APPENDIX 1

An independent review into 9 serious incidents within maternity services at Pennine Acute Hospitals NHS Trust.

January 2015

Contents

Section 1

1. About the report

This report presents the findings and conclusions of an independent review into a number of serious untoward incidents (SUIs) and their subsequent investigations which took place between Jan and July 2014 within maternity services at Pennine Acute NHS Trust.

The report does not provide the full specific clinical details of the nine serious untoward incidents that occurred during this time. It does, however, include a summary of each case and overall conclusions of the reviewers.

Full clinical details, together with reviewers' comments can be found in the appendices.

2. About the reviewers, process and terms of reference

2.1 The review has been commissioned on behalf of the Trust by Chief Nurse, Ms M Sunderland, and conducted by:

Mrs L Moore, midwife, supervisor of midwives and head of midwifery (ret'd).

Mr C Nwosu, Consultant Obstetrician & Gynaecologist at St Helen's and Knowsley NHS Trust.

2.2 Process

Each of the cases and its subsequent investigation has been reviewed, together with the relevant statements and with reference to national and local guidelines.

NB: The reviewers will not comment upon areas outside of their expertise.

2.3 Terms of Reference

The terms of reference were agreed in September 2014, and the commission agreed, to:

1. Provide a detailed case note review of recent cases that resulted in adverse outcomes for mothers or babies.
2. Advise whether the RCA investigation was satisfactory and identify any areas of concern with the RCA process and final reports.
3. Advise as to quality and appropriateness of the associated action plans and whether they have been embedded into practice.

3. Executive Summary

In July 2014, following the reporting of a number of serious incidents within maternity services, including three maternal deaths, Pennine Acute Hospitals NHS Trust commissioned an independent review to:

1. Provide a detailed case note review of recent cases that resulted in adverse outcomes for mothers or babies.
2. Advise whether the RCA investigation was satisfactory and identify any areas of concern with the RCA process and final reports.
3. Advise as to quality and appropriateness of the associated action plans and whether they have been embedded into practice.

Having agreed the terms of reference, the review took place using:

- The Trust's policy for the Management of Maternity Clinical Incidents
- The SI reports and action plans
- Chronologies of nine serious incidents
- National and local guidelines

The review was completed in January 2015. The findings included:

The population of women cared for at Pennine Acute NHS Trust is diverse and challenging, and includes a significant number of high-risk and vulnerable women.

It is not possible to make assumptions about the quality of care given to this population based on these cases alone.

There are clearly areas of good practice, which are appropriately noted and acknowledged during serious incident review, and which should be widely disseminated.

The maternal deaths do not appear to be the result in deficiencies in care.

The serious incidents have been thoroughly and comprehensively reviewed. Many of the areas identified by the reviewers have been addressed in the findings and recommendations of the Trust's serious incident panels, however an overview has shown that there are a number of key areas for further consideration and action:.

- **Clinical Risk Management**

  In some cases, risk management during the antenatal period and in labour were below standard, which may have contributed to the poor outcomes.

- **Clinical Leadership**

  In a number of cases, there has been a notable absence of clinical leadership in both medical and midwifery teams, resulting in a failure to adequately plan care.

- **Obesity Management**

Three of the cases reviewed involved women who were obese or morbidly obese, and one was overweight.

Although one third of the population is now thought to be obese, the risks to the obese pregnant woman are considerable, and include pre-eclampsia, venous thromboembolism and anaesthetic complications.

It would appear that the obesity which was evident in a number of the cases reviewed was not managed in line with local or national guidance. The service needs to be assured that there is a robust and effective pathway for the management of obesity in the community,

antenatal clinics, delivery suite and postnatal areas, and that all staff are made aware of guideline / pathway development

- **Serious Incident investigations**

The incidents reviewed were reported appropriately, in line with Trust guidance.

There is a clear, honest and open approach to identifying failings.

The investigations into the serious incidents were reviewed by an appropriately appointed panel.

A thorough and open approach was taken to establishing the time-line and chronology.

However:

The root cause was not always clearly defined.

Specific learning points were not always addressed in the recommendations.

Some of the recommendations are vague and difficult to measure.

The reviewers have made a number of recommendations which should be incorporated into an action plan in response to this review.

