SPSO Scottish Public Services Ombudsman

The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

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Scottish Parliament Region: Glasgow

Case ref: 201401527, Greater Glasgow and Clyde NHS Board - Acute Services Division
Sector: Health
Subject: Hospitals; clinical treatment; diagnosis

Summary
Mr C had an abdominal tumour, and saw a consultant who recommended that the tumour should be surgically removed. The consultant started Mr C on medication that helps to prevent dangerous rises in blood pressure related to the surgery he was due to undergo. In January 2013 Mr C completed a consent form agreeing to undergo surgery to remove the tumour. The form did not specify any potential risks of the operation that the surgeon performing the procedure had discussed with Mr C, or that any discussion had taken place around any extra procedures which may become necessary. Surgery took place the next day.

Mr C was then reviewed the following month by the surgeon who wrote to Mr C's GP to say that Mr C had reported difficulty with ejaculation but had experienced problems with this in the past. Mr C was seen by a urology doctor (specialising in problems of the urinary tract and reproductive organs) in November 2013, where Mr C said he was still having problems with ejaculation. Tests confirmed that Mr C had retrograde ejaculation (where semen enters the bladder rather than coming out of the penis). Mr C had further follow-up appointments with the consultant who had recommended the surgery, and the surgeon who had carried it out. Mr C complained to the Board about the lack of information he was given about retrograde ejaculation before the planned surgery, and that the surgeon had told him that he did not foresee any complications arising.

In the Board's response to Mr C's complaint, they did not clearly respond to Mr C's complaint about the information he was provided with during the consent process. Instead, they focused on the reasons why they felt it was unlikely that Mr C's operation was the cause of the retrograde ejaculation, and said that this was a problem Mr C suffered from in the past, which Mr C disputed. Mr C then complained to my office.

In considering Mr C's complaint, I took independent medical advice from a consultant urological surgeon who specialises in sexual dysfunction, who said that whilst the medication Mr C had been prescribed prior to the surgery (to regulate blood pressure) does have a side effect of causing retrograde ejaculation, this would only last for the short time the drug was prescribed and administered. My Adviser said that the surgical procedure Mr C had was not very common, and, therefore, it is logical to refer to data for similar and more common operations which take place in the same region of the body but for different conditions. For operations of a similar nature, my Adviser said that retrograde ejaculation is a rare but recognised side effect and this should have been discussed with Mr C when consent was obtained for the procedure. The Adviser also noted that there are other potentially very serious risks to major arteries and veins when undertaking surgery in this area.

Whether or not Mr C previously reported problems with retrograde ejaculation prior to surgery, I found this was only documented in the post-surgery notes taken a month after the surgery was carried out. There was nothing in the notes leading up to the surgery about this. In relation to the information Mr C was given, I consider that the surgeon should have warned Mr C about the possible risks or complications. Whilst the risk of this side effect occurring is very small, General Medical Council guidance says that patients must be told about recognised serious adverse outcomes, even if they are rare. There is no clear evidence to demonstrate this was done or indeed that discussion took place about other major structures close to the operative area being at risk of injury with possible significant consequences.

Redress and recommendations

The Ombudsman recommends that the Board:	*Completion date*
(i) apologise to Mr C for failing to ensure that he was fully informed of the risks associated with his surgery; and	15 July 2015
(ii) ensure that their consent policy includes guidance on the importance of accurately recording conversations with patients regarding risks and complications as part of the consent process.	12 August 2015

Who we are

The Scottish Public Services Ombudsman (SPSO) investigates complaints about organisations providing public services in Scotland. We are the final

stage for handling complaints about the National Health Service, councils, housing associations, prisons, the Scottish Government and its agencies and departments, the Scottish Parliamentary Corporate Body, water and sewerage providers, colleges and universities and most Scottish public authorities. We normally consider complaints only after they have been through the complaints procedure of the organisation concerned. Our service is independent, impartial and free. We aim not only to provide justice for the individual, but also to share the learning from our work in order to improve the delivery of public services in Scotland.

