General Practitioner, Dr B

A Medical Centre

A Report by the

Health and Disability Commissioner

(Case 14HDC01100)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. On Friday 25 July 2014, Ms A had a spinal fusion and decompressive surgery at a public hospital. On Tuesday 29 July 2014, Ms A was discharged from hospital with a hospital discharge form that outlined that she had been taking a 12.5mcg fentanyl patch every 72 hours for pain control. Ms A was given one 12.5mcg fentanyl patch and told to visit a general practitioner (GP) should she require more.

2. Following her discharge from the public hospital, Ms A went to her partner's home in another region, to recuperate.

3. On Friday 1 August 2014, Ms A visited a medical centre as a casual patient. Ms A was seen by GP Dr B for approximately 10 minutes, during which Ms A showed Dr B the hospital discharge form. At the appointment, Ms A complained of pain and an inability to sleep. Dr B prescribed Ms A with two boxes of five patches of 100mcg fentanyl. Dr B did not advise Ms A of possible fentanyl side effects.

4. Ms A filled Dr B's prescription at a pharmacy. The pharmacist dispensing the medication dispensed only one box of five patches, and advised Ms A to return if she required the second box.

5. After the prescription was filled, Ms A went to her partner's house and, being in pain, put on a 100mcg fentanyl patch. That evening, at approximately 1am, Ms A was taken to a local Emergency Department (ED) because she was dizzy, nauseous and had vomited. In the ED, Ms A's dose of fentanyl patch was decreased to 25mcg.

Commissioner's findings

6. By prescribing an excessive dose of fentanyl to Ms A, Dr B breached Right 4(1)[1] of the Code of Health and Disability Services Consumers' Rights (the Code). For failing to warn of the side effects of the medication that Ms A was being prescribed, Dr B breached Right 6(1)(b)[2] and Right 7(1)[3] of the Code. By having no clinical record of his appointment with Ms A, Dr B breached Right 4(2)[4] of the Code.

7. Dr B's decision to prescribe Ms A with 100mcg patches of fentanyl was an individual clinical decision. The medical centre was not directly or vicariously liable for Dr B's breaches of the Code.

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[1] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."
[2] Right 6(1)(b) states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including — (b) an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option."
[3] Right 7(1) states: "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of the Code provides otherwise."
[4] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

Complaint and investigation

8. The Commissioner received a complaint about the services provided to Ms A by Dr B at the medical centre on 1 August 2014. The following issues were identified for investigation:

   - *Whether Dr B provided an appropriate standard of care to Ms A on 1 August 2014.*
   - *Whether the medical centre provided an appropriate standard of care to Ms A on 1 August 2014.*

9. The parties directly involved in the investigation were:

Ms A	Consumer
Dr B	General practitioner/provider
The medical centre	Provider

Also mentioned in this report:

Dr C	General practitioner

10. Information from all parties was reviewed during the course of the investigation.

11. Independent expert advice was obtained from general practitioner Dr David Maplesden (**Appendix A**).

Information gathered during investigation

Background

12. Ms A, aged 51 years, had a history of musculoskeletal problems including neck stiffness and pain, and numbness in her fingertips, and she was a falls risk, as she was unsteady on her feet when walking. In early 2014, Ms A was diagnosed with a cervical spondylomyelopathy[5] C3–C6[6] and scheduled for corrective surgery at a public hospital on 25 July 2014.

13. Ms A has multiple drug allergies, such as to codeine[7] and antibiotics. In particular, Ms A suffers anaphylaxis[8] with non-steroidals[9] and tramadol.[10]

[5] Cervical spinal cord compression, mainly caused by one or more intervertebral disk protrusions.
[6] Cerebral vertebrae number 3 to 6 directly below the skull.
[7] An opioid pain medicine used to treat mild to moderate pain.
[8] A serious allergic reaction that is rapid in onset and may lead to morbidity.
[9] A class of drugs that provides analgesic (pain-killing) and antipyretic (fever-reducing) effects, and, in higher doses, anti-inflammatory effects.
[10] A narcotic-like pain reliever used to treat moderate to severe pain.

Surgery and hospital stay

14. On Friday 25 July 2014, Ms A was admitted for surgery at the public hospital and underwent a posterior spinal fusion[11] and decompressive laminectomy[12] C3–C6, with segmental internal fixation of spine 3 or 4 levels[13] under general anaesthesia. The surgery proceeded without complication and Ms A recovered in hospital from 25 July to 29 July 2014.

Discharge

15. On Tuesday 29 July 2014, after being seen by an orthopaedic consultant, a decision was made to discharge Ms A home. She went to her partner's home in another region to recuperate from the surgery.

Pain control

16. On discharge, Ms A was given a prescription for paracetamol.[14] Ms A was also given a 12.5mcg fentanyl patch and told to visit her GP if she required additional pain medication. Fentanyl is a synthetic opioid[15] available as a transdermal[16] patch. The patches are designed to be applied to the skin, through which they release a controlled amount of fentanyl over 72 hours. The patches come in varying doses of 12.5, 25, 50, 75 and 100 micrograms (mcg). Fentanyl is a Class B controlled drug under the Misuse of Drugs Act 1975.

