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Scottish Public Services Ombudsman Act 2002

Report by the Scottish Public Services Ombudsman
of an investigation into a complaint against

Grampian University Hospitals NHS Trust (the Trust)[1]

Complaint as put to the Ombudsman

1. The account of the complaint provided by Mr C is that in June 1998, a consultant gastroenterologist (the Consultant) at Aberdeen Royal Infirmary started him on alpha-interferon treatment for Hepatitis C. In January 1999, Mr C's GP (the first GP), informed him that the result of a blood test showed that he still had Hepatitis C. Mr C then made almost monthly telephone calls to the Consultant's Secretary (the Secretary) seeking an appointment with him but was told he would be sent for if the Consultant needed to see him. Mr C continued to receive monthly prescriptions of alpha-interferon until early October 1999 when the Consultant realised that Mr C was still receiving treatment and told him to discontinue. On 18 October, Mr C saw the Consultant but did not feel that he adequately addressed his concerns about the lack of monitoring during the past year and the severe side-effects that Mr C felt he had suffered as a result of the treatment. Mr C felt the Trust's response to his complaint was inadequate. An Independent Review was held but Mr C again felt the conclusions of the review were inadequate.

[1] Grampian University Hospitals NHS Trust was dissolved under The National Health Service Trusts (Dissolution) (Scotland) Order 2004 which came into force on 1 April 2004. On the same date an Order transferring the liabilities of the Trust to NHS Grampian came into effect.

2. The matters subject to investigation were that:

(a) explanations to Mr C about the lack of response to his enquiries about treatment were inadequate; and

(b) the alpha-interferon treatment was not followed according to the protocol indicated by the Consultant.

3. During 2002 the Health Service Commissioner for Scotland began to investigate this complaint against the Trust. This investigation was still in progress when the office of the Health Service Commissioner for Scotland ceased to exist on 22 October 2002. I therefore assumed responsibility for this investigation under the terms of Paragraph 4 of schedule 7 to the Scottish Public Services Ombudsman Act 2002. The investigation is now complete.

4. The Statement of Complaint for the investigation was issued on 24 April 2002. A Professional Assessor – a consultant physician – was appointed to advise on the clinical aspects of the case. The Professional Assessor's Report is produced in full at paragraph 47. Comments were obtained from the Trust and relevant documents were examined. Evidence was taken from Mr C, the Trust's Chief Executive, the Consultant and the second GP. Mr C's partner and a representative from Grampain Local Health Council also participated. A glossary of medical terms used in this report is set out in Appendix 1. This report does not include every detail investigated but no matter of significance has been overlooked.

5. An opportunity has been given for Mr C, the Trust and the second GP to comment on a draft of the factual part of this report prior to the addition of the Professional Assessor's and the Ombudsman's findings and recommendations.

Medical Background

6. Hepatitis C (HCV) is a highly infectious form of viral hepatitis. Chronic Hepatitis C is an inflammatory disease of the liver caused by Hepatitis C virus lasting six months or more. Diagnosis is by blood test. Chronic Hepatitis C may be treated with alpha-interferon, sometimes in combination with anti-virals (known as Combination Therapy). There is no vaccine for Hepatitis C, previously known as non-A, non-B hepatitis.

7. At the time referred to in this complaint (June 1998 to October 1999) a treatment available for Hepatitis C sufferers in Grampian was alpha-interferon injection. This treatment had not been approved for funding through the hospital service and was only available to those patients whose GP was willing to bear the cost. (The Consultant had submitted proposals for funding from the Health Board; this was linked to a request for combination treatment with an anti-viral called Ribavirin.)

8. The informal protocol in place for the interferon treatment required monthly blood tests and a visit to see medical staff every two to three months. There was no specific dedicated service for Hepatitis C patients and no nurse to monitor patients. (The Consultant had put in a request for such a service in 1997 but funding had not yet been made available.)

9. The local laboratory would not accept requests from a GP for the blood tests associated with interferon treatment (PCR and AAT). Such tests had to be requested by a consultant-led hospital clinic. As such it was not possible for Interferon treatment to be monitored within Primary Care and no shared-care protocol existed.

10. The Consultant explained during interview that while treatment with alpha-interferon alone could continue for up to 12 months, if after three months there was no improvement or reduction in the Hepatitis C viral load, there was unlikely to be any improvement thereafter and treatment was normally discontinued. The side-effects and cost made continuing impracticable unless the patient was additionally treated with Ribavirin.

11. Alpha-interferon treatment has a number of known side-effects. These include flu-like symptoms: fever, chill, headache, aching muscles and joints, feeling or being tired, diarrhoea, loss of appetite and temporary drop in bone marrow function causing a fall in white blood cell count. Occasional side-effects include skin rash or itching at injection site, depression, confusion or extreme sleepiness.

Chronology of Events

Background to the Treatment

12. Mr C contracted Hepatitis C in (very approximately) 1983. In November 1997 Mr C was referred to the Consultant by the infection unit for consideration of interferon treatment. Mr C had a consultation with the Consultant on 5 February 1998. The possibilities and problems of treatment for Hepatitis C were discussed. The Consultant mentioned alpha-interferon injections (adding that he was not keen on this) and the possibility of combination treatment with Ribavirin at a later date.