These include:

1. The service should take steps to strengthen clinical leadership and clinical risk management.
2. Staffing should be reviewed to ensure that safety can be assured. (The Trust is currently undertaking Birthrate Plus, and a draft report is expected in February.)
3. Staffing concerns must be appropriately escalated, and must include involvement of the duty Supervisor of Midwives.
4. The process for employing and managing locum doctors should be reviewed.
5. All serious incident reports should be 'quality checked' before submission, to ensure that the root cause is clearly established.
6. Recommendations made by the serious incident review panel must be clear and unambiguous.
7. Where individual failings have been identified, the reports must demonstrate that training / learning needs have been considered.
8. All available methods should be used to ensure that standards of documentation are improved where necessary.

Section 2

4. Summary of nine serious untoward incidents

The first three cases are of maternal death.

Maternal death is defined as ***'the death of a woman while pregnant or within 42 days of termination of pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental cause' (WHO, 2010).***

Maternal deaths are subdivided into deaths 'directly' related to pregnancy, which are resulting from conditions or complications or their management that are unique to pregnancy, occurring during the antenatal, intrapartum or postpartum periods, and those 'indirectly' related which result from pre-existing disease, or disease that develops during pregnancy not as the result of direct obstetric causes, but which were aggravated by the physiological effects of pregnancy. (CMACE Saving Mothers' Lives, 2011).

There is also a category of 'coincidental' maternal death, where the death would have occurred even if the woman had not been pregnant.

In two of the following cases, the post-mortem has been inconclusive, and subsequently it is not possible to ascertain whether the deaths, which did not appear to be directly related to the pregnancy, were indirect or coincidental.

Sections 4.1 – 4.9 (Pages 6 – 34) contain details of the individual cases and has been redacted in full in order to maintain the duty of confidentiality to patients.

Section 3

1. Overall conclusions of the reviewers

The population of women cared for at Pennine Acute NHS Trust is diverse and challenging, and includes a significant number of high-risk and vulnerable women.

It is not possible to make assumptions about the quality of care given to this population based on these cases alone. Indeed, this cluster could simply be a chance event.

There are clearly areas of good practice, which are appropriately noted and acknowledged during serious incident review.

There will always be occasions when things go wrong, and what is important is how the service deals with these situations, and how lessons learnt are subsequently disseminated.

Many of the areas identified by the reviewers have been addressed in the findings and recommendations of the serious incident panels, which are generally thorough and comprehensive.

The cases considered, however, do raise some areas of concern which should be addressed by the Trust.

Serious Incident investigations

The incidents reviewed were reported appropriately, in line with Trust guidance.

The serious incidents were investigated by an appropriately appointed panel, and a representative Supervisor of Midwives is included.

A thorough approach was taken to establishing the time-line.

Multi-disciplinary approach is taken in investigations and report writing.

Good practice is recognised.

In some cases, the root cause: 'A systematic process whereby the factors that contributed to an incident are identified.' As an investigation technique for patient safety incidents, it looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which an incident happened.' NPSA National Framework, (2010) was not clearly recognised during the panel investigation.

The panel recommendations do not always follow a logical, systematic pathway, and can be somewhat vague and general.

Specific learning points were not always addressed in the recommendations.

Failings made by individuals were not always addressed in the recommendations.

Clinical Risk Management

In some cases, risk management during the antenatal period and in labour were below standard, which may have contributed to the poor outcomes.

Midwives and obstetricians must be aware of the importance of risk assessment and early referral where appropriate.

Measures to improve the documentation of risk assessment and management must be undertaken.

There are a number of recommendations in the SI reports about updating staff, and of ensuring risk assessments take place. Whilst it is of course highly beneficial to ensure that all staff are informed of, and made aware of issues arising from these cases and the changes made, it is important that the service asks itself **how** such fundamental errors can occur.

Clinical Leadership

In some cases, there was a lack of leadership from both obstetricians and midwives. All women need to have their risks assessed and reviewed throughout pregnancy and labour. When needs change, clear plans must be documented in the records, and concerns must be documented and escalated appropriately.

There is a need for a clear leadership role on the part of the consultant obstetrician, who must be responsible for an overall and detailed risk assessment and plan of management for women with complex or high risk needs throughout pregnancy and labour. This is particularly pertinent at times of high activity.