Discharge plan

17. Ms A was given a copy of her *General Discharge Summary* (hospital discharge form) from the District Health Board (DHB) . The form outlines a "discharge plan" for Ms A as follows:

> "1. Discharge home.
>
> 2. No heavy lifting or straining of neck. Can wear Aspen collar[17] when mobilising for 6 weeks.
>
> 3. GP [general practitioner] clinic on Friday for wound check. Please note patient has multiple allergies to pain medications. The only medication she has tolerated in addition to paracetamol is fentanyl transdermal patch. Please consider prescribing additional patch if pain is too severe to be controlled with paracetamol alone.

[11] A procedure to fuse together the painful vertebrae so that they heal into a single, solid bone.
[12] A procedure to remove bone fragments and/or thickened tissues that are narrowing the spinal canal and squeezing spinal nerve roots.
[13] Stabilising the spine by internal fixation with metallic screws and rods and/or interbody devices.
[14] A pain reliever and a fever reducer.
[15] A chemical that resembles morphine in its pharmacological effects, it binds to opioid receptors primarily found in the central and peripheral nervous system and gastrointestinal tract.
[16] Delivered through the skin.
[17] A collar designed to restrict cervical flexion, extension and rotations.

Medications:

Paracetamol
Fentanyl patch 12.5 micrograms one transdermal patch every 72 hours.

Outpatient orthopaedic clinic follow-up with [orthopaedic surgeon] in 6 weeks with x-rays cervical spine AP and lateral on arrival."

Appointments at the medical centre

18. On Friday 1 August 2014 Ms A, along with her partner, attended the medical centre as a casual patient. Ms A told HDC that the purpose of the visit was to receive a prescription for further pain medication, and to have her wound checked (as per her hospital discharge form).

Dr B

19. At 12pm on 1 August 2014, Ms A was seen by GP Dr B.[18] There is no clinical record of this appointment.

20. According to Ms A, she saw Dr B for approximately 10 minutes. Ms A advised HDC that, during that time, Dr B asked a few questions but did not examine her. Dr B advised HDC that he did not examine Ms A during the consultation but afterwards saw her surgical wound when the practice nurse was changing Ms A's dressing (details below). In addition, Ms A told HDC that she "showed [Dr B] the [hospital discharge form] which stated that [she] required 12.5mcg fentanyl patches". Dr B wrote a prescription for fentanyl patches 100mcg — two boxes of five patches.

21. Dr B stated: "[Ms A] advised that she had multiple allergies to pain medications, and requested a renewal of the fentanyl patches which she stated were 12.5mcg in dose. I understood that [Ms A] had a history of multiple drug allergies and reactions, but that she had previously used fentanyl patches with good effect."

22. In regard to the hospital discharge form, Dr B told HDC: "While I do not recall seeing a copy of [the Discharge Summary], [Ms A] may have had a copy with her and may have shown it to me."

Rationale for prescribing 100mcg fentanyl patches

23. Dr B advised HDC: "[I]n hindsight, I realise that the decision I made [to prescribe [Ms A] with 100mcg fentanyl patches] under these circumstances was an error of judgement." Dr B stated:

> "When I saw her, [Ms A] complained that she was still in considerable pain and that she was unable to get any sleep. I understood from [Ms A] that she had not been receiving adequate analgesia from her post-operative discharge medication. Since she was not responding to the prescribed dose of fentanyl, I increased the dose to 100mcg/h transdermal patches and wrote a Controlled Drug Script Prescription Form[19] … I understand that incremental dose increases are recommended as per the MedSafe Data Sheet. However, based on her history,

[18] Dr B is a vocational member of the Royal New Zealand College of General Practitioners.
[19] A triplicate prescription form for controlled drugs, such as morphine and methadone.

> symptoms and signs she was exhibiting at the time of the consultation, I thought the increase in Fentanyl Patch dose was warranted."

24. In his response to my provisional decision, Dr B advised that he informed Ms A of the dose increase. Ms A advised HDC that Dr B told her that he increased the dosage to 100mcg; however, this meant nothing to her.

25. In regard to his decision to prescribe two boxes of 100mcg fentanyl patches, Dr B told HDC:

> "[I]t was not expected that [Ms A] would require prolonged use of analgesia, and in hindsight, I misguidedly tried to ensure that she would have sufficient to adequately manage her pain post-operatively and in the short term, without having to return for another GP visit, which would incur additional cost and inconvenience for her. I was concerned that [Ms A] not run out, as she had stated that she had exhausted her current supply of analgesia from the public hospital and that she was in escalating levels of discomfort. In retrospect I appreciate that what was prompted by care and concern for [Ms A] would have been better managed by providing her with sufficient fentanyl patches only until she could be reviewed and managed by her own GP."

Rationale for not explaining possible adverse effects of fentanyl

26. Dr B provided HDC with an explanation regarding why he did not explain the possible side effects of fentanyl to Ms A, as follows:

> "Because [Ms A] had previously used Fentanyl Patches with good effect, and had just been discharged from the public hospital on this medication, with this being a recommended repeat script, I believed that the original prescribing doctor at the Hospital would have explained the side effects, so I did not repeat that discussion at this time. I apologise if that assumption was not correct."

Clinical record of appointment

27. As stated above, there is no clinical record of Ms A's appointment with Dr B on 1 August 2014. Dr B told HDC: "I have gone back through our patient management system and find that I did not separately document a clinical encounter. This is unusual and I take full responsibility for this oversight. In over forty years of clinical practice, this is the first time an oversight in my note keeping has been called into question."