13. Following on from this meeting the Consultant wrote to the Consultant Physician from the infection unit (who had originally referred Mr C) on 17 February 1998, expressing concern over Mr C's anxiety levels at their meeting. The Consultant was reluctant to suggest alpha-interferon treatment as he did not think it clinically expedient (Mr C's condition showed no signs of serious deterioration). He remarked that Mr C was very keen on a trial of the treatment and was aware of his (the Consultant's) negative views on the matter. This letter was copied to Mr C's new GP (the second GP). In March 1998 Mr C was seen for review by the infection unit. The liver function tests were good but there was still a wait for further test results to determine suitability for treatment.

14. Mr C had another appointment with the Consultant on 27 April 1998 at which they discussed alpha-interferon treatment and its side-effects. After this meeting the Consultant wrote to the second GP. In his letter he reviewed the results of Mr C's viral load and genotype as being 'somewhat adverse to a good response to treatment'. He deliberated whether interferon would be of benefit and decided to discuss the matter further with Mr C within the next few weeks. The Consultant stated the side-effects of interferon treatment as 'fortunately, not too frequent'.

Treatment

15. On 6 June 1998 Mr C attended the hospital clinic and commenced alpha-interferon treatment with injections three times a week. The duration of treatment is listed as six months on the discharge sheet. On 7 June 1998 the Senior Registrar sent a letter to the second GP setting out the treatment and listing follow-up as; an outpatient review in one month, and therapy for three months (when blood tests to assess how treatment was working would be available).

16. On 14 July 1998 Mr C attended for the one month follow-up appointment and blood tests. On 15 July 1998 the Senior House Officer wrote to the second GP following on from the previous day's appointment. She stated that Mr C was anxious about aspects of his treatment but was willing to continue and was asked to return in two months for blood tests.

17. On 30 July 1998 Mr C wrote to another doctor who he was seeing for his gall bladder problems and cancelled his forthcoming operation. He also stated that he expected his interferon treatment to end in December 1998.

18. In a letter dated 12 August (sent 2 September) the Consultant wrote to the second GP noting that he had altered injections to an interferon pen to assist Mr C. The Consultant was unaware that Mr C had cancelled his gall-bladder operation and discussed the possibility of altering the September (three month) appointment to accommodate this event. He also mentioned the possibility of interferon treatment continuing with the addition of Ribavirin, which (he wrote) he could now prescribe on a named patient basis.

19. On 22 September Mr C attended the three month appointment. It is noted that he had palpitations and other symptoms. A three month follow-up period is noted on the medical notes. Also that day, the Consultant wrote to the second GP (sent 28 October). He did not have the results of the blood tests at that time but indicated that if the results were not satisfactory then the only alternative would be to prescribe interferon with Ribavirin, on a named patient basis.

Follow-up Treatment

20. On 14 December 1998 (letter sent 15 January 1999) the Consultant wrote to a GP (the third GP) with the results of Mr C's blood test, stating he believed that Mr C should now be offered treatment to include Ribavirin. The third GP was a GP in the same practice as Mr C's GP (the second GP). The letter made no reference to continuing or terminating the interferon treatment. The Consultant stated that he would contact Mr C to discuss this and arrange matters. The Consultant commented at interview that he must have assumed at this point that Mr C had ceased

taking interferon and accepted that consequently his letter to the third GP was not clear as to Mr C's continued use of interferon at that time.

21. In January 1999 Mr C learned that the results of the blood test showed that he still had Hepatitis C. There is no record of who he spoke to at the GP practice to obtain these results. Mr C believed it was not the second GP, but possibly another doctor in the practice, but was not sure. There are no records in the GP practice of this or any other contact with Mr C at the relevant time. In any event no formal notification was made to Mr C of his results.

22. Mr C then stated that he made almost monthly telephone calls to the Consultant's Secretary during the period January to June 1999 asking if the Consultant wanted to see him but was told that the Consultant would send for him if he needed to see him. No record was kept of calls to the Consultant but at Independent Review interview the Consultant's Secretary agreed that Mr C had been a regular caller. At interview the Consultant's Secretary explained that she believed that Mr C, in common with several of the Consultant's patients, was calling to enquire about the status of the Ribavirin application. She would intermittently make the Consultant aware of Mr C's calls but as he too believed they concerned the availability of Ribavirin he did not query this.

23. Between June and July 1999, Mr C believed that he had spoken to the second GP several times over this period and requested he contact the Consultant. There is no record of any conversations in the GP notes. There is also no record of any contact between the first GP and the Consultant.

24. On 11 August 1999, following a GP appointment, the second GP wrote to the Consultant regarding Mr C, querying if he had been 'lost to follow-up'. The Consultant has no record of receiving this letter.

