Scottish Parliament Region: Mid Scotland and Fife

Case 200601326: Forth Valley NHS Board

Summary of Investigation

Category

Health: Hospital; Fertility Service; Surgical Procedure; Clinical Care and Treatment; Fertility Treatment

Overview

The complainants, Mr C and Ms A, raised a number of concerns that, following a routine laparoscopy investigation for an infertility problem at Stirling Royal Infirmary (the Hospital) on 9 August 2005, Ms A was admitted as an emergency patient to the Hospital on 12 August 2005 and received inadequate care and treatment. Thereafter, Mr C and Ms A also complained that Forth Valley NHS Board (the Board) had not treated Mr C and Ms A either appropriately or fairly as patients of their Infertility Service (the Service).

Specific complaints and conclusions

The complaints which have been investigated are that:

(a) Ms A received inadequate care and treatment from the Hospital (*not upheld*); and

(b) the Board's infertility service made matters worse (*not upheld*).

Redress and recommendations

The Ombudsman has no recommendations to make.

Main Investigation Report

Introduction

1. The Ombudsman received a complaint from Mr C and Ms A, who stated that Ms A underwent a routine diagnostic laparoscopic examination at Stirling Royal Infirmary (the Hospital) on 9 August 2005 and was discharged home on the same day. However, she failed to recover, became unwell and had to be admitted back to the Hospital as an emergency patient on 12 August 2005. Thereafter, on 15 August 2005, Ms A underwent a laparotomy. Mr C and Ms A alleged that the laparoscopy investigation on 9 August 2005 went seriously wrong and complained about the subsequent care and treatment Ms A received at the Hospital, following her laparoscopic examination and events between 12 and 15 August 2005 which led up to the laparotomy. During the laparotomy Ms A had her left ovary and tube removed. Mr C and Ms A also complained that the Infertility Service (the Service) of Forth Valley NHS Board (the Board) made matters worse following Ms A's emergency admission to the Hospital, by the way they dealt with their complaint against the Hospital. They stated that, in their view, the Board had abandoned them with a worsened infertility problem than before they saw a Consultant (the Consultant) on 9 August 2005. Furthermore, Mr C and Ms A felt that the Board should not have refused them financial assistance towards subsequent fertility treatment, given that following Ms A's laparotomy on 15 August 2005 and subsequent medical problems, they had to attempt IVF with Ms A having only one ovary remaining and a reduction in available egg reserve. This was in addition to the infertility problems they had previously sought help with. Furthermore, in Mr C and Ms A's view, this may have rendered any existing low chance of natural conception as virtually nil.

2. The complaints from Mr C and Ms A which I have investigated are that:

(a) Ms A received inadequate care and treatment from the Hospital; and

(b) the Board’s infertility service made matters worse.

Investigation

3. The investigation of this complaint involved obtaining and reading all the relevant documentation, including correspondence between Mr C and Ms A and the Board. I have had sight of the Board's complaint file and Ms A's medical records. Advice was also obtained from the Ombudsman's medical adviser in obstetrics and gynaecology (Adviser 1), who reviewed all relevant documentation and medical records. I also met with the outgoing Ombudsman's medical adviser in gynaecology (Adviser 2) to discuss the case,

when he visited the office prior to his retirement. In addition, I reviewed the guidelines on diagnostic laparoscopy.

4. 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 the medical terms used in the report can be found at Annex 2. Mr C, Ms A and the Board were given an opportunity to comment on a draft of this report.

(a) Ms A received inadequate care and treatment from the Hospital

5. According to Mr C and Ms A, serious consequences resulted from the diagnostic laparoscopy Ms A underwent at the Hospital on 9 August 2005 for infertility issues. After she had undergone the diagnostic laparoscopy, Ms A was allowed home on that day, however she became unwell. Ms A was readmitted to the Hospital on Friday 12 August 2005 and underwent a laparotomy for a pelvic abscess on Monday 15 August 2005. As a consequence of this surgical procedure, her left tube and ovary were removed. As Ms A had lost an ovary, according to Mr C and Ms A, their chances of subsequent in vitro fertilisation (IVF) fertility treatment succeeding were significantly lowered. Furthermore, they stated that following Ms A's post-laparoscopy readmission to the Hospital, delays in carrying out appropriate investigations for three days (from Friday 12 to Monday 15 August 2005) caused Ms A prolonged suffering and ovary damage.

