Scottish Parliament Region: Central Scotland

Case ref: 201403214, Lanarkshire NHS Board
Sector: Health
Subject: Hospitals; clinical treatment; diagnosis

Summary
Mrs C was scheduled to have a colonoscopy procedure (examination of the bowel with a camera on a flexible tube) at Hairmyres Hospital. It had been planned that Mrs C would be under general anaesthetic. This was because a previous colonoscopy procedure using conscious sedation (to relax and provide pain relief) had been a painful experience for her. However, the operating theatre was unexpectedly unavailable so the procedure was carried out in the endoscopy unit using conscious sedation. Mrs C said that she experienced excessive pain and discomfort during the procedure, and continued to experience pain for more than a month afterwards. Mrs C said that she asked many times for the procedure to be stopped and nursing staff also asked for the procedure to be stopped. However, the doctors (a senior staff grade surgeon and a consultant colorectal surgeon) continued nonetheless. Mrs C said she had been left severely traumatised by what occurred.

As part of my investigation, I obtained independent advice from an adviser who is a consultant colorectal surgeon. Regarding Mrs C's complaint that the colonoscopy procedure went ahead without the general anaesthetic, the adviser said that, as Mrs C had prepared for the procedure and waited a long time that day, it was reasonable for it to be attempted using conscious sedation. However, it should have been clearly understood that if Mrs C experienced excessive discomfort, the procedure should be stopped immediately and rescheduled to be carried out using a general anaesthetic. The adviser considered that the consultant had not complied with General Medical Council guidelines on obtaining informed consent and had communicated with Mrs C poorly. They also found it concerning that these communication failings had not been acknowledged by the consultant or the board.

Mrs C complained that the procedure was carried out without a reasonable level of sedation. The adviser said that the sedation Mrs C received was not enough to provide her with an appropriate level of comfort. As it would have been unsafe to increase the sedation given to Mrs C, the procedure should have been stopped.

Mrs C also complained that the procedure was unreasonably continued despite her requests for it to stop. The adviser said that, in the initial absence of the consultant, it was reasonable for the surgeon to begin the procedure. However, the adviser considered the consultant made a serious error in not giving the surgeon a clear explanation of Mrs C's previous poor experience of colonoscopy and clear instructions to stop if the procedure was too painful or distressing for her. There was evidence in Mrs C's medical records that she and nursing staff asked the surgeon to stop and, in the adviser's view, on arriving to find both patient and nursing staff requesting that the procedure should be stopped, it was unreasonable for the consultant to have taken over and continued. The adviser considered that the evidence clearly demonstrated the withdrawal of Mrs C's consent for the procedure.

I upheld all the complaints. My investigation identified a number of serious failings including poor communication, poor record-keeping, poor understanding of the consent process, and a failure to stop the procedure when asked by Mrs C. I was also concerned that the board and the consultant did not appear to have understood, acknowledged or sufficiently appreciated the seriousness of the failings. Nor had they identified all the learning required or taken sufficient remedial action. I also noted the similarity of the circumstances of another recent complaint (case 201402959) and have taken the recommendations made in that complaint into account in making recommendations in this case.

Redress and recommendations

The Ombudsman recommends that the board:	*Completion date*
(i) and the consultant apologise to Mrs C for the failings identified in this complaint in relation to poor communication and in obtaining informed consent;	17 March 2016
(ii) share with the consultant the comments of the adviser in relation to obtaining informed consent from a patient;	17 April 2016
(iii) arrange for the consultant, if they have not already done so, to undergo training and a suitable continuing professional development course to improve their communication skills and understanding of the consent process and to	17 May 2016

