SPSO Scottish Public Services Ombudsman

The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

SPSO
4 Melville Street
Edinburgh
EH3 7NS

Tel **0800 377 7330**

SPSO Information **www.spso.org.uk**

SPSO Complaints Standards **www.valuingcomplaints.org.uk**

Scottish Parliament Region: North East Scotland

Case 201304325: A Medical Practice in the Grampian NHS Board area

Summary of Investigation

Category

Health: GP & GP Practices; clinical treatment; diagnosis

Overview

The complainant (Mr C) raised concerns about the care and treatment his wife (Mrs C) received from the GPs at the medical Practice (the Practice) from January to October 2013. Mrs C subsequently attended Aberdeen Royal Infirmary, where she was diagnosed with bowel cancer. Since the events within this complaint, Mrs C's condition deteriorated further, and she sadly died during the course of our investigation.

Specific complaint and conclusion

The complaint which has been investigated is that there was an unreasonable delay by the Practice in 2013 in diagnosing Mrs C's cancer (*upheld*).

Redress and recommendations

The Ombudsman recommends that the Practice:	*Completion date*
(i) apologise to Mr C for their failure to appropriately refer Mrs C for diagnosis of her cancer during the period from January to October 2013, and for the distress this caused her and her family;	19 December 2014
(ii) provide evidence that the actions set out in their Significant Event Analysis have been met, giving consideration to the NHS Education for Scotland Enhanced Significant Event Analysis approach;	19 January 2015
(iii) identify the training needs for the practice team relating to the issues raised in this complaint, and reflects these in appraisals and assessments; and	19 January 2015
(iv) explain what changes the Practice will introduce to ensure that, in future, their procedures for Significant Event Analyses are in line with national guidelines, and that they receive the prompt	19 January 2015

attention of the whole Practice.

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

Main Investigation Report

Introduction

1. During the period January 2013 to October 2013, Mrs C attended her medical practice (the Practice) with symptoms of lower abdominal pain, bloating, constipation, blood in her stools and weight gain. She was seen by a number of GPs at the Practice and various examinations and tests were carried out. However, Mrs C's condition continued to deteriorate and on 30 October 2013 Mrs C was admitted to the Royal Aberdeen Infirmary. Mrs C was subsequently diagnosed with bowel cancer.

2. Mr C and his wife submitted a formal complaint to the Practice on 14 November 2013 about the care Mrs C received prior to her diagnosis of cancer. The Practice responded on 3 December 2013. Mr C then submitted a complaint to my office. Sadly, Mrs C's condition continued to deteriorate after the events of this complaint, and she died during the course of our investigation.

3. The complaint from Mr C which I have investigated is that there was an unreasonable delay by the Practice in 2013 in diagnosing Mrs C's cancer.

Investigation

4. As part of my investigation of Mr C's complaint, I considered Mr C's submission to my office and reviewed the information obtained from the Practice including the relevant clinical records. My complaint reviewer obtained independent medical advice on Mrs C's care and treatment from a GP and a nursing adviser (the GP Adviser and the Nursing Adviser respectively). The Practice also provided comments on the draft of this report, and these have been discussed with the advisers.

5. 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 Practice were given an opportunity to comment on a draft of this report.

Complaint: There was an unreasonable delay by the Practice in 2013 in diagnosing Mrs C's cancer

6. Mr C complained about several aspects of the care provided to Mrs C by the Practice from January 2013 until her diagnosis on 30 October 2013. Mr C said the Practice failed to consider Mrs C's family history of cancer, explore Mrs C's symptoms further and consider other possible diagnoses. Mr C said

they incorrectly assessed Mrs C's pain in her left lower abdominal side as pelvic pain, failed to listen to Mrs C's concerns that the cause of her pain was something 'more sinister' and failed to assess her symptoms as indicative of cancer.

