External review of a sample of Local Supervising Authority (England) Supervisory Investigations into the standard of midwifery practice in Maternity Serious Incidents that were conducted between 1 April and 31 December 2016

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Executive summary

Background and context

The Nursing and Midwifery Council is required by the Nursing and Midwifery Order 2001 (the Order) to set standards for midwifery education, practice and conduct, and to take action when those standards are called into question. Prior to 1st April 2017 the Order required the establishment of a Local Supervising Authority (LSA) for Midwifery in every area in the UK. LSAs were responsible for the statutory supervision of midwives. The stated purpose of supervision of midwives was to protect women and babies by actively promoting a safe standard of midwifery practice. Supervision also provided a mechanism for support and guidance to every midwife practising in the United Kingdom.

Prompted by the brave efforts of three families, who raised complaints that related to local midwifery supervision and regulation[1] (PHSO 2013) and in response to the findings of the investigations into incidents at Morecambe Bay NHS Foundation Trust[2], the NMC commissioned The King's Fund in 2014 to undertake a review of the regulation of midwives across the United Kingdom. The King's Fund found[3] that the system of regulation of midwives was confusing for patients and the public. It also found that providers of maternity services were unclear about their responsibility to investigate midwifery practice when an LSA investigation was being undertaken. The King's Fund review findings recommended that midwifery supervision be removed from statute.

This recommendation was taken forward in accordance with the requirements of Section 60[4] of the Health Act 1999. With Parliamentary approval the NMC removed midwifery supervision from its regulatory legislation on 31st March 2017.

Until supervision of midwives was removed from statute, NHS England as the (then) LSA for England had a statutory responsibility for supervision of midwives practising in England. A function discharged by The Nursing Midwifery Council, through the Nursing Midwifery Order.

[1] Complaints raised by three families related to the failure of local midwifery supervision and regulation to identify poor midwifery practice" (The Parliamentary and Health Service Ombudsman (PHSO) 2013,),
[2] Kirkup B, The Report of the Morecambe Bay Investigation, (2015)
[3] Baird B et al, Midwifery Regulation in the United Kingdom, King's Fund
[4] http://www.legislation.gov.uk/ukpga/1999/8/section/60

Aims of review

This review was commissioned by NHS England in response to two previous commissions both of which related to the quality of midwifery supervision. Although statutory supervision has been removed and replaced with a new model of supervision called A-EQUIP[5], this review still provides a valuable opportunity to highlight areas where the quality of investigations can improve the involvement of service users.

The aims of this review are:

1. To establish whether each case included in this review has had a robust and objective Supervisory Investigation into the standard of midwifery practice and was undertaken in compliance with the relevant LSA process and guidelines.

2. To identify learning points that will inform and promote a strengthened investigatory process into incidents where there are concerns about the standard of midwifery practice.

3. To share the findings and learning points of this review with each of the sample cohort families; the relevant Trust, NHS Improvement and the Healthcare Safety Investigation Branch (HSIB).

Review cohort

The review sample is comprised of NHS maternity cases in England which resulted in poor maternal and/or fetal/neonatal outcome and was subject to a supervisory investigation between the months of April through to December 2016 inclusive.

The rationale for selecting this time period relates to the publication of the LSA single operating model in March 2016[6], which aimed to ensure a consistent approach to supervisory processes in England.

[5] A-EQUIP is an acronym for advocating and educating for quality improvement and does not involve the investigation of incidents or any regulatory activity/function

[6] Local Supervising Authorities Single Operating Model (England), NHS England (2016)

Review cohort sample

The review cohort sample comprised of 15 cases. Of the 15 cases reviewed, 9 of the service users (60%) elected to discuss their experience of undergoing an investigation with the reviewer. At 4 of the interviews (44%) the woman's partner was also present. Participants were advised that no individual issues, complaints or concerns could be dealt with in the interview setting, but that if the session raised any concerns or anxieties for them, the contact details of the Trust PALs or nominated contact person was available to them.

Findings

This section is divided into two sections and describes the findings from the case note review and the service user consultation. The overall findings of this review show that whilst the supervisory investigations into midwifery practice were undertaken in accordance with LSA policy[7] and accepted good practice standards[8]. For all cases included in the cohort sample, there was a failure to comply with statutory duty of candour. These findings are now described in detail.

Case note review

The reviewer found that in each case included in the cohort sample, the correct identification of root causes and lessons to be learnt were identified. This finding is based on each supervisory investigation utilising the case clinical documentation and key staff statements/interviews as evidence alone.

Evidence of service user engagement was found in the documentation of 8 (53%) of the total 15 supervisory investigation included in this review. There was no documented evidence of service user engagement in the documentation of the remaining 7 (47%) supervisory investigations.

[7] Ibid (n14)

[8] Adapted from *A review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged* Parliamentary and Health Service Ombudsman, Annex B

Service User consultation

Of the 15 cases reviewed, 9 service users (60%) consented to discuss their experience of undergoing an investigation with the reviewer. At 4 of the interviews (44%) the woman's partner was also present. Interviews were held either by telephone or in the woman's home or other convenient location.

It was not always possible for the reviewer to distinguish whether a participant's recollection of events related to a supervisory or trust investigation. All findings should therefore be interpreted as relating to the service users experience of *an* investigation rather than pertaining to a supervisory investigation alone.

Participants stated that when undertaking an investigation, equal weight should be given to a service user's evidence as that given to the documented records.

The reviewer found the majority of service users who participated in this consultation reported a poor experience of undergoing an investigation. This finding is consistent with the national picture for the standard of service user engagement in investigations across the NHS[9].

This consultation has not identified a best practice approach to the timing of service user engagement following a clinical incident. The findings show that the desired level of active participation in an investigation differs between service users. Some participants reported that they had been informed of an investigation too late (or indeed not at all) whilst other participants reported that they had been informed at too early a stage when they were feeling confused.

Some participant's stated that they wished to be involved after the investigation had been concluded so that they could be assured that the recommendations from their case had been actioned.

[9] Learning, candour and accountability, A review of the way NHS trusts review and investigate the deaths of patients in England, CQC (2016)

Conclusion

The findings from this consultation show that whilst supervisory investigations were undertaken for all cases included in the cohort sample of this review. There is however a need to consider the approaches for involving service users in clinical incident investigations. In their 2016 report[10] the CQC recommended that what service users can expect from an organisation when they are involved in an investigation process needs to be defined. The findings from this review firmly support that recommendation.

The current NHS Serious Incident framework published in 2015 sets expectations for when and how the NHS should conduct a safety investigation. This framework is currently being revised to better support the system to respond appropriately when things go wrong. The findings of this case note review and in particular the absence of evidence that the duty of candour had been upheld for all women and the experiences of families involved, will be shared with NHS Improvement to support the plans to improve the process for engaging with patients when things go wrong.

Recommendations

1) This report should be shared widely, including but not limited to:
    - service users who participated in the engagement consultation
    - service users who formed part of the cohort sample who did not participate in the engagement consultation but indicated on their consent form that they would like to receive the final report
    - Participating provider Trusts.
    - NHS Improvement for contribution to the review of the NHS Serious Incident framework
    - The Healthcare Safety Investigation Branch

[10] Ibid

1.0 Introduction

1.1 Overview of midwifery supervision and its removal from statute

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. The Order gives the NMC powers to set rules for the regulation of the practice of midwifery (article 42).

Prior to 1st April 2017, the Order required the establishment of a Local Supervising Authority (LSA) for Midwifery in every area and required midwives in that area to give notice of their intention to practise. The NMC set LSA reporting requirements that included: Annual Reports; LSA annual audits intended to monitor standards of supervision and midwifery practice.