28. The medical centre told HDC:

> "The lack of documentation with regards to the complainant's treatment is unusual and not a practice which [Dr B] and his colleagues in the practice are known for. [The medical centre] is committed to ensuring that our doctors practise safely and together address any identified areas that present a potential threat to patient safety."

29. In addition, Dr B advised HDC that the medical centre audited his clinical record-keeping and discovered that there may be an issue with the auto-save function on Dr

B's online clinical records. However, Dr B also advised that he was unaware of any other saving issues on 1 August 2014.

Appointment with practice nurse

30. Following her appointment with Dr B, Ms A had her dressings changed at 12.55pm by a practice nurse. The clinical notes record:

> "Fusion c4 c5 c6 Neck brace in situ, Fentanyl skin patch L) arm, Dressing down, wound cleaned small ooze area not moist no infection, dressing reapplied, advised re Opsite."[20]

The Pharmacy

31. Ms A's prescription was filled at a pharmacy. The pharmacist dispensed one box of five patches of fentanyl 100mcg and marked the second box as a repeat on the prescription.

Attendance at an Emergency Department (ED)

32. Ms A advised HDC that once the prescription was filled, she went home and put a patch on because she was in pain. That night, Ms A was dizzy and nauseous, and she vomited. Ms A was then taken to an ED at approximately 1am.

33. The clinical notes from the ED record that Ms A arrived at 1.40am on Saturday 2 August 2014. Ms A remained in the ED until 8.13am that same morning. The discharge summary outlines the reasons for Ms A's admission and the outcome:

> "Today went to GP [general practitioner] and got 100mcg Fentanyl patches. Nurse also checked neck wound: some ooze but healing well. Dressing changed.
>
> An hour after applying felt dizzy, nauseous and vomited. Felt heavy in body and crawling sensation.
>
> No rash noted.
>
> Patch removed about 6 hours after application …"

34. Ms A's observations were normal. Her discharge summary also noted:

> "Given 500mls IVF [intravenous fluid], ondansetron[21] and norflex[22] in ED. Nausea improved. Pain ongoing. Plan made with [Ms A] to replace fentanyl patch at 25mcg and to titrate up as tolerated. Will also use paracetamol and norflex. If ongoing issues with Fentanyl she will stop it and trial a period without it. If pain not controlled to see GP or return to ED."

Relevant policies at the medical centre

35. The medical centre told HDC that at the time of the events in question:

[20] Moist wound dressing.
[21] A drug used to block the action of chemicals in the body that can trigger nausea and vomiting.
[22] A drug that acts in the central nervous system to produce a muscle relaxant effect.

> "[The medical centre] had a procedure for Repeat Prescriptions as the Doctors felt it necessary that a uniform approach be adopted to repeat prescriptions throughout the practice. [The medical centre] does not have a policy on prescribing practice as [the medical centre] considered the achievement of the New Zealand Medical Council recertification requirements, maintenance of professional standards (MOPS) and CME [Continuing Medical Education] provided the necessary assurance to the organisation and our patients that our Doctors were competent and safe to practice including prescribing medicine. As a result of this complaint it has become evident to the organisation that a policy on prescribing practice is necessary."

36. The medical centre advised HDC that its prescribing policy was finalised in December 2014.

Changes to practice following complaint

Dr B

37. Dr B advised HDC:

> "Since this incident, the following has been done to ensure no recurrence:
>
> 1. Our Clinical Team has received a copy of this complaint and it is currently undertaking a significant event analysis. As part of this analysis, we are currently reviewing our processes around clinical record-keeping and documentation as well as appropriate opiate prescribing.
> 2. … I have also reviewed the MedSafe Data Sheet and hard copy of MIMS [medical information provider] about use and dosage of Fentanyl patches, and Fentanyl generally. I have contacted the coordinator of CME [Continuing Medical Education] for the [Primary Health Organisation] and she organised a lecture on Prescribing Opioids and Fentanyl in [2015]. I enclose a copy of an email confirming this. I will be attending that lecture.
> 3. While it is my usual practice already, I will not assume knowledge of information and when increasing any medication will provide an update to patients about the side effects and symptoms to watch out for.
> 4. I will personally be vigilant in ensuring all my patient consultations are fully documented."

The medical centre

38. The medical centre advised HDC that it has undertaken an internal investigation with relevant staff concerning the matters raised in the complaint. This investigation considered the practice's enrolment policies, cost of GP consultations, and the prescribing of fentanyl patches by Dr B. The medical centre advised HDC that it "recommended to [Dr B] that he undertake an Opiate Prescribing course to ensure he remains updated with prescribing guidelines". Furthermore, the medical centre advised:

"Changes which have been implemented as a result of this complaint include:

- Development of Good Prescribing Practice Procedure […]
- Attendance at CME session on Opioids & Fentanyl. Confirmation of [Dr B's] registration to attend our PHO CME on Opioids & Fentanyl scheduled for early 2015 has been received."

Medsafe

39. Medsafe (the New Zealand medicines and medical devices safety authority) has the following guidance on prescribing increases or decreases in the dosage of fentanyl patches:

"The dosage may subsequently be titrated upwards or downwards, if required, in increments of either 12.5 or 25 mcg/hour to achieve the lowest appropriate dose of Fentanyl depending on response and supplementary analgesic requirements."[23]

Medical Council of New Zealand

40. The Medical Council of New Zealand advised HDC that as a result of this complaint it is undertaking a performance assessment of Dr B. At the time of writing, the outcome of this assessment was not known.

