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: North East Scotland

Case ref: 201508183, A Medical Practice in the Grampian NHS Board area
Sector: Health
Subject: GP & GP Practices / Clinical treatment / Diagnosis

Summary
Mrs C's husband (Mr A) had been diagnosed with lung cancer and discharged to the care of his medical practice. To help manage Mr A's pain at the end of his life, Mrs C was allowed to administer a controlled drug. Despite this arrangement, Mrs C said that the practice failed to manage Mr A's pain reasonably and to make reasonable arrangements to ensure a sufficient amount of pain relief was available. Mrs C also said that the practice failed to communicate with her in a reasonable way about administering pain relief and to keep accurate records. Mrs C said that as a result of this, Mr A suffered intolerable pain before his death, which caused her extreme distress.

I took independent advice from a GP adviser. The adviser considered that in relation to treatment decisions and pain management, the standard of care and treatment provided was reasonable. Moreover, while there were administrative shortcomings in relation to record-keeping, these were not significant and had no detrimental clinical effect on Mr A's care. I accepted that advice. With regard to the governance arrangements in relation to Mrs C's administration of the medication, I found that there was effectively an informal arrangement between the practice and Mrs C which allowed Mrs C to administer a controlled drug without the practice first putting adequate safeguards in place or seeking guidance from a specialist. I agreed with the adviser that it was of concern that GPs continued to prescribe a controlled drug after expressing concerns that Mrs C had administered the medication without clinical advice. Furthermore, the practice failed to ensure that Mr A consented to the arrangement. I upheld this part of Mrs C's complaint and made recommendations.

Mrs C also said that the practice did not respond reasonably to her complaints. I found that the practice's handling of Mrs C's complaints was reasonable and so did not uphold this complaint.

Redress and recommendations
The Ombudsman recommends that the practice: *Completion date*

(i)	ensure the GPs who instructed Mrs C in relation to breakthrough medication and the other GPs who subsequently issued prescriptions for oxycodone seek support from the board's clinical support group, in relation to responsibilities for prescribing and consent under GMC (General Medical Council) guidance;	30 September 2016
(ii)	ensure the relevant GPs discuss the findings of this investigation at their annual appraisal;	30 September 2016
(iii)	ensure the relevant GPs familiarise themselves with the GMC guidance as a priority;	30 September 2016
(iv)	draft a protocol in conjunction with the board to support patients and/or carers to administer prescribed subcutaneous medication by injections; and	30 November 2016
(v)	apologise for the failings this investigation identified.	30 September 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 Mrs C. The terms used to describe other people in the report are explained as they arise and in Annex 1.

Introduction

1. Mrs C complained to the Ombudsman about the end of life care and treatment provided to her late husband (Mr A) by his medical practice in the Grampian NHS Board area (the Practice). Mrs C said the Practice failed to manage Mr A's pain reasonably and to make reasonable arrangements to ensure a sufficient amount of pain relief was available (particularly at the strength required), failed to communicate with her reasonably and keep accurate records. Mrs C also said there were discrepancies in the Practice's account. She told us that Mr A suffered intolerable pain before his death which caused her extreme distress and that this was exacerbated by the Practice's errors.

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

(a) the overall care and treatment which Mr A received from 11 February to 23 March 2015 was not of a reasonable standard, particularly in relation to pain management, record-keeping and communication (*upheld*); and

(b) Mrs C's complaint was not reasonably responded to (*not upheld*).

Investigation

3. In order to investigate Mrs C's complaint, my complaints reviewer examined all the information provided by Mrs C. They also reviewed a copy of Mr A's clinical records and Grampian NHS Board (the Board)'s complaint file. Finally, they considered the relevant guidance and obtained independent advice from an adviser who specialises in general practice (the Medical Adviser). In this case, we have decided to issue a public report on Mrs C's complaint because of my concerns about the governance arrangements in relation to the Practice allowing Mrs C to administer breakthrough medication to Mr A.

4. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. Mrs C and the Practice were given an opportunity to comment on a draft of this report. Mrs C complained about the Practice to the Board (on 9 May 2015), and the Practice's response to her complaint was subsequently issued by the Board (on 2 June 2015).