Local Supervising Authority

The LSAs were responsible for the statutory supervision of midwives. Statutory supervision applied to all registered midwives including those who worked outside of the NHS. The stated purpose of supervision of midwives was to protect women and babies by actively promoting a safe standard of midwifery practice. Supervision also provided a mechanism for support and guidance to every midwife practising in the UK. Each LSA appointed a practising midwife known as the Local Supervising Authority Midwifery Officer (LSAMO) who had responsibility for carrying out the statutory functions within the LSA area.

Supervisors of midwives

Each LSA appointed a number of Supervisors of Midwives (SoM) who were accountable in their role to the LSAMO. SoMs were experienced, practising midwives who had undergone education and training in the knowledge and skills needed to supervise midwives. Part of the role of a SoM was to investigate a midwife's practice following an untoward or serious incident and determine whether action was required. Recommended actions might include 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.

Supervisory investigations were conducted on behalf of the LSA and were independent of a Trust's clinical governance processes. As such, following an incident, a Trust was required to carry out its own investigation in compliance with the Trust's clinical governance processes. In some organisations a joint Trust and supervisory investigation was carried out. Prompted by the brave efforts of three families, who raised complaints that related to local midwifery supervision and regulation[11] (PHSO 2013) and as a result of investigations into incidents at Morecambe Bay NHS Foundation Trust in 2013[12], the Parliamentary Health Service Ombudsman[13] found that there was a structural flaw in the way midwifery regulation was organised, in that it combined both the requirement to investigate midwifery practice and to provide support for midwives. In response to these findings, the NMC in 2014 commissioned The King's Fund to undertake a review of the regulation of midwives across the United Kingdom. The King's Fund found[14] that the system of regulation of midwives was confusing for patients and the public. It also found that, following an incident, providers of maternity services were unclear about their responsibility to investigate midwifery practice when an LSA investigation was being undertaken. The King's Fund review findings recommended that midwifery supervision be removed from statute.

This recommendation was taken forward in accordance with the requirements of Section 60[15] of the Health Act 1999. With Parliamentary approval the NMC removed midwifery supervision from its regulatory legislation on 31st March 2017.

[11] Complaints raised by three families related to the failure of local midwifery supervision and regulation to identify
poor midwifery practice" (The Parliamentary and Health Service Ombudsman (PHSO) 2013,),
[12] Ibid (n1)
[13] Midwifery supervision and regulation: recommendations for change, Parliamentary and Health Service Ombudsman (2014) HC 865 London: The Stationery Office
[14] Ibid (n2)
[15] Ibid (n3)

1.2 Background to this review

This review was commissioned by NHS England in response to two previous commissions both of which related to the quality of midwifery supervision.

Until supervision of midwives was removed from statute, NHS England as the (then) LSA for England had a statutory responsibility for midwives practising in England. A function discharged by The Nursing Midwifery Council, through the Nursing Midwifery Order.

Within this statutory framework NHS England has previously commissioned:

1. The Graham (2015)[16] report into a complaint, submitted to NHS England, by Rhiannon Davies and Richard Stanton, regarding a Supervisory Investigation undertaken in 2009. The report included the following recommendation:

   To seek assurance that the weaknesses in the LSA investigatory process c2009 identified in this review are no longer inherent in the current process, the regional LSAMO's should:
   Undertake a national audit[17] of compliance with the scope and the standards of decision making required in a SoM investigation as set out in the LSA Review and Investigation Processes Policy (2013)[18].

In response to the above recommendation, NHS England then commissioned an audit to look at:

2. A random sample of midwifery Supervisory Investigations, carried out between 1st January 2014 and 31st December 2015. The samples were audited against the standards outlined in the Local Supervising Authority Review and Investigation Processes (LSA 2013). The audit identified varying levels of compliance with LSA guidance[19] and made several recommendations.

In response to the findings of the above mentioned audit, Rhiannon Davies and Richard Stanton supported by James Titcombe made the following recommendation:

[16] Graham, D. An External Review of a Supervisory Investigation in 2009 (2015)
[17] The LSA should seek assurance that the factors identified as common to both this review and the Morecambe Bay Review are isolated to these two events.
[18] Version:2 (2016) was used for this review as the definitive document for the months under review.
[19] Local Supervising Authority Review and Investigation Processes, LSAMO Forum UK, Policies for the statutory supervision of midwives, Version:2 (2016)

“An independent case note review should be undertaken of supervisory investigations identified from a sample of cases that were subject to the audit” (NHS England 2017).

The above recommendation was accepted by NHS England who commissioned this review as its final works in relation to statutory supervision.

1.3 Aims of review

The aims of this review are set out in the Terms of Reference (available at Appendix A) as:

4. To establish whether each case included in this review has had a robust and objective Supervisory Investigation into the standard of midwifery practice and was undertaken in compliance with the relevant LSA process and guidelines.

5. To identify learning points that will inform and promote a strengthened investigatory process into incidents where there are concerns about the standard of midwifery practice.

6. To share the findings and learning points of this review with each of the sample cohort families; the relevant Trust, NHS Improvement and the Healthcare Safety Investigation Branch (HSIB).

2.0 Method

This review was conducted by Debbie Graham, Independent Consultant Midwife, henceforth referred to as the reviewer.

The LSA national database holds details of every supervisory investigation undertaken in England and contains patient sensitive and legally privileged data. Following the removal of midwifery supervision from statute the data have been archived. Use of these data is subject to information governance processes, which have been strictly adhered to during this review.

2.1 Inclusion criteria

The review sample comprised of NHS maternity cases in England which resulted in poor maternal and/or fetal/neonatal outcome and was subject to a supervisory investigation between the months of April through to December 2016 inclusive.

The rationale for selecting this time period relates to the publication of the LSA single operating model in March 2016[20], which aimed to ensure a consistent approach to supervisory processes in England. Cases which occurred prior to April 2016 were included in this review if the supervisory investigation into the case was undertaken between 1st April and 31st December 2016 inclusive.

It was anticipated that a maximum of 20 cases would be included in this review; comprising of 5 cases from each of NHS England's four regions, namely: North, Midlands and East, London, South.

2.2 Identification of review cohort sample

Identification of supervisory investigations eligible for inclusion in this review was problematic as there was no national LSA coding system. With the assistance of the National Midwifery Supervision Programme Lead, the Regional Maternity Leads, the Deputy Regional Maternity Leads and their respective administrative support, the LSA database was searched. A total of 297 LSA case reviews were identified as having taken place in England between the months of April to December 2016 inclusive.

To identify the subset of cases that met the inclusion criteria for this review, analysis of the decision making tool for each of the 297 case reviews was undertaken. From this search a total of 47 investigations were identified as meeting the review inclusion criteria. Through a process of systematic sampling of all cases that met the inclusion criteria (n47), 20 cases (54%) were selected for inclusion in the review cohort.

In order to identify each of the service users in the cohort cases, information contained in the relevant Supervisory Investigation documentation was utilised. This was either: a hospital number, STEIS number, service user's initials, and/or a short description of the incident and the name of the investigating Supervisor of Midwives.

[20] Local Supervising Authorities Single Operating Model (England), NHS England (2016)

2.3 Obtaining consent

This was an ‘opt-in’ review therefore it required the signed consent of each woman included in the review cohort.

A standard letter, that included service user identifying information as described above, was sent from the relevant Regional Chief Nurse (or their delegate) to the Director of Nursing at each of the Trusts where the cohort women had received their maternity care. The letter provided information regarding the review, its aims and intended approach and requested the name and contact details of the identified service user.

As names and contact details became available to the reviewer, a standard letter was sent either by NHS England, or directly by the Trust (as preferred by some Trusts), to each of the identified women informing them of the review, its aims and requesting consent for their case to be included in the review. A consent form was enclosed with the letter which women were asked to sign and return within four weeks of receipt after which their case would be withdrawn from the review. The consent form included a tick-box option for women and their families to indicate if they wished to discuss their experience of undergoing a supervisory investigation with the reviewer. Women who ticked this box were first contacted by the reviewer by telephone and a face to face or telephone interview arranged. This work is discussed further at section 2.7 below. The consultation report is available at Appendix B.