Key events

7. Mrs C had a consultation with a GP (Doctor 1) on 23 January 2013, which was followed by an ultrasound scan on 8 March 2013. This was followed by another consultation with Doctor 1 on 28 March 2013 (following the scan results) and another on 1 May 2013. She subsequently had three consultations with the practice's nurse practitioner (the Nurse Practitioner) on 17 May, 5 June and 14 August 2013. After the second consultation, on 6 June 2013, the Nurse Practitioner made a routine referral for Mrs C to be assessed by a surgeon in relation to her haemorrhoids. This referral was co-signed by a GP (Doctor 3). On 27 September 2013 Mrs C had a telephone advice call with a GP (Doctor 2), and in October 2013 Mrs C had three consultations with Doctor 3 (on 9, 18 and 30 October). At each of these consultations Mrs C raised a range of symptoms relating to her bowel habit and pains in her abdomen. The details of each consultation are provided in the section relating to the advice we have received.

8. When Mr and Mrs C brought this complaint to the Practice, the complaint was discussed with other GPs in the Practice, and they were sent a response letter on 3 December 2013. Mr C brought the complaint to us, and we informed the Practice of the complaint on 28 January 2014. The Practice subsequently undertook a Significant Event Analysis (SEA), in April 2014, followed by discussion regarding an action plan at a practice meeting in August 2014 (shortly after Mrs C's death). The Practice have said that the SEA was delayed until they could ensure the appropriate team members could be present, to allow the meeting to be as meaningful as possible. It is not clear from the evidence we have been provided whether all those involved in Mrs C's care and treatment were present at the meeting.

The Practice's response

9. In their response to Mrs C's complaint, the Practice set out details of Mrs C's appointments and contacts with the Practice from January 2013 to October 2013. They also considered in more detail, whether they acted appropriately during Mrs C's final consultation prior to her admission to hospital, on 30 October 2013.

10. The Practice went on to try to address Mrs C's concerns. They recognised in retrospect that a referral could have been made earlier, and said that, given Mrs C's deterioration over the summer, it may have been appropriate for a new, urgent surgery referral at that point (subsequent to the routine referral made on 6 June 2013). They apologised for the upset and pain this delay caused to Mrs C. They also apologised for not admitting Mrs C to hospital on 30 October 2013, and the doctor responsible said he had reflected on his practice in light of this complaint.

11. The Practice informed us in October 2014 that they had conducted a SEA in April 2014, which was reviewed in August 2014. The content of this SEA was considered by the GP Adviser.

Relevant guidance

12. The advice I have received was based on four sets of guidelines for GPs to consider in relation to potential cancer diagnoses.

13. The GP Adviser referred to National Institute for Health and Clinical Excellence (NICE) Guidelines CG122: Ovarian cancer: The recognition and initial management of ovarian cancer. In these guidelines, section 1 covers detection in primary care. It states that, if a woman reports having significant symptoms on a persistent basis, then tests should be carried out. The symptoms include persistent abdominal bloating, feeling full and / or loss of appetite and pelvic or abdominal pain. It goes on to clarify that tests for ovarian cancer should be carried out in women of 50 years and over, who present with new symptoms of irritable bowel syndrome (IBS), because IBS rarely presents for the first time in women of this age.

14. Section 2 of the Guidelines CG122 covers the tests and further actions appropriate for suspected ovarian cancer. The initial test should be to measure serum CA125 (a blood test for a specific cancer marker). If this comes back as positive (with CA125 over a certain level), then an ultrasound scan of the abdomen and pelvis should be arranged. If the ultrasound suggests ovarian cancer, then an urgent referral for further investigation is advocated.

15. Finally, Guidelines CG122 say that if the tests do not suggest ovarian cancer, then further investigations should be carried out to find out what is causing the symptoms.

16. The NICE Guidelines 27: Referral guidelines for suspected cancer, Section 1.5 covers cancer of the lower gastrointestinal tract (the intestines) and sets out general recommendations.

