Case 200401897: A GP Practice in Forth Valley NHS Board area

Introduction

1. On 24 January 2005 the Ombudsman received a complaint from a man (referred to in this report as Mr C) about the decisions of two GPs in a GP practice (the Practice) to prescribe the drug diclofenac for his late aunt, Miss C, and then to give it on repeat prescription.

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

(a) diclofenac was prescribed by the first GP (GP 1) without proper account of Miss C's condition as a frail 92-year-old;

(b) diclofenac was made a repeat prescription by the second GP (GP 2).

3. Following the investigation of all aspects of this complaint I came to the following conclusions:

(a) not upheld, see paragraphs 37 to 40;

(b) upheld, see paragraphs 41 to 47.

4. In summary, I found that the initial prescribing decision was justified but that one of the GPs should have more fully assessed the situation before prescribing the drug as a repeat. In the light of these findings, the Ombudsman recommended that the Practice review their repeat prescribing mechanisms.

5. The Practice accepted the recommendation and have already acted on it (see paragraph 47).

Medical background

6. The British National Formulary (BNF) is an authoritative medical publication, containing information about medicines and their use. It includes much advice

about analgesia (pain relief) to help doctors in their prescribing decisions. Relevant examples of this are that it says: that analgesics are more effective in preventing pain than in relieving existing pain, so it is important to give them regularly; and that it is important to note that elderly people are particularly susceptible to side-effects in opioid analgesics, such as those containing codeine.

7. The BNF describes diclofenac as a drug used for pain and inflammation. Unlike paracetamol (a common pain reliever) it is a non-steroidal anti-inflammatory drug (NSAID). The BNF advises that paracetamol is a preferred analgesic for the elderly but that NSAIDs are particularly useful where (as in this case) an anti-inflammatory effect is needed in addition to the pain relief. And the BNF's advice about prescribing for the elderly is that paracetamol and a NSAID can be given together.

8. The BNF advises doctors to consider the gastro-intestinal and other possible side-effects in deciding which NSAID to choose because there are significant differences between NSAIDs in their side-effects. It describes diclofenac as having a low incidence of general side-effects, but, in relation to gastro-intestinal side-effects, it suggests that diclofenac presents an intermediate risk. (Some time after starting the drug, Miss C suffered a gastro-intestinal haemorrhage namely stomach/intestine bleeding.)

9. The clinical advisers who assisted in my investigation (see paragraph 12) have added that diclofenac and other NSAIDs can cause haemorrhage and gastro-intestinal ulceration, especially in the elderly (to whom this is a very dangerous condition) and in those with a known tendency or history of ulcers. And they advise that heart failure is a reason to exercise caution as NSAIDs can worsen this condition.

10. Part of Mr C's complaint was that diclofenac was prescribed without a so-called protector to lessen the risks of using a NSAID. To give a patient some protection, diclofenac can be given in an enteric-coated form and can be taken after food. Both of these were included as instructions on Miss C's prescription. Some protection can also be provided by prescribing a medication known as proton pump inhibitor with the NSAID. This is known as co-prescribing. The advisers have said that it is generally agreed that co-prescribing is not justified in

all cases but that there is no universal agreement about when it should be used. The BNF advice at the time was that, if NSAIDs continued to be needed for an elderly patient, protection should be considered. However, the advisers consider that such guidance was not by any means universally followed and that it should not automatically be assumed as a reasonable standard against which to measure GP care.

11. Mr C also wondered why an anti-inflammatory drug was used at all, given Miss C's age and frailty. Over the last few years there has been debate about a sub-group of anti-inflammatory drugs, commonly called Cox-2 inhibitors. They were considered to give similar benefits to other NSAIDs, but with a lower gastro-intestinal risk. However, the strength of evidence for this has been debated since their introduction, and serious cardiac and (probably) stroke effects have emerged. One Cox-2 drug has, therefore, been withdrawn and the others are no longer automatically regarded as a good choice (although this remains a matter of debate). These issues are covered in the BNF, and the Practice have indicated that the link between NSAIDs and gastro-intestinal problems has long been known to all GPs. The advisers support that view.

Investigation and findings of fact

12. I was advised by one of the Ombudsman's clinical advisers and by an adviser who was appointed specifically for this case (see reference in paragraph 9). Both are senior GPs of long experience. We examined the GP clinical records, nursing home records, GP complaint correspondence, Health Board Independent Review correspondence and the detailed answers to questions which I put to the Practice and to the nursing home where Miss C lived.