In recognition that discussing their case with the reviewer may raise concerns or anxieties for some of the cohort women and/or their families, the relevant Trust’s Patient Advice and Liaison Service (PALs) contact details or the contact details of a nominated person within the relevant Trust were made available for each woman. In the event that the reviewer formed the opinion that a given woman may contact a Trust, the reviewer sent an email to the Head of Midwifery advising them as such, thereby enabling preparation for the contact.

2.4 Collation of review cohort sample

Letters to service users were sent out from July to November 2017 inclusive. On receipt of a signed consent form by NHS England, a copy was forwarded to the relevant Trust and a request made for the notes pertaining to the maternity episode under review to be released to the reviewer. Trust response times for releasing the requested documents ranged from a few days to six weeks. Trusts that did not respond within two weeks of the initial request were sent regular email reminders, followed up by telephone prompts from the reviewer.

Two women returned their consent forms after the stipulated four weeks. As the maximum number of cases had not been reached, these cases were included in the final cohort and the relevant Trusts informed.

2.5 Cases withdrawn from cohort sample

Cases withdrawn from the review were replaced using systematic sampling from the remaining investigations identified within the same NHS England region as 'the withdrawn case'. This process was repeated until either no further cases within a given region were available or the review time frame did not allow further approaches to be made.

A total of 14 cases were withdrawn from the review and the relevant Trusts informed. The main reason for withdrawal was non consent by women whose case was selected for review. Any documents pertaining to the cases received by the reviewer were confidentially destroyed.

2.6 Final review cohort sample

The final cohort sample was 15 cases. Table 1 shows the cohort sample by region and by provider Trust. Table 2 shows the cohort sample by outcome

Table 1: cohort sample by region and provider Trust

NHS England region and participating Trusts	No. of cases
North 1. South Tees Hospitals NHS Foundation Trust 2. Calderdale and Huddersfield NHS Foundation Trust 3. Pennine Acute Hospitals NHS Trust 4. East Cheshire NHS Trust	4
Midlands and East 1. Basildon and Thurrock NHS Foundation Trust 2. Milton Keynes University Hospital NHS Foundation Trust 3. Bedford Hospital NHS Trust 4. Luton and Dunstable University Hospital NHS Foundation Trust	4
London 1. Barts Health NHS Trust 2. St George's University Hospitals NHS Foundation Trust 3. King's College *Hospital* NHS Foundation Trust 4. North Middlesex University Hospital NHS Trust	4
South 1. Ashford and St Peter's Hospitals NHS Foundation Trust 2. East Kent Hospitals University NHS Foundation Trust 3. Frimley Health NHS Foundation Trust	3
Total	**15**

Table 2: cohort sample by outcome:

Poor outcome	No of cases
Maternal	1
Neonatal/fetal	12
Maternal/neonatal/fetal	2
Total	**15**

2.7 Development of the review tool

Two review proformas were developed by the reviewer and are available at Appendix C:

Proforma 1	Was intended to review the standard of each Supervisory Investigation. It is based on the relevant LSA policy[21] and accepted good practice standards[22].
Proforma 2	Was intended to assess compliance with the statutory duty of candour good practice standards as set out in the relevant guidance.[23]

2.8 Conducting the review

This review was conducted from July to December 2017 inclusive. The review method involved elements of grounded theory and qualitative methodology.

Case note review

A critical review was undertaken by the reviewer of each of the cases in the sample cohort. Using the primary case notes obtained from the relevant Trust, the reviewer formed an expert opinion on the standard of midwifery care using evidence based guidance and practice relevant at the time of the incident. Utilising proforma 1 the reviewer's findings in each case were compared with the methodology and findings of the LSA investigation and an opinion formed on the quality of each of the supervisory investigations.

[21] Ibid (n14)

[22] Adapted from *A review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged* Parliamentary and Health Service Ombudsman, Annex B

[23] **Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20**

Service user consultation

Of the total 15 cases reviewed, 9 service users (60%) elected to discuss their experience of undergoing an investigation with the reviewer. At 4 of the interviews (44%) the woman's partner was also present. Interviews were held either by telephone or in the woman's home or other convenient location.

Each interview was conducted by the reviewer using the prompt statements as set out in proforma 2. The participant's responses were either noted down or tape recorded with the participant's permission. Participants were advised that their responses would be treated as confidential in that no response would be attributable to any person. In addition, the reviewer advised that no individual issues, complaints or concerns could be dealt with in the interview setting but that if the session raised any concerns or anxieties for them, the contact details of the Trust PALs or nominated contact person was available to them.

It was not always possible for the reviewer to distinguish whether a participant's recollection of events related to a supervisory or trust investigation. The findings from this consultation should therefore be interpreted as relating to the service users experience of *an* investigation rather than pertaining to a supervisory investigation alone.

The reviewer found the majority of service users who participated in the consultation reported a poor experience of undergoing an investigation. This finding is consistent with the national picture for the standard of service user engagement in investigations across the NHS. For further information and recommendations please see the Service User consultation report at Appendix B.

The next section of this report presents a table of the findings from the case note review of the standard of the supervisory investigations of the cohort group. The subsequent sections present the findings from each criterion, set out in the same order as review proforma 1. Conclusions and recommendations are presented in the final section of this report.

3.0 Case note review findings

Table 3 shows a summary of the review findings for each of the cases in the review cohort (n15) as assessed against the 8 review criterion in proforma 1

Table 3: a summary of the case note review findings

LSA Supervisory Investigation review data

√ = compliant, x = non-compliant		Supervisory Investigation case no.														
Criteria		**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**	**11**	**12**	**13**	**14**	**15**
1	The SoM fully investigated the midwife's practice as documented in the clinical records.	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
2	The incident chronology was determined	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
3	All issues identified by the reviewer were addressed	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
4	Key staff were interviewed	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
5	Key staff were asked to provide a written statement	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
6	No documentation was missing	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
7	The SoM documented communication with the parents/family	√	x	x	x	√	x	√	√	√	√	√	x	x	x	√
8	Compliance with statutory duty of candour[24] is documented	√	x	x	x	√	x	x	√	√	x	x	x	x	x	x

[24] **Ibid**

The above table shows:

Criterion 1

The SoM fully investigated the midwife's practice as documented in the clinical records

In all 15 cases, all (100%) were subject to a full investigation into the midwife's practice as set out in the clinical records.

It should be noted that this finding is based on the clinical records alone. It does not include the findings from the service user engagement consultation which are presented at Appendix B

Criterion 2

The incident chronology was determined

In all 15 cases the incident chronology was determined in all (100%) of the cases as demonstrated in each of the Supervisory Investigation reports.

Criterion 3

All issues identified by the reviewer were addressed

In all 15 cases (100%) all issues, as identified by the reviewer, were addressed in the supervisory investigation.

Criterion 4

Key staffs were interviewed

In all 15 cases (100%) staff identified by the reviewer as key to establishing the facts of the case, were interviewed.

Criterion 5

Key staffs were asked to provide a written statement

In all 15 cases (100%) the reviewer found documented evidence that key staff had provided a written statement.

Criterion 6

No documentation was missing

No documentation was identified as missing by the reviewer in any of the cohort cases (n15) (100%)

Criterion 7

The SoM documented communication with the parents/family

Of the 15 cases, 8 (53%) had documented evidence that a Supervisor of Midwives had communicated with the relevant parents/family regarding the Supervisory Investigation. There was no documented evidence in 7 (47%) of the cases.

At three interviews the participant informed the reviewer that the version of events documented in the chronology of the investigation report into their case differed from their own version of events. Each participant stated that they were not satisfied with the findings of the investigation into their case. The reviewer advised these service users that any outstanding issues should be explored further with the relevant Trust. Contact details for the relevant Trusts were provided by the reviewer.

For further information and discussion please see Service User Experience consultation report at Appendix B.

