

Scottish Parliament Region: Mid Scotland and Fife

Case 200502691: Forth Valley NHS Board

Summary of Investigation

Category

Health: Hospital; Maternity; Diagnosis and Clinical Treatment; Complaints Handling

Overview

The complainants (Mr C and Ms C) raised a number of concerns that Forth Valley NHS Board (the Board) did not properly diagnose potential complications with the twin babies Ms C was carrying, did not provide proper treatment to Ms C and the twin babies when those complications became critical and did not properly handle Mr C and Ms C's subsequent complaint.

Specific complaints and conclusions

The complaints which have been investigated are that the Board did not:

- (a) provide adequate clinical care to Ms C (*not upheld*); and
- (b) properly handle Mr C and Ms C's complaints (*not upheld*).

Redress and recommendations

The Ombudsman recommends that the Board:

- (i) consider including the recording of the depth of the deepest pool of fluid in each amniotic sac as part of their routine record of ultrasound scans; and
- (ii) provide an apology to Mr C and Ms C for the comments during the meeting of 24 February 2006 which were insensitive in the circumstances.

The Board have accepted the recommendations and will act on them accordingly.

Main Investigation Report

Introduction

1. On 27 March 2006, the complainants, referred to in this report as Mr C and Ms C, complained to the Ombudsman that Forth Valley NHS Board (the Board) had misdiagnosed the chorionicity (see Annex 2) of Ms C's pregnancy, that the care provided to Ms C and their twin babies had not been adequate when critical complications arose and that the Board had not properly handled the complaints that they had made about these matters.

2. The complaints from Mr C and Ms C which I have investigated are that the Board did not:

- (a) provide adequate clinical care to Ms C; and
- (b) properly handle Mr C and Ms C's complaints.

Investigation

3. I have examined the relevant medical records and complaint file from the Board. I have reviewed the copies of correspondence and comments submitted to the Ombudsman's office by Mr C and Ms C, including the correspondence and report of an outside expert who had been engaged to review the case notes of Ms C's care, and have sought the views of a medical adviser to the Ombudsman (the Adviser). I have set out my findings of fact and conclusion. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. Mr C, Ms C and the Board were given an opportunity to comment on a draft of this report.

4. This report necessarily contains a substantial amount of technical language and medical terms. Mr C and Ms C are familiar with these terms and they are explained in Annex 2.

(a) The Board did not provide adequate clinical care to Ms C

5. Ms C became pregnant in early 2005. Her obstetric care was undertaken by the Board. In June 2005 an ultrasound scan confirmed a twin pregnancy but the chorionicity of the pregnancy was not established. In August 2005 a further scan diagnosed the pregnancy as dichorionic diamniotic.

6. On 13 September 2005, Ms C was admitted to hospital because of a cessation of fetal movement. An ultrasound scan showed one baby to have died and the other to have intermittent slowing of her heart rate. A diagnosis of

twin to twin transfusion syndrome (TTTS) was made. This complication is unique to monochorionic pregnancies and it was, therefore, established that the diagnosis of a dichorionic pregnancy had been incorrect. The Consultant attending Ms C performed a scan and noted episodes of bradycardia and a suspected spinal problem in the surviving twin. The Consultant discussed the prognosis with Ms C but, as Mr C was on his way to the hospital, Ms C asked for there to be no more discussion until he arrived. The Consultant asked a midwife to attempt a cardiotography (CTG) trace on the surviving twin. Ms C was moved to the day care area and this trace was attempted. The midwife was unable to obtain a trace and the Consultant attempted a further trace herself. This proved difficult and other assessments, including an ultrasound scan, were made. The Consultant advised Mr C and Ms C of her concerns about the surviving twin. A caesarean section was performed and the twin babies delivered. The surviving twin sadly died 13 days later in the neonatal unit.

7. On 10 November 2005 Mr C and Ms C complained that the Board misdiagnosed the chorionicity of the pregnancy, that the worksheet used by the Board in making such a diagnosis was inappropriate and that pictorial records should have been made of the scan which would allow cross-referencing at a later date.