17. It stated that where lower gastrointestinal symptoms were unexplained, a digital rectal examination should be carried out wherever possible. If rectal bleeding was reported in patients of 40 years and over, along with a change in bowel habit towards looser stool and/ or increased stool frequency over a period of six weeks or more, then an urgent referral should be made.

18. The NICE Guidelines 27 were similar to the Scottish Intercollegiate Guidelines Network (SIGN) clinical guideline on the Diagnosis and Management of Colorectal Cancer (SIGN Guideline 126). This set out the expectation that all patients over 40 years that report new, persistent or recurrent rectal bleeding should be referred for investigation. It also specified that all patients with symptoms suggestive of colorectal cancer should have a full blood count, including a test for iron deficiency where there have been signs of anaemia. This guidance also stated that a 'watch and wait' approach was appropriate for patients under 40 years old, with low risk symptoms, and particularly if symptoms were transient.

19. More local guidance was also available from the North East Scotland Cancer Co-ordinating and Advisory Group, through their Suspected Cancer Urgent Referrals guide. This reflected the SIGN guidance, and indicated that, in relation to colorectal cancer, an urgent referral was expected if a patient presented with any one of a range of symptoms. These included a persistent change in bowel habit (of greater than six weeks), especially to looser stools, or with unexplained iron deficiency anaemia. The local guidance also mirrored the SIGN guidance in relation to limiting a watch and wait approach to patients under 40 years old.

20. The GP Adviser and the Nursing Adviser also referred to two guidance documents on SEAs. NHS Education for Scotland have produced Guidance for Primary Care Teams on SEA. This guidance aims to provide GP practices with the information they should need to conduct effective SEAs, aimed at improving health care and the patient experience. It specifies that GP practices should be committed to a routine and regular analysis of significant events.

21. The same organisation have also introduced a new approach to SEAs, known as Enhanced Significant Event Analysis. The aim of this new approach is to use an SEA to openly, honestly and objectively analyse patient safety incidents from a 'systems' perspective, with the focus on the systems in place which have failed, rather than the individuals involved. This is considered to be a more constructive approach to learning, resulting in more meaningful improvements to minimise the risks of an event happening again.

Advice obtained

22. The GP Adviser reviewed Mrs C's clinical records and provided me with comments on the care and treatment as described in the records. He considered that the first occasion where Mrs C's care should, without hindsight, have been different was the appointment she had on 23 January 2013 with Doctor 1.

23. At this consultation Mrs C had reported months of left sided abdominal pain, bloatedness and constipation. Doctor 1 considered a possible diagnosis of ovarian cancer due to the symptoms presented and Mrs C's age. The GP Adviser said that this was reasonable. However, Doctor 1 did not consider any other possible diagnosis, as the presenting symptoms were not specific to ovarian cancer alone. The GP Adviser was critical that neither a digital rectal examination nor any blood tests were carried out.

24. Doctor 1 was worried enough to investigate with a pelvic ultrasound. However, the NICE Guidelines CG122 recommend a blood test is carried out initially to check for a specific cancer marker (CA125), followed by an ultrasound if the blood test is positive.

25. NICE Guidelines CG122 also states that if there is a normal ultrasound then a different cause for the woman's symptoms needs to be considered. The ultrasound showed no signs of ovarian cancer. As the result was available to the Practice on 8 March 2013, another possible diagnosis should have been considered at this point.

26. The GP Adviser also said that left sided abdominal pain for some months should be considered a possible presenting sign of bowel cancer as it is a presenting symptom in 52 percent of patients with bowel cancer. As Mrs C exhibited no other possible red flag symptoms it was reasonable that Doctor 1 had a low index of suspicion at this time.

27. When Mrs C presented again to Doctor 1 on 28 March 2013 and was still complaining of lower abdominal pain, the GP Adviser considered that Mrs C should have had a digital rectal examination and full blood count. Instead Mrs C was recommended to continue with medication for constipation. When Mrs C raised concerns that the cause was more sinister Doctor 1 reassured her it was most likely constipation. The GP Adviser was also of the view that most GPs would at this point have made an urgent referral to a colorectal surgeon.