Response to provisional opinion

Dr B

41. In response to my provisional opinion, Dr B provided independent expert advice from GP Dr C. Dr B advised that, in particular, Dr C stated:

"1. … There are several factors that may have contributed to this error. Fentanyl has only recently been made more available for use in General Practice, as prior to being funded on the pharmaceutical schedule it was prohibitively expensive. Since then some GPs have become more experienced in using it, especially if they are very involved in Palliative Care, but there will be many GPs who never use this drug.

2. In my experience it is unusual for the hospital to use Fentanyl patches for post-operative pain relief, certainly at the time of discharge. In the […] DHB where I practice I have never encountered the use of it post operatively either in Public or Private surgical practice. […]

3. The patient reported that she was receiving inadequate pain relief from the 12.5 micrograms patch and so, reasonably, [Dr B] considered titrating the dose upwards. To those more familiar with the use of Fentanyl, the increased dosage by [Dr B] to 100 micrograms is a very significant jump. However, for a doctor who has spent his practising life thinking about effective morphine doses in Milligrams, trying to manage severe pain with doses of an unfamiliar agent that were one thousandth of the morphine dose, may have led [Dr B] to think that the hospital prescription of 12.5 micrograms was cautious, and that

[23] Available at http://www.medsafe.govt.nz/profs/datasheet/m/mylanfentanylpatch.pdf.

an increase to 100 micrograms was in order in light of the pain levels reported by the patient."

42. Furthermore, Dr C also considered: "Had [Dr B] made the correct dose titration then the patient would have been more than happy to have been well supplied with the medication, as the pain problem was likely to have persisted for several weeks, as this was a major orthopaedic spinal procedure." In his response to my provisional opinion, Dr B also noted that Ms A's next appointment with an orthopaedic surgeon was arranged for six weeks' time and, in prescribing two packs, he "sought to ensure that [Ms A] would have sufficient analgesia to manage her pain post-operatively".

43. Dr B noted that Dr C advised: "I do not think it is normal practice for doctors to routinely review the potential side effects of medications that have already been initiated by other medical practitioners every time they see a patient. There is simply not enough time in a day, let alone in a consultation."

44. Dr B told HDC: "[Dr C] expresses the view that a one off unusual lapse in failing to save a consultation note to the patients notes can happen to any GP when excessively busy …"

Relevant standards

45. The Medical Council of New Zealand publication *Good Prescribing Practice*, issued in April 2010, provides the following prescribing standards:

> "1. You should only prescribe medicines or treatment when you have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's needs and are therefore satisfied that the medicines or treatment are in the patient's best interests. […]
>
> - Be familiar with the indications, side effects, contraindications, major drug interactions, appropriate dosages, effectiveness and cost-effectiveness of the medicines that you prescribe […]
> - Ensure that the patient (or other lawful authority) is fully informed and consents to the proposed treatment and that he or she receives appropriate information, in a way they can understand, about the options available; including an assessment of the expected risks, side effects, benefits and costs of each option. Satisfy yourself that the patient understands how to take any medicine prescribed and is able to take it.
> - Never prescribe indiscriminately, excessively or recklessly […]
> - Keep a clear and accurate patient record containing all relevant clinical findings; decisions made; information given to the patient and the medicines and any other treatment prescribed."

Opinion: Dr B — Breach

Introduction

46. On Friday 1 August 2014, Dr B made multiple and serious errors in his treatment of Ms A. My expert general practitioner advisor, Dr David Maplesden, considered that the management of Ms A by Dr B would be met with severe disapproval by his peers. In particular, Dr Maplesden considered that Dr B's excessive dose prescription, his failure to give information to Ms A, and his lack of record-keeping is concerning. My consideration of those issues is as follows.

Excessive dose — Breach

47. On Tuesday 29 July 2014, Ms A was discharged from hospital with a 12.5mcg fentanyl patch and a hospital discharge form that stated that she was on "fentanyl patch 12.5 micrograms one transdermal patch every 72 hours". Ms A was told that she was required to visit a GP if she needed additional fentanyl patches.

48. On Friday 1 August 2014, Ms A attended the medical centre and was seen by Dr B. Ms A told HDC that she provided Dr B with the hospital discharge form, which stated that she was on 12.5mcg fentanyl patches. Dr B does not recall seeing the hospital discharge form, but instead recalls being told by Ms A that she was on 12.5mcg fentanyl patches. Regardless of how Dr B became aware of the dosage of Ms A's fentanyl patches, it is clear that he knew the dose Ms A was on. According to Dr B, he also knew that Ms A had multiple drug allergies and could not tolerate other forms of pain relief.

49. Dr B told HDC that Ms A complained of considerable pain and an inability to sleep. Dr Maplesden advised me:

> "Noting Fentanyl had been initiated in the public hospital by a specialist pain service primarily because of [Ms A's] intolerance of oral opioids, I think it was reasonable for [Dr B] to continue the drug if [Ms A] was continuing to complain of pain, although given her clinical situation (post-operative pain following very recent surgery) her pain levels would be expected to improve over time."

50. I agree with Dr Maplesden and consider that Dr B's decision to prescribe Ms A fentanyl patches was appropriate.

51. However, Dr B increased the dose of Ms A's fentanyl from 12.5mcg to 100mcg patches. Dr B told HDC that he did this because Ms A was not responding to the prescribed dose, and was complaining of pain and an inability to sleep.