The role of the SPSO is set out in the Scottish Public Services Ombudsman Act 2002, and this report is published in terms of section 15(1) of the Act. The Act says that, generally, reports of investigations should not name or identify individuals, so in the report the complainant is referred to as Mr C. The terms used to describe other people in the report are explained as they arise and in Annex 1.

Introduction

1. Mr C complained to the Ombudsman about not being warned of the risks of infertility associated with surgery to remove a para aortic paraganglioma (abdominal tumour). Following surgery at Gartnavel General Hospital, Mr C experienced difficulties ejaculating and further tests showed that he had retrograde ejaculation.

2. The complaint from Mr C I have investigated is that Mr C was not reasonably advised of the risk of developing retrograde ejaculation as a side effect of the surgery undertaken on 8 January 2013 (*upheld*).

Investigation

3. In order to investigate the complaint, my complaints reviewer sought information from both Mr C and Greater Glasgow and Clyde NHS Board (the Board), including copies of the complaint correspondence and clinical records. This information was reviewed and independent advice obtained from a consultant urological surgeon specialised in sexual dysfunction (the Adviser). In this case, we have decided to issue a public report because of the significant personal injustice to Mr C.

4. 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.

Complaint: Mr C was not reasonably advised of the risk of developing retrograde ejaculation as a side effect of the surgery undertaken on 8 January 2013

5. On 1 November 2012, Mr C saw a consultant physician (the Consultant Physician) who advised that he should have the abdominal tumour removed. Mr C had concerns about the operation and was referred to a surgeon (the Surgeon) in order that the benefits and risks of surgery could be discussed with him. The Consultant Physician also recommended commencing phenoxybenzamine therapy (medication to prevent dangerous rises in blood pressure related to surgical manipulation and removal of the tumour) in the run up to surgery if Mr C agreed to go ahead with the operation. From the clinical records available, it is unclear what risks or complications were discussed with Mr C. On 7 January 2013, Mr C completed a consent form agreeing to undergo surgery to remove the abdominal tumour. The consent form did not specify any potential risks of the operation that the Surgeon had discussed with Mr C or that

discussion had taken place around any extra procedures which may become necessary.

6. After the surgery was carried out on 8 January 2013, Mr C was then reviewed by the Surgeon on 15 February 2013 who wrote to Mr C's GP (the GP) advising that Mr C had reported difficulty with ejaculation but had experienced it in the past. However, the Surgeon further commented that he was sure it was the episode in hospital that had brought it on. When Mr C was reviewed by a urology doctor (the Urology Doctor) on 5 November 2013, it was noted that he was continuing to have problems with ejaculation. It was also documented that the phenoxybenzamine he was taking immediately prior to the surgery can cause retrograde ejaculation but that this was normally reversible on stopping it. Tests were arranged, and the results in December 2013 confirmed that Mr C had retrograde ejaculation. On 29 April 2014, Mr C saw the Consultant Physician who noted that Mr C had only taken the medication for a short period of time before surgery and considered it was unlikely that it would have caused the retrograde ejaculation to be irreversible. On 4 July 2014, Mr C was reviewed by the Surgeon who further noted in a letter to the GP that the surgery was unlikely to have caused the problem but 'one can never tell for sure'.

7. In Mr C's letter to the Board on 12 March 2014, he complained about the lack of information he was given about retrograde ejaculation before the planned surgery was carried out. Mr C also highlighted that the Surgeon had told him that he did not foresee any complications arising.

The Board's response to the complaint

8. In responding to the complaint on 8 April 2014, the Board did not clearly comment on the concerns Mr C raised about what information was discussed with him about risks associated with surgery. They concentrated on the reasons why they felt it was unlikely that Mr C's operation was the source of his retrograde ejaculation. The Board explained to Mr C that, because the paraganglioma was adjacent to the common iliac artery and not near the nerves (hypogastric plexus) that are important for sexual function, it would be unlikely that the operation was the source of the retrograde ejaculation. The Board further commented that the Urology Doctor had felt the problem with ejaculation was possibly related to Mr C's surgery but this opinion had not taken into account that Mr C had also experienced the ejaculation problem prior to surgery.