	provide evidence of this;	
(iv)	apologise to Mrs C for the failing identified in this complaint in relation to carrying out the procedure without a reasonable level of sedation;	17 March 2016
(v)	and the consultant apologise to Mrs C for the failings identified in this complaint in relation to poor communication, a failure to stop the procedure when asked by Mrs C, a poor understanding of the consent process, and poor record-keeping;	17 March 2016
(vi)	arrange for the consultant and the surgeon to undertake training, if they have not already done so, to improve their communication skills and an understanding of the consent process, particularly where a patient withdraws their consent;	17 May 2016
(vii)	bring to the attention of the consultant the comments of the adviser to give consideration to submitting a report about what occurred in Mrs C's case to a local morbidity and mortality meeting;	17 May 2016
(viii)	review the Global Rating Scale (GRS) data from all of their endoscopy units and reflect on the comments of the adviser in relation to achieving good GRS scores;	17 May 2016
(ix)	provide evidence that all their endoscopy units have standardised documentation for recording of patient discomfort during colonoscopy, in line with recommended practice;	17 May 2016
(x)	provide evidence that all their endoscopy units have standardised guidelines for procedural sedation and for withdrawal of consent;	17 May 2016
(xi)	consider, if they have not already done so, developing guidelines for all their endoscopy units in respect of recommendations (ix) and (x); and submit a synopsis of this case together with current standardised documentation and guidelines to their Endoscopy Governance Group in order to provide dissemination of learning and to minimise variability of colonoscopy practice within their hospitals; and	17 May 2016
(xii)	provide evidence of the action they say has been	17 May 2016

taken.

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 Mrs C The terms used to describe other people in the report are explained as they arise and in Annex 1.

Introduction

1. Mrs C complained to the Ombudsman about a colonoscopy procedure (the Procedure) she had at Hairmyres Hospital (Hospital 1) in January 2014.

2. Mrs C said she expected the Procedure to be performed using a general anaesthetic. This was because she had previously had a colonoscopy procedure using conscious sedation at Wishaw Hospital (Hospital 2) in May 2013 which had been abandoned as she had a poor tolerance of this type of procedure.

3. Due to an unexpected overrun in the operating theatre at Hospital 1, Mrs C did not have the Procedure in theatre using a general anaesthetic, as planned. The Procedure was instead carried out in the endoscopy unit at Hospital 1 (the Endoscopy Unit), initially by a senior staff grade surgeon (the Surgeon) and then by a consultant colorectal surgeon (the Consultant), using conscious sedation.

4. Mrs C said that, during the course of the Procedure, she experienced excessive pain and discomfort and despite she and members of the nursing staff present asking 'countless' times for the Procedure to be stopped, it was not. Mrs C said she has been left severely traumatised by what occurred.

5. Mrs C complained to Lanarkshire NHS (the Board), who apologised for the 'inconvenience and discomfort' caused to her and informed Mrs C that they had made a number of recommendations for change, to try to improve patients' experiences in future. The Board also met with Mrs C to discuss her concerns.

6. Mrs C was dissatisfied with the Board's response and complained to my office.

7. The complaints from Mrs C I have investigated are that the colonoscopy procedure:

(a) went ahead without the general anaesthetic Mrs C expected (*upheld*);
(b) was carried out without a reasonable level of sedation (*upheld*); and
(c) was unreasonably continued despite Mrs C's requests for it to stop (*upheld*).

Investigation

8. In order to investigate Mrs C's complaint, my complaints reviewer examined all the information provided by Mrs C, a copy of Mrs C's clinical records and the Board's complaint file. My complaints reviewer also obtained independent advice from a consultant colorectal surgeon (the Adviser). In this case, we have decided to issue a public report on Mrs C's complaint because the failings I found led to a significant personal injustice to Mrs C; and because the advice I received from the Adviser is that the Board and the Consultant do not appear to have sufficiently appreciated the seriousness of the failings in Mrs C's case, taken sufficient remedial action to address these failings and identified all relevant learning.

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

10. My office has also recently investigated a complaint about the Board where I have noted the similarity of the circumstances (complaint reference 201402959). I have taken into account the recommendations made in that case when determining what recommendations to make for this case.