52. Dr Maplesden advised me that it might have been reasonable to carefully titrate the dose of fentanyl upwards. However, Dr B intentionally increased Ms A's fentanyl patch strength from 12.5mcg to 100mcg. Dr Maplesden considers this decision to be "clinically inappropriate and had the potential to cause significant opioid-related side effects including respiratory depression and death".

53. Furthermore, Dr B's decision contradicted Medsafe advice, which clearly states that incremental increases of 12.5mcg or 25mcg of fentanyl should be considered.

54. In my view, Dr B made a serious error of judgement in prescribing Ms A with 100mcg fentanyl patches given her previous dose of 12.5mcg. The Medical Council of New Zealand's *Good Prescribing Practice* provides that a medical practitioner should "[n]ever prescribe indiscriminately, excessively or recklessly". I consider that Dr B's prescribing of 100mcg fentanyl patches was reckless.

55. In addition to increasing Ms A's dosage from 12.5mcg patches to 100mcg patches, Dr B prescribed two boxes of five patches. This supply would be enough for one month. Dr B told HDC that this was to save Ms A the inconvenience and expense of returning to a GP for additional pain management.

56. Dr Maplesden advised that because Ms A was not a chronic pain sufferer, "irrespective of the dose of fentanyl prescribed, [he] think[s] it was unwise of [Dr B] to have provided a one month supply of fentanyl patches without clear review over this period". I agree, and consider that the prescribing of two boxes of five patches of 100mcg fentanyl was careless. It would be expected that following surgery Ms A's pain levels would decrease and, therefore, reassessing her pain management requirements over that time would have been appropriate.

57. By increasing Ms A's dosage of fentanyl patches from 12.5mcg to 100mcg, and for providing Ms A with one month's supply of 100mcg fentanyl patches, I consider that Dr B failed to provide services with reasonable care and skill and therefore breached Right 4(1) of the Code.

Failure to provide appropriate information — Breach

58. Although Dr B told Ms A that he was increasing the dosage of fentanyl patches to 100mcg, he did not provide information to Ms A on possible fentanyl side effects. Nor did Dr B advise Ms A to stop taking the fentanyl patches when the pain abated. Dr B believed that the original prescribing doctor at the hospital would have explained the side effects, and so did not repeat the discussion during his appointment with Ms A.

59. Dr Maplesden is critical that "there was no discussion regarding side effects of the drug which might be associated with an increase in dosage". The Medical Council of New Zealand's Standards, *Good Prescribing Practice*, requires that a patient be fully informed of the treatment he or she is receiving.

60. Dr B had a duty to provide Ms A with information about the possible side effects of the medication that she was being prescribed. Dr B did not provide that information to Ms A. By failing to provide Ms A with the information that a reasonable consumer would expect to receive, I consider that Dr B breached Right 6(1)(b) of the Code. Without this information, Ms A was not in a position to make an informed choice, and give her informed consent to taking a higher dose. By failing to provide information to Ms A that would allow her to make an informed decision, I consider that Dr B also breached Right 7(1) of the Code.

Clinical record — Breach

61. On Friday 1 August 2014, Dr B either failed to document appropriately, or to save, the record of his appointment with Ms A. Dr B told HDC that this is unusual, and he

takes "full responsibility for this oversight". Dr B advised HDC that the error may have occurred because of a technical issue with the practice's information technology system. However, I also note that Dr B is unaware of any other issues with the saving of his clinical records on 1 August 2014.

62. Dr B's failure to document or save his documentation was a serious one. According to the Medical Council of New Zealand's *Good Prescribing Practice*, medical practitioners are required to keep clear and accurate patient records. This did not occur on Friday 1 August 2014.

63. Dr Maplesden is "critical Dr B made no clinical record of the consultation with Ms A, particularly as strong opioid analgesia was prescribed in the consultation". I agree with Dr Maplesden and consider that it was essential for Dr B to ensure that a record of his appointment with Ms A was saved.

64. As I have stated previously, "the importance of good record keeping cannot be overstated. It is the primary tool for continuity of care and it is a tool for managing patients."[24] Dr B's failure to make a clinical record of his consultation with Ms A was a breach of professional standards.

65. By failing to provide services that complied with professional standards, I consider that Dr B breached Right 4(2) of the Code.

Opinion: The medical centre — No breach

66. Dr B was an employee of the medical centre. Under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority may be vicariously liable for any act or omission by an employee. Under section 72(5) of the Act, it is a defence for an employing authority if it can prove that it took such steps as were reasonably practicable to prevent acts or omissions leading to an employee's breach of the Code. This Office has previously found providers not liable for the acts or omissions of staff, when those acts or omissions clearly relate to an individual clinical failure made by the staff member.[25]

67. In my view, Dr B's failure to provide appropriate services to Ms A were matters of individual clinical decision-making. The medical centre was entitled to rely on Dr B to provide care in accordance with well established clinical guidelines, and with reasonable care and skill.

68. The medical centre advised HDC that at the time of the events in question it did not have a policy on prescribing. Instead, the medical centre considered the achievement of Medical Council of New Zealand recertification requirements, maintenance of professional standards and continuing medical education provided the necessary

[24] Opinion 12HDC01019.
[25] Opinion 12HDC01483.

assurance to the organisation and its patients that doctors were competent and safe to practice including prescribing medication.

