

**The Scottish Public Services Ombudsman Act 2002**

# **Investigation Report**

UNDER SECTION 15(1)(a)

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**Case 201300451: Lanarkshire NHS Board**

**Summary of Investigation**

**Category**

Health: Hospital; Colorectal Surgery

**Overview**

The complainant (Mr C) raised a number of concerns that the diagnostic journey he underwent for an abdominal problem was unreasonable and has left him with on-going and debilitating symptoms.

**Specific complaint and conclusion**

The complaint which has been investigated is that Lanarkshire NHS Board's diagnostic actions were unreasonable (*upheld*).

**Redress and recommendations**

	<i>Completion date</i>
The Ombudsman recommends that Lanarkshire NHS Board:	
(i) ensure, as a matter of priority, the Consultant reflects on the events investigated and discusses all learning points at their next annual appraisal. Including when and how a cancer diagnosis is made and communicated;	19 January 2015
(ii) ensure that all the medical staff involved in this case are reminded of the importance of adhering to the General Medical Council guidance on record-keeping;	19 February 2015
(iii) urgently review the diagnostic process used for colon cancer, including the use of Multi-Disciplinary Team discussions, taking into account national guidance;	19 January 2015
(iv) issue a written offer for Mr C to insert a note of clarification in his clinical records where necessary, as mentioned in the draft complaint response;	19 December 2014
(v) review its monitoring process for the handling of	19 February 2015

complaints to ensure that a robust system is in place to prevent complaint responses that are due for issue being delayed and that if unavoidable delays occur, complainants are kept informed; and  
(vi) issue a written apology to Mr C for the failings identified during this investigation.

19 December 2014

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

## **Main Investigation Report**

### **Introduction**

1. On 24 August 2012 Mr C drank a coffee made with milk which was just going off and he later had a loose bowel movement. Mr C then suffered stomach pains and went to his General Practitioner (GP) four days later. The GP prescribed antibiotics which unfortunately did not agree with Mr C and he attended Monklands Hospital (the Hospital) on 2 September 2012. Mr C was admitted and he was examined by a consultant colorectal surgeon (the Consultant); he was scheduled to have a Computerised Tomography (CT) scan (a specialised type of x-ray using computers to give a detailed image of internal organs) and this took place on 8 September 2012. He was discharged from the Hospital later the same day.

2. On 20 September 2012 Mr C saw the Consultant as an out-patient and the Consultant diagnosed cancer of the large intestine. Mr C had a colonoscopy (examination of the intestines using a camera) and attempted biopsy (removal of a sample of tissue for scientific analysis) on 16 October 2012 and underwent investigative surgery on 13 November 2012. During this operation his intestine was punctured. Mr C had part of his intestine removed to repair the damage. No evidence of cancer was found. Since these events Mr C has been left with recurrent diarrhoea between two and five times a day.

3. Mr C complained to Lanarkshire NHS Board (the Board) on 5 February 2013 and his daughter also raised some further issues of concern on Mr C's behalf. The Board responded on 10 April 2013. Mr C was not satisfied with the response and wrote again to the Board on 8 May 2013. He did not receive a response to this letter.

4. Mr C, therefore, remained dissatisfied with the Board's response to his complaint and asked me to review his complaint on 18 September 2013.

5. The complaint from Mr C which I have investigated is that the Board's diagnostic actions were unreasonable.

### **Investigation**

6. I have carefully reviewed all of the documentation sent by Mr C and the Board, including copies of his clinical records. I have reviewed relevant national

clinical guidance and taken advice from one of my medical advisers, who is an experienced consultant colorectal surgeon (the Adviser).

7. 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: The Board's diagnostic actions were unreasonable**

8. Mr C stated that he had visited his GP after accidentally drinking a coffee made with sour milk and experiencing one episode of loose bowel movements and an ache in his stomach. He continued to have problems and attended the Accident and Emergency Department the Hospital on 2 September 2012. Mr C was admitted to the hospital and was scheduled for a CT scan which eventually took place on 8 September 2012. He was later discharged home. Mr C then attended an out-patient appointment with the Consultant on 20 September 2012.

