Scottish Parliament Region: Mid Scotland and Fife

Case 200502216: Forth Valley NHS Board

Summary of Investigation

Category

Health: Hospital; Medical

Overview

The aggrieved (Mr C) raised a number of concerns through his Member of the Scottish Parliament (Mr A) about the treatment his wife received at Falkirk Royal Infirmary (the Hospital) during 2003 and the way his complaint was handled.

Specific complaints and conclusions

The complaints which have been investigated are that:

(a) the clinical treatment which Mrs C received was inadequate *(not upheld)*; and

(b) the tone of one of the Board's response letters to Mr A was inappropriate *(not upheld)*.

Redress and recommendations

The Ombudsman has no recommendations to make.

Main Investigation Report

Introduction

1. On 13 March 2006 the Ombudsman received a complaint, through Mr A, from Mr C who had concerns about the treatment his wife (Mrs C) received at Falkirk Royal Infirmary (the Hospital) during 2003 and the way his complaint was handled.

2. The complaints from Mr C which I have investigated are that:

(a) the clinical treatment which Mrs C received was inadequate; and

(b) the tone of one of the Board's response letters to Mr A was inappropriate.

Investigation

3. In writing this report I have had access to Mrs C's clinical records and complaints correspondence between Mr C, Mr A, and Forth Valley NHS Board (the Board) who have administrative responsibility for the Hospital. I obtained advice from one of the Ombudsman's professional advisers (the Adviser), who is a consultant gastroenterologist with special expertise in liver disease, on the clinical aspects of the complaint.

4. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. An explanation of the abbreviations used in this report can be found at Annex 1 and a glossary of the medical terms can be found in Annex 2. Mr C and the Board were given an opportunity to comment on a draft of this report.

Clinical background

5. Mrs C had been admitted to the Hospital in April 2003 with liver failure having vomited blood. An upper gastrointestinal endoscopy demonstrated oesophageal varices and Helicobacter pylori (H.pylori) gastritis. The oesophageal varices were treated by application of bands, (strong rubber bands which stop the blood flow to the distorted veins and allows them to scar and prevent further bleeding), which during the endoscopy and the Helicobacter gastritis was treated with a five day course of Amoxicillin and Metronidazole plus a six week course of Lansoprazole. At further endoscopy one month later, on 2 June 2003, further bands were applied to the varices and a test performed which confirmed eradication of the H.pylori. Mrs C was referred by her GP to a Consultant Gastro-enterologist (the Consultant) on 22 July 2003 for an earlier than planned out-patient appointment with worsening abdominal swelling and a

skin rash. In his reply to the GP three days later the Consultant brought forward Mrs C's appointment from November 2003 to 29 August 2003 and suggested stopping her Spironolactone and adding two different diuretic medications. On 11 August 2003 Mrs C was admitted to the Hospital with severe liver failure. Despite treatment for liver failure and various infective complications, Mrs C's clinical condition deteriorated. Mrs C was assessed for possible liver transplantation but was judged to be too frail. Mrs C died on 9 December 2003 of liver failure due to cirrhosis caused by alcoholic liver disease.

(a) The clinical treatment which Mrs C received was inadequate

6. Mr C complained to the Board that he was concerned about various issues relating to his wife's treatment at the Hospital. He was concerned that Mrs C had been inappropriately prescribed lansoprazole in view of her medical history. He understood that in patients with severe liver disease the metabolism of the medication was prolonged when daily doses of 30mg are prescribed. He also felt that staff failed to monitor his wife adequately and that it had been inappropriate to change her clinic review from three monthly to four monthly (attended 10 July 2003 and next appointment made for 13 November 2003). Mr C also did not think it was appropriate for the Consultant to stop Mrs C's Spironolactone on the basis of the GP letter only and that he should have made arrangements to see Mrs C personally at an earlier clinic appointment.

7. On 9 August 2004, the Board's Director of Nursing (the Director) wrote to Mr C and explained that staff were aware that Mrs C had underlying liver disease but considered it appropriate to administer lansoprazole @ 60mg for six weeks to combat an infection. She also noted that that Mrs C's endoscopy was booked for May 2003 but moved to June 2003 as it was not deemed to be an urgent referral. It was also noted that the GP letter was received which mentioned that Mrs C had abdominal swelling and had developed a rash. The Consultant, who had never seen Mrs C before, suggested that he would arrange to see Mrs C at his clinic and stopped her Spironolactone medication in the meantime.

8. The Adviser told me that lansoprazole is one of a group of drugs known as H2 antagonists which block the production of gastric acid. Initially developed for the treatment of peptic ulcers, these drugs were found to have an antibacterial effect when used in a combination with certain antibiotics. This combination (triple therapy) is highly effective in the eradication of H.pylori in the stomach which then allows the gastritis to heal. Lansoprazole is metabolised in the liver.

When the liver is failing, metabolism of the drug is decreased so that it remains longer in the circulation. This means that the prescribed dose of drug can be reduced without much loss of efficacy. However, it is not necessary to reduce the dose in the elderly or in patients with liver disease since the drug is generally very safe and well tolerated. The dose prescribed for Mrs C was the standard dose that is extensively prescribed in triple therapy for H.pylori, with or without the presence of liver disease. The Adviser commented that it appeared Mr C had concerns that the dose which Mrs C received was toxic to patients with liver failure. The Adviser said that it was important to differentiate that toxic effects are dose related and adverse drug reactions are due to the patient's idiosyncratic reaction to a drug and is not dose related. Mrs C had no such reaction.