Criterion 8

Compliance with statutory duty of candour[25] is documented

Of the 15 cases there was documented evidence of compliance with the statutory duty of candour in 4 cases (26%). There was no documented evidence in 11 (74%) of the cases.

The statutory duty of candour[26] was introduced into healthcare in England in November 2014 and requires healthcare organisations to be open and honest with service users'/families following a clinical incident. The earlier framework *'Being Open'*[27] (2009) provided a best practice guide for all healthcare staff, including an outline of how to communicate with patients, their families and carers following harm.

The involvement of women and their families in the supervisory investigation process will be discussed further at Appendix B to this report.

[25] Ibid (n18) 3c; 4b

[26] The Serious Incident Framework, Supporting learning to prevent recurrence NHS England (2015) states: That the duty of candour require an NHS body to *Advise the relevant person what further enquiries the health service body believes are appropriate*

[27] Saying sorry when things go wrong, Being Open, Communicating patient safety incidents with patients, their families and carers, National Patient Safety Agency (2009) Gateway reference 13015

4.0 Conclusions

The reviewer found that each case included in the cohort sample, was subject to appropriate investigation which included for example the correct identification of root causes and lessons to be learnt. This finding is based on each supervisory investigation utilising the case clinical documentation and key staff statements/interviews as evidence alone.

Evidence of service user engagement was found in the documentation of 8 (53%) of the total 15 supervisory investigation included in this review. There was no documented evidence of service user engagement in the documentation of the remaining 7 (47%) supervisory investigations.

This finding is consistent with the national picture for the standard of service user engagement in investigations across the NHS. In their 2016 report the Care Quality Commission noted: (*T)throughout our review, families and carers have told us that they often have a poor experience of investigations…. The extent to which families and carers are involved in reviews and investigations of their relatives varies considerably.* [28]

It is recognised that following a clinical incident the engagement of the affected family is essential. Knowledge of how they will be able to contribute to the process of investigation, for example by giving evidence helps to provide affected families with confidence that the findings of an investigation will be robust, meaningful and that lessons will be learned from to prevent the likelihood of similar incidents happening again.

Further information, discussion and associated recommendations please see Service User Experience consultation report at Appendix B.

The current NHS Serious Incident framework published in 2015 sets expectations for when and how the NHS should conduct a safety investigation. This framework is currently being revised to better support the system to respond appropriately when things go wrong. The findings of this case note review and in particular the absence of evidence that the duty of candour had been upheld for all women involved and the

[28] Learning, candour and accountability, A review of the way NHS trusts review and investigate the deaths of patients in England, CQC (2016)

experience of families involved, will be shared with NHS Improvement to support the plans to improve the process for engaging with patients when things go wrong

5.0 Recommendations

This report should be shared widely, including but not limited to:

- service users who participated in the engagement consultation
- service users who formed part of the cohort sample who did not participate in the engagement consultation but indicated on their consent form that they would like to receive the final report
- Participating provider Trusts.
- NHS Improvement for contribution to the review of the NHS Serious Incident framework
- The Healthcare Safety Investigation Branch

Acknowledgements

This review would not have been possible without the cooperation and support of many people, to all of whom I wish to extend my thanks and gratitude. Special thanks are extended to NHS Improvements for their support and advice in the design of this review.

References

A review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged Parliamentary and Health Service Ombudsman, Annex B

Baird B et al, Midwifery Regulation in the United Kingdom, King's Fund

Graham, D. An External Review of a Supervisory Investigation in 2009 (2015)

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20

Kirkup B, The Report of the Morecambe Bay Investigation, (2015)

Learning, candour and accountability, A review of the way NHS trusts review and investigate the deaths of patients in England, CQC (2016)

Local Supervising Authorities Single Operating Model (England), NHS England (2016)

Local Supervising Authority Review and Investigation Processes, LSAMO Forum UK, Policies for the statutory supervision of midwives, Version:2 (2016)

Midwifery supervision and regulation: recommendations for change, Parliamentary and Health Service Ombudsman (2014) HC 865 London: The Stationery Office

Saying sorry when things go wrong, Being Open, Communicating patient safety incidents with patients, their families and carers, National Patient Safety Agency (2009) Gateway reference 13015

The Serious Incident Framework, Supporting learning to prevent recurrence, NHS England (2015)

Appendices:

Appendix A – Terms of Reference

Appendix B – Maternity Service User Experience Of Undergoing a Supervisory Investigation

Appendix C – Review Proformas

Website

http://www.legislation.gov.uk/ukpga/1999/8/section/60

Appendix A

A Terms of Reference

Terms of Reference

External review of a sample of Local Supervising Authority (England)

Supervisory Investigations into the standard of midwifery practice in Maternity Serious Incidents that occurred between 1 April 2016 and 31 December 2016

1.0 Introduction

This document sets out the terms of reference for an external review of a sample of maternity cases that were subject to an England Local Supervising Authority (LSA) Supervisory Investigation following a poor maternal or fetal outcome. A view on the standard of midwifery care will be reached by an expert midwife based on the evidence in each of the sample case's clinical records and the expert's findings will be compared to the findings in the corresponding Supervisory Investigation.

The review sample will comprise of 20 maternity cases that occurred within the four geographical regions of NHS England between 1st April 2016 and 31st December 2016 and will be conducted by independent midwifery expert Ms. Debbie Graham.

1.1 Background

This review follows on from two previous works commissioned by NHS England, namely:

1.1.1 The findings of the Graham (2015)[29] report into a complaint, submitted to NHS England, by Rhiannon Davies and Richard Stanton, regarding a Supervisory Investigation undertaken in 2009. The report included the following recommendation:

An audit should be undertaken to provide assurance to LSA England that: the weaknesses in the LSA Investigatory Processes c2009 identified in the investigation into the complaint are no longer inherent in the current process.

1.1.2 In response to the above recommendation, NHS England commissioned an audit of a random sample of midwifery Supervisory Investigations, carried out between 1st January 2014 and 31st December 2015 which were audited against the standards outlined in the Local Supervising Authority Review and Investigation Processes (LSA 2013).

1.1.3 The above mentioned audit identified varying levels of compliance with LSA guidance[30] and made several recommendations.

1.1.4 Based on the findings of the above mentioned audit Rhiannon Davies and Richard Stanton supported by James Titcombe made the following recommendation *"An independent case note review should be undertaken of supervisory investigations identified from a sample of cases that were subject to the audit*" (NHS England 2017).

1.1.5 NHS England has accepted this recommendation which informs these Terms of Reference. However to ensure that the proposed case note review involves

[29] Graham, D. An External Review of a Supervisory Investigation in 2009 (2015)
[30] Local Supervising Authority Midwifery Officer Forum (UK) policy and guidance 2013

recent supervisory investigations, the review sample will comprise of maternity cases that occurred between 1st April 2016 and 31st December 2016. The rationale for this relates to the publication of the LSA single operating model (NHS England 2016) in March 2016, which aimed to ensure a consistent approach to supervisory processes in England.

2.0 Purpose of external review

The purpose of this external review is to:

2.0.1 To establish whether each case included in this review, has had a robust and objective Supervisory Investigation into the standard of midwifery practice undertaken.

2.0.2 Identify learning points that will inform and promote a strengthened investigatory process into incidents where there are concerns about the standard of midwifery practice.

2.0.3 This external review will be limited to Supervisory Investigations that were undertaken on behalf of the LSA (England) between 1st April 2016 and 31st December 2016.

2.0.4 The review sample will comprise of maternity cases which resulted in a poor maternal or fetal outcome as set out in Option 2 in the accompanying Options for inclusion criteria, available at appendix 1

2.0.5 A critical review will be undertaken of each of the cases in the sample cohort. Using the primary case notes obtained from the relevant Trust, the reviewer will provide an expert opinion on the standard of midwifery care using evidence based guidance and practice relevant at the time of the incident. These findings will be compared with the methodology and findings of the LSA investigation.