25. Mr C continued to call the Consultant regularly and attempted to make an appointment through the Consultant's Secretary, until Tuesday 5 October when he insisted on talking to the Consultant, mentioning that he was still taking interferon. He was asked to call back the next day when

the Consultant's Secretary offered an appointment on his return from an imminent holiday. Mr C requested that he have his blood test prior to his holiday and was offered this on 8 October.

26. On 8 October 1999, Mr C attended an appointment with the Registrar for blood tests. At Mr C's request on the day and because of his level of distress, the Consultant attended him too. When the Consultant was made aware that Mr C was still taking interferon, he told him to discontinue immediately.

27. On 18 October 1999, the Consultant had an appointment with Mr C. Following this the Consultant wrote to the third GP (not the second GP). The letter stated that Mr C had been 'lost to follow-up' and that Mr C had contacted the Consultant's Secretary 'on one or two occasions', but it had not been appreciated that he was still on interferon.

Chronology of the Complaint

Local resolution

28. On 18 October 1999 Mr C made an oral complaint to the Trust about the care and treatment he had received from the hospital. On 23 November he wrote to the Complaints Officer providing a detailed account of his complaint. Mr C complained that he did not feel that the Consultant adequately addressed his concerns about the lack of monitoring during the past year and about the severe side-effects that he felt he had suffered as a result of the treatment.

29. The Chief Executive of the Trust replied on 3 February 2000. He apologised for the lack of clarity in the Consultant's letter to the third GP which meant that Mr C had continued to be treated with alpha-interferon without being monitored. He acknowledged that Mr C should have been monitored. He further explained that the Consultant's Secretary 'was also unaware that you were still receiving interferon therapy, otherwise the necessary arrangements for testing and follow-up would have been made'. The letter also contained an apology for the fact that Mr C had 'suffered much anxiety and distress because you were not followed up appropriately' and a further apology for the failure to monitor Mr C while he was receiving treatment.

Independent Review

30. On 15 March 2000 Mr C requested an Independent Review which was granted. The Independent Review Panel was convened on 6 December. In April 2001 Mr C received the draft copy of the report.

31. The final report by the Independent Review Panel was issued on 19 July 2001 and on 20 August the Chief Executive wrote to Mr C outlining action he had taken on the recommendations made by the Independent Review Panel.

32. Summary of the Independent Review report:

> 'Term 1 – To determine the reasons for the communication problems which occurred between all parties involved in [Mr C's] treatment and whether lessons can be learned from the experience.
>
> 'The panel recommends that the Trust takes steps to remind all medical staff that communication from hospital to GP should be clear, unequivocal and as timely as possible. A mechanism should be considered for highlighting substantial delays in reporting test results so that interim measures can be taken to keep patients informed.
>
> 'In addition, the Trust should consider monitoring the workload of medical secretaries so that temporary work overload, which is leading to significant delays in correspondence being sent, can be identified and alleviated.
>
> 'Term 2 – To determine why [Mr C] underwent a period of Interferon treatment without regular monitoring.
>
> 'The panel was pleased to note that resources have been allocated for a nurse-led Hepatitis C clinic in the current financial year (2001) and recommends that this facility, with a database for patient monitoring and follow-up, be established with all haste. The panel concurs with [the Consultant's] view that no further treatment with Interferon/Ribavirin be considered until this facility is established.

'The panel also urges Grampian University Hospitals Trust to consider establishing a shared care protocol between the hospital and general practitioners for such patients. The panel was of the view that patients should be given clear written information on what they should expect from such a shared care protocol.

'Term 3 – To determine whether, as a result of his extended treatment with Interferon, there has been or is likely to be, any detriment to [Mr C's] Health.

'From the evidence presented, the Panel concluded [that Mr C's] extended treatment with Interferon was not detrimental to his physical health as he described but that an element of emotional trauma and depression may have resulted. It is quite possible that the lack of monitoring and communication from the hospital contributed to this'.

Complaint to the Health Service Commissioner (HSC)

33. Mr C complained to HSC about the care and treatment he received at Aberdeen Royal Infirmary between June 1998 and October 1999.

Investigation

Mr C's evidence

34. Mr C said that when he started the alpha-interferon treatment he could remember somebody saying that he would receive it for six months but that somebody else said 12 months. It may have been the Consultant but Mr C could not be sure because he was under pressure at that time. He certainly felt that the information available was inadequate, for example he was not given any information about the type or regularity of the monitoring he would receive throughout the treatment. He returned to the clinic for a blood check one month after starting the treatment and returned two months later for another blood check. He then waited for the result of this blood test and continued to receive repeat prescriptions for alpha-interferon. He believed that his GP and the Consultant were communicating with each other and was naïve about the

structure and procedures in the NHS. He thought everything was okay as nobody was telling him otherwise.

35. He received the results of the blood test in January 1999 from his GP surgery and then telephoned the Consultant's Secretary asking if the Consultant wanted to see him. He assumed that the Consultant's Secretary knew he was still receiving alpha-interferon treatment and did not ask her directly about this, which he regretted. He then telephoned her monthly thereafter asking if the Consultant wanted to see him and the answer was always 'no'. He found the telephone calls stressful but made many at the instigation of his mother who was concerned about his deteriorating health.

