Scottish Parliament Region: Highlands and Islands

Case 201102612: Highland NHS Board

Summary of Investigation

Category

Health: Hospital; Maternity ward; clinical treatment

Overview

The complainants (Mr and Mrs C) lost their son (Baby A) following his premature birth on 5 January 2011. Their complaint concerns the care and treatment provided at Caithness General Hospital, Wick (Hospital 1) and Raigmore Hospital, Inverness (Hospital 2) during and after Mrs C's pregnancy. Mr and Mrs C believe that they received a poor standard of care from both Hospital 1 and Hospital 2 and said that the loss of Baby A has had a devastating effect on their lives.

Specific complaints and conclusions

The complaints which have been investigated are that Highland NHS Board (the Board):

(a) unreasonably failed to follow Royal College of Obstetricians and Gynaecologists (RCOG) Guidelines when carrying out Mrs C's amniocentesis procedure (*upheld*);

(b) inappropriately carried out the amniocentesis procedure in Hospital 1, despite an earlier NHS Quality Improvement Scotland audit report suggesting this should not happen (*not upheld*);

(c) unreasonably failed to inform Mr and Mrs C that Baby A had an abdominal wall defect which was detected at the time of the amniocentesis procedure (*upheld*);

(d) unreasonably failed to inform Mr and Mrs C that Baby A was born with a beating heart and Mr and Mrs C were not given the opportunity to hold him (*upheld*);

(e) inappropriately placed Baby A in what looked like a cardboard box (*not upheld*); and

(f) unreasonably failed to arrange a consultant review to determine what went wrong and what implications this could have for a future pregnancy (*upheld*).

Redress and recommendations

The Ombudsman recommends that the Board:		*Completion date*
(i)	ensure that each operator at Hospital 2 is compliant with the RCOG Green Top Guideline No 8 on amniocentesis;	20 February 2013
(ii)	review the amniocentesis consent form and patient information sheet used at Hospital 2, so as to take account of the five good practice points referred to in paragraph 17;	20 February 2013
(iii)	issue Mr and Mrs C with a full and sincere apology for the failings identified in Complaint (a);	19 December 2012
(iv)	review the local guidance at Hospital 1 and Hospital 2 concerning suspected fetal abnormalities discovered on any obstetric ultrasound scan. Where an abnormality is suspected there should be a clear pathway for specialised fetal medicine assessment and no delay in referral of the patient to a specialised hospital department;	20 February 2013
(v)	issue Mr and Mrs C with a full and sincere apology for the failings identified in Complaint (c);	19 December 2012
(vi)	provide evidence of the review of the guidelines for staff referred to in the letter from Doctor 3 to Mr and Mrs C dated 21 April 2011;	20 February 2013
(vii)	reflect on the Adviser's comments about examination options after a stillbirth/late miscarriage where the baby has a structural abnormality; and	20 February 2013
(viii)	review Hospital 2's post mortem patient information sheet and consent form, so as to include the four examination options listed in paragraph 74.	20 February 2013

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

Main Investigation Report

Introduction

1. Mrs C became pregnant with her second pregnancy. In November 2010, she underwent a test for the possibility of Trisomy 21 (Down's Syndrome). The test results indicated a heightened risk of Down's Syndrome. Therefore, in December 2010 Mrs C underwent an amniocentesis, a prenatal diagnostic procedure which can assess whether the unborn baby could develop, or has developed, an abnormality or serious health condition. The procedure involves a needle being used to extract a sample of amniotic fluid, the fluid that surrounds the developing baby in the womb.

2. The amniocentesis was performed on 7 December 2010 when Mrs C was 18 weeks pregnant. The procedure was carried out by Doctor 1, an obstetrician at Caithness General Hospital, Wick (Hospital 1), who made three needle insertions in order to extract a sample of amniotic fluid. At the time of the amniocentesis Baby A was found to have an abdominal wall defect but Mr and Mrs C were not informed of this at the time.

3. On 20 December 2010 Mrs C's waters broke. She contacted Hospital 1 and was advised to go to her local health centre, where she was examined and sent home. On 21 December 2010 Mrs C started bleeding and contacted Hospital 1, where she was advised to wait at home due to adverse weather. On 22 December 2010 she attended Hospital 1, where she and Mr C were then informed that Baby A had an abdominal wall defect. The following day she suffered severe pains and was taken by ambulance to Hospital 1, where she was advised that she was likely to miscarry.

4. Mrs C was subsequently transferred to Raigmore Hospital, Inverness (Hospital 2) where she went into labour at 22+ weeks and delivered Baby A prematurely on 5 January 2011. Sadly Baby A did not survive.

5. Mr and Mrs C complained to Highland NHS Board (the Board) about the amniocentesis procedure, raising concerns that Doctor 1 had failed to follow Royal College of Obstetricians and Gynaecologists (RCOG) Guidelines. They also questioned why the amniocentesis was carried out in Hospital 1, despite an earlier NHS Quality Improvement Scotland (QIS) report suggesting this was not appropriate. The amniocentesis identified that Baby A had an abdominal wall

defect but this was not communicated to Mr and Mrs C at the time the procedure was performed.

