Southern District Health Board

Surgical Registrar, Dr B

A Report by the

Health and Disability Commissioner

(Case 11HDC00710)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of Contents

Executive summary

1. On Monday 9 May 2011, Ms A attended an Emergency Department (ED), complaining of sudden onset epigastric pain, nausea and vomiting. Ms A was on a local methadone maintenance programme (MMP) but had not had her usual daily dose for that day.

2. At 10.14am Ms A was triaged. At 11.13am she was assessed by an ED registrar. At 12 noon the ED care plan was completed. At 2.30pm a surgical trainee intern and surgical registrar assessed Ms A. Ms A's usual daily dose of methadone was not established or recorded by various staff throughout the day. Ms A's local community pharmacist recalled being contacted by a DHB doctor by telephone to discuss the dosage, but the doctor's identity could not be established, and the call was not documented.

3. At 8pm surgical registrar Dr B reviewed Ms A. Dr B discussed Ms A's methadone dosage and documented that the usual dose was 37mls. (It was in fact 37*mgs* of a 5mg/ml strength solution, equalling 7.4mls.)

4. Dr B told Ms A that she could not give her methadone for the night, but would be able to administer her usual methadone once reconciliation of the dose was confirmed by Community Alcohol and Drug Services (CADS).

5. Dr B then prescribed and charted 37mls instead of 37mgs of a 5mg/ml strength solution of methadone (meaning it totalled five times the usual daily dose).

6. Dr B asked the on-call surgical house officer, Dr D, to contact CADS to confirm the usual dose. Dr D expected that CADS would not be available after hours. This was confirmed when she telephoned and received an answer machine message. Dr D verbally let the admitting team know this.

7. Dr B was made aware by Dr D that CADS was not contactable. Dr B's communication with Dr D was not documented for the morning team to follow. Ms A was transferred to the surgical ward at 10pm.

8. The (incorrect) dose was given as charted by a ward nurse the following morning. The ward stocked only 10mg/ml strength liquid methadone, so Ms A was given 18.5ml, which equated to 185mg. The error was picked up by a rotational ward pharmacist around noon on 10 May. Medical staff, the pharmacy manager, and Ms A were all promptly told of the error. Ms A was monitored, spent some time in HDU, and was given a dose of an opiate antagonist. Ms A made a good recovery and was discharged on 12 May 2011.

9. Appropriate investigation and review was initiated by the DHB. Dr B took full responsibility for charting the incorrect dose of methadone, reflected on the incident, and made changes to her practice.

10. The DHB Event Review's key findings identified contributing deficiencies in the DHB's policies and procedures. At the time of the event, there was no hospital policy in place regarding inpatient prescribing of methadone for patients on an MMP. Action was taken, in conjunction with CADS, to rectify this.

11. Southern DHB does not have an organisational system for formal medicine reconciliation.[1]

Findings summary

12. Dr B did not reconcile or confirm Ms A's appropriate dosage of methadone, and subsequently prescribed an incorrect dose. As the responsible and prescribing clinician, Dr B did not provide services with reasonable care and skill, and she therefore breached Right 4(1)[2] of the Code of Health and Disability Services Consumers' Rights (the Code). By failing to effectively communicate with her colleagues that the methadone dosage had not yet been confirmed and required reconciling, Dr B did not ensure continuity of services and breached Right 4(5)[3] of the Code.

13. Southern DHB did not comply with relevant professional standards for medicine reconciliation and therefore breached Right 4(2) of the Code.[4]

Complaint and investigation

14. The Commissioner received a complaint from Ms A about the services provided by Southern DHB. The following issues were identified for investigation:

- *Whether Southern District Health Board provided Ms A with care of an appropriate standard between 9 May 2011 and 12 May 2011.*
- *Whether Dr B provided Ms A with care of an appropriate standard between 9 May 2011 and 12 May 2011.*

15. Information was obtained from:

Ms A	Consumer/Complainant
Southern District Heath Board	Provider
Dr B	Surgical Registrar

[1] Southern DHB advised that it commenced work on medicine reconciliation on one area of the medical wards in February 2013. Also see paragraphs 20–23.
[2] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."
[3] Right 4(5) states: "Every consumer has the right to co-operation among providers to ensure quality and continuity of services."
[4] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

Dr C	ED Registrar
Dr D	Surgical House Officer
Ms E	Former Surgical Trainee Intern
Ms F	Community Pharmacist
Ms G	Rotational Pharmacist, the hospital
Dr H	Surgical registrar
RN I	Registered nurse

16. Independent expert advice was obtained from Professor Pat Alley, General Surgeon, and is attached as **Appendix B**.

Information gathered during investigation

17. This case is about the appropriateness of the dose of methadone provided to Ms A on 10 May 2011. Ms A was on a methadone maintenance programme (MMP)[5] and, in May 2011, her usual daily dose of methadone was 37mgs of a 5mg/ml strength solution (7.4mls).

Presentation to ED — 9 May 2011

18. On Monday 9 May 2011, Ms A was admitted to hospital via the ED. Ms A was triaged by an ED nurse at 10.14am. She had sudden onset epigastric pain, nausea and vomiting. Ms A had been vomiting since Saturday morning and was feeling unwell.