9. The Adviser said Mrs C was first seen in the Consultant's clinic on 3 April 2003 by a senior doctor. This was six weeks after the GP referral. She was admitted to the Hospital following a bleed on 26 April 2003 and discharged on 1 May 2003 but seen for a further band ligation on 3 June 2003 which was some four weeks later. At that time the situation appeared to be stable and a further review endoscopy was planned for eight weeks time. In the meantime she was seen at a follow-up on 11 July 2003 which was five weeks after the endoscopy. A further out-patient review was planned for 16 weeks later – about 13 weeks after the endoscopy. Bearing in mind Mrs C was under the care of her GP, the Adviser did not regard these timescales as unreasonable. In the event Mrs C's liver failure progressed and she developed a new problem (an extensive skin rash) that precipitated her locum GP to request an earlier appointment. In the Adviser's view Mrs C was adequately monitored.

10. The Adviser commented that Spironolactone is a relatively weak diuretic and the Consultant's suggestion, prior to the accelerated appointment, that it should be stopped and replaced with a more powerful combination of diuretics (plus fluid restriction) to control her increasing ascites was a reasonable suggestion. The Adviser noted the Consultant specifically did not comment on Mrs C's rash without first examining her and from the content of the Consultant's letter of 25 July 2003 to Mrs C's GP it is clear that he did not act on the GP letter alone but had reviewed the information in her clinical record before exercising his clinical judgement.

11. The Adviser concluded that liver failure is a complicated illness with many upsetting complications. The Adviser understood how distressing it would have

been for Mr C to witness the downward spiral of end stage liver disease. However, on the basis of the information provided the Adviser could find no evidence to suggest that Mrs C's clinical management fell below a standard that should normally be expected.

(a) Conclusion

12. Mr C was concerned about the medications which had been prescribed for Mrs C and felt that her care and treatment were not adequately monitored. The Board had tried to provide Mr C with explanations but he remained dissatisfied with their responses. The advice which I have received, and accept, is that Mrs C's clinical management was of a reasonable standard. Appropriate medication and treatment had been provided and action had been taken to ensure that she was monitored at regular intervals. Accordingly I do not uphold this aspect of the complaint.

(b) The tone of the Board's response letter to Mr A was inappropriate

13. Mr C said that as the Board were not addressing his concerns he contacted Mr A in January 2005. Mr A forwarded a note of Mr C's concerns as set out in a handwritten A4 size double sided sheet of paper to the Chief Executive of the Board. Mr C felt that the Board's response to Mr A's letter was derogatory and sarcastic in the way it referred to his 'handwritten note'.

14. The Director's response to Mr A's letter included '…Unfortunately the handwritten note was a little vague about specific areas of concern and who may be involved…'. 'in the note there were several remarks about out-patient clinic appointments but no specific complaint is raised … 'There is a comment in the handwritten note that nine days following …'.

15. The Director wrote to Mr A on 21 April 2005 and said it had been noted that the response to Mr A's letter did not provide Mr C with sufficient information. It was decided that matters might be progressed if a meeting was held with Mr C and a Unit Nurse Manager. The meeting took place on 17 May 2005 and it was noted that apologies were offered to Mr C and an assurance was given that it was an innocent form of words and not intended to cause distress.

(b) Conclusion

16. Mr C felt that continual reference by the Director to his handwritten note was both sarcastic and derogatory. I note that apologies were later provided by

the Unit Nurse Manager who explained that an innocent form of words had been used and it was not intended to cause distress. Ultimately this issue is one of interpretation and to an extent I can see how Mr C would have been dissatisfied with the form of wording which was used. I note that staff found the handwritten note, which was attached to Mr A's letter, to be vague and as a result they decided that further information was required. Staff should take care when responding to complaint letters in case the tone or contents might cause concern or offence. I am pleased to note that the Board acted on the matter before the complaint was raised with the Ombudsman's office in that a meeting was held and Mr C has received apologies for the distress that had been caused. In circumstances where the matter has already been addressed and actioned by the Board the Ombudsman's office does not technically uphold the complaint as there is no further concerns to be addressed. Therefore, I do not uphold this complaint.

27 March 2007

Annex 1

Explanation of abbreviations used

Mr C	The aggrieved
Mr A	The complainant
The Hospital	Falkirk Royal Infirmary
Mrs C	The aggrieved's wife
The Board	Forth Valley NHS Board
The Adviser	A clinical adviser to the Ombudsman
H.pylori	Helicobacter pylori gastritis
The Consultant	The Consultant Gastro-enterologist responsible for Mrs C's treatment
The Director	The Director of Nursing

Annex 2

Glossary of terms

Amoxicillin	Antibiotic
Ascites	Accumulation of fluid in the abdomen
Cirrhosis	A condition where the liver becomes scarred and reduces its ability to function
Diuretics	Medications that cause an increased volume of urine to be excreted. They are used to correct fluid retention
Endoscopy	A medical procedure where a flexible tube is inserted down the patient's throat to allow visual examination of the interior of a hollow body organ
Helicobacter pylori gastritis	Inflammation of the lining of the stomach caused by infection with a bacterium called helicobacter pylori
Lansoprazole	Medication that blocks the production of acid by the stomach
Metronidazole	Antibiotic
Oesophageal varices	Abnormal dilated veins in the lower oesophagus
Spironolactone	Diuretic medication