9. The Consultant told Mr C that he had cancer of the large intestine and that he required to have an operation. Mr C was concerned that he was given this diagnosis before any biopsy (where a small sample of tissue is taken for testing in the laboratory) was carried out.

10. As this appointment took place on the day before Mr C went on holiday, the operation was arranged to take place on his return. Mr C had a colonoscopy (where a tube carrying a camera and an instrument for taking a biopsy (sample of tissue) is inserted into the stomach and/or intestine) on 16 October 2012. This investigation had been supposed to include a biopsy, but Mr C was told that there was nothing to take a biopsy of, as everything was clear. Mr C then had key-hole surgery (where an operation is done via a very small incision, often using small flexible cameras to give an internal view) undertaken by the Consultant on 13 November 2012.

11. During the surgery Mr C's large intestine was punctured and the Consultant had to proceed to open surgery (where a large incision is made to give the surgeon access to the relevant organ(s)). The Consultant had to remove a part of Mr C's large intestine. Mr C stated that he was then told that the Consultant had mistaken an adhesion (where scar tissue forms at the site of previous surgery) from the removal of his appendix some 50 years ago, for a

tumour. Mr C said that he was told that he had never had cancer and had not needed surgery in the first place.

12. Mr C stated that since the operation he has experienced recurrent diarrhoea and that the whole experience had caused him and his wife considerable stress.

13. In the letter sent to Mr C on 10 April 2013, the General Manager of the hospital (the Manager) stated that when the Consultant examined Mr C in hospital on 5 September 2012 the Consultant could feel a mass (lump) on Mr C's right side and requested a CT scan. The Manager apologised for, the fact that the scan did not take place until 8 September 2012.

14. The Manager went on to explain that the CT scan revealed a three centimetre mass with 'significant associated regional Lymphadenopathy (enlarged lymph nodes [part of the Lymphatic system which transports the Lymph fluid (containing water, proteins and other essential elements) around the body])'. This was reported as highly suspicious of a caecal (at the beginning of the large intestine) tumour. The Board acknowledged that Mr C had been given a diagnosis of cancer before all the investigations were completed.

15. The Manager then outlined the investigations and treatment Mr C had received, including the colonoscopy and that the original laparotomy (also known as 'key-hole' surgery) was changed to open surgery. The letter continued that the results of the colonoscopy showed what was thought to be a tumour but that the Consultant did not know at the time if it was cancerous or not.

16. The Manager stated that it was while removing a mass of dense adhesions at the site of Mr C's previous appendectomy that the large intestine was punctured. The Consultant, therefore, decided to go to open surgery; removed the damaged part of the intestine; and then re-joined the large and small intestines.

17. The letter continued that there had been no way that the Consultant would have been able to exclude the presence of cancer in the light of the CT findings and the findings of their examinations of Mr C prior to the operation. The Manager said that the only way to confirm this was to remove a specimen and send it for laboratory analysis.

18. The Manager's letter also addressed, and apologised for, a number of other issues mentioned in Mr C's original complaint to the Board, including delays and cancellations of appointments and communication difficulties. Mr C then raised a number of issues about the Board's response, in a letter dated 8 May 2013. Mr C was concerned about what he considered to be a number of inaccuracies in the board's letter, but he did not receive a reply to his letter.

19. In answer to my complaint reviewer's enquiries, the Board responded in a letter dated 28 November 2013 and signed by the Director of Nurses, Midwives and Allied Health Professionals (the Director). The Director acknowledged that although a draft letter had been compiled in response to the concerns Mr C had raised about the Manager's letter, it was not sent. The Director also apologised for this oversight and stated that she would raise this with the relevant department.