19. The triage documentation noted Ms A's presenting history and that she received methadone. There was no patient alert on the existing patient management system (from Ms A's previous interactions with DHB services) that Ms A was on an MMP.

Reconciliation process

20. Medicine reconciliation is a process where health professionals collect the most accurate list of medicines a consumer is already taking (as well as any allergies or adverse reactions) and compare that list against the prescribed medicines for that consumer. Collecting the list may often initially involve discussions with consumers and their family or caregivers, prior to using secondary sources (such as GPs or community pharmacies for example). Reconciliation is performed to ensure that the prescribed medicines are appropriate and at the appropriate dose. Any discrepancies

[5]The methadone maintenance programme is a government-funded outpatient programme operated from clinics by Community Alcohol & Drug Services (CADS). Methadone is a synthetic opiate-based drug made for this programme worldwide. It is an oral drug administered daily to help stabilise opiate addiction. The Southern DHB Mental Health and Addictions Provider Arm delivers a diverse range of services to adults aged 18–65 in both community and in-patient settings. The Drug and Alcohol Services' Outpatient treatment programme includes a methadone programme.

are checked, documented and reconciled.[6] The prescriber is ultimately responsible for ensuring reconciliation is completed.

21. Medicine reconciliation is an evidence-based process that has been shown to significantly reduce medication errors caused by incomplete or insufficient documentation of medicine-related information at transition of care points (for example, at admission, at transfer from ED to a ward, and at discharge back to primary care). This collaborative practice involves the use of paper or electronic tools to assist the documentation and communication of the medicine reconciliation process, enabling information to be presented and transferred in a standardised or structured way.[7]

22. No formal organisational process or standard operating procedure outlining accountabilities and responsibilities for medicines reconciliation was in place at the hospital at the time of Ms A's admission.

23. The means of reconciling medicines in place at the time of Ms A's admission was centred on individual medical officers and staff reconciling the medicines prescribed with the medicines listed as being taken by the patient. Secondary sources of information available to staff at the time were used for confirmation of medicines and their doses, in order to detect any discrepancies requiring follow-up. Staff performed the whole process in accordance with their own individual professional standards and existing DHB policy regarding medicines management.[8]

Assessment by ED registrar

24. At 11.13am Ms A was assessed by ED registrar Dr C. Dr C noted: "On Methadone programme — has not had Methadone this morning." Ms A's usual daily methadone dose was not recorded. On examination, Ms A's upper abdomen was tender. Dr C prescribed paracetamol, intravenous (IV) morphine, and anti-nausea medication ondansetron.

25. Dr C said that administration of methadone had no role in the ED management. She stated that she had prescribed IV morphine and therefore had no reason to clarify the dose of methadone. The DHB advised that it is standard practice in ED to treat pain regardless of methadone intake, and to not administer additional doses of methadone whilst in the ED — this practice is to safeguard the ED from being utilised for additional methadone doses. Dr C said that Ms A informed her of the details of the

[6] Sometimes referred to in the literature as verification or clarification.

[7] For further information regarding HQSC medicines reconciliation work streams, see http://www.hqsc.govt.nz/our-programmes/medication-safety/projects/medicine-reconciliation.

[8] Southern DHB provided HDC with a copy of its "Management of Medicines" policy, which outlines the principles and practice of managing medicines in the region. The policy sets out prescribing procedures, and refers to the relevant legislation and guidelines such as the Medicines Regulations 1984 and the Prescribing Guide. The policy notes that all staff involved in the management of medicines should receive regular training on the supply, prescription and administration of medicines, and that staff must be assessed and approved to undertake these tasks.

community pharmacy where she usually obtained her methadone. Dr C documented this on the ED assessment sheet.

Community pharmacy contacted

26. Ms F, the community pharmacist, advised HDC that on Monday 9 May 2011 Ms A did not collect her methadone from the pharmacy. Ms F said that on that day she received a phone call from a doctor at the hospital requesting the dosage of methadone that Ms A took. Ms F could not recall the time of the call or the name of the doctor.

27. Ms F recalls telling the doctor that the daily dose was 37mg and that the pharmacy dispenses 5mg/ml methadone and gives 7.4ml of this solution to Ms A. Ms F recorded a note of the conversation shortly afterward.

28. Ms A's hospital notes do not record any details of a call to the community pharmacy. Dr C said she does not recall calling the community pharmacy. The DHB told HDC that it had asked all staff who had made entries in Ms A's notes whether they had contacted the community pharmacy. No one indicated that they had done so. The DHB could not ascertain who made the call. The DHB said that it was possible that a staff member called the community pharmacy but did not document this.

29. At 12 noon the ED patient care plan documentation was completed and recorded Ms A's use of methadone under "medications". Her usual dosage was not recorded.

Afternoon assessment by surgical staff

30. At 2.30pm, Ms A was assessed in ED by a surgical trainee intern, Ms E, and a surgical registrar, Dr H. Ms A's presenting symptoms of nausea were recorded. It was noted that Ms A was feeling hot and cold, but had no headache or change in bowel habit or urinary problems. Ms E noted that Ms A had not eaten on the previous Friday and denied high alcohol intake or use of any drugs in the previous few days.

