Scottish Parliament Region: Central Scotland

Case 201201639: Lanarkshire NHS Board

Summary of Investigation

Category

Health: Hospital; Gynaecology and Obstetrics (Maternity)

Overview

The complainant (Mrs C) raised a number of concerns that sub-standard ultrasound equipment or human error meant that a pregnancy she conceived during her fifth cycle of Intra Uterine Insemination (IUI) treatment was not detected. Mrs C complained that this resulted in the pregnancy being destroyed during the sixth cycle of IUI treatment.

Specific complaints and conclusions

The complaints which have been investigated are that:

(a) it was unreasonable that Mrs C's pregnancy was not detected on 30 and 31 August 2011 (*not upheld*);

(b) the scanning equipment used on 30 and 31 August 2011 was not of a reasonable standard (*upheld*); and

(c) it was inappropriate that no record was made of the irregular pain and discomfort Mrs C experienced during the procedure carried out on 1 September 2011 (*not upheld*).

Redress and recommendations

The Ombudsman recommends that Lanarkshire NHS Board:	*Completion date*
(i) issue a written apology for the failing identified; and,	22 June 2013
(ii) review the IUI recording form to incorporate space for recording symptoms reported by the patient.	22 August 2013

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

Main Investigation Report

Introduction

1. Mrs C was undergoing Intra Uterine Insemination (IUI) treatment at the Monklands Infertility Unit (the Unit) and had been through five cycles by August 2011. She had three ultrasound scans, on 23, 30 and 31 August 2011, in preparation for her sixth cycle. No pregnancy was detected and Mrs C underwent an IUI procedure on 1 September 2011.

2. During the procedure Mrs C experienced and reported unusual irregular pain and discomfort. The associate specialist fertility nurse (the Nurse) administering the procedure stopped the procedure and then re-started a few minutes later. The Nurse then managed to complete the IUI procedure.

3. Mrs C experienced bleeding on the weekend of 3 and 4 September 2011 and attended Wishaw General Hospital (the Hospital). She was reviewed by a doctor on 6 September 2011, who noted bleeding and abdominal cramps. An ultrasound scan was undertaken on 13 September 2011, which showed a small intra uterine gestation sac.

4. Further scans were done on 15; 19; and 22 September 2011 when the sac was still apparent. An additional ultrasound scan was undertaken on 29 September 2011 where the sac and a haematoma were seen. It was also recorded that Mrs C had been suffering from cramps and bleeding from the previous day.

5. Mrs C was referred to the Early Pregnancy Assessment Service (EPAS) at the Hospital where a miscarriage was confirmed on 5 October 2011. Mrs C underwent a surgical evacuation on 7 October 2011.

6. Mrs C complained that due to the failure to detect her pregnancy she not only lost a viable pregnancy but possibly has also lost the opportunity to conceive in the future.

7. The complaints from Mrs C which I have investigated are that:

(a) it was unreasonable that Mrs C's pregnancy was not detected on 30 and 31 August 2011;

(b) the scanning equipment used on 30 and 31 August 2011 was not of a reasonable standard; and

(c) it was inappropriate that no record was made of the irregular pain and discomfort Mrs C experienced during the procedure carried out on 1 September 2011.

Investigation

8. My complaints reviewer examined relevant documentation provided by Mrs C and Lanarkshire NHS Board (the Board); copy clinical records; and relevant national and local guidance. My complaints reviewer also took advice from two of my independent advisers: a consultant gynaecologist (the Gynaecology Adviser); and a senior nurse (the Nursing Adviser). Explanations of terms and abbreviations used are contained in Annexes 1 and 2, attached to this report.

9. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. Mrs C and the Board were given an opportunity to comment on a draft of this report.

(a) It was unreasonable that Mrs C's pregnancy was not detected on 30 and 31 August 2011

10. Mrs C had undergone five cycles of IUI treatment by August 2011 which used a combination of drugs (to stimulate the production of ova) and IUI. In Mrs C's case the drug used was Ovitrelle, which is usually given between 12:00 and 15:30 on the day prior to the planned IUI, with the IUI procedure being undertaken 24 hours after the administration of the drug. This would be the date that ovulation would be calculated to have taken place.

