Scottish Parliament Region: Highlands and Islands

Case 200500779: Shetland NHS Board

Summary of Investigation

Category

Health: Hospital

Overview

The complainant (Mrs C)'s late husband (Mr C) was given an angiogram test (which showed serious blockages in his heart arteries) in September 2004. She felt that he might have lived if he had had an angiogram in October 2003 because she felt that an earlier view of his arteries would have enabled him to have further treatment, such as surgery, earlier, when he would have had a better chance of survival. As it was, the later angiogram, and, therefore, the later diagnosis meant that by the time he had further treatment (surgery), he was at very high risk of not surviving it. Indeed, he did die shortly after such surgery.

Specific complaint and conclusion

The complaint which has been investigated is the timing of an angiogram *(not upheld).*

Redress and recommendation

The Ombudsman has no recommendation to make.

Main Investigation Report

Introduction

1. I shall refer to the complainant as Mrs C. On 17 June 2005 the Ombudsman received her complaint that her late husband (Mr C)'s angiogram in September 2004 should have been done in October 2003, when he had his first heart attack, because this would have given him a better chance of survival. (Mr C died in hospital in September 2004.)

2. The complaint from Mrs C which I have investigated is about the timing of the angiogram.

Investigation

3. I was assisted in the investigation by three of the Ombudsman's clinical advisers, a consultant cardiac surgeon, a senior nurse and a renal consultant[1]. In the report I refer to them, respectively, as Advisers 1, 2 and 3. Their roles were to explain to me, and to comment on, aspects of the complaint. As appropriate, we examined the papers provided by Mrs C, the Board's complaint file and clinical records and the 1998 Scottish Intercollegiate Guidelines Network (SIGN) guideline, *Coronary revascularisation in the management of stable angina pectoris* (more information about this guideline, and the role and status of SIGN guidelines generally, is set out at Annex 2). We also examined replies to enquiries which I put to the Board and discussed a meeting which I had with the Director of SIGN to discuss interpretation of SIGN guidelines.

4. To identify any gaps and discrepancies in the evidence, the content of relevant correspondence on file was checked against information in the clinical records and was compared with my own and the advisers' knowledge of the issues concerned. I am, therefore, satisfied that the evidence has been carefully examined and tested robustly. The advisers' advice has also been checked to ensure that it followed (where appropriate) from documentary evidence and was clear. In line with the practice of this office, the standard by which the events were

[1] A kidney specialist. His advice was sought on whether the fact that Mr C had kidney problems should have been a factor in deciding when he needed to be referred for angiography – see paragraphs 18 and 22.

judged was whether they were reasonable, in the circumstances at the time in question. 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. 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.

5. Relevant extracts from the SIGN guideline are set out at Annex 2.

Complaint: The timing of the angiogram

6. I turn now to the complaint. A reminder of the terms used is at Annex 1. Mr C, who was aged 69 at the time, was admitted to the Gilbert Bain Hospital, Lerwick (which I shall refer to as Hospital 1) three times in October 2003 because of heart attacks. An exercise tolerance test was done in December 2003 to try to diagnose the cause but no conclusive result was possible because Mr C could not complete the test.

7. A consultant physician and nephrologist (whom I shall call Consultant 1) reviewed Mr C at an out-patients clinic of Hospital 1 in January 2004. He then wrote to Mr C's GP, explaining the inconclusive result of the exercise test and commenting that Mr C looked well and was on appropriate medication. In particular, he said that, as Mr C was not getting any further chest pain, he did not think a coronary angiogram (see next paragraph) was needed. He also said that he had asked Mr C to see the GP again if he developed anginal chest pain. (Angina is the chest pain felt by patients with coronary artery disease.)

8. An angiogram is a test where x-ray pictures are taken of the heart whilst dye is injected into the coronary (ie heart) arteries. Its purpose is to show any blockages so that any appropriate further action, such as surgery, can be considered. It is an invasive (in other words, more serious than non-invasive) test, and the advisers consider that other methods, such as history taking, examination, exercise testing and perfusion scanning, are less direct, but less risky, ways of telling whether there are blockages in the arteries.

9. Another consultant physician (Consultant 2) at Hospital 1 reported to the GP in April and May 2004 that a second exercise test was also inconclusive – again, because Mr C was physically unable to complete it. The April letter said that, although Mr C had chest pain in bed at night, which sounded like heart pain, this did not tie in with Mr C's good capacity for exercise (Consultant 2 said that Mr C told him that he walked half a mile uphill each day). The May letter said that the risks of angiography were not justified because Mr C was experiencing no angina pain at present and because his condition was well controlled with medical therapy (drugs). (I note here that Mrs C felt Mr C should have been asked to detail his alleged daily half mile uphill walk (because she disputed it) and that confirmation should then have been sought from her. She also felt it was misleading to refer to the exercise tests as 'inconclusive': Mr C had been unable to complete them.)