13. Mr C and the Practice have commented on a draft of this report.

14. By way of background, I should explain that as Mr C had been dissatisfied by the Practice's responses to his complaint, he requested an Independent Review from one of Tayside NHS Board's Independent Review Panel (IRP) conveners. The convener declined, and as Mr C disputed some of her comments and still wanted the Practice issues to be addressed, his complaint to the Ombudsman was about the convener. I concluded that the convener's decision to refuse an IRP had been taken in accordance with NHS guidance and I did not uphold that complaint.

But I judged that it was appropriate to look at the substance of the complaint, which was about two GPs at the Practice. I shall generally refer to them as the Practice in this report but emphasise that the complaint is not about other GPs in the Practice.

Complaints (a) and (b)

15. I turn now to the events in question. I would normally cover the two aspects of the complaint separately. In this case, however, it makes sense to tell Miss C's story chronologically, covering the issues as they arise.

Miss C's history and GP 1's diagnosis and prescribing decision on 2 April 2003

16. Miss C was a frail 92-year-old who was placed in a nursing home in August 2002 after a long hospital admission. Two hospital letters to the Practice indicate that her medical condition at that time included limb fractures from falls, heart beat irregularities, constipation, cognitive impairment (ie loss of some brain functions) and some feelings of paranoia. Her various medications included a laxative (for constipation) and long-term use of paracetamol (for pain relief).

17. Miss C's GP care in the nursing home was given by the same Practice that had attended to her for many years. Throughout her time in the home she had a paracetamol prescription for use when required. The home's medication administration records show that by early October 2002 she was taking the maximum prescribed dose (eight a day) every day. These records correspond with the Practice's records of the amount of paracetamol which they prescribed and so can be taken as accurate.

18. The nursing home records show that Miss C complained about pains in her legs on 31 March 2003. As these seemed to have worsened a couple of hours later, the notes question whether a GP visit or prescription might help. The notes for 1 April say that Miss C woke at 04:00 that day with pain in the right knee, which was very swollen. She went back to sleep after being given paracetamol. Paracetamol was given again during the day (1 April) and, on being contacted, a GP from the Practice prescribed Movelat by telephone for the nursing home to apply direct to Miss C's knees for pain relief.

19. Following Mr C's request for a GP visit, GP 1 attended on 2 April. Her clinical

notes record that there was swelling, heat and pain to the right knee. She diagnosed cellulitis. The advisers have explained that cellulitis of the legs is a fairly common skin infection, especially in the elderly (although more often of the calf/shin than the knee). They agree with GP 1's statement to me that cellulitis is characterised by red, swollen, painful and tender skin. GP 1 prescribed 50 mg of enteric-coated diclofenac twice daily (enough for 14 days), to be taken after food, and 250 mg of flucloxacillin (an antibiotic) three times daily (enough for ten days).

20. Mr C's complaint expressed concern about prescribing diclofenac for someone of his aunt's age and frailty because of the apparent lack of protection, such as the co-prescribing of a proton pump inhibitor (as explained in the medical background section of this report) and because of the risks (also explained in that section).

21. GP 1 told me that it was difficult to be sure about the level of Miss C's pain because of the communication difficulties caused by her cognitive impairment. But she clearly felt pain on having her knee moved. GP 1 judged, therefore, that the paracetamol that Miss C had been taking long-term for pain was inadequate for this new pain and that the pain was, therefore, of a mixed cause – in other words, the causes of the old and the new pain.

22. GP 1 explained to me what guided her prescribing decision. She said that benzylpenicillin (or similar) with flucloxacillin was the Practice's antibiotic treatment of choice for cellulitis. But as it was not uncommon to choose just one of these, she prescribed flucloxacillin alone. And she said that, in line with BNF advice on prescribing for the elderly, her usual practice with frail, elderly patients was to prescribe only 250 mg three times daily because of the possibility of concentration of drugs in the tissues of such patients.

23. When considering what analgesia to prescribe, GP 1 told me that it was clear that the paracetamol alone (which Miss C had been taking long-term at its maximum dose) was not enough. The next step increase in analgesia could have involved the use of codeine, which is an opioid drug. However, as stated in the BNF (and the medical background to this report) as a point of importance, the elderly are particularly susceptible to the side-effects of opiates, such as confusion and constipation. Miss C had a history of both. GP 1 was also aware of advice in

the BNF about the use of NSAIDs as being particularly useful for patients with pain and inflammation and the BNF's advice that escalation of analgesia in the elderly, where paracetamol was not working, could include paracetamol given with a low-dose NSAID. She said that the dose of diclofenac which she prescribed was low, at a total of 100 mg daily, rather than the usual dose of 150 mg daily.