11. The Gynaecology Adviser explained that gestation is usually calculated from the first day of the last menstrual period and ovulation and the fertilisation of the ovum occurs on day 14. Thus a woman would be considered to be two weeks pregnant on the day of ovulation. For the fifth cycle Mrs C underwent the IUI procedure on 8 August 2011.

12. She then experienced bleeding on 21 August 2011 which was thought to be her menstrual period and that the IUI procedure had not produced a pregnancy. An ultrasound scan was done on 23 August 2011 (by which time Mrs C would have been estimated to have been approximately four weeks pregnant) which showed a thin endometrium of 4.2 millimetres. The Gynaecology Adviser considered that this was in keeping with a woman who was not pregnant and had recently started a menstrual period. The

Gynaecology Adviser also commented that it would not be possible to detect a pregnancy at this very early stage.

13. By the time the scans of 30 and 31 August 2011 were done the Gynaecology Adviser noted that the endometrium had thickened but no gestation sac was detected. The Gynaecology Adviser stated that at this stage of pregnancy (approximately five weeks) it would be possible for a gestation sac not to have been identified.

14. The Gynaecology Adviser stated that the hormone Human Chorionic Gonadotrophin (HCG) can indicate pregnancy when seen at levels of between 1,000 and 2,400 International Units (IU) per litre of blood. The HCG then shows in the urine sample that is used for pregnancy testing.

15. However, the Gynaecology Adviser was of the view that there was no indication of the need to test the HCG at this stage based on the results of the scans and in any case any reading would have been inaccurate due to the recent injection of Ovitrelle.

16. The Gynaecology Adviser was, therefore, of the view that, based on the information available to the clinicians caring for Mrs C at the time, including the information provided by the scanning equipment to which I refer in complaint (b) below, it was not unreasonable that her pregnancy was not detected in August 2011.

17. In a formal response to the Scottish Public Services Ombudsman (SPSO) dated 21 August 2012 the Board stated that the information provided by Mrs C in August 2011 appeared consistent with the results of the scans, ie her menstrual period had started and the fifth cycle of treatment had been unsuccessful.

18. The Board also provided a copy of a statement from the consultant gynaecologist (the Consultant) in charge of Mrs C's care at the Unit made during the Board's investigation of the complaint. The Consultant stated that in the light of Mrs C's case the members of the Womens' Services Department, of which the Unit was a part, had discussed the events 'at length' and were considering changing their protocol to include pregnancy tests in addition to ultrasound scans before IUI treatment is commenced.

(a) Conclusion

19. I note that the case has been discussed among relevant staff at the Board and the treatment protocol is under review. However, on the basis of the evidence and advice available I am satisfied that the clinicians made their decisions based on the information available to them at the time. The advice I received was that the decisions made were not unreasonable in the circumstances. I therefore do not uphold this complaint.

(b) The scanning equipment used on 30 and 31 August 2011 was not of a reasonable standard

20. The ultrasound scanner used in the Unit was different to the one used in the EPAS and other areas within the Board region. The Board have conceded that it was not as sensitive as the other types of scanner. Mrs C complained that had different, more sensitive equipment (similar to that used in the EPAS) been used in August 2011 at the Unit her pregnancy might have been detected.

21. My complaints reviewer noted that in a statement as part of the Board's investigation of Mrs C's complaint, the Consultant expressed concerns about the quality of images produced by the scanner in use at the Unit at the time of the events complained of. The statement was made in March 2012 and recorded that she had experienced problems with the ultrasound equipment which had been reported on DATIX 'on many occasions'. DATIX is an electronic system used in the NHS to report incidents affecting patients.