28. Both the GP Adviser and Nursing Adviser were critical of the consultations Mrs C had with the Nurse Practitioner at the Practice, who saw her on 17 May, 5 June and 14 August 2013. In particular, at the appointment on 17 May 2013, Mrs C reported softening of stools, bleeding when opening bowels and tenesmus (the constant feeling of needed to pass stools despite an empty colon). All three of these symptoms are red flags for a possible cancer diagnosis and the GP Adviser considered that it was unreasonable at this stage not to make an urgent referral for suspected cancer to the Colorectal department. Instead, a routine referral was made on 6 June to the General Surgery department, and this was co-signed by Doctor 3.

29. The Nursing Adviser noted that the Nurse Practitioner should have referred Mrs C to the GP for further examination or advice following her initial consultation with Mrs C, as she had presented with clear signs of bowel cancer, and was in too much pain to be fully examined. She concluded that her care was unreasonable.

30. When Mrs C was seen by Doctor 3 on 9 October 2013 it was commented that her symptoms presented like IBS (a common bowel disorder with no known cause which cases painful cramps, bloating, constipation and diarrhoea). However, the GP Adviser stated that IBS does not typically develop as a new presentation in women in their 50s, as per Guidelines CG122.

31. The GP Adviser was also critical that when Mrs C spoke to Doctor 2 at the Practice on 27 September 2013, to try to speed up her referral, the GP did not follow up on her referral, insist it be brought forward, or make a new urgent referral. He indicated that if Doctor 2 had done this Mrs C would have been seen within two weeks.

32. The GP Adviser did say that, based on Doctor 3's notes, his assessment and examination at the consultation with Mrs C on 30 October 2013 were reasonable. He noted Mrs C's symptoms and considered the cause as being an obstruction of her bowel. He also recommended treatment for constipation and advised to return if the symptoms worsened. However, Doctor 3's record of Mrs C's pain level is at great variance to Mrs C's and her family's account. If Mrs C was in as much pain as her family have said, the GP Adviser said she should have been admitted to hospital as an emergency that morning.

33. The GP Adviser was critical that the GPs at the Practice consistently took an approach that assumed a low risk explanation, rather than taking the opposite approach. He noted that, early on, Mrs C's symptoms could have been attributed to common medical problems. However, they could equally represent a sinister medical problem, as was the case. He considered that the practitioners should have weighed up the balance of risk in this case. He said that the evidence indicated that the GPs at the practice appeared to have a low index of suspicion that the symptoms were caused by a serious underlying medical problem. He explained that, in order to diagnose cancer early, there needs to be an assumption that red flag symptoms are treated as suspicious. This would include a consideration of more sinister diagnoses, followed by full investigation and early referral for specialist investigations.

34. The GP Adviser also considered the impact of the delayed diagnosis on Mrs C's health and future prospects. He was guarded in judging what could have been found if alternative investigations had been conducted, and what impact that could have had on her prognosis. However, he said that, in a best case scenario, it may have been possible to diagnose Mrs C's cancer nine months earlier, and that logic would suggest that this would have given her a better prognosis.

35. The GP Adviser was critical of the SEA conducted by the Practice. The GP Adviser noted that the SEA report had been drafted by Doctor 3, and then considered at a meeting when Doctor 3 was not present. He was also critical of the timescales, as the report was written six months after Mrs C's admission to hospital, and the evidence indicated that it was not discussed for a further four months. The GP Adviser was critical of the Practice's report that this was the first time when all relevant staff members could be available. He noted that good practice it to have multi-disciplinary meetings at least once a quarter and ideally every month, to discuss complex patient needs. He explained that this

recommendation now forms part of the Quality and Outcomes Framework, an optional part of the GP contract that most practices sign up to.