8. The Board responded to Mr C and Ms C on 20 December 2005. The Board accepted that both the June and August 2005 scans had incorrectly diagnosed the chorionicity of the pregnancy. The Board also explained that they felt the worksheets were appropriate. The Board advised Mr C and Ms C that no picture of the scan view used to determine the chorionicity of the pregnancy had been filed in the case notes and that this issue would be discussed and considered as part of a regular review of services. The Board offered their apologies for the distress caused by the misdiagnosis of chorionicity.

9. Mr C and Ms C subsequently asked the Board if a pictorial record of the scans should have been filed with the case notes and requested a meeting with some of the Board's senior staff to further discuss their complaint. A meeting was held with Mr C on 24 February 2006. The Board explained that still images of scans were not particularly useful for subsequent referral as the scan was a dynamic image. The Board's view was that the most important aspect was the recording of the findings of the scan, and that this had been done for all of

Ms C's scans. The Board explained that the sonographers had believed the scans showed no cause for concern and, therefore, no pictorial record had been kept. The Board confirmed that they had no policy of retaining pictorial records of scans. The Board explained that the misdiagnosis of chorionicity had been reached with reference to the scan and other measurements made at the time. The Board's apologies for the misdiagnosis were reiterated to Mr C.

10. The Board suggested that an independent review of the case notes be undertaken and a consultant from another Health Board (the Outside Consultant) was engaged to undertake this. In his report the Outside Consultant concluded that it was disappointing that the correct chorionicity had not been diagnosed but that he did not believe the misdiagnosis contributed to the eventual outcome as no ultrasound signs of TTTS were detected at the August scan.

11. I sought the opinion of the Adviser on this aspect of Mr C and Ms C's complaint. He advised me that the actions undertaken by the Board at the June scan were unsatisfactory, in his opinion, because they did not correctly diagnose the pregnancy as monochorionic. Had the correct diagnosis been made it would have been likely that Ms C would have been offered enhanced scanning during the mid-point of her pregnancy (between 16 and 22 weeks). However, he agreed with the Outside Consultant that, since the August scan had not shown any signs of TTTS, enhanced scanning would not have influenced the final outcome. The Adviser told me that the subsequent scans were carried out satisfactorily in his opinion, noting that establishing chorionicity becomes more difficult as a pregnancy progresses.

12. The Adviser noted that following Mr C and Ms C's complaint, the Board had reviewed and altered their procedures for performing ultrasound scans and recording their results. The Adviser told me that he was reassured by the altered procedures and that effective steps had been taken to ensure that sonographers were properly advised of the need to record relevant measurements, seek a second opinion on chorionicity if necessary and place a hard copy image of the scan on the case notes. However, he was concerned that the depth of the deepest pool of fluid in each amniotic sac was not routinely recorded.

13. In their complaint of 10 November 2005, Mr C and Ms C questioned why a nuchal translucency test (NT test) had not been carried out. Mr C and Ms C felt

that this should have been undertaken as there had been incidence of spina bifida in Ms C's family and they believed an NT testing was an accepted part of the diagnostic process in such circumstances and would have alerted the Board to the existence of TTTS.

14. In their response of 20 December 2005, the Board told Mr C and Ms C that Quality Improvement Scotland had recommended that NT testing should be introduced nationally by 2007 but that, at that point, the Board were not in a position to offer routine NT testing due to the additional resources that would be required to undertake it. They also explained that the incidence of spina bifida in Ms C's family was not relevant to NT testing being undertaken and stated that NT thickness measurements can be used in the early detection of TTTS when combined with first and/or second trimester serum screening for chromosomal problems, but as they do not routinely undertake such screening they do not offer NT testing in multiple pregnancies as a method of detecting TTTS.

15. In his report, the Outside Consultant stated that 'it is not possible to determine that NT is a definitive test for accurately predicting those monochorionic twins destined to develop TTTS'.