6. Mr and Mrs C also raised concerns surrounding the birth of Baby A, including the fact that they were not informed that he had been born with a beating heart and they had not been offered the opportunity to hold him. They were also distressed that he was placed in what looked like a cardboard box. Mr and Mrs C also complained that, following Baby A's birth, a subsequent consultant review was not arranged to determine what went wrong and what implications it could have on future pregnancies.

7. Mr and Mrs C were dissatisfied with the Board's response to their complaint and complained to this office.

8. The complaints from Mr and Mrs C which I have investigated are that the Board:

(a) unreasonably failed to follow RCOG Guidelines when carrying out Mrs C's amniocentesis procedure;
(b) inappropriately carried out the amniocentesis procedure in Hospital 1, despite an earlier QIS audit report suggesting this should not happen;
(c) unreasonably failed to inform Mr and Mrs C that Baby A had an abdominal wall defect which was detected at the time of the amniocentesis procedure;
(d) unreasonably failed to inform Mr and Mrs C that Baby A was born with a beating heart and Mr and Mrs C were not given the opportunity to hold him;
(e) inappropriately placed Baby A in what looked like a cardboard box; and
(f) unreasonably failed to arrange a consultant review to determine what went wrong and what implications this could have for a future pregnancy.

Investigation

9. The investigation involved obtaining and reviewing all of the information received from Mr and Mrs C and the Board, including copies of the relevant medical records and policies and guidelines. My complaints reviewer also met with Mr and Mrs C. Clinical advice was also obtained by my complaints reviewer from an experienced Consultant Obstetrician (the Adviser) and this too has been taken into account.

10. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. An explanation of the abbreviations used in this report is contained in Annex 1. A glossary of terms used in this report is contained in Annex 2. Mr and Mrs C and the Board were given an opportunity to comment on a draft of this report.

(a) The Board unreasonably failed to follow RCOG Guidelines when carrying out Mrs C's amniocentesis procedure

11. Mr and Mrs C raised concerns that Doctor 1, who carried out the amniocentesis on Mrs C, had failed to follow RCOG Green-top Guideline No 8 on Amniocentesis and Chorionic Villus Sampling. The RCOG Guideline states that its aim is to set a series of evidence-based standards to ensure a high level and consistency of practice in the provision and performance of amniocentesis and chorionic villus sampling.

12. Mrs C's amniocentesis was originally scheduled to be performed on 1 December 2010 but was deferred until 7 December 2010 because of bad weather. Mrs C was 18 weeks pregnant when the amniocentesis was performed by Doctor 1, who made three needle insertions in order to extract a sample of amniotic fluid. In the course of the amniocentesis, Baby A was found to have an abdominal wall defect (thought to be an exomophalos) but Mr and Mrs C were not informed of this at the time.

13. In their response dated 22 September 2011 to Mr and Mrs C, the Board said that Doctor 1, who is a member of the RCOG, had followed the RCOG Guideline, which was not obligatory to follow, in as much as he could. However, the Board had in place their own protocols, which were obligatory. The Board stated that any deviations from these protocols were questioned and had to be explained. The Board said that Doctor 1 had followed these protocols thoroughly and had carried out the amniocentesis procedure correctly.

14. I sought clarification about the protocols referred to in paragraph 13 and received a statement from Doctor 1 who said that the comment made was a general one about RCOG Guidelines. He added 'we do not have a protocol for the Amniocentesis to follow in the NHS Highland; otherwise I would have followed it'.

Clinical advice

15. The Adviser first considered whether consent had been properly obtained from Mrs C in relation to the amniocentesis. The Adviser noted that Mrs C was in her second pregnancy; she had a previous successful pregnancy resulting in the birth of her daughter. Mrs C had consented for a quadruple screening test for Trisomy 21 (Down's Syndrome). This is a commonly used screening test involving the drawing of maternal blood and the analysis of four pregnancy related hormones, in addition to information such as maternal age, which produces a risk for Down's Syndrome. Mrs C screened positive, with a risk of 1:32.

16. The Adviser noted from Mrs C's medical records that on 25 November 2010 she saw Doctor 2 at Hospital 1, when the result of the screening test was explained to her. She was offered an amniocentesis and the risks and complications of the procedure were discussed with her and she accepted. Mrs C had also signed a consent form which stated 'Amniocentesis because of high risk for Downs'. The Adviser was provided with a copy of this. While the Adviser concluded that written consent for the amniocentesis was obtained from Mrs C, he told my complaints reviewer there was no documentation which told him exactly what was discussed with Mrs C during this consultation. There was also no mention in the consent form that a written information leaflet about amniocentesis was given to Mrs C.

17. The Adviser also told my complaints reviewer that he considered it to be good practice to include on a consent form for amniocentesis the following: a) the reason to do the amniocentesis; b) the miscarriage risk (commonly quoted at between 0.5 and 1 percent); c) the risk of a failed procedure (commonly quoted at less than 1 percent); d) the risk of a failed analysis (whereby no result is obtained, commonly quoted at less than 1 percent); and e) where a result is difficult to interpret (commonly quoted at less than 1 percent).