20. As the Director's letter did not actually address any of the issues Mr C had raised with the Board in his letter of 8 May 2013, my complaints reviewer wrote to the Board again on 20 December 2013. The Director responded on 16 January 2014. The letter addressed the issues Mr C had raised and included an offer to Mr C to insert a note of clarification of his version of events in his clinical records. A copy of that letter has been provided to Mr C.

21. My complaints reviewer had also asked for information on whether or not the Consultant had had any similar incidents of damage to a patient's organs during key-hole surgery such as Mr C had experienced. The Director stated that in the past three years the Consultant had had no similar incidents.

#### *Advice obtained*

22. The Adviser reviewed all of the relevant documentation, including Mr C's clinical records and also referred to the national guidance as set out in Appendix 3.

23. The Adviser was of the view that a wait of three days as an in-patient for a CT scan was not unreasonable. However, the Adviser considered that it was unreasonable that Mr C did not have a biopsy before the Consultant told him that he had cancer. The Adviser stated that according to national guidance, colon cancer should ideally be confirmed by histology (scientific analysis in the laboratory). However, where an unequivocal mass had been detected by a high

quality double contrast barium enema (where x-rays are taken after a liquid which shows opaque on x-rays is inserted into the colon) or CT colonography (which is a different, more specialised type of CT scan than Mr C had had), and the patient has symptoms strongly suggestive of cancer, histology is not essential.

24. The Adviser stated that it would not have been possible to have been certain that there was a cancer in Mr C's colon without a biopsy. The Adviser continued that CT scanning is not an ideal test to make or exclude the diagnosis of colon cancer. The Adviser was of the view that the Consultant should have discussed with Mr C the possibility of cancer as an explanation for the mass seen on the CT scan, but should have made it clear to him that the final diagnosis would not be known until a pathologist (a specialist in analysing tissue and other samples to identify disease) had analysed a specimen of tissue taken from the suspected tumour.

25. The Adviser noted that a consultant radiologist (a specialist in taking and reviewing various images including x-rays, CT scans etc) who reported on Mr C's CT scan stated that colon cancer was likely; and they recommended that this be confirmed by further investigation such as colonoscopy and biopsy. Mr C went on to have a colonoscopy but no biopsy was taken because it was not possible to reach the caecum during the procedure. The Adviser was of the view that this should have been considered as an incomplete colonoscopy. Normal practice, according to national guidance, would then have been either to have repeated the colonoscopy or request either a CT colonography or barium enema.

26. As stated above, the Adviser said that if a patient is displaying symptoms strongly suggestive of cancer and other tests have confirmed that a mass is present, a biopsy and histology are not essential. However, in this case there was no record of such unequivocal findings. The Adviser noted that in their comments to the complaints team to assist with the drafting of the second response to Mr C, the Consultant had recorded:

'... What was not made clear to [Mr C] on the day of the colonoscopy was that we were unable to get into the caecum to completely clear his colon [large intestine]. ...'

27. On the decision to proceed to laparoscopy, the Consultant's comments included:



'... and the fact that on repeated examinations [Mr C] did have a mass in the right iliac fossa [abdomen]. This is a finding that was confirmed by myself and a senior registrar at the time ...'

28. The Adviser stated that there was no evidence in Mr C's clinical notes to corroborate this statement and the record of the Consultant's examination of Mr C the day after the colonoscopy does not show that they found a mass. The Adviser said that there was no record of any entry by the Consultant that shows that the Consultant detected and documented the presence of an abdominal mass themselves. In general the Adviser felt that the team caring for Mr C consistently failed to document their alleged findings that his abdominal mass persisted.

29. The Adviser also stated that all patients with colorectal cancer should have the benefit of a suitably informed surgical opinion and their management should be discussed by the Multi-Disciplinary Team (MDT – a group of practitioners from various disciplines such as surgical specialists; radiologists; nurses; oncologists etc. who meet to discuss how patients with suspected cancer will be managed). There was no evidence that Mr C's case had been discussed by the MDT until after he had his surgery. The Adviser confirmed this did not accord with national guidance.

