Scottish Parliament Region: Glasgow

Case 200501279: Greater Glasgow and Clyde NHS Board

Summary of Investigation

Category

Health: Hospital; Urology

Overview

The complainant (Mr C) raised a number of concerns about the care and treatment which he had received from Greater Glasgow and Clyde NHS Board (the Board) since 1996 for his erectile dysfunction. Mr C was particularly concerned that he had been asking for a penile implant operation for a number of years and only in 2005 had the Board agreed to consider him for the procedure.

Specific complaints and conclusions

The complaints which have been investigated are that:

(a) it was unreasonable for the Board to have taken nine years to agree to Mr C's request to be considered for a penile implant operation (*partially upheld*);

(b) the Board failed to correctly perform a Nesbit's operation, to correct the bend in Mr C's penis, which resulted in the bend moving from the base to half way up Mr C's penis (*no finding*);

(c) Mr C did not have his follow-up appointment three months after his operation, as planned, and had to contact the hospital to ask for the appointment to be arranged (*partially upheld*);

(d) the Board failed to provide Mr C with appropriate care and treatment for his erectile dysfunction (*not upheld*); and

(e) the Board failed in their handling of Mr C's case from the point at which he was advised that he would be considered for the penile implant operation, ie July 2005, onwards, including that Mr C was later advised by the Board that the operation was not available within the NHS in Glasgow (*upheld*).

Redress and recommendations

The Ombudsman recommends that the Board:

(i) apologise to Mr C for the delay in providing his penile implant operation, for adding his name to the waiting list prematurely and not advising him of

the conditions and restrictions which applied and for the delay in his follow-up appointment for the Nesbit's operation;

(ii) take steps to ensure that, early, well documented psychiatric reports are produced in future cases of this type when requested or required; and

(iii) take appropriate steps to ensure that, in future cases of this type, patients' names are not added to waiting lists prematurely and that they are advised of any conditions or restrictions which apply.

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

Main Investigation Report

Introduction

1. Since July 2002 the complainant (Mr C) sent several letters of complaint to Greater Glasgow and Clyde NHS Board (the Board) about the treatment he received for his erectile dysfunction. Mr C was unhappy with the Board's formal response to his complaints. The complaints Mr C brought to the Ombudsman are summarised below.

2. Mr C complained that over the years he had been seen by several medical staff at the Board for his erection problem but the Board had failed to resolve them. He stated that his life had 'been hell' and that he had asked for a 'tube' to be inserted in his penis. Mr C claimed that he was advised by a private consultant in 1996 that an implant would be the best thing for him and that the operation could be performed the following week. He stated that he has been going to the NHS for 30 years and had tried everything to sort out his problem.

3. Mr C explained that a Consultant Urologist (Consultant 1) at Gartnavel General Hospital (Hospital 1) performed an operation to correct a bend in his penis which resulted in the bend moving from the base to the middle of his penis and that he had had to point out that the bend was there. He complained that he was not seen three months after his operation as he should have been and that, even though he was attending a local health centre at the time, he had to go to Hospital 1 about this and 'kick up hell'. Mr C also complained that although a Consultant Urological Surgeon (Consultant 2) at Stobhill Hospital (Hospital 2) said, in January 2005, that Mr C would receive the penile implant operation, the operation had not yet taken place.

4. Mr C claimed that on 24 June 2005 Consultant 2 again said that he needed an implant but did not want to give it to him 'in case [Mr C] ran riot'. Mr C believed that it was known in 1996 what he needed and was concerned that he may have to wait another five years until he got the penile implant operation. Mr C stated that he felt he had been very much let down by the Board.

5. The complaints from Mr C which I have investigated are that:

(a) it was unreasonable for the Board to have taken nine years to agree to Mr C's request to be considered for a penile implant operation;

(b) the Board failed to correctly perform a Nesbit's operation, to correct the

bend in Mr C's penis, which resulted in the bend moving from the base to half way up Mr C's penis;

(c) Mr C did not have his follow-up appointment three months after his operation, as planned, and had to contact the hospital to ask for the appointment to be arranged; and

(d) the Board failed to provide Mr C with appropriate care and treatment for his erectile dysfunction.

6. As the investigation progressed, I identified issues concerning the information provided to Mr C on the availability of the penile implant operation. I, therefore, informed the Board and Mr C that the investigation would additionally consider that:

(e) the Board failed in their handling of Mr C's case from the point at which he was advised that he would be considered for the penile implant operation, ie July 2005, onwards, including that Mr C was later advised by the Board that the operation was not available within the NHS in Glasgow.

7. Mr C also complained about the medical treatment which he had received for his condition when he was in prison. Complaints about the provision of medical treatment in prison are not within the remit of the Ombudsman's office and this part of Mr C's complaint was, therefore, not investigated.

