as part of its advice to the Council, to appraise the King's Fund's approach.
- 11 The Ombudsman advised the NMC to establish a partners' group for the review as a means of involving bodies that may have a role to play in changes to the framework.

### **Contextual matters**

#### *Kirkup Investigation*

- 12 The English government has launched its own investigation into failings in maternity care at Morecambe Bay which is due to submit its report to the Secretary of State in February 2015. The NMC has given evidence to the investigation and maintained contact throughout the conduct of the review.

#### *Public Administration Select Committee*

- 13 The English Public Administration Select Committee holds the PHSO to account and held a hearing in 2014 to assess the impact of the Ombudsman's report on midwifery regulation. The NMC was among those giving evidence. In September 2014 the Chair of the Committee, Bernard Jenkin, wrote to the minister Dan Poulter following the hearing in these terms:

*We are not satisfied with the slow progress in relation to midwifery supervision, to remove the conflict of interest identified by the Ombudsman. You undertook to move swiftly following the King's Fund report due in [sic] February next year. We urge you to introduce legislation or take account via a section 60 Order before the general election.*

### *Review of Healthcare Inspectorate Wales (HIW)*

- 14 On 8 January 2015 the Welsh Assembly published an independent review of the role of HIW, which is the Local Supervising Authority for Wales. The review concluded that:

*HIW's primary role is to regulate healthcare services to ensure patients receive high quality and effective care. The supervision of midwives involves the regulation of a profession, as opposed to the inspection of a health service.*

### **Guernsey**

- 15 The Council has received regular updates on the NMC's involvement with maternity services in Guernsey. We published the reports of an extraordinary review on 30 October 2014. Events in Guernsey might be said to reflect a number of the concerns about the current framework highlighted by the Ombudsman.

### **Key considerations for Council**

- 16 The Midwifery Committee met on 21 January 2015 to consider the report. The Council will want to take the advice of Midwifery Committee in reaching its conclusions.
- 17 Council is advised to accept the main recommendation in the King's Fund report:

*The NMC as the health care professional regulator should have direct responsibility and accountability solely for the core functions of regulation. The legislation pertaining to the NMC should be revised to reflect this. This means that the additional layer of regulation currently in place for midwives and the extended role for the NMC over statutory supervision should end.*

- 18 In taking its decision, Council may want to consider the following:

#### **Evidential matters**

- The King's Fund found no risk based evidence to justify an additional tier of regulation for midwifery
- The additional tier did not appear to have a positive impact on the quality of referrals to fitness to practise as measured by the likelihood of case to answer findings or sanctions.
- In high profile cases involving shortcomings in maternity, the additional tier of regulation did not appear to have had a decisive positive impact on outcomes.
- The assessment of the King's Fund was that most of the work carried out under the aegis of the current arrangements is not what

it describes as ‘core regulation’ – it is work that is at the supportive, developmental and leadership end of the continuum set out by the King’s Fund in paragraph 6.2 (p.11) of its report.

### **Comparators**

- The King’s Fund found no other profession with an infrastructure comparable to statutory supervision.
- There are other health and care professions (though not nursing) where the custom of practice of supervision is well established without being statutory.

### **Perceptions**

- The perception of service users and the public was that if things went wrong, they wanted a clear single process for addressing shortcomings.
- The King’s Fund found that for some providers of maternity services the existence of a parallel framework around midwifery had a negative impact on their grasp of their own responsibilities for midwifery.
- The PSA’s views about midwifery regulation are summarised in paragraph 5 above. The PSA attended the recent partners’ meeting for this review and confirmed its support for the King’s Fund recommendations.
- The English Ombudsman, whose concerns about supervision led to this review, supports the recommendations and is satisfied that they address the issues she raised.

### **The future of supervision outside regulation**

- 19 Council’s core concern will be the fitness for purpose and safety of the regulatory model over which it presides.
- 20 However, throughout this process Council has been mindful of the strength of feeling among midwives about the value of supervision. The King’s Fund found that most midwifery stakeholders were not wedded to the link between regulation and supervision on principle; rather, they were concerned that without statutory force supervision would cease.
- 21 A subsequent consideration will be that any transition takes stock of the value added by the current arrangements to inform decisions about the future. It would not be in the NMC’s gift to direct the actions of others but the NMC would retain a keen interest, not least in the context of revalidation.

## Next steps

- 22 *If the Council supports the recommendation* we have no powers to change the NMC's legislation and will need to seek government support and parliamentary time to do so. The current government has committed to supporting legislative change if needed. The timing of the forthcoming general election means that there is little prospect of immediate change. Nevertheless, it is important that legislators understand Council's position at the earliest opportunity.
- 23 We are required by statute to consult on changes to our legislation, and DH would also need to hold a consultation. It is envisaged these consultations would need to cover changes to the Order and the repeal of Midwives Rules and Standards.
- 24 Without an immediate prospect of legislative change, Council may also wish to authorise a small number of interim changes to the standards component of the Midwives Rules and Standards, which can be managed without the involvement of DH, but would also require consultation.
- 25 If Council accepts the recommendation we would write, as part of a wider communications plan, to providers, explaining Council's decision and next steps, and reiterating their responsibilities as employers of midwives.
- 26 *If the Council does not support the recommendation* we will need to clarify how we would wish midwifery regulation to be specified in any future Law Commission Bill after the election.

### Public protection:

- 27 This work arose from public protection concerns raised by the Parliamentary and Health Service Ombudsman in England, and is principally concerned with ensuring our regulatory model is playing an effective and appropriate role in public protection.

### Resource implications:

- 28 The total cost of the work of the King's Fund is £345k and the work IPSOS/MORI contributed to the review was an additional £88k. If Council accepts the King's Fund's recommendation and the legislative changes are made the NMC will need to assess the likely impact on fitness to practise referrals of midwives. As set out in the King's Fund report, the principle costs of the current framework are met by the sector.

### Equality and diversity implications:

- 29 To our knowledge no explicit equality and diversity concerns have been raised in the course of the review, which had fairness and transparency as part of its terms of reference. However, if the review results in legislative change we envisage completing an equalities

impact assessment.

- Stakeholder engagement:** 30 The King's Fund engaged extensively with stakeholders during the course of the review and also issued a wider call for evidence. The NMC established a Partners' Group for the review and has also kept other key stakeholders informed throughout.
- Risk implications:** 31 The King's Fund address risks in the conclusion of the report. Risks to the NMC depend on Council's decision and will need to be set out in full once its decision is known.
- Legal implications:** 32 If Council accepts the recommendation of the King's Fund, legislative change will be required. In addition to our own legislation there may be requirements to change wider legislation in which the role of the LSA is embedded, e.g. where the body fulfilling the function of the LSA is specified.