10. On 31 May 2004 Mr C was admitted to Hospital 1 because of chest pain. He was discharged on 1 June 2004. Also on 1 June, Hospital 1 sent a referral request to the cardiology department of a hospital (Hospital 2) in another NHS board's area, explaining Mr C's history and asking them to do an angiogram. (Hospital 1 did not have the facilities for an angiogram to be done there.) In other words, Hospital 1's decision to request an angiogram was prompted by the 31 May 2004 admission.

11. Mr C was admitted to Hospital 2 in July 2004 because of Hospital 1's referral request. A consultant cardiologist at Hospital 2 (Consultant 3) decided to do a myocardial perfusion scan instead of an angiogram because of the possibility that that might give a diagnosis (with less risk). He said he could do an angiogram later if that was indicated. Perfusion scanning is a radioactive method of assessing how much blood is going to various regions of the heart.

12. The perfusion scan gave a result of 'normal' (although, unusually, this turned out to be a false result). In September 2004 Mr C was admitted again to Hospital 2 because of continuing chest pain and was given an angiogram, which showed severe coronary artery disease. Very sadly, however, after various treatments, including surgery, Mr C died in Hospital 2 later that month because of another heart attack, with extensive bleeding into dead muscle.

13. As part of the response to Mrs C's complaint to the Board, Consultants 1 and 2 gave further explanations (in various letters and at meetings) about their decisions not to arrange an earlier angiogram. I summarise these at paragraphs 14 to 15. I should add firstly that, in explaining her complaint, Mrs C said that, since Mr C's heart attacks in October 2003, his memory had been affected, so that he could not remember what chest pain he had had. She said this affected his descriptions of his symptoms when explaining them to doctors. She also told me that on many occasions, she said this to Consultant 1 and to nurses at Hospital 1. The Board told me that the two consultants said that Mr C did not show evidence of vagueness or confusion at any of his hospital attendances and that no one, including Mrs C, other relatives, the GP or nursing staff, indicated to them that Mr C was confused during the time in question.

Consultant 1

14.

> 'When I saw Mr C in January 2004 it is clear he was not having chest pain, despite modest activity. It is not common practice to offer angiography to such patients because the chances of finding a significant remediable lesion are low. I see many, many patients with chest pain and I use the same criteria for each one in deciding whether to make an angiography referral. Such a decision is based on risk. In patients [like Mr C], whose angina was stable, rather than unstable, a risk assessment is required – in line with the SIGN guideline. Such an assessment involves various factors, the most important (and the one used by most cardiologists) being the presence or not of chest pain. On questioning, Mr C denied any chest pain on exertion, which made him low risk and, therefore, not an appropriate patient for angiography at the time I saw him. From my many conversations with cardiologists [at Hospital 2] over the years, I am confident that their advice would have been to continue with medical management [drugs] because of the lack of symptoms.
>
> If we referred patients like Mr C there would be a long waiting list, which could disadvantage patients who did have relevant symptoms and who could, therefore, benefit from early angiography. Additionally, one must remember that the angiography itself carries a risk, which is small but includes death, heart attack and heart rupture'.

Consultant 2

15.

> 'Mr C tended to deny having chest pain. The guidelines for angiography referral are related to symptoms so, in the absence of Mr C's complaining of any, a referral was not appropriate.'

16. When the Board received Mrs C's complaint, the Chief Executive asked a medical manager, whom I shall call Manager 1, to investigate it. I summarise at paragraph 17 some of the points made by the Chief Executive and Manager 1 in internal correspondence and in letters to Mrs C.

17.

> 'During one of Mr C's [Hospital 1] admissions in October 2003, transfer to [Hospital 2's] Coronary Unit for an angiogram was inappropriate as he was having a heart attack. Current guidelines/agreed protocols were followed. The criteria for angiograms are where there is clinical necessity in patients who are actively or severely symptomatic. As soon as [Mr C] reported significant symptoms they were acted on. On direct questioning Mr C absolutely denied having chest pain. There is nothing a clinician can do if a patient does not reveal symptoms. [Manager 1] contacted the GP about this; and the GP, too, stated that Mr C often made light of his symptoms and would have tended to deny having much chest pain.'