2.0.6 Any findings identified during this review process that indicate previously unidentified incidents or omissions will be reported through the appropriate escalation and governance processes, including through local risk management systems to the National Reporting and Learning System, and will be managed in accordance with the Duty of Candour. A summary of these findings will be included in the final report. Recommendations will be made for individual Trust's Board to regarding the issues identified.

3.1 Objectives for external review

3.1.1 To establish, based on the evidence in the clinical notes, whether each of the Supervisory Investigations:

- Was undertaken in accordance with the guidelines and process for investigation into a midwife's fitness to practice by a Supervisor of Midwives on behalf of the LSA.
- Established the facts of the incidents
- Identified the standard of midwifery practice
- Identified areas of best practice
- Identified systemic issues which needed to be addressed
- Identified lessons to be learned

3.1.2 To identify common weaknesses/omissions in the investigatory process within the cohort sample.

3.1.3 To share the findings and learning points of this review with each of the cohort sample families; the relevant Trust and NHS Improvements.

4.0 Key deliverables external review

A final External Review Summary Report will be produced that will include:

- Key facts and findings from the review
- Recommendations for realistic, effective and sustainable actions to address the learning points identified by this review.

5.0 Timescale for the external review

This external review is to be completed within 70 days of commission. An External Review Summary Report is to be submitted within X days of commission.

6.0 Accountability

This review will be accountable to the Chief Nursing Officer, as the professional lead for Midwifery in England.

7.0 External review sponsor/commissioner

Professor Jacqueline Dunkley-Bent (Head of Maternity, NHS England) is the commissioned review sponsor and is responsible for providing professional leadership and guidance for the project and to the Chief Nursing Officer.

8.0 Programmed management

Jason Westwood, LSA National Supervision Taskforce Project Manager, is responsible for managing the PMO function, ensuring that project support and administration is delivered to the External Reviewer.

In addition the Project Manager will ensure that the External Reviewer has access to the Local Supervising Midwifery Officers or their replacement Supervisors (England) as required enabling the Reviewer to access all documentation required undertaking the identified reviews.

9.0 Stakeholders/audience

Key stakeholders in this review include the following:

- Original family and their advocate
- The relevant Trusts where each of the cohort sample incidents occurred
- Midwifery LSAMOs or their replacement Supervisors (England)
- Women and their families whose cases are included in the review cohort sample

10.0 Methodology

Preparation	Identify: • All cases that meet inclusion criteria on LSA database • Subset of cases for inclusion in the review by use of systematic sampling • All relevant documentation required for each case including primary case notes held by relevant Trust • Key and extended stakeholders • Time frame for completion of review
	Engage with identified organization and share the objectives of review
	Obtain details of contact person within identified organization to assist the review
	Request documentation from relevant contact person within identified organization
	Collate documentation
	Meet with External Review commissioners and advocates whose recommendations led to this external review
Data collection	Read all submitted documentation
	Review standard of midwifery care and treatment as evidenced in each of the case records and where possible benchmark the standard of care for compliance with relevant national guidance and local Trust policies at the time
	Seek the consent of, and interview families[31] identified on a case by case basis to understand their experience of the LSA supervisory investigation. Contact details of support services provided by the relevant Trust will be given to each of the interviewed families in recognition that our approach may raise issues for them.
Organizing and analyzing	Incident mapping e.g. tabular timeline based on each of the case records

[31] We must be mindful that not all women and their families will welcome an approach regarding their case. Special caution must be taken to avoid approaching families at an especially sensitive time e.g. date of baby's birth, date of incident etc. and consideration given to cases of particularly sensitive timings being excluded from the cohort sample.

data	Formulate an expert opinion on the standard of midwifery practice benchmarked against national guidance at the time of the incident based on the evidence contained in each of the case records
	Identify contributory factors and root causes where that information is available in each of the case records.
	Identify weaknesses/omissions in supervisory investigation practice common to cohort sample by thematic analysis based on the evidence contained in each of the case records
	Compare review findings with previous Supervisory Investigation findings
	Develop recommendations
	Draft report and circulate to relevant key stakeholders
	Collate key stakeholders responses
Final report	Write and submit final report

11.0 Communication and progress updates

- All communication will be through the Review Sponsor
- Progress updates will be provided through a weekly update call and short written brief with the Review Sponsor. It will be the responsibility of the Review Sponsor to keep the key stakeholders informed of progress
- A draft report will be provided to the Review Sponsor within tbc days of commission. The Review Sponsor will share the draft report with the key stakeholders for their consideration.
- The External Reviewer will collate and consider all responses to the draft report within an agreed timeframe before producing a final report which will be submitted to the Review Sponsor by tbc.

12.0 Exclusions and limitations

This external review will be based on a comparison of the information contained in the records of the Supervisory Investigations with the clinical case notes that recorded the care provided to the patients who were involved in the incidents in question. This external review is therefore not an investigation into the incidents themselves. It will assess the quality of the supervisory investigations and wherever possible assess the quality of care provision based on the clinical case notes.

This external review will therefore not seek to generate new evidence or insight that is not contained within the records of the supervisory investigation or clinical case notes.

Appendix 1

Audit of LSA England Supervisory Investigations

Options for inclusion criteria

	Sample Option per LSA area	Comments
1	Proportion of all LSA Supervisory Investigations within a given 12 month period	Sample data set would be very broad in both the 12 and 6 months options. The resulting audit will therefore be less focused, more difficult to analyses, less likely to identify themes; validate findings
2	Proportion of all LSA supervisory investigations where there was a poor maternal or fetal outcome	Although smaller sample pool than option 1, variables in sample cases likely to render findings less focused as above. Cases for inclusion in the review will be identified by systematic sampling.
3	Proportion of all LSA supervisory investigations where there was a poor fetal outcome	Smaller sample pool therefore improved audit focus than options 1 and 2.
4	Proportion of all LSA supervisory investigations where there was a poor neonatal outcome at birth	Smaller sample pool therefore improved audit focus than options 1, 2 and 3
5	Option 3 or 4 above with inclusion criteria of ***only*** midwifery-led cases	Smaller sample pool therefore improved audit focus than options 1, 2, 3 and 4. Audit will include only midwifery practice. ? ease of identifying midwifery-led cases

6	Option 5 above with inclusion criteria of cases that were ***only*** investigated by a Supervisor of Midwives (i.e. the provider Trust did not conduct a Serious Incident investigation through its own Clinical Governance processes)	As option 5 ? ease of identifying cases that were not also investigated by maternity provider Trust

Appendix B

B Maternity Service user Experience

Maternity Service User Experience of undergoing a Supervisory Investigation

1.**0 Introductions**

The review sample was comprised of NHS maternity cases in England which resulted in poor maternal and/or fetal/neonatal outcome and was subject to a supervisory investigation between the months of April through to December 2016 inclusive. These works were conducted by Debbie Graham, Independent Consultant Midwife, henceforth referred to as the reviewer

The purpose of these works was to establish whether each case included in this review, has had a robust and objective Local Supervising Authority (LSA) Supervisory Investigation into the standard of midwifery practice undertaken. Included in the review Terms of Reference is the requirement to:

> *Seek the consent of, and interview families identified on a case by case basis to understand their experience of the LSA supervisory investigation.*

Discussing safety incidents promptly, fully and compassionately can help service users cope better with the after-effects[32]. Following a clinical incident the affected family wish to know: what happened, why it happened and, if mistakes were made, that they have been identified and lessons learned to help prevent the same mistakes recurring. Good practice guidance on engaging with service users following a clinical incident is available for healthcare organisations, including the **'***Being Open'*[33]framework (2009) and the statutory duty of candour[34], which was introduced into healthcare in England in November 2014 and requires healthcare organisations to be open and honest with service users'/families following a clinical incident.

