Scottish Parliament Region: Glasgow

Cases 201200390: Greater Glasgow and Clyde NHS Board - Acute Services Division

Summary of Investigation

Category

Health/ Hospital; Gynaecology & Obstetrics (Maternity); clinical treatment; diagnosis

Overview

The complainant (Mr C) and his wife (Mrs C) underwent a cycle of infertility treatment towards the end of 2011. This did not lead to pregnancy. Thereafter, the Greater Glasgow and Clyde NHS Board (the Board) told Mr and Mrs C that because the hormone that indicated Mrs C's ovarian reserve was low, they would not be offered a further cycle of treatment using her eggs. Instead, they were offered a further cycle with a donated egg. Mr C alleged that this decision was contrary to his and his wife's right of access to NHS treatment and against guidelines on the provision of fertility treatment in Scotland. He further complained that the delays in the process reduced their chances of success.

Specific complaint and conclusion

The complaint which has been investigated is that the Board failed unreasonably to provide a second cycle of fertility treatment of Mr C's choosing *(upheld).*

Redress and recommendations

The Ombudsman recommends that the Board:		*Completion date*
(i)	apologise to Mr C for the failures identified;	19 July 2013
(ii)	offer him £6,000 in the event that he seeks assisted conception treatment privately;	19 July 2013
(iii)	amend their policy on assisted conception to clarify that patients may not be eligible for further NHS treatment if response to treatment is poor; and	19 July 2013
(iv)	consider introducing a protocol to fast track patients with a potentially poor ovarian reserve.	19 July 2013

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

Main Investigation Report

Introduction

1. Mr C suffers from a serious life threatening genetic disease, one of the side effects of which is male infertility. He was due to be married in summer 2009 and he and his partner were keen to start a family. In anticipation of this, as spontaneous conception was unlikely, on 5 February 2009, they were referred by the consultant physician treating Mr C for assisted conception treatment. Mr C and his wife (Mrs C) were seen by a doctor in the fertility unit on 4 November 2009 and he backdated their referral to February 2009. At the same time, he wrote to the consultant physician saying that there was a 22 month wait for treatment. He also referred Mr C to an urologist for sperm retrieval.

2. Test results for Mrs C, also on 4 November 2009, showed that the level of an anti-mullerian hormone (AMH), which indicated her ovarian reserve, was 5.2.

3. Mr C was seen by the urologist on 23 March 2010 and he underwent successful sperm retrieval on 23 July 2011. Shortly afterwards, on 12 August 2011, Mrs C's AMH was measured as less than four. She was later given an ovarian stimulating hormone and egg retrieval took place on 28 October 2011. A single egg was retrieved and successfully fertilised, and the single embryo was transferred on 31 October 2011. This did not lead to pregnancy. The Greater Glasgow and Clyde NHS Board (the Board) subsequently took the view that because Mrs C's AMH was low (less than 4) they would not offer a further cycle using her eggs. Instead, Mr and Mrs C were offered a further cycle of fertility treatment with a donated egg.

4. Mr C complained that the decision to offer him and his wife a further cycle with a donated egg was contrary to his rights to access NHS treatment and to the guidelines on the provision of fertility treatment in Scotland. He also said that delays in the process (from February 2009 until July 2011) meant that Mrs C's AMH fell. Notwithstanding, Mr C said that he and his wife had had a reasonable expectation that a second cycle of in vitro fertilization (IVF) would be provided, on the same basis as the first because, until November 2011, staff told them that they were entitled to it.

5. After the Board's offer of IVF was limited to treatment with a donated egg, Mr C complained on 5 December 2011. The Board responded on

16 January 2012. However, Mr C remained unhappy with their reply and brought his complaint to me.

6. The complaint from Mr C which I have investigated is that the Board failed unreasonably to provide a second cycle of fertility treatment of Mr C's choosing.

Investigation

7. As part of the investigation, all the information provided by Mr C and by the Board was given careful consideration. This included Mr and Mrs C's relevant clinical records, all the complaints correspondence, the Board's policies on assisted conception treatment and a report by the Expert Advisory Group on Infertility Services in Scotland (EAGISS). My complaints reviewer also discussed the complaint with Mr C and obtained independent clinical advice from a consultant in obstetrics and gynaecology (the Adviser) who specialised in assisted conception. The information he provided was also taken into account.