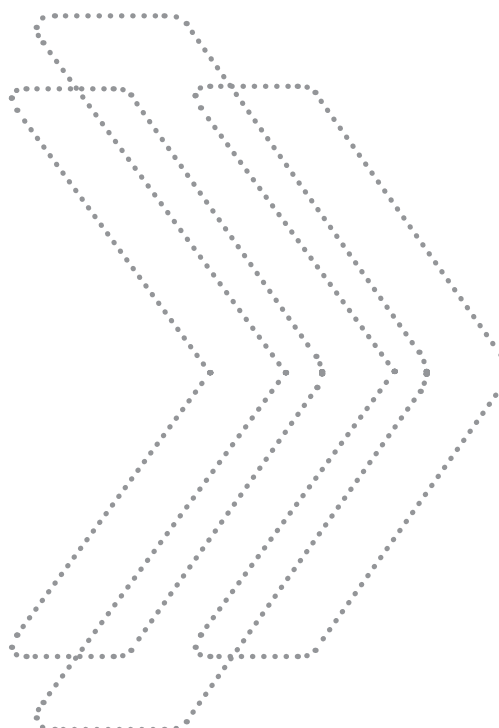
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# Midwifery regulation in the United Kingdom

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## Table of contents

1.	Introduction .....	2
2.	Terms of reference .....	2
3.	The current system of midwifery regulation .....	3
4.	Methodology for this review.....	6
5.	Context .....	7
6.	Defining regulation and supervision: a conceptual framework .....	10
7.	Key regulatory tasks in protecting the public .....	12
7.1	Core functions of regulation .....	12
7.2	Tackling problems early .....	14
8.	Other functions of the current model of midwifery regulation.....	19
8.1	Supporting and developing staff.....	19
8.2	Leadership of the profession .....	21
8.3	Strategic leadership.....	22
9.	Independent midwives.....	22
10.	Conclusions and recommendations.....	23
10.1	Core functions of regulation.....	23
10.2	Tackling problems early .....	24
10.3	Other functions .....	25
11.	Risks, complexity and transition.....	26
12.	Recommendations for other partners.....	27
	References .....	29
	Acknowledgements.....	31

## 1. Introduction

- 1.1 Midwifery regulation is based on a model established in 1902 and the principles have remained essentially unchanged since that time. The scope of midwifery regulation has since expanded to cover a wide range of activities, some of which are defined in legislation while others have developed into custom and practice. This has taken midwifery regulation beyond the usual scope of the professional regulator, meaning that midwifery is regulated differently to the other health care professions.
- 1.2 There is a lack of quantifiable evidence about the impact of the current system of midwifery regulation on public protection and there is a wide range of divergent and conflicting opinion expressed by stakeholders. We have considered these views and the evidence available and set them in the context of the current approach to health care professional regulation in the United Kingdom.
- 1.3 Modernising all of the elements that currently sit within the scope of midwifery regulation will require a response from a wider set of stakeholders than the professional regulator alone, simply because this scope has moved beyond the standard functions of a professional regulator. Our recommendations therefore focus on roles and accountabilities for the wide range of functions carried out under the auspices of midwifery regulation and attempt to address the question 'what is the role of a health care professional regulator and what role do other players in the system have?'

## 2. Terms of reference

- 2.1 This report was commissioned following the Parliamentary and Health Service Ombudsman (PHSO) in England's investigations into three cases arising from failures in maternity care at Morecambe Bay NHS Foundation Trust along with a thematic report *Midwifery supervision and regulation: recommendations for change* (Parliamentary and Health Service Ombudsman 2013). This report recommended that:
  - midwifery supervision and regulation should be separate
  - the NMC should be in direct control of regulatory activity.
- 2.2 In addition, the Professional Standards Authority (PSA) was given the opportunity to contribute its perspective to the report and added that:
  - there is a lack of evidence to suggest that the risks posed by contemporary midwifery require an additional tier of regulation – bringing into question the proportionality of the current system when compared to that operating for other professions

- the imposition of regulatory sanctions or prohibitions by one midwife on another without lay scrutiny is counter to principles of good regulation in the post-Shipman era.

2.3 At its meeting on 29 January 2014 the NMC accepted the PHSO's finding that midwifery regulation was structurally flawed as a framework for public protection and approved an immediate review of midwifery regulation, which The King's Fund was commissioned to undertake. The review was asked to consider potential models for the future of midwifery regulation, with particular reference to the PHSO's recommendations, taking into account the wider concerns of the PHSO and the PSA as set out in the PHSO report. The recommendations would have regard to:

- public protection
- proportionality
- public confidence in the regulatory model, which, post-Shipman, includes the expectation that regulatory decisions are not taken by professionals in isolation
- the PSA's standards of good regulation
- public assurance about the responsibility and accountability of service providers for the quality of maternity services
- fairness to midwives whose fitness-to-practise is called into question.

2.4 The review would also have regard to the NMC Council's interest in distinguishing two aspects of the review:

- 'the link between supervision and regulation and... the future of supervision and the supporting infrastructure if it were no longer part of the regulatory framework.' (NMC Council minutes, 29 January 2014)

### **3. The current system of midwifery regulation**

3.1 There are around 37,000 midwives currently registered to practise in the United Kingdom mainly working in NHS organisations, with some employed by private sector organisations including agencies and a small number (around 150) operating as independent midwives. There are a number of components to the regulation of health care in the United Kingdom:

- the regulation of organisations
- the regulation of individuals as employees of organisations
- the regulation of individuals as members of professions.

3.2 Due to differences in the way that health care is organised across England, Scotland, Wales and Northern Ireland, the regulation of organisations and employees of organisations differs between the four countries but the regulation of most other health care professionals, including midwives, is UK-wide.

### *Legislative framework for nurses and midwives*

- 3.3 The Nursing and Midwifery Order 2001 grants the Nursing and Midwifery Council (NMC) powers to regulate midwifery and nursing in the United Kingdom, similar to those powers available to the other health care professional regulators. These powers include establishing and maintaining a register of all qualified nurses and midwives eligible to practise in the UK; setting standards for their education, practice and conduct; and taking action when those standards are called into question. All nurses and midwives must complete continuing professional development and demonstrate continued fitness-to-practice in order to be re-registered every three years.

### *Additional powers for the regulation of midwives*

- 3.4 The Order contains an additional set of powers for the NMC to set rules related to midwifery. These rules provide midwives with an extra layer of regulation known as 'statutory supervision'. Any changes to the Order and rules are subject to parliamentary process and cannot be changed unilaterally by the NMC. The Order requires a Local Supervising Authority (LSA) to be established in each of the four countries of the United Kingdom and requires midwives to give notice to an LSA when they intend to practise in that area. It stipulates that LSAs must supervise midwives in their area in line with the NMC's Rules and Standards (set out in *Midwives Rules and Standards 2012* (Nursing and Midwifery Council 2012)). The standards can be changed by the NMC but only after consultation. This additional power for the NMC to ensure supervision goes back to the model first established in 1902 when midwives were working as independent practitioners and county and borough councils were given powers to keep records of midwives in their area. No other health profession operates this model either in the United Kingdom or internationally.

### *Local Supervising Authorities (LSAs)*

- 3.5 There is a designated LSA for each of the four countries of the United Kingdom.
- The LSA for England is NHS England. There are four LSA clusters: North; Midlands and East; London and South. Through contractual agreements NHS England is also the LSA for overseas territories including the Channel Islands and the Isle of Man.
  - In Scotland, Health Boards carry out the functions of the LSA. There are two regions: the South East and West of Scotland; and the North of Scotland.
  - In Wales Healthcare Inspectorate Wales (HIW) acts as the LSA, on behalf of the Welsh Government.
  - In Northern Ireland the Public Health Agency (PHA) is the LSA.

