

NCT summary and critique of the review methodology for ‘The London Project – A confidential enquiry into a series of term babies born in an unexpectedly poor condition’ by CMACE

Abstract

This summary and critique focuses on the review methodology and results. It does not include comment on the recommendations.

Panels appointed by CMACE to assess why there appeared to be higher numbers of adverse outcomes in women cared for by the Albany Group Practice midwives judged that in 6/10 cases where a baby was diagnosed with hypoxic-ischaemic encephalopathy (HIE) in which there were ‘complications’ encountered during labour, these were not responded to appropriately (‘overlooked’). In all Albany cases with a poor outcome (group A), the panels judged that aspects of care contributed to poor outcome (12/12). However, the methodology of the review is unclear and appears to have a number of serious weaknesses.

- There is no comparative statistical analysis using trust-wide data, or comparing community-based midwifery care with hospital-base care, or comparing Albany Practice care with matched samples or populations of these two groups.
- The time period selected for the review is not explained or justified. It appears to have been selected to reflect Albany Midwifery care in the poorest light.
- The methodology and the assessment method are not described explicitly and it appears that bias may have been introduced, including selection bias in the cases that are compared (groups A, B and C), bias among the panellists regarding their views about medical versus a social model of care, and bias due to unblinding of cases before panellists’ judgements were made.
- Findings regarding individual cases are not presented, perhaps to protect anonymity. This obscures transparency.
- The number and make up of the panels that carried out the review are not made clear. It is not revealed how many of the panellists had experience of community-based care based on a social model, as opposed to hospital-based management within a medical model.

1 Introduction

- 1.1 The report describes an enquiry carried out by the Centre for Maternal and Child Enquiries (CMACE) using a comparative methodology. This summary and critique details some key comments on the strengths and weaknesses of the methodology, including a focus on the background, aim of the enquiry, methodology, the results and interpretation.

2 Background

- 2.1 King's College Hospital NHS Foundation Trust (referred to below as 'Kings') commissioned CMACE to carry out the review in 2009 having 'identified' that over a 31 month period the number of admissions of term infants with serious morbidities including hypoxic-ischaemic encephalopathy (HIE) was comparatively 10 fold greater amongst women under the care of the Albany Group Practice (referred to below as 'the Albany') than women cared for by other Kings midwifery group practices or by hospital midwives.' The report states that 'local risk management procedures had been carried out in all cases but no particular issues had been identified with only a minority of cases having significant errors identified'.

3 Critique of background

- 3.1 The background to the report is inadequate in that:
- it fails to describe the local risk management procedures or the monitoring and evaluation that had been carried out prior to the CMACE enquiry;
 - there is no acknowledgement of the particular characteristics of the Albany or the history of the working relationship between Kings and the Albany practice;
 - no quantitative data are provided to support the claim that there was comparatively a '10 fold' greater incidence of HIE amongst babies born to women under the care of the Albany, compared with:
 - a) other Kings midwifery group practices, or
 - b) by hospital midwives.

4 Aim

- 4.1 Kings commissioned CMACE to 'provide an independent review using confidential enquiry methodology'.
- 4.2 The aim of the investigation was to:
- gain a better understanding of why there appeared to be higher numbers of adverse outcomes in women cared for by the Albany Group Practice midwives so that any necessary changes can be made both for the

Albany and maternity care in general to improve the safety of mothers and babies under the care of the King's maternity unit.

5 Critique of the aim

- 5.1 The overall aim of the enquiry concerns us for several reasons.
- 5.2 The enquiry appears to be potentially biased, stating that the objective was to 'gain a better understanding of why there appeared to be higher numbers of adverse outcomes in women cared for by the Albany' rather than to establish whether or not there was evidence of disproportionately poor outcomes in term babies. By this stage of the report, there is already a presumption made that the incidence of HIE is greater.
- 5.3 The trust commissioned the enquiry, rather than it being initiated by a third party, and cases during a 31 month period were selected as the subject of the enquiry, an arbitrary period when the Albany were deemed to have a 10-fold increase in HIE cases, yet Albany had been delivering care on behalf of the trust for almost a decade.
- 5.4 There was also an objective to learn lessons about whether the safety of mothers and babies could be improved. There was no commitment to look at issues of safety in the context of offering choice or in terms of overall quality of service where aspects of care such as relationship might be considered. The approach therefore comes from a medical model of care perspective, rather than encompassing issues defined as important within a social model of care perspective.
- 5.5 The NCT believes that clinical safety is an important criterion for a maternity service, but not the sole important criterion.