18. The Adviser also explained that although women are commonly consenting for exclusion of Down's Syndrome they need to understand that if a full karyotope is being performed, which occurred in Mrs C's case, there is a possibility that it could detect a different problem and this may require further investigation and or referral to other specialists. The Adviser reviewed the patient information sheet on amniocentesis which Hospital 1 provided to patients and noted that, while the sheet covered points a), b), d) and e) above, it did not cover point c).

19. The Adviser also provided advice on the amniocentesis performed on Mrs C. The Adviser noted that Doctor 1 had made three needle insertions whilst performing the amniocentesis. According to the Adviser, the RCOG Guideline clearly states that if there is a failure after two needle insertion attempts to obtain amniotic fluid, then referral to another more experienced doctor should be made (see Annex 3). In Mrs C's case, the Adviser considered that the RCOG Guideline should have been followed by Doctor 1. Therefore, Doctor 1 should have stopped the procedure after the failure of the second needle insertion and made an offer to Mrs C to refer her to a more experienced operator. This would have meant referral to Hospital 2. The Adviser informed my complaints reviewer that only if Mrs C had refused to travel and requested continuation of the procedure should Doctor 1 have continued with the third needle insertion. If this is what happened then Doctor 1 should have documented this in Mrs C medical records. However, the Adviser could find no record of such a discussion within Mrs C's medical records, although he considered that implied (verbal) consent was obtained from her. I have seen from a statement made by Mrs C she said that Doctor 1 did not ask her permission for a third attempt to be made.

20. The Adviser explained that the amniocentesis should have been a very straightforward and easy procedure for the following reasons: a) the amniocentesis was performed at 18+ weeks and generally the more advanced gestational age the easier amniocentesis is because there is more fluid and a larger amniotic fluid cavity (18 weeks being quite an advanced gestational age for amniocentesis as most amniocentesis will be performed around 16 weeks); b) the placenta was on the posterior wall, meaning there would be no risk of hitting it, making a large 'window' for safe needle insertion; and c) Mrs C's body mass index (BMI) was documented at 26, which the Adviser did not consider would have caused a problem.

21. The Adviser noted there was a completed amniocentesis procedure form in Mrs C's medical records. It stated that a 22-gauge needle was used; that real time ultrasound was used throughout the procedure; that asepsis was performed; and that three insertions were commenced, with clear amniotic fluid obtained. The Adviser has stated that the use of real time ultrasound and a 22-gauge needle was compliant with good practice and the RCOG Guideline, although he was unable to assess from Mrs C's medical records and the other information supplied by the Board if asepsis included sterile gloves, sterile gel

and sterile probe cover. The use of a surgical cleaning fluid, sterile gloves, sterile gel and ultrasound probe within a sterile bag would be considered to fulfil the definition of asepsis. There was also no note in Mrs C's medical records about the amount of fluid withdrawn, which has been routine practice to document in fetal medicine units the Adviser has worked in.

22. The Adviser considered it disappointing that it was unclear and not documented in Mrs C's medical records why the amniocentesis procedure was difficult. Following Mr and Mrs C's complaint, Doctor 1 had provided further information. From this, it appeared that with the first needle insertion a spot was selected for the amniocentesis whereby the needle was not long enough to reach the amniotic cavity. With the second insertion, the membranes were tented and so the needle could not be advanced through the amniotic fluid. However, the Adviser did not understand why the 22-gauge needle was not long enough. He explained that a longer needle may be necessary with women who have a high BMI but Mrs C's BMI was only 26. Therefore, he would have expected a standard 22-gauge needle to be long enough to perform an amniocentesis. Tenting of the membrane is also uncommon. The Adviser expressed his concern that this reflected Doctor 1's lack of experience in performing the amniocentesis.

23. While the Adviser could see no evidence that the third insertion was performed incorrectly, the first and second needle insertions concerned him, particularly the tenting with the second needle, which might have stripped the amniotic membrane from the uterine wall. The Adviser has, however, commented that it was reassuring that there was no bloody tap (where blood is found in the amniotic fluid) with the third needle insertion.

24. Accordingly, the Adviser stated his conclusion that 'because it took 3 attempts to get a [amniotic fluid] sample in a woman who appears to have characteristics favouring successful amniocentesis that the operator had inadequate experience in this procedure'.

25. The Adviser was asked by my complaints reviewer to comment on whether he considered there was any evidence that the amniocentesis contributed in any way to the subsequent complications which resulted in Baby A's premature delivery and death.

26. The Adviser stated that following the rupture of the membranes around Baby A between 19 and 25 December 2010, the histological examination of the placenta suggested an infection of the placenta and umbilical cord, therefore, suggesting the primary cause of Baby A's death was chorioamnionitis, an inflammation of the fetal membranes due to a bacterial infection. This, the Adviser explained, was presumed to have been caused by an ascending infection from the vagina into the uterine cavity once the protective membranes around Baby A had ruptured. Coliform organisms (bacteria commonly found in the maternal lower gut) were isolated and may have been the causative organisms.