The role of the labour ward co-ordinator is to ensure that the women in her care are allocated to the most appropriate midwife, and an overview of all cases must be maintained at all times. An experienced, senior midwife, it is her role to support and advise more junior staff, particularly at times of high activity. In some of the cases, the co-ordinator did not exercise effective leadership. This was not always recognised by the panel.

Obesity Management

In line with general population, some of the cases reviewed involved women who were obese. The risks to the morbidly obese pregnant woman are, however, considerable, and include pre-eclampsia, venous thromboembolism and anaesthetic complications.

Obese women can, and do, have normal, low-dependency pregnancy and births, but this depends upon a high level of surveillance, risk assessment and control underlying their care.

RCOG / CMACE guidance 'Management of Women with Obesity in Pregnancy' (2010) states that:' Obesity in pregnancy is associated with an increased risk of a number of serious adverse outcomes, including miscarriage, fetal congenital anomaly, thromboembolism, gestational diabetes, pre-eclampsia, dysfunctional labour, postpartum haemorrhage, wound infections, stillbirth and neonatal death. There is also evidence to suggest that obesity may be a risk factor for maternal death.'

It would appear that the obesity evident in the group reviewed was not managed in line with national and local guidance, and the service needs to be assured that the robust and effective pathway in place is implemented at all levels.

Staffing

A number of these incidents occurred at periods of high activity. Given the unpredictable nature of maternity services, there will always be times when excessive activity creates difficulties. The service must remain safe, however, and the Trust should ensure that staffing levels are adequate for the workload. Birthrate Plus should be considered. The service must ensure that there is a robust escalation process when high activity occurs, and that the senior team take appropriate steps to move staff appropriately. In addition, the Supervisor of Midwives should be informed.

Documentation

Failings in documentation were a recurring theme identified by the RCA panels, and the directorate should be able to demonstrate that effective steps have been taken to ensure that improvements are made.

Recommendations

1. Staffing issues where safety is compromised must be appropriately escalated, and must include involvement of the duty Supervisor of Midwives.
2. Managers must ensure that the process for escalating concerns is clear.
3. The process for employing and managing locum doctors should be reviewed.
4. The directorate should review its management of obesity in pregnancy, labour and the postnatal period, and that guidelines are appropriately implemented.
5. All serious incident reports should be 'quality checked' before submission, to ensure that the root cause clearly established.
6. Recommendations made by the serious incident review panel must by clear and unambiguous.
7. Where individual failings have been identified, the reports must demonstrate that training / educational needs have been considered.
8. Senior managers must ensure that training / educational needs are addressed where leadership has failed.

9. Serious incident reviews must be signed off by a nominated senior manager from the appropriate specialty.
10. The directorate should ensure that all mandatory training is up to date for all disciplines of staff, including record keeping and interpretation of CTG.
11. All available methods should be used to ensure that standards of documentation are improved where necessary.
12. The Trust must be assured that a robust system is in place to ensure the regular and timely review, implementation and audit of guidelines in accordance with Trust policy.

Appendices

1. **Terms of Reference (attached)**

2. **<u>Clinical details of each case with reviewers' comments</u>**

Appendix 2 contain the detailed case history of each individual cases and has been redacted in full in order to maintain the duty of confidentiality to patients.

CLINICAL REVIEW OF OBSTETRIC SERVICES AT BOTH NORTH MANCHESTER & ROYAL OLDHAM HOSPITAL SITES

1. BACKGROUND

The Pennine Acute Hospitals NHS Trust has requested an external review of the in-patient Obstetric services within the Trust in order to assess clinical safety and effectiveness following a number of serious incidents. The review will focus on both medical and midwifery standards and practice and make recommendations for any areas where improvement is required.

2. TERMS OF REFERENCE

2.1 Structure and function of the review

2.1.1 Review current Obstetric services in-patient provision with regards medical and midwifery cover

2.1.2 Review practices and operations on each site; determining areas of weakness or inconsistency across the two sites

2.1.3 Review the communications within the Obstetrics teams – consultants, other medical staff, midwives and support staff and advise if these are optimal; or provide suggestions as how they could be improved.

