SPSO Scottish Public Services Ombudsman

The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

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Scottish Parliament Region: Mid Scotland and Fife

Case ref: 201406099, Fife NHS Board
Sector: Health
Subject: Hospitals; clinical treatment; diagnosis

Summary
Mr C had surgery for bowel cancer and then started chemotherapy to reduce the risk of his cancer recurring. He suffered significant gastrointestinal side effects from the chemotherapy, including abdominal cramps and diarrhoea. He went to the emergency department at Victoria Hospital but his oncology consultants (cancer specialists) were not told about his visit. A week later, Mr C started to have regular sickness and diarrhoea and he visited his GP twice for treatment. Three days before his second cycle of chemotherapy, Mr C was reviewed by an associate specialist oncologist, who assessed Mr C's diarrhoea as grade 0 (on a scale of zero to five, where grade 5 is the most severe). The oncologist pre-authorised the administration of the drugs at a reduced dosage and made a note that Mr C's side effects should be observed closely. Mr C continued to experience diarrhoea and he reported this to the nurses at the chemotherapy unit when he went to receive the second cycle of chemotherapy. His condition deteriorated over the next few days and NHS 24 referred him to Victoria Hospital, where a scan showed evidence of severe chemotherapy-related inflammation, and possible perforation, of the colon. Mr C's chemotherapy was stopped and he had an operation on his colon, spending five weeks in hospital.

Mr C complained that his symptoms of chemotherapy toxicity were not recognised within a reasonable time and that he should not have been given another cycle of chemotherapy treatment.

I took independent advice from an adviser who specialises in oncology. The adviser said that the symptoms Mr C described amounted to grade 2 or 3 diarrhoea. The board's guidance stated that further treatment should not have been prescribed until the diarrhoea had settled to grade 1 or lower. The adviser found that the toxicity assessment by the associate specialist oncologist was inadequate and that further chemotherapy should not have been prescribed. He also said that when Mr C reported his on-going diarrhoea to nursing staff, they should have asked for medical advice before administering chemotherapy. The adviser said that Mr C should have been able to easily get advice about his

problems, for example, from a 24-hour cancer treatment telephone helpline. He commented that the lack of access to a single point of advice about chemotherapy-related problems resulted in poor communication of these problems to the oncology team treating Mr C.

The advice I have received is that Mr C had considerable difficulty accessing medical advice when he developed problems. I found that there were failings at almost every contact Mr C had with health care professionals in relation to the second cycle of chemotherapy and that the system in place to ensure he was treated safely was inadequate. I found that better arrangements were needed to ensure that patients were properly assessed on the day of treatment at the chemotherapy unit, and that the nursing staff must raise any concerns with medical staff. In view of the failings identified, I upheld the complaint and made recommendations.

Redress and recommendations

The Ombudsman recommends that the Board:	*Completion date*
(i) bring the failures to the attention of relevant staff and ensure they are addressed as part of their annual appraisal;	29 January 2016
(ii) review the governance arrangements of this unit in light of my findings; and	29 January 2016
(iii) apologise to Mr C for the failures my investigation identified.	29 January 2016

Who we are

The Scottish Public Services Ombudsman (SPSO) investigates complaints about organisations providing public services in Scotland. We are the final stage for handling complaints about the National Health Service, councils, housing associations, prisons, the Scottish Government and its agencies and departments, the Scottish Parliamentary Corporate Body, water and sewerage providers, colleges and universities and most Scottish public authorities. We normally consider complaints only after they have been through the complaints procedure of the organisation concerned. Our service is independent, impartial and free. We aim not only to provide justice for the individual, but also to share the learning from our work in order to improve the delivery of public services in Scotland.

The role of the SPSO is set out in the Scottish Public Services Ombudsman Act 2002, and this report is published in terms of section 15(1) of the Act. The Act says that, generally, reports of investigations should not name or identify individuals, so in the report the complainant is referred to as Mr C. The terms used to describe other people in the report are explained as they arise and in Annex 1.

Introduction

1. Mr C complained to the Ombudsman that his symptoms of toxicity (from chemotherapy treatment) were not recognised within a reasonable time and he should not have been given a further cycle of chemotherapy treatment, and it was unreasonable to have expected him to know that he should have stopped taking the medication.

2. The complaint from Mr C I have investigated is that Fife NHS Board (the Board)'s actions in relation to continuing Mr C's chemotherapy with a second cycle were unreasonable (*upheld*).