24. GP 1 also told me that she was aware that Cox-2 inhibitors (see medical background) had to be used with caution in patients with heart problems, such as Miss C, and that, at the time, it was not standard practice to co-prescribe a protector such as a proton pump inhibitor. Having, therefore, excluded choices which she judged to be less suitable, GP 1 concluded that the best option in this prescribing situation was a 14-day course of two daily 50 mg doses of diclofenac which were enteric coated and were to be taken after food. (The medical background section of this report explains the protection offered by these means.)

Development of Miss C's condition, and the repeat prescribing

25. GP 1's records for the 2 April 2003 visit end, 'follow up if not settling'. GP 1 told me that she discussed this point at the time with the nursing home nurse who was in attendance and that the usual practice would be for the home to contact the Practice if their concerns continued. The Practice also explained that their visits to the home would be at the home's request except in exceptional cases, such as cases that would clearly need further visits. The Practice also said that cellulitis was a common condition, that the home was particularly good at giving appropriate clinical feedback of this sort to the Practice, and that the nurses' competence and experience suggested that the staff would be capable of supervising Miss C's care and contacting the Practice if necessary.

26. The diclofenac and flucloxacillin were duly started. The nursing home records say that the right knee remained painful on 3 and 4 April but was less painful on the 5th. The notes for the 7th say that there were no complaints of pain, and, for the 8th, that the knee was much better. Miss C's usual routine continued, and her knee is not referred to again in these daily notes until 19 April, when it is recorded as being less painful. The 23 April notes record Miss C as continually saying that her knees were painful. 24 April shows less pain and 25 April records the knees as painful when moved. The next record is on 2 May, describing the right knee as looking less inflamed and causing less discomfort on movement. No mention is

made of Miss C's knees in the nursing home records after that date.

27. The nursing home's medication administration records show that Miss C was given diclofenac continuously until taken into hospital on 30 May 2003. In other words, after GP 1's prescription, which was intended to be short term, repeat prescriptions were issued for Miss C.

28. In his complaint, Mr C said that the diclofenac was prescribed because of the diagnosis of cellulitis, which he said could be cleared up within ten days. And the diclofenac had only been intended as a short-term prescription. Therefore, he reasoned that the continued prescribing of the diclofenac was wrong, particularly given Miss C's age and condition.

29. The Practice have explained the repeat prescribing to me. They said that if a drug for one of the Practice's patients was still needed after a short-term prescription, the nursing home would ask the Practice for it. A GP at the Practice would consider its need, having regard to the reduced GP scrutiny that would exist if the drug were issued as a repeat prescription and having satisfied himself or herself that there was a method in place for ongoing clinical review. He or she could then instruct a repeat prescription. After two short-term prescriptions (by GP 1 and GP 2), the diclofenac was made a repeat by GP 2. The Practice also explained that the fact that the skilled staff of the nursing home had requested more diclofenac indicated its ongoing need and effectiveness. They considered that if it had not been effective or appeared to have side-effects, the nurses could have requested a review or a different drug. The Practice indicated that this was very common practice in medicine. They said that no review date was given for the repeat prescription because review of repeats was a function of a patient's clinical condition, rather than a function of the Practice's repeat-prescribing system. (The patient's clinical condition was left to the nursing home to assess.)

30. As the diclofenac was intended as a short-term prescription, I asked the Practice what 'short term' meant in this situation. They quoted from the BNF, which I confirm states that a full pain-relieving effect should normally be felt from a NSAID within a week, although an anti-inflammatory effect may not be achieved (or may not be clinically assessable) for up to three weeks.

Miss C's death, the Practice's review of her treatment, and developments in clinical practice since then

31. The next relevant nursing home notes are for 30 May 2003, which say that Miss C woke at 02:00, with a small amount of blood around the rectum and that ten minutes later she experienced significant haematemesis (vomiting of blood). The out-of-hours GP service was called, and their records show them as seeing Miss C soon afterwards and as having identified that the drugs currently being taken by Miss C included diclofenac, paracetamol and laxative. (The nursing home's medication administration records show that the flucloxacillin (which GP 1 had prescribed on 2 April 2003) stopped when the initial course had been completed.) Miss C was admitted immediately to a local hospital. While there, her condition worsened and she sadly died there on 20 June 2003. The advisers have described the gastro-intestinal haemmorhage which she suffered as an extremely serious event in anyone and particularly so in a frail, elderly person.