6 Methodology

- 6.1 The confidential enquiry methodology used by CMACE was employed in order to 'determine whether and to what extent there is a pattern of recurrent avoidable factors associated with adverse outcomes in a care system'.
- 6.2 In this instance, groups of anonymised case records were 'analysed by multi-disciplinary enquiry panels of senior professionals including midwives ..., consultant obstetricians, consultant neonatologists and healthcare managers'.
- 6.3 Three groups of case notes were compared:

- Group A - women receiving care from Albany who were identified as having adverse neonatal outcomes (11 cases of HIE and 1 of hypoglycaemic brain injury);
- Group B - also women receiving care from Albany identified as not having HIE cases (10 non-HIE cases)
- Group C - women receiving care from other Kings community midwives [NB these were women selected from a group who had relatively poor outcomes] (11 cases with 'unexpected admission to NICU').

6.4 Interviews were also carried out by 'an external senior obstetrician and senior midwife nominated by CMACE' with midwives, doctors and managers at Kings and a presentation was made 'in confidence' to a Plenary Multidisciplinary Committee of experts, prior to the report being drawn up with recommendations for change being agreed by the committee.

7 Critique of methodology

- 7.1 No definition is given of the way that HIE was defined by Kings. No details are provided of the incidence of HIE within population of women cared for by the Albany. No comparative data from babies born to women receiving either hospital based care or from other community group practices are provided, and therefore no statistical analysis of significance. Therefore the claim that 'serious morbidities including hypoxic-ischaemic encephalopathy (HIE) was comparatively 10 fold greater amongst women under the care of the Albany Group Practice than women cared for by other Kings hospital midwives' cannot be tested.
- 7.2 It is of concern that all the cases were not reviewed by one panel. It is not clear how many panels reviewed the cases, nor the make-up of each panel in terms of professional participation and the seniority and experience of the different professionals involved. The lack of transparency is problematic.
- 7.3 The methodology involved developing a 'consensus' of the panellists' judgements about standards of care. The method of a) appraising the quality of care and b) reaching a consensus are not described, nor is it clear whether any opposing views could be recorded. It is likely that there will have been some differing views amongst such a multi-disciplinary group and these should have been noted.
- 7.4 The comparative method used is not adequately described and justified.
- 7.5 It is not made clear how the cases in the control or comparison groups (groups B and C) were selected. As these were selected by Kings, with no

- description of the selection process, there is the potential for the introduction of bias.
- 7.6 We would expect the comparison cases (groups B and C) to be matched with group A (e.g. in terms of social deprivation level) or to be selected at random from within the relevant group. Given the small size of these populations, matching would be difficult. Comparisons between groups A and B would be likely to determine whether there were variations in practice within the Albany which contributed to poorer outcomes, using the rationale of a case-control study. Any apparent differences in treatment or care might be confounded if there were differences between the populations.
- 7.7 The numbers in the sample are too small to make statistical comparisons.
- 7.8 There is no comparison with hospital-based care, neither statistical comparison nor case review comparison. Cases could have been selected from those receiving hospital care who had 'unexpected admission to NICU' (like group C) or who had normal neonatal outcomes (like group B). The absence of comparison with hospital-based care, means that it is not possible to conclude whether any deficiencies in practice affect the Albany in particular, community-based care, or care throughout the trust.
- 7.9 It is a strength that all case records were reviewed anonymously. However, it is a weakness that in each case, the baby's clinical condition was revealed prior to a judgement being made about whether care was substandard.
- 7.10 It is not clear which midwives, doctors and managers 'at the Trust' were interviewed, nor how they were selected. The methodology for conducting the interviews is not made explicit, nor how qualitative data resulting from them was analysed or presented. There is potential for bias in this part of the process.

8 Results

8.1 Results tables¹ were provided on the following:

Table 1	Deprivation quintiles
Table 2	Obstetric risk factors identified at booking
Table 3	Obstetric risk factors overlooked at booking
Table 4	Previous medical history /risk factors identified at booking
Table 5	Medical risk factors overlooked at booking
Table 6	New risk factors identified (later) in the antenatal period

¹ The descriptions and labels are those used in the report.