6. In addition, Mr C and Ms A said that when further surgery was carried out, due to a misdiagnosis of suspected bowel injury instead of tubal/ovary injury, this resulted in a much greater abdominal surgical incision than may have been necessary. As a result, they stated that 'we have both suffered ill health since the laparoscopy and suffered a subsequent miscarriage'. Mr C and Ms A alleged that there was an apparent deficiency in patient risk assessment procedures prior to Ms A's laparoscopy as, despite Ms A being at increased risk of an infection / a tubo ovarian abscess complication, the higher risk status was not communicated to her, was overlooked (or dismissed as insignificant) and no precautionary measures were implemented by the Hospital to reduce risk. Mr C and Ms A also raised concerns why a CT scan was delayed until Monday 15 August 2005, as they said the scan had been requested on Saturday 13 August 2005.

7. The Board commissioned an independent review (the Review) and a report into Mr C's and Ms A's complaint (the Report), which I have seen. The Review was conducted by an external Consultant Gynaecologist (the Reviewer). While Mr C and Ms A acknowledged that the Report, dated 1 August 2006, addressed several key concerns they had raised and was generally factually correct, they stated that it failed to establish a precise cause of Ms A's tubo-ovarian abscess which had formed post-laparoscopy. Adviser 1 also observed that no actual cause of the abscess had been established. Mr C and Ms A noted that it was recorded within the Report that Ms A was in a higher risk group of patients susceptible to infection and complications, such as tubo-ovarin abscess formation. Furthermore, the Report outlined that the higher risk status resulted from factors related to Ms A's medical history, which included endometriosis, hydrosalpinx, previous surgery to remove a cyst and a possible weakened immune system from previous chemotherapy. Mr C and Ms A stated 'we feel that this raises a crucially important issue that merits further investigation, in that there appears to have been a procedural deficiency in the way [Ms A] was clinically risk assessed, prior to the laparoscopy'. Furthermore, Mr C and Ms A alleged that consent was taken, yet the potential risk of the diagnostic investigation (the laparoscopy) was not explained and, in particular, no account was taken of the fact that Ms A was at a higher than normal risk of the tubo-ovarian abscess/infection. They stated that 'despite being a higher risk patient, because of an apparently inadequate risk assessment procedure, a precautionary antibiotic was not given. If a thorough risk assessment/ explanation had been given and an antibiotic used to reduce the risk to the patient then perhaps there would have been significantly less chance of the complication' (see paragraph 5). I discussed the prescribing of antibiotics at this stage with Adviser 2 and, in his view, these were not necessary as there was no clinical reason for doing so. This supported the Reviewer's observation that, during Ms A's laparoscopy, she noted there was no evidence of pelvic infection and, in her view, it was correct that antibiotics had not been administered.

8. Within the Report, the Reviewer made no criticism of the management of Ms A's hospital care. I have noted that within Mr C and Ms A's letter dated 12 January 2007 to the Board, they accepted the Report as a second opinion, however they did not consider it entirely independent and stated the Reviewer belonged to 'an established network between consultants'.

9. Within the Board's reply to Mr C and Ms A, dated 7 March 2007, the Board addressed this issue and stated that both Mr C and Ms A had been consulted

and had agreed to the choice of the Reviewer, before the Board had referred their case to her (see paragraph 8).

10. Adviser 1 considered the care and treatment Ms A received at the Hospital. He observed her past medical history (see Annex 4) and that Ms A was 39 years old when she underwent the laparoscopy and laparotomy.

11. Adviser 1 observed from Ms A's medical records that, on 9 August 2005, the Consultant performed the diagnostic laparoscopy on Ms A (see paragraph 1 and paragraph 5) and that the operation note had recorded Ms A's right tube was normal with no adhesions. The right ovary was densely adherent to the pouch of Douglas (the space behind the uterus) and barely visible behind the left ovary. The left tube was not visible and the left ovary was enlarged by a 5 centimetre endometriotic cyst.