- 3.6 All incidents, complaints and concerns involving midwives are notified to the LSA which oversees a preliminary investigation of the role of the midwife. If necessary there is then a fuller supervisory review that can result in a local action plan for the midwife, a formal LSA practice programme or referral to the NMC for a full fitness-to-practise investigation. The LSA can also immediately suspend a midwife from practising anywhere in the LSA area if they believe there is a major risk to mothers and babies.
- 3.7 Each LSA discharges its duties through a registered midwife known as the Local Supervising Authority Midwifery Officer (LSAMO) who has responsibility for carrying out the statutory LSA functions in all midwifery services, whether NHS or independent. At the time of this review there are ten LSAMOs in England, two in Wales, two in Scotland and one in Northern Ireland. Their role includes:
- 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
  - ensuring midwives have 24-hour access to a supervisor of midwives
  - accessing initial and continuing education and training for supervisors of midwives
  - leading the development of standards and audit of supervision
  - determining whether to suspend a midwife from practice
  - investigating cases of alleged misconduct or lack of competence
  - being available to women if they wish to discuss any aspect of their midwifery care that they do not feel had been addressed through other channels.
- 3.8 The LSAMO is selected and employed by the LSA, although the person specification and role criteria are specified by the NMC. Each LSAMO compiles an annual report for the NMC that outlines supervisory activities over the past year, key issues, audit outcomes and emerging trends affecting maternity services. The NMC monitors the quality of the LSAs through a quality assurance framework, carried out by a third party.
- 3.9 Each LSAMO appoints a number of supervisors of midwives (SoMs), with a recommended ratio of 1 SoM to 15 midwives. The NMC specifies the standards to which SoMs are trained. Every midwife must have a named SoM, who must meet with each midwife for whom they are a named supervisor at least once a year. Midwives must have 24-hour access to an SoM. SoMs attend training before being appointed, and they are accountable in their role to the LSAMO. Most SoMs undertake their supervisory duties in organisations where they hold substantive midwifery posts and have on average 7.5 hours a month of protected time to carry out their duties (Rogers and Yearley 2013) although some areas have chosen to appoint a smaller number of full-time SoMs. Training and additional pay in the form of an honorarium is funded by the employer.

SoMs are also available to women and families who should be able to contact an SoM at any time.

3.10 SoMs also have a role in investigating untoward or serious incidents, notifying the LSAMO when an investigation is being carried out and about the action required upon completion of their investigation. When carrying out these investigations the SoM is responsible to the LSAMO not to an employer. Changes to the *Midwives rules and standards 2012* mean that midwives should not be investigated by their named SoM.

#### **4. Methodology for this review**

4.1 We used a variety of methods to investigate the options for the regulation of midwifery including:

- a literature search and analysis that considered evidence about the regulation of midwives in the United Kingdom; regulation of other health care professionals in the United Kingdom; international regulation of midwives; and risk and midwifery
- face-to-face and telephone interviews with around 40 stakeholders identified by the NMC across all four countries, and a small number of family members of those affected by incidents involving midwives
- an analysis of NMC fitness-to-practise data for 2013/14
- a review of the LSA reports from 2012/13
- a selected call for written evidence from stakeholders identified by the NMC which received responses from the Care Quality Commission; Royal College of Obstetricians and Gynaecologists; Foundation Trust Network (now NHS Providers); Parliamentary Health Service Ombudsman for England and the Lead Midwife for the Education UK Executive.

4.2 We have also drawn on the work of Ipsos MORI who were separately commissioned by NMC to carry out focus groups and interviews with midwives, supervisors of midwives, heads of midwifery, directors of nursing and members of the public (including recent midwifery service users, parents and non-parents). In total, 30 interviews and 11 groups were carried out in October and November 2014. This research included participants from all four countries and we have incorporated their findings into this report.

4.3 As the legislation relating to the regulation of midwifery applies across the United Kingdom we have ensured in all aspects of this work that we have engaged with stakeholders in each of the four countries.

4.4 To note, where we refer to 'some stakeholders' we mean a significant minority. We have not attributed quotes to specific individuals or organisations unless we had specific prior agreement that they would be identified. We do identify the

broad source of the quote: for example a national stakeholder or a family member affected by incidents involving midwives.

- 4.5 In gathering qualitative evidence for this report we interviewed stakeholders to gather views on the current system and potential proposals for an alternative system. After a first round of interviews we did not find clear suggestions for any alternative model but did find significant confusion over the concept of 'regulation'. As a result we developed a conceptual framework presented later in this report and then carried out a second round of interviews with those stakeholders to discuss the framework and to talk through alternative scenarios for a future model of regulation. We also developed a set of criteria against which to assess alternative models, drawing upon the terms of reference.
- 4.6 In undertaking this review we make a caveat about the evidence. In health care 'evidence' is a rigorously defined concept with the randomised control trial (RCT) usually set as the gold standard. In this review while it was always unlikely that RCT evidence would be available, it is the case we have also been unable to find significant quantitative evidence about the impact of the current system of regulation on the protection of the public or any quantifiable evidence about the nature of the underlying risk to be mitigated.

## **5. Context**

### *Parliamentary and Health Service Ombudsman report*

- 5.1 Our work was commissioned as a direct result of the PHSO in England's report *Midwifery supervision and regulation: recommendations for change* in 2013 (Parliamentary and Health Service Ombudsman 2013), published following investigations into complaints from three families about Morecambe Bay NHS Foundation Trust. In the report the PHSO concluded: '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]'. To an extent, the NMC has already taken action to try to mitigate these perceived conflicts although the NMC cannot make fundamental changes within the current legislative framework. The incidents in Morecambe Bay took place in 2008 and in 2012 the NMC issued new rules that meant that midwives could not be investigated by their named supervisor. Possibly because of this, we did find that some stakeholders expressed the view that the concerns outlined in the PHSO's report related to an investigation at only one organisation and may not represent practice in other organisations, and occurred under different rules to those now pertaining. However, while our report was commissioned by the NMC in direct response to the PHSO's report into Morecambe Bay, potentially similar concerns have now been reported in Guernsey and we found a significant number of other drivers for change that we have taken into consideration and which are outlined below.



### *Professional Standards Authority*

- 5.2 The Professional Standards Authority (PSA), as overseer of the performance of the health care professional regulators, had also expressed concerns about the proportionality of the regulatory system for midwifery, the opportunity for lay involvement and also the need for the NMC to have clear accountability for regulatory actions. In a submission to the Public Administration Select Committee the PSA highlighted the changes in professional regulation as a response to the Shipman inquiry that have changed the national approach to professional regulation. The White Paper *Trust, assurance and safety* (Department of Health 2007) gave parity to lay and professional membership of Councils, removing the direct influence of the professions over regulation 'moving away from self-regulation to a shared approach that clearly prioritised the interests of patients and the public'. The evidence stated:

*Seen in this context the Supervisor of Midwives role is a clear candidate for reform as it demonstrates 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 undermine confidence in regulation.*  
(Professional Standards Authority 2014).

### *Responses to the second Francis inquiry*

- 5.3 Since Robert Francis's report of his public inquiry into the failings at the Mid Staffordshire NHS Foundation Trust was published in February 2013 (The Mid Staffordshire NHS Foundation Trust Public Inquiry 2013) the health service in England has had an increased focus on quality and safety, which has implications for professional regulation. The Clwyd review (Clwyd and Hart 2013) of how the NHS handles complaints, and the increased focus on transparency, openness and candour has had an impact on the way in which incidents are investigated. *Hard truths*, the Department of Health's response to Francis and associated reports, emphasised the need for professional clinical leadership within organisations (Department of Health 2013a).

### *Law Commissions' review of regulation*

- 5.4 In 2011 the government asked the Law Commissions to review the complex legislation surrounding professional regulation and bring forward proposals to modernise and simplify professional regulation law. The Commission's report on the regulation of health care professionals and the subsequent draft Bill, presented to parliament in 2014, concluded that there is a need to streamline and unify the diverse systems of regulation of health care professionals and to improve the speed at which fitness-to-practise cases are resolved (Law Commission *et al* 2014).

### *Revalidation*

- 5.5 The NMC has committed to introducing a system of revalidation for nurses and midwives by the end of 2015 and a model for revalidation will be piloted in early 2015. It is expected that any revalidation model would be the same for both nurses and midwives, and will be an employer-based model. The rationale for this is to ensure that employers have greater awareness of the nursing and midwifery code and have greater clarity over their responsibilities in employing registered professionals, consistent with the second Francis inquiry. Under revalidation, nurses and midwives will be required to declare that they have met the requirements for practice hours and continuing professional development; reflected on their practice, based on the requirements of the Code, using feedback from service users, patients, relatives, colleagues and others; and received confirmation from a third party.

