SPSO Scottish Public Services Ombudsman

The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

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Case 201302900: Western Isles NHS Board

Summary of Investigation

Category
Health: Hospital; Gynaecology, consent, communication, adverse incident reporting

Overview
The complainant (Mrs C) complained to Western Isles NHS Board (the Board) that a locum consultant gynaecologist (Consultant 1) had not carried out the operation originally agreed between her and her consultant gynaecologist (Consultant 2). She was further concerned that Consultant 1 incorrectly told her the agreed operation had been carried out; she later discovered it had not been.

Mrs C also complained that she had been given inaccurate information about her post-operative complications.

Specific complaints and conclusions
The complaints which have been investigated are that:
(a) Consultant 1 unreasonably failed to carry out a full hysterectomy as agreed with Consultant 2 (*upheld)*;
(b) Consultant 1 provided inaccurate information about the procedure he had carried out (*upheld)*; and
(c) the Board provided an inadequate explanation concerning the complications which arose during Mrs C's surgery (*upheld*).

Redress and recommendations

The Ombudsman recommends that the Board:	*Completion date*
(i) apologise to Mrs C for the failings identified in complaint (a); in particular, that they did not afford her the opportunity to have the operation she had previously agreed with Consultant 2;	18 April 2015
(ii) ensure that the comments of the Adviser, in relation to the issue of consent; are brought to the attention of the relevant staff;	18 May 2015

(iii)	review the procedures for arranging locum surgical cover, so as to ensure that the locum has the requisite surgical skills and expertise;	18 May 2015
(iv)	apologise to Mrs C for the failing identified in complaint (b), that Consultant 1 provided her with incorrect information about her operation;	18 April 2015
(v)	review their current significant adverse event guidance in light of the Adviser's concerns detailed in this report and share the Adviser's comments with the relevant staff; and	18 May 2015
(vi)	ensure they have a clear policy in place concerning the transfer of patients from one consultant's care to another.	18 May 2015

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

Main Investigation Report

Introduction

1. The complainant (Mrs C) was unhappy that her operation, which was carried out in October 2011 by a locum consultant gynaecologist (Consultant 1), had not been carried out as she had earlier agreed in consultation with her consultant gynaecologist (Consultant 2). The operation was to remove all but the neck of her womb and both her ovaries (a sub-total hysterectomy and bilateral oophorectomy). Mrs C was also concerned that Consultant 1, who carried out the operation, deliberately misled her immediately after the operation. Mrs C complained that Consultant 1 gave her false reassurances that he had carried out the correct operation.

2. Mrs C raised her concerns with Western Isles NHS Board (the Board) in April 2012. The Board provided written responses and arranged meetings with Mrs C to discuss her concerns. However, Mrs C's concerns remained. She also became concerned about the explanation offered by the Board about the complications she suffered following the operation. Mrs C brought her complaints to this office in October 2013.

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

(a) Consultant 1 unreasonably failed to carry out a full hysterectomy as agreed with Consultant 2;

(b) Consultant 1 provided inaccurate information about the procedure he had carried out; and

(c) the Board provided an inadequate explanation concerning the complications which arose from Mrs C's surgery.

Investigation

4. During the course of the investigation of this complaint, my complaints reviewer examined copies of Mrs C's clinical records and the Board's complaint correspondence and made several written enquiries of the Board. In addition, independent clinical advice was also obtained from a specialist gynaecological adviser (the Adviser) who also reviewed Mrs C's clinical records, the Board's complaint file and the Board's responses to our enquiries. Mrs C also provided her recollections of events and copies of her correspondence with the Board.

5. 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.

Background

6. Mrs C had a history of gynaecological problems going back over a number of years. In June 2011, Mrs C had a consultation with Consultant 2 when various treatment options for the management of her symptoms were discussed, which included an operation to remove all but the neck of her womb and both her ovaries (a sub-total hysterectomy and bilateral oophorectomy). At this meeting Mrs C agreed to proceed with a sub-total hysterectomy, which was arranged for September 2011. At the consultation, Mrs C was uncertain about the removal of her ovaries and was advised to further consider their removal and to make a decision before the operation. On the day prior to the planned date of Mrs C's operation, Consultant 2 had a discussion with her and recorded that Mrs C had decided to proceed with a sub-total hysterectomy and the removal of both her ovaries and a consent form was signed by Mrs C to this effect. However, Mrs C was unwell on the planned date and the operation was rearranged for 21 October 2011. Three days before this revised operation date, Consultant 2 was unexpectedly absent from work and the Board arranged for Consultant 1 to undertake Consultant 2's work, including Mrs C's operation.

7. Consultant 1 met Mrs C and discussed the impending operation on 20 October 2011. The consent form signed by Mrs C that day referred to the operation as a 'sub-total hysterectomy' with no mention of removal of both ovaries.