36. In relation to the content of the SEA, the GP Adviser noted that some of the actions that were identified were appropriate, but that several required the provision of further evidence or information, to show they had been implemented. He was also critical that the role of the Nurse Practitioner was not being effectively supported and that there needed to be clearer guidance from the GPs on when nurse practitioners should ask for advice, particularly when patients present with red flag symptoms for cancer. He noted that there should be no further delays in providing the Nurse Practitioner with the support and guidance she needed.

Conclusion

37. When Mrs C attended the Practice it was the responsibility of the staff to adequately assess and consider possible diagnoses and refer as necessary for further investigation. It is clear that, while ovarian cancer was a valid consideration based on Mrs C's age and symptoms, no alternative diagnoses were considered by Doctor 1. If an alternative diagnosis had been considered when Mrs C's ultrasound came back clear, other investigations should have been arranged.

38. I am critical that, when the diagnosis of ovarian cancer was ruled out no further investigations were made to establish a full diagnosis. Mrs C's symptoms were considered serious enough in January 2013 to warrant an ultrasound, but were not considered serious enough in March 2013 to warrant a blood test or referral to an alternative specialist.

39. Doctor 1 also did not follow current practice on diagnosing ovarian cancer. Current practice would involve an initial blood test for a marker for ovarian cancer. If this had been done, another sample could also have been taken, to test for anaemia (a low red blood cell count which can indicate bowel cancer).

40. I am also concerned by the consultations that Mrs C had with the Nurse Practitioner. Mrs C presented with clear red flag symptoms for bowel cancer but no urgent referral was made, and none of the GPs were consulted. Mrs C's care was managed under this Nurse Practitioner for four months of the time period examined here and clear bowel cancer symptoms were not acted on appropriately.

41. With this information available on Mrs C's medical record I am critical that neither Doctor 2 nor Doctor 3 recognised the red flag symptoms either. In June 2013 Doctor 3 co-signed a referral, but there is no evidence of any conversation about Mrs C's condition or symptoms. In September 2013 Doctor 2 should have made an urgent referral based on Mrs C's recent history and on-going symptoms.

42. In October 2013 Doctor 3 diagnosed possible IBS, despite no investigations having been done to rule out bowel cancer, and in spite of the rarity of IBS presenting later in life. I am critical that at this point Doctor 3 considered a best case scenario, which was highly unlikely, in favour of making investigations into a more serious diagnosis.

43. Lack of action by various members of the Practice team left Mrs C and her family feeling unsupported when they were concerned about the seriousness of her condition. It had a traumatic impact on them when Mrs C was finally diagnosed, with serious questions about whether her prognosis could have been influenced by an earlier referral. Even if an earlier referral would not have changed her prognosis, it may have allowed Mrs C more time with her family, and greater opportunities to plan their time together.

44. In this case, my concern extends beyond the diagnostic process. The Practice have reported that they conducted an SEA, subsequent to the complaint coming to my office. The Practice have said that this was delayed in order to ensure that all the relevant staff were available for the meeting. While there were several people involved in Mrs C's care, it is not reasonable for an SEA to be delayed to this extent after the events. In the event, it is not clear from the minutes whether Doctor 3 was actually present at the SEA meeting itself.

45. While the Practice did identify some useful learning points in their SEA, they did not pick up effectively on all the issues of concern, and which the GP Adviser would have expected them to. In particular they did not pick up on the need for immediate additional guidance for the Nurse Practitioner.

46. The GP Adviser noted the requirements for regular team meetings as set out in the GP contract. This means that the Practice should have had the opportunity to discuss the case in December 2013 at the latest.

47. I am concerned that the failings identified in this case reflect wider issues within the Practice in terms of the assessment of risk, and the consideration and investigation of possible diagnoses, including more sinister diagnoses. The GP Adviser highlighted his concerns in this regard, and given the number of practitioners involved in Mrs C's care and treatment, I consider this to be a critical issue. The Practice should reflect on this and identify ways to ensure that any red flag symptoms are treated with appropriate suspicion, so that these events are not repeated.