12. Adviser 1 noted that on 12 August 2005 Ms A had complained of abdominal discomfort, shoulder pain, nausea and an inability to keep liquids or solids down. Following his examination of Ms A, her local GP (the GP) noted within his records that she looked unwell, she was apyrexial, she had tachycardia of 120 beats per minute and was normotensive. The GP recorded Ms A's abdomen as looking distended, noted that she experienced discomfort during abdominal examination and that bowel sounds were heard. The GP referred Ms A back to the Hospital as an emergency patient.

13. Thereafter, Adviser 1 observed from the medical records that, on arrival at the Hospital on 12 August 2005, Ms A was clerked in by the gynaecologist Senior House Officer (the SHO). By this time Ms A was pyrexial; her temperature was 38.4. Routine blood tests were taken, including a C reactive protein (CRP). A high vaginal swab was obtained and an abdominal x-ray ordered. Intravenous antibiotics were commenced. Plain abdominal x-rays showed dilated groups of small bowel. Ms A was given intravenous fluids and referred for review by the Consultant. Blood results became available at this time, which revealed a raised white cell count and a raised CRP. This test result suggested the presence of infection (see Annex 2). Surgical review took place later that day, with findings as above. According to the medical records, the working diagnosis was 'obstruction/collection'. Adviser 1 stated 'I take this to mean possible abscess formation. By this time a naso-gastric tube had been passed and Flagyl had been added to the antibiotics prescribed.'

14. The next morning (13 August 2005) Adviser 1 noted from the medical records that Ms A slept well and had not complained of pain. Her temperature had settled at 36.2. Pulse was recorded as 96 beats per minute. A medical review later that day recorded that Ms A's temperature was settling, that her abdomen was less painful but still distended. It was also noted that that there was minimal drainage via the naso-gastric tube and the bowel sounds were very sparse. The abdomen was described as moderately distended but generally soft. Adviser 1 observed that, later that day, a further surgical review was carried out at 16:45. It was recorded 'Not distressed. Temperature 37.45. Pulse 125. Blood pressure 100/65. Soft abdomen, distended + no peritonism. Bowels moved today. Diagnosis / small bowel ileus due to intraperitoneal sepsis. Suggest repeat x-ray abdomen today. CT scan, abdomen and pelvis. Chase stool culture and sensitivity.'

15. Adviser 1 considered from these medical entries that Ms A's condition had not altered significantly and that a further surgical review was undertaken the following day – Sunday 14 August 2005. At that stage, Ms A was transferred to the surgical ward. A CT scan was carried out on Monday 15 August 2005, which showed free fluid and dilated loops of small bowel with a possible inflammatory mass in the pelvis. On the basis of this scan, a laparotomy was undertaken later that same day. The operation was carried out by the surgical team with the Consultant in attendance (see paragraphs 5 and 11).

16. From the operational record, Adviser 1 observed that Ms A's abdomen was opened through a mid-line incision which revealed several loops of small bowel folded (an overlying omentum) and stuck down into her pelvis. When this was freed up, it was noted that there was an abscess which appeared to originate from her left fallopian tube. A sizeable endometric cyst was drained and revealed that her left fallopian tube was filled with pus. This was cut free and a left salpingoophorectomy (the removal of Ms A's left tube and ovary) was then performed by the Consultant (see Annex 2).

17. Thereafter, Adviser 1 considered Mr C and Ms A's complaint, regarding an apparent deficiency by the Hospital in patient risk assessment procedures prior to Ms A's laparoscopy (see paragraph 5). He considered that, prior to the laparoscopy on 9 August 2005, the obstetric and gynaecological history of Ms A included several Bartholins abscesses, two normal vaginal deliveries, cold coagulation treatment to the cervix and a laparoscopic left ovarian cystectomy.

At the time of the ovarian cystectomy, adhesions were noted in the pelvis and endometriosis was diagnosed (see Annex 4).