8. Immediately following the operation on 21 October 2011, Mrs C required a blood transfusion and was transferred to the High Dependency Unit on 22 October 2011. Mrs C made a steady improvement after this. On 25 October 2011, Mrs C discussed her operation with Consultant 1 who, she recalled, advised that he had performed a sub-total hysterectomy and removed her right ovary and left what remained of her left ovary. Mrs C was discharged on 27 October 2011.

9. Mrs C had a follow-up appointment on 8 December 2011 with Consultant 1 and was discharged from follow-up at that time. Mrs C was re-referred to Consultant 2 in March 2012 suffering from right lower abdomen pain. At that appointment Mrs C learned that her ovaries had not been

removed. Consultant 2 suggested Mrs C raise the apparent confusion with Consultant 1, who subsequently wrote to Mrs C in April 2012 confirming that he had not removed her ovaries.

(a) Consultant 1 unreasonably failed to carry out a full hysterectomy as agreed with Consultant 2

10. The complaint refers to a 'full' hysterectomy. The clinical definition of this refers to the removal of the complete womb including the cervix. It is agreed by all parties that Mrs C had a sub-total hysterectomy (removal of the womb but not the cervix). In Mrs C's case 'full' is used to describe an operation to remove the ovaries in addition to a sub-total hysterectomy.

Mrs C's Complaint

11. In her complaint, Mrs C said that she expected and wanted a sub-total hysterectomy and removal of her ovaries. Mrs C understood from her discussions with Consultant 2 that this was the operation she would have. She believed this was the operation she had consented to on 20 October 2011. Mrs C also said that Consultant 1 had confirmed to her on 25 October 2011 that this was the operation he had carried out. She said she only learned that this was not the case following her re-referral to Consultant 2 for on-going pain.

12. Mrs C said that she has since been advised that because of the scarring caused by previous operations it is no longer advisable to have her ovaries removed and she has had to endure on-going pain and debility.

The Board's response to Mrs C

13. The Board advised that Consultant 1 recalled that Mrs C had told him on 20 October 2011 she did not wish to have her ovaries removed because this would mean she would have to take hormone replacement therapy. Consultant 1 remembered that Mrs C had later changed her mind in the operating theatre, immediately prior to the operation on 21 October 2011. According to Consultant 1, Mrs C had advised theatre staff that she wished to have her ovaries removed and the staff then told him. In the event, Consultant 1 said he felt that the level of adhesion, caused by scarring from Mrs C's previous operations, which he found while operating meant it was not safe to remove Mrs C's ovaries and he had not done so. Consultant 1 noted in his comments to the Board that he may have confused Mrs C's case with another case when he had spoken with Mrs C following her surgery and given her the wrong information. Consultant 1 apologised for this.

14. The Board noted that they had contacted other members of staff who were present in the operating theatre when Mrs C had her operation and the following days of Mrs C's admission. The Board said that none of the staff could recall Mrs C changing her mind about the removal of her ovaries or discussing this with Consultant 1. The Board noted that some time had elapsed since the events in question and staff recall was impacted by this.

Advice obtained

15. The Adviser made a number of comments about the evidence available to him from the medical records and the information provided by the Board.

16. The Adviser noted that the consent form signed by Mrs C on 20 October 2011 referred only to a sub-total hysterectomy and made no mention of ovary removal. The corresponding clinical record contained a brief reference by Consultant 1 which stated 'does not want ovaries out'. The Adviser expressed surprise at this as it was clear that the operation Mrs C had previously discussed with Consultant 2 did include the removal of her ovaries but there was no record of why Mrs C had apparently later changed her mind or of any discussion about this. The Adviser also noted that the format of the consent form signed by Mrs C was not in line with the guidance issued by the Board at that time. The Board later explained to my complaints reviewer that the preferred consent form had not been universally adopted at that time but that it was now used by all teams.

17. The Adviser told my complaints reviewer that if Mrs C had changed her mind in the operating theatre, as suggested by Consultant 1, then the consent form should have been amended to reflect this. Otherwise the operation could have been performed without the necessary consent. The Adviser would also have expected the operation notes to refer to the further change of plan if Consultant 1 later decided it was too risky to remove Mrs C's ovaries.

18. The Adviser expressed concern that Consultant 1, who was unfamiliar with Mrs C's case, was asked to take on at short notice what was going to be a challenging and complex operation, in view of Mrs C's clinical history of previous operations and the scarring associated with that. In addition, the Adviser was also concerned that Consultant 1 may not have had the necessary expertise and requisite skills to perform such a difficult and complex operation. He noted the Board's view that Consultant 1 was experienced in this general

operation but that they had indicated Consultant 1 would not be expected to undertake the level of dissection which the Adviser considered would always have been needed in Mrs C's case. The Adviser concluded that the Board had not taken adequate steps to ensure that Consultant 1 could cover the specific surgery which had originally been scheduled for Consultant 2.

