Scottish Parliament Region: Glasgow

Case 200501972: Greater Glasgow and Clyde NHS Board

Summary of Investigation

Category

Health: Hospital

Overview

The complainant (Mr C) raised a number of concerns about the treatment which his wife (Mrs C), who suffered from liver disease, received at Glasgow Royal Infirmary (the Hospital) up to and including March 2003.

Specific complaints and conclusions

The complaints which have been investigated are that:

(a) the treatment which Mrs C received was inadequate including that a liver biopsy was not carried out (*not upheld*); and

(b) staff failed to discontinue inappropriate medication *(upheld)*.

Redress and recommendations

The Ombudsman has no recommendations to make.

Main Investigation Report

Introduction

1. On 20 October 2005 the Ombudsman received a complaint from Mr C about the treatment which Mrs C, who suffered from liver disease, received at the Hospital up to and including March 2003. Following Mrs C's death on 16 March 2003 the Procurator Fiscal authorised a Post Mortem and conducted an enquiry which was concluded in April 2005. Mr C was under the impression that a report was to be issued but this was not the case. He said that he could have complained to Greater Glasgow and Clyde NHS Board (the Board) but felt that he would only be repeating the questions which he had already raised with the Procurator Fiscal. It was decided that after such a time it would not be reasonable to advise Mr C to formally complain under the NHS complaints procedure and that the complaint was suitable for investigation by the Ombudsman.

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

(a) the treatment which Mrs C received was inadequate including that a liver biopsy was not carried out; and

(b) staff failed to discontinue inappropriate medication.

Investigation

3. In writing this report I have had access to Mrs C's clinical records and papers relating to the Post Mortem and the Procurator Fiscal's enquiry. I made a written enquiry of the Board. I obtained advice from two of the Ombudsman's professional advisers (Adviser 1 who is a hospital consultant and Adviser 2 who is a pharmacist) 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 is contained in Annex 1. A glossary of the medical terms is at Annex 2. Mr C and the Board were given an opportunity to comment on a draft of this report.

(a) The treatment which Mrs C received was inadequate in that a liver biopsy was not carried out; (b) staff failed to discontinue inappropriate medication

5. Mr C said that his wife had had liver problems since 1993, when a liver abnormality had been diagnosed as a result of blood tests, yet no specific

diagnosis had been made. Mr C's concerns were that although Mrs C's liver problems had been evident for ten years at no time did she undergo a liver biopsy which he believed was a principal diagnostic tool and could have led to a definitive diagnosis. Mr C was aware that Mrs C had failed to attend out-patient appointments but this was because she was continually being told nothing was wrong. He said that Mrs C was admitted to the Hospital on 7 March 2003 with symptoms related to her diabetes. She was prescribed glimepiride but soon after this her liver failed and she died on 16 March 2003. Mr C said that although Mrs C had previously been prescribed glimepiride in 2001 she had not been taking it. Mr C believed the Hospital reported the death to the Procurator Fiscal as it appeared Mrs C's death could have been caused by the glimepiride. Mr C said the Procurator Fiscal enquiry found that Mrs C suffered from cirrhosis of the liver but there was no evidence to conclude that Mrs C's death was caused by the medication. Mr C was aware that glimepiride carried a warning from the manufacturer that it is not suitable for patients who have serious liver disease. He felt it was wrong that staff had prescribed such medication which could have proved fatal.

6. As the Board had not had the opportunity to respond to Mr C's complaint I wrote to them and asked for comments. I asked whether it was felt that staff should have taken action to establish the cause of Mrs C's liver abnormality; whether there was a reason for not carrying out a liver biopsy; and the rationale behind the prescribing of glimepiride.

7. The Board sought comments from a Professor of Endocrinology and a Consultant Physician who reviewed Mrs C's records from 1994 to 2003. In summary it was explained that the results of Mrs C's liver function tests in 1994 were mildly abnormal. The abnormalities resolved spontaneously. Repeat tests taken in 1999/2000 were reported as being normal with the exception of a small varicosity (swelling) in a dilated blood vessel. The plan was to review Mrs C at the out-patient clinic to ensure that she had no progressive abnormality but she defaulted on two occasions and the GP was informed of this. While a biopsy, if taken during 1994/5 or 1999/2000, might have provided additional information there was no obvious signs of underlying cirrhosis evident to staff and a liver biopsy was not clinically justified at those times. It would also not have been appropriate to carry out a liver biopsy during Mrs C's final illness as she was very unwell and the procedure would have been at great risk without any potential benefit.

8. In regard to the prescribing of glimepiride, it was explained that at a previous admission from 23 January 2003 to 14 February 2003 it was noted that Mrs C had already been taking glimepiride for a considerable time (between 2000 and 2001) and the assumption was made that it had been initiated by her GP, therefore, it was continued. The Board stated that glimepiride has an excellent safety record for patients such as Mrs C who was clinically obese and a diabetic and would only be contraindicated in a patient with severe liver disease. A CT scan taken at that time showed no evidence of cirrhosis. However, the potential for an adverse reaction to glimepiride was noted when Mrs C was admitted to hospital on 7 March 2003 and the medication was stopped. Abnormal liver function is a potential side-effect of this medication and in retrospect it would have been appropriate for medical staff to have considered that there was a drug related cause for the abnormal liver function and stop any potential causal agents. It was thought the relatively short term continuation of the drug by hospital staff during the admission from 23 January 2003 to 14 February 2003 was, on its own, insufficient to account for the very marked deterioration in liver function that resulted in Mrs C's death.