(a) The colonoscopy procedure went ahead without the general anaesthetic Mrs C expected

What Mrs C said

11. Mrs C said on the day of the Procedure, after a wait of approximately two hours, an anaesthetist spoke to her and explained the process for a general anaesthetic. Mrs C said that after waiting several more hours the Consultant spoke to her and told her he was too busy to carry out the Procedure. Mrs C said she was very upset by this because she had fasted since the previous day and had been waiting hours for the Procedure to be carried out. According to Mrs C, the Consultant had a 'poor attitude' and reluctantly agreed to the Procedure being carried out that day.

12. Mrs C said that the Consultant did not explain the consent form for the Procedure and she did not realise she had consented to the Procedure being carried out using conscious sedation rather than a general anaesthetic. According to Mrs C, it was only when a member of the nursing staff took her to the Endoscopy Unit rather than the operating theatre she learned that she was not to have a general anaesthetic.

The Board's response

13. The Board said Mrs C had previously suffered chronic abdominal pain. Therefore, following a discussion by the gastro-intestinal multi-disciplinary team, it was decided to carry out the Procedure as it was thought that obtaining biopsies could help to rule out the possibility of Mrs C having inflammatory bowel disease.

14. The Board said that Mrs C was scheduled to have the Procedure carried out using a general anaesthetic in the operating theatre. Unfortunately, on the day concerned the theatre was extremely busy, due to an unexpected and complex surgical procedure. According to the Board, the Consultant came out of the theatre to explain to Mrs C there was a good chance that the Procedure using a general anaesthetic might have to be postponed. As Mrs C was understandably unhappy and was extremely keen for the Procedure to go ahead, the Consultant, therefore, offered Mrs C the Procedure using conscious sedation in the Endoscopy Unit to which Mrs C had consented.

15. The Board said the Consultant had obtained formal consent from Mrs C for the Procedure using conscious sedation which allowed for the Procedure to take place within the Endoscopy Unit rather than in theatre. According to the Board, the Consultant said he felt that Mrs C had understood the difference between a general anaesthetic and conscious sedation, which would mean that Mrs C was conscious but drowsy.

16. A room in the Endoscopy Unit was available for Mrs C to have the Procedure and she was accompanied into the room by a member of the nursing staff, who had made Mrs C aware of the fact that she would be having the Procedure by conscious sedation.

17. The Board said they and the Consultant had acknowledged the failings of the Consultant in their communication with Mrs C, with regard to obtaining consent for the procedure and this was acknowledged at a meeting with Mrs C in June 2014.

18. In light of a recent legal decision, the Board have informed my office that they have been reviewing their consent policy and will be producing a best practice guidance which is currently being finalised and which advises clinicians

that seeking informed consent immediately prior to a procedure should be avoided unless clinically necessary.

Advice received

19. The Adviser told my complaints reviewer that, as Mrs C had undergone bowel preparation and was distressed by the long wait for the Procedure to be carried out, it was entirely reasonable that the Procedure should have been attempted using conscious sedation. However, the Adviser said that it should have been quite clear, given Mrs C's previous experience at Hospital 2, that if she experienced excessive discomfort during the Procedure it should be stopped immediately and re-scheduled for completion using a general anaesthetic as originally planned.

20. The Adviser reviewed the consent form signed by Mrs C and noted it stated 'colonoscopy under sedation'. While the Adviser told my complaints reviewer the consent form which Mrs C signed was accurate, they were of the view the context in which consent was obtained by the Consultant was not of a reasonable standard. The Adviser said the reason for this was because Mrs C had been unhappy with the alleged 'poor attitude' of the Consultant and it appeared that Mrs C, even after signing the consent form, was not clear that the Procedure was to be carried out using conscious sedation. The Adviser considered that the Consultant's communication with Mrs C was poor.

