Scottish Parliament Region: Central Scotland and Glasgow

Cases 200503162, 200602726 & 200700502: A Medical Practice, Lanarkshire NHS Board; Lanarkshire NHS Board; and Greater Glasgow and Clyde NHS Board

Summary of Investigation

Category

Health: FHS – GP & GP Practice; clinical treatment/diagnosis
Health: Hospitals; orthopaedics; clinical treatment/diagnosis
Health: Hospitals; oncology; clinical treatment/diagnosis

Overview

The complainant (Mr C) had a lump on his lower left leg removed in 1998 at Stonehouse Hospital (Hospital 1). This was diagnosed at the time as a benign fibromatosis. Some years later, Mr C became aware of a second lump close to the site of the first and he consulted his GP, on 12 July 2004. Mr C was referred by his GP to Hairmyres Hospital (Hospital 2).[1] The referral letter referred to the lump as a recurrence of a 'ganglion' which had been removed in 1998. Following removal of the second lump in May 2005 at Hospital 2, Mr C was diagnosed as having a rare form of cancer and referred for further treatment to a specialist group at the Beatson Centre in Glasgow (the Centre).[2] Mr C complained to the Ombudsman about the GP's diagnosis in the referral letter. In the course of the Ombudsman's investigation, samples from the lump removed in 1998 were re-examined and also found to be cancerous. Concerns were raised that this had not been diagnosed by Hospital 1 in 1998 and also about the treatment Mr C had received in 2004/2005 from Hospital 2 and in 2005 from the Centre. As a result, the investigation was widened to include these aspects of his care.

Specific complaints and conclusions

The complaints which have been investigated are that:

(a) a GP unreasonably misdiagnosed a lump on Mr C's leg as a ganglion (*not upheld*);

[1] Lanarkshire NHS Board are responsible for Hospital 1 and Hospital 2.
[2] Greater Glasgow and Clyde NHS Board are responsible for the Centre.

(b) the care and treatment provided by Hospital 1 and Hospital 2 was inadequate (*not upheld*); and
(c) the care and treatment provided by the Centre was inadequate (*not upheld*).

Redress and recommendations

The Ombudsman recommends that:

(i) the Practice feed back to clinical staff the adviser's comments in connection with note keeping and referral letters;
(ii) this report be shared with the clinical staff involved in Mr C's care and treatment by Lanarkshire NHS Board to consider whether the learning identified could be shared more widely; and
(iii) Lanarkshire NHS Board consider whether the procedures in place are adequate to ensure that the outcomes of tests are appropriately communicated to GP Practices.

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

The Ombudsman has no recommendations in respect of Greater Glasgow and Clyde NHS Board.

Main Investigation Report

Introduction

1. The complainant, Mr C, attended his general practice (the Practice) on 12 July 2004. Mr C had a lump on his lower left leg. Mr C had had a previous lump removed from the same leg in 1998 at Stonehouse Hospital (Hospital 1). This had been diagnosed at the time as a benign fibromatosis. The GP who examined the lump in 2004 referred Mr C to Hairmyres Hospital (Hospital 2) and, in the referral letter of 20 July 2004, described the lump as a ganglion. In June 2005, Mr C was diagnosed with a rare form of cancer – a monophasic synovial sarcoma. The Consultant Pathologist who made the diagnosis (Consultant 1) noted that some fibromatosis could also present similar to the cellular pattern seen in the histology but that, in this case, this was not fibromatosis. Mr C was referred to the West of Scotland sarcoma group, based at the Beatson Centre in Glasgow (the Centre), for specialist treatment. In September 2005 Mr C complained to the Practice and, subsequently, in November 2005 to Lanarkshire NHS Board (Board 1) on a number of points including: that no advice had been given to him in 1998 that this may recur or what to do if it did; that there had been no information in his GP records about the diagnosis in 1998; that the GP had been wrong to diagnose this as a ganglion.

2. The complaint from Mr C which I have investigated is that a GP unreasonably misdiagnosed a lump on Mr C's leg as a ganglion (complaint (a)).