18. In Adviser 1's view, he did not consider that any additional precautions were required to be taken by the Hospital prior to or during the laparoscopy and stated 'I concur with [the Reviewer's] opinion that the formation of a tubo-ovarian abscess following laparoscopy is very rare' (see paragraph 7). Furthermore, he considered that '[the Consultant] and his team acted entirely reasonably in not anticipating this complication or taking any particular additional precaution to prevent their occurrence.'

19. In this regard, Adviser 1 referred to an advice sheet from the Royal College of Obstetricians and Gynaecologists regarding diagnostic laparoscopy, which identified that the overall risk of complications from diagnostic laparoscopy was approximately 2 in 1,000 and that infections, or the development of a pelvic abscess, was not regarded as a complication to be considered or discussed (see paragraph 3).

20. Adviser 1 addressed Mr C and Ms A's concern why a CT scan was delayed until Monday 15 August 2005 when they said it had been requested on Saturday 13 August 2005. In addition, he also considered Ms A's question whether an earlier laparotomy would have enabled her ovary to have been preserved.

21. Adviser 1 confirmed from the notes of a meeting that took place on 29 May 2006 between a consultant gynaecologist (the Gynaecologist), a midwife manager (the Midwife), Mr C and Ms A, that within their discussions they considered why Ms A waited three days to undergo a CT scan (see paragraph 21). He observed that the Gynaecologist suggested possible reasons for the alleged delay in performing the CT scan and stated she was not certain if the CT scan was available over the weekend. The Gynaecologist answered Mr C's direct question 'Why did they wait' and stated that possibly the CT scan was thought not necessary at that time and said that repeat x-rays had been performed on the Saturday.

22. Adviser 1 stated that he was not in a position to say whether or not a CT scan would have been available over the weekend in the Hospital (on Saturday 13 and/or Sunday 14 August 2005). However, in his view the majority of hospitals have facilities to carry out CT scans urgently when necessary. He

stated 'from my reading of the notes, it would appear that [Ms A's] condition was improving (her temperature had settled and her pain was decreasing) over the weekend and I would take the view that it was perfectly reasonable not to carry out a CT scan until Monday' (see paragraph 16). In my review of this meeting note and all relevant documentation, there is no record I have seen that the CT scan was requested on Saturday 13 August 2005.

23. Furthermore, Adviser 1 considered that the working diagnosis was one of infection somewhere in the abdomen and that the doctors had quite correctly treated this with antibiotics. Thereafter, Ms A's condition had improved. Adviser 1 considered it was not possible for him to state what, if any, difference there would have been in the findings of a CT scan had it been carried out on Saturday 13 August 2005, as opposed to a CT scan carried out on Monday 15 August 2005. In Adviser 1's view, 'it is highly likely that the abscess was already present and that the findings will have been the same. I do not therefore think that it would have made any difference to the eventual outcome, but it would be true to say that [Ms A] might have had her laparotomy two days earlier and would have therefore been in discomfort for a shorter length of time' (see paragraph 20). However, Adviser 1 repeated his earlier observation that it was perfectly reasonable medical management to wait for a CT scan to be performed on the Monday. Furthermore, in his view, had Ms A's condition deteriorated over the weekend, he had no doubt that either an urgent CT scan would have been undertaken or a laparotomy would have been carried out.

(a) Conclusion

24. Mr C and Ms A's distress is understandable, given that they feel that Ms A received inadequate care at the Hospital and, in their view, this may have adversely affected their chances of any future successful conception.

25. I have considered carefully Adviser 1's opinion that the Consultant and team at the Hospital provided appropriate care and treatment towards Ms A and that they had correctly diagnosed Ms A's abdominal condition and treated it accordingly and in good time with antibiotics (see paragraph 5 and paragraph 23). Furthermore, I share Adviser 1's view that the development of the pelvic abscess (medically assessed as an unusual occurrence by the Royal College of Obstetricians and Gynaecologists) was not regarded as a complication to be considered or discussed prior to Ms A's laparoscopy (see paragraphs 18 and 19).