### *Organisational issues: England and Wales*

- 5.6 In England, the restructuring of the NHS has also prompted a reassessment of midwifery supervision. Currently, NHS England is the LSA that has responsibility for statutory supervision of midwives in England. Some stakeholders told us that it was their understanding that this responsibility for professional regulation is at odds with NHS England's role as a commissioning body and consequently they expect NHS England will seek to review this function. In Wales a review of Healthcare Inspectorate Wales concluded that the system regulator was not the appropriate body to be the LSA (Marks 2014).

### *Financial*

- 5.7 While not an explicit driver for change, the LSA elements of midwifery regulation are different from the regulation of most other health care professions in not being funded by the health care professionals themselves. Midwives pay for registration with the NMC. However, the cost of the LSAMO is funded by the LSA; the costs of training for SoMs and any extra pay is met by the employer; and the cost of practice development programmes for midwives subsequent to an investigation is also met by the employer. Stakeholders made it clear to us that any regulatory model needs to have sufficient resources for its effective delivery, although some noted that this system had successfully forced investment in midwifery services that might not have otherwise occurred.

### *Risk*

- 5.8 As part of this review we looked for, but did not find, quantified evidence of the risks posed by midwifery practice, as compared to other professions. Clinical negligence claims relating to maternity care represent the highest value and second highest number of such claims reported to the NHS Litigation Authority,

although this represented less than 0.1 per cent of births during the time period studied (NHS Litigation Authority 2012). The evidence base on the risks around maternity is increasing and includes recent NICE guidance. However, there are no studies related to the risk associated with midwives, as opposed to other professionals involved in maternity care. The recent attempts to address the issue of the insurability of independent midwives have further explored the issue of risk in midwifery. A report commissioned by the Royal College of Midwives (RCM) and the NMC found that 'there is no current means by which claims [in obstetrics, gynaecology and midwifery] can be separated out and analysed to create a reliable risk profile for midwives alone' (Flaxman Partners *et al* 2011). Some stakeholders we interviewed felt many nursing roles were difficult to distinguish from midwives in the degree of (unquantified) risk that they dealt with.

### *International trends in regulation of midwives*

5.9 The International Confederation of Midwives set global standards for midwifery regulation (2011) to promote regulatory mechanisms that protect the public, to be achieved through following these six main functions:

- setting the scope of practice
- pre-registration education
- registration
- relicensing and continuing competence
- complaints and discipline
- codes of conduct and ethics.

5.10 These standards do not contain a system of statutory supervision like that operated in the United Kingdom but state that regulation should be midwifery-specific, with the governance of the regulator having a majority of midwives although that is not consistent with wider UK trends in health care professional regulation which requires a lay majority. There is no uniform model for regulation of midwives internationally. Different arrangements exist across European Union states where in some cases midwives are regulated with nurses and in other cases with doctors. In New Zealand there is a consistent framework for regulation across the health professions but individual regulatory bodies, including a separate Midwifery Council. In the United States midwives are mainly governed by State Boards of Nursing because in many US states midwives must also be qualified nurses. Given this situation there is no straightforward learning to be taken from other countries' approaches to midwifery regulation.

## **6. Defining regulation and supervision: a conceptual framework**

6.1 Our research identified significant confusion around the terminology used in midwifery regulation and supervision. Different stakeholders defined regulation

and supervision in different ways and used the term 'statutory supervision' to refer to a wide range of functions. This confusion is understandable and arises from two key factors.

- The definition and tasks associated with being the 'professional regulator' of midwifery. We have defined these as the core functions of regulation in the conceptual framework below. In general, this represents the tasks of the professional regulators in the United Kingdom for the health care professions other than midwifery.
- The current actual role of the NMC as pertaining to midwifery combines this core role with a wider set of other responsibilities including that of the oversight of statutory supervision as set out in earlier sections above.

6.2 During the course of our research we developed a conceptual framework that provides an overview of the current tasks undertaken under the auspices of midwifery regulation.

<b>Current functions of midwifery regulation</b>					
	<b>Key regulatory tasks protecting the public</b>		<b>Other</b>		
<b>Overview of task</b>	<i>Core functions of regulation</i>	<i>Identifying and tackling problems early</i>	<i>Supporting and developing people</i>	<i>Leading the profession</i>	<i>Strategic oversight of midwifery services</i>
<b>Who is responsible?</b>	Regulator	Employers	Employers and midwives		
	LSA/LSAMO/SoM				
<b>Specific tasks</b>	setting standards; maintaining the register; taking action to ensure fitness-to-practise.	Investigating incidents; a 'sub-fitness to-practise (FTP)' process	clinical supervision; mentorship; ongoing development; 24-hour telephone support.	developing best practice; supporting women.	oversight of midwifery services; local/regional strategic lead.

6.3 In the sections that follow we discuss the findings from our research using the framework above. It is important to say that all of the functions identified here are felt to be important and useful – our work has focused on *who* is most appropriately responsible and accountable for these functions rather than questioning their value per se.

6.4 Currently the LSA's remit stretches across all these functions and by extension, so does the NMC (if not directly). As a result, for midwifery, the NMC undertakes a range of functions unique among professional regulators in the United Kingdom.

## **7. Key regulatory tasks in protecting the public**

### **7.1 Core functions of regulation**

7.1.1 The White Paper *Trust, Assurance and Safety* (Department of Health 2007), published following the Shipman inquiry, was clear that the focus of the professional regulators should be protecting the public rather than protecting the profession. The Law Commission review (Law Commission *et al* 2014) also concluded that the main objective of the health care professional regulators should be to protect, promote and maintain the health, safety and wellbeing of the public and the Health and Social Care (Quality and Safety) Bill currently in parliament seeks to give all the health care professional regulators the overarching objective of public protection. However, there are many other players in the health care system for whom this duty could also be said to be paramount, certainly when interpreted in its broadest sense. As the Law Commission noted, 'professional regulation is one element of a much broader system of ensuring patient and service user care' (Law Commission *et al* 2014).

7.1.2 We need to note that the lack of clarity over what is meant by 'public protection' can be a cause of disagreement. This is because while the NMC's role as a professional regulator means it is clearly responsible for one element of public protection (the core minimum functions set out above, in common with other regulators), some interpreted 'public protection' more broadly to capture functions that for other professions may fall to other organisations to ensure, eg, employers, other regulators, and other stakeholders including (in England) commissioners. While there is no doubt that these other functions can contribute to 'public protection' in this broader sense, the question is again whether these are best undertaken by the NMC: in short, that while the NMC is there to protect the public, not all public protection is the appropriate business of the NMC.

7.1.3 The system of professional regulation in the United Kingdom is designed to protect the public by ensuring that if a patient is seen by a health care professional, such as a doctor or a midwife, the patient can trust that the practising clinician is in a regulated profession, trained, subject to standards and accountable if those standards are not met. Based on evidence drawn from the literature on health care professional regulation, we have defined the core minimum functions common to all health care professional regulators as:

- the registration and renewal of registration of professionals

- ensuring the quality of pre-registration and to a varying degree, post-registration education and training
- setting standards for professional conduct and practice and ensuring ongoing practice standards (for example, through revalidation)
- the investigation and adjudication of fitness-to-practise cases.

7.1.4 The NMC is required by the Nursing and Midwifery Order 2001 (Nursing and Midwifery Council 2014) to carry out these functions for midwives. The core functions of regulation for midwifery are, on the whole, directly carried out by the NMC. It was clear from our research that some midwives feel distanced from these core functions of regulation and from the NMC and some midwives felt that the role of the regulator should be to represent, as well as to regulate, the profession. A lack of interaction with the NMC during the course of their career, coupled with a perception of a lack of representation of midwives within the NMC, was a reported cause for ambivalence towards the NMC, or at times negativity.