32. Part of Mr C's complaint was that Miss C's death could have been avoided had more care been given to the prescribing decisions.

33. The Practice told me that they held a critical-incident review to discuss whether any other approach could have been used in Miss C's treatment, based on clinical evidence at that time about the use of NSAIDs. They considered the advice in the BNF (see the medical background section of this report). They also searched relevant literature to identify whether there was any clinical consensus about the best choice out of the options of: low-dose NSAID; NSAID with a protector, such as a proton pump inhibitor; Cox-2 inhibitor; or Cox-2 inhibitor with a protector. This search did not identify any consensus of opinion. In other words, the Practice did not find any recommended evidence-based strategy. The Locality Prescribing Adviser at the Health Board's Primary Care Division (known as a Trust at that time) told the Practice that no national guidance was held by them or by colleagues whom they had approached nationally on the Practice's behalf. In the absence of clear guidance, the Practice felt, therefore, that in any future cases, each GP would make their own prescribing choice on a patient-by-patient basis, balancing the benefits and risks regarding that individual.

34. The Practice also explained in detail what they had been doing since that time. For example, they explained the efforts they had been making to keep up-to-date

with the developing clinical thoughts about analgesia, such as the risks associated with Cox-2 inhibitors. They had also identified evidence which they felt in the future could possibly allow better risk assessment of patients. In October 2004, the Practice also received guidance from the Primary Care Division, suggesting that patients over 65 have a protector in future. The adviser considers this to be particularly reassuring.

35. The Practice also pointed out to me that the new national contract, under which GPs have worked since April 2004, encourages GP practices to record the clinical reason for the prescription of a medication on a repeat basis. They said that improvements in the national GP computer software in mid-2005 had enabled the Practice to do this.

Conclusions and recommendations

36. As far as possible, and as explained throughout this report, I have checked the information on file by cross-referral with other information on file and by comparison with advice in the BNF. The BNF is produced by the British Medical Association and the Royal Pharmaceutical Society of Great Britain under the authority of a Joint Formulary Committee which comprises representatives of those two professional bodies and of the UK Government Health Departments. Statements, including the advice from the advisers, have been checked to identify apparent gaps and discrepancies, which have then been challenged. I am, therefore, satisfied that the evidence in this report has been adequately tested and that the advisers' advice is appropriate.

(a) Complaint that diclofenac was prescribed by GP 1 without proper account of Miss C's condition as a frail 92-year-old

37. The advisers confirm that Miss C's symptoms on 2 April 2003 matched the characteristics of cellulitis. Because Miss C had been on a maximum dose of pain reliever (paracetamol) for many months before developing knee pain on 31 March 2003, they consider that it was appropriate for GP 1 to conclude that the pain on 2 April was of mixed cause. As Miss C was in pain when GP 1 visited on 2 April, it was clear that the paracetamol alone was not enough.

38. The advisers have explained that, for a patient of Miss C's age and frailty, this was a difficult dilemma. For example, some of the analgesics which were stronger

than paracetamol could cause constipation and confusion; Miss C had a history of both. And opioid analgesia would not be a usual choice for an elderly person with a history of falls, like Miss C. The Practice also quoted accurately the BNF prescribing advice. And the Practice said that diclofenac was one of the NSAIDs on the usage list of the Health Board's Primary Care Division, that the prescribed dose was low, that an enteric-coated form was prescribed and that the drug was to be taken after food. A Cox-2 inhibitor would not have been suitable because of the possibility of cardio-vascular problems (and, indeed, the most commonly used of these has since been taken off the market for that reason). With the benefit of hindsight, the advisers feel that a protector (such as a proton pump inhibitor) would have been desirable but they emphasise that in 2003 this was not standard practice. As I must judge the events against what should reasonably have happened, given the circumstances at the time in question, I can only conclude that GP 1 cannot be criticised for not prescribing such a protector.

39. Against this difficult clinical background, the advisers consider that the dilemma facing GP 1 on 2 April 2003 was a genuine one, that she performed a competent clinical assessment of Miss C's condition and that, after weighing the arguments for and against various treatment options, she prescribed appropriately.