26. In addition, I have considered carefully Adviser 1's comments that it was likely that the abscess was already present and that the findings would have been the same had the CT scan been carried out on Saturday 13 August 2005 instead of Monday 15 August 2005 (see paragraphs 20 to 22). Accordingly, having taken all these factors into account, I do not uphold this complaint.

(a) Recommendation

27. The Ombudsman has no recommendations to make.

(b) The Board's infertility service made matters worse

28. Mr C and Ms A told me that, in their view, the Board had not treated them either appropriately or fairly as patients. They alleged that the Board had failed to provide them with any NHS assistance with subsequent infertility treatment, following Ms A's laparoscopy and laparotomy and the possible avoidable resultant loss of an ovary and reduction in available egg reserve (see paragraph 5).

29. I have seen, from the notes of the meeting held on 29 May 2006 (see paragraph 21), that the Gynaecologist explained to Mr C and Ms A that the Board does not offer IVF by itself, as it is a small health board and has a small budget for funding specialised services. They offer help with funding for the treatment through a contract with other health boards. Nevertheless, Ms A fell outside the Board's criteria to fund IVF treatment.

30. Within the Report, the Reviewer stated that she had no criticism of the way Ms A had been managed (see paragraph 8) and, furthermore, she did not think that the removal of the left tube and ovary had a significant adverse effect on the possible outcome of any future fertility treatment Ms A may undergo. In addition, she stated that there was evidence that the removal of a damaged fallopian tube prior to IVF treatment improved fertility.

31. The Reviewer also confirmed that Mr C and Ms A were not eligible for NHS funded treatment by the Board. This decision was related to Ms A's age and the fact that she had two children from a previous relationship (see paragraph 29).

32. In addition, the Reviewer opined that the complication which followed the laparoscopy (see paragraphs 13 to 16) had not adversely affect Ms A's fertility management and, therefore, had not changed her funding status.

33. Adviser 1 observed that Ms A had previously been investigated for infertility and Mr C and Ms A stated that they had been referred to the Hospital with an infertility problem. He noted Mr C and Ms A's view that the removal of Ms A's ovary and loss of critical egg reserve had further reduced their chances of having a child by IVF treatment (see paragraph 1). Mr C and Ms A stated that Ms A's pelvic infection and surgery may also have rendered any existing low chance of natural conception as virtually nil (see paragraphs 1 and 24).

34. Adviser 1 focussed on Mr C and Ms A's allegation that they believed the Board should have offered them NHS assistance for IVF treatment following Ms A's laparoscopy and laparotomy, as they felt their situation was better (and their chances to conceive were better) before they saw the Consultant on 9 August 2005 (see paragraphs 5 and 29).

35. In Adviser 1's view, it appeared that the basis of Mr C and Ms A's argument was that they considered the employees of the Board to be at fault. As a consequence, they felt that the Board should compensate them for this by offering NHS funded IVF treatment. According to Adviser 1, 'Since I can find no fault in the actions of the medical staff responsible for Ms A's care, I do not think this line of argument is sustainable' (see paragraphs 25 and 26).

(b) Conclusion

36. Mr C and Ms A felt that the Board had abandoned them and failed them, as the Board had failed to provide any NHS assistance with subsequent IVF infertility treatment, following Ms A's laparoscopy and laparotomy.

37. I have read carefully all the relevant paperwork (see paragraph 3) and I have not seen any evidence to support this view. I have reviewed the Board's policy on funding IVF treatment and note that Ms A falls outwith these criteria. Furthermore, I agree with Adviser 1's opinion that, as he could not find fault with the actions of the Hospital's medical staff responsible for Ms A's care and as Ms A was not eligible for NHS funded treatment by the Board, the Board had dealt with this matter appropriately. Having taken all these circumstances into account, I do not uphold this complaint.