36. During a telephone conversation with the Consultant's Secretary in early October 1999, Mr C insisted that the Consultant see him and that blood tests be taken. During this conversation, the Consultant's Secretary realised Mr C was still receiving alpha-interferon treatment. She arranged for blood tests to be taken but said that Mr C would not be able to see the Consultant at that test. When Mr C saw the House Doctor for his blood test, he outlined the side-effects he was experiencing and explained that he had not seen the Consultant for over a year. He became very upset and the Consultant came to see him but did not respond to his questions. Mr C saw him the following week but felt that the Consultant did not take his concerns seriously and failed to properly conduct a physical examination and investigate the numerous physical side-effects he was experiencing at that time. He next saw the Consultant in December 1999 and again outlined the physical difficulties he had experienced. Mr C later sought a further meeting to discuss non-clinical issues because he was using his clinical appointments to discuss aspects of his complaint. This was refused; the Complaint Manager said that the Consultant would answer all his questions at his clinical appointment in March 2000.

37. When Mr C first made his complaint, he sought an explanation for what had happened and an acknowledgement that the Trust staff had made a mistake. Mr C said he had a good quality of life before the treatment started and had been very active; he had enjoyed diving, hill

walking and academic studies which had led to qualifications. He felt that Hepatitis C predisposed him to the side-effects he was experiencing and that the treatment was a catalyst that brought them on. He said the Consultant never acknowledged that he had suffered as a result of the treatment or taken his side-effects seriously because to do so, he would have to then accept liability for the lack of monitoring. Since then, he had been diagnosed with a lung and heart condition, and nervous system damage. An x-ray also disclosed that he had crushed vertebrae which a rheumatologist believed was an old injury. All he had wanted was for the doctors to acknowledge their mistake and refer him to the appropriate people to treat his ailments.

The Consultant's evidence

38. The Consultant explained he had been conservative in providing treatment and spent time with each patient before doing so. He saw Mr C on three occasions prior to the commencement of treatment.

39. When asked about monitoring, the Consultant said that before treatment commenced, the patient would see the pharmacist who provided information and leaflets about Hepatitis C and alpha-interferon. He thought the pharmacist would probably have repeated what he himself told every patient he treated with alpha-interferon, but he also personally explained that it would be a three month trial, and the position would be reviewed then. Nurses would then show patients how to inject, providing needles etc and the patient would be asked to come back at monthly intervals for an enzyme check. The Consultant saw Mr C approximately three months into treatment and explained that he would check his enzymes and viral load. Thereafter, he should have been seen at monthly intervals for blood tests and at three monthly intervals by medical staff, usually the Consultant. It was only if the patient had far to travel he would make arrangements with the GP. The Consultant said not providing patients with information about length of treatment in writing was a systems failure which had now been rectified. There is also now a Hepatitis C nurse dedicated to dealing with patients, monitoring etc. The Consultant did not believe that Mr C had not been told that it would be only a three month trial; he may have been told that treatment would

continue up to six to twelve months if he responded well. He recognised from Mr C's letters that he may have been confused about the process.

40. The Consultant explained that his Secretary's office had been adjacent to his and they had a close and effective working relationship. She was exceptionally busy; it took four to six weeks to issue a letter and on one particularly busy day she had handled 46 telephone calls. He had informed some patients who had not responded to alpha-interferon that he would offer them Ribavirin when it was available. At the time, he and his Secretary believed that Mr C fell into this category of patients and he was put into a separate 'Ribavirin file'. She received regular telephone calls from Mr C who, the Consultant believed, did not state until September 1999 that he was not receiving blood tests and was still on alpha-interferon. Before that telephone call, his Secretary therefore thought he was enquiring about the availability of Ribavirin. The Consultant did not as a rule talk to patients over the telephone because it was an inappropriate forum to discuss serious and sensitive conditions such as Hepatitis C and cancer. He made exceptions for patients who had to travel long distances, but otherwise he would offer appointments.

41. A blood test was taken shortly after his Secretary became aware that Mr C was still taking alpha-interferon. The Consultant became aware of Mr C's distress during this appointment and spoke to him. He then spent a long time with him a week or two later and saw him two or three times in the three to six months afterwards. Mr C therefore had ample opportunity to explore with his Consultant what had gone wrong. He said he was very sure he had discussed the clinic's failure to monitor Mr C throughout his treatment, explained it was a systems failure for which he was partly responsible and that he had apologised to Mr C unreservedly. He was also sure that he had physically examined Mr C during his appointments and had taken action to refer him for further investigation with regard to the pains in his back and ankle.