Comments from the Ombudsman's Advisers

18. Adviser 1 made the following points:

- looked at individually, each episode of care by Consultant 1 and Consultant 2 was appropriate; however
- from around January 2004, Mr C's care should have been considered as a total picture, rather than simply as individual episodes. A man of 69, with kidney dysfunction, known previous heart attacks, multiple episodes of chest pain which required hospital admissions and one inconclusive exercise tolerance test, should have been recognised as a candidate for early coronary angiography in case he had (as he turned out to have) coronary artery disease;
- Mr C did experience harm that could possibly have been avoided by an earlier angiogram. An earlier angiogram would have given him a better

chance of living longer. This is because his condition became so poor that he was an exceptionally poor risk for the surgery which he did have shortly before he died. However, his death was a natural progression of his coronary artery disease.

19. Adviser 2 said that if, as Mrs C recalled (see paragraph 13), nursing staff had been told formally that Mr C might mis-represent episodes of pain because he might be unable to remember them, she would expect such statements to be recorded in the nursing notes. No such record appears. Adviser 2 considers the nursing records to be of a reasonable standard and to give a good picture of Mr C's condition, care and treatment.

20. Adviser 3's comments appear at paragraph 22.

Further comments from the Board and Mrs C

21. In line with our usual practice, Consultant 1 and Consultant 2 were invited to comment on the criticism at paragraph 18(b), and, later, both the Board and Mrs C were given the opportunity to comment on a draft of this report. In the light of the advice summarised at paragraph 18(b), that draft upheld Mrs C's complaint. Paragraphs 22 and 23 summarise the key comments made.

22. In commenting on paragraph 18(b), Consultant 1 and Consultant 2 quoted paragraph 2.3.1 of the SIGN guideline (see Annex 2). They said that, when Consultant 1 saw Mr C in January 2004, the exercise test had been inconclusive. On being questioned, Mr C said he was not getting any chest pain. When Consultant 2 saw him in April 2004, Mr C had some chest pain in bed at night but said he could walk half a mile uphill every day without symptoms. The consultants considered that the SIGN guideline's paragraph 2.3.1 was not relevant at that point because of Mr C's lack of symptoms. They added that, when Mr C was admitted to Hospital 1 in May 2004, the decision to refer for angiography was taken because he now did have further chest pain despite optimal medical therapy and, therefore, the SIGN guideline was now relevant. They considered that the SIGN guideline had been followed and that Mr C's care and treatment had been appropriate. Consultant 1 and Consultant 2 repeated much of their thinking in their comments on a draft of this report, adding that they did make decisions on the basis of considering the totality of Mr C's situation and that clinical thinking in 2003 was far

less clear in respect of the relevance of kidney dysfunction than is now the case. (In relation to this point, Adviser 3 has commented that at that time the emphasis had been on patients who were on dialysis – which Mr C was not – because of the well-recognised high incidence of coronary heart disease in that group of patients. Renal impairment would have carried little or no weight in a decision whether to perform coronary angiography.)

23. Some of Mrs C's views have been reflected elsewhere in this report. In commenting on a draft of it, she explained some of her concerns again. She also referred to Consultant 1's view (paragraph 14) that, if he referred patients like Mr C for angiography at Hospital 2, a long waiting list would develop. Mrs C felt that he was stepping inappropriately into the political field in this regard.

Conclusion

24. At paragraphs 3 to 4, I outlined my method of investigation. This has been a particularly difficult complaint to consider. In reaching my conclusions, I have taken full account of the advice I have received. However, it may be helpful if I reiterate here that the role of the Advisers is to explain certain aspects, such as medical issues, of a case and to offer an opinion. But it is not for them to reach a decision on a case: that is the role of the investigative staff, acting on the delegated authority of the Ombudsman. As I noted in paragraph 4, the standard I must apply in reaching a conclusion is whether the actions to which the complaint relates were reasonable, in the circumstances at the time in question. In this context, decisions and actions are reasonable if they 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. The fact that, in particular circumstances, one doctor might do one thing and another doctor might do something else does not necessarily mean that either is wrong. Both might fall within the boundaries of reasonable practice.

25. In reaching a view on whether what happened in Mr C's case was within the bounds of reasonable practice, I have needed to take account of the SIGN guideline on *Coronary revascularisation in the management of stable angina pectoris*. It is important to remember that this is a guideline: it is not mandatory. As is stressed in the preface to this particular guideline (see Annex 2), standards of medical care are determined on the basis of all clinical data available for an

individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to a particular guideline will not ensure a successful outcome in every case, nor should a guideline be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor in light of the clinical data presented by the patient and the diagnostic and treatment options available. This was confirmed by the Director of SIGN when I met her to discuss how she would expect SIGN guidelines to be interpreted. She explained that the guidelines can only be as prescriptive as the body of clinical evidence behind them. Where, as in this case, the guideline necessarily has to allow wide scope for interpretation, the crucial element is the symptoms presented by the patient.