Relevant guidance

5. General Medical Council (GMC) guidance for general practitioners (GPs) on Good Medical Practice in relation to responsibility for prescriptions,

documentation about training, supervision and consent, and issues around consent generally state that:

> 'You are responsible for the prescriptions you sign and for your decisions and actions when you supply and administer medicines and devices or authorise or instruct others to do so. You must be prepared to explain and justify your decisions and actions when prescribing, administering and managing medicines …
>
> Documents you make (including clinical records) to formally record your work must be clear, accurate and legible. You should make records at the same time as the events you are recording or as soon as possible afterwards ….
>
> Clinical records should include:
>
> a relevant clinical findings;
> b the decisions made and actions agreed, and who is making the decisions and agreeing the actions;
> c the information given to patients;
> d any drugs prescribed or other investigation or treatment; and
> e who is making the record and when.
>
> You must work in partnership with patients, sharing with them the information they will need to make decisions about their care, including:
>
> a their condition, likely progression and the options for treatment, including associated risks and uncertainties;
> b the progress of their care, and your role and responsibilities in the team;
> c who is responsible for each aspect of patient care, and how information is shared within teams and among those who will be providing their care.'

Clinical Background

6. Mr A was admitted to Aberdeen Royal Infirmary and diagnosed with lung cancer. He was discharged from hospital on 11 February 2015 to the care of the Practice. Mr A received regular visits from GPs at the Practice and pain relief was administered by both district nurses and GPs. On 17 March 2015, one of the GPs told Mrs C that she could give breakthrough medication for Mr A's pain. Mr A died at home on 23 March 2015.

(a) The overall care and treatment which Mr A received from 11 February to 23 March 2015 was not of a reasonable standard, particularly in relation to pain management, record-keeping and communication

7. Mrs C said that the Practice failed to provide a reasonable standard of palliative care to Mr A and control his pain in a reasonable way, particularly from 16 March until 23 March 2015. For example, Mrs C told us that on 23 March 2015, medication at a particular strength was not available and so a second syringe driver programme was prepared to take the volume of the lower strength but it had no detrimental effect only because Mr A died before the syringe driver was needed, and that the Practice failed to obtain sufficient medication at the strength required for the driver. Mrs C also raised concerns about record-keeping errors, particularly in relation to the strength and quantity of medication and that at one point there were two 'current' prescriptions for Mr A. Finally, Mrs C was concerned that the Practice did not in fact discuss Mr A's case with a palliative care consultant (the Consultant) after 12 March 2015 as the Practice had indicated and that the Practice had also failed to communicate with Mrs C in a reasonable way about administering pain relief.

The Practice's response

8. In the response to Mrs C's complaint, the Practice set out their account of events. The main points in relation to what the Practice said about the medical issues raised were:

- no medication errors occurred and Mr A did not miss any medication;
- there is evidence Mrs C provided medication without authorisation from the clinical team;
- midazolam was discontinued on 19 March 2015 to prevent Mrs C over-medicating Mr A;
- it was difficult to obtain the medication at the strength required from pharmacies but Mr A did not miss any medication due to supply issues and the second syringe driver was not required;
- there was a balance between pain and sedation and rapid increases of medication could result in respiratory depression and premature death, and guidelines were followed appropriately;
- specialised advice was taken from the Consultant on four occasions;
- staff were under intense pressure due to volume of complaints made by Mrs C and the home visits were very challenging for staff; and

- providing palliative care was difficult in this case and medical staff did their best to provide the best care and treatment (the Practice noted that no breakthrough medication was required in the last three days of Mr A's life).