42. There had not been a shared care arrangement with Mr C's GP, who was a very good and caring doctor, and the Consultant accepted that while the GP prescribed the drug, his clinic was responsible for monitoring patients. He accepted responsibility for his letter to the third GP which

did not categorically state that alpha-interferon treatment should be discontinued, but believed the fact that Mr C continued to receive prescriptions for eight months without anybody noticing the lack of monitoring also raised questions about the system. Unfortunately he did not receive the second GP's letter of 11 August 1999 which raised Mr C's treatment with him. However, he stated that if he had intended for Mr C to continue with his treatment, he would have arranged for him to come up for his next month's blood test when he saw him in September 1998, and so he considered that Mr C must have been told but misunderstood.

43. The Consultant had first alerted the Health Board in 1994/1995 to the problems of managing patients with Hepatitis C. The consultant said patients like Mr C exposed the inadequacies of the system. Patients were not given appointments to 'report in' as a matter of course because of the pressures on his clinic, which was unsatisfactory. Notwithstanding his belief that the causes of Mr C's lack of monitoring were 'multifactorial', as the Consultant in charge of the case he took responsibility for it and for the haphazard way in which patients were treated. However, the Consultant said he had been very clear about what he said to patients and Mr C was the only patient who had misunderstood. When Mr C's case came to light, the Consultant had informed the Health Board he would not treat Hepatitis C patients until he had sufficient resources (these were not put in place until two months before his retirement in January 2001).

The second GP's evidence

44. The second GP said that when Mr C had been assigned to his list of patients, he had already been receiving interferon treatment and his previous GP (first GP) had prescribed on at least two occasions. None of the correspondence from the hospital had asked him to monitor Mr C's progress on the treatment or provided any other instructions; there was no shared care protocol. Where there is an established shared care protocol, the surgery prescribes the medication and they carry out any blood, blood pressure etc tests necessary for monitoring. All results would be sent to the Consultant at the hospital and the surgery would have clearly defined guidelines. He was aware that Mr C was attending the Hepatitis C clinic at the hospital, and assumed that, as they were responsible for this aspect of Mr C's care, they would manage everything

in relation to his alpha-interferon treatment. The second GP believed his responsibilities regarding Mr C's alpha-interferon treatment were solely to issue the prescription. It was and continues to be, the hospital's responsibility to: make decisions about dose, how it is administered and who should administer it; consider the patient's response to treatment, monitor blood and side-effects; and decide when to stop treatment.

The Trust Chief Executive's evidence

45. The Chief Executive said he felt the core issues were those identified in the Statement of Complaint but Mr C also raised an issue about advocacy, a feeling that he was very much alone and the victim of the system. He therefore met Mr C but did not invite the clinician involved to attend because he did not believe the issues were primarily clinical but more the way the system had handled Mr C. However, he and the Complaint Officer found it difficult to crystallise Mr C's underlying complaint. The Trust did not have the funding at that time to prescribe alpha-interferon through the hospital pharmacy and patients would only receive it if the GP agreed to prescribe it, which was unsatisfactory. He said the Trust had accepted the Independent Review Panel's recommendations, which said Trust patients should not have dangerous drugs, or drugs which are part of a significant regime, prescribed by GPs on their behalf. The Trust stopped this practice on receipt of the Independent Review Panel's report and also issued a general letter to Consultants saying that clarity in communication with GPs was essential.

46. In the Trust's written response to the Ombudsman's office the Trust's Chief Executive said in part: 'We accept that the account of the complaint as provided in the Statement of Complaint accurately reflects [Mr C's] main concerns as dealt with by the Trust. [We] acknowledge[d] that a misunderstanding about the ongoing follow up of [Mr C] resulted in his being prescribed interferon therapy for longer than had been anticipated. Misunderstanding between the Consultant's Secretary and [Mr C], who was concerned about still receiving interferon treatment, further complicated the situation. At the time [Mr C] was also waiting to hear about further treatment with Ribavirin. The [Consultant's] Secretary thought that [Mr C's] telephone calls related to Ribavirin and she was unaware that [Mr C] was continuing on interferon. We accept that there

was a lack of monitoring. We recognise that this has led to a significant amount of distress and anxiety for [Mr C]. Both the Consultant and I have apologised personally and through correspondence for this situation'.

Opinion of the Ombudsman's Professional Assessor

47. I reproduce next, in its entirety, the report prepared by the professional assessor who was appointed to give advice on the complaint.

Basis of report

(i) The report is based on Mr C's clinical records and background documents and correspondence relating to the complaint provided by the Ombudsman.

Background

(ii) The patient was referred to the Consultant by a Consultant Physician at the infection unit on 20 November 1997. The Consultant Physician had undertaken liver biopsy and serological tests including Hepatitis C genotyping (confirmed type 1b).

(iii) Mr C was seen by the Consultant on 5 February 1998. The Consultant was 'inclined not to treat him but he is extremely keen to be given a trial. It may be possible to add in Ribavirin on a named patient basis'.

(iv) A letter from the Consultant on 27 April 1998 said 'He could be offered a trial of Interferon. A 3 month trial of treatment with Interferon would give some indication of response and failure to do so means he could be considered for additional Ribavirin'.

(v) Interferon treatment was commenced on 6 June 1998. Treatment was commenced as an inpatient. The discharge summary states 'we plan to continue therapy for 3 months and at that stage repeat his qualitative HCV PCR to assess the response to treatment'.