16. I sought the opinion of the Adviser on this aspect of Mr C and Ms C's complaint. He advised me of his opinion that NT testing is not sufficiently sensitive to justify its use as a test for early signs of TTTS.

17. I will deal now with several specific complaints made by Mr C and Ms C. Mr C and Ms C complained that no CTG trace had been successfully carried out on 13 September 2005. The Board told them that CTG traces had been attempted but no interpretable trace had been made due to the position of the babies and that several attempts to undertake an interpretable trace had been made by the midwife and the Consultant.

18. Mr C and Ms C complained that Ms C had been taken to what they believed was a non-clinical area (the Day Care Area) when the midwife attempted a CTG trace. The Board told Mr C and Ms C that the move to the Day Care Area had been made to allow space for the CTG to be attempted. At the subsequent meeting with the Board, they agreed that the use of the Day Care Area had not been ideal and the General Manager for Women and Children at the hospital said that she would look into this issue further.

19. I asked the Board whether this had been done. They advised me that the midwife had been asked why she had taken Ms C to the Day Care Area. The midwife said that she had felt it would be kinder to use the Day Care Area rather than take Ms C to a busy labour ward. However, the Day Care Area had been locked when the midwife attempted to access it and so she moved Ms C into another room while she gained access to the Day Care Area. The exact timeline of events at this point is unclear, and as a result of this, a documentation review group was set up which the midwife joined and made valuable contributions to. The Board also told me that the Day Care Area was a clinical area where CTGs were usually performed.

20. Mr C and Ms C complained that the Consultant had not discussed with them the risks to Ms C of a Caesarean section, although she had made clear the risks to the surviving twin. The Board advised Mr C and Ms C that the Consultant believed she had taken appropriate actions and counselled them appropriately on the risks involved in the Caesarean section.

21. The Outside Consultant concluded that the management of Ms C on 13 September 2005 was 'not substandard'. He did not comment specifically on any of the other issues Mr C and Ms C raised apart from the issue of the advice given on the risks involved in a Caesarean section which he commented was an extremely difficult area to counsel prospective parents about and gave his opinion that it was reasonable to proceed with the Caesarean section in the circumstances.

22. The Board confirmed to me that the Outside Consultant's report had been written and finalised independently of the Board.

23. I sought the opinion of the Adviser on the issues Mr C and Ms C raised about Ms C's care on 13 September 2005. With reference to the CTG tracings he told me that the circumstances would have made the obtaining of a CTG tracing difficult. The Adviser could not comment on what specifically had been said to Mr C and Ms C in relation to the Caesarean section as no notes of this discussion exist. However, he did comment that in the circumstances it would be understandable if detailed discussion of maternal risks had not been undertaken and pointed out that Caesarean sections, though not risk-free, are now rarely associated with major problems.

(a) Conclusion

24. The Adviser described the actions of the Board at the June scan as unsatisfactory because they did not result in a correct diagnosis of the pregnancy as monochorionic. The Outside Consultant described this outcome as 'disappointing'. Both the Adviser and the Outside Consultant agree, however, that a correct diagnosis of chorionicity at any stage would not have altered the eventual outcome. Overall, my conclusion on this point concurs with that of the Outside Consultant. It is also important to note that, following Mr C and Ms C's complaint, the Board reviewed and made alterations to their procedures for performing ultrasound scans and recording their results. The Adviser commented that these steps had addressed the issues he had identified with the Board's actions, with the exception of the routine recording of the depth of the deepest pool of fluid in each amniotic sac.

25. Both the Adviser and the Outside Consultant agree that NT testing is not a reliable, definitive test to determine whether or not monochorionic twins would develop TTTS, and I agree with them. I, therefore, conclude that it is reasonable that the Board did not offer either routine NT testing or specifically recommend it in Ms C's case.

26. It is disappointing that a CTG trace could not be obtained on 13 September 2005, however, both the midwife and the Consultant made attempts to obtain a trace in circumstances which, as the Adviser told me, would have made obtaining a trace very difficult. Given this, I have concluded that this aspect of Ms C's care was satisfactory.