*There's a lack of midwifery representation at the NMC. There is nobody there who is a midwife. It is quite specialised and there is nobody representing our profession at the top level.*

Supervisor of Midwives (Ipsos MORI research)

Some stakeholders also had criticisms about the NMC's fitness-to-practise processes, but these were outside the scope of our review even if they were clearly seen by stakeholders as part of the current landscape of professional regulation.

7.1.5 There are some functions carried out by the LSA/LSAMO that could be defined as core functions of regulation, including the submission of the annual intention to practise and the ability of the LSAMO to suspend a midwife from practice immediately in that particular LSA. As the NMC is not in direct control of the LSA it cannot be said to have clear oversight of these regulatory actions.

7.1.6 The ability of the LSAMO to suspend was seen as a benefit by some stakeholders. Analysis of LSA reports from 2012/13 suggested that this power was used on 18 occasions during the year, of which 8 were in London and a further 6 in the south of England. Scotland had no suspensions, Wales had two and Northern Ireland had one. The ability to suspend relates only to practice in a single country– it would not necessarily prevent a midwife who was suspended in Wales registering to practise over the border in England. It was suggested by some stakeholders that improvements to the speed of application of interim suspension orders by the NMC has reduced the need for this power to be retained at LSA level although it is possible not all stakeholders were aware of the recent improvements to the speed of this process. In 2013/14 the NMC imposed 15 interim suspension orders on midwives (this figure excludes those who are dual-registered).

## 7.2 Tackling problems early

7.2.1 Unlike any other health care profession, midwifery has an extra layer of regulation that we have termed a 'sub fitness-to-practise' (sub-FTP) process. Any incident, complaint or concern involving a midwife should be notified to the LSA by the local supervisor of midwives who then performs a preliminary investigation and if necessary a fuller supervisory review of the role of the midwife or midwives in the incident. In 2012/13, 639 supervisory investigations were carried out (though these may have involved more than one midwife). These investigations happen in parallel to any provider-led investigation. Investigations can result in sanctions, in the form of a local action plan, a formal LSA practice programme (a minimum of 150 hours and a maximum of 450 hours of training) or referral to the NMC for a full fitness-to-practise investigation. Changes to the sanctions as a result of the revised *Midwives rules and standards 2012* (Nursing and Midwifery Council 2013), which were implemented in 2013, mean that analysis of the data is not straightforward, but in 2012/13 128 midwives in the United Kingdom were recommended a period of supervised practice or an LSA Practice Programme and 22 midwives were referred to the NMC by the LSA for assessment of their fitness-to-practise. Some of these midwives were referred because they did not successfully complete or refused to participate in a LSA practice programme or period of supervised practice.

*Does the sub fitness-to-practise approach affect the volume and quality of referrals to the NMC?*

7.2.2 The current system may prevent an individual from being referred to the NMC and allow remediation at a local level. This could be both a benefit (ensuring low-level problems are proportionately addressed, with an emphasis on practice development) or a disadvantage (delaying or preventing referral of appropriate cases to the NMC). In theory, this sub-FTP process should filter complaints to the NMC, meaning that cases that referred are more appropriate and are more likely to result in sanction. We hypothesised that there would be a difference in the fitness-to-practise data between nurses and midwives, but our analysis of the limited FTP data available from the NMC revealed no significant difference in the proportion of referrals to the NMC found to have 'no case to answer' between nurses, midwives or dual registered registrants (36 per cent, 40 per cent and 33 per cent of total referrals respectively). In summary, the evidence is not available to prove that the current system does prevent unnecessary referrals to the NMC or that it delays necessary referrals.

*Provider responsibility for clinical governance*

7.2.3 Perhaps the main issue identified by our research on this function was the confusion between the provider's role in investigations and the role of the midwifery supervisory investigation. Providers are responsible for the quality of

the services they provide and as such have responsibility to ensure appropriate clinical governance and oversight. In its response to our call for evidence, the Care Quality Commission (CQC) stated:

*We consider that a proportionate regulatory framework would take into account the responsibilities of the individual registrant to maintain the requirements for professional registration under the NMC code in the context of the systems and processes required of his/her employer to provide safe services.*

Care Quality Commission.

Previous work on professional regulation by The King's Fund has recognised that the way health care is delivered is changing to a more system-based approach. Mistakes are often likely to be due to a combination of factors, many outside the control of any one professional, and investigatory systems need to recognise this (The King's Fund 2006).

7.2.4 The debate generated during this research centred on whether the sub-FTP process provided a helpful safety net or counterbalance, or an unhelpful confusion of ownership with providers on this issue. Some stakeholders, particularly midwives, liked the idea that parallel investigations could provide a richness and robustness to the process, allowing participants to bounce ideas and thoughts off each other. However, others felt two investigations could create a confusion of responsibility while also making the process too lengthy and others thought it was an inefficient use of resources; a single, properly run investigation should suffice. While providers valued the expertise of SoMs, they felt that the current process was unhelpfully disconnected from organisations' clinical governance responsibilities. For example, one national stakeholder told us:

*The employer should be in full control of fitness-to-practise or else how will they learn and help others learn?'*

National stakeholder

*I have, for years, grappled with trying to understand the separation of supervision of midwifery sitting outside employers. There's this blurring of boundaries that at times becomes difficult... I find executive directors of nursing find it hard to get their head around the role of the LSAMO and how midwives can go outside of the line-management processes with employers, outside to LSAMO.*

Director of Nursing (Ipsos MORI research)

7.2.5 A number of stakeholders claimed that the independence of SoMs provided an additional safety net in cases where clinical governance was failing to protect the public:



*Trust employees work from a different agenda to the independent statutory function of supervisors of midwives and there is a very real risk that issues would not be addressed as it could give the trust a poor reputation.*

National stakeholder

*I have seen incidents in nursing where I've thought that might not have happened had there been a similar regulation system as midwives. If you take supervision away then there is the expectation that the employer now has to hold itself to account and that's where you don't have that external checking mechanism.*

Supervisor of Midwives (Ipsos MORI research)

7.2.6 While the results of the full investigations are yet to be published, events at Morecambe Bay, and most recently in Guernsey, suggest that where an organisation's clinical governance processes are not functioning effectively, SoMs have not always succeeded in providing an effective backstop. However, while these failures are relatively well known, we do not know if there may be cases where SoMs have provided such a backstop. There is also a risk that this confusion undermines the responsibilities of providers in investigations and therefore weakens one stage in the process towards potential referral to the NMC. As such this confusion could be seen to undermine one element (provider responsibilities) in the overall approach toward professional regulation.

*Lack of transparency and clarity for service users*

7.2.7 The Ipsos MORI research found that the public had an inherent trust in the NHS and in midwives but questioned the complexity of the current regulatory system and the value of two investigations being conducted in parallel. Most public participants in the research, and indeed the family members we spoke to, wanted investigations to be transparent, accountable and straightforward where service users and their families are kept up-to-date with progress and understand what is happening with their complaint or issue. They felt that having two separate investigations compromised these values somewhat as it would be hard for them to follow the progress of both. They were uncertain what would happen if the two investigations didn't concur about next steps or sanctions and were concerned that this would cast further doubt on the process.

