Pharmacist, Mr B

Pharmacy

A Report by the

Health and Disability Commissioner

(Case 19HDC02146)

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report relates to the care provided to a man when he presented to a pharmacy, and highlights the importance of identifying a patient correctly before dispensing medication, and of following relevant professional guidelines.

2. On 14 November 2019, the man presented to the pharmacy and was waiting in line to receive his daily 11mg dose of methadone as part of the Opioid Substitution Treatment Programme. The pharmacist finished administering a dose to a client, and then identified the client he thought would be next to step up to receive a dose. Whilst the pharmacist had turned away to measure the correct dose for that client into a cup, the client left the room, and the man — who had been standing behind the intended client but was unseen owing to his size — stepped forward and was waiting when the pharmacist returned to the counter with the dose he had just measured.

3. As a result, inadvertently the man was given and consumed another patient's methadone dose of 75mg — almost seven times his usual dose. The pharmacist informed the man of the error as soon as he realised what had happened, and subsequently the man drove himself home before being taken to hospital by his family as a precaution.

Findings

4. The pharmacist failed to identify that the wrong client was standing in front of him, and dispensed the man another client's methadone dose. The pharmacist also allowed the man to drive home after the overdose, without advising him of the risks of doing so and the need to seek medical assistance and/or call an ambulance. Accordingly, the pharmacist failed to adhere to the professional standards set by the Ministry of Health and the Pharmacy Council of New Zealand, as well as the pharmacy's SOPs, and the Commissioner found him in breach of Right 4(2) of the Code.

5. The Commissioner considered that the pharmacy had taken steps to prevent the pharmacist's failures, and was not vicariously liable for the pharmacist's breach of the Code. However, the Commissioner was critical that the pharmacy had not updated relevant SOPs to reflect changes that had been made.

Recommendations

6. The Commissioner recommended that the pharmacist arrange for an assessment through the Pharmaceutical Society of New Zealand, present an anonymised version of this case to his colleagues, and provide the man's family with a written apology.

7. The Commissioner recommended that the pharmacy review and update its SOPs to reflect the changes made since these events, arrange refresher training for its staff in relation to dispensing and administering methadone, and conduct an audit on errors or near misses in relation to the dispensing of methadone and staff compliance with SOPs.

Complaint and investigation

8. The Health and Disability Commissioner (HDC) received a complaint from Mr A's daughter about the services provided to her father by Mr B at the pharmacy. The following issues were identified for investigation:

- *Whether Mr B provided Mr A with an appropriate standard of care in November 2019.*
- *Whether the pharmacy provided Mr A with an appropriate standard of care in November 2019.*

9. The parties directly involved in the investigation were:

Mr B Pharmacist/provider
Pharmacy/provider

10. Further information was received from the district health board.

11. Independent expert advice was obtained from a pharmacist, Ms Sharynne Fordyce (Appendix A).

Information gathered during investigation

Background

12. Mr A (aged in his sixties at the time of these events) had a medical history that included chronic obstructive pulmonary disease[1] and previous intravenous drug use. Mr A had been prescribed a daily dose of methadone[2] as part of the Opioid Substitution Treatment (OST) Programme.[3] The Controlled Drug Prescription form read as follows:

> "Methadone hydrochloride.
> 2mg [milligrams]/1ml oral solution
> 11mg daily (made up to 50ml with diluent for TTA [to take away])
> [The] Pharmacy COP [consume on premises]
> TTA Sat[urday]/Sun[day]."

13. This report concerns the care provided to Mr A at the pharmacy when he presented for his daily methadone dose.

[1] A group of lung diseases that block airflow and make it difficult to breathe.
[2] An opioid used for maintenance therapy in opioid dependence and for chronic pain management.
[3] An initiative that offers people who are dependent on opioids (such as heroin) an alternative, prescribed medicine — most typically methadone or buprenorphine — which is swallowed rather than injected.

Incident on 14 November 2019

14. At approximately 8.10am on 14 November 2019, Mr A presented to the pharmacy to receive his daily dose of 11mg methadone. Mr B[4] was the sole rostered pharmacist on that morning, and one other staff member — a retail assistant — was working in the pharmacy.

15. Mr B told HDC that at this time only the rear part of the dispensary was open in order to allow for discrete access for OST clients, and four to five OST clients were waiting in the room for their methadone doses.

16. Mr A was waiting in line to receive his dose. Mr B finished administering a dose to a client, and then identified the client he thought would be next to step up to receive a dose. Mr B then turned away to go back into the dispensary to locate that client's name on the list of clients for the day, and measured the correct dose for that client into a cup.

17. In the meantime, the client thought by Mr B to be the next client had left the room, and Mr A, who had been standing behind the intended client but had not been seen because of his size, stepped forward and was waiting when Mr B returned to the counter with the dose he had just measured.