Investigation

8. My investigation of this complaint involved obtaining and reviewing Mr C's relevant medical records and the Board's complaint file as well as the correspondence submitted by Mr C to this office. I made extensive enquiries of the Board and assessed the responses and documentation provided, including the 'Scottish Executive[1] Health Department Directorate of Service Policy and Planning' letter on new interventional procedures (the Directive) and the Board's 'New Interventional Procedures, Process for Clinicians To Follow If They Wish to Undertake a New Interventional Procedure' (the Process and Policy Document). I have sought clinical and specialist advice from a specialist external professional adviser (the Adviser - a Consultant Urologist) who was provided with all the documentation held by the Ombudsman's office on Mr C's complaint. This report necessarily contains technical language, much of which

[1] On 3 September 2007 Scottish Ministers formally adopted the title Scottish Government to replace the term Scottish Executive. The latter term is used in this report as it applied at the time of the events to which the report relates.

has been used by the Board in their communications with Mr C. The full glossary of terms is contained in Annex 2.

9. I have not included in this report every detail investigated but 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.

History of Complaint

10. The following paragraphs give a summary of the history of the treatment of Mr C's erectile dysfunction by the Board as contained in his medical records.

11. The records show that Mr C has been suffering from erectile difficulties since around 1993 and was seen by a private Consultant Urologist (Consultant 3) in March 1996 about his erectile dysfunction. The records state that Consultant 3 recommended intracavernosal injection and vacuum therapy, although Mr C was of the view that he was told that a penile implant would be the appropriate treatment. On 4 April 1996 Mr C was referred to the Urology Clinic at Hospital 1 by his GP. He was seen by a Senior House Officer (SHO) at the clinic in November 1996. The SHO noted that Mr C had a history of erectile dysfunction, that he separated from his wife approximately ten years earlier and prior to that had enjoyed a full sexual relationship. He stated that Mr C subsequently became involved with another woman and became 'increasingly anxious about his ability to perform which manifested in him being unable to gain erections'. The SHO noted that this relationship subsequently floundered and since then Mr C had become increasingly anxious about being involved with other women. It was also noted that Mr C usually woke with an early morning erection and was able to masturbate at least once a week. The SHO stated that Mr C was 'not keen' for the intercavernosal injection or vacuum therapy treatment which had previously been suggested by Consultant 3 in March 1996 and had read about penile implants but felt that he could not afford that privately. The SHO said that although it appeared, from the records, that Consultant 3 had made no mention of a penile implant, Mr C was 'keen for this'. The SHO said he felt Mr C's 'main problem [was] actually anxiety related' and that Mr C would benefit from a course of counselling. Mr C was referred to a sexual therapist in December 1996.

12. Mr C received counselling at an appointment with a psychosexual therapist later that month. In January 1997, as a result of this appointment, the therapist wrote to the SHO at the urology clinic at Hospital 1 asking for Mr C to

attend for injection therapy. Mr C's GP also made a further referral to the urology clinic at Hospital 1 in May 1997 in which he stated that Mr C had asked for a 'prosthesis'.

13. Before an appointment could be arranged, Mr C was sent to prison from 10 July 1997 to 7 July 2000.

14. On 14 July 2000 Mr C was again referred by his GP to the urology clinic at Hospital 1 for further treatment of his erectile dysfunction. Mr C then began a series of treatments at the urology clinic at the hospital. These included Viagra, injection treatment, intra–urethral muse and sexual counselling. The records show that the Viagra and muse treatments were unsuccessful and stated that Mr C indicated he was not happy to self-inject. During this time, on 18 April 2001, an appointment was made with Consultant 1, at Mr C's request, to discuss penile implants. After the appointment, Consultant 1 wrote to Mr C's GP describing Mr C as having 'a somewhat unusual personality' and a 'rather complicated social life' with no regular partner. He stated '[Mr C] seems to feel that what he really wants is a penile prosthesis to be inserted but I would be reluctant to suggest this at this stage as it is a fairly irrevocable step and if he does indeed have an unstable personality could cause problems'. Consultant 1 noted that when he injected Mr C with Caverject Mr C obtained a complete erection 'adequate for sexual intercourse'. As Mr C was not keen to self-inject, he was offered other less invasive treatments.