21. The Adviser said that the General Medical Council (GMC) guidance 2008: patients and doctors making decisions together (the GMC Guidance) states that the doctor must:

(a) 'listen to patients and respect their views about their health;
(b) discuss with patients what their diagnosis, prognosis, treatment and care involve;
(c) share with patients the information they want or need in order to make decisions;
(d) maximise patients' opportunities, and their ability, to make decisions for themselves;
(e) respect patients' decisions'

22. In the Adviser's view, the Consultant had not complied with the GMC Guidance and had not obtained informed consent from Mrs C.

23. The Adviser also considered the action which the Board stated they were taking following Mrs C's complaint. The Adviser noted that the Board stated that the Consultant will write something different on consent forms, as opposed to the normal practice of specifying 'under sedation'. The Adviser said it appeared to him that the Board and the Consultant had missed the point in relation to the action that the Consultant now proposed to take. The Adviser said that informed consent is not about obtaining a signed form; rather it is about an appropriate dialogue between the doctor and the patient.

24. The Adviser told my complaints reviewer that the Board and the Consultant had also not acknowledged the failings of the Consultant in their communication with Mrs C, with regard to obtaining consent for the Procedure. The Adviser said the Consultant should acknowledge that his communication with Mrs C on the day and his attempt at gaining consent for the Procedure were not to standard.

25. The Adviser, therefore, considered that the Consultant should undertake training and a suitable continuing professional development course to improve their communication skills and understanding of the consent process.

(a) Decision

26. Mrs C had attended Hospital 1 expecting the Procedure to be carried out under a general anaesthetic, given her previous poor experience at Hospital 2. The operating theatre, however, was unexpectedly unavailable and so Mrs C could not have the Procedure under a general anaesthetic, as planned.

27. The advice I have received from the Adviser, which I accept, is that given Mrs C had prepared for the Procedure and she had been waiting a lengthy period of time to have the Procedure it was, therefore, reasonable to perform the Procedure using conscious sedation in the Endoscopy Unit on the clear understanding that if Mrs C experienced excessive discomfort during the Procedure it should be stopped immediately and re-scheduled for completion using a general anaesthetic as originally planned.

28. I also accept that the consent form signed by Mrs C for the Procedure was technically accurate, given that it stated Mrs C was to have a 'colonoscopy under sedation'. However, it was, in my view, essential that Mrs C clearly understood what she was consenting to and the implications of this, particularly considering her previous difficult experience at Hospital 2, when a colonoscopy

procedure had to be abandoned due to her poor tolerance. The advice I have received is that the Consultant's communication with Mrs C was poor and their actions did not comply with the GMC Guidance on obtaining consent from a patient and, as a result, Mrs C did not realise what she had consented to. I, therefore, consider there was a failure by the Consultant to obtain informed consent from Mrs C.

29. It is also of concern that neither the Board nor the Consultant has acknowledged the failings of the Consultant in their communication with Mrs C in relation to obtaining informed consent prior to the Procedure. I am critical of these failings.

30. In view of my findings, I uphold this complaint.

(a) Recommendations

31. I recommend that the Board:	*Completion date*
(i) and the Consultant apologise to Mrs C for the failings identified in this complaint in relation to poor communication and in obtaining informed consent;	17 March 2016
(ii) share with the Consultant the comments of the Adviser in relation to obtaining informed consent from a patient; and	17 April 2016
(iii) arrange for the Consultant, if they have not already done so, to undergo training and a suitable continuing professional development course to improve their communication skills and understanding of the consent process and to provide evidence of this.	17 May 2016

(b) The colonoscopy procedure was carried out without a reasonable level of sedation

What Mrs C said

32. Mrs C said that, prior to the Procedure being carried out, she had spoken to a member of the nursing staff and explained that she would be unable to tolerate the Procedure unless she was sedated. Mrs C said the nurse assured her she would have double the usual sedative and she would not suffer pain during the Procedure.

33. Mrs C also said she assumed the Surgeon, who she had been told was to carry out the Procedure, would know that she had previously undergone a similar colonoscopy procedure at Hospital 2, that the sedation had been unsuccessful and that, as a result, the procedure was stopped.