18. Mr B told HDC that it is his usual practice to say the client's name before providing the client's dose, as this further ensures that the correct person is being medicated, but on this occasion he omitted this step owing to a distraction. He said that when he returned to the counter with the dose, a client had come forward and was standing directly behind Mr A, which the pharmacy does not allow, and so he asked the client to move away. Mr B stated: "It was in that moment that I failed to correctly identify my client and allowed the dose to be consumed by [Mr A] ..."

19. As a result, inadvertently, Mr A was given and consumed another patient's methadone dose of 75mg — almost seven times his usual dose of 11mg.

20. Mr B told HDC that both Mr A and the other client were known to him. Mr B stated:

> "I am at a loss to explain why I didn't notice that it wasn't the intended client standing there when I returned with the dose but there were a couple of steps that I performed too quickly which, had they been done more deliberately, may have prevented the error."

21. Mr B told HDC that a couple of contributing factors led to the error. One was the pharmacy's long-standing practice of allowing more than one client into the room at a time, and another was the pharmacy's decision to change its clear plastic cups to paper cups. He stated:

[4] Mr B is registered with the Pharmacy Council of New Zealand. He is also a member of the Pharmaceutical Society of NZ and the National Organisation of Opioid Treatment Providers. Mr B is the director and sole owner of the pharmacy.

> "We had, some months earlier, changed to biodegradable paper pottles to bring the doses out in from a clear plastic one. In discussions with [Mr A] in the days after the event he pointed out that this prevented him from checking that it looked like the correct dose. We present doses undiluted to clients for this very reason — so they can see what volume they have been dispensed."

Follow-up actions

22. After consuming the methadone dose, Mr A left the pharmacy and began walking to his car. Mr B then went back into the dispensary and saw the dose that was dialled into the dispensette,[5] and realised that he had given Mr A the wrong dose. He told HDC that as soon as he realised that an error had been made, he immediately left the pharmacy and spoke to Mr A before he could get into his car.

23. Mr B informed Mr A of the error and the dose he had received inadvertently. In a letter to HDC, Mr A stated:

> "Several times [Mr B] asked if I and other road users would be safe. I assured him the 2 kilometres or 5–6 min[ute] drive would be totally fine and it was. I knew my tolerance level and experience with this medication was safe for myself and others especially knowing the same distance and time I needed to travel."

24. The dispensing incident reporting form documented that Mr A appeared to be calm and not upset by the error. The form stated:

> "[Mr B] asked [Mr A] where he was going next, and he said straight 'to his wife' and, when asked specifically about this, reassured [Mr B] that there would be someone with him all the time."

25. Mr B told HDC that he did not advise Mr A of the need for him to be assessed medically, because Mr A refused to remain at the pharmacy once he knew the amount of the overdose. Mr B noted that, like any other patient in the health system, OST clients are able to refuse to follow the advice they are given. He stated that he believes it would have been unreasonable for him to try to overpower Mr A so as to force him to stay at the pharmacy.

26. Mr B stated that based on his knowledge of the pharmacokinetic properties of methadone, Mr A's repeated reassurances that he would be all right with that dose, and noting that the distance Mr A was proposing to drive was very short and that Mr A would be in the company of another adult once he drove home, he immediately focused on the next option available for getting Mr A medical attention before the onset of effects of the overdose.

27. At approximately 8.30am, when the Opioid Recovery Service (ORS) opened, Mr B telephoned and spoke to a registered nurse. The ORS notes record that Mr B explained what had happened and that the pharmacy had told Mr A to call back in three hours' time, and enquired whether there was anything else that ORS could do. Mr B told HDC that he

[5] A bottle-top dispenser used to measure and dispense medications.

recalls saying that the pharmacy was going to call Mr A in three hours' time, not the other way around.

28. The nurse discussed this case with a consultant psychiatrist, who advised that Mr A would need to attend the Emergency Department (ED) if he had any health concerns. The nurse then telephoned Mr A, who was at home alone when she rang, and advised him that he would need to seek medical attention owing to his size[6] and history of COPD, and the likelihood that he would be less likely to tolerate any respiratory depression from the increased dose of methadone.

29. Mr A was then driven to the ED by his daughter, and arrived at 9.29am. Because of the potential complications with respiration depression from his COPD, he was kept in hospital as a precaution until later that evening.

Subsequent events

30. Mr B told HDC that he was kept up to date with Mr A's progress throughout the day by ORS, and he made several verbal apologies to Mr A as part of subsequent conversations regarding the incident. Mr B stated that Mr A assured him that he was happy with the actions and changes that were made as a result of the error.

31. Mr A told HDC: "I thought [Mr B] was very professional and [I] continue to have trust in his work."

32. Mr A does not support the complaint that his daughter made to HDC.

Standard Operating Procedures (SOPs)

33. At the time of these events, the pharmacy had an SOP for methadone dispensing. It stipulated:

> "**Consume on premises**
> …
> Using the client's full name as provided by them, find their name on the administration record.
> …
> Pump dose into plastic sampler cup take the dose. Doses are brought out to the patient undiluted as this allows for the client to see the volume and comment if it doesn't look right …"

34. Mr B told HDC that as the owner and sole director of the pharmacy, it is his responsibility to develop and implement the SOPs, as well as to review and update them when needed.