27. After his report on the case had been issued, the Outside Consultant advised Mr C that his view on the standard of care provided to Ms C on 13 September 2005 in regard to the use of the Day Care Area was not accurately reflected in his report. It is not clear why the Outside Consultant did not include this in his report given that he alone had been responsible for its content, nor why he did not, thereafter, clarify his opinion to the Board. For the avoidance of doubt, I have considered that the Outside Consultant's final report as issued to the Board as being his final view, not his subsequent comments. However, the Board gave a reasonable explanation of why Ms C had been taken to the Day Care Area and they had previously reflected on this and reached the conclusion that this had not been an ideal situation. I have concluded that the decision to take Ms C to the Day Care Area was reasonable in the circumstances.

28. In the absence of detailed notes on the discussion the Consultant had with Mr C and Ms C regarding the risks of a Caesarean section, I have not been able to reach a conclusion on this point, but I agree with the Adviser's opinion that in the circumstances it would be understandable if detailed discussion of maternal risks had been afforded less priority than discussion of the second twin's chances of survival.

29. While it was disappointing that the chorionicity of Ms C's pregnancy was not diagnosed correctly, I do not believe the misdiagnosis, though it led to the Board reviewing and altering their procedures, was the result of inadequate clinical care. As noted above, the Board's not undertaking NT tests in Ms C's case was reasonable. Similarly, I believe that the care provided to Ms C on 13 September 2005 was adequate given the circumstances. As I have outlined, it has not been possible for me to reach a conclusion on the issue of the discussions regarding the risks of a Caesarean section. However, given all of the above, I do not uphold the complaint.

(a) Recommendation

30. As noted above, the Board reviewed and altered some of their procedures following Mr C and Ms C's complaint, and I commend them for this. However, the Adviser identified one further procedural alteration that I believe would result in further good practice. Therefore, the Ombudsman recommends that the Board consider including the recording of the depth of the deepest pool of fluid in each amniotic sac as part of their routine record of ultrasound scans.

(b) The Board did not properly handle Mr C and Ms C's complaints

31. Following the sad events of September 2005, a meeting was held on 21 October 2005 between Mr C and Ms C and some of the senior clinical practitioners involved in the case. Mr C and Ms C complained formally in writing to the Board on 10 November 2005. They received a letter from the Patient Relations Officer (Officer 1) on 15 November 2005. This letter clarified the Board's understanding of Mr C and Ms C's complaints, explained how the complaint would be investigated and advised them that a formal response should be received within four weeks. This was followed up by Mr C and Ms C by email and in telephone conversations. Officer 1 advised Mr C that the formal response was likely to be delayed, and it was ultimately sent on 20 December 2005.

32. Mr C contacted Officer 1 on 22 December 2005 and advised that he and Ms C were not satisfied with the formal response. During their discussion a further meeting with senior staff was offered. Mr C and Ms C wrote again to the Board on 6 January 2006 outlining both the issues they felt had not been addressed in the formal response and the issues they had with the formal response itself. Officer 1 acknowledged receipt of this letter on 10 January 2006. Officer 1 sent an email to Ms C on 16 January 2006 advising her that two senior members of staff, the Clinical Chair of the Board (the Clinical Chair) and the General Manager of the hospital (the General Manager), would meet with Mr C and Ms C to discuss their concerns further. However, the Clinical Chair was not available until February. Following consultation with Mr C and Ms C the meeting was arranged for 24 February 2006.

33. Several issues were discussed at the meeting, including the keeping of pictorial records, NT testing, the development of a care management pathway for twin pregnancies, the diagnosis of TTTS, the care and treatment of Ms C on 13 September 2005 and Mr C and Ms C's dissatisfaction with the management of the complaint. The areas where Mr C and Ms C still had issues with the Board were agreed and the Board's apologies for the distress caused were reiterated.