(vi) A letter from the Consultant to a Consultant Surgeon on 7 August 1998 stated 'we will be testing his PCR and enzymes in a few weeks

time and if they are unaffected by the Interferon then clearly we will stop it'.

(vii) *A letter from the Consultant to the first GP on 12 August stated 'We will check his CPR and if it is unaltered we have the option of either discontinuing therapy or adding in Ribavirin on a named patient basis which I am now able to do'.*

(viii) *Mr C was seen by the Consultant on 22 September 1998. A letter to the first GP (typed on 28 October 1998) stated 'I have checked his PCR and enzymes. If there is no satisfactory effect we should be able to get Ribavirin before long. I am able to get some on a named patient basis'. At the bottom of the notes describing that consultation is written '3 months'. It appears that the Consultant planned to review the patient three months later.*

(ix) *There is no record that the patient was reviewed in the outpatient clinic three months later. However a letter was dictated by the Consultant on 14 December 1998 (and typed on 15 January 1999). A letter to the third GP stated 'the PCR is positive. I think I can get Ribavirin. I will make contact with him to get him up here'.*

(x) *No blood tests were performed between September 1998 and October 1999. There is no record that Mr C attended the Consultant's clinic during that period.*

(xi) *The Consultant wrote to the third GP on 18 October 1999 and admitted that Mr C had been a victim of misunderstanding. The letter stated 'I think I had assumed when I wrote to you in December that he had in fact stopped his Interferon'.*

(xii) *A subsequent letter from the Consultant to the second GP was dictated on 21 December 1999 and typed on 25 January 2000.*

(xiii) *A letter from Mr C to the Consultant dated 4 September 2000 stated 'I have discharged you as my physician'.*

(xiv) A formal letter of complaint was submitted by Mr C to the Trust on 23 November 1999. Subsequently an Independent Review Panel was convened and submitted a report. On 20 August 2001 the Trust Chief Executive wrote to Mr C and described the action which would be taken in response to the Independent Review Panel report. He advised Mr C that a patient has a right to refer the matter to the Ombudsman. The matter was subsequently referred to the Ombudsman by the patient on 24 August 2001.

Explanations to Mr C about the lack of response to his enquiries about treatment were inadequate

(xv) It is extremely difficult to address this issue. It is clear and consistent in the interview records that Mr C made a number of enquiries via the Consultant's Secretary during his period of unsupervised treatment. The documents provided are not a prospectively collected record of contacts made by Mr C. Therefore we have slightly discrepant reports about the frequency of contact between September 1998 and October 1999. A record of telephone patient enquiries was not made by the Consultant's Secretary during that period. There was no recording of telephone conversations. Mr C continued to inject interferon during that period. Two possible conclusions can be drawn. It is possible that the Consultant's Secretary was not made aware by Mr C that he was continuing to use interferon. It is also possible that the Consultant's Secretary would not be aware that Mr C's interferon therapy should have been discontinued when the positive blood test (from the September 1998 clinic) result became available. The frequency of telephone contact and the exact content of the telephone calls cannot be deduced from the available information.

(xvi) The issue of response to his enquiries has been explained to Mr C on a number of occasions. The explanations have been consistent and have repeatedly made the point that the Consultant's Secretary thought that Mr C's enquiry was one of many enquiries from a number of patients concerning the availability of Ribavirin therapy. It is assumed that the Consultant's Secretary understood that the interferon should have been stopped pending availability of

Ribavirin. Under that circumstance the Consultant's Secretary must have been unaware (despite the telephone conversations) that Mr C was continuing his interferon therapy.

(xvii) In my opinion the explanations to Mr C about the lack of response to his enquiries have been adequate. The explanations however emphasise the inadequacy of the implementation of a treatment protocol. This issue is also subject to investigation.

The alpha-interferon treatment was not followed according to the protocol indicated by the Consultant

(xviii) A careful reading of Mr C's medical file makes it quite clear that the protocol for Hepatitis C antiviral therapy was inadequate in its implementation and prone to error. The protocol implementation was prone to error for a number of reasons:

(1) There was no written protocol to be shared by the Consultant with colleagues, with General Practitioners or with patients.

(2) There was disassociation of protocol management from drug prescription. Under most circumstances interferon was prescribed by the General Practitioner since funding for the drug was not made available by the Trust.

(3) The protocol was in a state of evolution from interferon monotherapy to combination interferon and Ribavirin therapy.

(4) An exact date and a means for procurement of Ribavirin had not been established. The issue of drug funding and service delivery was being addressed by the Trust and by the Health Board at about that time (and subsequently). Under these circumstances it is not surprising that Mr C's treatment was not delivered according to the Consultant's plan. Indeed some of the Consultant's correspondence suggests that the interferon would continue until Ribavirin was available. However some correspondence more explicitly states (for instance letter from the Consultant to a Consultant Surgeon

on 7 August 1998) that the interferon will be stopped if the blood tests performed in September show failure of response.