8. While this report does not include every detail investigated, I am satisfied that no matter of significance has been overlooked. Mr C and the Board were given an opportunity to comment on a draft of this report.

Complaint: The Board failed unreasonably to provide a second cycle of fertility treatment of Mr C's choosing

9. Essentially, Mr C said that the Board's decision not to provide a second cycle of fertility treatment using Mrs C's eggs was not reasonable, particularly in light of the EAGISS framework and the delays in the fertility process between 2009 and 2011 (see paragraph 4 above) which meant that Mrs C's AMH levels fell. Mr C also said that he and his wife were not told until November 2011 that a second cycle would depend upon them meeting certain clinical criteria.

10. In relation to Mr C's complaint, it is understood that the EAGISS report outlined a framework for infertility services which was developed to provide equity of access and to improve the overall quality and effectiveness of services. It included recommended eligibility criteria for assisted conception funded by the NHS and stated that assisted conception should be offered to those couples who meet all the listed criteria including clinical criteria. These criteria do not make reference to ovarian reserve.

11. These recommendations were accepted by the Scottish Government who said that the report represented the way forward for infertility services in Scotland. Health boards were asked to work towards full implementation of the recommendations within existing resources. It was the Scottish Government's view that the recommendations would provide equity of access to services and treatment.

12. On responding to the complaint (by letter of 16 January 2012), the Board said that when Mrs C commenced a cycle of IVF she had an AMH of less than 4. They said this was suggestive of a severely reduced ovarian reserve and highly likely to be associated with a reduced, or indeed, no response to ovarian stimulation. They commented that, in the past, they would not have offered even one cycle of ovarian stimulation to patients with an AMH of this level. However, they went on to say, they accepted that biology was not an exact science and they, therefore, reviewed their policy as it was felt that it was reasonable to offer patients with an AMH of less than 4 one cycle of treatment as some patients will not behave in a way expected by their AMH, in other words, as their response may be better than expected. The Board confirmed that this was discussed with all patients in this situation and that Mr and Mrs C would have been advised that one cycle of treatment would be offered. However, they added, those who had a predicted poor response needed to have at least two eggs retrieved before they would be offered a further IVF cycle. The Board said that an AMH level of 5.2 (when it was first measured) was still low indicating a reduced ovarian reserve and that it was impossible to say if Mrs C's response to stimulation would have been different had it been performed earlier. In their view, a further cycle using Mrs C's eggs would have a very small chance of success. In the circumstances, they said they would discuss the possibility of continuing a second cycle with egg donation. Nevertheless, they acknowledged that this was not something that all couples would wish to pursue.

13. In relation to the delays, the Board said that, historically, sperm retrieval had taken place in urology theatres by a urologist in the hospital, a short distance from the embryology laboratory. The urology service moved sites to another hospital and the urology theatre lists were, therefore, undertaken on a different site a few miles away from the laboratory. The Board said that it took some time (20 months) for the necessary infrastructure to be put in place for the procedure to be performed safely and efficiently, but, once referred on to the assisted conception service, all patients were placed on the waiting list in date

order. They said they had no arrangement to fast-track patients. The Board confirmed that each year the service in the hospital was contracted to provide a certain number of cycles of infertility treatment to other health boards and the agreed number was always provided. Occasionally, they said, health boards requested additional cycles and, depending on capacity and funding, they were provided (on a very limited basis). The Board were aware of the Scottish Government's pledge to reduce waiting times to twelve months for commencement of treatment from March 2015.

14. In response to enquiries, the Board said that in the main, patients being offered assisted conception treatment at the unit met the criteria set out in the EAGISS framework and that consultants had discretion in relation to the framework. The Board also said that review of a treatment cycle was good clinical practice.