15. On 1 October 2001 Consultant 1 again wrote to Mr C's GP noting that 'the penile prosthesis has been a recurring theme' with Mr C during his appointments at the clinic. He explained 'For a number of reasons I have considerable reservations about this. [Mr C]'s background does suggest a fairly strong psychiatric element to his erectile dysfunction, and I do wonder really [if] he would cope with the complexities of using prosthesis. In addition, a prosthesis in a stable relationship with a caring partner is often very satisfactory but in the situation in which [Mr C] wishes to use it, namely as an aid to obtaining a sexual partner when he does not have one might not be particularly satisfactory'. Consultant 1 indicated that he was in the process of arranging for Mr C to be reviewed at the psycho-sexual counselling clinic. On 12 July 2002, after seeing Mr C, a nurse specialist from the psycho-sexual counselling clinic wrote to Consultant 1 regarding Mr C's attendance at the clinic. She noted that Mr C 'still feels that a penile implant is the answer and nothing else will do'. She explained that Mr C was very difficult to engage in psycho-sexual counselling as

his views and feelings were not open to discussion or negotiation. She added '[Mr C]'s feeling is that his penis does not work now and the situation cannot be any worse if he has an implant and might be better'. She explained that she would be seeing Mr C again at the clinic.

16. On 2 September 2002 Consultant 1 wrote to Mr C reiterating that the correct treatment for Mr C was injection therapy, offering to provide this treatment and again stating that he was not prepared to recommend that a penile implant be inserted. On 10 September 2002 Mr C attended a further appointment at the urology clinic at Hospital 1. The medical notes state Mr C indicated he did not want to try intracavernosal injections again as he felt that he would be unable to inject himself and that he decided he would not try a vacuum erection device. It was noted that Mr C indicated he still wanted to go down the line of penile prosthesis and was not interested in alternative treatments.

17. Nonetheless, the treatment continued and on 26 February 2003, during a program of injection treatment at Hospital 1, Consultant 1 noted there was 'quite a marked bend' in Mr C's penis. Consultant 1 recorded 'It looks as though in addition to [Mr C]'s erectile failure he has in addition some Peyronie's disease'. Consultant 1 said 'I have suggested that we get [Mr C] in in due course to do a Nesbit's operation to straighten up the penis'. He explained 'I think provided that we can get his penis to be straight, he would then have a perfectly adequate erection with 20mcg of Caverject to allow him to achieve normal intercourse and I hope that the outcome of this will prove to be satisfactory'.

18. The Nesbit's operation and a foreskin trim were performed by Consultant 1 on 29 May 2003 and the operation note stated that Mr C would be reviewed 'in three months time when all is healed to re-institute [Mr C]'s injection treatment'. In a letter to Mr C's GP, Consultant 1 explained the follow-up arrangements for the operation. Mr C's follow-up appointment eventually took place on 15 October 2003, one and a half months after the intended date. In his letter to Mr C's GP, Consultant 1 apologised for 'some failure' in organising the appointment and advised Mr C's penis now had a 'little bend to the left'. He explained that he thought the bend should not be sufficient to prevent intercourse and that part of the problem was that the bend which was corrected by the operation was not marked and perhaps would not, under normal circumstances, have merited correction. Consultant 1 explained that he would continue to treat Mr C's condition with Caverject.

19. On 18 November 2003, Consultant 1 wrote to Consultant 2 at Hospital 2 to arrange for Consultant 2 to carry out an assessment of Mr C. He provided information on Mr C's history of treatment at the clinic and noted with recent escalating doses of Caverject Mr C 'does get an almost full erection although it isn't still completely rigid'. Consultant 1 explained that he felt that a penile implant was not the appropriate treatment and that Mr C could be managed with less invasive methods. He added 'my reason for my suggesting you see him is not because I am referring him for an operation, but that I feel that assessment by the individual who would do that operation, and if you agreed, re-enforcement of my advice against the operation would be helpful'. He went on the say 'I really am concerned that for various reasons surgery is not the appropriate way to proceed'.

20. After Mr C missed two appointments, Consultant 2 finally saw him on 29 June 2004 and afterwards indicated in his letter to Consultant 1 that he concurred with Consultant 1's thoughts about Mr C's personality and approach to sexuality and sexual function. Consultant 2 stated that he did not think that a penile implant was a realistic option for Mr C and, having given Mr C a higher dose of Caverject with fairly positive results, recommended further injection treatment. Mr C has advised that he was unable to attend the second missed appointment as he was being allocated a housing association house that day. He said that he went to the hospital later that day and explained the reasons for his failure to attend the appointment to the staff on reception.

21. On 30 June 2005, after trying further treatments, Consultant 2 performed a penile insufflation and cavernosometry on Mr C. On 31 August 2005 Consultant 2 wrote to Mr C's GP advising him of this. He noted 'insufflation showed a straight penis with no obvious Peyronie's disease. There was a mild deviation to the left to an insignificant degree'. He concluded 'I think [Mr C]'s only option would be a penile implant. I do, however, feel in view of some of his personality issues psychological assessment would be worthwhile'. When making the referral to a Consultant Psychiatrist, Consultant 2 explained '[Mr C] has erectile dysfunction and would require an implant. I have some reservations about him in terms of personality and approach to sexual relationships. There is marked aggressive expressive feelings when discussing women and in the absence of a partner I think a psychosexual evaluation from yourself would be very valuable prior to me considering implant surgery'.