9. In response to enquiries by my complaints reviewer about the administration of breakthrough medication, the Practice said that Mrs C's case had been an exception. The Practice had allowed her to administer the breakthrough medication because Mr A (on 16 March 2015) was very distressed with pain and it would have taken some time for a visit from healthcare professionals. On 17 March 2015, a GP agreed with Mrs C that she could administer breakthrough medication but that she must seek medical advice first and in circumstances where the wait for a healthcare professional visit would be longer than one hour. The Practice said Mrs C was aware of the administrative responsibility of documenting when doses were given and that a balance of remaining drugs could be checked, and that she documented these doses correctly in the nursing notes. The GP and district nurse assessed that Mrs C would be competent in administering the medication required and that no specific training was necessary. In the event of an overdose, resuscitation would not have been appropriate given the grave nature of Mr A's condition. Mrs C was advised to seek advice before administering a drug to allow professional assessment of pain and to prevent an overdose. On 20 March 2015, a GP expressed concerns that Mrs C had not asked for their consent before administering the breakthrough medication and said they had stressed to her that she could only give the medication if she asked for medical advice first. The GP also informed Mrs C that if she did not follow instructions, adult protection would become involved and Mr A could be removed from the house because medical staff had a responsibility to vulnerable adults. The Practice confirmed they had no evidence that Mr A consented to Mrs C administering a controlled medicine and assumed that implied consent was given as she would only have given medication if Mr A had been distressed and/or in pain.

10. My complaints reviewer also made enquiries with the Board, who confirmed that they have no protocols, procedures or guidelines in place for staff working within the Board area to support patients and/or carers to administer prescribed subcutaneous medication by injections.

Advice obtained

11. The Medical Adviser carefully considered all the evidence available including Mr A's clinical records and said that there was evidence that co-ordinated and holistic care was provided by a multi-disciplinary team (at the Practice) who also took specialist advice from the Consultant and there was no evidence of an unreasonable standard of palliative care. There was no evidence that an incorrect dose of oxycodone (an opioid-based analgesia to treat severe pain and a controlled medicine under the Misuse of Drugs legislation) was administered on 17 March 2015; while there was a calculation error in recording the remaining number of vials of oxycodone left on the controlled balance sheet, this was not a prescribing instruction. It was the Medical Adviser's view that this would not have led a reasonable clinician to miscalculate a subsequent dosage particularly as the strength given was accurately recorded. It was not, therefore, an error in prescribing or in the administration of the drug and the Medical Adviser did not consider this transcribing error had any detrimental effect on the clinical management of Mr A's symptoms nor that it caused any injustice.

12. The Medical Adviser further noted that in palliative care services there would always be a number of patients whose pain was difficult to control and whose pain did not respond as readily as others, but that this was not due to the fault of the clinicians involved but to the varied responses patients had to different medications. In this case, the clinical notes evidence management of cancer pain with the appropriate medication and increasing doses to try and control Mr A's pain. The Medical Adviser concluded that the care provided was in keeping with national guidelines[1] for pain management.

13. In response to Mrs C's concerns, that the Practice failed to have reasonable arrangements in place to ensure the sufficient supply of medication at the strength required, the Medical Adviser said that there was a supply problem with getting oxycodone (at the right specification) for the syringe driver (on 23 March 2015), but that the source of supply issue lay with the pharmacy (or with the suppliers the pharmacy used). The evidence from the clinical records confirmed that GPs at the Practice attempted to source the oxycodone but when they were unable to ensure its availability, they decided to set up two syringe drivers with a different dilution of oxycodone, which was available in the

[1] Scottish Palliative Care Guidelines; Scottish Intercollegiate Guidelines Network (106): Control of Pain in Adults with Cancer

house and would have achieved the same painkilling effect albeit delivered through two separate syringes. The Medical Adviser considered this alternative to be reasonable and said it was not uncommon for some patients to have two syringe drivers instead of one at times, and concluded that there was no evidence that there was insufficient medication for the syringe driver. The clinical records also showed that on 23 March 2015, Mr A was 'Cheyne stoking and barely responsive', which described a type of breathing that patients do when they are dying. The Medical Adviser noted that Mr A was unconscious and dying and as such was in no obvious pain or distress, and so the time it would have taken in setting up a new syringe driver did not have a detrimental effect on him. The Medical Adviser also referred to the fact the one of the GPs secured a prescription from the Consultant, which was processed by the hospital pharmacy (when they were unable to get oxycodone from local pharmacy), and said the Practice was not in a position to collect the medication (most families would collect the medication themselves or wait for delivery directly by the pharmacist) but that the GP ensured they had enough medication to administer pain relief by two syringe drivers until a hospital colleague brought the oxycodone to the surgery that day.