Both the duty of candour and the *Being Open* framework stipulate that following a clinical incident, a healthcare organisation should acknowledge, apologise and explain what went wrong. The *Being Open* framework states: (*I) t is important to remember that saying sorry is not an admission of liability and is the right thing to do.*[35]

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[32] Crane M. What to say if you made a mistake. *Med Econ*. 2001; 78: 26–8, 33–6

[33] Saying sorry when things go wrong, Being Open, Communicating patient safety incidents with patients, their families and carers, National Patient Safety Agency (2009) Gateway reference 13015

[34] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20

[35] Ibid (n6)

The LSA document relevant to this review was *LSA Review and Processes, Version 2,* dated 20th November 2013[36] (the policy).

This review has two important limitations:

1. The reviewer noted during each of the interviews, a lack of clarity as to whether recalled events related to a supervisory or trust investigation. All findings should therefore be interpreted as relating to the service users experience of *an* investigation rather than pertaining to a supervisory investigation alone.

2. An unintentional bias may have been built into the methodology (set out below) in that service users who had issues with the investigation into their case which remained outstanding may have been more likely to agree to be interviewed.

The remainder of this report describes the consultation process and provides an analysis of the responses with recommendations.

[36] Local Supervising Authority Review and Investigation Processes, LSAMO Forum UK, Policies for the statutory supervision of midwives, Version: 2 (2016)

2.0 Method

This was an 'opt-in' review and therefore required the signed consent of each woman included in the cohort. A standard letter was sent either by NHS England or directly by the provider Trust (as preferred by some Trusts), to each of the cohort women informing them of the review, its aims and requesting their consent for their case to be included in the review. A consent form was enclosed with the letter which women were asked to sign and return within four weeks of receipt after which their case would be withdrawn from the review. The consent form included a tick-box option for women and their families to indicate if they wished to discuss their experience of undergoing a supervisory investigation with the reviewer. Women who ticked this box were first contacted by the reviewer by telephone and a face to face or telephone interview arranged. Letters to service users were sent out from July to November 2017 inclusive.

A total of 15 women consented for their case to be included in the case notes review of the supervisory investigation into their case. Of these women 9 consented to be interviewed (60%) regarding their experience of being subject to a supervisory investigation. At 4 of the interviews (44%) the woman's partner was also present. The reviewer captured the couple's experiences at each of these interviews. The couple's responses to each statement were then amalgamated by the reviewer and are presented below as the experiences of one participant. Interviews were held either by telephone (n4) or in the participant's home or other convenient location (n5)

Table 1 shows the cohort sample by the outcome for each woman who participated in this consultation (n9)

Table 1: cohort sample by outcome

Poor outcome	**No of cases**
Neonatal/fetal	7
Maternal/neonatal/fetal	2
Total	**9**

The interview statements were developed by the reviewer and are based on good practice standards in compliance with the statutory duty of candour. Each interview was conducted by the reviewer using the prompt statements as set out in proforma 2 available at appendix 1. The participant's responses were either noted down or tape recorded with the participant's permission. Participants were advised that their responses would be treated as confidential in that no response would be attributable to any person. The reviewer advised that no individual issues, complaints or concerns could be dealt with in the interview setting but that if the session raised any concerns or anxieties for them these should be addressed by the provider Trust. The contact details of the relevant Trust Patient Advice and Liaison Service (PALs) or nominated contact person was made available to participants by the reviewer. In addition, in the event that the reviewer formed the opinion that a given woman may contact a Trust, the reviewer sent an email to the Head of Midwifery advising them as such, thereby enabling preparation for the contact.

In analysing the service user consultation findings the written notes and recordings from each session were analysed and themes identified before being themed together. This method uses elements of grounded theory research and involves reading and re-reading responses, looking for similarities and differences[37]. Themes emerge from word repetitions, key words and comparing and contrasting statements with each other taking care to accurately reflect what each participant was saying.

The next section of this report presents a table of the findings from this consultation. The subsequent sections present the findings from each statement, set out in the same order as the consultation proforma. Recommendations are presented in the final section of this report.

[37] Hitchcock, G. and Hughes, D. 1995 Research and the Teacher 2nd ed. London Routledge

3.0 Findings

Table 2 shows a summary of the consultation findings for each of the cases in the review cohort (n9) as assessed against the 22 review criterion in proforma 2

Table 2: summary of service user experience consultation findings

	Interview statement	Agree	Undecided	Disagree
1	I was informed both verbally and in writing that a supervisory investigation was being undertaken into my case	**4**	**1**	**4**
2	I understood that a supervisor of midwives would review the standard of midwifery practice in my case and was aware of what a supervisory investigation could and could not do	**1**	**1**	**7**
3	The supervisory investigation process was described to me and a likely timescale given both verbally and in writing	**3**	**1**	**5**
4	I was given the name and contact details of the SoM carrying out the investigation	**4**		**5**
5	I had a face to face meeting with the SoM carrying out the investigation into my case	**2**	**2**	**5**
6	I was advised both verbally and in writing on how I could contribute to the investigation process			**9**
7	My views were sought on how I wished to be involved with the investigation		**1**	**8**
8	I received both written and verbal updates on the progress of the investigation at regular intervals			**9**
9	I felt able to raise any concerns I had with the investigating SoM	**2**		**7**
10	My voice was heard	**2**		**7**
11	I felt an equal partner in the investigatory process			**9**
12	I had confidence in the supervisory investigation process to resolve any concerns I may have had		**2**	**7**
13	The investigation findings were explained to me both verbally and in writing		**1**	**8**
14	All of my questions were answered	**4**		**5**
15	I am confident that all of the facts relating to midwifery practice in my case have been established, and any lessons to be learnt identified and acted upon	**1**	**2**	**6**
16	I am happy with the time it took to complete the investigation	**2**	**3**	**4**
17	The outcome decision recommendations were explained to me both verbally and in writing	**2**		**7**
18	I was treated with courtesy, sensitivity and respect at all times	**2**	**3**	**4**
19	My privacy and confidentiality was protected at all times	**3**	**4**	**2**
	Interview statement	**Agree**	**Undecided**	**Disagree**
20	I was given both verbal and written information regarding where I could get support e.g. counselling/independent advice	**1**		**8**
21	I could access translator services if I needed them	**n/a**		
22	I received both a verbal and written apology from the Trust			**9**

Statement 1

I was informed both verbally and in writing that a supervisory investigation was being undertaken into my case

Of the total (15), 9 participants consented to be interviewed

- 4 (44%) agreed with this statement
- 5 (56%) disagreed with this statement. All 5 (100%) participants recalled being informed either verbally or in writing that a Trust investigation would take place. Of these participants (n5) the reviewer found written documentation in the LSA records of 2 (40%) participants that a letter informing them of the intended supervisory investigation had been sent to them. Documentation also recorded that the LSA had not received a response to their letter from these participants.

The findings from the responses to this statement indicate a lack of clarity between investigations undertaken by a SoM on behalf of the LSA and that undertaken by the provider Trust under their Clinical Governance processes. During interviews the reviewer observed that participants were often unclear as to whether a particular aspect of their experience they were recalling related to a supervisory or Trust investigation. An example being, one participant who was recalling her experience of, what she believed to be, a meeting with a SoM to the reviewer recalled the presence of a consultant obstetrician at the meeting. Although it is possible that a joint supervisory and Trust meeting was held, it is also possible that the participants was recalling a meeting that related to a provider Trust investigation only. This confusion is reflected in the responses received to all of the statements in this review.

Statement 2

I understood that a supervisor of midwives would review the standard of midwifery practice in my case and was aware of what a supervisory investigation could and could not do

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 1 (25%) agreed with this statement
- 1 (25%) was undecided
- 2 (50%) disagreed with this statement.