27. The Adviser, therefore, concluded that he could not refute or confirm and neither did he believe anyone could say whether the amniocentesis contributed to Baby A's premature delivery. He added that the rupture of membranes may have been caused by the amniocentesis and Baby A's death would have to be counted as a procedure related loss in terms of an audit of service. However, it was also possible the rupture of the membranes was unrelated to the amniocentesis.

(a) Conclusion

28. Having taken account of the Adviser's comments, I am concerned about the lack of record-keeping in relation to what exactly was discussed with Mrs C during the consultation on 25 November 2010 with Doctor 2 and in the course of the amniocentesis on 7 December 2010 with Doctor 1.

29. Significantly, I am critical of the fact that the Adviser can find no record of a discussion within Mrs C's medical records about what Doctor 1 discussed with Mrs C after the second failed needle attempt when performing the amniocentesis. In the absence of such evidence, this has led me to conclude that Doctor 1 did not make an offer to Mrs C to refer her to another doctor after the second failed needle insertion and, therefore, did not follow the RCOG Guideline.

30. It is also of concern that while the Adviser saw no evidence that the third needle insertion was not performed correctly, he considered it disappointing that it was unclear and not documented in Mrs C's records why the amniocentesis procedure was difficult given that, for the reasons set out in paragraph 19, it should have been a straightforward and easy procedure. In addition, the Adviser has observed there is no record in Mrs C's medical notes of what

occurred during the amniocentesis in relation to the performance of asepsis and about the amount of amniotic fluid that was withdrawn, which the Adviser has told my complaints reviewer is routine practice to document in fetal medicine units where he has worked.

31. Furthermore, the Adviser can find no evidence that a patient information sheet on amniocentesis was given to Mrs C. I have also taken account of the Adviser's comments that the patient information leaflet on amniocentesis provided by the Board (while covering the good practice points a), b), d), and e) listed at paragraph 17), did not cover point (c) concerning a 'failed procedure'.

32. It has become evident in this investigation that no protocols exist (see paragraph 14). Mr and Mrs C could construe that the comments in the letter to them dated 22 September 2011 from the Chief Executive were misleading (see paragraph 13).

33. For all these reasons and having carefully considered the advice I have received from the Adviser on this complaint, which I accept, I am satisfied there was a failure by the Board to follow the RCOG Guideline when carrying out Mrs C's amniocentesis procedure. Therefore, I uphold the complaint.

(a) Recommendations

34. I recommend that the Board:	*Completion date*
(i) ensure that each operator at Hospital 2 is compliant with the RCOG Green Top Guideline No 8 on amniocentesis;	20 February 2013
(ii) review the amniocentesis consent form and patient information sheet used at Hospital 2, so as to take account of the five good practice points referred to in paragraph 17; and	20 February 2013
(iii) issue Mr and Mrs C with a full and sincere apology for the failings identified in Complaint (a).	19 December 2012

(b) The Board inappropriately carried out the amniocentesis procedure in Hospital 1, despite an earlier QIS audit report suggesting this should not happen

35. Mr and Mrs C were concerned to learn that the amniocentesis was carried out in Hospital 1, despite an earlier QIS audit report (the Audit Report) advising that such procedures should stop taking place at Hospital 1. They felt that as the Audit Report was published in November 2010 there had been enough time to implement its findings. Therefore, amniocentesis services at Hospital 1 should have been stopped before Mrs C underwent the procedure there in December 2010.

36. In response, the Board stated that amniocentesis is no longer being performed at Hospital 1. The reason for this was a response by the Board to recommendations from the Audit Report. After a review process through the Board's Maternity Services Strategy and Co-ordination Group (the Strategy and Co-ordination Group), which was chaired by the Director of Nursing who is the Board's lead executive for maternity care and whose other members include the Medical Director and senior clinicians involved in the delivery of maternity care, amniocentesis was discontinued at Hospital 1.

37. Discussions around the RCOG Guideline were already under way before the Audit Report was published. When the Audit Report was published this was also included in subsequent deliberations. Time was needed to 'grasp' the recommendations and discuss its implementation. A one month period following the release of the Audit Report was too short a time to enable comprehensive discussion and a structured implementation of the changes. In November 2010, it was noted that a robust system was in place to record procedures/outcomes. However, only two out of six consultants providing amniocentesis procedures were formally trained to the level stipulated in the RCOG Guideline. The Board had to balance the risk of this against the practicality of delivering this time sensitive procedure.

38. Following the Audit Report, QIS recommended that health boards should adhere to 30 procedures a year per operator. This required to be discussed within the Board, to consider the impact of the recommendations and the associated risks. It was agreed this would be further discussed in February 2011 at a meeting of the Strategy and Co-ordination Group. In February 2011, it was decided to discontinue the amniocentesis service at Hospital 1 and consider whether two or three operators based at Hospital 2

would be required to meet the service needs for Highland. A formal proposal was prepared and brought back to the next Strategy and Co-ordination Group meeting in May 2011. In the meantime, it was decided that all women requesting amniocentesis would be referred to Hospital 2, where the service would be provided by three operators.