14. Related to this, having considered the Practice's response and the clinical entries, the Medical Adviser said the description of these events appeared consistent and there were no obvious discrepancies between the Practice's response and clinical records. As for the pharmacist's account, this confirmed that all prescriptions were dispensed but did not go into any detail of what occurred that day. Having carefully reviewed all the evidence available about this event, the Medical Adviser was satisfied that the sequence of events occurred as described by the Practice and that the problem with the supply of oxycodone did not lie with them. Moreover, when it was evident there was a supply problem, the GPs at the Practice made reasonable efforts to actively source a supply from elsewhere.

15. Turning now to events before then, the Practice acknowledged that one of the GPs at the Practice forgot to order medication on 16 March 2015, but remembered afterwards and arranged to order and collect it the following day. If there had been no medication available, then the Medical Adviser said it could have had an adverse effect on Mr A, in that he could have suffered poor pain control, but the medication was sourced and delivered. The Medical Adviser added that there was no evidence that this human error had any effect on the overall clinical outcome or on Mr A's pain control.

16. My complaints reviewer asked the Medical Adviser about Mr A's decision on 16 March 2015 that he did not want to be alert but asleep until he died and feel any more pain before his death. The Medical Adviser said that the aim of pain management was to control the pain and associated distress but not to sedate or anaesthetise a patient and so although sedation could be a side-effect of opiates, it would not be reasonable for a GP to purposely and directly increase analgesic to render a patient unconscious.

17. Turning now to the record-keeping issues Mrs C raised, my complaints reviewer asked the Medical Adviser if there was any evidence of medication errors and whether midazolam (a controlled medicine that was prescribed to Mr A for 'terminal restlessness' which was a common symptom found in patients towards the end of their life) was prescribed in a reasonable way. The Medical Adviser said that Mr A was visited regularly by a clinician and there was evidence of active communication between medical and nursing staff about his care. After considering the evidence, the Medical Adviser concluded that: there was no evidence any medication was administered to Mr A that should have been discontinued; there was no evidence a medication dosage was missed nor that the patient was distressed due to any absence of medication; and there was no evidence of administrative errors (including the time it took to discontinue a duplicate prescription) which led to any detrimental effect on Mr A.

18. With respect to midazolam, the Medical Adviser noted that the Practice had changed the midazolam prescription from an 'as required only' instruction to adding it to the syringe driver, so that a steady dose could be delivered to Mr A over a 24-hour period. This change was made on 19 March 2015 by one of the GPs. (The Medical Adviser explained that the syringe driver was prepared and attached to the patient by district nurses alone.) In the Practice's response to Mrs C's complaint, they stated that 'the midazolam was discontinued on 19 March 2015 to prevent over medication by [Mrs C]'. The Medical Adviser said that this did not accurately reflect what occurred; the dose of midazolam was changed so that it would be added to a 24-hour syringe driver. The Medical Adviser noted that this change occurred because the GPs were concerned that Mrs C may administer the medication as an 'as required dosage' without first seeking medical approval, which was based on the concerns that Mrs C had administered oxycodone previously without medical approval. My complaints reviewer asked the Medical Adviser about Mrs C's concerns that changing the prescription of this drug caused extreme distress to Mr A in the

early hours of 20 March 2015 and possible danger to him because nursing staff were unable to give him breakthrough midazolam by injection to relieve his distress and agitation and had to give him a lorazepam tablet instead. However, the Medical Adviser said that lorazepam was used as an appropriate alternative to midazolam, which was well recognised by the aforementioned national guidelines for pain management. The Medical Adviser added that lorazepam tablets could be absorbed in the mouth and there was no evidence that Mr A came to any harm from taking this medication in tablet form.