15. Specialist advice was obtained in this case and the Adviser was asked to review Mr and Mrs C's relevant clinical records. The Adviser said that the original indication for proceeding with IVF was Mr C's medical condition. However, Mrs C's reduced ovarian reserve was identified as early as 4 November 2009 with an AMH of 5.2. They said this would have placed her towards the lower end of the spectrum although clearly not as low as a subsequent AMH of less than 4 on 12 August 2011. The Adviser confirmed that AMH accurately predicted the yield of eggs and associated live births and was independent of age. He added that it was recognised that there was a degree of variation occurring across cycles but in Mrs C's case the two results were consistent. However, the Adviser stressed that the low AMH was not the reason for denying treatment as an AMH of less than four had been identified in August 2011 but a cycle, nevertheless, commenced in October 2011.

16. The Adviser went on to say there was an expected reduction in ovarian response with age and that this was reflected in the guidelines. However, the ovarian reserve did not always match chronological age and, decreased AMH levels suggested a reduced ovarian follicle pool and hence ovarian reserve. He said that the Board recognised that treatment should not be refused based on AMH alone. He said that this was the case with Mr and Mrs C; it was a combination of the poor response to treatment (explained by the poor ovarian reserve highlighted by the AMH) that led to the decision by the Board not to proceed with the second cycle of treatment using Mrs C's own eggs rather than the decision being based on AMH alone. The Adviser went on to comment that

the Board did not deny treatment and offered to proceed with treatment that gave a reasonable chance of success (albeit by egg donation).

17. The Adviser said that in relation to the first cycle of treatment, the Board took note of the AMH level to determine the most appropriate stimulation protocol to maximise response and that this was good practice. He explained that the principal determinants of IVF success were age and egg yield, but that a low AMH and poor response to treatment were indicators of poor reserve and future poor yield. The Adviser, therefore, agreed that it would have been clinically inappropriate for the Board to offer a further cycle using Mrs C's eggs. He said that General Medical Council guidelines placed a duty on the clinician to 'provide effective treatments based on the best available evidence and ensure the investigations or treatment provided must be based on the assessment you and the patient makes on the needs and priorities and on your clinical judgement on the likely effectiveness of the treatment options'.

18. Having said that, the Adviser said there seemed to have been a significant delay in instituting treatment. The original referral from the consultant physician was at the beginning of February 2009, yet it was not until nine months later that Mr and Mrs C were seen by a doctor in the fertility unit, who made a commitment to backdate the referral to 5 February 2009. Nonetheless, despite a referral to urology for sperm retrieval on 4 November 2009, this did not occur until 23 July 2011. In the Adviser's view, the Board had not fully explained this (other than saying there was a lack of a transport incubator) nor said how they were going to reduce waiting times. In 2011, it appeared that the unit was treating only one patient a week which seemed to the Adviser to be surprisingly low. He said it was not clear why Mr and Mrs C were not given higher priority based on Mrs C's relatively low AMH of 5.2 on 4 November 2009. The Adviser said it would have been reasonable to fast track Mrs C (given her low ovarian reserve) in the same way that it was reasonable to prioritise older women. The Adviser added that the 20 month period from the time of the referral by the professor to the time of sperm retrieval played a significant role in this delay, because once sperm was available the cycle of treatment commenced expeditiously. In the Adviser's view, the shortcomings he identified may well have contributed to the poor outcome. He said that it was not possible to predict what would have happened had there not been a delay, but a poor ovarian reserve would not improve with time.

19. Referring to the Board's policy, the Adviser said it did not refer directly to the subject of ovarian reserve but did refer to the impact of age and BMI on the success of treatment. However, the Board considered this further; their document of 17 August 2011 (to be signed by patients) acknowledged information provided to patients, including that they understood that they would not be eligible for any further NHS treatment if, amongst other things, response to treatment was poor. However, the Adviser said that there was no evidence in the relevant clinical records that this document was shared with Mr and Mrs C (or that they were told this) or that it was incorporated into the Board's policy. Finally, the Adviser said that the Board's response that there was discretion in relation to the EAGISS framework was reasonable which also recognised that clinicians must keep up-to-date with the latest developments within the specialty.