(5) I see no claim in the documents that treatment was followed according to the Consultant's protocol. Indeed the eventual disparity between the Mr C's actual treatment and the Consultant's proposed treatment is clearly detailed by subsequently discussions between all parties and Mr C, and is explicit in the Independent Review Panel's report.

Conclusion

(xix) In the matters subject to investigation by the Ombudsman it is my conclusion that explanations to Mr C about the lack of response to his enquiries have been adequate. The responses per se may have been inadequate but the issues surrounding communication between Mr C, the Consultant's Secretary and the Consultant have been adequately explored and appropriately explained to Mr C.

(xx) That alpha-interferon treatment was not followed according to the protocol indicated by the Consultant is true. The reasons for this have been explored and detailed. Adequate explanation has been provided to the patient.

Findings

48. Mr C suffered from chronic Hepatitis C. He commenced interferon treatment for this condition in June 1998. In the first months of his treatment, up until (and including) September 1998, Mr C was monitored and underwent appropriate blood tests. From October 1998 until October 1999 Mr C, not having been told otherwise, continued to take regular injections of interferon but was not monitored or undergoing blood tests. In October 1999 he ceased the treatment on the instructions of the Consultant. The Consultant was unaware that Mr C had continued to take the interferon after September 1998. Mr C complained that he had repeatedly tried to check whether he should be continuing with the treatment and had never received an adequate explanation of why he did not received a response to his questions. Mr C also complained that he had not been monitored in the prescribed manner.

49. In reaching my findings and conclusions I have taken into account the views of the assessor. He has explained that the Consultant kept no record of contacts between patients and his office at the relevant time. Without such records it is only possible to draw an inference from the evidence of both Mr C and the Consultant's Secretary. The assessor has stated that there are two possible conclusions: the Secretary was not aware Mr C continued to take interferon or she was not aware that interferon therapy should have been discontinued after the positive blood test (blood taken September 1998). The assessor points out that at this time the Secretary also dealt with inquiries from a number of patients concerning the availability of new treatment using Ribavirin. I note that when interviewed by the Independent Review Panel the Consultant's Secretary explained she believed Mr C was calling to enquire about the status of the Ribavirin treatment. The assessor is of the view that the Secretary would have understood that interferon should have been stopped pending the availability of Ribavirin and must therefore have been unaware that Mr C continued to take interferon. I accept that this is the most probable explanation of events.

50. In his evidence the Consultant stated that he met with Mr C on a number of occasions to discuss what had gone wrong. He had explained that it was a systems failure for which he was partially responsible and had apologized to Mr C unreservedly. The question of communication problems between all parties involved in Mr C's care was discussed. This raised the question of why Mr C's repeated calls had not alerted the Consultant to his continued use of interferon. The Independent Review Panel reached the same conclusion as the assessor.

51. I accept that there was a fatal misunderstanding on the part of the Consultant's Secretary who would otherwise have alerted the Consultant to Mr C's continuing to take interferon and allowed the Consultant to take action earlier. The question I have been asked to consider is whether Mr C had been given an adequate explanation of this. While it is understandable that Mr C is unhappy with the lack of response to his many calls, I must concur with the assessor that Mr C has had an explanation of events.

52. As the assessor has pointed out the explanations provided to Mr C at Independent Review emphasize the inadequacy of the protocol for interferon therapy. I have also considered whether the protocol was correctly implemented during Mr C's care. I note that the Consultant, at interview, stated that the protocol was a three month trial during which blood is tested monthly followed by a review. If after this review there was value in continuing the patient would continue to take interferon while having monthly blood tests and being reviewed at three monthly intervals by medical staff. I have reviewed the evidence obtained from the Consultant, the second GP and Mr C. It is clear that following the three month review appointment in September 1998 Mr C was not given monthly blood tests and was not reviewed at three monthly intervals by medical staff.

53. The assessor has pointed out a number of flaws inherent to this protocol these being; no written protocol available to colleagues, GP's or patients; the drug was prescribed independently of the protocol (this was necessary because the only available funding was via the GP not the Trust); the protocol was undergoing a period of change while the new drug (Ribavirin) was being introduced and the date for this introduction was not yet fixed. Given the lack of a robust protocol it is perhaps not surprising that Mr C did not receive the appropriate on-going care and that this error continued undetected for so many months.

54. In summary, while I do not condone the system that permitted Mr C's calls to go unheeded for so long, I believe that Mr C has had an adequate explanation about the lack of response to his inquiries about treatment. I, therefore, do not uphold the first heading of the complaint as put. I have noted, however, that there were a significant number of failures in implementation and that Mr C was not monitored in accordance with the protocol. I, therefore, uphold the second heading of the complaint as put and find that there was a service failure on the part of Grampian University Hospitals NHS Trust.