39. In May 2011, a paper prepared on the rationalisation of the Board's amniocentesis service was discussed by the Strategy and Co-ordination Group. It was noted that the issue associated with variation in procedural technique was readily corrected. However, the issue of operator experience as reflected in the number of procedures undertaken annually was more challenging to address. It was noted the RCOG recommendation of 30 procedures per year to maintain operator competence was an increase of the previous requirement of ten procedures annually. It was noted that the number of 30 was arbitrary and not evidence based. It also stated that operators performing less than this number should ensure that they had audit processes in place to provide evidence of safety. It was projected that around 90 amniocentesis procedures were being undertaken and if three operators continued to perform the procedures the number required would be maintained. However, as the number of procedures was expected to reduce this could go down to two operators. It was agreed to reduce to three operators and to review after a year. Changes were implemented in February 2011 and amniocentesis was now performed at Hospital 2 under the care of three consultants.

Clinical advice

40. The Adviser has told my complaints reviewer that in his view the Board were attempting to balance patient risk against service provision in a very rural area. In his opinion, as a consultant obstetrician, a time frame of three months to consider the Audit Report and produce an action plan seemed reasonable. He supported the Board's response on this complaint and would not have expected the Board to have immediately stopped all amniocentesis at Hospital 1 following the issue of the Audit Report.

41. The Adviser noted that the Board made the decision that amniocentesis should no longer be performed at Hospital 1. Patients requiring amniocentesis now have this procedure carried out at Hospital 2 in order to limit the number of operators performing this procedure.

(b) Conclusion

42. The advice I have received from the Adviser is that, in his professional opinion, the Board could not have reasonably been expected to immediately stop all amniocentesis procedures at Hospital 1 by December 2010. I accept this advice. Therefore, I do not uphold the complaint.

(c) The Board unreasonably failed to inform Mr and Mrs C that Baby A had an abdominal wall defect which was detected at the time of the amniocentesis procedure

43. Mr and Mrs C complained that, at the time Mrs C had the amniocentesis procedure, they were not told that this had shown Baby A had an abdominal wall defect. They were only told over two weeks later.

44. In response to the complaint, the Board stated that the purpose of an amniocentesis was to obtain a sample of amniotic fluid. The technique involved used ultrasound scanning to assist the doctor in directing the sampling needle. The purpose of the ultrasound in the amniocentesis was not to gain a detailed scan of the baby.

45. At the end of the amniocentesis, the radiographer advised Doctor 1 that she thought she had seen an abdominal wall defect which might be an omphalocele, which are commonly associated with chromosomal abnormalities and other anatomical abnormalities such as cardiac defects and gastrointestinal anomalies. It was felt this could be confirmed during the 20 week anomaly scan when Baby A had grown more and defects could be seen more easily, as well as the result of the amniocentesis being available. This was not discussed at the time with Mr and Mrs C on the basis that the amniocentesis was the priority. The Board have acknowledged that this should have been discussed with Mr and Mrs C at the time and have apologised to them that this did not happen.

Clinical advice

46. The Adviser told my complaints reviewer that the detection of an abdominal wall defect in the fetus is a significant abnormality. There are two types: an exomphalos, (also known as omphalocele). This was the condition that the ultrasonographer detected at the time of the amniocentesis when Mrs C was 18 weeks and one day pregnant. It is a serious condition. It consists of a herniation of the fetal bowel (and can include other intestines such as the liver) into the umbilical cord. It can be associated with chromosomal abnormalities which are fatal, such as Edward syndrome and Patau syndrome. Exomphalos

can also be associated with other structural abnormalities, particularly cardiac abnormalities. The prognosis/survival of a baby with this condition is mainly dependent on whether the fetus has other abnormalities (either chromosomal or structural) or whether it is an isolated condition. If it is an isolated condition the prognosis is generally much more favourable, although large exomphalos can be difficult to treat after birth. The other type is gastroschisis - this is a less serious condition than exomphalos and is not associated with chromosomal and other structural problems.

47. The Adviser disagreed with the Board that it was appropriate to wait until the 20 week scan before informing Mr and Mrs C about the abdominal wall defect. The Adviser explained to my complaints reviewer that a fetal anomaly scan can be performed between 18+0 to 20+6 weeks. In the Adviser's view, a full anatomy scan should have been performed at the 18+1 week amniocentesis if an exomphalos was suspected. Mr and Mrs C should have been informed of the findings and should have been offered referral to a fetal medicine unit (for example, in Glasgow or Aberdeen) for further assessment, including cardiac echocardiography that produces an image of the heart. If Mr and Mrs C had accepted referral to a fetal medicine unit then the Adviser would have expected the fetal medicine unit to have seen them within five working days, which would have allowed time for the initial results of the amniocentesis to be available.

48. The Adviser therefore, considered that Mr and Mrs C received substandard care with regard to the management of the suspected abdominal wall defect in Baby A.