(a) Conclusion

19. I consider that it was Mrs C's wish that she have an operation to remove her ovaries, as she had agreed with Consultant 2. Although Mrs C did not sign a consent form for an operation to include the removal of her ovaries in October 2011, I am satisfied that she believed she had, given her previous discussions with Consultant 2 and as she had previously signed a consent form which included the removal of her ovaries in September 2011. To that extent, I consider the consent obtained in October 2011 was not properly informed.

20. There is no contemporaneous written record of Mrs C changing her views about the removal of her ovaries at the time she signed the consent form in October 2011 or immediately prior to the operation, as Consultant 1 suggested. There is also no record that Consultant 1 decided he could not go ahead with the removal of the ovaries once the operation had begun. If these events happened, there should have been a record made and there was not.

21. The Adviser told my complaints reviewer that he did not consider the Board had taken adequate steps to ensure that Consultant 1, who was providing cover for Consultant 2, had the necessary expertise to undertake the operation arranged for Mrs C, which the Adviser described as 'complex' and 'challenging', given the likelihood of scarring from her previous operations. While the Adviser felt it was correct that Consultant 1 did not undertake such a risky operation, I note he considered that it was unreasonable for the Board to arrange for Consultant 1 to perform this particular operation given Mrs C's known history.

22. I, therefore, consider that the consent for Mrs C's operation was not properly obtained; that Consultant 1 did not appear to have the necessary expertise to undertake the difficult operation that Mrs C had agreed with Consultant 2; and that Consultant 1's recall was incorrect and/or the record keeping was deficient. I regard these matters as serious failings and it is of concern that such failings occurred. For all these reasons, I uphold this complaint.

23. Therefore, I have made the following recommendations to the Board.

(a) Recommendations

24. I recommend that the Board:	*Completion date*
(i) apologise to Mrs C for the failings identified in complaint (a); in particular, that they did not afford her the opportunity to have the operation she had previously agreed with Consultant 2;	18 April 2015
(ii) ensure that the comments of the Adviser, in relation to the issue of consent, are brought to the attention of the relevant staff; and	18 May 2015
(iii) review the procedures for arranging locum surgical cover, so as to ensure that the locum has the requisite surgical skills and expertise.	18 May 2015

(b) Consultant 1 provided inaccurate information about the procedure he had carried out

Mrs C's Complaint

25. Mrs C said that she discussed her operation with Consultant 1 while she was in the hospital following her operation. She said that Consultant 1 advised her that he had removed her right ovary and partially removed the left ovary. Mrs C later questioned this when she met with Consultant 2 in March 2012 and was advised her ovaries had not been removed.

The Board's response to Mrs C

26. The Board advised Mrs C that Consultant 1 may have confused his cases and passed on inaccurate information. They noted that Consultant 1 had not intentionally lied.

Advice obtained

27. The Adviser noted an entry in Mrs C's clinical records post-operatively stated 'operation explained'. He explained to my complaints reviewer that, given the apparent changes to the consented operation both immediately prior to and during the operation, he would have expected considerably more detail to be discussed with Mrs C and noted in the records. The Adviser found Consultant 1's explanation (that he may have mixed-up two patients) was not acceptable. The Adviser told my complaints reviewer that Consultant 1 should have had the correct notes in front of him at the time of his discussion with

Mrs C. The Adviser said that this was particularly important where the patient was not previously known to the consultant, as in this case.

(b) Conclusion

28. The Board accepted that Consultant 1 may have provided inaccurate information to Mrs C. There is no evidence of what information was provided to her and Mrs C's actions were consistent with her understanding that her ovaries had been removed. While I have seen no evidence to suggest there was any deliberate intention to mislead Mrs C, I agree with the Adviser that it was not acceptable to confuse patients in this way and the potential impact it may have on them. I am, therefore, critical of Consultant 1 for the confusion caused to Mrs C. Based on these findings, I uphold this complaint.

29. I have, therefore, made the following recommendation.

(b) Recommendation

30.	I recommend that the Board:	*Completion date*
(i)	apologise to Mrs C for the failing identified in complaint (b), that Consultant 1 provided her with incorrect information about her operation.	18 April 2015

(c) The Board provided an inadequate explanation concerning the complications which arose during Mrs C's surgery

Mrs C's complaint

31. Mrs C said the Board's response to her complaint stated she was transferred to the High Dependency Unit following her operation only as a precautionary measure. At the time Mrs C said that her husband was told she had a possible internal bleed and may require more surgery. Mrs C needed a blood transfusion and had very low haemoglobin levels.