22. The records show that Mr C was assessed by a Consultant Psychiatrist on 8 December 2005, who wrote to Consultant 2 the next day noting that Mr C now had a 'steady girlfriend' and advising 'there is no contra-indication on psychiatric grounds for [Mr C] to have a 'penile implant''.

23. On 14 December 2005 Consultant 2 wrote to Mr C's GP advising him of the outcome of the assessment and confirming that he had put Mr C's name on the waiting list. The letter was copied to Mr C.

24. On 9 March 2006, in response to a letter of enquiry from Mr C, Consultant 2 confirmed that Mr C had been on Consultant 2's waiting list since 14 December 2005.

(a) It was unreasonable for the Board to have taken nine years to agree to Mr C's request to be considered for a penile implant operation; and (d) The Board failed to provide Mr C with appropriate care and treatment for his erectile dysfunction

25. The information below (paragraphs 26 to 34) is a summary of the Adviser's opinion on the above heads of complaint.

26. Mr C presents with a difficult case of erectile dysfunction. In 1996 it was documented that Mr C was able to obtain early morning erections and, later, that Mr C had a good response to intracavernosal injection therapy, which suggests there is a strong likelihood that Mr C's erectile difficulties were due to a psychological cause. Treatment options at that stage would have been either to have referred him for psycho-sexual counselling or, alternatively, intracavernosal injection therapy or a vacuum erection device. These treatment options were offered to Mr C and, therefore, his management was of a standard level of practice.

27. It is quite clear from the documentation that Mr C was not keen for any of these treatments and immediately, from the start of his consultations, wished to have a penile prosthesis inserted. The reason for this is unclear and it would be unusual, in my experience, to have a patient who wished to go straight to a penile prosthesis without having tried other methods of treatment.

28. Following this time, Mr C did take drugs such as Viagra and Uprima and did not obtain a response to these. It is also clear that, on occasions, he was able to obtain erections satisfactory or hard enough for intercourse, as

documented by the clinicians, but on other occasions the erection was inadequate. This is not an uncommon problem, especially in the clinical setting. Over the years, Mr C's erectile dysfunction, in my opinion, was treated in an appropriate manner. Because Mr C has not responded to intracavernosal injection therapy he has been finally offered a penile prosthesis, which in my opinion would be the only option in this kind of case.

29. Although it would appear that Mr C has 'waited' nine years for a penile implant, this must be said with caution as it is quite clear that Mr C has refused or not used treatment recommendations such as intrarcavernosal injection therapy from the original consultation in 1996. He also refused a vacuum erection device and it is quite clear that he would appear to have been fixated with the concept of a penile implant from his original consultation. In my opinion a ten year wait for a penile implant would be a long wait, however, given the fact as outlined in Consultant 1's letters that the insertion of a penile implant is an irreversible procedure and in fact can lead to significant complications such as infection and erosion, I think it is perfectly reasonable that Mr C waited for a time period before an implant had been agreed to. I also believe that this was done in the patient's best interests as again detailed in Consultant 1's letters. In other words, it would not be in his best interests without adequate psychiatric assessment and psycho-sexual counselling to consider a penile implant in a man who appears to have no physical basis to his erectile difficulties. For this reason, he was referred to a number of clinics for a number of treatments for his erectile dysfunction and, therefore, I do not think it would be unreasonable for him to have waited a period of time for surgery. It is also quite clear that he failed to attend clinic on two occasions and it would also appear from the notes that he did not conform to treatment ie did not in fact inject himself with Caverject.

30. Overall, I feel that Mr C has received appropriate counselling regarding his sexual dysfunction. There is clearly a question over the suitability in implanting a prosthesis in Mr C from what I can see from the notes. There appears to be a reason for the fact that the clinicians concerned did not feel comfortable placing an implant in Mr C for other 'psychological reasons', which do not appear to be outlined or explained. However, it would seem that, from the information on file, the psycho-sexual counsellor did not feel that there are any contraindications to Mr C having an implant.

31. Overall the quality of the clinical records is good and I would commend the

clinicians, including Consultants 1 and 2 in their record-keeping and documentation of consultations. The Board's response to Mr C's complaints has been prompt and has been dealt with adequately with referral to Consultant 1.