9. Adviser 1 said that liver biopsy would normally be the definitive investigation to establish the cause of liver disease. However, this procedure is not only difficult but potentially dangerous to patients such as Mrs C who was grossly obese. It is a matter of clinical judgement as to whether a liver biopsy was appropriate. Adviser 1 concluded that it was not appropriate to perform a liver biopsy in 1995. Adviser 1 said that a scan showed an enlarged spleen in 1995. An endoscopy confirmed gastric varices in August 1999 which would suggest a significant degree of chronic liver disease or cirrhosis. It was at this point that Adviser 1 believed the risk/benefit ration for liver biopsy had changed. Adviser 1 continued that the risk of a biopsy at that time could have been minimised if performed with the guidance of real time ultrasound or alternatively transfer Mrs C to an appropriate centre for transjugular biopsy. Adviser 1 concurred that a biopsy was not appropriate in the final stages of Mrs C's illness as the risks had increased whilst any benefits would have been diminished. Adviser 1 said that once cirrhosis had occurred there was no evidence that the sad outcome could have been avoided by an earlier biopsy.

10. Adviser 2 said that it appeared Mrs C was prescribed glimepiride by her GP for control of her diabetes some two years before her death. On admission to hospital on 23 January 2003 the records indicate Mrs C was taking 2mg daily but Mr C did not believe that Mrs C had in fact been taking the medication.

Adviser 2 told me this was not unusual as a number of patients who are mildly diabetic can often maintain their circulating blood glucose levels within acceptable limits by dietary control alone. Adviser 2 noted Adviser 1's comments that Mrs C had exhibited clear clinical signs of advanced liver disease of long standing and that there is evidence that she was in liver failure for a period of approximately one year prior to her death. The dose of glimepiride was well within the standard dose-range and as Mrs C's liver disease pre-dated the administration of glimepiride by the Hospital then it can be concluded that there is no link between the use of the medicine prescribed by the Hospital and the onset of liver failure.

11. Adviser 2 questioned the use of glimepiride in a patient who was known to be obese with chronic advanced liver disease. Although not strictly contraindicated, glimepiride should be used with caution in patients with mild to moderate liver dysfunction because of an increased danger of hypoglycaemia and such patients should be assessed on the basis of risk-to-benefit prior to the commencement of treatment. Adviser 2 felt that it was not possible to conclude that Mrs C's liver disease was worsened by the use of glimepiride but the clinical team should have been aware of the potential for such complications and have monitored the situation more closely.

(a) Conclusion

12. Mr C had concerns about the length of time staff took to diagnose the cause of Mrs C's liver problems and that a liver biopsy should have been performed. Adviser 1 has explained that for many years Mrs C's liver problems resolved themselves and that staff did monitor the situation. However, the situation changed in 1999 and it was at that time that staff might have considered a liver biopsy with appropriate care, albeit with a risk somewhat higher than normal. However, at that time Mrs C liver function tests were normal and the evidence for cirrhosis was slight. Matters were also affected by Mrs C's non attendance at out-patient clinics which may have led to an earlier diagnosis. However, a procedure such as a liver biopsy carries a significant risk versus benefit especially when the patient is grossly obese as was the case with Mrs C. I have not seen evidence that the treatment which was provided to Mrs C was inadequate and in light of the advice which I have received I have decided not to uphold the complaint.

(a) Recommendation

13. The Ombudsman has no recommendations to make.

(b) Conclusion

14. Mr C had concerns that Mrs C should not have been prescribed glimepiride. The advice which I have received and accept is that glimepiride should be used with caution in patients with mild to moderate liver dysfunction and should only be prescribed after an appropriate assessment has been undertaken. It is also noted that Mrs C was already in liver failure when she was admitted to hospital on 23 January 2003 and as such the administration of the medication during this admission was not the cause of her liver failure. I note that the Board has accepted that staff should have been aware of the potential for problems to arise with the prescribing of glimepiride for Mrs C and accordingly I uphold this complaint.

(b) Recommendation

15. The Ombudsman has no recommendations to make.

23 May 2007

Annex 1

Explanation of abbreviations used

Mr C	The complainant
Mrs C	Mr C's wife
The Hospital	Glasgow Royal Infirmary
The Board	Greater Glasgow and Clyde NHS Board
Adviser 1	Ombudsman's professional adviser – hospital consultant
Adviser 2	Ombudsman's professional adviser - pharmacist

Annex 2

Glossary of terms

CT Scan	Computed Tomography – detailed x-ray taken by computer
Cirrhosis	Chronic liver disease
Endoscopy	View of the inside of a body cavity using an endoscope
Gastric varices	Dilated blood vessels
Glimepiride	Medication for diabetes
Hypoglycaemia	Drop in the level of glucose in the blood
Liver biopsy	Procedure to obtain a sample of liver tissue
Transjugular liver biopsy	Biopsy obtained through the jugular vein
Ultrasound	View of internal body organs using soundwaves