(c) Conclusion

49. The clinical advice I have received is that an abdominal wall defect in the fetus is both a significant abnormality and a serious condition. Therefore, a full anatomy scan should have been performed at the amniocentesis if an exomphalos had been suspected. Furthermore, it is of serious concern and I am critical of the Board that Mr and Mrs C were not informed, as they should have been, of the finding at the time the amniocentesis was performed, in order that they could have been offered an immediate referral to a specialised fetal medicine unit.

50. The Adviser has been unequivocal in his advice to me that the care which Mr and Mrs C received with regard to the management of the suspected abdominal wall defect in Baby A was substandard. Therefore, I have concluded

that the Board did unreasonably fail to inform Mr and Mrs C of an abdominal wall defect in Baby A which was detected at the time of the amniocentesis procedure. Accordingly, I uphold the complaint.

(c) Recommendations

51.	I recommend that the Board:	*Completion date*
(i)	review the local guidance at Hospital 1 and Hospital 2 concerning suspected fetal abnormalities discovered on any obstetric ultrasound scan. Where an abnormality is suspected there should be a clear pathway for specialised fetal medicine assessment and no delay in referral of the patient to a specialised hospital department; and	20 February 2013
(ii)	issue Mr and Mrs C with a full and sincere apology for the failings identified in Complaint (c).	19 December 2012

(d) The Board unreasonably failed to inform Mr and Mrs C that Baby A was born with a beating heart and Mr and Mrs C were not given the opportunity to hold him

52. Mr and Mrs C complained that Baby A was born with a beating heart but they only discovered this on reading Mrs C's medical notes at a later date. They complained that they had not been told prior to Baby A's birth that this might happen. Mrs C says that as a mother she will never get over the fact that Baby A was born alive, that they were not given the opportunity to hold him and that he was not given the chance to die in their arms.

53. In response, the Board acknowledged the distress that Mr and Mrs C would have experienced on discovering that Baby A had a beating heart on delivery, when they read the medical notes. They stated that if there is a known possibility of a baby being born alive this would be explained to the parents. However, on occasions, it may not be known if a baby is going to be born with a beating heart. The Board apologised to Mr and Mrs C for the trauma they had experienced as a result of this. Hospital 2's maternity department was reviewing their policies on miscarriages and stillbirths and it was intended this would form part of ongoing training for all staff groups.

Clinical advice

54. The Adviser noted that there was a retrospective entry made in Mrs C's case records by the midwife who attended the birth of Baby A (the Midwife). It stated that Baby A was delivered at 07:15 with fetal heart beating but seemed to have passed away very quickly, within one minute of his birth. According to the Board, this record was completed and signed by the Midwife. It was also documented in the medical records that an offer was made to Mr and Mrs C to hold Baby A after his birth.

55. The Adviser has told my complaints reviewer that if Baby A had shown signs of life he would have expected the Midwife to have informed Mr and Mrs C and given them the chance to hold Baby A with the expectation that he would gently pass away in their arms. However, the Adviser suspected in this particular case there was simply no time for the Midwife to inform Mr and Mrs C before Baby A's heart stopped beating. Also, the Adviser considered that the Midwife would have been mindful of managing the delivery of the placenta (the afterbirth).

56. At 22 weeks gestation the Adviser would not have expected the neonatal team to have been called or for any attempt at resuscitation of Baby A to have been made. This would be compliant with the 2008 guidance from the British Association of Perinatal Medicine on management of the extreme preterm baby, which does not recommend resuscitation under 23+0 weeks. If Mr and Mrs C did not want to hold Baby A then the Adviser would have expected the Midwife to have placed Baby A in a cot and for a member of staff to stay with Baby A until his heart stopped beating.

57. However, the Adviser was of the view that Mr and Mrs C should have been informed that Baby A had a heartbeat at delivery and should not have read this for the first time when they saw the medical records.

(d) Conclusion

58. The Adviser has found no evidence that the guidance referred to in paragraph 56 was breached and I accept that advice.

59. It is documented in the medical records that an offer was made to Mr and Mrs C to hold Baby A. This is disputed by Mr and Mrs C. Given the conflicting evidence, I am unable to reach a conclusion whether or not such an offer was made to them. However, I have taken account of the advice from the Adviser

that he considers Mr and Mrs C should have been informed that Baby A had a heartbeat at delivery. Given this, I consider that that during the birth of baby A, the Board unreasonably failed to inform Mr and Mrs C that Baby A was born with a beating heart and in doing so, Mr and Mrs C were denied the opportunity to hold Baby A while his heart was beating. For these reasons I uphold this complaint.

60. Understandably Mr and Mrs C, as the Board have conceded, were traumatised when they learned that Baby A had a heartbeat at delivery and they were not told at the time. They are still clearly distressed by the failure to inform them. The Board have already apologised to them for this failing and undertaken a review of their policies on miscarriages and stillbirths. In view of this and the apology made, I have no recommendation to make.