Table 7	New risk factors overlooked
Table 8	Care plans developed in pregnancy
Table 9	home birth preference
Table 10	Standard of assessment
Table 11	Standard of advice
Table 12	Complications encountered in labour
Table 13	Later complications overlooked
Table 14	Standard of fetal monitoring
Table 15	Intermittent auscultation
Table 16/18	CTG warranted/employed/interpreted correctly
Table 19	Neonatal comparisons
Table 20	Significance of any factors relating to labour contributing to neonatal management
Table 21	Deficiencies in communication
Table 22	Timeliness and appropriateness of referral to obstetricians
Table 23	Adherence to DH, RCOG, NICE guidance
Table 24	Standard of documentation
Table 25	Care contributed to poor outcome
Table 26	A better outcome was possible

- 8.2 The panels judged that in 6/10 group A cases in which there were 'complications' encountered during labour, these were not responded to appropriately ('overlooked'), compared with 0/2 cases for group B and 3/3 cases in group C.
- 8.3 Fetal monitoring and interpretation of findings was criticised, particularly among Group A cases (tables 14-18). Management of the care of the baby after birth was criticised, particularly among group A cases (in 7/11 cases neonatal management deemed to be 'poor') (table 19).
- 8.4 Communication between community midwives and obstetricians was seen as deficient in 11/12 group A cases (table 21).
- 8.5 Adherence to guidelines was considered poor in 11/12 group A, 6/10 group B cases and 9/11 group C cases (table 23).
- 8.6 Concerns were also raised about the informality of notes written, and lack of adequate documentation and use of partograms.
- 8.7 In all group A cases (12/12) the panels judged that aspects of care contributed to poor outcome.

9 Critique of results

- 9.1 The results list demonstrates that the focus of the enquiry was exclusively on risks and risk management issues. There is no information on the midwife-woman relationship or women's views about their preferences and their care and the support provided. There is a little information about the provision of information. All of these aspects of care are a well established part of woman-centred family-oriented care. The narrow focus seems to disregard the principle of a holistic approach.
- 9.2 The results section of the report is thin, consisting mainly of information presented in table format. However, the structure varies; there is no text commentary accompanying some tables, yet other tables are followed by critical commentary about the data presented, sometimes with additional information. There is limited signposting, no description of an entire process, nor clear development of an argument.
- 9.3 Table 7 refers to 'new risk factors overlooked' but does not describe what these risk factors were. It is not therefore apparent whether they were major or moderate risk factors, nor whether their clinical significance was clear cut or open to clinical judgement.
- 9.4 It is not clear how the panels knew about the risk factors (table 7) if they were not documented in the case notes. This is not explained.
- 9.5 Neither is it clear whether the panellists believed that the midwives who had 'overlooked' risk factors (table 7), either at booking or later on, were unaware of the existence of risk factors, unaware of their clinical significance, might take a different view on their severity, or might be taking account of the factor but had not documented it in the woman's notes. The lack of transparency in the report is problematic.
- 9.6 In places, the text discussing the results and aspects of individual cases does not indicate to which group the cases refer. It is therefore not clear whether the cases refer to the Albany care (group A or group B) or to other community based practices (group C). The commentaries accompanying tables 8 and 19 are examples.
- 9.7 The implied criticism of the care of a woman with a diagnosed breech (obstetric review not sought for some days) does not state the group this cases from, nor the weeks of gestation when the breech was diagnosed. (Was it necessary to seek an obstetric opinion immediately?) The report does not acknowledge that there are different interpretations of the risk associated with vaginal breech birth in the index and subsequent pregnancy.

- 9.8 The report refers to risk factors being 'occasionally overlooked' (page 8) by which the panels meant either 'not recognised or documented as recognised'. It is not clear what evidence the panels used to reach this conclusion; was this evidence from case notes (in which case, would not details have been documented) or from interviews? This should have been made explicit.
- 9.9 There is considerable commentary alongside table 9. The comments made about home birth preference and actual home birth being more common in group A may be subject to bias as the selection of cases to group B (and also to Group C) has not been described. No measure of statistical significance is provided.
- 9.10 There is criticism of midwifery practice in terms of leaving women alone in pain during labour. It is not clear where the information has been taken from. Labour is a painful process and women usually cope at home with support of family members. The implied criticism might reflect prejudice towards a medical model of care. Women's views were interpreted by 'the panel', yet the source of the data on which they draw is unclear and the make up of 'the panel' is not described.
- 9.11 Group A midwives are criticised for writing in a woman's notes that care at home from two (known) midwives might be safer than care in hospital. If the woman was of low obstetric risk at that stage, this might indeed be the case. Details of any risk factors are not noted.
- 9.12 Table 12 lists types of 'complications encountered during labour' but these are not defined or quantified.
- 9.13 The description of the table 20 data is unclear and there is no accompanying commentary.
- 9.14 All of the community midwives were criticised for failing to adhere to DH, RCOG and NICE guidelines. The absence of any reference to RCM, NMC or other midwifery guidelines seems to reinforce a medical model of care perspective having been adopted.
- 9.15 The commentary accompanying table 23 notes that a midwife did not act as a 'woman's advocate' when she declined treatment because she did not persuade her to accept medical help. Whilst there may be issues to address, the report is based on a medical model of care and does not encompass the concepts of women's autonomy and the development of the relationship between woman and midwife – except in a negative way to suggest that midwives have undue influence over the women in their care (page 25).