3. As the investigation dealt with information in a referral letter to a hospital, Mr C's clinical records were reviewed by both GP and hospital advisers to the Ombudsman (Advisers 1 and 2). The records contained information about Mr C's subsequent treatment and Adviser 2 said that he felt the treatment provided by Hospital 2 and the Centre should also be reviewed and, given the nature of Mr C's cancer, this should be done by an additional adviser with specific sarcoma expertise (Adviser 3). Mr C, Board 1 and Greater Glasgow and Clyde NHS Board (Board 2) were advised that my investigation was being extended to cover the care and treatment they had provided to Mr C in 2004/2005. Adviser 3 asked for the original samples from 1998 and arranged for these to be re-examined. It was confirmed that this lump had also been cancerous. I, therefore, informed Board 1 and Mr C that the investigation would additionally consider the care and treatment provided by Hospital 1 in 1998. The additional complaints which I have investigated are that:

(a) the care and treatment provided by Hospital 1 and Hospital 2 was inadequate; and
(b) the care and treatment provided by the Centre was inadequate.

4. Board 1 and Board 2 were both provided with a copy of the clinical advice received by Adviser 3 which contained comments and information of possible relevance to Mr C's further management; specifically, that the diagnosis of the original lump had now changed. Both Boards commented in detail on the advice and, as a result, further advice was sought from a second sarcoma specialist (Adviser 4).

Investigation

5. In investigating this complaint I have reviewed the clinical records and relevant correspondence. I have taken advice from four different clinical advisers. Medical terms are set out in a glossary in Annex 2 and abbreviations in Annex 1.

6. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. Mr C, the Practice, Board 1 and Board 2 were given an opportunity to comment on a draft of this report.

Background

7. On 30 November 1998, Mr C attended Hospital 1 and had a lump removed from his lower left leg. The records indicate that a biopsy was taken and this was noted to be a benign fibromatosis.

8. On 12 July 2004 Mr C presented at his GP surgery with a second lump, close to the scar from the first operation. The referral letter from the GP dated 20 July 2004 stated:

> 'Would you kindly review this gentleman who presented with a ganglion in the distal part of the left leg measuring 2cm x 1cm. He says this causes a problem in the way of pain when he accidentally injured that area. I understand that the previous ganglion was removed in November 1998'

9. Mr C was reviewed by an Orthopaedic Consultant (Consultant 2) on 17 November 2004 at Hospital 2. Consultant 2 noted that the fibromatosis diagnosed in 1998 had returned and placed Mr C's name on a waiting list for an operation to remove this and for a biopsy to be taken. The second lump was removed in an operation on 31 May 2005. The biopsy taken that day was noted

to be unusual and sent for further advice to the Centre and subsequently, in late June 2005, diagnosed as a monophasic synovial sarcoma. Mr C was referred to the Centre, where his care was managed by the specialist sarcoma group. A sarcoma surgeon (Consultant 3) referred Mr C for chemotherapy and radiotherapy, having first considered whether attempts should be made to re-operate (see paragraph 31).

(a) A GP unreasonably misdiagnosed a lump on Mr C's leg as a ganglion

10. Given the subsequent diagnosis, it is clearly the case that the lump on Mr C's leg was not a ganglion. However, this diagnosis was made some time after the examination by the GP in July 2004. The question, therefore, is whether the referral letter and actions of the GP, as a result of Mr C's attendance on 12 July 2004 were reasonable, given the evidence at the time.[3] The GP records and the referral letter were reviewed by Adviser 1. Adviser 1 first pointed out that this was an unusual case. In 23 years of GP practice, he had never had a patient diagnosed with synovial sarcoma. Conversely, he had had many patients who had had ganglions.

11. Following his consideration of the clinical records, Adviser 1 said that the GP's action in referring at the first presentation seemed reasonable and also that nothing indicated this should have been referred more urgently.

12. Adviser 1 added that, in his view, the note of the consultation and the referral letter itself could have been better expressed and, specifically, that they should have included more detail of the symptoms, examination and then either a diagnosis or list of possible diagnoses. The notes should have contained a management plan. Adviser 1 also noted that the diagnosis of the previous lump had not been a ganglion but fibromatosis. However, this information came from the hospital records and there was no note of the 1998 diagnosis on the GP's file in July 2004. He said, given this, this should not have been diagnosed by the GP. However, Adviser 1 confirmed that, even if the information of the previous diagnosis of fibromatosis had been available, this would not have changed the level of urgency given to the referral.

[3] By reasonable, I mean whether the decisions and actions taken were within the boundaries of what would be considered to be acceptable practice by the medical profession in terms of knowledge and practice at the time.

13. In summary, Adviser 1 felt that the GP's actions followed 'normal, ordinary, reasonable, GP care' and added that the comments he had made on note-keeping should be seen as indicators of possible improvements rather than being too critical of the GP's actions.