34. Mrs C said she was not given appropriate sedation and, as a result, the pain she felt during the Procedure was the 'worst she had ever experienced' and was 'horrific'.

The Board's response

35. The Board said that as the Consultant was initially caught up with a surgical case in the operating theatre, the Procedure was started by the Surgeon, a senior staff grade surgeon, who was competent in carrying out colonoscopies.

36. According to the Board, the Procedure was undertaken with 'safe, maximal, permissible' intravenous sedation. Mrs C received five milligrams of midazolam (three milligrams at the start of the procedure and a further two milligrams 19 minutes into the Procedure) and 50 milligrams of pethidine, in line with the Board's protocol for intravenous sedation during colonoscopy in the Endoscopy Unit. A copy of the Board's protocol was supplied to my office.

Advice received

37. The Adviser told my complaints reviewer that his review of Mrs C's medical records had confirmed she had received five milligrams of midazolam and 50 milligrams of pethidine intravenously. The Adviser said the combination and dose of the sedatives given to Mrs C was appropriate. The Adviser explained that to have given Mrs C more would not have been safe. The Adviser said, however, that the sedation given to Mrs C was not adequate to provide her with an appropriate level of comfort for the Procedure. Therefore, the proper action would have been to stop the Procedure.

(b) Decision

38. The advice I have received from the Adviser is that the sedation Mrs C received was not sufficient in order to provide her with an appropriate level of comfort during the Procedure. As it would have been unsafe to increase the sedation given to Mrs C, the Procedure should have been stopped. Therefore, I uphold this complaint.

39. In view of my finding I have made the following recommendation.

(b) Recommendation

		Completion date
40.	I recommend that the Board:	
(i)	apologise to Mrs C for the failing identified in this complaint in relation to carrying out the Procedure without a reasonable level of sedation.	17 March 2016

(c) The colonoscopy procedure was unreasonably continued despite Mrs C's requests for it to stop

What Mrs C said

41. Mrs C said that she asked the Surgeon 'countless' times to stop the Procedure because of the severe pain she was experiencing but they refused to do so. Mrs C said that the Consultant, who took over and completed the Procedure, also ignored her continued requests to stop the Procedure. According to Mrs C, requests from nursing staff to stop the Procedure were also disregarded.

42. Mrs C said she felt 'violated' by the experience and she has been left 'emotionally scarred' and 'angry'. Mrs C said she continued to suffer pain and discomfort for more than a month after the Procedure was carried out and is fearful of having another colonoscopy procedure.

The Board's response

43. The Board said the Surgeon was joined by the Consultant as soon as he had finished in the operating theatre and took over the colonscope (the Scope) in order to confirm its position. The Consultant was aware that Mrs C was complaining of pain, which was also highlighted by the endoscopy nursing staff who were present.

44. The Board said that the Scope could not be withdrawn immediately after Mrs C complained of pain as the Procedure was extremely complex due to the complexity of Mrs C's anatomy, as a result of her previous bowel surgery and intra–abdominal adhesions. The Consultant took over conducting the Procedure as the discomfort Mrs C was experiencing made it extremely difficult to judge the actual position of the Scope in the colon. In the circumstances, photographs were taken along with biopsies.

45. The Board said safety had to be maintained before withdrawal of the Scope and a blind withdrawal of the Scope at that stage could have resulted in bowel perforation or bleeding.

46. According to the Board, throughout the Procedure Mrs C's cardio-respiratory status was monitored and remained extremely stable. An abdominal examination was also carried out to ensure Mrs C was stable and the Procedure was completed without any technical complications.

47. The Board said that the Consultant was extremely sorry to learn that Mrs C had an unpleasant experience during the Procedure and he had no hesitation in apologising for the inconvenience and discomfort Mrs C faced during the Procedure. The Board also offered their sincere apologies.