9. Mr C wrote to the Board again highlighting that he had not experienced or reported problems with ejaculation prior to the surgery on 18 January 2013. In response to this, the Board said that on 15 February 2013, the Surgeon had noted in the clinic letter to the GP that Mr C had experienced difficulty with ejaculation in the past.

Relevant guidance

10. The General Medical Council (GMC) publishes national guidance on consent issues for registered doctors. Their publication entitled 'Consent Guidance: Discussion side effects, complications and other risks' (the GMC guidance) states:

> '28. Clear, accurate information about the risks of any proposed investigation or treatment presented in a way patients can understand, can help them make informed decisions. The amount of information about risk that you should share with patients will depend on the individual patient and what they want or need to know. Your discussions with patients should focus on their individual situation and the risk to them.
>
> Risks can vary from common but minor side effects, to rare but serious adverse outcomes possibly resulting in permanent disability or death.
>
> 29. In order to have effective discussions with patients about risk, you must identify the adverse outcomes that may result from the proposed options. This includes the potential outcome of taking no action. Risks can take a number of forms, but will usually be:
> (a) side effects
> (b) complications
> (c) failure of an intervention to achieve the desired aim.
>
> 32. You must tell patients if an investigation or treatment might result in a serious adverse outcome, even if the likelihood is very small. You should also tell patients about less serious side effects or complications if they occur frequently, and explain what the patient should do if they experience them.'

11. The Board's consent policy sets out that health professionals must ensure that before they commence any treatment or intervention, they discuss the significant risks associated with the intervention. It further states that 'It is

essential for health professionals to document clearly both a patient's agreement to the intervention and the discussions that led up to that agreement'.

Medical advice

12. The Adviser said that retrograde ejaculation is a reported side effect of phenoxybenzamine but this would only last for the short time that the drug was prescribed and administered. The Adviser further commented that Mr C's possible temporary loss of sexual function would not have influenced the decision about the administration of this treatment.

13. The Adviser further said that because retroperitoneal dissections for intra aortic paragangliomas are uncommon, and there is no large database of side effects of treatment specific to these tumours, it is logical to refer to data for similar and more commonly performed operations to the same anatomical region but for different pathologies. The Adviser referred to the very similar operation of retroperitoneal lymph node dissection for testis cancer that has been performed more frequently and where the side effects are better reported. Published literature by the National Institute of Clinical Excellence Guideline Interventional Procedures Programme 158 March 2006 suggests that retrograde ejaculation occurs in one percent of patients undergoing surgical exploration of the para aortic strip. The Adviser considered that the risk of retrograde ejaculation would be very similar in Mr C's surgery as surgical dissection is carried out in the same retroperitoneal area using similar techniques. The Adviser explained that Mr C's parganglionoma was in close proximity to the superior hypogastric plexus, therefore, there was a significant risk of unintended injury to nerve fibres contained within this plexus, possibly due to excessive heating from dissection devices. The Adviser explained further that, it is these nerve fibres that transmit the autonomic nerve impulses which are essential to bring about normal erectile and ejaculatory functions. The Adviser highlighted that retrograde ejaculation is particularly important to a younger man who still wishes to father children and who may decide to have his sperm banked pre-operatively.

14. The Adviser further highlighted that there were other major structures that were close to the operative area and were, therefore, also at risk of being injured with potentially catastrophic consequences. These included the major arteries and veins to the lower extremities and on each side.

15. Whilst the operation record of 18 January 2013 suggested that no unforeseen events or complications had occurred, the Adviser was concerned that the consent form did not list any possible complications, therefore, it would seem that they were not discussed with Mr C. The GMC guidance sets out that any serious side effect or complication, even if the likelihood of it occurring is small, should be discussed with the patient and stated on the consent form. The Adviser also noted that the consent form template did not have any questions or prompts for the clinician about entering complications and risks. The Adviser concluded that a more thorough discussion about the benefits and risks of the surgery should have taken place with Mr C and that the Board should amend their consent form to ensure this information is accurately captured.