31. Ms A advised Ms E that she was on the MMP and talked about her previous medical history.[9] The medication history notes "Methadone" but nothing is recorded in the space marked "dose". Ms E said that as Ms A was not being admitted at that stage, and Ms E did not have prescribing rights, she felt that, if Ms A was admitted, her dosage of methadone would need to be confirmed by the doctor prescribing it.

32. An examination revealed that although Ms A was tender in the epigastric region of her abdomen, she had no abdominal anatomical abnormality. She had blood taken for analysis.

[9] Ms A's history included previous contact with DHB Services, meaning her status on the MMP was available on the DHB intranet through those services Ms A had received treatment from.

Surgical registrar treatment plan

33. Dr H recorded a provisional diagnosis of gastritis, noting that the charted Mylanta[10] and Losec[11] were "not much help". He discussed Ms A's presentation with his consultant and documented the consultant's advice that if the current pain relief was not able to "get on top of the pain" within the next hour, the consultant was "not [averse] to Methadone". A trial of pain relief was planned with the option of Ms A being admitted to a surgical ward if the pain relief was unsuccessful. Ms A was prescribed intravenous (IV) fentanyl 100mg.[12]

34. At 7.15pm, Ms A reported that the fentanyl was not relieving her pain, and she was prescribed an alternative IV analgesic, clonidine 15–30mg.

Dr B review — 8.15pm

35. General surgical registrar, Dr B, was the on-call evening surgical registrar, on duty between 4.30pm and 10.30pm on 9 May 2011. At 4.30pm, Dr H handed over Ms A's care to Dr B.

36. Dr B saw Ms A at 8.15pm. Dr B noted that Ms A had been receiving treatment in ED for symptomatic relief, and a full admission note had been completed by Ms E. Dr B said that she assured herself that Ms A was well and stable, and that she could have a normal diet and her usual medications.

37. Dr B said: "I did not see it as necessary to document my exam when my findings at this point concurred with the notes already made." Dr B stated:

> "I went back to see [Ms A] to enquire about her regular Methadone dosage. She informed me that her usual dose was 37mls. I documented 37mls of Methadone on the last page of [Ms A's] admission note. When I charted her medications for symptomatic relief including her Methadone, I realised that there were several strengths of Methadone. I went and asked [Ms A] the strength of her Methadone, to which she replied 5mg/ml. I prescribed [Ms A] Methadone 37mls with strength 5mg/ml. [Ms A] told me that she had missed her Methadone for that day and did not want to miss her next dose. I reassured [Ms A] that I could not replace her Methadone for the night but will be able to administer her usual Methadone once reconciliation of the dosage was done with CADS.
>
> I asked the on call surgical house officer, [Dr D], to contact CADS to confirm the dosage of the Methadone."

38. Ms A's initial complaint to HDC, via her lawyer, stated that there "may initially have been a misunderstanding about [her] normal dose when she was admitted…". In response to my provisional decision, Ms A recalled that she was adamant that she told

[10] A liquid antacid.
[11] Losec is used for the relief of reflux-like symptoms — heartburn or regurgitation.
[12] A narcotic analgesic.

Dr B that her usual dose of methadone was 37mg and that she had no doubt that phonetically she said "37 migs".

Attempt to call CADS

39. Dr B said that she was under the impression that Dr D had attempted to call the community pharmacy to confirm the dosage. However, Dr D said she did not call the community pharmacy.

40. Dr D was the acute admitting surgical house officer in ED when Ms A was admitted. Dr D told HDC that she offered to call CADS on behalf of those staff admitting the patient. She expected CADS would not be open after hours, and this was confirmed when she telephoned CADS and received an answer machine message only. Dr D said she explained this to the admitting team. The call was not documented.

41. Dr B acknowledged that Dr D advised her that she had tried to call CADS to follow up Ms A's methadone dosage. However, Dr B was unaware that Dr D had not documented that point for the team in the morning to follow up.

Prescribing error

42. Dr B had recorded in Ms A's clinical record: "Admit tonight. N [normal] diet. Go on Methadone 37mls — missed today."

43. Dr B told HDC:

> "In retrospect, I think I made an error which I greatly regret: I should have removed (by striking it out) my prescription for the Methadone when I learned from [Dr D] that the dosage could not be confirmed by CADS. I also could have alerted the night staff to the issue when we handed over, but clearly confirmation of the dosage was going to have to wait until the day staff began work again. … [A] clear note should have been made of the difficulty [Dr D] had encountered in contacting CADS, as a means of handing the issue over to the team who would care for [Ms A] the next day. I regret that I did not check that [Dr D] had done this."

44. At 9pm the surgical ward notified ED that a bed was available for Ms A.

Surgical ward admission — 10pm

45. Ms A was admitted to the surgical ward at 10pm. A Short Stay Surgical Care Plan (<48HRS) was completed by a registered nurse (RN). The plan noted that Ms A was on the MMP. The RN said that she received handover from ED nursing staff as per usual practice. Dr D was off duty when Ms A was transferred to the ward.