32. In my opinion, the treatment that Mr C has received has been appropriate in terms of erectile dysfunction. However, I feel that there has been a lack of communication from the Psychiatric Department regarding the psychiatric assessment for this patient which is clearly important when undertaking a penile prosthesis in cases such as this. Had a definitive report been available which documented either a cause ie psychiatric problem (for his erectile dysfunction) or alternatively a personality disorder to account for his demand for a penile prosthesis at an earlier stage then he may have had a penile implant inserted in a shorter timeframe. However, it is clear that the reluctance to place an implant in this man was perfectly justified as his etiology for erectile dysfunction was unknown and, furthermore, Mr C did not wish to comply with conventional treatments. Given the fact that there is an approximately 20% dissatisfaction rate from penile implant surgery, overall the measures undertaken by the clinicians in this case were entirely appropriate.

33. It is clear from the notes that Mr C has sought a penile implant for a number of years without wishing to use any other treatments. It is also clear to me that the clinicians involved have tried their utmost to treat Mr C to an appropriate level of care. I do not believe his treatment has been substandard, although he should have undergone earlier psychiatric assessment and this should have been full and complete with good documentation within the notes, so a decision regarding a penile implant could have been made at an earlier stage. I have no doubt that psychotherapy would not have been successful for Mr C and ultimately he would still have demanded a penile implant despite this treatment.

34. Overall, I feel that Consultant 1 has acted in Mr C's best interest, although once a formal psychiatric assessment was done and it was deemed that there was no psychiatric reason to withhold the implant operation, the operation should have been conducted at an earlier stage.

35. During my enquiries the Board advised that Consultant 1 had retired in 2005 and was, therefore, not available for questioning.

(a) and (d) Conclusion

36. Although Mr C first appears to have requested a penile implant in 1996, Mr C was in prison for three years, from July 1997 to July 2000, and was not the responsibility of the Board during that period. It would, therefore, be more accurate to say that Mr C had 'waited' six years to be considered by the Board for the operation.

37. It is clear that the penile implant operation is viewed as a last resort in the treatment of Mr C's condition and the Board were right to be reluctant to provide this operation because its success was not guaranteed and the operation was irreversible. I consider the Board acted in Mr C's best interests by providing him with appropriate alternative treatment for his condition and Mr C's refusal to consider the full range of treatment options has been unhelpful in the treatment of his erectile dysfunction. However, had a definitive report been available documenting whether there was a psychological reason for Mr C's demands for the penile implant, then Mr C may have had the implant inserted sooner.

38. I conclude that it was reasonable for the Board to have waited a number of years before considering Mr C for the implant but that, had a well documented psychiatric report been available at an earlier stage, then the wait for the operation could have been reduced. I, therefore, partially uphold head of complaint (a).

39. I agree with the Adviser's opinion on the Board's overall treatment of Mr C's condition and conclude that the care and treatment which Mr C received from the Board was appropriate. I, therefore, do not uphold head of complaint (d).

(a) Recommendation

40. The Ombudsman recommends that the Board apologise to Mr C for the delay in providing his penile implant operation and take steps to ensure that early, well documented psychiatric reports are produced in future cases of this type when requested or required.

(b) The Board failed to correctly perform a Nesbit's operation, to correct the bend in Mr C's penis, which resulted in the bend moving from the base to half way up Mr C's penis; and (c) Mr C did not have his follow-up appointment three months after his operation, as planned, and had to contact the hospital to ask for the appointment to be arranged

41. In an internal email dated 6 April 2005, generated as a result of one of Mr C's letters of complaint, Consultant 1 said that one of the complications of Caverject injections can be that a bend develops in the penis, but in Mr C's case it was 'not too clear whether the site of the deformity coincided with the injection site'. He explained that he performed the Nesbit's operation 'whereby incisions opposite the bend are made and closed transversely to create an opposite bend which corrects the deformity'. He stated 'All this would have been explained to [Mr C]'. Consultant 1 added that the resulting bend 'did not seem severe, and was to the left, rather than dorsally (as the original one was) suggesting that one of the two incisions used to correct it had slightly overcompensated. I would emphasis that even the original deformity was not great and the new one less so, and in someone who was having regular sexual activity would probably not have created a practical problem – in which case surgery would not have been indicated. It is extremely difficult to manage erectile dysfunction 'in the cold' ie when the patient has no regular sexual partner, and this is one of the problems we have had in dealing with [Mr C]'. Consultant 1 acknowledged that there had been a delay in the arrangements for Mr C's follow-up appointment but said 'what actually happened and how the appointment was made is not clear'.

42. The information below (paragraphs 43 to 45) is a summary of the Adviser's opinion on the above heads of complaint.

43. The Nesbit's procedure was performed in order to straighten Mr C's penis. The bend may have occurred due to Peyronie's disease in itself or, alternatively, the most likely cause for the bend in Mr C's penis would have been the injection therapy. The bend, however, was not severe enough to prevent sexual intercourse.