(a) Conclusion

14. When Mr C attended Hospital 2 in May 2005, he had every reason to believe the removal of the lump would be straightforward. I understand the concern and distress Mr C and his family have undergone and will continue to undergo, given the diagnosis of cancer that followed.

15. However, the actions of the GP in July 2004 require to be seen in the light of the information available to her on that date (see paragraph 27). The cancer with which Mr C has been diagnosed is very rare and, while Adviser 1 has some concerns about record and note-keeping, he has said the GP followed 'normal, ordinary, reasonable, GP care'. In the circumstances, I do not uphold this complaint.[4] The advice I have received does, though, provide an opportunity for learning and improving on practice and the Ombudsman, therefore, makes the following recommendation.

(a) Recommendation

16. The Ombudsman recommends that the Practice feed back to clinical staff the adviser's comments in connection with note keeping and referral letters.

(b) The care and treatment provided by Hospital 1 and Hospital 2 was inadequate

17. Mr C's clinical records were initially reviewed by Adviser 3. Adviser 3 noted that the original lump did not present with any of the significant features of a soft tissue sarcoma. He said, as a result, he had no concerns about the actions taken in 1998. Mr C had only had one of the suspicious features of a soft tissue sarcoma and the chance of this being malignant was only 16 percent. However, Adviser 3 was concerned that the histology had not been reviewed following the diagnosis of the second lump in 2005 and advised that this now be done. As stated in paragraph 4, this revealed that the lump in 1998 had also been a sarcoma. Adviser 3 was also concerned that the recurrence of the lump did not appear to have led Consultant 2 to consider the possibility that

[4] Mr C has been concerned that the GP did not have the clinical information from his previous diagnosis in 1998 on record. This is dealt with under heading (b).

cancer could be present and tests carried out prior to the re-excision. In his complaint to Board 1, Mr C had also said that he felt there had been a delay in diagnosis by Consultant 2. In particular, had it been known the lump had been a sarcoma prior to the procedure to remove this in May 2005, a wider excision would likely have been made.

18. In their response to Adviser 3's concerns, Board 1 provided detailed comments from different members of staff involved in Mr C's care. Consultant 2 said that in deciding how to proceed he had taken into account the appearance of the lump and the previous diagnosis from both the histology and an ultrasound scan taken in 1998. Consultant 2 said he was also aware that the waiting list for an MRI scan, which may have provided more information prior to the removal of the second lump, would have been lengthy. The Consultant Pathologist (Consultant 4) who reviewed the histology in 1998 had reviewed the histology again during the course of this investigation. Consultant 4 accepted he had misinterpreted the original biopsy. He also noted that such sarcomas were not often encountered in routine samples in a general laboratory. He was concerned that a misdiagnosis had been made and had asked four of his colleagues to review the samples blind, three had made the same diagnosis of fibromatosis and only one correctly diagnosed the sample. This was a colleague who had worked at the Centre and had specialist experience. Consultant 4 said he had done so to try to explain how the situation had occurred and had noted the points made by Consultant 1 at paragraph 1. He concluded: 'My regret at this mistake cannot be adequately stated.' Board 1 also provided comments from a review of Mr C's care taken by an orthopaedic staff surgeon who had been present on both occasions Mr C had been admitted.

19. Adviser 4 reviewed the clinical records, Adviser 3's comments and the comments provided by Board 1. Adviser 4 agreed that the examination and assessment in 1998 were satisfactory. The ultrasound did not show any evidence of a muscle lesion and, therefore, an excision biopsy had been an appropriate action. It was noted that the diagnosis was of an incompletely excised fibromatosis. Adviser 4 said that this was a benign condition and the diagnosis fitted with the clinical presentation. Adviser 4 said at this stage there

had been no need for a second opinion and it was highly unlikely that a review of the histology should have been called for at this point.[5]

20. However, Adviser 4 was concerned about the follow-up care provided to Mr C in 1998. Given the diagnosis of the lump as fibromatosis and not a ganglion, Mr C should have been advised that he should seek clinical advice if there was any sign of a recurrence. Mr C has said he was aware of a recurrence from about 2001 but was unconcerned and only returned to his GP when his lump became painful. There was no sign in the notes that any clinical information had been sent to the GP or that Mr C had been advised to this effect.

21. In considering the actions of Consultant 2, Adviser 4 said the clinical presentation was again consistent with fibromatosis and the action taken to arrange a re-excision was appropriate. There was no indication that urgent removal or further tests had been required on the basis of the evidence available to Consultant 2. If Mr C had been correctly advised to return on a recurrence he would likely have been seen sooner by Consultant 2 but the treatment would have followed the same course.