*It's a great system if you want to confuse someone. I was never told how to complain, never told what a supervisory midwife was. Then when I looked into it, I couldn't find out who the supervisory midwife was. Then I was told the lady who did the risk assessment she'd gone off sick and whenever I wrote they said, well, she's not back at work yet. I mean, I wrote thousands of emails in total and really had not one clear answer yet.*

Family member

7.2.8 What is most important to families is that their concerns are acknowledged and lessons learnt so that others do not experience what they did and this applies to any model of regulation and complaints. The current system, where it has failed, has obstructed this process, enabling all involved to obfuscate responsibility for learning lessons:

*It's not about half truths, it's about being totally open and honest, and saying, yes, this did happen. Nothing's going to ever change the fact that my daughter's dead. But, they should learn lessons and things should be different, so that another family don't ever go through what we went through.*

Family member

#### *Conflict of interest*

7.2.9 The Parliamentary and Health Service Ombudsman (PHSO) had highlighted the potential for a conflict of interest if a supervisor undertook an investigation into the midwife for whom they were the named supervisor. One service user who participated in an Ipsos MORI focus group expressed this concern:

*The only thing that would worry me is if it was the midwife's own supervisor... they've known them over the years and they might be like 'Oh, she's made a silly mistake'. I'd want an outside supervisor to come in definitely... who didn't know her and who just went on the facts.*

Service user (Ipsos Mori research)

7.2.10 The changes to the *Midwives rules and standards 2012* (Nursing and Midwifery Council 2013) attempted to address this by making it clear that a midwife could not be investigated by their named supervisor and evidence from our stakeholders suggests that many employers have already taken steps that they believe will mitigate the issues raised by the PHSO's report. In Wales and parts of London further attempts to mitigate a conflict of interest are being made by employing full-time SoMs who can only investigate cases in organisations where they are not employed. This aims to address the potential conflict from investigations being undertaken by a supervisor who is part of the wider team within an organisation, even if they are not the named supervisor of the midwife under investigation.

7.2.11 Some members of the public and midwives who participated in the Ipsos MORI research welcomed the investigation by local SoMs as they felt there were benefits to the investigator having a familiarity with the front line and understanding the local context and challenges midwives face. Others argued that conflict of interest cannot be removed entirely in any model: the employer too will have an interest in any sub-FTP investigation whether a midwife is found to be fit to practise or not.

*If an employer's having management issues with somebody and then something happens with practice, does that make them more readily keen to send somebody to the NMC? And, equally, they've got a midwife who they know is fantastic or they think is fantastic, are they more likely to think, 'Oh, I don't want to send her to the NMC because I know she does a really good job'?*

Midwife (Ipsos MORI research)

- 7.2.12 Despite the steps taken to mitigate conflict of interest, the current model still relies on regulation by peers. Following the Shipman inquiry, the health care professional regulators have moved away from a system of peer-regulation to one of a shared approach with patients and the public, whereas the current sub-FTP process does not require external scrutiny of decisions.

#### *Oversight by the regulator*

- 7.2.13 The sub-FTP process is carried out at arms-length from the NMC and the NMC is not in direct control of the regulatory actions and sanctions carried out in its name. By comparison, the General Medical Council's (GMC) pilot 'affiliate' programme, while attempting to address the regulatory gap between local concerns and referral to the GMC, was premised on the fact that the GMC's regulatory responsibilities should not be expanded into areas that rightly remain the responsibility of local employers (GMC 2010).

#### *Quality and timeliness of investigations*

- 7.2.14 Some stakeholders and midwives highlighted the complexity of the skills needed to successfully carry out investigations and expressed doubts about whether the time available to supervisors of midwives to carry out their duties (on average 7.5 hours per month) provided sufficient space for timely investigations. The changes to midwifery supervision in Wales and London attempted to address this by creating full-time supervisors of midwives who could be trained in investigation. However, it was notable in our research that midwives and supervisors of midwives valued this aspect of the SoM role less than the supportive role and suggested if they had to lose one function then it would be the investigatory one.

#### *Tracking of low-level concerns*

- 7.2.15 In September 2012, the Health and Care Professions Council (HCPC) commissioned Picker Institute Europe to explore public and professional views and understandings of public protection (Moore *et al* 2013). This study found that focus group participants wished to be protected from health professionals and services who are 'repeat offenders' or those whom they believe to have 'slipped through the cracks'. There was also a particular concern about health or

care professionals moving from one employer to another and concealing a history of 'minor' issues that, taken together, might suggest impaired fitness to practise. The LSAMO database was felt by stakeholders to address this issue by preventing midwives subject to investigations and fitness-to-practise programmes from moving area without the information about them following on. This was felt to be of particular importance in London where there were multiple potential employers in a small geographical area.

### *Proactive regulation*

- 7.2.16 Some stakeholders expressed the view that the current system 'saves midwives for the profession' by avoiding unnecessary referrals to the NMC and by putting in place actions to deal with low-level issues, giving employers confidence that the issues had been addressed so they were able to keep midwives in their jobs. One stakeholder stated, 'Most midwifery incidents are not malevolent, they are negligence or errors of judgement so the best way of protecting the public is enabling [midwives] to have someone to talk to, to have a system that enables them to get training.' Other stakeholders were clear that it should not be the job of regulation or a regulatory system to protect midwives, only to ensure a fair and proportionate process.

*And that's what we complained about, not only the lack of [any focus on root cause analysis], but the whole thing is set up to avoid it. It protects the profession or protects the organisations that run the profession most, rather than protecting the public.*

Family member

- 7.2.17 That stakeholders raised the issue of 'saving midwives for the profession' reinforces concerns over the potential perceived conflict of interest between maintaining professional standards as the professional regulator and wider professional concerns that are fundamentally (and in all other professions) the responsibility of others in the system.

## **8. Other functions of the current model of midwifery regulation**

The following section of our report considers the elements of our conceptual framework that fall outside the scope of our focus on the key tasks in protecting the public.

### **8.1 Supporting and developing staff**

- 8.1.1 'First and foremost, we should want to get staff experience right because it is the right thing to do' (Cornwell 2009). The current system of midwifery regulation does include supporting and developing staff and this element was without doubt extremely important to most stakeholders we interviewed, particularly midwives and, indeed, for many this was their key issue of concern.

This view is supported by others. For example, the NHS Constitution for England sets out a clear pledge that the NHS will be a good employer that supports its staff and cares about their health and wellbeing (Department of Health 2013b).

- 8.1.2 A systematic review of perceptions of statutory supervision found that 'the potential for supervision to enhance practice varied according to the nature of the relationship between midwife and supervisor' (Henshaw *et al* 2013). Butterworth *et al* (2007) reviewed the current state of knowledge of the benefits of clinical supervision more generally and found that the literature typically asserts the value of peer support, frequently on the basis of interviews with staff who report it as beneficial but another study found no evidence specifically linking clinical supervision to patient outcomes (Carson 2007). We also found that despite the lack of evidence many midwives did believe that there were benefits to service users.

*I think if you get rid of supervision it becomes very reactive, so you're waiting for a problem and then you're reacting to it. Whereas supervision, it's very preventative. It's very, pre-empting a problem.*

Midwife (Ipsos MORI research)

- 8.1.3 Research found that those training to become SoMs cited providing support for midwives as the main reason for entering training (Rogers and Yearley 2013). Midwives and SoMs in the focus groups run by Ipsos MORI felt that this role was an integral part of regulation – this idea of 'regulation via support', including tasks like the annual review, was seen as a proactive form of regulation that helped to pick up and address issues early. It was also clear that many SoMs were providing support beyond the narrow role laid out in the *Midwives rules and standards 2012*, for example, providing clinical practice development.

- 8.1.4 Some stakeholders also saw the role that SoMs have in providing clinical supervision, mentorship and preceptorship as exemplary practice that other professions should have access to.

*I would like to see the nursing profession having the same kind of preceptorship support, somebody to go to, access to somebody 24 hours. That's really good practice.*

National stakeholder.