46. The progress notes recorded by the RN noted that Ms A was prescribed intravenous fentanyl for pain, and "[n]o Methadone for tonight as can't be confirmed if she had Methadone at home, as per handover". During the night shift (11pm to 7am) Ms A was given two doses of fentanyl 30mg for abdominal pain.

Tuesday 10 May

47. The next morning, 10 May 2011, Ms A was reviewed by a surgical consultant. Ms A complained that her abdominal pain score was 7 out of 10. However, her observations were stable and she was showing no signs of infection. The treatment plan entered into the clinical notes was for a soft diet, omeprazole to treat her gastric reflux, and for her to continue with pain relief and anti-nausea medication. The surgical team considered that Ms A's condition would settle with time.

Administration of incorrect dose

48. At about 9am on 10 May 2011, RN I followed instructions and gave Ms A her prescribed medications and signed the Record of Administration form. The (incorrect) dose was given as charted. The ward stocked only 10mg/ml strength liquid methadone, so Ms A was given 18.5ml, which equated to 185mg.

49. RN I said that Ms A was anxious to receive the methadone as she had missed her dose the previous day. The methadone was charted as "5mg/ml, 37mls". Ms A told HDC that she was struck by the volume of solution she was given and queried it. As per DHB policy, RN I checked the dose with a nursing colleague. On reflection at the time, she did think that the dose was high; however, she was aware that some patients receive high doses.[13]

Pharmacist routine check

50. Later that morning, the rotational pharmacist conducting a routine check of the ward's medication charts, Ms G, identified that Ms A had been given an incorrect dose of methadone — five times the usual dose. Ms G stated:

> "I arrived on [the ward] at approximately 11.30am on Tuesday 10 May to carry out usual ward activities. When I came to view [Ms A's] drug chart (at approximately 12.15pm), I noted she had been charted Methadone (and the drug chart read 'Methadone 5mg/ml, 37mls') thus I phoned the patient's community pharmacy[14] (it was documented in the notes this was [the community] pharmacy). I advised the community pharmacy that [Ms A] was currently an inpatient and thus would not need a supply of Methadone from them until notified of her discharge. The community pharmacist said that a doctor from the hospital … had phoned previously to ascertain [Ms A's] dose. I also enquired what dose of Methadone [Ms A] had been receiving prior to her admission to hospital. I was advised by [the community] pharmacy that her current dose was 37mg (of a 5mg/ml liquid = 7.4ml)."

51. Ms G stated that she checked the dose again with the pharmacist, since there was a discrepancy between the pharmacy's dose and what was charted in Ms A's hospital

[13] The DHB advised that methadone doses vary widely from patient to patient, and that the actual dose needs to be confirmed prior to prescribing. According to the clinical director of CADS, most people on the Methadone Programme are prescribed a dose anywhere from 60mgs to 150mgs. Approximately five percent of methadone programme patients are on doses higher than this.
[14] Ms F concurred that on Tuesday 10th May, the hospital pharmacy rang her to ask about the dose.

prescription sheet. Ms G checked Ms A's clinical record to ascertain whether the methadone had been signed for as given, and found that it had. Ms G asked RN I what exact dose and strength of methadone she had given Ms A. RN I told Ms G that the ward stocked only the 10mg/ml strength of liquid methadone, so she had given Ms A 18.5ml, which equated to 185mg.

Staff and patient made aware of error

52. Ms G notified the surgical house officer about the drug error, and the house officer immediately advised Ms A. The house officer then contacted his registrar, who arrived on the ward and also spoke to Ms A about the medication error.

53. Ms G advised a DHB Department Manager of the incident. At 12.20pm, the house officer recorded in Ms A's clinical record:

> "Advised by ward pharmacist that pt received 37 x 5 mg of Methadone instead of her usual 37mg Methadone.
>
> This dose was charted wrong by the admitting registrar.
>
> Please monitor RR [respiration rate] and call OCHS [on-call house surgeon] if <10, any deterioration in GCS [Glasgow Coma Scale] or any concerns. Please monitor RR and GCS hourly.
>
> Ward pharmacist will advise regarding time and size of next dose."

54. At 1.10pm, the surgical registrar was called to review Ms A, because of a decrease in her respiration rate. The registrar contacted the consultant who advised that it was unlikely that Ms A would need to be given naloxone[15] but, as it might be required, it should be charted.

Transfer to HDU

55. Ms A was transferred to the surgical high dependency unit (HDU) at 1.15pm for closer monitoring. Her respiration rate was noted to be 16 breaths per minute when awake[16] but her respiration rate consistently decreased to between 8 to 16bpm when asleep. Naloxone was then given as charted at 2.30pm.

Discharge

56. Ms A responded well to treatment and made a satisfactory recovery. Ms A was discharged on 12 May 2011 with a plan for her regular dose of Methadone to be restarted by the CADS case manager.

Follow-up actions by DHB

Incident classification and investigation

[15] Drug used to counter the effects of opiate overdose.
[16] Normal range 12–20bpm.

57. An incident form was submitted by the Charge Nurse Manager on 11 May 2011.[17] The incident was classified as an SAC2 (Severity Assessment Code)[18] event on 12 May 2011, and an investigation commenced. The investigation was led by a Service Manager. Senior DHB Executive staff were notified of the incident on 17 May 2011. A Reportable Event Brief was sent to the Ministry of Health on 31 May 2011.