35. At the time of these events, documentation on the SOPs indicated that they were overdue for a review. The "Incident Reporting" SOP was noted to be due for review in November

[6] Mr A weighed 51kg at the time of these events.

2018, the "Dispensing Error" SOP was due for review in December 2016, and the "Methadone Dispensing" SOP was due for review in May 2019.

36. Mr B told HDC that the SOP system used at the pharmacy does not automatically update the review date when an SOP has been reviewed and updated, and requires the pharmacist to remember to change the date manually. He stated:

> "It appears that I have sometimes omitted to update the date during my review of the SOPs. This is a failure to update the date, rather than a failure to review the SOPS. I am sorry for this omission and will ensure I have a better process written down to remind myself to update the date when I review an SOP."

Further information

Mr B

37. Mr B expressed regret at the error that occurred, and told HDC that he has reflected "at length" about how to change his practice to prevent a recurrence of this mistake. He said that he has been working through the process of reviewing the incident with his colleagues to help with this reflection, and stated:

> "However, in the end, the individual pharmacist must focus, apply themselves conscientiously to the task at hand and not allow distractions or possible familiarity with the process and the patients get in the way of good practice."

38. Mr B has since made several changes to his dispensing process that have the effect of double-checking the dose and slowing down the process.

Pharmacy

39. The pharmacy told HDC that after this incident, it assessed what had happened and the changes that could be made to prevent a recurrence. In addition to staff training and personal reflection, the pharmacy made the following changes to its practice:

a) A limit of four clients in the "methadone room" at any one time was set, and then subsequently updated to one client at any one time.

b) Methadone doses are now presented in clear plastic pottles.

c) Clients have been asked not to stand behind the client being administered the dose.

d) All of the relevant SOPs have been reviewed and updated.

Response to provisional opinion

Mr B and the pharmacy

40. Mr B was provided with the opportunity to comment on the provisional report, both in his capacity as the sole director of the pharmacy and as the provider in this case, and his comments have been incorporated where relevant. He stated:

"This incident has resulted in a number of changes to mine and [the pharmacy's] procedures that have resulted in an improved quality of service that we provide our Opioid Substitution Treatment (OST) clients."

Relevant standards

41. The Ministry of Health's New Zealand Practice Guidelines for Opioid Substitution Treatment (2014) (Opioid Substitution Treatment Guidelines) state:

"9.2.1 Dispensing

Safe dispensing of OST medication involves ensuring the legality of prescriptions; positively identifying clients (if necessary checking recent photographs provided by the specialist service or prescriber and/or checking photo identification provided by clients); and following correct labelling, record-keeping and filing procedures …

Opioid substitution medication — in particular, methadone — can cause death from overdose if the incorrect dose is dispensed …

…

9.3.6 Dispensing errors

Pharmacists must have procedures in place to minimise the chances of an error in dispensing. If a client receives a higher than normal dose of methadone, the potential for complications, including death, may be high. With buprenorphine the risk is much lower; however, on becoming aware of a dispensing error in this case, the pharmacist must still alert the client and prescriber, following the procedure outlined below so that appropriate monitoring and actions (such as reducing or stopping the following days dose) can occur. Pharmacists should immediately report all suspected errors to the client and the prescriber or specialist service. They should inform the client of the need for urgent medical assessment, and call an ambulance if necessary.

…

Overdosing

Where a pharmacist has administered more than the prescribed dose, he or she must follow this procedure:

- The pharmacist must immediately advise the client of the error and the need for them to be medically assessed within 3–4 hours. The onus should not be solely on the client to seek medical assistance. The pharmacist, the prescriber or the specialist service key worker may need to facilitate a medical assessment.
- The pharmacist must warn the client of the risks associated with extra drug use, and against driving or operating machinery.

- The pharmacist should immediately contact the prescriber or specialist service, who may decide that the client requires hospitalisation. Following such a decision, the pharmacist should either telephone for an ambulance and keep the client at the pharmacy until it arrives, or accompany the client to the hospital to ensure that admitting staff receive clear information on the circumstances.
- If the client has left the pharmacy before the mistake is realised, the pharmacist must advise the prescriber or specialist service as soon as possible. The pharmacist must make a reasonable attempt to contact the client to request they seek a medical assessment as soon as possible. If the pharmacist is unable to contact the client, the responsibility to continue to attempt contact will sit with the prescriber (or delegated person). The pharmacist should also notify the prescriber in writing of the incident and any actions taken …"

42. The Pharmacy Council of New Zealand's Competence Standards for the Pharmacy Profession (2015) state that the pharmacist:

> "Domain O1: Health and medicine management:
>
> …
>
> O1.4.1 Advocates for, and ensures patients access and receive quality services and care commensurate with their health needs
>
> …
>
> O1.4.3 Acts to optimise health outcomes by identifying and mitigating potential sources of error in service delivery
>
> …
>
> O1.4.6 Effectively uses systems to record accurate, complete and timely patient information, maintaining privacy and security of the information
>
> …
>
> Domain O3: Supply and administration of medicines:
>
> …
>
> O3.1.3 Applies knowledge in undertaking a clinical assessment of the prescription to ensure pharmaceutical and therapeutic appropriateness of the treatment and to determine whether any changes in prescribed medicines are warranted
>
> …
>
> O3.2.1 Maintains a logical, safe and disciplined dispensing procedure
>
> …
>
> O3.2.5 Accurately records details of medication incidents and actions taken, including clinical and professional interventions, to minimise their impact and prevent recurrence
>
> …
>
> O3.4.1 Makes clinical assessment of the appropriateness of the medicine for a specific patient in order to administer it or to supervise the patient self-administering

O3.4.2 Follows relevant policies, procedures and documentation requirements for the administration of medicines

O3.4.3 Obtains appropriate consent to administer the medicine

…"

Opinion: Mr B — breach

Introduction

43. As a registered pharmacist, Mr B was responsible for providing services in accordance with the Code of Health and Disability Services Consumers' Rights (the Code) — that is, the health services provided by Mr B were required to be of an appropriate standard, and to comply with all professional and other relevant standards.

44. Mr B was the sole pharmacist at the pharmacy on the morning of 14 November 2019, and was responsible for dispensing methadone to consumers under the OST Programme, as per their prescriptions. Mr B dispensed a methadone dose intended for another client to Mr A, and, as a result, Mr A consumed almost seven times his usual dose of methadone. Subsequently, Mr A drove home and self-presented to the ED at the public hospital after being persuaded to seek medical assistance by ORS.

Dispensing error

45. When Mr A presented to the pharmacy at 8.10am on 14 November 2019, four to five other consumers were waiting in the methadone dispensing room for their doses. Whilst Mr A was waiting in line to receive his dose, Mr B identified the client he thought would be next to step up to receive a dose, and went to measure the correct dose for that client into a cup. When he returned, Mr B failed to notice that the expected client had left the room that Mr A had taken his place, and that Mr A was not the client for whom Mr B had just measured a dose.

46. Mr B told HDC:

> "I am at a loss to explain why I didn't notice that it wasn't the intended client standing there when I returned with the dose but there were a couple of steps that I performed too quickly which, had they been done more deliberately, may have prevented the error."

47. Mr B said that it is his usual practice to say the client's name before providing the dose, as this further ensures that the correct person is being medicated, but on this occasion he omitted this step owing to a distraction.

48. The Pharmacy Council of New Zealand's Competence Standards for the Pharmacy Profession (2015) provides that a pharmacist "[m]aintains a logical, safe and disciplined

dispensing procedure", "[a]cts to optimise health outcomes by identifying and mitigating potential sources of error in service delivery", and "[f]ollows relevant policies, procedures and documentation requirements for the administration of medicines".

49. In addition, the Ministry of Health's New Zealand Practice Guidelines for Opioid Substitution Treatment (2014) (Opioid Substitution Treatment Guidelines) state:

> "Safe dispensing of OST medication involves ensuring the legality of prescriptions; positively identifying clients (if necessary checking recent photographs provided by the specialist service or prescriber and/or checking photo identification provided by clients); and following correct labelling, record-keeping and filing procedures …"

50. The Opioid Substitution Treatment Guidelines also require that pharmacists have procedures in place to minimise the chances of an error in dispensing, owing to the high potential for complications and death in the event that a client receives a higher than normal dose of methadone. I note that Mr B's usual process when dispensing methadone is to say the client's name before handing out a dose, and he acknowledged that he failed to do so on this occasion.

51. At the time of these events, the pharmacy had an SOP for methadone dispensing, which provided for:

> "Using the client's full name as provided by them, find their name on the administration record.
> …
> Pump dose into plastic sampler cup take the dose. Doses are brought out to the patient undiluted as this allows for the client to see the volume and comment if it doesn't look right …"

52. My expert pharmacist advisor, Ms Sharynne Fordyce, advised:

> "[Mr B] contravened the [Opioid Substitution Treatment] guidelines by not 'positively' identifying the client. By implication, a positive identification of the client helps to ensure that the patient is matched with their prescribed dose, and this step was omitted. By not using clear disposable cups, a visual check of the dose volume was not easily accessible to either the client or pharmacist. These two actions resulted in an overdose of methadone being given to [Mr A], which constitutes a severe departure from accepted practice."

53. I agree with this advice. Mr B's failure to identify that the wrong client was standing in front of him was compounded by his use of an opaque cup. Mr B told HDC that the pharmacy had decided to change its dispensing cups from clear plastic cups to paper cups; however, I note that the above SOP at the time did not reflect this change, and required that plastic cups be used to allow the client to see the volume dispensed. The SOP also stated that clients must give their full name before their dose is dispensed, which Mr B

omitted to request. This would have provided an extra safety net in order to ensure that the correct person received the correct dose.