(b) Conclusion

22. It is not disputed that the diagnosis given in 1998 was wrong. It is also not disputed that the GP had no clinical information about the diagnosis or any advice that had been given to Mr C in the notes she had before her in 2004 (see paragraph 29). Mr C's own actions clearly support his contention he was not advised to return if the lump recurred.

23. Taking the issue of the misdiagnosis first, Adviser 4 has said that the diagnosis given was in line with both the ultrasound and the physical appearance of the lump. There would have been no reason for Consultant 4 to have asked for this to be reviewed by an expert pathologist. Consultant 4 reviewed the histology again and also arranged for colleagues to review this. This showed that only one colleague with specialist expertise would have diagnosed this. While it has now been established that this was a misdiagnosis, Consultant 1 has noted that the presentation was similar to that of fibromatosis.

[5] It was only after a review of the second histology by an expert at the Centre in 2005 that the diagnosis was made.

24. This has been a difficult decision to make. It is clear that a misdiagnosis was made by Consultant 4 and I would commend him for his openness about this and the way he has sought to understand the reason for this. It should be noted that he reviewed this himself, on the basis the histology had been requested, and before the new diagnosis had been made. As with the GP's actions, Consultant 4's misdiagnosis needs to be considered in the light of his experience as a general pathologist and the other information available at the time. Account also needs to be taken of the advice given by Adviser 4 that there was nothing in 1998 that should have prompted a review and that Consultant 4's diagnosis was in line with the other clinical evidence. Clinical diagnosis can be difficult and complex and, particularly in the case of rare conditions, misdiagnoses are made which are not a result of carelessness but are reasonable based on the evidence. After very careful consideration and taking into account all the available evidence, I have, therefore, decided not to uphold this complaint.

25. It is clear that the misdiagnosis in 1998 does provide an opportunity for learning and improved practice. Consultant 4, in reviewing the histology and asking colleagues to do so, has ensured that some learning has already occurred. The Ombudsman, therefore, recommends that this report be shared with members of the clinical team involved in Mr C's care to consider whether further learning could be shared more widely.

26. Mr C has raised concerns about the communication between the Board and the GP practice and said he was not appropriately advised in 1998 that he should return to the Practice if the lump recurred. The discharge letter sent to the Practice in 1998 refers to the removal of the lump but was sent before the histology had been examined. A reference is made to an out-patient appointment within a week's time. There are no notes of this or of any subsequent contact with the Practice or Mr C. It is difficult after this length of time to confidently state there was no contact between Hospital 1 and the Practice, following the report of the pathology which is in the Hospital records. However, I accept Mr C's statement that, whatever the cause of the failure, he was not appropriately advised and there is no evidence of written contact between Hospital 1 and the Practice.

27. I am aware systems and procedures will have changed since 1998, the Ombudsman, therefore, recommends that Board 1 consider whether the

procedures in place are adequate to ensure that the results of the histology would now be communicated appropriately to the Practice.

(b) Recommendation

28. The Ombudsman recommends that:

(i) this report be shared with the clinical staff involved in Mr C's care and treatment by Board 1 to consider whether the learning identified could be shared more widely; and

(ii) Board 1 consider whether the procedures in place are adequate to ensure that the outcomes of tests are appropriately communicated to GP Practices.

(c) The care and treatment provided by the Centre was inadequate

29. In his advice, Adviser 3 queried the decision by Consultant 3 not to re-excise the lump in 2005 once it was diagnosed as a sarcoma and also that chemotherapy as well as radiotherapy had been offered. He felt that the benefits of chemotherapy were slight and, in his view, wide local re-excision should have taken place.

30. In their response to Adviser 3's concerns, Board 2[6] said that they had asked the Medical Director of the Centre (the Director) to review Mr C's clinical notes. The Director said that the pathology of the second lump had been reported to one of their consultant pathologists (Consultant 1). The slides and his diagnosis of this as a sarcoma had been discussed at the next available weekly multi-disciplinary sarcoma group. Following this discussion, CT and MRI scans were arranged. The CT scan of the chest showed no metastatic disease and the Director confirmed that, at this stage, a re-excision with radiotherapy was recommended. However, the MRI scan on the ankle was negative and Consultant 3 felt he could not target re-excision. Any surgery undertaken would, therefore, have been mutilating and would have affected lower limb function. In the circumstances, Consultant 3 decided that chemotherapy should be recommended to help control any microscopic disease. The Board stated that Mr C was counselled that chemotherapy might help and agreed to this.