58. Dr B stated to the DHB during its investigation:

> "I take full responsibility in charting the wrong dose of Methadone for [Ms A] when she told me that she took 37 millilitres (mls) at the initial first consultation. ... I am very sorry that a simple charting error had caused five times the overdose of Methadone to [Ms A] whom subsequently required HDU monitoring. My lack of foresight to cross out the drug until confirmation by CADS the next morning was partly due to the pressure of ensuring that [Ms A] was given her Methadone first thing in the morning as she missed her dose on that day. …
>
> Upon reflection on this event, I realise the strategies in preventing prescribing drug error:
>
> 1. All medications need to be charted in milligrams (mg).
>
> 2. All medications need to be clarified and validated from a reliable source — GP letter, pharmacy prescription, drug blister pack list, CADS, etc."

59. Dr B told HDC that since the event, the changes she has made to her practice include:

- ensuring reconciliation of medications; and
- providing good and clear instructions including documentation for subsequent patient treatment management.

Event Review Summary

60. The final report was completed on 29 August 2011. An Event Review Summary was signed off by a senior medical staff member on 26 September 2011. The incident was also discussed at a meeting of the SAC1 and SAC2 Review Committee on 28 September 2011.

61. The Event Review Summary noted that:

[17] Southern DHB has a policy that details the process for managing incidents in Southern DHB, to ensure that all incidents, including "near misses" are responded to effectively. The policy describes the incident management responsibilities of the organisation, managers and individuals, and defines the types of incident that require reporting to the National Central Agency.

[18] The New Zealand Incident Management System *Guide to using the Severity Assessment Code* outlines that the Severity Assessment Code (SAC) is the method used by any person who has identified an incident, to determine the appropriate action to take. The score is ascertained by rating the consequence of the incident and its likelihood of occurrence.

a. The hospital uses either 10mg/mL or 2mg/mL methadone elixir, whereas community pharmacies use from 1 to 10mg/mL with 5mg/mL as the most popular concentration used.

b. Ms A's methadone dosage was unable to be verified with CADS owing to her after-hours admission. It was documented in nursing notes on the night admission that Ms A was not to have methadone then as it was not able to be confirmed whether she had had methadone at home prior to admission.

c. Southern District Health Board does not have a process for formal medicine reconciliation for any medications. Such a process involves medicines being checked at critical handover times when patients are admitted to or discharged from hospital, but involves significant resourcing to achieve.[19] The clinician responsible for the patient's treatment reconciles medicines prescribed with medicines listed as being taken by the patient, using a second source of information as confirmation, in order to detect discrepancies which require follow-up.

   Currently, the medical officer responsible for the patient prescribes the medicines using the information he or she has available at the time.

d. There was no alert on the patient management system indicating that Ms A was on a methadone maintenance programme. An alert would not have prevented incorrect prescribing; however, it is a requirement. It is important that the actual dose (milligrams) is not confused with volume (millilitres). Extra care has to be taken with Controlled Drugs prescribing, and checks made to ensure correct dosage by contacting the patient's usual pharmacy or the prescribers, ie CADS, or delaying the dose until this information is available.

Recommendations and actions arising from review

62. The recommendations and actions arising from the review were:

a. On 2 June 2011 a Medication Safety Alert was issued by a senior hospital pharmacy staff member to DHB staff, instructing staff to always prescribe liquid opioid in milligrams because of the different strengths available.

b. Methadone medicine reconciliation is to be part of the Prescribing Policy and included in the orientation for all staff.

c. Consideration was to be given to increasing pharmacist support to wards so that errors could potentially be identified before medication administration.

d. Nursing staff were to be instructed to administer liquid medication only if prescribed in milligrams.

63. At the time of the incident, there was no official hospital policy in place regarding inpatient prescribing of methadone for patients on an MMP. A policy relating to the safe and effective treatment of patients who are receiving methadone for the purpose

[19] The minutes of the Hospital SAC1 and SAC2 Review Committee meeting on 28 September 2011 state that the bed to pharmacist ratio would not allow for medication reconciliation.

of assisting with treatment for opioid dependency, who are admitted to the hospital, has now been developed and finalised in conjunction with senior staff of CADS.

Responses to provisional opinion

Dr B

64. In response to my provisional opinion, Dr B reiterated that:

- she acknowledged that her actions resulted in Ms A receiving a level of care which was inadequate both in terms of the Code, and in terms of what she expected of herself as a medical professional;
- since the incident, she has reflected on her actions and how she can modify and improve her practice;
- all medications she now prescribes are documented from reliable sources such as a pharmacy, previous medication charts, medical notes, or by sighting the medications a patient may have brought with them. Unless the dosage of a medication can be confirmed, it is not charted;
- as a prescribing officer, it is her responsibility to ensure that any and all communications surrounding a prescription, including the need to reconcile, are documented.