16. In the Board's response to a draft version of this report, they stated:
'It is inappropriate to compare lesions of primary nerve pathology, which can give rise to symptoms as a result of that pathology, with operative procedures where primary pathology is in lymph nodes and nerve injury results as a consequence of operation. Mr C's symptoms preceded his operation and were thus in all probability caused by his paraganglioma and not his subsequent laparoscopic resection.'

17. In response to these comments, the Adviser said that it was possible Mr C's retrograde ejaculation existed before the operation because his paraganglioma was having a direct effect on the retroperitoneal autonomic nerve plexus. However, if Mr C had admitted he had retrograde ejaculation already, this should have been stated in the clinical notes or on the consent form. The Adviser further highlighted that most of the published data on retroperitoneal surgery report the incidence of retrograde ejaculation which suggests it is a recognised side effect and, therefore, is in no doubt that the risk of retrograde ejaculation should have been discussed with Mr C when consent was obtained.

Decision

18. I have considered the information provided to this office from both the Board and Mr C, along with the independent specialist advice obtained. The Board's response to the complaint concentrated on the reasons why they felt it was unlikely that Mr C's operation was the source of his retrograde ejaculation rather than what information was shared with him during the consent process about risks and complications associated with surgery.

19. I note the opinions of the Consultant Physician, the Urology Doctor, and the Adviser, that phenoxybenzamine could cause retrograde ejaculation but that Mr C was only on it for a short period of time and the effects are reversible upon stopping it. The clinical records leading up to the surgery did not document that Mr C had reported problems with retrograde ejaculation. The record about Mr C having experienced previous problems was only documented at the follow-up appointment four weeks after surgery. Mr C disputes that he said this or that he suffered from the problem beforehand. In any case, from the advice I have received, there is published guidance on the risk of retrograde ejaculation occurring in one percent of patients undergoing surgical exploration of the para aortic strip, albeit for testis cancer surgery, which involves similar techniques to the same anatomical area. Whilst the risk of this occurring is very small, given the GMC's guidance that patients must be told about recognised serious adverse outcomes, even if they are rare, I consider that the surgeon should have warned Mr C of this potential adverse outcome. There is no clear evidence to demonstrate this was done or indeed that discussion took place about other major structures close to the operative area being at risk of injury with possible significant consequences. In view of this, I uphold the complaint.

20. I have made two recommendations below based on my findings. In developing this recommendation, I have taken into account a previous one made to the Board in respect of a similar case (reference 201203939). Specifically, about reviewing their consent form with a view to including a separate section for recording possible risks and complications which the Board subsequently put in place.

Recommendation

21. I recommend that the Board:	*Completion date*
(i) apologise to Mr C for failing to ensure that he was fully informed of the risks associated with his surgery; and	15 July 2015
(ii) ensure that their consent policy includes guidance on the importance of accurately recording conversations with patients regarding risks and complications as part of the consent process.	12 August 2015

22. We will follow-up on these recommendations. The Board are asked to inform us of the steps that have been taken to implement these

recommendations by the date specified. We will expect evidence (including supporting documentation) that appropriate action has been taken before we can confirm that the recommendations have been implemented.

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Annex 1

Explanation of abbreviations used

Mr C	the complainant
the Board	Greater Glasgow and Clyde NHS Board
the Adviser	An adviser to the Ombudsman who is a consultant urological surgeon specialised in sexual dysfunction
the Consultant Physician	a doctor working for the Board
the Surgeon	a surgical doctor working for the Board
the GP	Mr C's general practitioner
the Urology Doctor	a doctor working for the Board with specialised knowledge and skill regarding problems of the urinary tract and reproductive organs
GMC	General Medical Council

Annex 2

Glossary of terms

para aortic paraganglioma	abdominal tumour
phenoxybenzamine therapy	medication to prevent dangerous rises in blood pressure related to surgical manipulation and removal of the tumour
retrograde ejaculation	where semen enters the bladder rather than coming out of the penis/ instead of emerging through the penis
retroperitoneal	part of the abdominal cavity

Annex 3

List of legislation and policies considered

The General Medical Council Consent Guidance: Discussion side effects, complications and other risks

National Institute of Clinical Excellence Interventional Procedures Programme 158 March 2006