31. Adviser 4 said Consultant 1 was a recognised expert and the diagnosis was clearly correct. He said it was not clear why the original histology was not

[6] Board 2 are responsible for the Centre.

re-examined but he added that it would have made 'little difference in terms of future planning'. Adviser 4 agreed with Adviser 3 that the standard treatment would have been wide local re-excision with radiotherapy and only possibly chemotherapy. However, he noted that further surgery was seriously considered by Consultant 3 but that it was decided further surgery would be unlikely to 'achieve reasonable function of the lower limb'. In the circumstances, the decision to use radiotherapy rather than surgery was reasonable. Adviser 4 also noted that Mr C was informed of the possible benefit of chemotherapy and he had no criticism that this was discussed with Mr C or given as treatment.

(c) Conclusion

32. Adviser 3 was concerned that the decision had been made not to operate further on Mr C's leg but to treat with chemotherapy. Board 2 have provided detailed reasons why this decision was made and Adviser 4 has said that, in his view, their decision was reasonable. On this point, it is significant to note that the initial course of treatment considered was that suggested by Adviser 3 and the decision not to follow this standard treatment was made on the basis of the particular circumstances of Mr C. It is also evident that Mr C was given full information about his treatment and I would again like to note that Mr C did not raise concerns about his treatment by the Centre. In all the circumstances, I do not uphold this complaint.

33. In closing, I would like to say that this has been a particularly difficult complaint to consider. It is extremely unusual that an investigation will reveal a wrong diagnosis has been made, particularly after such a length of time. The rarity of Mr C's cancer has meant seeking appropriate expert advice from a very small pool of experts. This unfortunately took some time and caused significant delay. This has, therefore, been a very difficult period for Mr C and I would particularly like to thank him and all those involved in this complaint for their patience.

34. The Practice and Board 1 accepted the recommendations and will act on them accordingly. The Ombudsman asks that the Practice and Board 1 notify her when the recommendations have been implemented.

35. The Ombudsman has no recommendations in respect of Greater Glasgow and Clyde NHS Board.

Annex 1

Explanation of abbreviations used

Mr C	The complainant
The Practice	Mr C's general practice
Hospital 1	Stonehouse Hospital: the hospital Mr C attended for removal of the lump in 1998
Hospital 2	Hairmyres Hospital: the hospital Mr C attended for removal of the lump in May 2005
Consultant 1	The Consultant Pathologist at the Centre
The Centre	The West of Scotland Sarcoma Group based at the Beatson Centre
Board 1	Lanarkshire NHS Board
Board 2	Greater Glasgow and Clyde NHS Board
Adviser 1	GP Adviser to the Ombudsman
Adviser 2	Hospital Adviser to the Ombudsman
Adviser 3	Adviser to the Ombudsman with specialist sarcoma expertise
Adviser 4	Adviser to the Ombudsman with specialist sarcoma expertise
The GP	The general practitioner who examined Mr C on 12 July 2004
Consultant 2	The Orthopaedic Consultant who examined Mr C on 17 November 2004

Consultant 3	The Sarcoma Surgeon from the Centre
Consultant 4	The Consultant Pathologist who reviewed the histology in 1998
The Director	The Medical Director at the Centre

Annex 2

Glossary of terms

Benign	Not malignant. A benign tumour does not invade surrounding tissue or spread to other parts of the body
Biopsy	The removal of a sample of tissue for purposes of diagnosis
CT scan	Computerised tomography scan: pictures of structures within the body created by a computer which takes the data from multiple x-ray images and turns them into pictures on a screen. A CT scan can reveal information about soft tissue not seen in conventional x-rays
Excision	Surgical removal
Fibromatosis	A condition which leads to the formation of benign tumours consisting mainly of fibrous tissue
Ganglion	A type of cyst containing clear fluid or jelly
Histology	The study of the form of structures seen under the microscope. In this report, it usually refers to samples prepared for such examination
Lesion	A general term referring to an abnormality involving any tissue or organ due to any disease or any injury
Metastatic	In this context it would refer to the possibility of sarcoma that is spreading into other body tissues through the lymphatic system or blood

	stream. This was not found to be the case
MRI Scan	A magnetic resonance imaging scan: a radiology technique that uses magnetism, radio waves and a computer to produce images of body structures
Monophasic synovial sarcoma	A synovial sarcoma is a malignant soft tissue tumour which arises near, but not in, a joint. It can occur in two types - mono or biphasial - and this refers to the cell structure