65. *Southern DHB*

In response to my provisional opinion, Southern DHB's comments included that:

- it fully accepted its responsibility as an organisation for the error that led to this complaint. It also felt that as an organisation it could do much better in having safeguards in place to support prescribers in avoiding errors, particularly in situations where an on-call resident medical officer is called on to prescribe medication for a patient that has been within the organisation for some hours;
- a number of factors resulted in this incident, and a number of individuals were involved in Ms A's care leading up to it;
- it has benchmarked itself against five other DHBs, and those five DHBs advised Southern DHB that they did not undertake medicine reconciliation for 100% of patients in all areas of the hospital;
- there is now improved access for hospital prescribers to dosages and treatments patients are on, which is updated daily by CADS. In addition, when a patient is admitted to a ward, a message is sent to advise that a patient is on opioid substitution treatment, and the appropriate service should be contacted for further details;
- it concluded that it can and will do more in regard to medicines safety within the DHB, but it does not believe that having a formal medicine reconciliation process in place would have been likely to prevent the error in this case.

Opinion: Breach — Dr B

66. On 9 May 2011, Dr B prescribed and then charted 37mls instead of 37mgs of a 5mg/ml strength solution of methadone for Ms A — five times her usual daily dose. Dr B did not reconcile or verify Ms A's appropriate dosage prior to doing so, and the incorrect dose was later administered by an RN.

67. I am mindful of the advice of my expert advisor, Professor Pat Alley, that:

> "[t]his particular prescribing practice (of transcribing doses of medication based on volunteered information) is fraught with difficulty. Even the most well-meaning, intelligent and articulate patients under the stress of an admission to hospital may make errors in their description of their medication. To compound that there is also wide-spread and understandable confusion in the minds of the lay public about the difference between **millilitres** and **milligrams.** Because of these important factors it is entirely unreasonable and unrealistic that prescribing staff should rely particularly on the verbal presentation of dosages of any medication from the patient."

68. Dr B's documentation was also inadequate. A clear record should have been made of the difficulty Dr D had encountered in contacting CADS, as a means of effectively communicating and handing over the issue to the morning team to ensure quality and continuity of services. I acknowledge that Dr B took full responsibility for her error and made appropriate changes to her practice to prevent the likelihood of any recurrence. Dr B has also acknowledged that her communication with Dr D should have been much clearer and documented to allow the morning team to know that the dosage required confirmation.

69. I acknowledge that it appears that a DHB staff member (unidentifiable by the DHB or the community pharmacy) did actually call the community pharmacy to clarify the dose, but did not then proceed to document the call. I also note that Ms A's prior contacts with DHB health services should have resulted in an alert being placed on the Patient Management System at the time of those earlier contacts, but this had not occurred.

70. I have carefully considered the responses to my provisional opinion. I remain of the opinion that, as the responsible and prescribing clinician, Dr B did not provide services with reasonable care and skill, and she therefore breached Right 4(1) of the Code. By failing to effectively communicate with her colleagues that the methadone dosage had not yet been confirmed and required reconciling, Dr B did not ensure continuity of services, and breached Right 4(5) of the Code.

Opinion: Breach — Southern District Health Board

71. In my view, shortcomings in medicines management at Southern DHB contributed to Dr B's failure to reconcile the appropriate methadone dosage for Ms A. This case

reinforces the risks posed to patients when accurate medicines reconciliation does not occur.

72. I accept that Southern DHB was entitled to expect Dr B to comply with the existing DHB policy, and her own individual professional standards, regarding prescribing practices. However, in my opinion, Southern DHB equally has a responsibility to have a structured organisational approach in place to support its staff, minimise potential harm to patients, and ensure that each health practitioner involved in a medicine reconciliation process is able to fulfil his or her obligations. In my view, Southern DHB did not fulfil its responsibilities in this case, as outlined below.[20]

73. In relation to inpatient prescribing of methadone for patients on an MMP, my expert advised that "any institution which deals with MMP should have a specific policy/SOP around Methadone inpatient prescribing and dispensing but I accept the nuances of this are not covered or abundantly clear in the legislation". At the time of Ms A's admission, Southern DHB had no such policy in place.

74. The NZS standard requires medicines reconciliation to be part of a DHB's medicines management system. Furthermore, the HQSC standard for medicines reconciliation explicitly expects a DHB to have a current local medicine reconciliation policy that outlines the requirements, in line with standards, for accountability and responsibility lines as well as standard operating procedures (eg, instructions on how each health practitioner is expected to undertake the medicine reconciliation process). Despite these standards, an organisational system for formal medicines reconciliation was not in place at the time of Ms A's admission.

75. I have carefully considered the DHB's submissions in response to my provisional opinion. However, I agree with my expert's advice that "there should have been some formal process around medicines reconciliation, irrespective of the clinician undertaking such a process". In my view, Southern DHB should have had a comprehensive system for medicine reconciliation, requiring a structured, streamlined and effective process.

76. I remain of the opinion that Southern DHB did not comply with relevant professional standards for medicine reconciliation and therefore breached Right 4(2) of the Code.