- 8.1.5 However there was a lack of consensus on whether responsibility for ensuring good clinical supervision should be the role of the regulator: one stakeholder said, 'good clinical supervision needs to be in place for lots of professional groups... but it's not the role of the regulator'. Some felt that practice development midwives or clinical practice facilitators should be able to pick up this type of supervisory support. Many stakeholders suggested that the fact that this form of supervision was lodged in statute ensured that it happened for midwives, where it often did not for other professions. Many were also

concerned that if a requirement for supervision was not a statutory requirement, either for the regulator or for employers, then employers were unlikely to prioritise it and consistency of approach would also be at risk. Employers expressed mixed views on this:

*As an employer I have a huge role in making sure that staff are developed and supported in doing their job and actually the supervisor of midwives is supplementary to that. I suppose what I'm trying to get at is if you took the supervisor of midwives away people would still be supported and developed because as an organisation that, there's a huge, huge weight on us to do that anyway.*

Head of Midwifery (Ipsos MORI research)

*I'm not comfortable with the supervisor of midwives and the LSAMO role ceasing to exist because they provide very substantial support... to me, the LSAMO is slightly detached from the employer and they give a more independent view.*

Director of Nursing (Ipsos MORI research)

8.1.6 For many midwives and indeed other stakeholders the assertion that employers would anyway provide supervision was unconvincing as they argued that they could see that supervision was not provided in such a way to nurses and to other health care professionals, at least not universally.

## **8.2 Leadership of the profession**

8.2.1 During the course of our research we identified a number of roles carried out by the LSAMO and SoM that could be described as providing professional leadership. The role of SoM has changed greatly since a seminal 1998 study by Stapleton (Stapleton *et al* 1998). Previously, the focus had been on checking the annual intention to practise and completion of the annual review but preparation courses were getting longer and roles expanding (Rogers and Yearley 2013). SoMs are also available to discuss care with women – either post-birth or when discussing options for birth – and often play a leadership role within their organisation. One example cited to us included a group of supervisors who supported local midwives when the midwives disagreed with a change in practice suggested by the local obstetricians:

*They stood in between the midwives and the obstetricians essentially to protect the midwives.*

National stakeholder

8.2.2 In their job description, LSAMOs have tasks that include being involved in the development, delivery and monitoring of pre-registration midwifery programmes and being available to women if they wish to discuss any aspect of their midwifery care that they do not feel had been addressed through other channels.

## 8.3 Strategic leadership

8.3.1 LSAMOs often provide strategic leadership for maternity services in the United Kingdom. Their annual reports include undertaking annual audits of local maternity services and providing evidence of developing trends that may impact on the practice of midwives. In England in particular, where the abolition of the strategic health authorities removed regional leadership for service development, LSAMOs were often the only person identified as the senior strategic leader for midwifery and maternity services in an area:

*Take NHS London, for example, which of course has got the most maternity units and the most midwives in the whole of the UK, I mean they haven't actually got a midwifery adviser outside the LSA.*

National stakeholder

8.3.2 We also heard of an example of an LSAMO who had picked up a high stillbirth rate in her region and subsequently developed a change programme that she was able to implement as she had oversight of the SoMs in each maternity unit and was therefore able to implement change without employer buy-in. One LSAMO reported that 80 per cent of her work was related to improving services, rather than regulation. However, this does mean that much of the information received by the NMC in the annual LSAMO reports contains information over which NMC has no locus to act, for example, caesarean birth rates or the number of times admissions were suspended at a particular hospital. Many of these messages would be better made to other stakeholders in the health care system (although the relevant stakeholder will differ across the four countries of the United Kingdom).

## 9. Independent midwives

9.1 There are around 150 independent midwives in the United Kingdom, mainly based in London and other urban areas. Our interviews and the Ipsos MORI focus groups found that independent midwives often saw the current system of midwifery regulation as punitive and not reflective of the practice of independent midwives. Notably, independent midwives tended to have more negative perceptions of regulation and felt midwifery was over-regulated. This dissatisfaction appeared to be due, in part, to changes made to indemnity insurance. However, they also felt that midwives should be more autonomous than nurses as they have more of a support role through a life stage, rather than a medical role of treating illness, injury or disease. The perceived over-regulation of midwives was seen to reflect that these values were not recognised. Several of those we spoke to would prefer to seek their own professional supervision rather than be subject to oversight by midwives employed by NHS provider organisations.

9.2 Midwives wishing to practise alone, or in organised groups not as employees of the NHS, have had difficulty in obtaining the professional indemnity insurance required by EU Directive (2011/24/EU) and are likely to move towards a more organisational-based model. While in England they are currently exempt from CQC registration if they meet the criteria of solely providing care in a woman's home and not under contract from NHS, the Department of Health has proposed removing this exemption. This will also require independent midwives to be subject to clinical governance requirements.

## 10. Conclusions and recommendations

Taking into account our caveats about the availability of quantifiable evidence and the conflicting views of stakeholders, we have addressed the question: 'what is the role of a health care professional regulator and what role do other players in the system have?' and our conclusions and recommendations are set out below. The core recommendation is that:

**The NMC as the health care professional regulator should have direct responsibility and accountability solely for the core functions of regulation. The legislation pertaining to the NMC should be revised to reflect this. This means that the additional layer of regulation currently in place for midwives and the extended role for the NMC over statutory supervision should end.**

The de facto implication of this recommendation is that for the NMC the system of regulation for midwives would be the same as for nurses, as we found no risk-based evidence to conclude that an alternative model is justified. We go on to provide further detail around this recommendation below.

### 10.1 Core functions of regulation

10.1.1 The NMC as the health care professional regulator should have direct responsibility and accountability for the core functions of regulation, that is:

- the registration and renewal of registration of professionals
- ensuring the quality of pre-registration and post-registration education and training
- setting standards for professional conduct and practice and ensuring ongoing practice standards (for example, through revalidation)
- the investigation and adjudication of fitness-to-practise cases.

10.1.2 The existence of the LSAs as separate structures does not meet the criteria of the regulator having clear oversight of regulatory decisions and we recommend that ***the LSA structure should be removed from statute as it pertains to the NMC.***



10.1.3 One undoubted challenge for this review has been the variety of current practice across the United Kingdom (and within England) in how areas actually apply the rules. Useful work has been done by the LSAMO Forum to attempt to achieve a higher degree of consistency across the United Kingdom and yet the models employed by LSAMOs still differ across the country. This lack of consistency underlines the lack of control the NMC has in operating and overseeing this system despite being ultimately responsible for its outcomes. We tested a scenario whereby the NMC would address this issue by absorbing the functions of the LSA. However, as can be seen in the following sections this does not address the fact that the LSAMOs are carrying out roles which, while valuable to the wider health care system, are not the responsibility of the regulator and in turn raise conflicts with other criteria.

## **10.2 Tackling problems early**

10.2.1 Our research did not find evidence either that the risks associated with midwifery required an additional layer of regulation compared to all other health care professionals or that the risks did not require it. The sub-FTP investigatory process causes confusion for patients and the public and can result in a lack of clarity for providers over their responsibility. This confusion and potential conflict has remained despite efforts to manage the relationship between the SoM and provider investigation. It is likely that further clarification could help reduce this confusion, however, at its core remains the fact that having two investigations is inherently more complex than the systems operating for all other professions and as such will always represent a difficulty. In addition, the sub-FTP process as currently constructed does not ensure lay involvement in these regulatory decisions or sufficient involvement of families in establishing investigatory evidence. While some saw benefits in the power to quickly suspend midwives, these powers are less material given that the NMC's own processes have recently been improved. The investigatory role of SoMs and LSAMOs represents a small minority of the work that they do.