69. I consider this appropriate, and agree with Dr Maplesden, who advised that "currently the Royal New Zealand College of General Practitioners standards would probably regard the development of such a policy as 'gold standard' rather than required standard".

70. Since Ms A's complaint, the medical centre advised HDC that it has developed a "Good Prescribing Practice Procedure".

71. I consider that Dr B's decision to prescribe Ms A with 100mcg fentanyl patches was an individual clinical decision, rather than a result of the medical centre's processes. As such, I do not consider that the medical centre is directly or vicariously liable for Dr B's breaches of the Code.

Recommendations

72. I recommend that Dr B undertake professional training on the importance of, and expectations for, clear, full and accurate medical documentation, and report to HDC within three months of the date of this report.

73. I recommend that the Medical Council of New Zealand report to HDC on the outcome of the performance assessment undertaken regarding Dr B.

74. I recommend that the medical centre:

a) Undertake an audit of Dr B's clinical record-keeping and provide a copy of this audit to HDC within three months of the date of this report; and

b) Review its internal investigation process following sentinel clinical events and report to HDC on the outcome of this review within three months of the date of this report.

Follow-up actions

75.
- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand, the Royal New Zealand College of General Practitioners and the DHB, and they will be advised of Dr B's name.
- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent general practitioner advice to the Commissioner

The following expert advice was obtained from general practitioner Dr David Maplesden on 14 October 2014:

"1. Thank you for providing this file for advice. To the best of my knowledge I have no conflict of interest in providing this advice. I have reviewed the available information: complaint from [Ms A's sister]; response from [Dr B]; GP notes [the medical centre]; response from [the medical centre] manager; clinical notes [ED]; clinical notes [the public hospital]; response [the pharmacy] and copy of relevant SOPs [Standard Operating Procedures].

2. [Ms A's sister] complains about her sister's management by [Dr B] — in particular that he prescribed [Ms A] an excessive dose and amount of Fentanyl patches on 1 August 2014 and this led to [Ms A] suffering symptoms of overdose of the medication sufficient to require treatment at [the ED] later that night.

3. [Ms A] states [Dr B] did not use the correct controlled drug form initially and the pharmacy had to request one from him. However, for the following reasons I feel unable to comment further on this aspect of the complaint: no copy of a computer generated prescription was retained by the pharmacy if they did receive one; there is no indication from the PMS [Practice Management System] records viewed that a prescription was generated from within the PMS; [Dr B] maintains the correct controlled drug form was provided; the pharmacy response has no reference to receiving an incorrect prescription form or having to specifically request the controlled drug form (H572). The current Misuse of Drugs Regulations (1977)[1] are perhaps less than explicit with reference to computer generated controlled drug prescriptions stating (under Section 29 (5)(1)):

A prescription for the supply of a controlled drug that is intended for human use and that is a Class A controlled drug, a Class B controlled drug, or a specified Class C controlled drug must be —

(a) on a paper form provided by the Director-General and completed in the handwriting of the controlled drug prescriber [referring to form H572]*; or*

(b) on a paper form that is electronically generated by the controlled drug prescriber from an approved system ['approved system' not further defined]

4. Brief clinical synopsis from available documentation

(i) [Ms A] underwent a C3–C6 decompression and instrument fusion at [the public hospital] on 25 July 2014. She was known to have allergies/adverse reactions to a number of medications including some commonly used analgesics but tolerated a

[1] Accessed 14 October 2014 from: http://www.legislation.govt.nz/regulation/public/1977/0037/latest/DLM55901.html?search=ts_regulation_MISUSE+OF+DRUGS_resel&p=1

trial of IV fentanyl via patient controlled analgesia (PCA) for immediate post-operative pain relief. After proving intolerant of oral oxycodone, post-operative analgesia was maintained with fentanyl patches initiated at a dose of one 12.5microgram (mcg) patch per 72hrs on the morning of 27 July 2014 (0640hrs). Just prior to discharge on 29 July 2014 [Ms A] was briefly reviewed by the inpatient pain service as it was felt simple analgesia (paracetamol) would not provide sufficient pain relief on discharge. The pain consultant recorded: *Continue fentanyl patch 12.5 mcg 3/7–5/7 then → GP….* The fentanyl 12.5mcg patch was therefore renewed at 1040hrs on 29 July 2014 just prior to [Ms A's] discharge. A copy of the hospital discharge summary was evidently provided to [Ms A] and she states she showed this to [Dr B] at her subsequent consultation with him. The summary includes *GP clinic on Friday* [1 August 2014] *for wound check. Please note patient has multiple allergies to pain medications. The only medication she has tolerated in addition to paracetamol is fentanyl transdermal patch. Please consider prescribing additional patch if pain is too severe to be controlled with paracetamol alone.* Under a list of discharge medications (although not recorded in the dedicated area on the summary form) is *Fentanyl patch 12.5 micrograms one transdermal patch every 72 hours.*

Comment: Discharge summary documentation might have been improved by recording the time and date of application of the most recent fentanyl patch, and including fentanyl in the appropriate dedicated area on the discharge summary. It is evident the intention and expectation was that [Ms A] might require further short-term use of the fentanyl patch if her pain levels did not rapidly improve to a point where they could be controlled with paracetamol alone, but that pain levels should reduce as her neck healed post-surgery ie no expectation that increasing levels of analgesia or prolonged use of opioid analgesia would be required.