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 5 (100%) disagreed with this statement

Samples of direct quotes from participants to this statement are:

> *"I wasn't exactly sure how this would work and I was not aware of the extent "(*of the investigation)
>
> *"I thought everyone would be looked at"*

These findings suggest that the scope of a supervisory investigation was poorly understood within the sample group. This finding is applicable to both the supervisory and Trust investigations.

Statement 3

The supervisory investigation process was described to me and a likely timescale given both verbally and in writing

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 3 (60%) agreed with this statement
- 1 (20%) was undecided

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 5 (100%) disagreed with this statement

The findings to the responses to this statement relates to both supervisory and provider Trust investigations.

Statement 4

I was given the name and contact details of the SoM carrying out the investigation

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 3 (75%) agreed with this statement
- 1 (25%) disagreed with this statement

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 5 (100%) disagreed with this statement.

Of the 5 participants who were aware of a provider Trust investigation only, 1 (20%) recalled being given the name and contact details of the person undertaking the Trust investigation.

Statement 5

I had a face to face meeting with the SoM carrying out the investigation into my case

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 2 (50%) agreed with this statement. One reported that she had an initial meeting with a SoM followed by a second meeting on completion of the investigation. One respondent informed the reviewer that she had only been invited to meet with the investigating SoM after the investigation had been completed rather than at the start of the investigation as she would have wished.
- 2 (50%) disagreed with this statement.

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 5 (100%) disagreed with this statement

Of the 5 participants who were aware of a provider Trust investigation only:

- 4 reported meeting with a representative undertaking the Trust investigation.
- 1 reported that she had not had an opportunity to discuss her case with any healthcare professional. She informed the reviewer that she remained very upset by her experience and would like to have spoken to someone. The reviewer advised this participant to contact her provider Trust to address any outstanding issues. A contact details for the relevant Trust were provided by the reviewer.

Statement 6

I **was advised both verbally and in writing on how I could contribute to the investigation process**

Of the total number of participants interviewed all (n9) disagreed with this statement whether it applied to a supervisory or Trust investigation

Samples of direct quotes from participants to this statement are:

> *"I would have liked to have been involved from the beginning as what is written in my notes and what actually happened is different"*
>
> *"I was very tired when I was first contacted and on reflexion I had more questions"*

Of the total respondents to this statement (n9) 8 (89%) expressed a wish to be involved in the investigatory process. Of these respondents, 3 raised concerns that the investigation into their case was based solely on midwifery documentation and their version of events, which differed from that documented in their clinical notes, had not been taken into account. The reviewer advised each of these participants to contact the relevant provider Trust to address any outstanding issues. Contact numbers for the relevant Trust PALs or equivalent service were also given to the participants by the reviewer.

Statement 7

My views were sought on how I wished to be involved with the investigation

Of the total 4 participants who reported that they had been aware that a supervisory investigation would take place

- 1 (25%) was undecided. This participant reported that she and her partner had been consulted on whether they wished to be involved but not how. However she reported that she was satisfied by the way the investigation was conducted
- 3 (75%) disagreed with this statement

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 5 (100%) disagreed with this statement

There was varying opinion amongst the respondents as to the best timing and way to involve service users in an investigation. 3 participants recounted being approached whilst still in-patients by a member of the maternity staff (it was not clear in each case whether this was a SoM or Trust investigator) to inform them that an investigation would be carried out. All 3 respondents expressed an opinion that this was inappropriate as they were unable to concentrate at this time and therefore fully appreciate what was being said to them.

Statement 8

I received both written and verbal updates on the progress of the investigation at regular intervals

Of the total number of participants interviewed all (n9) disagreed with this statement whether applied to a supervisory or Trust investigation

Statement 9

I felt able to raise any concerns I had with the investigating SoM

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 2 (50%) agreed with this statement

- 2 (50%) disagreed with this statement

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 5 (100%) disagreed with this statement – this response applied to the Trust investigation

Samples of direct quotes from participants to this statement are:

> *"I did raise my concerns but I only had the opportunity after I received the report"*
>
> *"We raised our concerns but felt we weren't listened to"*

Statement 10

My voice was heard

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 2 (50%) agreed with this statement – 1 of these respondent's reported that she felt both she and her husband were listened to.
- 2 (50%) disagreed with this statement

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 5 (100%) disagreed with this statement

Statement 11

I felt an equal partner in the investigatory process

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 1 (20%) agreed with this statement
- 3 (80%) disagreed with this statement

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 5 (100%) disagreed with this statement

Samples of direct quotes from participants to this statement are:

> *"We had a personal view and this was difference from the midwives professional stance. It would have been helpful if we had an advocate who was there for us"*
>
> *"We had the initial engagement and then the report came. We were not actively encouraged to participate."*
>
> *"We would have taken up the opportunity to be more involved"*

It is unclear whether these findings relate to supervisory and/or Trust investigations.

Statement 12

I had confidence in the supervisory investigation process to resolve any concerns I may have had

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 2 (50%) were undecided on this statement
- 2 (50%) disagreed with this statement

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 4 (100%) disagreed with this statement

Samples of direct quotes from participants to this statement are:

> *"I half did and I half didn't. For example the SoM mentioned that the midwives were really upset which wasn't helpful"*
>
> *"I didn't really know what to expect"*

Statement 13

The investigation findings were explained to me both verbally and in writing

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 1 (25%) agreed with this statement

- 1 (25%) was undecided. This respondent's version of the events under investigation differed from that documented in her clinical notes by the attending midwife. The investigating SoM offered to meet with the participant to discuss the findings of the investigation. However the couple did not wish to meet with the SoM whilst issues remained outstanding.

- 2 (50%) disagreed with this statement. One of these responder's informed the reviewer that she had received a copy of the Trust investigation report

Of the 5 participants' who reported being either undecided or unaware that a supervisory investigation would take place

- 5 (100%) disagreed with this statement – these responses related to the Trust investigation

Of the total number of participants interviewed who reported being subject to a Trust investigation only (n5):

- 2 received a copy of the Trust final report. Neither of these participants received a verbal explanation of the investigation findings.

- 1 received a document which she described as a 'risk assessment' that did not contain an explanatory narrative

- 2 had not received a copy of their Trust investigation report or received a verbal explanation of the investigation findings.

Statement 14

All of my questions were answered

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 3 (75%) agreed with this statement. 1 of these respondent's indicated that she was *"not happy with a couple of the answers but it* (the SoM investigation report) *was detailed"*

- 1 (25%) participant disagreed with this statement. This related to the differing versions of events as described above.

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place:

- 1 agreed with this statement in relation to the Trust investigation. However, this respondent commented that she remained '*uneasy'* regarding the incident events.

- 4 (100%) disagreed with this statement – these responses related to Trust investigations

Statement 15

I am confident that all of the facts relating to midwifery practice in my case have been established, and any lessons to be learnt identified and acted upon

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place:

- 1 (25%) agreed with this statement

- 2 (50%) were undecided. Both of these respondents expressed uncertainty whether the recommendations from their cases had been acted upon.

- 1 (25%) disagreed with this statement

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place:

- 1 (25%) was undecided – this related to the Trust investigation. This respondent expressed uncertainty that all of the *'background'* events that may have contributed to her incident and not just the midwife's practice had been investigated.

- 4 (75%) disagreed with this statement

Samples of direct quotes from participants to this statement are:

"We would have like it but we didn't receive feedback"
"The Head of Midwifery visited us (at home) *but gave the impression that she didn't want to get involved"*

Statement 16

I am happy with the time it took to complete the investigation (the LSA standard for completion of investigation is 60 working days)[38]

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 2 (50%) agreed with this statement. Of these respondent, 1 investigation was completed in 60 working days and 1 was completed in 75 working days
- 1 (25%) was undecided. This respondent's investigation was completed in 55 working days
- 1 (20%) disagreed with this statement. This respondent's investigation was completed in 60 working days.