54. Mr B's actions in this case were potentially life-threatening, and contravened both the Pharmacy Council of New Zealand and Ministry of Health guidelines, as well as the pharmacy's SOPs. Mr B's dispensing on this occasion did not meet the standard of care that Mr A should have received.

Subsequent actions following dispensing error

55. Opioid Substitution Treatment Guidelines stipulate that where a pharmacist has administered more than the prescribed dose, the following procedure must be followed:

> "• The pharmacist must immediately advise the client of the error and the need for them to be medically assessed within 3–4 hours …
>
> • The pharmacist must warn the client of the risks associated with extra drug use, and against driving or operating machinery.
>
> • The pharmacist should immediately contact the prescriber or specialist service, who may decide that the client requires hospitalisation. Following such a decision, the pharmacist should either telephone for an ambulance and keep the client at the pharmacy until it arrives, or accompany the client to the hospital to ensure that admitting staff receive clear information on the circumstances."

56. Once Mr B went back to the dispensary, he realised that he had given Mr A another consumer's methadone dose erroneously, and that the dose was almost seven times the amount that Mr A usually received. Mr B immediately left the pharmacy to advise Mr A of the error before he could get into his car. Mr B did not advise Mr A of the need for him to be assessed medically, and allowed him to drive home without ensuring that he would receive medical assistance.

57. Mr B stated that based on his knowledge of the pharmacokinetic properties of methadone, Mr A's repeated reassurances that he would be all right with that dose, the short distance that Mr A had proposed to drive, and that Mr A would be in the company of another adult once he drove home, he then focused on the next option available for getting Mr A medical attention before the onset of effects of the overdose. Mr B called ORS at approximately 8.30am, and ORS then informed Mr A of the need to seek medical assistance.

58. Ms Fordyce advised that the accepted practice, particularly with this level of overdose, would be to ensure that the client stayed on site while medical assistance was called, or to make arrangements to get the client to the nearest hospital, accompanied by next of kin or the pharmacist. She stated:

> "In this case there has been a severe departure from accepted practice. Given the substantial nature of the overdose arrangements should have been made to get [Mr A] medical attention and/or to a hospital as soon as possible. Despite [Mr A's]

protestations he should not have been allowed to drive anywhere, but remained on site, in view of the pharmacist, preferably with a support person present until medical attention was organised.

Another course of action would have included directing an ambulance to the address that [Mr A] was supposedly heading to. This would have been an appropriate course of action given that the [ORS] professional was not going to be available until at least 20 minutes after the incident, due to the 'phones not being switched over' until 8.30am. It was left to the [ORS] professional to convince [Mr A] to seek medical attention at the hospital."

59. I accept this advice. While Mr B could not have forced Mr A to stay if he did not wish to, Mr B needed to advise Mr A of the risks of leaving in the circumstances. In the context of Mr A having been given almost seven times his usual dose of methadone and his medical history of chronic obstructive pulmonary disease, it is concerning that Mr B did not advise Mr A against driving and of the need to seek medical attention, or ensure that Mr A would receive medical assistance by calling an ambulance.

60. In my view, the actions taken by Mr B once he was aware of Mr A's overdose were inadequate, unsafe, and contrary to the Ministry of Health guidelines.

Conclusion

61. In summary, Mr B failed to adhere to the professional standards set by the Ministry of Health and the Pharmacy Council of New Zealand, as well as the pharmacy's SOPs, by:

a) Failing to identify that the wrong client was standing in front of him, and dispensing Mr A another client's methadone dose; and

b) Allowing Mr A to drive home after the overdose without advising him against doing so and the need to seek medical assistance and/or to call an ambulance.

62. As a result of the dispensing error, Mr A received almost seven times his usual dose of methadone and required hospitalisation. Allowing him to drive home also potentially endangered Mr A and the public. For the reasons above, I find that Mr B breached Right 4(2)[7] of the Code.

Opinion: Pharmacy

Dispensing error and follow-up actions — no breach

63. As a healthcare provider, the pharmacy was responsible for providing services in accordance with the Code. In addition, the pharmacy also had a responsibility for the

[7] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

actions of its staff. In this case, I consider that the errors that occurred did not indicate broader systems or organisational issues, and that they were entirely individual failures. Therefore, I consider that the pharmacy did not breach the Code directly.

64. In addition to any direct liability for a breach of the Code, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any acts or omissions of its employees. Mr B was an employee of the pharmacy at the time of these events. As set out above, I have found that Mr B breached Right 4(2) of the Code for failing to adhere to the professional standards set by the Ministry of Health, the Pharmacy Council of New Zealand, and the pharmacy's SOPs.

65. However, a defence is available to the employing authority of an employee under section 72(5) of the Act if it can prove that it had taken such steps as were reasonably practicable to prevent the acts or omissions.