34. Following the meeting it was decided to seek an independent review of the care provided to Ms C, and this was arranged with the Outside Consultant, who was contacted on 20 April 2006 and the Outside Consultant's final report was provided to the Board in late July 2006. In the meantime, the Board reviewed their procedures in the light of Ms C's experience and implemented various procedural alterations. Throughout this process, a dialogue with Mr C and Ms C was maintained to keep them informed of the Board's progress. The Board arranged a meeting with Mr C on 9 August 2006 to share the Outside Consultant's report with him. At the meeting Mr C told the Board that he and Ms C remained dissatisfied with the care that had been given and some of the Board's procedures and that he would continue to pursue his complaint with the Ombudsman.

35. Mr C and Ms C complained that their complaints to the Board had not been adequately handled. They were particularly concerned that during the meeting on 24 February 2006, the Clinical Chair commented that the meeting would not have been required had the second twin survived. Mr C and Ms C also complained that the complaint had not been handled fairly and impartially.

36. I asked the Board for their comments on the appropriateness of the Clinical Chair's remarks at the meeting. The Board advised me that the comment was made in the context that a difficult judgement had been made where there was a high chance of a poor outcome. The Board felt that had the second twin survived, the judgement would not have been questioned in the same way and it was less likely that the couple would have been so unhappy with the care given.

(b) Conclusion

37. The Board dealt well with Mr C and Ms C's complaints in terms of giving prompt, informative and adequate responses to their complaints and enquiries and ensuring that Mr C and Ms C were kept informed of the progress of the Board's actions. As noted in paragraph 30 above, the Board took adequate and meaningful action to address the issues raised by Ms C's experience and Mr C and Ms C's complaint. In terms of fairness and impartiality, the Board's internal investigation was undertaken appropriately in this regard and, in addition to this, the Board engaged the Outside Consultant to review the case. On receipt of the Outside Consultant's report the Board ensured that the actions that were already underway addressed any concerns raised in that report. However, the comments made by the Clinical Chair at the meeting on 24 February 2006 were poorly judged. Regardless of whether or not there was any objective truth to the Clinical Chair's comments, I consider they were insensitive in those circumstances. Nonetheless, having considered the Board's actions overall, I have concluded that their handling of the complaint was commendable and, on balance, I do not uphold the complaint.

(b) Recommendation

38. As noted above, the Board's actions in responding to Mr C and Ms C's complaints were commendable, however, the Ombudsman recommends that the Board provide an apology to Mr C and Ms C for the comments during the meeting of 24 February 2006 which were insensitive in the circumstances.

39. The Board have accepted the recommendations and will act on them accordingly. The Ombudsman asks that the Board notify her when the recommendations have been implemented.

Explanation of abbreviations used

Mr C and Ms C	The complainants
The Board	Forth Valley NHS Board
The Adviser	The medical adviser to the Ombudsman
TTTS	Twin to twin transfusion syndrome
The Consultant	The Consultant attending Ms C on 13 September 2005
CTG	Cardiotography
The Outside Consultant	An expert consultant from outside the Board's area
The Day Care Area	A non-clinical area
Officer 1	The Patient Relations Officer of the Board
The Clinical Chair	The Clinical Chair of the Board
The General Manager	The General Manager of the hospital where Ms C had been cared for
NT test/testing	Nuchal translucency test/testing

Glossary of terms

Amniotic Sac	The inner pair of membranes that hold a developing foetus
Bradycardia	A heartbeat too slow for the subject's medical condition
Caesarean section	A form of childbirth where the baby is delivered via a surgical incision through the uterus
Cardiotography (CTG)	A means of recording the fetal heartbeat
Chorion/Chorionicity	The outer pair of membranes that hold a developing foetus
Diamniotic	Diamniotic twins develop in two separate amniotic sacs
Dichorionic	Dichorionic twins develop in two separate chorions
Monochorionic	Monochorionic twins develop in a single chorion
Nuchal Translucency	Nuchal translucency can be tested for abnormalities in the foetus
Quality Improvement Scotland	A special Health Board responsible for improving patient care across NHS Scotland
Sonographer	Medical staff who operate ultrasonic imaging devices
Spina bifida	A developmental birth defect resulting in an incompletely formed spinal cord