44. It would appear from the operation notes that Mr C had a bend which was on the dorsum of the penis, or his penis bent up, but there is no documentation on the degree of curvature. It would appear post-operatively Mr C developed a lateral bend to the penis which is unusual given the fact that surgery would have been performed on the opposite side of the bend. This could possibly mean, as

documented in Consultant 1's letters, that too much of an ellipse was taken during the Nesbit's procedure and this had caused the residual bend. However, it is quite clear the bend was deemed on artificial erection not to be of the extent to interfere with intercourse or penetrative sex.

45. Regarding the follow-up of this patient, he should have ideally been seen at six weeks and then three months following surgery. There would have appeared to have been an unnecessary delay in his follow-up although I do not feel that this would have contributed to any potential complications.

(b) Conclusion

46. It is clear from the medical records that the Nesbit's operation removed the original bend in Mr C's penis, but resulted in a bend at the opposite side of his penis. It is noted that Consultant 1 has said that the original deformity was 'not great' and 'the new one less so'. However, it is not possible to determine, from the medical notes, the actual degree of the curvature and there is no information on file detailing whether Mr C was advised prior to the Nesbit's operation that, due to the procedure adopted, the operation could result in the bend moving from one side of his penis to the other. As previously noted, Consultant 1 has now retired and would not be available for comment. Therefore, in light of the lack of evidence in this area, I am unable to make a finding on this complaint.

(c) Conclusion

47. It is clear that there was a one and a half month delay in Mr C's follow-up appointment. Although it is noted that the Adviser said this would not have contributed to any potential complications, the delay obviously caused Mr C some concern. I, therefore, partially uphold this complaint.

(c) Recommendation

48. The Ombudsman recommends that the Board apologise to Mr C for the delay in his follow-up appointment.

(e) The Board failed in their handling of Mr C's case from the point at which he was advised that he would be considered for the penile implant operation, ie July 2005, onwards, including that Mr C was later advised by the Board that the operation was not available within the NHS in Glasgow

49. On 10 April 2006, during the course of this investigation, Mr C wrote to the Ombudsman's office to complain that he still had not had his penile

operation or been provided with a date for the operation. I forwarded the letter to the Board and asked them to respond. On 25 July 2006 the Board wrote to Mr C in response to the 10 April letter and other letters of complaint which Mr C had sent to the Board during that period. The Board explained the history of their treatment of Mr C's condition and confirmed that 'following a positive report from the Psychologist, [Consultant 2] placed [Mr C] on his waiting list on 14 December 2005 for a penile implant'. The Board went on to say 'However, unfortunately, this procedure is not currently available within NHS Glasgow and would require to be approved by the Clinical Governance Committee before consideration for funding can be taken forward. At this stage, we are unable to offer you a date for your surgery and I am sorry for any further upset this may cause'. They said 'The Urology Clinical Service Manager and [Consultant 2] have been requested to develop the Clinical Governance case for this interventional procedure and we will update you on the progress with this as soon as we have the decision from the Clinical Governance Committee. We will then seek funding if the Clinical Governance Committee supports the interventional procedure'.

50. As a result of this information, I made several enquiries of the Board over the following months in order to try to obtain a clear picture of how the Board had handled Mr C's case after Consultant 2 had added Mr C's name to his waiting list. I was concerned that Mr C had assumed that as he was on the waiting list he would get the procedure in due course when, in fact, it appeared that the operation may not have been available. In their responses, the Board explained 'In the past, one piece penile implants were the only device available to Urology Consultants to offer patients with erectile dysfunction who required penile implant. The decision to proceed to a one piece implant has to be carefully assessed, as it is viewed as a last resort treatment and is a clinical decision made by the Consultant. Generally, only patients in a stable relationship with a long-term understanding partner would be considered for such a procedure, because of its irreversibility and associated difficulties encountered. However, there is no dedicated funding for penile implant and, in the past, the procedure would only have been done on an individual basis, and following careful review of the clinical care and counselling of both the patient and partner. In [Mr C]'s case he did not have a partner, he did not meet the criteria and there were less invasive medical options available to him, which have proved effective in the past for other patients. Additionally, a clinical decision was made by [Consultant 1] that the one piece implant was not appropriate for [Mr C]'. The Board later confirmed that Mr C was on

Consultant 2's waiting list for a new 2/3 part inflatable penile implant.