66. At the time of these events, the pharmacy had comprehensive SOPs in place for methadone dispensing, dispensing errors, and incident reporting. Mr B told HDC that he was aware of these SOPs, as he was involved in updating the old SOPs to the ones in place on 14 November 2019. Whilst I note that there were some issues with the SOPs (discussed further below), in my view, the issues did not contribute to the errors that occurred in this case. I also note that my expert advisor, Ms Fordyce, considers that the contents of the SOPs in place at the pharmacy at the time of events fell within accepted practice.

67. In light of the above, I consider that the pharmacy had taken steps that were reasonably practicable to prevent Mr B's failures. Accordingly, I do not find the pharmacy vicariously liable for Mr B's breach of the Code.

Updating SOPs — adverse comment

68. Whilst the SOPs at the pharmacy met the accepted standards at the time of these events, my expert advisor noted that each SOP for Incident Reporting, Dispensing Errors, and Methadone Dispensing were overdue for review. She stated that it is accepted practice to review SOPs regularly to ensure best practice, particularly when employing new staff, and to have a record of all staff having read relevant SOPs.

69. Mr B told HDC that the SOP system used at the pharmacy does not automatically update the review date when an SOP has been reviewed and updated, and stated:

> "It appears that I have sometimes omitted to update the date during my review of the SOPs. This is a failure to update the date, rather than a failure to review the SOPS. I am sorry for this omission and will ensure I have a better process written down to remind myself to update the date when I review an SOP."

70. Whilst the SOPs had apparently not been overdue for a review at the time of these events, I remind the pharmacy of the importance of having a correct and current record of pharmacy SOPs.

71. In addition, Ms Fordyce advised that it is the accepted standard, after such an error has occurred, to review all SOPs affected or involved in the event and rewrite SOPs accordingly. She stated that "this is done to improve pharmacy practice and procedure, and to help prevent a repeat occurrence of the event". She noted that despite the relevant SOPs having been reviewed as a result of this incident, they do not reflect the changes that have been made since and reported to HDC. Below, I have recommended that the pharmacy review and update its SOPs to reflect the changes that have been made since these events.

Recommendations

72. I recommend that Mr B:

a) Arrange for an assessment through the Pharmaceutical Society of New Zealand regarding the dispensing of methadone and positively identifying the intended client, and provide evidence to this Office, within six months of the date of this report, confirming the outcome of the assessment.

b) Present to his colleagues, using an anonymised version of this case as an example and referring to the Ministry of Health guidelines, the importance of appropriate follow-up actions subsequent to a methadone overdose. Evidence that this has been done is to be provided to HDC within three months of the date of this report.

c) Provide Mr A's family with a written apology for the breach of the Code identified in this report. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding.

73. I recommend that the pharmacy:

a) Review and update its SOPs to reflect the changes that have been made since these events. Evidence that this has been done is to be sent to HDC within two months of the date of this report.

b) Arrange refresher training for its staff in relation to dispensing and administering methadone, and confirm to HDC that the training has occurred, within six months of the date of this report.

c) Conduct an audit, for a period of one month, on the following matters:

- Any errors or near misses in relation to dispensing of methadone, and common themes or patterns found; and
- Staff compliance with page 99 of the SOPs regarding "methadone dispensing and consuming".

The results of the audit are to be sent to HDC within six months of the date of this report.

Follow-up actions

74. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Pharmacy Council of New Zealand, and it will be advised of Mr B's name.

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 Pharmaceutical Society of New Zealand, the Health Quality & Safety Commission, and the New Zealand Pharmacovigilance Centre, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from Ms Sharynne Fordyce:

"**19HDC02146**

I, Sharynne Fordyce, have been asked to provide an opinion to the Commissioner on Case number 19HDC02146 and have read and agreed to follow the Commissioner's Guidelines for Independent Advisers.

My qualifications include a Diploma of Pharmacy, and a Masters of Clinical Pharmacy. I have worked in Retail Pharmacy for over 30 years, both in New Zealand and in England, and also work for the Wairarapa DHB.

Background.

[Mr A] presented to [the pharmacy] on 14 November 2019, for his usual Opioid Substitution Treatment medication. He was erroneously given a 15 ml dose of Biodone Forte, by [Mr B], that was meant for someone else, instead of his usual 2.2ml dose. [Mr A] drove home from the pharmacy, and was subsequently taken to hospital later that day due to possible overdose risks.

Advice requested

Please advise whether you consider the care provided met accepted standards in all the circumstances and explain your rationale. For each question, please advise:

a) What is the standard of care/accepted practice and what are the relevant guidelines?

b) Has there been a departure from accepted practice? If so, to what degree: mild, moderate or severe?

c) What recommendations for improvement would help prevent a similar occurrence in future?