- 9.16 Midwives were criticised for not giving women more guidance about decision-making: 'the counselling seemed extreme in its non-directional manner', a view which was 'reinforced during the interviews which took place during the enquiry' (p25).
- 9.17 In summary, potential bias and absence of a fully reported, well structured and transparent review process makes the comparative results of the cases reviewed, and the judgement of the panellists, subject to question.

10 CMACE conclusions

- 10.1 The CMACE review raised concerns about home birth practice (including information-provision and lack of guidance, risk assessment and transfer to hospital), about neonatal resuscitation, training, communication, leadership and teamworking. The view of the enquiry panels was that the Albany midwives were not meeting required standards in planned assessment of place of birth. They are advised to follow national guidelines by "actively encouraging" women at risk of poorer outcomes to give birth in hospital.
- 10.2 The quality of monitoring and interpretation (IA and CTG) and of neonatal resuscitation was also questioned by the panels and it was suggested that further education and better teamworking was needed to ensure a higher standard of care.
- 10.3 Conflict and antagonism between hospital staff and the Albany midwives are identified. It was felt that poor relationships between hospital staff and at Kings and the Albany midwives may have affected the way care was delivered to women.
- 10.4 Workload issues were raised. It was noted that the Albany midwives carried a caseload of 1:36 women as the primary midwife, acting as the second midwife to a further 36 women, compared with an average midwifery staffing ratio of 1:28 in the Kings hospital. Despite the continuity of support provided by the midwives, including to women and families transferring to hospital for antenatal, intrapartum or neonatal care, Albany practice was criticised in terms of the 'volume and intensity of work'.
- 10.5 Recommendations included: promotion of better teamworking, good record-keeping, appropriate caseload level/deployment of midwives and shared learning from adverse incidents, clarification of the contract between Albany and Kings, and action to ensure that Albany midwives were familiar with the practices and environment of Kings (where approximately half the women cared of by Albany gave birth).

- 10.6 There was no recommendation from CMACE that the contract with the Albany practice be suspended. There was no suggestion that concern for safety of babies and mothers was at such a level that women booked with Albany midwives should have that service withdrawn.

11 Critique of CMACE conclusions

- 11.1 No meaningful or reliable evidence is presented that the women and babies in the review would have had better outcomes with care in hospital at Kings. There was no rigorous quantitative analysis and individual cases that were reviewed were not matched.
- 11.2 The CMACE Panels concluded that caseload midwifery results in midwives (inevitably) working for prolonged and unbroken periods of time without any data being provided to support the statement. There is acknowledgement but little detailed consideration, from a woman's perspective, of how Albany midwives worked to support and protect their clients, for example when they attended hospital and encountered a different approach to care and advice giving.
- 11.3 There is no acknowledgement that there are both benefits and risks (including risks arising from poor care) in all environments, and that the benefits, risks and side effects are influenced by the prevailing philosophy of care. The strengths of the Albany model were not explored, but the supposed weaknesses were set out in some detail. Neither the strengths nor the weaknesses of hospital-based care, for either low-risk or all-risk women, were the subject of the review, demonstrating a prior assumption that the Albany practice was problematic and the practices of the mainstream services were beyond reproach..

12 NCT Conclusion

- 12.1 There is insufficient evidence presented by the CMACE review to assess the safety of the Albany practice and Kings in terms of both perinatal mortality and serious morbidity. If such evidence exists it should be made available immediately.
- 12.2 We note with concern the apparent breakdown of a trusting and open relationship between Kings hospital staff and the Albany practice. It appears that a clash between cultures and models of care may have adversely affected communication, transfer and referral. This may have had an impact on the quality of care for women and babies, but this cannot be judged in isolation and out of context.