51. The Board explained that the Directive issued in January 2004, which was implemented by the Board in December 2004, stated that any clinician planning to undertake a new interventional procedure should seek the approval of their organisation's Clinical Governance Committee before carrying out the procedure. They said that this meant that procedures such as 2/3 part inflatable penile implant surgery required to be submitted for approval by the Clinical Governance Committee but that the older style one piece semi rigid penile implant surgery did not require clinical governance approval as it was already an established procedure undertaken by the Board. The Board said 'the Urology Consultants who perform penile implant surgery in Glasgow had been asked to submit a new interventional procedure request in relation to use of a 2/3 part implant for erectile dysfunction treatment. The Clinical Service Manager and Urology Consultants have collated information of the clinical evidence and criteria for treatment, but have not yet finalised the paper which will go to the Clinical Governance Group for peer review. Once the submission has been agreed by the Clinical Service Manager and Lead Clinician, the process will involve presentation to the Clinical Governance Committee for agreement as an accepted change in treatment. If agreed by the Clinical Governance Committee, the proposal would then be taken forward for funding via the [Board]. We are unable to provide a timescale for completion of this process at present'.

52. The Board provided me with a copy of the Directive as well as their own Policy and Process Document on new interventional procedures, which implemented the terms of the Directive. The Directive states 'an interventional procedure should be considered new if a doctor no longer in a training post is using it for the first time in his or her clinical practice'. When questioned, the Board said that Consultant 2 had performed the new inflatable implant procedure before in the NHS but that these were in 'special' one-off cases considered on an individual patient basis and were prior to the implementation of the Policy and Process Document. They explained that the Management Team within the Surgical Directorate were satisfied that the procedure required a Clinical Governance Review and approval in line with the Directive on New Interventional Procedures. They said 'Robust clinical evidence for the use of the new penile implant (versus the old implant) and agreement on the criteria and competence of the surgeon is required prior to the submission of the clinical business case to provide this as a mainstream service provision'.

53. The Board further explained that when a decision is made to offer a patient the option of a penile implant, as this procedure is not routinely available from the Board, the Consultant adds the patient to his waiting list with an ASC code or 'availability status code', which means that the availability of the operation is not guaranteed. Thereafter, each patient is considered for surgery on an individual basis.

54. The Board advised that in light of the correspondence from the Ombudsman's office, from Mr C himself and the clinical psychological review, Consultant 2 undertook a review of Mr C's case and 'thinks it would now be prudent to proceed to offer treatment to [Mr C]. From his own findings [Consultant 2] is suggesting the insertion of a semi rigid penile implant would be more satisfactory than the new inflatable device that [Consultant 1] had suggested. This semi rigid device would not require clinical governance approval ... [Consultant 2] has advised that initially [Mr C] had a degree of Peyronie's disease and an inflatable implant would have therefore been indicated. However, [Consultant 2] has now clinically reviewed [Mr C] on a number of occasions and considers there is currently no evidence of Peyronie's disease so a semi rigid implant would be more satisfactory in a gentleman of his age. [Consultant 2] has arranged to see [Mr C] on 19 January [2007] to discuss this with him and if he is happy, to arrange for a semi rigid implantation'.

55. In response to my questions about what type of implant procedure (semi rigid or inflatable) would have been originally available, the Board advised that a semi rigid implant would have been available at the time of Mr C's original consultations with Consultant 1, however, Consultant 1 had decided to refer Mr C to Consultant 2 who was a specialist in Andrology. They said that Consultant 2 was being asked for clinical expertise as well as his opinion on Mr C's suitability for implant surgery. They advised the referral was complex because of both the Peyronie's disease and the erectile dysfunction problem Mr C was experiencing. The Peyronie's disease would have prevented a semi rigid implant working. At that time Mr C, therefore, required investigation for Peyronie's disease. However, while under Consultant 2's care, this condition seemed to resolve without further treatment being required. The Board said Consultant 2 had confirmed that the condition can resolve without specific medical intervention and that this became evident during Consultant 2's review of Mr C in 2007. They said the issue of psychological evaluation also required to be discussed and the insertion of any implant could present a significant

impact on a patient's life.

56. Consultant 2 met with Mr C on 19 January 2007 and they agreed to the semi rigid implant and the surgery took place on 12 March 2007.

57. When questioned, the Board confirmed that Consultant 2 had not actually met with Mr C since June 2005 and that, by 'review of [Mr C] this year', they meant Consultant 2's most recent review of Mr C's case history. The Board acknowledged that when Consultant 2 last met with Mr C, in June 2005, he noted that Mr C had 'a straight penis with no obvious Peyronie's disease'. They explained that Consultant 2 'said by 'no Peyronie's' he would generally mean no deformity on erection. However, he advises that Peyronie's not only causes deformity (which would only be straightened by an inflatable implant) but causes fibrosis in the penis which may make an inflatable the only option (because of the size and physical qualities only available in the inflatable models). Final review of Mr C [on 19 January 2007] suggested a satisfactory, soft, non-scarred penis and as such semi rigid was selected due to the ease of insertion and preferred use in an older man with limited dexterity, and no regular sexual partner'.