2.1.4 To identify or suggest any further training requirements for the team.

2.1.5 To recognise areas of good practice

2.2 Clinical outcomes/indicators

2.2.1 To review current governance arrangements in place with regards to -

- Incident reporting & investigation, action planning and lessons learned
- To review patient complaints, action planning and lessons learned
- Morbidity and mortality meetings
- Risk assessments

2.2.2 To identify and areas of current risk in respect of clinical safety providing recommendations in line with best practice

2.2.3 To review any local audits undertaken; or recommend audits to be carried out.

2.2.4 To review submission of data to national databases and registries, and suggest if this can be enhanced.

2.2.5 To review outcome data for the service and individual clinician's for the last two years against relevant national indicators

2.2.6 To review any patient experience surveys available, or recommend surveys to be carried out.

2.3 Specific Case Reviews

2.3.1 To provide a detailed review of the recent serious cases and advise whether the RCA investigation was satisfactory, areas of concern addressed in the action plans and changes arising from action plans embedded and still in place.

2.3.2 To recommend any other specific cases that the reviewers identify in the course of reviewing the terms of reference detailed above.

3. METHOD

The review group will undertake a site visit to meet with staff and determine further information requirement

In the first instance a case note review of the serious cases leading to adverse outcomes in the last 3 years will be undertaken, including an evaluation of the action plans resulting from the case investigation.

Dependant on the findings of the case note analysis, the review group may then be asked to undertake a wider study of practices, relationships and clinical outcomes.

4. MEMBERSHIP

The review group will be made up of – Consultant Obstetrician and Head of Midwifery from an external Trust.

5. AUTHORITY

The team is authorised by the Trust Chief Nurse to seek any information it requires in order to fulfil its terms of reference.

6. REPORTING ARRANGEMENTS

To ensure the project is completed within the given timeframe producing an interim and final report to the Chief Nurse. The initial draft report will be written by the review group and subject to assessment by Divisional Director, Clinical Director and Head of Midwifery for accuracy in first instance.

The report will then be submitted to the Chief Nurse of the Pennine Acute Hospitals NHS Trust. Access to the final report will be available to those involved in the service as quality improvement within the local service will be best delivered if the report is shared with relevant members of the organization.

7. GOVERNANCE

The report will be advisory only. The responsibility for the governance of the services remains solely with the Pennine Acute Hospitals NHS Trust.

The report will assess the Obstetric services and the supporting governance and quality measures. It will not assess or report on individual performance or competences within any staff group.

May 2014

Pennine Review

Addendum – Woman K

This additional report relates to a 10th case which was not included in the original review but the external reviewers were subsequently asked to review.

The first eight pages contain details of the individual case and has been redacted in full in order to maintain the duty of confidentiality to patients. The appendix has also been redacted as it contains the full patient case history.

These comments are pertinent to this case.

The reviewers' view is that:

- Clinical risk assessment in labour was suboptimal in this case and may have contributed to the poor outcome.
- The lack of obstetric and midwifery leadership is evident in this case.
- The root cause of this case must include a midwifery and obstetric failure to carry out detailed and thorough risk assessments in labour, and to plan care accordingly.

Recommendations

The following recommendations made in our original report are pertinent to this case:

1. Staffing issues where safety is compromised must be appropriately escalated, and must include involvement of the duty Supervisor of Midwives.
2. Managers must ensure that the process for escalating concerns is clear.
3. The process for employing and managing locum doctors should be reviewed.
4. All serious incident reports should be 'quality checked' before submission, to ensure that the root cause clearly established.
5. Recommendations made by the serious incident review panel must by clear and unambiguous.
6. Where individual failings have been identified, the reports must demonstrate that training / educational needs have been considered.
7. Senior managers must ensure that training / educational needs are addressed where leadership has failed.
8. Serious incident reviews must be signed off by a nominated senior manager from the appropriate specialty.

9. The directorate should ensure that all mandatory training is up to date for all disciplines of staff, including record keeping and interpretation of CTG.
10. All available methods should be used to ensure that standards of documentation are improved where necessary.
11. The Trust must be assured that a robust system is in place to ensure the regular and timely review, implementation and audit of guidelines in accordance with Trust policy.

In addition

12. Clinical risk management, both midwifery and obstetric, must be demonstrably strengthened.

References

1. Royal College of Obstetricians & Gynaecologists Green-top Guideline No. 45, Birth after Previous Caesarean Birth (Feb 2007).
2. Royal College of Obstetricians & Gynaecologists Green-top Guideline No. 26, Operative Vaginal Delivery (Jan 2011).
3. Sambrook, J., Malpositions and Malpresentations, Patient UK – Evidence Summaries, (2014).