Investigation

3. In order to investigate Mr C's complaint, my complaints reviewer examined all the information provided by Mr C. They also reviewed a copy of Mr C's clinical records and the Board's complaint file. Finally, they obtained independent advice from an experienced consultant oncologist adviser (the Medical Adviser) on the clinical aspects of the complaint. In this case, we have decided to issue a public report on Mr C's complaint because the failings I found led to a significant personal injustice to Mr C, and to highlight the need to consider patients' needs when peripheral units provide chemotherapy treatment and disseminate the learning from this case to other health boards.

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

Relevant guidelines

5. The South East Scotland Cancer Network issued guidelines (the Board's protocol) on the management of chemotherapy toxicity and stated that the capecitabine (oral chemotherapy) should be continued only if the grade of diarrhoea was at one (or zero) and discontinued for grades two to four. The guidelines also stated that healthcare professionals should ensure that the patient knows what to look for and has specific telephone numbers to call should their condition worsen (and inform GP team if needed). Other relevant guidance included the summary of product characteristics for capecitabine which provided guidance on the use of this medication and specific guidance on the management of treatment related diarrhoea.

Background

6. On 27 December 2013, Mr C underwent surgery for bowel cancer, and adjuvant chemotherapy commenced on 13 January 2014 to reduce the risk of subsequent cancer recurrence. Mr C then experienced significant gastrointestinal side-effects, including abdominal cramps and diarrhoea. On 17 January 2014, Mr C attended the emergency department (at Victoria Hospital). Healthcare professionals there did not inform the oncology consultants of Mr C's attendance. Mr C started to have sickness and diarrhoea regularly from 24 January 2014 onwards. He saw his GP on 27 and 30 January 2014 as he continued to experience diarrhoea. On 31 January 2014, Mr C was reviewed by the Associate Specialist Oncologist who assessed Mr C's diarrhoea as grade 0 and reduced his dose for the next cycle of chemotherapy (to be administered by nursing staff on 3 February 2014), and on the electronic system noted that the side-effects should be observed closely. Mr C had five episodes of diarrhoea that day. He continued to experience diarrhoea over the next few days and reported this to nursing staff when he attended the clinic on 3 February 2014 for the second cycle of chemotherapy. Mr C's condition deteriorated over the next few days. He attended his GP again on 6 February 2014, and on 8 February 2014 was referred to Victoria Hospital by NHS 24. A computerised tomography scan showed evidence of severe chemotherapy-related colitis and possible perforation of the bowel. Mr C underwent an operation (ileostomy and mucous fistula) on 13 February 2014 and chemotherapy treatment stopped. He was discharged on 13 March 2014.

Complaint: The Board's actions in relation to continuing Mr C's chemotherapy with a second cycle were unreasonable

7. Mr C complained that his symptoms of toxicity was not recognised within a reasonable time and that the communication failures between the various health care professionals he saw exacerbated the problem. He said he should not have been given a second cycle of chemotherapy treatment on 3 February 2014, and it was unreasonable to have expected him to know that he should have stopped taking the medication.

The Board's response

8. The Board explained that Mr C had been offered adjuvant chemotherapy because there was a spread of his bowel cancer into one of his lymph nodes. The Consultant Oncologist discussed the proposed chemotherapy and the side effects with Mr C, and emphasised that gastrointestinal toxicity (abdominal pain,

diarrhoea and vomiting) could be a major issue. The Consultant Oncologist always emphasised to patients that if they had diarrhoea in excess of three to four times daily, they should stop taking the chemotherapy tablets and contact the oncology unit (or GP). Patients were given a card with all the contact numbers and an information sheet at the end of chemotherapy. When Mr C attended the emergency department because of abdominal pain, the oncology consultants were not informed of this or copied into correspondence from the emergency department to his GP. The Board said that this area of communication had been highlighted to emergency department staff in the past and would continue to be emphasised to promote better communication between clinicians. The Board also said it was likely the accumulating chemotherapy effect was responsible for the several bouts of diarrhoea Mr C experienced on 28 January 2014, although the antibiotics prescribed by his GP may also have contributed. When he was reviewed by the Associate Specialist Oncologist on 31 January 2014, they assessed Mr C's pervious diarrhoea as grade 2 (grade 5 being the most severe) and the worst during his chemotherapy cycle was grade 3 (on 28 January 2014). Mr C continued to experience diarrhoea over the next three days and still suffered from grade 2 diarrhoea on the day he attended his chemotherapy. The Consultant Oncologist confirmed the protocol stated that toxicity should either be resolved, or at grade 1 or better to proceed with chemotherapy. The Consultant Oncologist acknowledged this highlighted one of the challenges of performing toxicity assessment three days before chemotherapy administration and apologised that the protocol did not appear to have been followed in this instance. The Consultant Oncologist said that all chemotherapy units in the South East Scotland Cancer Network have been alerted to the importance of assessing patients who have had pre-authorised chemotherapy. The Consultant Oncologist also explained that while the staff nurse contacted the Associate Specialist Oncologist about Mr C's low potassium level (when Mr C attended the clinic on 3 February 2014 for chemotherapy), they did not refer to his on-going diarrhoea and said either nursing staff should have alerted medical staff or not proceeded with chemotherapy. The Consultant Oncologist apologised for this.