10.2.2 In the course of our research we tested two scenarios with stakeholders and focus group participants that suggested that the NMC could run a sub-FTP process at regional level, recruiting practising midwives who could be deployed to provide expert advice to provider-led investigations. We concluded, as did the GMC in its development of its affiliate model that this retained confusion with local employer responsibilities. For doctors, the GMC has developed a regional employer liaison programme to help employers tackle issues locally and the NMC is also developing a model to provide more direct support to employers pre-FTP. We also found that an NMC-run regional sub-FTP model would fail on the criteria of being fair to midwives as it could lead to a situation of double jeopardy. For example, a midwife undergoing a employer-led investigation with formal NMC input could find themselves investigated twice by an NMC investigator if they were subsequently referred for a fitness-to-practise hearing. It also leaves in

place the risk of conflict in cases where a provider disagrees with the NMC expert representative. In addition, creating a sub-FTP process run by the NMC for midwives would essentially mean that midwifery regulation was cross-subsidised by nurses unless the structure of the registration fee was raised for midwives. We did not find evidence of enhanced risk in midwifery to justify either the cost of such a model or, more fundamentally, why midwifery should diverge even further away from the approach to professional regulation adopted for other professions. We recommend that ***the sub-FTP process involving additional investigations and sanctions should be removed from statute.***

### 10.3 Other functions

The conclusions we have reached about the key tasks in protecting the public have led us to conclude that the other tasks currently carried out by the LSAMOs and SoMs, while many consider them to be valuable and useful tasks, are not the function of a health care professional regulator. As such, other players in the system will need to take responsibility for deciding the future approach to these functions.

#### *Supporting and developing people*

- 10.3.1 Our terms of reference asked us to have regard to the future of supervision and the supporting infrastructure if it were no longer part of the regulatory framework.
- 10.3.2 While clearly valued and of benefit to midwives, the functions of support and development, leadership of the profession and strategic clinical leadership are not the role of the regulator. We believe that others in the health care system should take on responsibility for ensuring these functions continue.
- 10.3.3 Access to a wide range of support, including peer support, mentoring and clinical supervision, is important for all health care professionals, including midwives. Models of clinical supervision outside a line management arrangement exist for other professions, for example, psychologists and social workers. However, we do not believe that it is the role of the regulator to provide access to such models. Indeed, the PHSO report that led to this review identified the risk of a conflict of interest from attempting to combine both professional regulation and supervision, and in the course of this review the evidence we found of confusion around the role of the NMC in 'representing' midwives and its potential to 'save midwives for the profession' provide support for this concern. There are a number of options available to the system to ensure that midwives continue to have access to specialist support. For example, a duty to access support could form part of the codes for all health care professionals; the system regulators could emphasise it (for example, in England, CQC could include within its key lines of enquiry for maternity services a question about whether employers are providing this support). In addition, the unions representing midwives may wish

to consider their role in supporting midwives undergoing provider-led investigation or fitness-to-practise proceedings.

- 10.3.4 Providing support to women to talk about aspects of their care, for example, supporting them in accessing a home birth, was identified as a valuable role of the SoM and, in some cases, the LSAMO. While having this resource for women is no doubt useful, it cannot be the job of the health care professional regulator to provide that resource. Organisations providing maternity care will need to consider how they will continue to provide access to such a resource.

#### *Leading the profession*

- 10.3.5 LSAMOs and SoMs play an important role in providing professional leadership for midwifery at regional and local level. Other stakeholders, including the Royal College of Midwives and directors of nursing need to consider how to fill both current gaps in professional leadership for midwifery and any gaps that would emerge as a result of a change to NMC's regulatory functions.
- 10.3.6 As stated, we tested a scenario with stakeholders and focus group participants where the LSAMOs would be employed by the NMC rather than the LSA but found that moving the role to the direct control of the NMC would, in effect, be emphasising the NMC's ability to provide professional leadership that we do not think is part of a health care regulator's remit and risks again diverting the NMC from its core role. Indeed, the NMC is not constituted to provide this leadership at present and does not have the levers in any of the four countries to actually fulfil this role at present. Absorbing the LSAs would underline this existing tension. In addition, these roles would essentially mean that midwifery leadership would be cross-subsidised by nurses unless the structure of the registration fee was changed for midwives.

#### *Strategic oversight of maternity services*

- 10.3.7 LSAMOs have played an important role in providing strategic oversight of maternity services, particularly in England. The reorganisation of the NHS in England means there is currently no obvious home for that role. However, this cannot be part of the regulator's remit as it would fail on the criteria that information is going to the regulator about activities over which it has no power to act. NHS England and, to a lesser extent, the Welsh Assembly, Scottish Government and Northern Ireland Assembly should assure themselves that they have adequate facility for accessing strategic input into the development of maternity services.

## **11. Risks, complexity and transition**

- 11.1 There are a number of risks inherent in any transition. Not least, due to the lack of a quantifiable evidence base, we cannot show that any of the issues outlined

above have damaged the quality of care, just as we cannot show that the additional layer of regulation to which midwives are subject provides any quantifiable benefits either. Our qualitative evidence (particularly in terms of the views of stakeholders) has often been contradictory and our recommendations will not find consensus. At the outset, it should be noted, for example, that while the NMC accepted the Parliamentary and Health Service Ombudsman's finding that midwifery regulation was structurally flawed as a framework for public protection, some of the midwives we interviewed did not share this view. Significant legislative change would be needed to bring about the changes. In particular, we would flag three key risks that will need to be considered:

- That the current sub-FTP process has deflected referrals to the NMC and its withdrawal may lead to an increase in referrals that will prove difficult for the NMC to manage.
- That other stakeholders will not want to or succeed in, preserving midwifery supervision and that once the current statutory system has been dismantled will look to re-allocate the investment elsewhere. While this review argues that supervision should not ultimately be the responsibility of the NMC, there is a risk that no-one else will accept the responsibility either. This is a complex issue: each of the four countries of the United Kingdom could design their own approach because, once removed from the NMC, midwifery supervision will cease to be a UK-wide issue.
- There will be costs involved in any transition. In particular, the impact of change would be felt by a number of stakeholders. LSAMOs would find their role redundant unless all of the four countries decide to re-create a role focusing on the responsibilities other than those reserved to the NMC. Universities which currently provide the formal preparation courses for supervisors of midwives would lose this function. Supervisors of midwives may lose the extra remuneration they receive, although employers could choose to keep their supportive role and remunerate it accordingly.

## **12. Recommendations for other partners**

12.1 Much of our report has focused on issues that are outside the remit of the NMC as a professional regulator. As such, our report necessarily contains recommendations for others in the system in addition to the NMC:

- We have noted the lack of quantitative evidence on the risks inherent to the professions and the impact of professional regulation on mitigating them. As such the Department of Health and Professional Standards Authority should undertake research to establish a methodology and data to underpin the understanding of risk and the impact of professional regulation on reducing that risk and ensuring protection of the public.
- The Departments of Health should ensure that best practice in complaints procedures continues to be implemented, ensuring that investigations are

transparent, accountable and straightforward and that service users and their families are kept up-to-date with progress and understand what is happening with their complaint or issue.

- The Departments of Health should consider how best to ensure access to ongoing supervision and support for midwives and for other health care professionals.
- Unions representing midwives will want to consider what the changes would mean to their role in supporting midwives undergoing provider-led investigation or fitness-to-practise proceedings.
- Organisations providing maternity care should consider how they will continue to provide access for service users to discuss aspects of their care.
- The Royal College of Midwives and directors of nursing should consider how to fill both current gaps in professional leadership for midwifery and any gaps that would emerge as a result of a change to the NMC's regulatory functions.
- NHS England, the Welsh Assembly, Scottish Government and Northern Ireland Assembly should assure themselves that they have adequate facility for accessing strategic input from the midwifery profession into the development of maternity services.

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