48. The Practice could be assisted in this endeavour by the new Enhanced Significant Event Analysis approach developed by NHS Education for Scotland. This approach provides the opportunity for teams to review their practice and identify ways of improving systems to improve patient safety. It would be a very helpful way for the Practice to identify ways in which their existing systems could be improved, without criticising the role or actions of individual team members.

49. I am conscious that, after the events within the scope of this investigation, Mrs C's cancer was treated, but ultimately returned. Mr C has raised concerns about further delays in diagnosing the return of Mrs C's cancer. While I have no knowledge or evidence in relation to the later period of Mrs C's care and treatment by the Practice, it would have been appropriate for them to undertake a prompt SEA, potentially in December 2013. This was when Mrs C first complained, and this would have given the family greater assurance that the Practice were keen to learn from Mrs C's experiences and improve practice for the future.

Recommendations

50. I recommend that the Practice:	*Completion date*
(i) apologise to Mr C for their failure to appropriately refer Mrs C for diagnosis of her cancer during the period from January to October 2013, and for the distress this caused her and her family;	19 December 2014
(ii) provide evidence that the actions set out in their SEA have been met, giving consideration to the NHS Education for Scotland Enhanced Significant Event Analysis approach;	19 January 2015

(iii)	identifies the training needs for the practice team relating to the issues raised in this complaint, and reflects these in appraisals and assessments; and	19 January 2015
(iv)	explain what changes the Practice will introduce to ensure that, in future, their procedures for SEAs are in line with national guidelines, and that they receive the prompt attention of the whole Practice.	19 January 2015

51. The Practice have accepted the recommendations and will act on them accordingly. The Ombudsman asks that the Practice notify him when the recommendations have been implemented.

Annex 1

Explanation of abbreviations used

Mrs C	the complainant's late wife
the Practice	a Medical Practice in the Grampian NHS Board area
Mr C	the complainant
the GP Adviser	GP adviser to the Ombudsman
the Nursing Adviser	nursing adviser to the Ombudsman
Doctor 1	one of the GPs at the practice
Doctor 3	one of the GPs at the practice
Doctor 2	one of the GPs at the practice
SEA	Significant Event Analysis
NICE	National Institute for Health and Care Excellence
IBS	irritable bowel syndrome
SIGN	Scottish Intercollegiate Guidelines Network

Annex 2

Glossary of terms

anaemia	a condition caused by low red blood cell count in the blood
antigen marker	a biological marker detected in blood. If levels of it are elevated it can indicate cancer
bowel cancer	cancer of the bowel, can also be called colon or rectal cancer
colorectal cancer	cancer of the colon, rectum and anus
colorectal surgeon	a specialist in diseases of the colon, rectum and anus
gastrointestinal tract	the intestines
irritable bowel syndrome (IBS)	a common bowel disorder with no known cause which cases painful cramps, bloating, constipation and diarrhoea
ovarian cancer	cancer of the ovaries
tenesmus	a clinical symptom of feeling the need to pass stools, despite an empty colon

Annex 3

List of legislation and policies considered

National Institute for Health and Clinical Excellence Guideline 27: Referral guidelines for suspected cancer (2005).

National Institute for Health and Clinical Excellence Guideline CG122: The recognition and initial management of ovarian cancer (2011)

Scottish Intercollegiate Guidelines Network (SIGN) Guidance 126: Diagnosis and Management of Colorectal Cancer (2011)

North East Scotland Cancer Co-ordinating and Advisory Group: Suspected Cancer Urgent Referrals (2009)

NHS Education for Scotland, Significant Event Analysis: Guidance for Primary Care Teams (2011)

NHS Education for Scotland, Enhanced Significant Event Analysis – A Human Factors Approach (2014)