30. The Adviser stated that a laparoscopy is an invasive procedure which carries risk. This was demonstrated by the accidental puncturing of Mr C's intestine, although there is no evidence to suggest that this was due to any failing on the part of the Consultant.

31. In addition, the Adviser stated that it is often very difficult to see small cancers with the laparoscope (an instrument used to introduce special surgical instruments to the abdomen) which does not make it an appropriate diagnostic tool in the absence of the other investigations to which the Adviser previously referred. The Adviser was concerned that there did not appear to have been any review of the CT findings nor any attempt to use other, less invasive methods to establish a diagnosis before proceeding to laparoscopy.

32. On the matter of whether Mr C's on-going altered bowel habit was caused by the treatment he had, the Adviser was of the view that this was likely. The Adviser said that altered bowel habit is a recognised consequence of the surgery that Mr C underwent.

33. Finally, the Adviser was asked to comment on the responses from the Board to the complaint. The Adviser was of the opinion that the Board's offer to Mr C to place a record of his version of events in the clinical records was reasonable and appropriate.

34. One of Mr C's questions in his second letter had been whether or not he should have undergone a Magnetic Resonance Imaging (MRI – a special type of image using a magnetic field) scan. The Board's viewpoint was that MRI scanning would not normally be used in investigating caecal cancer and the Adviser agreed with this view.

35. The Adviser also noted that the Board had acknowledged and apologised for various issues of miscommunication. However, the Adviser considered that, as referred to above, the Board's stated view that a number of clinicians had confirmed that Mr C had a persistent mass, was not supported by the clinical records

#### *Conclusion*

36. The standard upon which I base my decisions is 'reasonableness': that is, were the actions taken – or not taken – reasonable in the circumstances and based on the information available to the clinicians involved at the time?

37. The Adviser set out that Mr C's diagnostic journey did not follow the course recommended by the national guidance referred to in Annex 3 to this report, and that the decision to proceed to laparoscopy was precipitous. I was concerned that this went ahead without being discussed at the MDT which the Adviser said should normally happen. We cannot at this point now know what course of action the MDT would have recommended, but had Mr C's case been discussed, it is possible that some of the less invasive investigations that the Adviser has referred to may have been suggested and undertaken instead.

38. Mr C may then have received the news that he did not have cancer without the need for the laparoscopy. There is no evidence that the damage to Mr C's large intestine was caused through any incorrect action of the Consultant. Such damage is a known risk of this type of procedure. However, it is unfortunate that Mr C has been left with on-going symptoms that affect his daily life. While I am sure it was a relief for Mr C to have found out that he did

not, in fact, have cancer, this must have been tempered by the overall outcome for him.

39. Therefore, based on all the evidence and advice available to me, I uphold this complaint.

40. I now turn to the issue of the response to Mr C's complaint by the Board. Although this issue did not form part of Mr C's complaint to SPSO, the reason he brought his complaint to my office was that he had not received a response to his second letter of complaint to the Board. I, therefore, considered that this was an aspect that needed to be addressed, and I exercised my discretion under the SPSO Act 2002 to do so.

41. The Board responded to the letters of complaint that Mr C and his daughter had sent to them in February 2013, on 10 April 2013. This was following a slight delay in obtaining Mr C's consent to deal with the letter sent by his daughter. This was received by the Board on 7 March 2013. Therefore, the response Mr C received was sent after 23 working days, which is slightly outside the 20 working days set out in the national guidance on handling NHS complaints published by the Scottish Government. An extract of this guidance is set out at Appendix 3 to this report.

42. Mr C then wrote again to the Board on 8 May 2013, to raise further questions and point out what he considered to be a number of inaccuracies in the Board's letter of 10 April 2012. As referred to above, he received no response to that letter. When my complaints reviewer queried this with the Board, I was concerned to be told that the issue of this response had been delayed after there had been a delay in receiving further comments from the Consultant, and due to staffing issues. I do not consider that this was acceptable and I have, therefore, made a recommendation below to address this.