Other comment

77. The methadone dosage was recognised as being higher than usual by the RN who eventually administered the methadone, RN I. Nurses who are responsible for administering a patient's medication should be mindful of the appropriateness of the medication they are administering. However, I acknowledge that the dosage had been prescribed and charted by Dr B, the dosage was at a level at the higher end of the

[20] Also see Appendix A: Relevant Standards.

dosage spectrum but still within a therapeutic range, and that RN I discussed it with a nursing colleague, in line with DHB policy, before administration.[21]

Recommendations

78. In my provisional report, I recommended that Dr B and Southern DHB provide formal written apologies to Ms A for breaching the Code and that the apologies be sent to HDC as soon as possible for forwarding to Ms A. In response, Dr B and Southern DHB provided formal written apology letters and these were forwarded on to Ms A by HDC.

79. I recommend that Southern DHB, in light of this report and my expert's comments, report back to me by **30 August 2013** on its consideration of and/or progress toward:

    a. sharing important pharmacological patient information between the DHB and local community pharmacies;

    b. establishing a formal medicine reconciliation process for Southern DHB, such as that outlined and supported by the Health Safety and Quality Commission's Medication Safety Programme and its accompanying standards, which are endorsed by the Health Information Standards Organisation; and

    c. increasing pharmacist support on hospital wards.

80. I also recommend that Southern DHB update HDC by **30 August 2013** on the effectiveness of the changes it has made since these events, including reference to an evaluation of:

    a. the medication safety alert issued regarding the prescribing of liquid opioids;

    b. methadone medicine reconciliation as part of prescribing policy;

    c. nursing staff being instructed to administer liquid medication only if prescribed in milligrams; and

    d. the finalised hospital policy and procedures produced relating to inpatient prescribing of methadone for patients on an MMP.

[21] My in-house clinical advisor advised that the overall dose administered to Ms A was at the higher end of the scale, but some patients with very high prior levels of opiate abuse would be on such doses for maintenance. While there was a significant risk of toxicity from such a dose, because Ms A was not opiate or methadone naïve, her risks of toxicity were somewhat lower, and this was illustrated by the decision to monitor her initially rather than immediately administer the opiate antagonist naloxone.

Follow-up actions

81.
- A copy of this report with details identifying the parties removed, except Southern DHB and the expert who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name.

- A copy of this report with details identifying the parties removed, except Southern DHB and the expert who advised on this case, will be sent to the Royal Australasian College of Surgeons, DHB Shared Services, the Health Quality and Safety Commission, the National Health Board (Ministry of Health), and the National Association of Opioid Treatment Providers, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Relevant standards

Individual

82. The Medical Council of New Zealand statement *Good prescribing practice* (April 2010) states that:

> "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.
>
> …
>
> To ensure that your prescribing is appropriate and responsible you should:
>
> …
>
> Be familiar with the indications, side effects, contraindications, major drug interactions, appropriate dosages, effectiveness and cost-effectiveness of the medicines that you prescribe…"

83. The Health Quality and Safety Commission document *Medicine Reconciliation Standards* (Safe Medication Management Programme, Version 2.0, January 2011)[22] outlines that "these standards apply to any person or organisation that provides medicine reconciliation within the NZ health and disability sector".

The relevant standards are:

> "1. Accountabilities and Responsibilities
>
> Standard 1.1 Personal
>
> All registered health practitioners involved in medicine reconciliation are responsible and accountable for the accuracy and quality of information provided to support the medicine reconciliation process at a given point in time."
>
> and
>
> "2. Process
>
> Standard 2.1 Collect
>
> The health practitioner collects the most accurate list of medicines, allergies, and adverse drug reactions (ADRs) using a minimum of two source types."

[22] The standards have since been updated to version 3.0 (September 2012) and subsequently endorsed by the Health Information Standards Organisation (HISO) — a committee that reports to the National Health IT Board.

Organisational

84. The Health Quality and Safety Commission document *Medicine Reconciliation Standards* (Safe Medication Management Programme, Version 2.0, January 2011) states:

> "Organisational
>
> Standard 1.3 Each organisation ensures that each health practitioner involved in the medicine reconciliation process is able to undertake their role and responsibilities competently.
>
> *Criteria* The criteria required to achieve this outcome include:
>
> 1.3.1 The organisation ensures that there is a current local medicine reconciliation policy that outlines the requirements in line with the standards for:
>
> - accountability and responsibility lines
> - standard operating procedures e.g. instructions on how each health practitioner is expected to undertake the medicine reconciliation process
> - education and training
> - measuring and reporting
>
> …"

Sector Standard — Organisational

85. The HQSC Medicine Reconciliation Standards complement Standards NZ, Health and Disability Standard NZS 8134.1.3:2008 — including Medicine Management Standard 3.12:

> "Consumers receive medicines in a safe and timely manner that complies with current legislative requirements and safe practice guidelines.
>
> *Criteria* The criteria required to achieve this outcome shall include the organisation ensuring:
>
> 3.12.1 A medicines management system is implemented to manage the safe and appropriate prescribing, dispensing, administration, review, storage, disposal, and medicine reconciliation in order to comply with legislation, protocols, and guidelines.
>
> …"

Appendix B — Independent General Surgeon's advice to the Commissioner

The following expert advice was obtained from Professor Pat Alley, General Surgeon.