26. The guideline does not say that patients must be referred for angiography in particular circumstances. It merely notes circumstances in which angiography is appropriate, 'can be very helpful' or where 'most experts agree that patients … should be offered angiography'. This means that two people may take different actions yet both be acting within the SIGN guideline. I am satisfied that paragraph 2.3.3 of the guideline (see the last quotation at Annex 2) means that it might be within the bounds of reasonable practice not to refer a patient such as Mr C for angiography. Paragraph 2.3.3 advises that angiography is appropriate (and it is put no more strongly than that) in patients who have had inconclusive non-invasive tests and who continue to have chest pain which is severe or frequent or who continue to have chest pain that results in recurrent hospital admission. Mr C had had inconclusive testing (that is, testing from which no conclusion could be reached). However, as far as can be proved, the two consultants were not made aware of any 'continuing' chest pain that was 'severe or frequent'. And Mr C did not 'continue' to have chest pain that resulted in 'recurrent hospital admission'. After his admissions in October 2003, he had no chest pain that resulted in any hospital admission until the end of May 2004. That is when Hospital 1 made an angiogram request. (I should add here that I do not consider that Consultant 1's comment about waiting lists (see Mrs C's concern at paragraph 23) was inappropriate. We would not expect clinicians to add patients inappropriately to waiting lists because it would be an inappropriate use of NHS resources and because of the unfairness which this could cause to patients who were, rightly, on the list.)

27. Moving on from the SIGN guideline, I turn now to the crucial question of what symptoms were presented to Consultants 1 and 2. Mrs C said that her husband was not able to give reliable information to doctors. In her view, following his heart attacks in October 2003, his memory had been affected, so that he could not remember what chest pain he had had. Similarly, he had not been able to walk uphill for half a mile daily – as he was said to have told doctors he could – and she thought that statement should have been checked with her. She said that she had told Consultant 1 and nurses at Hospital 1 on many occasions about her husband's forgetfulness. And she thought that the fact her husband was unable to complete exercise tolerance tests should in itself have been regarded as significant, rather than merely leading to the test results being recorded as 'inconclusive'.

28. I am satisfied that, in using the term 'inconclusive', the two consultants were fully aware that the tests had not been completed. 'Inconclusive' simply means that, for whatever reason, no conclusion could be reached from the tests. In considering the tests in relation to the appropriateness of angiography, the consultants said that they were guided by the SIGN guideline (see Annex 2). In other words, I am satisfied that no incorrect action, decision or interpretation was done or made because of any misunderstanding of the tests' outcome.

29. Evidence from the Board (based on notes made at the time in question as part of the clinical records) is that Mr C clearly stated that he was walking half a mile uphill every day and that, on direct questioning, he absolutely denied having chest pain. I accept that, unless the doctors had clear grounds for doubting what they were being told, they had to accept it. Mrs C said that she had repeatedly told Consultant 1 and nurses at Hospital 1 about her husband's forgetfulness, but there is no record of that in either the medical or nursing notes. That does not mean that the information was not given by Mrs C – although the absence of any reference to it in the generally comprehensive nursing notes may be an indication that whatever was said did not register with the nurses as formal representations of clinical significance. Be that as it may, in the absence of relevant records and so long after the event, it is simply not possible for me to prove what was said or not said about Mr C's memory. In other words, there is no evidence that Consultant 1 or Consultant 2 had reason to believe that Mr C had more chest pain than he or the GP were reporting.

30. I have said (see paragraph 11) that Consultant 3 decided to do a perfusion scan, intending to do an angiogram later if necessary, because such a scan might give a diagnosis - but with less risk than an angiogram. It was particularly unfortunate that the scan falsely (see paragraph 12) gave a result of 'normal' because, if it had shown an accurate result, one would assume that an angiogram would have been done. This might have produced a different outcome for Mr C. However, that is speculative: one cannot say that it would have been the case.

31. Mr C was, instead, referred for an angiogram on 1 June 2004. Should he have been referred earlier? I have explained (see paragraph 26) that it became clear to me that, as far as can be proved, Mr C's symptoms did not fall within the description at paragraph 2.3.3 of the SIGN guideline (that is, he did not appear to have continuing chest pain which was severe or frequent or which resulted in recurrent hospital admission). I have also explained the importance which the SIGN Director said should be given to the patient's presenting symptoms when considering cases under the SIGN guideline in question. I have set out in paragraphs 26 to 29 some of the difficulties in coming to firm conclusions about what symptoms Mr C was displaying in the period in question, particularly in relation to chest pain and the outcome of exercise tolerance tests. As to kidney dysfunction, Adviser 3 has said (see paragraph 22) that, at the time in question, renal impairment would have carried little or no weight in a decision whether to perform coronary angiography.