#### *Recommendations*

43. I recommend that the Board:	<i>Completion date</i>
(i) ensure, as a matter of priority, the Consultant reflects on the events investigated and discusses all learning points at their next annual appraisal. Including when and how a cancer diagnosis is	19 January 2015

- made and communicated;
- (ii) ensure that all the medical staff involved in this case are reminded of the importance of adhering to the General Medical Council guidance on record-keeping; 19 February 2015
  - (iii) urgently review the diagnostic process used for colon cancer, including the use of Multi-Disciplinary Team discussions, taking into account national guidance; 19 January 2015
  - (iv) issue a written offer for Mr C to insert a note of clarification in his clinical records where necessary, as mentioned in the draft complaint response; 19 December 2014
  - (v) review its monitoring process for the handling of complaints to ensure that a robust system is in place to prevent complaint responses due to be issued being delayed and that if unavoidable delays occur, complainants are kept informed; and 19 February 2015
  - (vi) issue a written apology to Mr C for the failings identified during this investigation. 19 December 2014

44. 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.

**Explanation of abbreviations used**

Mr C	the complainant
GP	General Practitioner (a doctor who sees patients in the community)
the Hospital	Monklands Hospital
the Consultant	the consultant colorectal surgeon who treated Mr C
the Board	Lanarkshire NHS Board
the Adviser	the Ombudsman's professional adviser
the Manager	the General Manager of Monkland's Hospital
the Director	the Director of Nurses, Midwives and Allied Health Professionals at the Board

### Glossary of terms

adhesion	where scar tissue forms at the site of previous surgery
barium enema	where x-rays are taken after a liquid which shows opaque on x-rays is introduced into the intestines
biopsy	where a sample of tissue is removed for testing
caecum	the start of the large intestine
colon	large intestine
Colonoscopy	inspection of the intestine using a tube fitted with a small camera
CT Colonography	a specialised type of CT scan [see below]
Computerised Tomography (CT) scan	a special type of imaging using computers to provide images of the internal organs and structures
histology	the scientific analysis of tissue and other samples to identify disease
key-hole surgery	where investigations and/or surgery is carried out via a small incision using specialised instruments, for example laparoscopy [see below]
laparoscope	the instrument used to perform a Laparoscopy [see below] can contain a camera and/or special surgical instruments

laparoscopy	a procedure using special instruments to investigate and/or operate upon the abdomen
mass	lump or tumour [see below]
Multi-Disciplinary Team (MDT)	a group of practitioners such as surgeons, radiologists [see below], oncologists [see below] specialist nurses etc. who discuss how patients with suspected cancer will be managed
Magnetic Resonance Imaging (MRI)	a special imaging technique using a magnetic field
oncologist	cancer specialist
open surgery	where surgery is done via a large incision
pathologist	specialist who undertakes the scientific analysis of tissue samples etc
radiologist	specialist in taking and analysing various types of image, including x-rays, CT and MRI scans
right iliac fossa	upper right abdomen
tumour	cancerous growth

## Extracts of national guidance considered

### SIGN guidance

The Scottish Intercollegiate Guideline Network (SIGN) produce guidelines on the investigation, management and treatment of many medical conditions. Guideline 126 deals with the 'Diagnosis and Management of Colorectal Cancer'. The guidance includes:

'...

#### 7 Diagnosis

Three methods have been shown to be effective in the primary diagnosis of colorectal cancer: endoscopy; double contrast barium enema; and [CT] colonography. ...

**7.1 ENDOSCOPY** [Any instrument used to obtain a view of the interior of the body. Consists of a tube with a light and an optical system or miniature video camera.]

... is a very sensitive diagnostic test for colorectal cancer and has the major advantages of allowing both biopsy and polypectomy (surgical removal of polyp(s) (benign growths)) and does not involve exposure to ionising radiation ...