(e) The Board inappropriately placed Baby A in what looked like a cardboard box

61. Mr and Mrs C complained that following Baby A's birth he was placed in what looked like a cardboard box on top of a bed trolley in the delivery room. They did not recall him being wrapped in a blanket, only that just a cover was placed over him. They felt that Baby A had been discarded by medical staff.

62. The Board in response stated they were sorry Mr and Mrs C felt that Baby A had been discarded. As part of the Board's investigation of their complaint, the obstetric notes had been checked and the Midwife who had been involved in Mrs C's care had been interviewed. All babies born in such circumstances are wrapped and placed in a small cot and the Midwife recalled doing this with Baby A. Staff fully acknowledged the distress experienced by parents who lose their baby and, therefore, tried to ensure they were sensitive to the needs of parents.

Clinical advice

63. The Adviser, having reviewed the medical records, noted a statement was obtained from the Midwife in which she stated that Baby A was placed in a cot. The Adviser said that he expected Baby A to be wrapped by the delivering midwife and gently placed in a cot and he can see no evidence that Baby A was inappropriately placed.

(e) Conclusion

64. The Board have already expressed regret that Mr and Mrs C believed that Baby A was inappropriately placed in what looked like a cardboard box. However, the Board have also provided reasons why in their view they consider this had not occurred. On the basis of the conflicting evidence presented to me and uncertainty, I am therefore, unable to conclude satisfactorily what Baby A was placed in, following his birth. Therefore, I do not uphold the complaint.

(e) Recommendations

65. I have no recommendations to make.

(f) The Board unreasonably failed to arrange a consultant review to determine what went wrong and what implications this could have for a future pregnancy

66. Mr and Mrs C raised concerns that Hospital 2 failed to arrange for a consultant to examine Baby A to determine the cause of the abdominal wall defect. They felt this was due to the complete breakdown in communications between clinical staff during the Christmas holiday period. They stated that Mrs C's consultant only met with them on a few occasions as she was on leave and so was not on duty when Mrs C gave birth to Baby A.

67. There was a special baby care unit in Hospital 2 and they felt that there must have been someone available to examine Baby A after his premature birth, specifically the abdominal wall defect. However, this did not happen. This had made them feel that Baby A did not matter.

68. The Board conceded that a doctor should have attended to Baby A to ascertain the complications and to see if there were implications for future pregnancies. This would be considered normal practice. The Board, on behalf of staff, apologised that this did not take place and said that they would endeavour to ensure that such reviews took place consistently in the future.

69. However, two review meetings had taken place in April 2011 attended by obstetricians and midwives, including those involved in the care of Mrs C at both Hospital 1 and Hospital 2 and in the community, at which Mr and Mrs C's case was discussed. Internal reviews were routinely carried out when there was an adverse outcome. The Board stated their purpose was to give clinicians the opportunity to consider if things could have been done differently and to identify lessons to be learned from the care of patients.

Clinical advice

70. The Adviser noted that Mr and Mrs C's concerns were reviewed by Doctor 3 in Hospital 2 on 25 February 2011 to address (i) what had occurred and the implications for the future and (ii) their concerns about care. The Adviser reviewed Doctor 3's letter, dated 3 March 2011, to Mr and Mrs C. He told my complaints reviewer that, in his view, the letter had comprehensively addressed both matters.

71. The Adviser also reviewed Doctor 3's further letter to Mr and Mrs C, dated 21 April 2011, in which she stated that she was disappointed there was not a more detailed examination of Baby A by a senior doctor and that they would review the local guidance. The Adviser could find no documentation in the medical records that such a review had been carried out. This letter also implied to the Adviser that the local arrangement at Hospital 2 was for an obstetrician to review the body of a baby who had been stillborn or as a result of the mother suffering a miscarriage.

72. The Adviser noted that Mr and Mrs C were offered a post mortem but declined. There is a copy of the post mortem consent form within the medical records and a note to say that Mr and Mrs C did not wish a post mortem examination. However, the Adviser was unable to determine from the medical records what was actually discussed with Mr and Mrs C and whether they were offered an external examination by a pathologist. The Adviser has explained to my complaints reviewer that in an external post mortem the pathologist examines the external appearance of the baby, taking medical photographs and then completing a report.

73. The Adviser considered that where a stillbirth or miscarriage occurred the appropriate person to examine the baby is a perinatal pathologist. In the case of Baby A, such a pathologist would have been appropriate so as to try and determine if he had an exomphalos or a gastroschisis. In his view, such a pathologist should have examined Baby A, providing Mr and Mrs C were prepared to consent to this.

74. The Adviser further considered that the post mortem information sheet and consent form used by Hospital 2 could be improved by including the following four examination options after a stillbirth or late miscarriage where the baby has

a structural abnormality: (i) a full post mortem; (ii) a limited post mortem; (iii) an external examination by a pathologist; and (iv) a placental examination.