48. The Board said that they did not carry out Serious Event Review because the events which occurred did not meet the criteria for such a review. However, the Consultant had carried out a significant event analysis and had reviewed this at his recent appraisal. The Board's Divisional Medical Director – Acute, as responsible officer had confirmed that the Consultant included all aspects of the complaint and that he will continue to participate in the Global Rating Scale (GRS) audit of his own practice. As a result , the Board said that the Consultant had changed his practice for complex colonoscopies scheduled for theatre and the following changes would be made:

- the nature of the proposed sedation/anaesthesia will be clarified on the consent form and in medical correspondence; and
- in future, the Consultant will not undertake such procedures in the Endoscopy Unit in situations where theatre/anaesthetic facilities are unavailable, and will ensure clear communication with patients.

Advice received

49. The Adviser said that a colonoscopy can be an uncomfortable procedure. It is recommended that the patient's estimate of comfort should be recorded on a simple scale such as: 1 - no or minimal discomfort; 2 - mild discomfort; 3 - moderate discomfort; and 4 - severe discomfort.

50. The Adviser noted from Mrs C's medical records that, when she had the colonoscopy procedure at Hospital 2 in May 2013, a pain scoring system was in place. Mrs C's pain scoring during this procedure was documented as 'moderate' and the procedure was 'abandoned due to poor tolerance'. The

Adviser said that Hospital 2's endoscopy unit had documented patient discomfort according to the recommended scale.

51. The Adviser told my complaints reviewer that, while Hospital 2 had documented Mrs C's discomfort during the attempted colonoscopy in May 2013 according to the recommended scale, there was no evidence of an equivalent pain scoring system in use for the Procedure carried out at Hospital 1. The Adviser said that the Board should, therefore, ensure that all their endoscopy units have standardised documentation in line with recommended practice.

52. The Adviser also told my complaints reviewer that, in the absence of the immediate availability of the Consultant to undertake the Procedure, it was reasonable to allow the Surgeon to start the procedure. The Consultant, however, should have been given explicit instructions to halt the Procedure immediately if it was proving to be painful to Mrs C.

53. The Adviser noted that the endoscopy care plan for the Procedure documented that the nursing staff and Mrs C had asked the Surgeon to 'stop' the Procedure but they had continued. The Adviser also noted from an entry made by a member of the nursing staff in the endoscopy care plan that when the Consultant took over the Procedure he took immediate steps to attempt to reduce Mrs C's discomfort, by removing a lot of air. However, it was also recorded in the care plan that the Consultant 'did not immediately withdraw' the Scope. In the Adviser's view, when the Consultant came into the Endoscopy Unit and encountered Mrs C and nursing staff all requesting that the Procedure should be stopped, the Consultant should have removed the Scope. The Adviser told my complaints reviewer that it had not been reasonable for the Consultant to continue with the Procedure and to take biopsies.

54. In the view of the Adviser, the fact that both Mrs C and the nurses in attendance asked for the Procedure to stop demonstrated clearly that Mrs C had withdrawn her consent and the Procedure should have been stopped well before the point that the Consultant took over the Procedure.

55. The Adviser considered that the Consultant had made a serious error, as he had arranged for the Surgeon to attempt the Procedure using conscious sedation without providing a clear explanation of Mrs C's previous poor colonoscopy experience and without clear instructions for the actions to be taken if she was in pain or distress. The Adviser also told my complaints

reviewer that the Consultant should acknowledge that he made this serious error and should apologise for the consequences of this mistake.

56. The Adviser noted that, following Mrs C's complaint to the Board, the Consultant had apologised 'for the distress [Mrs C] had faced' and he was 'in full appreciation and [had] sympathy for the unpleasant experience she had faced'. Although the Consultant stated it 'may have been better' either to have either cancelled the Procedure or to have started the Procedure himself rather than the Surgeon, the Adviser said that the Consultant had fallen short of acknowledging that he made an error at any point. In addition, the Consultant should have acknowledged that the Procedure should have been ended at a much earlier stage.