#### 7.2 RADIOLOGICAL DIAGNOSIS

... CT colonography, has been shown to be the most accurate and best tolerated radiological imaging method of diagnosing colorectal cancer; it is gradually replacing the use of double contrast barium enema (where a liquid which contains a substance that shows up well under X-ray is inserted into the rectum before X-ray examination is carried out) ...

...

### 8 Surgery

#### 8.1 PREOPERATIVE STAGING

...

An important aspect of preoperative staging is complete visualisation of the large bowel. Synchronous cancers occur in 5% of patients, and these



may not be readily detectable at surgery. When a cancer has been diagnosed, a complete colonoscopy, barium enema or CT colonography should be carried out before surgery whenever possible. ...'

### **GMC guidance**

The General Medical Council (GMC) is the regulatory body for doctors in the UK and also publishes guidance on good practice and ethics. Their publication 'Good Medical Practice: Providing good clinical care' in force in 2012 included:

'...

2. Good clinical care must include:

- (a) adequately assessing the patients conditions, taking account of the history ... the patient's views, and where necessary examining the patient
- (b) providing or arranging advice, investigations or treatment where necessary

...

3. In providing care you must:

...

- (b) prescribe drugs or treatment, ... only when you have adequate knowledge of the patient's health, and are satisfied that the drugs or treatment serve the patient's needs

- (c) provide effective treatments based on the best available evidence

...

- (f) keep clear, accurate and legible records, reporting the relevant clinical findings, the decisions made, the information given to patients, and any drugs prescribed or other investigation or treatment

- (g) make records at the same time as the events you are recording or as soon as possible afterwards

...

- (i) consult and take advice from colleagues where appropriate

'...'

### **NHS complaints handling guidance**

On 28 March 2012 the Scottish Government issued updated 'Guidance on Handling and Learning from Feedback, Comments, Concerns and Complaints about NHS Health Care Services' (the Guidance). The Guidance was based on legislation, advice and guidance contained in documents such as 'the Patient Rights (Scotland) Act 2011'; 'Patient Rights (Complaints Procedure and

Consequential Provisions) (Scotland) Regulations 2012' and 'Can I help you? – NHS Complaints Procedure 2005'. The Guidance includes:

### **3.9 Acknowledging a complaint**

3.9.1 Complaints that cannot be resolved within 3 working days ... should be acknowledged within 3 working days of receipt using the complainant's preferred method of communication.

...

### **3.13 Timescales**

3.13.1 It is important that a timely and effective response is provided in order to resolve a complaint, and to avoid escalation. Investigation of a complaint should therefore be completed and a response issued, wherever possible, within 20 working days following the receipt of the date of the complaint.

3.13.2 There may be circumstances where some complaints are so complex in nature that the detailed investigation takes longer than 20 working days. Difficulties accessing relevant staff and the use of alternative dispute resolution are examples of situations which may make it difficult to meet the 20 working day target.

3.13.3 Where it appears that the 20 working day target will not be met, the [complainant] must be informed of the reason for the delay with an indication of when a response can be expected. The letter should also indicate that the Ombudsman may be willing to review the case at this stage if they do not accept the reasons for the requested extension.

...

### **3.12 Report of the Investigation**

...

3.12.2 ... In accordance with the Complaints Directions, the report must include the conclusions of the investigation and information as to any remedial action taken or proposed as a consequence of the complaint. The quality of the report is very important and in terms of best practice should:

- Be clear and easy to understand, written in a way that is person-centred and non confrontational;

- Avoid technical terms, but where these must be used ... an explanation of the term should be provided;
- Address all the issues raised and demonstrate that each element has been fully and fairly investigated;
- Include an apology where things have gone wrong ...;
- Highlight any area of disagreement and explain why no further action can be taken;
- Indicate that a named member of staff is available to clarify any aspect of the letter; and,
- Indicate that if they are not satisfied [they can contact SPSO] – details of how to contact [SPSO] should be included in the response.

...'