(b) Recommendations

38. The Ombudsman has no recommendations to make.

Annex 1

Explanation of abbreviations used

Mr C and Ms A	The complainants
The Hospital	Stirling Royal Infirmary
The Service	The Board's Infertility Service
The Board	Forth Valley NHS Board
The Consultant	The Hospital Consultant who carried out the diagnostic laparoscopy and the surgical laparotomy on Ms A
Adviser 1	The Ombudsman's Medical Adviser in obstetrics and gynaecology, who reviewed the case
Adviser 2	The retiring Ombudsman's Medical Adviser in obstetrics and gynaecology, who reviewed the case
The Review	Independent Review commissioned by the Board
The Report	The Report of the Review
The Reviewer	The external consultant gynaecologist who conducted the Review and was the author of the Report
The GP	Ms A’s local general practitioner
The SHO	The senior gynaecologist house officer
The Gynaecologist	The Hospital’s consultant gynaecologist
The Midwife Manager	The midwife

Annex 2

Glossary of terms

Adhesions	Internal scars/tissues stuck together/adherent to each other. An almost inevitable consequence of surgery, also caused by infection and endometriosis, among other things
Bartholin abscess	An abscess of the vulvovaginal gland
Bowel ileus	Temporary absence of the normal contractility of the bowel, common after abdominal surgery and in the presence of sepsis
Chemotherapy	Drug treatment used for cancer
Clerked in	The process of taking a patient's history and recording it in the notes, when admitted to hospital
Cold coagulation treatment of cervix	Heat treatment to the neck of the womb, used to destroy abnormal tissue/prevent bleeding
C Reactive Protein (CRP)	Non-specific blood test with raised levels in the presence of infection
Computerised Tomography scan (CT Scan)	A special x-ray sending out multiple images of sequential tissue slices
Cyst (ovarian)	A fluid filled sac which develops in an ovary
Diagnostic laparoscopy	Examination of the abdomen and pelvis by keyhole surgery
Dilated	Enlarged
Distended	To expand from, or as if from internal pressure

Endometriosis	A condition in which normal endometrial tissue (the lining of the uterus) grows outside the uterus
Flagyl	Antibiotic to treat infection
Hydrosalpinx	Accumulation of serous (clear) fluid in the fallopian tube
Hysterosalpingogram (HSG)	Specialist x-ray of the reproductive system
Intravenous	Into the vein
Intraperitoneal Sepsis	Bacterial infection within the abdomen
In Vitro Fertilisation (IVF)	Treatment aiming to achieve a pregnancy, involving the fertilisation of eggs outside the body
Laparoscopy	A test using a laparoscope: a thin lighted tube used to visualise the contents of the abdomen
Laparoscopic left ovarian cystectomy	Removal of a cyst from the left ovary, using keyhole surgery
Laparotomy	A surgical procedure involving an incision through the abdominal wall, to gain access into the abdominal cavity
Marsupilisation	Form as a pouch
Naso-gastric tube	Plastic tube inserted through the nose and passed into the stomach to empty the stomach contents
Normotensive	Having normal blood pressure
Omentum	The fatty curtain attached to the lower edge of

	the stomach which lies in front of the intestines
Ovary	Female organ which produces eggs
Peritonism	Pertaining to inflammation of the membrane which lines the abdomen and other organs
Pyrexial/apyrexial	Raised temperature/the absence of fever
Salpingoophorectomy (left)	Removal of left tube and ovary
Spontaneous vaginal delivery	Normal delivery of a baby
Tachycardia	Rapid heart rate
The tube appeared patent	The tube was open
Uterus	Womb
Pelvic abscess/tubo ovarian abscess	An abscess in the pelvis, involving the tube and ovary
Spasm	Tightening/contraction

Annex 3

List of legislation and policies considered

Diagnostic Laparoscopy: Royal College of Obstetricians and Gynaecologists (April 2007)

Annex 4

Ms A's medical history (see paragraph10)

1983	marsupilisation of Bartholins abscess
1986	marsupilisation of Bartholins abscess
1988	Bartholins abscess
1989	spontaneous vaginal delivery
1991	spontaneous vaginal delivery
1994	Bartholins abscess treated conservatively
1999	diagnosed with prooomyeloctic leukaemia
2003	treatment to the cervix for a virus
2004	laparoscopic left ovarian cystectomy. Endometriosis present in the pelvis and adhesions noted.
July 2005	hysterosalpingogram (HSG): this showed a left sided hydrosalpinx but the tube appeared patent. On the right side there was spasm with no spill of dye from the tube