The Board's response

32. In their response, the Board noted that Mrs C was transferred to the High Dependency Unit as a precautionary measure because of her low blood pressure readings. They also noted that she was assessed for possible intra-abdominal bleeding but this was excluded by an ultrasound scan.

Advice obtained

33. The Adviser told my complaints reviewer he was very concerned with regard to the post-operative management of Mrs C. The Adviser was further

very concerned that the Board's response to what had occurred seemed to demonstrate a lack of understanding that Mrs C clearly had suffered post-operative complications, an intra-abdominal bleed, following the operation. The Adviser noted this was managed conservatively at the time by transfusion alone. The Adviser explained that he was also concerned there was insufficient evidence of detailed consideration of the bleeding and the possibility of further surgery. He noted that this was also reflected in a failure to regard this as a significant adverse event, as he would have expected. The Adviser was, therefore, critical of the Board on these matters.

34. The Board later provided my office with copies of their policies on reporting of adverse events. The Adviser reviewed these policies. The Adviser noted that Adverse Incident Management and Learning Policy, Version 1 (the Policy), was the policy current at the time of Mrs C's operation.

35. The Policy defined an adverse event as:

> 'an event that causes, or has the potential to cause, unwanted effects involving the safety of patients, users, staff or other persons – or which results in loss or damage. Such incidents would include (amongst other examples) loss, harm or injury arising from a clinical procedure, treatment or episode of care, or loss, harm or injury arising from unexpected hazards, or actual or threat of physical/verbal abuse.'

36. The Adviser noted the Policy did not specifically list complications of surgery as an example of an issue to be reported and that other complications relevant to Mrs C's case, namely major haemorrhage and transfer to the High Dependency Unit, were also not listed as examples. He regarded these omissions as a failing in the Policy.

37. The Adviser told my complaints reviewer that while the list of examples given in the Policy did not include complications of surgery, major haemorrhage or transfer to the High Dependency Unit, it highlighted that the list was not exhaustive. The Adviser considered Mrs C's complications following surgery did meet the definition of an adverse event in the Policy and should, therefore, have been reported as such. The Adviser considered that it was the Board's responsibility to ensure that their staff fully understood the Policy on this matter, by means of regular in-house training.

38. The Adviser further noted that the lack of recording of the detail of the post-operative events in Mrs C's case limited his ability to grade the significance of the event and led him to conclude that there was a risk that post-operative events were being underreported.

39. The Adviser also expressed concern that the Board lacked a clear policy concerning the transfer of a patient from one consultant's care to another and this had also impacted on Mrs C's care as identified in complaint (a) and complaint (b). In the Adviser's view, the same lack of recording also hampered the Board's ability to respond to Mrs C's concerns and provide her with an adequate explanation.

(c) Conclusion

40. The Adviser is strongly of the view that Mrs C suffered a potentially significant intra-abdominal bleed, which should have been reported as a significant adverse event.

41. I also note the concern expressed by the Adviser that the Board lacked a clear policy concerning the transfer of a patient from one consultant's care to another and this had impacted on Mrs C's care as identified in complaint (a) and complaint (b).

42. Given the advice I have received from the Adviser, I am critical of what I consider is the serious failure to treat and report Mrs C's intra-abdominal bleed as a significant adverse event and also the Board's lack of a clear policy concerning the transfer of a patient from one consultant's care to another.

43. Therefore, I uphold this complaint.

44. I have made the following recommendations to address the failings that have been identified in this complaint.

(c) Recommendations

45. I recommend that the Board:	*Completion date*
(i) review their current significant adverse event guidance in light of the Adviser's concerns detailed in this report and share the Adviser's comments with the relevant staff; and	18 May 2015

(ii)	ensure they have a clear policy in place concerning the transfer of patients from one consultant's care to another.	18 May 2015

46. 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
Consultant 1	a locum gynaecologist who covered for Consultant 2
Consultant 2	Mrs C's gynaecologist
the Board	NHS Eileanan Siar / Western Isles NHS Board
the Adviser	a specialist gynaecological adviser to the Ombudsman
the Policy	Western Isles Health Board 'Adverse Incident Management and Learning Policy, Version 1

Annex 2

Glossary of terms

bilateral oophorectomy	an operation to remove both ovaries
significant adverse event	an undesired harmful effect resulting from a medication or other intervention such as surgery
sub-total hysterectomy	an operation to remove all but the neck of the womb

Annex 3

List of legislation and policies considered

Western Isles Health Board 'Adverse Incident Management and Learning Policy, Version 1

Western Isles Health Board 'Adverse Incident Management and Learning Policy, Version 2

Western Isles Health Board 'Incident Reporting, Management and Learning Policy, Version 3