22. The statement continued that the management of the Unit was 'well aware' of the problems and that the scanner had since been replaced with one giving 'far superior' resolution. However, the Consultant also stated that had Mrs C actually conceived in her fifth cycle, at the scan taken on 23 August 2011 she would only have been four weeks pregnant and a scan taken that early may not have revealed the pregnancy.

23. The sister in charge of the Unit (the Sister) also made a statement dated 4 April 2012 which included that the staff had had problems with the previous scanner and that it had been reported on DATIX and to management 'on a few occasions'. However, the Sister's statement continued that no problems with imaging had been recorded on Mrs C's notes. The Sister also stated that the possibility of the pregnancy showing on the scan undertaken on Mrs C on 23 August 2011 would have been 'minimal'.

24. In the response to the SPSO dated 21 August 2012 the Board stated that the scanner used at the time of the events complained of was of a 'reasonable standard' but acknowledged that the resolution and picture quality were 'lower than scanners available elsewhere' within the Board's region. The Board also provided evidence that the scanner had received its annual service on 31 August 2011 and no problems had been found.

25. The response continued that the scanner had since been replaced as part of the Board's rolling replacement programme.

26. The Gynaecology Adviser was unable to say for certain whether Mrs C's pregnancy would have been detected on 30 or 31 August 2011 if a different scanner had been used, but stated that it may have been. The Gynaecology Adviser noted that both the Consultant and the Sister had reported their concerns about the quality of images produced by the scanner in use in the Unit at the time. The Gynaecology Adviser, therefore, considered that for the clinical purposes for which the scanner was being used in the Unit, it was not fit for purpose.

(b) Conclusion

27. The Board's responses to Mrs C and the SPSO on this matter stated that no problems had been recorded with imaging during Mrs C's scans and that the scanner in use at the time was of a 'reasonable' standard. I note the view of the Gynaecology Adviser that it was not now possible to know whether Mrs C's very early pregnancy would have shown up had a different scanner been used.

28. The Board contends that the scanner was of a reasonable standard but the images produced were clearly not fit for purpose in the context of the usage within the Unit. On this basis I uphold this complaint.

29. I note that the scanner has now been replaced and that the Consultant stated that the images now obtained in the Unit are 'far superior'. Therefore, although I am upholding this complaint I am making no recommendation in respect of the equipment currently used in the Unit.

30. However, I am concerned that despite being aware of the concerns expressed by the Consultant and the Sister about the quality of the images produced by the scanner the Board did not replace the scanner until it came due for replacement under the 'rolling replacement programme'. Nor did the

Board mention the concerns expressed by the staff in the responses to either Mrs C in their final response to her on 26 April 2012 or in the formal response to the SPSO some four months later on 21 August 2012.

(b) Recommendation

31. I recommend that the Board:	*Completion date*
(i) issue a written apology to Mrs C for the failing identified.	22 June 2013

(c) It was inappropriate that no record was made of the irregular pain and discomfort Mrs C experienced during the procedure carried out on 1 September 2011

32. Mrs C stated that during the procedure on 1 September 2011 she experienced unusual pain and discomfort which she reported to the Nurse. The procedure was stopped for a few moments and then completed.

33. In her statement to the Board as part of their investigation of Mrs C's complaint, the Nurse stated that when Mrs C experienced pain during the procedure she stopped and checked Mrs C's cervix for signs of infection. The Nurse stated that infection would be the usual cause of pain during the IUI procedure. No infection was found and the nurse attempted the procedure again and was able to complete it. The Nurse stated that at the time Mrs C did not appear to experience pain during the second attempt at IUI.

34. In a further internal email to the Service Manager of the Woman's Services Directorate, the Nurse confirmed that pain would not normally be documented unless the pain actually prevented the procedure being completed. She explained that this was because patients often did experience some pain and/or discomfort during the IUI procedure.