"My name is Patrick Geoffrey Alley. I am a vocationally registered general surgeon employed by Waitemata District Health Board. Additionally I am the Director of Clinical Training for that DHB.

I graduated M.B.Ch.B from the University of Otago in 1967. I gained Fellowship of the Royal Australasian College of Surgeons by examination in 1973. After postgraduate work in England I was appointed as Full Time Surgeon at Green Lane Hospital in 1977. In 1978 I joined the University Department of Surgery in 1978 as Senior Lecturer in Surgery. I was appointed as Full Time Surgeon at North Shore Hospital when it opened in 1984. I am a Clinical Associate Professor of Surgery at the University of Auckland, have chaired the Auckland branch of the Doctors Health Advisory Service for many years and have formal qualification in Ethics which is utilised as a member of two institutional ethics committees. One is at Waitemata DHB, the other at Mercy Ascot Hospital. I declare no conflict of interest in this case.

Clinical Narrative

This has been exhaustively covered in the literature that accompanied the file that was sent to me. Essentially, and in brief, Ms A was admitted on the 9th May 2011 with upper abdominal pain. As part of her past history it was known that she was on a Methadone programme. The patient volunteered that she was in fact on 37ml of Methadone and she was duly charted that amount. This was approximately five times the intended dose which was 37mg of Methadone. She required some interventions to manage this over-dosage but did make a full recovery.

In the accompanying literature there are a number of submissions from nursing and medical staff and also annotations from both the pharmacy that dispensed her Methadone and from the hospital pharmacist. I have read these carefully.

The practitioner who actually prescribed the incorrect dose is very remorseful and concerned at this error and appears to have good insight into the prescribing deficit that she was party to. The other medical staff seem to have performed their duties entirely satisfactorily. Special mention should be made of [Dr D] the on call surgical house surgeon; she made attempts to contact the Community Alcohol and Drug Service but received only an answer phone message. This phone call was to ascertain the correct dose of [Ms A's] Methadone. [This sentence redacted as it is not material to the clinical advice.]

Commentary

This particular prescribing practice (of transcribing doses of medication based on volunteered information) is fraught with difficulty. Even the most well-meaning, intelligent and articulate patients under the stress of an admission to hospital may

make errors in their description of their medication. To compound that there is also wide-spread and understandable confusion in the minds of the lay public about the difference between **millilitres** and **milligrams.** Because of these important factors it is entirely unreasonable and unrealistic that prescribing staff should rely particularly on the verbal presentation of dosages of any medication from the patient. Further (and I concede that this was never raised as a submission) patients cannot be reasonably expected to "know the difference" between dosage amounts and strengths so that when [Ms A] was presented with an apparently large dose of medication she may well have assumed this was another formulation of Methadone.

The systems deficit that I have identified in this particular case can best be described as a communication lapse. As mentioned above there was clearly imperfect communication between the patient and the prescribing doctor. At the next level there was poor communication between the on-call house surgeon and the prescribing registrar even though, as mentioned in the clinical narrative, the house surgeon did all and more than should be reasonably expected of her.

There has also been imperfect communication between the prescribing doctor, the hospital pharmacy and the pharmacy from which [Ms A] obtained her Methadone. Given that all pharmacies are under the administrative umbrella of the DHB then the DHB must accept some responsibility for this imperfect communication. Some DHBs are able to do this through a shared database but that is by no means the national rule.

By inference of the times registered in the note most of [Ms A's] admission took place during daylight hours so one cannot claim that access to pharmacy advice was unavailable.

Conclusion

I would judge this to be a moderately severe departure from clinical practice by both the prescribing doctor and the District Health Board. While the patient did not suffer a seriously bad outcome there certainly was the potential for this to occur. I would make the following recommendations:-

- That those Methadone patients do carry some form of identification as to the particular medicine they are taking. I know this is standard practice in some DHBs.
- That the DHB highlights this issue to their staff to avoid any other errors of transcription of medication.
- It should be possible for pharmacological information of this nature to be shared between DHBs and private pharmacies.
- I understand there is a group known as the National Association of Opioid Treatment providers that meet regularly. Ministry of Health officials attend also. Using this example with the protection of identity might be worthwhile as an exercise to improve information sharing with a view to minimising harm caused by such events.

P.G. Alley FRACS"

Further advice
Additional comments were requested from Professor Alley.

Professor Alley was asked whether he considered it reasonable to expect the DHB to have had an Organisational Formal Medicine Reconciliation process or SOP in place at the time of these events. He responded:

> "Absolutely, there should have been some formal process around medicines reconciliation, irrespective of the clinician undertaking such a process. In the pharmacy literature this emerged approx 2005/6. We are 7 years on now. Safety and Quality in Medicine started the work, which then passed to Quality Improvement Commission, and now the Health Quality and Safety Commission. A Quality and Risk report on Safety Quality and Medicines was from [the region] at the time — so they would have been well aware of the importance of this."

Professor Alley was asked whether he considered it reasonable to expect the DHB to have had in place an additional prescribing policy specific to methadone. He replied:

> "Any institution which deals with MMP should have a specific policy/SOP around Methadone inpatient prescribing and dispensing but I accept the nuances of this are not covered or abundantly clear in the legislation."