(f) Conclusion

75. I accept there was no failure by the Board in arranging a consultant review of the concerns raised by Mr and Mrs C. Nevertheless, the Board have conceded there was a failure by a senior doctor to examine Baby A following his birth, to ascertain the complications and the implications for future pregnancies. Therefore, while I acknowledge that the Board have apologised to Mr and Mrs C for this, in view of their admitted failing I uphold this complaint. As there appears to be no evidence with the documents supplied to my office by the Board that a review has been carried out, I have asked the Board to provide this as part of my recommendations.

76. In addition, the Adviser has raised concerns that he was unable to determine from the medical records what was actually discussed with Mr and Mrs C about a post mortem examination of Baby A. In particular, whether they were offered an external examination by a perinatal pathologist, as the Adviser considers they should have been. In my view, it is essential that a proper record of such an important discussion is made, particularly at what is clearly a very distressing time for parents who have just lost a baby. I am critical of the fact that this appears to be yet a further example of a failure to keep a proper record of what was discussed with Mr and Mrs C. I have also noted the comments of the Adviser that the post mortem information sheet and consent form used by Hospital 2 could be improved.

77. Therefore, as part of my recommendation in this complaint, I have asked the Board to reflect on the comments of the Adviser on this complaint and also to review Hospital's 2 post mortem patient information sheet and consent form so as to include the four options listed in paragraph 74.

(f) Recommendations

78. I recommend that the Board	*Completion date*
(i) provide evidence of the review of the guidelines for staff referred to in the letter from Doctor 3 to Mr and Mrs C dated 21 April 2011;	20 February 2013
(ii) reflect on the Adviser's comments about examination options after a stillbirth/late miscarriage	20 February 2013

	where the baby has a structural abnormality; and	
(iii)	review Hospital 2's post mortem patient information sheet and consent form, so as to include the four examination options listed in paragraph 74.	20 February 2013

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

Annex 1

Explanation of abbreviations used

Mr and Mrs C	The complainants
Doctor 1	The doctor who performed the amniocentesis at Hospital 1
Hospital 1	Caithness General Hospital, Wick
Baby A	Mr and Mrs C's son
Hospital 2	Raigmore Hospital, Inverness
The Board	Highland NHS Board
RCOG	Royal College of Obstetricians
QIS	Quality Improvement Scotland
The Adviser	A clinical adviser to the Ombudsman
The RCOG Guideline	Royal College of Obstetricians and Gynaecologists Green-top Guideline No.8 on Amniocentesis and Chorionic Villus Sampling published June 2010
Doctor 2	The doctor who met with Mr and Mrs C at Hospital 1 to discuss the amniocentesis
BMI	Body Mass Index
The Audit Report	QIS Report titled: Amniocentesis and Chorionic Villus Sampling in Scotland. An audit of techniques and outcomes of all procedures over one year in

	Scotland 1 May 2008-30 April 2009
The Strategy and Co-ordination Group	NHS Highland's Maternity Services Strategy and Co-ordination Group
The Midwife	The Midwife who attended the birth of Baby A
Doctor 3	A Consultant in Obstetrics and Gynaecology at Hospital 2 who reviewed the concerns raised by Mr and Mrs C

Annex 2

Glossary of terms

Amniocentesis	A prenatal diagnostic procedure which can assess whether the unborn baby could develop, or has developed, an abnormality or serious health condition
Asepsis	Clinical practices used to prevent infection
Crioamnionitis	An inflammation of the fetal membranes due to a bacterial infection
Exomophalos, also known as omphalocele	A type of abdominal wall defect in which the intestines, liver and occasionally other organs remain outside of the abdomen in a sac because of a defect in the development of the muscles of the abdominal wall
Gastroschisis	A hole in the abdominal wall where the intestines protrude through the abdominal wall
Karyotype	A test to examine chromosomes in a sample of cells, which can help identify genetic problems as the cause of a disorder or disease

Annex 3

List of legislation and policies considered

Royal College of Obstetricians and Gynaecologists Green-top Guidelines No.8 June 2010 - Amniocentesis and Chorionic Villus Sampling

'Section 8
What is required for training and maintaining good practice in amniocentisis or CV's'
Operators carrying out unsupervised amniocentisis and CVs should be trained to the competencies expected of subspeciality training in fetal medicine the RCOG Fetal Medicine Advanced Training Skills Module (ATSM) or other international equivalent.

Clinical skills models, assessment of interaction with patients and supervised procedures should be an integral part of training.

Competency should be maintained by carrying out at least 30 ultrasound guided invasive procedures per annum.

Units and operators should carry out continuous audit of frequencies of multiple insertion, failures, bloody taps and post procedure losses.

Very experienced operators (more than 100 per annum) may have a higher success rate and a lower procedure-related loss rate. Occasional operators who perform a low number of procedures per annum may have increased rates of procedure-related loss.

Further opinion should be sought from a more experienced operator if difficulties are anticipated or encountered and

'… a more experienced operator should be consulted if two attempts at uterine insertion have failed to produce an adequate sample for analysis'.

NHS Quality Improvement Scotland (QIS) Report titled: Amniocentesis and Chorionic Villus Sampling in Scotland: An audit of techniques and outcomes of all procedures over one year in Scotland 1 May 2008 - 30 April 2009