19. In response to Mrs C's concerns about the recording chart for the syringe driver on 20 March 2015, the Medical Adviser stated that recording charts were for clinicians to use and if the chart page had been misfiled, it would have been easily located in the patient nursing record. The Medical Adviser noted the recording chart for 20 March 2015 and found no problems with it, adding that they had no concerns if it had been filed in a different section as this would not have had a detrimental clinical effect on Mr A's care.

20. Turning now to communication, and communication between the GPs at the Practice and the Consultant, the GPs had recorded four clinical contacts with the Consultant from 12 March 2015 (on 12, 13, 16 and 20 March 2015) in the clinical records. Having considered the entire clinical record in this context, the Medical Adviser was satisfied from the entries that the GPs did obtain advice from the Consultant on these occasions and that there was no evidence that the clinical entries made by the GPs were falsified. The Medical Adviser further explained that it was not unusual for GPs to call specialists to ask for advice in which case the onus to record and/or document this in the patient's clinical notes lay with the GP. Moreover, the relevant entries in this case appeared to be a first-hand account of the conversations between the GPs and the Consultant and made at the time of the conversations (or soon after).

21. In relation to communication between Mrs C and the Practice about administering breakthrough medication for pain relief, the Medical Adviser noted the evidence that a GP explained to Mrs C (on 17 March 2015) that she could give breakthrough medication via a subcutaneous route (by injection) as long as she discussed this first with health care professionals. The evidence from the clinical records indicated that Mrs C gave breakthrough medication (oxycodone) once on 17 March 2015, twice on 18 March 2015, and once on 19 and 20 March 2015. There was also a clinical entry (on 20 March 2015) that Mrs C acknowledged that she gave breakthrough medication on one occasion without

seeking medical advice first, although the Medical Adviser said the clinical records indicated that this happened on at least one other occasion. The Medical Adviser reviewed the information provided by the Practice and said that they had not provided evidence that there was effective governance in place. In particular, there was no evidence of any training for Mrs C in terms of drug administration nor any recording in the clinical records to clarify this. Neither was there any evidence that this arrangement or alternative option was discussed with Mr A nor that he consented to this agreement, particularly as the clinical records noted (on 26 February 2015) that he had capacity and so there was no reason why this arrangement should not have been discussed with him. Moreover, the Practice failed to stop the arrangement despite clinically documenting their concerns that Mrs C had administered medication without clinical advice. The Medical Adviser said that these shortcomings were contrary to GMC guidance.

22. The Medical Adviser concluded that there was no evidence the care and treatment provided by the GPs caused any direct clinical injustice to Mr A, and that the aforementioned administrative shortcomings were not significant and were addressed directly within a reasonable time by clinicians. However, they remained concerned about the issues relating to Mrs C's administration of breakthrough medication without appropriate governance and documentation. Moreover, GPs continued to prescribe oxycodone for breakthrough pain despite their concerns that Mrs C had administered medication out-with the agreed instructions and out-with any robust governance arrangements including a lack of documented patient consent. The Medical Adviser said that this fell below a reasonable standard.

(a) Decision

23. Mrs C complained that the Practice failed to provide a reasonable standard of care and treatment to Mr A. In reaching my decision, I have carefully considered Mrs C's account of what happened and Mr A's clinical records. The advice I have accepted is that, in relation to treatment decisions and pain management, the standard of palliative care and treatment provided was reasonable. Clearly, Mrs C was concerned about whether the Practice had reasonable arrangements in place to ensure a sufficient supply of medication and she referred to a number of record-keeping errors about this. The Medical Adviser said that the issue of supply lay with the pharmacy; that the Practice took reasonable action when they could not obtain particular medication (or medication at the required strength) at times; and that the transcribing errors

and misfiling had no detrimental clinical effect on Mr A's care. I accept that advice. I also recognise Mrs C's concern about the Practice's contact with the Consultant. In this respect, I note the contacts recorded in the clinical records. I am satisfied that these clinical entries and the GPs' subsequent treatment decisions and management of Mr A were consistent with the timeline of events in relation to Mr A's deteriorating condition and care and treatment provided.