58. The Board added '[Consultant 2] has said that he still retained significant doubts over [Mr C]'s suitability for treatment and surgery which renders him sexually active. He was concerned that [the Consultant Psychiatrist]'s report may not have covered all aspects and had considered whether a further forensic psychology review would have helped. However, following discussions with the General Manager and Clinical Services Manager and review of past correspondence on the case between [Consultant 1] and the Director of Public Health, it was felt that further assessment in this area was unlikely to be of help in reaching the decision on appropriateness of implant treatment'.

59. The Board conceded that, in terms of managing Mr C's expectations, perhaps they should not have added Mr C's name to the waiting list until it was clear what surgery was appropriate and that the operation being considered was available.

60. The Adviser said that he did not feel that the choice of a semi rigid implant versus an inflatable implant would make any difference to the outcome of Mr C's care. He explained that the only factor which determines whether or not a patient will have an inflatable device is whether they are manually dextrous

enough to have the device.

(e) Conclusion

61. When Mr C's name was added to the waiting list for a penile implant operation in December 2005, Mr C was reasonably of the impression that, in the fullness of time, the operation would go ahead. It is clear that, prior to receiving the Board's letter of 25 July 2006, Mr C had not been advised that the availability of the 2/3 piece inflatable implant was subject to a number of administrative restrictions. It is noted that Mr C only received this information after writing repeated letters of complaint to the Board.

62. The Board have indicated that, even though the records show that Mr C received a satisfactory psychological assessment for his suitability for the implant operation prior to being placed on the waiting list, they were not entirely satisfied with this outcome and considered that a further psychological review may be necessary. It is clear that this had not been communicated to Mr C at any stage. The Board have also advised that Consultant 2 was able to consider Mr C for the semi rigid implant because Mr C's Peyronie's disease had resolved itself 'without further treatment being required'. However, it is clear that Consultant 2 had not seen Mr C since June 2005, when he had already noted 'no obvious Peyronie's disease' and that the Board's decision to offer Mr C the semi rigid implant was made without any new information on the Peyronie's disease or a further psychological review of Mr C having being made.

63. Although the Board have now operated on Mr C, it is clear that, from the point at which Mr C's name was added to the waiting list for the operation, they failed to advise him of any of the conditions or restrictions which applied in his case. It is noted that the Board have conceded that they may have acted prematurely in adding Mr C's name to the waiting list. I consider the Board failed in their handling of this aspect of Mr C's case and I, therefore, uphold this complaint.

(e) Recommendation

64. The Ombudsman recommends that the Board apologise to Mr C for their failings in this area and take appropriate steps to ensure that, in future cases of this type, patients' names are not added to waiting lists prematurely and that they are advised of any conditions or restrictions which apply.

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

accordingly. The Ombudsman asks that the Board notify her when the recommendations have been implemented.

Annex 1

Explanation of abbreviations used

Mr C	The complainant
The Board	Greater Glasgow and Clyde NHS Board
Consultant 1	Consultant Urologist
Hospital 1	Gartnavel General Hospital
Consultant 2	Consultant Urological Surgeon
Hospital 2	Stobhill Hospital
The Directive	'Scottish Executive Health Department Directorate of Service Policy and Planning' letter on new interventional procedures
The Policy and Process Document	The Board's 'New Interventional Procedures, Process for Clinicians To Follow If They Wish to Undertake a New Interventional Procedure'
The Adviser	The Ombudsman's Consultant Urologist
Consultant 3	Private Consultant Urologist
SHO	Senior House Officer

Annex 2

Glossary of terms

Andrology	Branch of medicine concerned with conditions specific to the male reproduction system
Caverject	Self injection treatment for erectile dysfunction which allows normal erections/sexual activity
Cavernosometry	A technique in which fluid is pumped into the penis and measures the vascular pressure in the corpus cavernosum
Intra – urethral muse	Urethral suppository
Intracavernosal injections	Injection into a cylinder shaped vascular tissue body (corpora cavernosa) in the penis
Nesbit's operation	Operation whereby incisions opposite the bend in the penis are made and closed transversely (lying across at right angles) to create an opposite bend which corrects the deformity
Penile insufflation	Procedure where saline is blown into the penis to allow any deformity to be assessed
Penile prosthesis implant	Piece of plastic inserted into penis which makes it permanently stiff – mechanism to achieve natural erection destroyed as a result
Peyronie's disease	A development of plaques within the erectile tissue of the penis that cause the penis to bend on erection
Uprima/Viagra	Oral drugs used to treat erectile dysfunction
Vacuum erection device	Mechanism for increasing blood supply to the penis

Annex 3

List of legislation and policies considered

Scottish Executive Health Department Directorate of Service Policy and Planning' letter on new interventional procedures

The Board's 'New Interventional Procedures, Process for Clinicians To Follow If They Wish to Undertake a New Interventional Procedure'