(ii) On 1 August 2014 [Ms A] attended [Dr B] at [the medical centre]. She attended as a casual patient as she was convalescing with family in that area. [Ms A's sister] states [Dr B] *asked a few questions. He did not examine [Ms A] and wrote a prescription for* [fentanyl] *patches 100mcg* [sic] *— two boxes of 5 patches.* [Dr B] states in his response: *When I saw her, [Ms A] complained she was still in considerable pain and that she was unable to get any sleep … Since she was not responding to the prescribed dose of Fentanyl, I increased the dose to 100mcg/h transdermal patches and wrote a Controlled Drug Script Prescription Form … I understand that incremental dose increases are recommended as per the MedSafe data Sheet. However, based on her history, symptoms and signs she was exhibiting at the time of the consultation, I thought an increase in Fentanyl patch dose was warranted.* [Dr B] states he did not discuss potential side effects of the medication with [Ms A] as he assumed this would have been done in [the public hospital] when she was initiated on the medication. [Ms A] then saw the practice nurse to have her dressing changed. [Dr B] did not enter any clinical notes for the consultation. He states this was an oversight and an aberration from his usual practice. [Dr B] does not recall whether or not [Ms A] showed him the [public hospital] discharge summary.

(iii) The practice nurse has recorded re-dressing [Ms A's] neck wound. The wound was clean with minimal ooze. Observation of a fentanyl patch in situ is also recorded.

(iv) [Ms A] collected her prescription from [the pharmacy]. Only one box of five 100mcg patches (sufficient for 15 days) was provided, the other to be provided as a repeat if required. I have viewed the pharmacy SOPs in relation to controlled drug dispensing and counselling for dispensed medications and these appear consistent with accepted practice. A dose of 100mcg fentanyl patch or higher would not necessarily be unusual for a patient with chronic malignant pain in whom the dose had been gradually titrated upwards over time. While this dose was inappropriate for [Ms A] (see later discussion) there was no reason for the pharmacist to suspect the dose was inappropriate for [Ms A] — [Ms A] was a casual patient whose medical history was unknown to the pharmacist, with a prescription from a local doctor on the appropriate controlled drug form. I do not believe it was necessarily appropriate for the pharmacist to explore [Ms A's] medical history prior to dispensing the medication, and it would be expected that a patient whose dose of fentanyl had been titrated upwards to the level prescribed would be well aware of the potential side effects of the drug (ie initiating fentanyl patches at a dose of 100mcg would not be common unless it was related to transfer from a high dose of oral opioid). Had [Ms A] been a patient known to the pharmacy, and known to be opioid naïve or previously on low-dose opioid, it would have been inappropriate to dispense the prescribed medication. A copy of the prescription has been viewed. It records [Ms A] as having a [local] address, and the prescription reads *fentanyl 100mcg/h transdermal patch. One patch every 3 days. 2 packs of 5.*

(v) [Ms A] went home, removed her old fentanyl 12.5mcg patch and applied a 100mcg patch about 1800hrs 1 August 2014. About an hour later she began feeling nauseated and dizzy and she began vomiting. She evidently removed the patch about midnight and was taken to [the ED] arriving 0140hrs 2 August 2014. She was noted to have satisfactory vital signs and was treated with anti-emetics and IV rehydration. She did not appear narcosed and naloxone was not charted or administered. She had increased pain levels and fentanyl patch 25mcg strength was applied at 0508hrs with good relief. A muscle relaxant (orphenadrine) was also provided. Initial MO assessment notes include *unsure of fentanyl patch* [dose] *in [the public hospital] … Imp: reaction to fentanyl patch. Discussed with [Ms A] — limited analgesic options. Happy to trial fentanyl at lower dose (25mcg) while in ED, to titrate up at home according to pain levels …* Discharge summary includes the additional information *If ongoing issues with fentanyl she will stop it and trial a period without it. If pain not controlled to see GP or return to ED.* There is no record on the discharge summary (or in the notes viewed) regarding any prescription for fentanyl patches provided to [Ms A] on discharge. The intention may have been for her to attend her GP to discuss ongoing pain management once the current 25mcg patch was exhausted. [Ms A] was discharged at 0810hrs on 2 August 2014.

5. With respect to expected standards of prescribing, I have used the Medical Council of New Zealand publication 'Good Prescribing Practice' April 2010[2]. The publication includes the following comments:

(i) *You should only prescribe medicines or treatment when you have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's needs and are therefore satisfied that the medicines or treatment are in the patient's best interests.*

(ii) *Be familiar with the indications, side effects, contraindications, major drug interactions, appropriate dosages, effectiveness and cost-effectiveness of the medicines that you prescribe … Never prescribe indiscriminately, excessively or recklessly … Prescribe in accordance with accepted practice and any relevant best practice guidelines.*

(iii) *Keep a clear and accurate patient record containing all relevant clinical findings; decisions made; information given to the patient and the medicines and any other treatment prescribed.*

6. With respect to best practice prescribing of fentanyl patches I have referred to BPAC publications from 2008 and 2010[3] which includes the following information:

(i) *Fentanyl patches may be useful for people with stable, persistent, chronic pain conditions, who are unable to take oral morphine or cannot tolerate morphine-associated adverse effects. Fentanyl may also be a more suitable option than morphine for patients with renal failure. Fentanyl patches are not an appropriate choice for rapid pain management and should not be used in opioid-naïve patients with non-cancer related pain.*

Comment: Noting fentanyl had been initiated in [the public hospital] by a specialist pain service primarily because of [Ms A's] intolerance of oral opioids, I think it was reasonable for [Dr B] to continue the drug if [Ms A] was continuing to complain of pain, although given the clinical situation (post-operative pain following very recent surgery) her pain levels would be expected to improve over time (ie she was not, at this point, a 'chronic pain' sufferer). Irrespective of the dose of fentanyl prescribed, I think it was unwise of [Dr B] to have provided a one month supply of fentanyl patches without clear plans for review within that period.