35. The Nursing Adviser considered that ideally any unusual symptoms should be noted but that the standard forms used by the Unit to record the IUI procedures did not provide space to make any such notes. The Nursing Adviser, therefore, considered that it was not unreasonable that no record of the pain reported by Mrs C was made. The Nursing Adviser further stated that the Nurse had followed reasonable practice by stopping the procedure, checking for infection and then trying again a few minutes later. The Nursing Adviser did suggest that the standard forms could be adapted to allow space to record unusual symptoms.

(c) Conclusion

36. Mrs C stated that she experienced pain during the procedure which was unusual for her. The Nurse acknowledged that Mrs C reported pain but that she could find no obvious cause for the pain and was able to complete the procedure at the second attempt. Therefore, she did not record the pain as it had not caused the procedure to be abandoned.

37. The advice I received was that it was reasonable for the nurse to stop when Mrs C reported the pain, to check Mrs C and then make a second attempt at the procedure. The Nursing Adviser also considered that in the absence of a designated space to do so, it was reasonable in the circumstances for the Nurse not to record the pain Mrs C reported.

38. Therefore, based on the evidence and advice available to me I do not uphold this complaint.

39. However, I consider that it would be reasonable for the nurses undertaking IUI procedures to be able to record any symptoms of pain or discomfort reported by patients. This would allow staff to see whether or not such symptoms were usual for that patient and take any appropriate action. Therefore, although I am not upholding this complaint, I have made a recommendation below.

(c) Recommendation

40. I recommend that the Board:	*Completion date*
(i) review the IUI recording form to incorporate space for recording symptoms reported by the patient.	22 August 2013

41. 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

Mrs C	The complainant
IUI	Intra Uterine Insemination
The Unit	Monklands Infertility Unit
The Nurse	The Associate Specialist Fertility Nurse
The Hospital	Wishaw General Hospital
EPAS	Early Pregnancy Assessment Service
Lanarkshire NHS Board	The Board
The Gynaecology Adviser	The Consultant Gynaecologist Professional Adviser
The Nursing Adviser	The Senior Nurse Professional Adviser
HCG	Human Chorionic Gonadotrophin
SPSO	The Scottish Public Services Ombudsman
The Consultant	The Consultant Gynaecologist in charge of Mrs C's care
The Sister	The Sister in charge of the Unit

Annex 2

Glossary of terms

Abdominal	In the area of the stomach
Cervix	Neck of the womb (see below)
Embryo	Fertilised egg which can grow into a baby
Endometrium	The lining of the womb which thickens to prepare for implantation of an embryo. The endometrium is shed during the menstrual period (see below) if an embryo is not implanted
Gestation	Period during which a fertilised egg develops into a baby that is ready to be delivered
Haematoma	Blood clot
Human Chorionic Gonadotrophin	A female hormone which increases during pregnancy
Intra Uterine Gestation Sac	A bag-like structure within the womb
Intra Uterine Insemination	Insertion of sperm to the womb in a clinical setting
Menstrual period	The monthly cycle of shedding the endometrium. Women experience bleeding and sometimes cramping pains
Miscarriage	The spontaneous loss of an embryo
Ova	Plural of ovum (see below)
Ovitrelle	A synthetic version of HCG used to stimulate egg production in infertile women

Ovulation	The process of releasing an ovum (see below) to travel via the fallopian tube to the womb
Ovum	Egg cell which once fertilised can become an embryo
Sperm (spermatozoon)	Male sex cell which fertilises the ovum
Surgical evacuation	Removal of the contents of the womb
Ultrasound scanning	A specialist, non-harmful, scanning technique using sound waves to produce images of the body that can be observed on a screen or transferred to photographic film
Uterus or Womb	Part of the female reproductive organs in which an embryo will grow

Annex 3

List of legislation and policies considered

The Obstetrician & Gynaecologist – Pregnancy of unknown location: an evidence-based approach to management. October 2008

American Pregnancy Association – Human Chorionic Gonadotrophin: The Pregnancy Hormone

Royal college of Obstetricians and Gynaecologists – Green-top Guideline No 25 The Management of Early Pregnancy Loss October 2006

Human Fertilisation & Embryology Authority – Record keeping and document control