In particular, please comment on:

1. The appropriateness of the dispensing of methadone to [Mr A] on 14 November 2019.

a) All relevant guidelines for dispensing methadone are covered in the New Zealand Practice Guidelines for Opioid Substitution Treatment 2014.

Section 9.1.1 deals with providing a confidential service free from discrimination 'for example, by making available a discreet area for supervised consumption'

Section 9.1.2 deals with training for staff dispensing methadone 'should have specific training in opioid dependence treatment'

Section 9.2.1 deals with safe dispensing of methadone including 'positively identifying clients (if necessary checking recent photographs provided by the specialist service or prescriber and/or checking photo identification provided by clients)' and accurate measurement of methadone 'Acceptable methods for measuring methadone are a self-zeroing dose-measuring pump/burette (eg, Dispensette®)' Table 6 in section 9.2 states 'Measure dose using syringe, burette or Dispensette® into clear, disposable cup'.

It would also be accepted practice to have other staff available on the premises as a safety precaution, in the case of an emergency, be it a medical event or personal safety.

It is accepted practice in many, if not most pharmacies, to have all doses pre-poured and labelled for the day, with the name of the client and the dose of methadone on the label. This prompts a second check for both the correct patient and dose, and enables more timely dispensing to the clients.

In keeping with the above guidelines [Mr B] provided a discreet place for consumption, had appropriate training, and used the correct equipment for measuring.

b) [Mr B] contravened the above guidelines by not 'positively' identifying the client. By implication, a positive identification of the client helps to ensure that the patient is matched with their prescribed dose, and this step was omitted. By not using clear disposable cups, a visual check of the dose volume was not easily accessible to either the client or pharmacist. These two actions resulted in an overdose of methadone being given to [Mr A], which constitutes a severe departure from accepted practice.

c) Recommendations for improvement would include

— ensuring positive identification of the client, including confirming the client's name

— using clear disposable cups

— having the doses pre-poured and labelled for the day — acknowledging that it is the pharmacy's responsibility to have in place procedures that both ensure patient safety and fit in with staff workflow

— only one client at a time waiting in the room — lessens chance of distraction.

2. The adequacy of safety netting advice provided to [Mr A] after the dispensing error.

a) The relevant guidelines from the New Zealand Practice Guidelines for Opioid Substitution Treatment 2014 are covered in Section 9.3.6 Dispensing Errors — Overdosing. It states

— 'The pharmacist must immediately advise the client of the error and the need for them to be medically assessed within 3–4 hours. The onus should not be solely

on the client to seek medical assistance. The pharmacist, the prescriber or the specialist service key worker may need to facilitate a medical assessment.'

- 'The pharmacist must warn the client … against driving or operating machinery.'
- 'The pharmacist should immediately contact the prescriber or specialist service, who may decide that the client requires hospitalisation. Following such a decision, the pharmacist should either telephone for an ambulance and keep the client at the pharmacy until it arrives, or accompany the client to the hospital to ensure that admitting staff receive clear information on the circumstances.'

The accepted practice, particularly with this level of overdose, would be to ensure the client stayed on site, within view of the pharmacist, or a staff member, while medical assistance was called, or arrangements were made to get the client to the nearest hospital, accompanied by next of kin or the pharmacist. The client should not be driving a vehicle, or left to decide for themselves whether or not they needed medical care.

Accepted practice would also include notifying the local opioid treatment service as soon as possible, who in many areas, have an on-call mobile phone number. This also ensures another professional is able to monitor the client, and provide information to the hospital/medical care if needed.

b) In this case there has been a severe departure from accepted practice. Given the substantial nature of the overdose arrangements should have been made to get [Mr A] medical attention and/or to a hospital as soon as possible. Despite [Mr A's] protestations he should not have been allowed to drive anywhere, but remained on site, in view of the pharmacist, preferably with a support person present until medical attention was organised. Another course of action would have included directing an ambulance to the address that [Mr A] was supposedly heading to. This would have been an appropriate course of action given that the [ORS] professional was not going to be available until at least 20 minutes after the incident, due to the 'phones not being switched over' until 8.30am. It was left to the [ORS] professional to convince [Mr A] to seek medical attention at the hospital.

c) Recommendations for improvement would include

- always having at least two staff members on site when the methadone is being dispensed (either in the discreet methadone area or waiting to dispense methadone until the pharmacy is open) so there is staff available to help in such situations
- on no account letting the client drive away until medical assessment has been carried out. In this instance an ambulance could have been directed to the address to which [Mr A] was to drive and/or have a staff member accompany him.

— having current next-of-kin details for each client in case of emergencies. These details could then have been used to direct an ambulance, or to check that [Mr A] had indeed arrived at the address.

— ensuring a procedure for such an event is included in appropriate SOPs e.g. Dispensing errors, Methadone Dispensing.