Conclusion

20. Mr C complained that the Board's decision not to fund another cycle of fertility treatment of his choosing was unreasonable in light of the EAGISS framework and the delays in the process also, that he was told that he was entitled to a second cycle. However, the NHS is not required to fund every treatment available and health boards make decisions all the time about what treatment to give patients; failure to provide treatment is not in itself unreasonable.

21. It is clear that Mr C feels strongly that the Board's decision not to offer him and his wife a further cycle using Mrs C's eggs was not reasonable. However, I have concluded that it was reasonable (in light of the advice I have accepted); the decision was clinically sound and within the framework accepted by the Scottish Government. Having said that, there were a number of failures by the Board that are of concern. Firstly, it is good practice to ensure that patients are made aware of any criteria for treatment when they begin that treatment. The Board said it was their usual practice to tell patients that a second cycle would depend upon their response to treatment, but there was no evidence that Mr C was made aware of this until November 2011. I am critical of this. The Board subsequently introduced an information form to be signed by patients which addressed this. Secondly, and more significantly, I am concerned about the significant delays in the process relating to sperm retrieval and that the Board failed to fast track Mr and Mrs C from 4 November 2009 when they became aware of Mrs C's poor ovarian reserve. The advice I have accepted is that these delays may have been a contributory factor to the poor outcome. This

was an injustice in that Mr and Mrs C were precluded from another potential cycle of fertility treatment using Mrs C's eggs.

22. In cases where I find maladministration that has caused injustice to an aggrieved person, my primary objective is to put the aggrieved person in the position he or she would have been in, had the maladministration not occurred in the first instance. The circumstances of some of the complaints I receive mean that it is not always possible to achieve this. This complaint is one such case. It is not possible to replicate the outcome of the treatment which should have been given to Mr and Mrs C in a more timely manner. Having said that, Mr and Mrs C should be given another opportunity of fertility treatment in light of the injustice they suffered. Therefore, in coming to a decision on redress in this case, I have been guided by the cost of provision of assisted conception treatment outside the National Health Service and come to the figure outlined in paragraph 24.

23. While the Board's decision not to fund a second cycle of fertility treatment was a reasonable clinical decision, I am extremely concerned about the delay endured by Mr and Mrs C, and the level of communication with them. This has led me to conclude that the Board's actions were unreasonable. Taking this into account, I uphold the complaint and I make a number of recommendations to address the failures identified including one to address the impact of the delays. Although the Board's decision not to offer a second cycle using Mrs C's eggs was clinically sound, I appreciate that Mr C feels strongly about this. He is seeking a second cycle to resolve his complaint but I cannot recommend that a health board provides treatment that is not clinically justified. Nevertheless, in recognition of the impact the delay had on the outcome for Mr and Mrs C, in that a potential opportunity was missed, I recommend that the Board apologise to Mr C and offer him financial redress in the event that he seeks assisted conception treatment privately. Also, that the Board amend their policy on assisted conception to clarify that patients may not be eligible for further NHS treatment if response to treatment is poor. I further recommend that the Board consider introducing a protocol to fast track patients with a potentially poor ovarian reserve.

Recommendations

24. I recommend that the Board:	*Completion date*
(i) apologise to Mr C for the failures identified;	19 July 2013

(ii)	offer him £6,000 in the event that he seeks assisted conception treatment privately;	19 July 2013
(iii)	amend their policy on assisted conception to clarify that patients may not be eligible for further NHS treatment if response to treatment is poor; and	19 July 2013
(iv)	consider introducing a protocol to fast track patients with a potentially poor ovarian reserve.	19 July 2013

25. 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 C	the complainant
Mrs C	the complainant's wife
AMH	anti-mullerian hormone
The Board	Greater Glasgow and Clyde NHS Board –Acute services Division
IVF	in vitro fertilization
EAGISS	Expert Advisory Group on Infertility Services in Scotland
The Adviser	a consultant in obstetrics and gynaecology who provided advice

Annex 2

Glossary of terms

Anti-mullerian hormone	a substances produced by cells in ovarian follicles
Ovarian reserve	a term used to determine the capacity of the ovary to provide eggs that are capable of fertilization resulting in a pregnancy