9. The Board further explained that Mr C continued to experience diarrhoea and said that it was not documented (on 4 February 2014) whether he stopped chemotherapy as originally instructed by the Consultant Oncologist. The outcome of his visit to his GP on 6 February 2014 was not reported to oncology staff. The Consultant Oncologist acknowledged that Mr C's case represented the challenges of logistically providing chemotherapy service at a peripheral unit

where an oncologist was not available at all times. It also highlighted potential issues regarding oral chemotherapy with patients performing their own toxicity assessment prior to each dose. The Consultant Oncologist recognised this could be difficult but emphasised they always stressed that patients with concerns should contact one of the individuals listed on the card. Edinburgh had a telephone line (patients were triaged into a red, amber and green alert system) but this had not yet been introduced in Fife. A memo had been issued to all the peripheral units to advise chemotherapy nurses on what to do if they were concerned about on-going toxicity when chemotherapy had been pre-authorised. The Consultant Oncologist said it was highly regrettable that Mr C had to suffer such difficulties and was deeply sorry for his experiences. It was recognised, however, that chemotherapy was associated with a mortality rate that had to be minimised as much as possible. It was hoped that the eventual introduction of the cancer treatment helpline and the establishment of treatment protocols and pathways as well as the memo to chemotherapy units would contribute to this.

10. The Board said that the Associate Specialist Oncologist told them he had graded Mr C's diarrhoea as one for a few days prior to 30 January 2014 and in the morning of the consultation, it was zero. It was their professional opinion that Mr C was fit to proceed with the second cycle of chemotherapy with a 20 percent dose reduction and he advised Mr C to watch closely for side-effects. This information was reiterated in the patient information leaflet. The Associate Specialist Oncologist was not made aware that following this consultation Mr C's diarrhoea worsened over the weekend. He was told that Mr C had been admitted to hospital on 13 February 2014 and was surprised to learn he continued to take his chemotherapy medication despite worsening toxicities and suggested to ward doctors to discontinue this immediately. The Associate Specialist Oncologist saw Mr C on 13 February 2014 in the ward and asked him why he had continued to take the medication. The Associate Specialist Oncologist appreciated this may have seemed abrupt to Mr C considering he was unwell and was very sorry for this. The Associate Specialist Oncologist was concerned for Mr C's safety and well-being. Since the complaint, they had reflected on the events and would discuss Mr C's experience with their colleagues to better organise the safety network for patients undergoing oral chemotherapy.

Medical advice

11. The Medical Adviser said that there appeared to be a discrepancy between the symptoms that Mr C recorded and the assessment made by The Associate Specialist Oncologist on 31 January 2014. The Medical Adviser said that the symptoms described by Mr C amounted to at least grade 2 if not grade 3 diarrhoea and according to Board protocol and guidance on the use of medication prescribed, further treatment should not have been prescribed until the diarrhoea had settled to no more than grade 1. Also, the chemotherapy prescription chart documented 5 kilograms of weight loss over the three weeks since the previous cycle which had not been explained. This suggested worst toxicity than had been documented. The Medical Adviser, therefore, concluded that an inadequate assessment was made on 31 January 2014, and further chemotherapy should not have been prescribed (which was to be administered by nursing staff on 3 February) on the basis of the symptoms reported by Mr C. Given that Mr C continued to experience diarrhoea over the next few days, the Medical Adviser said it was clear that nursing staff should have sought medical advice before administering chemotherapy.

12. My complaints reviewer asked if the information provided to Mr C was reasonable. The Medical Adviser said whilst there was evidence that Mr C was given clear information about stopping treatment in certain circumstances, he should have been able to access advice from the treating team about what to do when those problems arose. It was clear from Mr C's complaint that he had considerable difficulty accessing such advice, having been turned away from the ward he had been told to contact and subsequently challenged when he attended the emergency department that he should not have been there with the chemotherapy related problem. He should have had access to a 24-hour telephone helpline to receive advice about how to manage the problems he was experiencing. It appeared that the service was available to patients in Edinburgh but not to those in Mr C's area at that time.