32. Consideration of the Board's comments on a draft of this report thus made it clear that the 'whole picture' view that we had originally taken (see paragraph 18) was not supported by the evidence in the way that had appeared to be the case. Therefore, taking all factors into account, I see no grounds for concluding that the decision not to refer Mr C for angiography before 1 June 2004 fell outwith the boundaries of reasonable clinical practice. I do not uphold the complaint.

Recommendation

33. The Ombudsman has no recommendation to make.

30 January 2007

Annex 1

Explanation of terms used

Mrs C	The complainant
Mr C	Mrs C's husband
The Board	Shetland NHS Board
Hospital 1	The Gilbert Bain Hospital, Lerwick
Hospital 2	The hospital in another NHS board's area to which Mr C was admitted
Adviser 1	Consultant cardiac surgeon adviser to the Ombudsman
Adviser 2	Senior nurse adviser to the Ombudsman
Adviser 3	Renal consultant adviser to the Ombudsman
Consultant 1	Consultant physician and nephrologist, Hospital 1
Consultant 2	Consultant physician, Hospital 1
Consultant 3	Consultant cardiologist, Hospital 2
Manager 1	Manager at Shetland NHS Board who investigated Mrs C's complaint
GP/s	General practitioner/s at Mr C's GP Practice
SIGN	The Scottish Intercollegiate Guidelines Network, who produced a series of guidelines

Annex 2

Glossary

Angiogram	An invasive test where x-ray pictures are taken of the heart whilst dye is injected into the coronary (heart) arteries. Its purpose is to show any blockages so that any appropriate further action, such as surgery, can be considered
Perfusion scan	A diagnostic test using radioactivity to assess how much blood is going to various regions of the heart

Annex 3

List of legislation and policies considered

The Scottish Intercollegiate Guidelines Network (SIGN)

SIGN were established in 1993 by the medical Royal Colleges to develop evidence-based national guidelines for NHS Scotland. In 2005, SIGN became part of NHS Quality Improvement Scotland (QIS). QIS were established as a Special Health Board in 2003, in order to act as the lead organisation in improving the quality of healthcare delivered by NHS Scotland. QIS's roles include providing clear advice and guidance to NHS Scotland on effective clinical practice, in order that changes can be made to the benefit of patients, and setting clinical and non-clinical standards of care to help improve performance and set targets for continuous service improvement.

Clinical guidelines

Clinical guidelines have been defined as systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. Guidelines are 'tools for making decisions in health care more rational for improving the quality of health care delivery and for strengthening the position of the patient'.

SIGN have the responsibility for producing clinical guidelines for NHS Scotland. The evidence-based guidelines developed by SIGN are derived from a systematic review of the scientific evidence followed by the considered judgement of the Guidelines Development Group for each guideline.

Implementation of SIGN guidelines is the responsibility of NHS boards. SIGN guidelines provide the evidence base for many of the standards developed by QIS. When elements of SIGN guidelines are incorporated into QIS's 'essential' standards, they are obligatory.

The SIGN guidelines applicable in this case

In 1998 SIGN produced guidelines on *Coronary revascularisation in the management of stable angina pectoris* (SIGN Publication 32). The guideline is prefaced by notes for users which include:

‘This guideline is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor in light of the clinical data presented by the patient and the diagnostic and treatment options available.'

The following sections of the guideline are of particular relevance to this case:

'2.3.1 … The severity of symptoms indicating the need for coronary angiography will vary depending on the patient's (and doctor's) perception of their illness. However, most experts agree that patients with … symptoms on minimal exertion or at rest … despite optimal medical therapy [drugs] … should be offered angiography. … Coronary angiography is appropriate in patients who have limiting angina, despite optimal medical therapy, and may, therefore, benefit symptomatically …

2.3.3 … There are a number of patients who continue to have chest pain but either cannot perform an exercise tolerance test or have satisfactory non-invasive investigations. These patients may be regular attenders at their general practitioner's surgery and often have frequent admissions to hospital with chest pain. … [An] angiogram can be very helpful in excluding obstructive coronary artery disease, removing uncertainty about the diagnosis, reassuring the patient … . Coronary angiography is appropriate in patients in whom non-invasive tests have been inconclusive or negative, but who continue to have chest pain which is severe, frequent, or resulting in recurrent admission to hospital.'

SIGN Publication 32 is currently under review. A new guideline on coronary heart disease is due to be launched in February 2007.