Recommendations

55. In considering the need to make recommendations I am mindful of the recommendations made by the Independent Review Panel with

particular reference to the need for a properly constituted and managed nurse-led Hepatitis C clinic and the need for a shared protocol for this service. These recommendations were accepted by the Trust who undertook to cease any interferon/Ribavirin treatment until such time as this recommendation could be enacted. Given that there has been a significant time lapse since the Panel's report I have asked the Trust for a statement on the current situation (the full text of this is contained in Appendix 2). I am pleased to note that there have been a number of significant changes to the system for interferon (and other anti-viral) therapy since the events of this complaint. There is now a dedicated Nurse Specialist with prescribing being done within the Hospital and a comprehensive system for monitoring. In these circumstances I have concluded that the Trust have taken action to address the issues raised by this complaint and have no further recommendation to make with regard to procedural changes. Such improvements in the service should significantly reduce the likelihood of similar problems arising in the future.

56. I have not upheld Mr C's complaint that the explanations given to him about the lack of response to his enquiries were inadequate. However, I have upheld Mr C's complaint that the alpha-interferon treatment was not followed according to the protocol indicated by the Consultant. Notwithstanding the fact that steps have now been taken to address this matter, I am of the view that Mr C suffered an injustice as a result of the service failure I have identified. I note that the Trust Chief Executive has apologised to Mr C for these failings (see paragraph 29 above) and therefore have no further recommendation to make with regard to this aspect of the complaint.

Professor Alice Brown
Scottish Public Services Ombudsman

6 September 2004

Appendix 1

Medical Glossary

Alpha-interferon	Interferon alpha is a man-made copy of a substance that is made naturally by some types of white blood cell. The body makes interferon as part of the immune response, when the body reacts to infection or to cancers.
Anti-virals	An agent that kills a virus or that suppresses its ability to replicate and, hence, inhibits its capability to multiply and reproduce.
Interferon	A family of naturally-occurring proteins that are produced by cells of the immune system. Interferons direct the immune system's attack on viruses, bacteria, tumours and other foreign substances that may invade the body. Once interferons have detected and attacked a foreign substance, they alter it by slowing, blocking, or changing its growth or function.
PCR and AAT	PCR viral load test: this quantitative test looks for the virus and estimates the number of HCV viruses per ml of blood. The AAT test is a sensitive screening test used to detect autoimmune diseases.
Protocol	The plan for a course of medical treatment.
Ribavirin	Ribavirin is an antiviral drug. It is used in combination with interferon for the treatment of chronic Hepatitis C. Although the exact mechanism of its action is unknown, it is thought to interfere with the production and/or action of viral DNA and RNA which are critical to the survival and multiplication of the virus.
Viral Load	The number of viral particles in a sample of blood plasma.

Appendix 2

Statement from NHS Grampian Consultant Gastroenterologist of the current provision of care of patients with Hepatitis C

In response to the letter from the Ombudsman, I would like to outline the current provision of care of patients with Hepatitis C who are going on for treatment. The patients are seen by me with the Clinical Nurse Specialist prior to starting treatment. At the first visit, they are instructed how to administer the injection themselves and are given four weeks treatment. The patients are then given the follow up appointments for the duration of the treatment whether this be six months or twelve months. The funding of the treatment comes via the Hospital and therefore I personally write the prescriptions and the prescriptions are dispensed by the Hospital pharmacy. The Clinical Nurse Specialist personally hands the medication over to the patients and therefore the GP has no role in the prescription of anti-viral therapy. The patient is followed up initially weekly and then monthly. They have blood tests at each visit and these are checked by the Clinical Nurse Specialist on the computer the next day. In discussion with me, any relevant changes to the medication are made and the patient is informed normally by telephone by the Clinical Nurse Specialist. There is written communication at each clinic visit to the General Practitioner. If the patients fail to turn up for an out patient clinic appointment, they do not receive any further anti-viral therapy as it is only given out at the clinic. On an odd occasion, a GP will arrange for some blood tests to be taken for patients if they come from a far distance i.e. Banff or Shetland. The Clinical Nurse Specialist checks the results the day after they are taken and again appropriate action is taken. The patients are given both the British Liver Trust and NHS Grampian leaflets for Hepatitis C and also a commercially sponsored booklet on Hepatitis C treatment called Taking Control. The patients have adequate time to discuss the treatment with the Clinical Nurse Specialist and Consultant before commencing on it. The proposed duration of treatment is discussed with the patient before commencing treatment and is highlighted by the fact they are given all their out patient clinic appointments on their first visit.

There was a problem with secretarial support in the unit and there is a part-time secretary employed within the blood borne virus fund which ensures that letters are typed rapidly, normally within one week of the clinic appointment.

The Clinic Nurse Specialist took up post in March 2002.

There are no shared care protocols for General Practitioners as the medication is prescribed by me and along with the Clinical Nurse Specialist, we are responsible for the blood tests and action taken upon them.

Glossary

Mr C	The complainant
Consultant	The Gastrointestinal Consultant responsible for Mr C's alpha-interferon treatment
Secretary	The Consultant's Secretary
First GP	Mr C's GP at the time treatment commenced, who retired during the course of treatment
Second GP	Mr C's GP after the retiral of the first GP
Third GP	Another GP in the same GP practice as the First and Second GP