13. In relation to the Board's position that there were inherent difficulties in peripheral units providing chemotherapy treatment, the Medical Adviser responded that a delay of three days between a toxicity assessment and delivering chemotherapy was standard practice in many UK oncology centres (or units). However, there were problems in this case and the Medical Adviser reiterated that the evidence suggested the assessment made on 31 January 2014 was not a true reflection of the situation at that time and when the chemotherapy nursing staff expressed concern about continuing treatment

they should have sought medical advice rather than proceeding with treatment. It was not acceptable for the Board to simply state that there were inherent difficulties in peripheral units providing chemotherapy treatments; if those units did not have appropriate governance arrangements in place to safely administer chemotherapy, then they should not be giving treatment. The problems that Mr C experienced, and in particular the need for the second major operation, were almost certainly related to having been given a further cycle of chemotherapy when it should have been withheld. The Board have highlighted to staff the need for chemotherapy nurses to contact medical staff if they have concerns about a patient on the day of treatment which goes some way to address the issue, but a more robust system would include some form of documentation that the nurses had assessed the patient on the day of treatment and excluded any new or on-going problems. Furthermore, the fact that patients did not have ready access to a single point of advice should they develop problems during chemotherapy treatment resulted in poor communication of such problems to the treating (oncology) team. The Board should, therefore, ensure that patients have 24 hour access to a telephone advice service should they develop chemotherapy related toxicity and consider extending the cancer treatment helpline available to patients in Edinburgh to patients treated at the unit as soon as possible.

14. Since receiving this advice, the Board told my complaints reviewer that there was now a helpline (staffed 24 hours a day and seven days a week) for all patients on chemotherapy where they could discuss any concerns and which allowed them to be seen to be treated appropriately as necessary.

Decision

15. Mr C complained that the Board's actions in relation to continuing a second cycle of chemotherapy were unreasonable. In reaching my decision, I have taken into account Mr C's clinical records and the advice I have received. While the Board implicitly accepted failings, they said it was always emphasised to patients that if they had severe diarrhoea, they should stop taking the chemotherapy tablets and contact the oncology unit or their GP. However, the advice I have accepted is that Mr C had considerable problems accessing medical advice and it was clear that patients did not have ready access to a single point of advice should they develop problems, which resulted in poor communication of such problems to the treating team at the unit. Furthermore, I am concerned about the Board's position that there were inherent difficulties in peripheral units providing chemotherapy treatment; it is my view that those units

must have appropriate governance arrangements in place to administer chemotherapy safely. It is clear to me that there were failings at almost every contact Mr C had with health care professionals in relation to the second cycle of chemotherapy and that the system in place to ensure he was treated safely was inadequate. The Medical Adviser recommended that more robust arrangements were required to ensure that patients were appropriately assessed on the day of treatment, and concerns raised with medical staff, and also to ensure that patients had 24 access to telephone advice should they develop chemotherapy related toxicity. I accept that advice. My findings are that the failings led to a significant injustice to Mr C in that he suffered gastrointestinal toxicity and had to have a life-saving operation because he had been given a further cycle of chemotherapy when this should have been withheld. I uphold the complaint.

Recommendations

16. I recommend that the Board:	*Completion date*
(i) bring the failures to the attention of relevant staff and ensure they are addressed as part of their annual appraisal;	29 January 2016
(ii) review the governance arrangements of this unit in light of my findings; and	29 January 2016
(iii) apologise to Mr C for the failures my investigation identified.	29 January 2016

17. The Board have accepted the recommendations and will act on them accordingly. We will follow-up on these recommendations. The Board are asked to inform us of the steps that have been taken to implement these recommendations by the date specified. We will expect evidence (including supporting documentation) that appropriate action has been taken before we can confirm that the recommendations have been implemented.

Annex 1

Explanation of abbreviations used

Mr C	the complainant
Fife NHS Board	the Board
the Medical Adviser	one of the Ombudsman's advisers who specialises in oncology
the Oncologist Consultant	an oncologist consultant at the hospital
the Associate Specialist Oncologist	an associate specialist oncologist at the hospital

Annex 2

Glossary of terms

adjuvant chemotherapy	additional cancer treatment given after the hormone therapy etc)
ileostomy	an operation which involves the removal of the large colon and sometimes the rectum
mucous fistula	the remaining colon following an ileostomy

Annex 3

List of legislation and policies considered

South East Scotland Cancer Network - guidelines on the management of chemotherapy toxicity

Summary of Product Characteristics for capecitabine - guidance on its use including specific guidance on the management of treatment related diarrhoea