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 5 (100%) disagreed with this statement. All 5 participants stated that they were unaware of when the supervisory investigation was commenced and completed. 3 of these respondents reported that they had received a final investigation report from their provider Trust. The reviewer was informed that, one was completed in 6 months, one had taken 10 months and one had taken 1 year to complete. It was not within the remit of this consultation to verify these reported findings.

[38] Ibid (n7) Table 1, Step 2

Statement 17

The outcome decision recommendations were explained to me both verbally and in writing

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 2 (50%) agreed with this statement.
- 2 (50%) disagreed with this statement. 1 respondent had declined to meet with the investigating SoM as differing accounts of the incident remained outstanding.

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 5 (100%) disagreed with this statement – these responses related to Trust investigations

Statement 18

I was treated with courtesy, sensitivity and respect at all times

Of the 4 participants' who reported that they had been aware that a supervisory investigation would take place

- 2 (50%) agreed with this statement
- 1 (25%) was undecided
- 1 (25%) disagreed with this statement

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 4 (100%) disagreed with this statement

Samples of direct quotes from participants to this statement are:

> *"We thought we would be invited to be on the panel. We phoned the secretary twice for dates but we were never called back. Then we were told that the investigation was completed"*
>
> The Trust are *"Trying to avoid me because they made a mistake"*
>
> *"Not answering our questions and the letter we received lacked sympathy they did not offer condolences"*

Statement 19

My privacy and confidentiality was protected at all times

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 2 (50%) agreed with this statement
- 1 (25%) was undecided
- 1 (25%) disagreed with this statement

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 2 (20%) agreed with this statement – this related to Trust investigations
- 2 (50%) were undecided
- 1 (20%) disagreed with this statement

Samples of direct quotes from participants to this statement are:

> *"We had no contact so we don't know who was spoken to"*
>
> *"The meetings were held in a room off the maternity corridor and we bumped into people we knew who were going home with their new baby and they wondered what we were doing there. This really affected the way I felt in the meeting"*

Statement 20

I was given both verbal and written information regarding where I could get support e.g. counselling/independent advice

Of the 4 participants who reported that they had been aware that a supervisory investigation would take place

- 1 (25%) agreed with this statement
- 3 (75%) disagreed with this statement

Of the 5 participants who reported being either undecided or unaware that a supervisory investigation would take place

- 5 (100%) disagreed with this statement

Statement 21

I could access translator services if I needed them

This statement did not apply to all (n9) of the participants

Statement 22

I received both a verbal and written apology from the Trust

Of the total number of participants (n9), all (100%) disagreed with this statement. 2 respondents (22%) reported receiving a verbal apology. However both of these respondents commented that they did not think that the apology they received was meaningful.

Samples of direct quotes from participants to this statement are:

> *"We were seen by the Head of Midwifery immediately after* (the incident) *and she said that under duty of candour she had to give us an apology. It would have been better if she hadn't said anything"*
>
> *"We were given an apology at the meeting but it wasn't from the heart, it was just formal"*

Statement 23

Any other comments

Samples of direct quotes from participants are:

> *"I was given papers for the community midwife when I was discharged from hospital but they never came and I haven't had contact with the hospital so I still have them"*
>
> *"The doctor said after surgery 'we are surprised you are alive'. I was too upset to ask for an investigation and I didn't know one had happened. We would like another baby but I am too scared after last time"*
>
> *"There should be more support for families following an incident – we really feel let-down"*

These responses illustrate the impact not experiencing a meaningful, supportive and inclusive investigatory process may have on service users.

4.0 Conclusion

It was not always possible for the reviewer to distinguish whether a participant's recollection of events related to a supervisory or trust investigation. All findings should therefore be interpreted as relating to the service users experience of *an* investigation rather than pertaining to a supervisory investigation alone.

The reviewer found the majority of service users who participated in this consultation reported a poor experience of undergoing an investigation. This finding is consistent with the national picture for the standard of service user engagement in investigations across the NHS. In their 2016 report the Care Quality Commission (CQC) noted: (*T)hroughout our review, families and carers have told us that they often have a poor experience of investigations…. The extent to which families and carers are involved in reviews and investigations of their relatives varies considerably.* [39]

It is recognised that following a clinical incident the engagement of the affected family is essential. Knowledge of how they will be able to contribute to the process of investigation, for example by giving evidence helps to provide affected families with confidence that the findings of an investigation will be robust, meaningful and that lessons will be learned from to prevent the likelihood of similar incidents happening again.

This consultation has not identified a best practice approach to the timing of service user engagement following a clinical incident. The findings show that the desired level of active participation in an investigation differs between service users. Some participants reported that they had been informed of an investigation too late (or indeed not at all) whilst other participants reported that they had been informed at too early a stage when they were feeling confused. However, all participants stated that they wished to be involved throughout an investigation. In particular, participants stated that when undertaking an investigation, equal weight should be given to the service user's evidence as that given to the documented records. Furthermore, some participant's stated that they wished to be involved after the investigation had been

[39] Learning, candour and accountability, A review of the way NHS trusts review and investigate the deaths of patients in England, CQC (2016)

concluded so that they could be assured that the recommendations from their case had been actioned.

The current NHS Serious Incident framework published in 2015 sets expectations for when and how the NHS should conduct a safety investigation. This framework is currently being revised to better support the system to respond appropriately when things go wrong. The findings of this case note review and in particular the absence of evidence that the duty of candour had been upheld for all women and the poor experience of families involved, will be shared with NHS Improvement to support the plans to improve the process for engaging with patients when things go wrong

5.0 Recommendations

This report should be shared widely, including but not limited to:

- service users who participated in the engagement consultation
- service users who formed part of the cohort sample who did not participate in the engagement consultation but indicated on their consent form that they would like to receive the final report
- Participating provider Trusts.
- NHS Improvement for contribution to the review of the NHS Serious Incident framework
- The Healthcare Safety Investigation Branch

Acknowledgements

This review would not have been possible without the cooperation and support of many people, to all of whom I wish to extend my thanks and gratitude. Particular thanks are extended to the service users who kindly shared their experiences with me

Appendix C

Service User Consultation proforma

C Review proformas

Case note review proforma 1

	Criteria
1	The SoM fully investigated the midwife's practice as documented in the clinical records
2	The incident chronology was determined
3	All issues identified by the reviewer were addressed
4	Key staff were interviewed
5	Key staff were asked to provide a written statement
6	No documentation was missing
7	The SoM documented communication with the parents/family
8	Compliance with statutory duty of candour is documented

Service users' experience review proforma 2

	Interview statements	Agree	Undecided	Disagree
1	I was informed both verbally and in writing that a supervisory investigation was being undertaken into my case			
2	I understood that a supervisor of midwives would review the standard of midwifery practice in my case and was aware of what a supervisory investigation could and could not do			
3	The supervisory investigation process was described to me and a likely timescale given both verbally and in writing			
4	I was given the name and contact details of the SoM carrying out the investigation			
5	I had a face to face meeting with the SoM carrying out the investigation into my case			
6	I was advised both verbally and in writing on how I could contribute to the investigation process			
7	My views were sought on how I wished to be involved with the investigation			
8	I received both written and verbal updates on the progress of the investigation at regular intervals			
9	I felt able to raise any concerns I had with the investigating SoM			
10	My voice was heard			
11	I felt an equal partner in the investigatory process			
12	I had confidence in the supervisory investigation process to resolve any concerns I may have had			
13	The investigation findings were explained to me both verbally and in writing			
14	All of my questions were answered			
15	I am confident that all of the facts relating to midwifery practice in my case have been established, and any lessons to be learnt identified and acted upon			
16	I am happy with the time it took to complete the investigation			
17	The outcome decision recommendations were explained to me both verbally and in writing			
18	I was treated with courtesy, sensitivity and respect at all times			
19	My privacy and confidentiality was protected at all times			
20	I was given both verbal and written information regarding where I could get support e.g. counselling/independent advice			
21	I could access advocacy/translator services if I needed them			
22	I received both a verbal and written apology from the Trust			