(ii) *Start with the lowest possible dose, based on the patient's opioid history and pain condition. Calculate the patient's 24 hour morphine (or morphine equivalent) dose and convert this to the appropriate fentanyl patch dose … Fentanyl patches should not be used for rapid titration in pain control. Fentanyl patches have a 6–17 hour half-life and take at least 24 hours to reach a steady plasma level. If a patient is suffering from serious adverse effects e.g. respiratory*

[2] Accessed 14 October 2014 at: http://www.mcnz.org.nz/assets/News-and-Publications/Statements/Good-prescribing-practice.pdf
[3] BPAC. Widened access to fentanyl patches. Best Practice Journal. 2008. Issue 16
BPAC. Snippets: Fentanyl patches. Best Practice Journal 2010. Issue 33.

depression, on removal of the patch it will take at least 24 hours for levels to drop significantly.

Comment: [Ms A] had tolerated 12.5mcg fentanyl patches over the five days prior to her seeing [Dr B]. Her pain was apparently not optimally controlled with this following discharge and it might have been reasonable to carefully titrate the dose of fentanyl upwards following clinical assessment to exclude any sinister cause for the pain exacerbation (such as wound infection), and making arrangements for review to assess the adequacy of an increase in analgesia. The absence of a contemporaneous clinical record makes it difficult to comment on adequacy of assessment undertaken by [Dr B] although it is clear he established [Ms A] was using a 12.5mcg fentanyl patch and that he intended to increase the dose to 100mcg because of her pain (ie this was not an unintentional prescribing error). As noted above, such rapid titration of fentanyl is not consistent with recommended practice, nor is it consistent with the manufacturer's recommendations[4] which state: [following conversion from oral opioid] *the dosage may subsequently be titrated upwards or downwards, if required, in increments of either 12.5 or 25 micrograms/hour to achieve the lowest appropriate dose of fentanyl depending on response and supplementary analgesic requirements.* [Dr B] intentionally increased [Ms A's] fentanyl patch strength from 12.5mcg (equivalent to < 60mg oral morphine per 24hrs) to 100mcg (equivalent to 315–404mg oral morphine per 24hrs) which was clinically inappropriate and had the potential to cause significant opioid-related side effects including respiratory depression and death[5]. It is fortunate [Ms A] was able to remove the patch after six hours before serum levels of the drug would be expected to maximise. Given [Dr B] was increasing the dose of fentanyl prescribed, I am critical also of his failure to reiterate to [Ms A] common potential dose-related side effects of opioids.

7. Conclusion: I am critical that [Dr B] intentionally prescribed [Ms A] an excessive dose of fentanyl. This illustrates a lack of knowledge of the drug and the manner in which it should be used. I am critical of the amount prescribed (one month supply) without plans for review within that period, and that there was no discussion regarding side effects of the drug which might be associated with an increase in dosage. I am critical [Dr B] made no clinical record of the consultation with [Ms A], particularly as strong opioid analgesia was prescribed in the consultation. Taking all of these factors into account, I feel the management of [Ms A] by [Dr B] would be met with severe disapproval by my peers. I feel this case also raises issues of clinical competency and patient safety, and referral of [Dr B] to the Medical Council of New Zealand might be appropriate in this regard."

[4] Available at: http://www.medsafe.govt.nz/profs/datasheet/m/mylanfentanylpatch.pdf
[5] Jumbelic M. Deaths with transdermal fentanyl patches. Am J Forensic Med Pathol. 2010. 31(1):18–21

The following additional expert advice was obtained from general practitioner Dr David Maplesden on 5 February 2015:

> "According to the RNZCGP recommendations on expected standards (Aiming for Excellence — RNZCGP Standard for New Zealand General Practice) the practice should have had a policy in place regarding repeat prescribing but the publication does not specify having a policy on controlled drug prescribing (it was not a repeat (non face to face) prescription. Notes in the publication related to medication management include: 'Putting processes in place to prevent differences in prescribing is essential to protect patients. The risks of prescribing errors and the risks inherent in having different practices between primary and secondary systems can be mitigated through prudent management. The appropriateness of long-term repeat prescribing and repeat prescribing without consultation will always be a matter of professional judgement. When assessed against accepted standards of best practice in the profession, prescribing must be capable of withstanding scrutiny.' The purpose of having a policy on prescribing of controlled drugs is to ensure a consistent approach is taken to such prescribing within the practice (particularly for casual patients and by locum doctors) and that the prescribing is consistent with recommended best practice. This reduces the risk of prescribing error when several doctors might be involved in prescribing for a particular patient, and also reduces the risk of individual doctors being subject to exploitation by controlled drug abusers because they have become known as a 'soft touch'. However, I acknowledge currently the RNZCGP standards would probably regard the development of such a policy as 'gold standard' rather than required standard … I do not feel the measures described apply to practice processes but relate more to individual competency and, even then, not specifically to controlled drug prescribing."