40. I accept that advice. Therefore, I do not uphold Mr C's complaint about GP 1's prescribing decision on 2 April 2003.

(b) Complaint that diclofenac was made a repeat prescription by GP 2

41. I feel it would be appropriate at this point to say that one of Miss C's repeat diclofenac prescriptions was issued after her admission to hospital; this might have indicated an inappropriate prescription. This was not raised by Mr C in his complaint and, therefore, did not form part of the investigation. However, Mr C may find it helpful to know that I can confirm that the advisers and I are entirely satisfied with the explanations given by both the Practice and the nursing home in this respect. Very broadly, the explanations concern nursing home prescribing cycles (a copy of which the advisers and I have seen) and Practice and pharmacy processing timescales.

42. The Practice have said that the nursing home were particularly good at feeding back appropriate clinical information to them and that the ongoing need for, and

suitability of, diclofenac was evidenced by the home's ongoing requests. However, the advisers consider that the crucial point here was the use of a pain reliever which had a risk of side-effects, especially in the elderly and with prolonged use. On 2 April 2003 GP 1 made a diagnosis of cellulitis as the cause of Miss C's new pain. It would be reasonable to expect that the cellulitis would be cured or improved by the diclofenac and flucloxacillin, which would result in a reduction in pain, which could mean that diclofenac would no longer be needed.

43. The advisers do not believe that nursing home staff, however competent, can be relied on to make decisions about withdrawing analgesia that may no longer be necessary. From the home's point of view, Miss C had been in pain on 2 April, when the diclofenac was first prescribed, and her pain decreased after taking the drug. That could be regarded by the home as a satisfactory outcome, justifying a request for further prescriptions. But such a request was not evidence in itself that the medication was still needed. It might well have been needed, but only a medical assessment could have determined that. The nursing staff's satisfaction with Miss C's clinical condition was only one factor to take into account. It was the Practice's responsibility, not the nursing home's, to take account of the whole picture, particularly the increased risk of side-effects with the passage of time. The whole picture would have included consideration of the short-term nature of the condition (the cellulitis) that had led to the original prescription and the risks of long-term diclofenac use in the elderly. The use of a review date for repeat prescriptions could have been a helpful back-up, but no review date was set because the Practice relied on patients' clinical conditions to prompt reviews, and in Miss C's case, that clinical condition was left to the judgement of the nursing home staff.

44. The advisers conclude, therefore, that after the cellulitis had been successfully treated, the need for further prescriptions of diclofenac was not fully assessed by GP 2 in line with his responsibilities. Crucially, however, they say that it cannot be concluded that the continued diclofenac caused, or contributed to, the haematemesis or that it shortened Miss C's life. Haematemesis is a recognised risk of NSAIDs but it can have other causes, so there is no evidence that the bleeding was caused by the diclofenac.

45. I accept this advice. Therefore, I uphold Mr C's complaint about the repeat

prescribing to the limited extent indicated by paragraph 44 of this report.

46. The changes stated by the Practice about recording the reasons for converting a short-term prescription into a repeat (see paragraph 35) are welcome but, in the advisers' opinion, do not go quite far enough. The Ombudsman, therefore, recommended that the Practice draw up procedures to ensure that a doctor carries out an assessment when he or she is considering converting a prescription to a repeat. In cases where there is significant risk, an adequate assessment would involve consideration of the clinical notes and of the whole picture, such as any increased risks with continued use of a drug.

47. I am pleased to report that the Practice have carried out this recommendation. I have seen a copy of a reminder which the Practice have issued to all their GPs about the importance of assessment before converting a prescription to a repeat. I have also been assured that that need was stated to the GPs at a Practice meeting and that a copy of the reminder is to be kept in the pack which the Practice retain for use by GPs who work temporarily at the Practice (locums).

27 June 2006

Annex 1

Explanation of abbreviations used

Mr C	The complainant
Miss C	Mr C's aunt
GP	General practitioner
The Practice	Miss C's GP practice
GP 1	The GP who first prescribed diclofenac
GP 2	The GP who prescribed diclofenac as a repeat prescription
The BNF	The British National Formulary, a medical publication about medicines
Analgesia	Medication for pain relief
Gastro-intestinal haemorrhage	Stomach/intestine bleeding
Haematemesis	Vomiting of blood