57. The Adviser was of the view that the Board should have carried out a Serious Event Review because what had occurred to Mrs C during the Procedure was an adverse event which had resulted in harm to Mrs C.

58. The Adviser also told my complaints reviewer that the Procedure documentation in Mrs C's medical records did not accurately reflect the Procedure undertaken. In particular, the Adviser said the documentation did not mention the difficulty encountered during the Procedure or provide a plan for follow-up. The Adviser explained that the British Society of Gastroenterology guidelines state that withdrawal of consent must be documented in a patient's medical records and Good Surgical Practice guidance (2014) recommends that records of operative procedures should include a record of 'any problems/complications' and 'detailed postoperative care instructions'. The Adviser said this was not done in Mrs C's case.

59. The Adviser also told my complaints reviewer that the post procedure letter from the Surgeon to Mrs C's GP did not mention any difficulty encountered during the Procedure.

60. As such, the Adviser said both the Surgeon and the Consultant should acknowledge that their documentation fell short of the standard expected by the British Society of Gastroenterology guidelines and the Good Surgical Practice guidance (2014).

61. Although the Board and the Consultant had apologised and advised of action taken following Mrs C's complaint to the Board, the Adviser said it was

unclear whether the Board had understood or sufficiently appreciated the seriousness of the failings in Mrs C's case, identified all the learning required and taken sufficient remedial action. Given the seriousness of the failings identified, the Adviser made a number of suggestions in respect of action that should be taken.

62. In particular, the Adviser considered the Board should provide evidence that the Consultant and the Surgeon have undergone training in relation to improving their communication skills and their understanding of the consent process, particularly where a patient withdraws their consent. We received advice that, as part of the learning process, the Consultant should submit a report about what occurred in Mrs C's case to a local Morbidity and Mortality meeting as this would ensure both personal reflective practice and wider dissemination of learning.

63. The Adviser said the Board should review the GRS data from all of its endoscopy units. This is a quality improvement and assessment tool for the gastrointestinal endoscopy service. The Adviser told my complaints reviewer that it was known that practitioners who carry out a high volume of colonoscopies, particularly those practitioners who have undertaken additional training, tend to have higher GRS ratings. The Adviser told my complaints reviewer that the Board should, therefore, give consideration to limiting colonoscopy procedures to those practitioners who undertake a high volume of procedures and have consistently good GRS scores.

64. Advice was also received from the Adviser that all of the Board's endoscopy units, in order to minimise variability of colonoscopy practice within their hospitals, should ensure they have standardised documentation and guidelines for assessing and recording of patient pain and discomfort during a colonoscopy, in line with recommended practice, and also in relation to sedation and withdrawal of consent. The Board have since stated that each of their three endoscopy units have such documentation in place and the Board's Endoscopy Governance Group will review this to ensure consistency.

65. I have addressed these issues in the recommendations set out in paragraph 69 of this report.

(c) Decision

66. The investigation of Mrs C's complaint has identified a number of serious failings in this case by the Consultant and the Surgeon including poor communication; a failure to stop the Procedure when asked by Mrs C; a poor understanding of the consent process; and poor record-keeping. I also accept that there was a serious failure by the Board and the Consultant to acknowledge these failings. As a result, Mrs C suffered a painful and distressing experience which, unfortunately, has had a lasting effect upon her. This was, in my view, further aggravated by the fact that it was known prior to the Procedure being carried out that Mrs C had a poor tolerance of this type of procedure and she had wanted to avoid a repetition of the previous painful experience she had undergone at Hospital 2. I am critical of these failings.

67. I acknowledge the actions which the Board say they and the Consultant have taken following Mrs C's complaint and that they have apologised to Mrs C. Nevertheless, taking account of the advice I have received, I am concerned that the Board and the Consultant do not appear to have understood, acknowledged or sufficiently appreciated the seriousness of the failings in this case, identified all the learning required or taken sufficient remedial action.