24. Turning now to communication with Mrs C about administering pain relief, she maintained in the strongest terms that she had not been instructed she could give the breakthrough injections only after checking with health care professionals first; and only if they could not attend for at least an hour from when it was required; and that she always sought healthcare professionals' consent before doing so, after her conversation one of the GPs on 19 March 2015. In this respect, I note that the GPs' account and the entries in the clinical records differs from Mrs C's account. Both Mrs C's recollection and the Practice's account are detailed and consistent. Having considered the matter carefully, I am unable to reconcile these different accounts. It is not that I disbelieve Mrs C, but that I have to reach a decision based on evidence. Nevertheless, given the failings around the governance arrangements in relation to Mrs C's administration of breakthrough medication, I find that the standard of medical care and treatment provided was not reasonable. I am extremely concerned about what was effectively an informal arrangement between the Practice and Mrs C which allowed Mrs C to administer a controlled drug without the Practice first putting adequate safeguards in place or seeking guidance from a specialist (such as the accountable office for controlled medicines in their area or palliative care services). Furthermore, I agree with the Medical Adviser that it is of concern that GPs continued to prescribe a controlled drug after expressing concerns that Mrs C had administered the medication without clinical advice. I am also critical that the Practice failed to ensure that their patient, Mr A, consented to this arrangement and of their poor response to my complaints reviewer's enquiry about this. I uphold the complaint. I intend to write to the GMC to draw their attention to my concerns about the risks to patient safety arising from the lack of governance arrangements and documented patient consent in this case.

(a) Recommendations

25. I recommend that the Practice: *Completion date*

(i) ensure the GPs who instructed Mrs C in relation to 30 September 2016

	breakthrough medication and the other GPs who subsequently issued prescriptions for oxycodone seek support from the Board's clinical support group, in relation to responsibilities for prescribing and consent under GMC guidance;	
(ii)	ensure the relevant GPs discuss the findings of this investigation at their annual appraisal;	30 September 2016
(iii)	ensure the relevant GPs familiarise themselves with the GMC guidance as a priority;	30 September 2016
(iv)	draft a protocol in conjunction with the Board to support patients and/or carers to administer prescribed subcutaneous medication by injections; and	30 November 2016
(v)	apologise for the failings this investigation identified.	30 September 2016

(b) Mrs C's complaint was not reasonably responded to

26. Mrs C said the Practice's response to her complaint was unreasonable and failed to address all the issues raised.

NHS complaints process

27. Scottish Government guidance[2] on complaints handling states that the response, in terms of best practice, should address all the issues raised and, wherever possible, be issued within 20 working days of receipt of the complaint.

Advice obtained

28. I asked the Medical Adviser if the Practice's response to Mrs C's complaint was reasonable from a clinical point of view. The Adviser said that the response was detailed and comprehensive and addressed all the clinical issues raised in a reasonable way, as well as acknowledging administrative errors. However, there was an error in that medication was not discontinued as such but changed from 'as required' to being added to the syringe driver.

(b) Decision

29. Mrs C complained that the Practice failed to respond to her complaint in a reasonable way. I note Mrs C's concerns that the Practice failed to respond to all the issues raised. The advice I have accepted is that the response was

[2] Scottish Government (2012) Can I Help You? Guidance for handling and learning from feedback, comments, concerns or complaints about NHS healthcare services

comprehensive and addressed all the clinical issues raised in a reasonable way, with one exception. I appreciate that Mrs C disagrees with much of what was said, but that is not in itself evidence of maladministration. While I consider that the response could and should have been clearer about the prescription of midazolam, I am satisfied that on the whole the response was reasonable. On balance, therefore, I do not uphold the complaint.

30. We will follow-up on the recommendations. The Practice 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

Mrs C	the complainant
Mr A	the complainant's husband
the Practice	a medical practice in the Grampian area
the Board	NHS Grampian Board
the Medical Adviser	an adviser to the Ombudsman who specialises in general practice
GMC	General Medical Council
GPs	general practitioners
the Consultant	a consultant in palliative care at Aberdeen Royal Infirmary