68. Given the failings I have identified, I therefore, uphold the complaint and I have made a number of recommendations to address these failings.

(c) Recommendations

69. I recommend that the Board:	*Completion date*
(i) and the Consultant apologise to Mrs C for the failings identified in this complaint in relation to poor communication; a failure to stop the Procedure when asked by Mrs C; a poor understanding of the consent process; and poor record-keeping;	17 March 2016
(ii) arrange for the Consultant and the Surgeon to undertake training, if they have not already done so, to improve their communication skills and an understanding of the consent process, particularly where a patient withdraws their consent;	17 May 2016
(iii) bring to the attention of the Consultant the comments of the Adviser at paragraph 62 of this report so they can give consideration to submitting	17 May 2016

	a report about what occurred in Mrs C's case to a local morbidity and mortality meeting;	
(iv)	review the GRS data from all of their endoscopy units and reflect on the comments of the Adviser at paragraph 63 of this report in relation to achieving good GRS scores;	17 May 2016
(v)	provide evidence that all their endoscopy units have standardised documentation for recording of patient discomfort during colonoscopy, in line with recommended practice;	17 May 2016
(vi)	provide evidence that all their endoscopy units have standardised guidelines for procedural sedation and for withdrawal of consent;	17 May 2016
(vii)	if they have not already done so, consider developing guidelines for all their endoscopy units in respect of recommendations (v) and (vi); and submit a synopsis of this case together with current standardised documentation and guidelines to their Endoscopy Governance Group in order to provide dissemination of learning and to minimise variability of colonoscopy practice within their hospitals; and	17 May 2016
(viii)	provide evidence of the action they say has been taken, as set out in paragraphs 18 and 48 of this report.	17 May 2016

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

Annex 1

Explanation of abbreviations used

Mrs C	the complainant
the Procedure	a colonoscopy procedure
Hospital 1	Hairmyres Hospital, East Kilbride
Hospital 2	Wishaw General Hospital
Endoscopy Unit	the endoscopy unit at Hairmyres Hospital
the Surgeon	a senior staff grade surgeon at Hairmyres Hospital
the Consultant	a consultant colorectal surgeon at Hairmyres Hospital
the Board	Lanarkshire NHS Board
the Adviser	a consultant colorectal surgeon who provided independent advice on the clinical care and treatment provided to Mrs C
GMC	General Medical Council
the Scope	a colonoscope
GRS	Global Rating Scale

Annex 2

Glossary of terms

colonoscope	a long flexible tube used to examine the lining of the bowel
colonoscopy	a test to look at the interior lining of the bowel
conscious sedation	the use of medication to make a person feel drowsy and relaxed
endoscopy	a test to look inside the body
general anaesthetic	a medical treatment to make a person unconscious and unable to feel pain
Global Rating Scale (GRS)	a quality improvement and assessment tool for the gastrointestinal endoscopy service
midazolam	a medication used to reduce anxiety and produce drowsiness before certain medical procedures
pethidine	a medication to relieve pain

Annex 3

List of legislation and policies considered

British Society of Gastroenterology Guidance for Obtaining a Valid Consent for Elective Endoscopic Procedures

British Society of Gastroenterology Guidelines on Safety and Sedation during Endoscopic Procedures [2003]

Healthcare Improvement Scotland, Learning from adverse events through reporting and review, a national framework for Scotland: Second Edition

General Medical Council Guidance 2008: Consent: patients and doctors making decisions together

NHS Lanarkshire - Hairmyres Hospital - Withdrawal of consent in Endoscopy Unit

NHS Lanarkshire - Safety and sedation during endoscopic procedures

Quality in screening colonoscopy: position statement of the European Society of Gastrointestinal Endoscopy (ESGE). Rembracken B et al., Endoscopy 2012; 44: 957-968

Good Surgical Practice (2014): a collaboration between the four United Kingdom and Ireland Surgical Royal Colleges and the Surgical Speciality Associations