3. The adequacy of the pharmacy's follow up actions including its incident reporting.

a) The relevant guidelines from Opioid Substitution Treatment 2014 are covered in Section 9.3.6 Dispensing Errors — Overdosing 'The pharmacist should also notify the prescriber in writing of the incident and any actions taken' and in [the pharmacy's] SOPs for Incident reporting and Dispensing Errors, which require an incident report to be filled in, the Pharmacy Defence Association (PDA) be informed and staff briefing to be carried out to ensure staff know what to do if event occurs again.

It would also be accepted practice for a written apology to be supplied to the client, particularly as this error involved hospitalisation, and to have personally checked on [Mr A's] health status while in hospital and after he returned home, ensuring initially that he had accessed appropriate medical care.

b) There has been a moderate departure from accepted practice. After informing [Mr A] of the error, [Mr B] made no further enquiries himself of [Mr A's] progress while in hospital or after he returned home. There is no mention of informing the prescriber in writing, of the incident, or of a written apology to [Mr A] — although there is a written letter from [Mr A] expressing his continued faith in [Mr B's] professional services.

The pharmacy's incident reporting as regards notifying PDA and filing an Incident Form are within accepted practice and company SOPs.

c) Recommendations for improvement would include

— closer follow up of client after incident, including hospital contact if appropriate

— written letter of apology to client.

4. The adequacy of the standard operating procedures in place at [the pharmacy] at the time of the event.

a) The contents of the Standard Operating Procedures (SOPs) in place at [the pharmacy] at the time of the incident fell within accepted practice, with one each for Incident Reporting, Dispensing Errors and Methadone Dispensing. The Methadone Dispensing SOP did include the requirement to correctly identify the patient. It would be accepted practice, however, for the Dispensing Error SOP to include advice on obtaining medical assistance for the patient if required, which the existing SOP did not contain. All three procedures were also overdue a review at the time of the event and it is accepted practice to regularly review SOPs to ensure best practice, particularly when employing new staff, and to have a record of all staff having read relevant SOPs.

b) There has been a mild departure from accepted practice in that all three mentioned SOPs were overdue a review at the time of the error, one as much as 3 years. It is important to have a correct and current record of pharmacy SOPs, particularly when employing new staff, and to show commitment to reviewing procedures. The omission from the Dispensing Error SOP in regards to obtaining appropriate medical care if needed is also a mild departure from accepted practice.

c) Recommendations for improvement would include

— a plan to ensure all SOPs are kept current

— Dispensing Errors SOP needs to emphasise the requirement of appropriate medical care for the client

— a record of staff having read relevant SOPs and be familiar with them.

5. The adequacy of the standard operating procedures in place at [the pharmacy] that were implemented after the event.

a) After such an event accepted practice would be to review all SOPs affected or involved in the event and rewrite SOPs accordingly. This is done to improve pharmacy practice and procedure, and to help prevent a repeat occurrence of the event. The rewrite would normally happen after a full staff debrief with all staff likely to be involved in these procedures, with staff encouraged to contribute suggestions.

b) The Dispensing Errors SOP has been rewritten to include the need for prompt and appropriate medical care to be given to the client if needed. The Methadone Dispensing and Incident Reporting SOPs do not appear to have been rewritten at all after the event and as such do not include any adjustments to practices, including those stated in [Mr B's] letter. [Mr B] does state an intention to do so but not to have done so, particularly as the dates on the SOPs indicate [Mr B] has recently reviewed them after the event, would constitute a mild to moderate departure from accepted practice.

c) Recommendations for improvement would include

— ensure new or reviewed SOPs reflect changes that are happening or about to happen.

6. The adequacy of the changes made by [the pharmacy] as a result of this event.

a) It would be accepted practice to have incorporated any proposed changes in procedures into recently reviewed SOPs. These proposed changes would incorporate new processes or behaviour that would help to ensure this type of event did not happen again. It would also be standard practice to hold a staff meeting, with minutes being recorded, to discuss the event fully including all correct and incorrect processes that occurred. Given the timing of the event and staffing issues at [the pharmacy] it would have been acceptable to hold a meeting with those staff available within a short time frame, and make suitable adjustments to procedures and SOPs. Any staff not present would be able to access the minutes and the new, reviewed SOPs, with

more discussion at a later date. After such an event it would be accepted practice to change procedures that led directly to the error, such as having photographs of all clients available to dispensing pharmacists, having another staff member available on site when dispensing methadone, using clear plastic disposable cups, and limiting number of clients in the room to one only. Only the plastic cups have been addressed.

b) Although some changes were made to the Dispensing Errors SOP none have yet been made to the other two SOPs involved, despite these SOPs being reviewed after the event, and these proposed changes being mentioned in [Mr B's] letter to HDC. Changes directly related to the cause of the event have not all been included in [Mr B's] list, such as including photographic identification of all clients. This is a mild to moderate departure from accepted practice.

c) Recommendations for improvement would include

— photographic identification of all clients available to dispensing pharmacists

— at least one other staff member available on site to help in an emergency if needed

— pre-pouring and labelling of doses

— restrict clients in room to one at a time.

7. Any other matters — none.

Sharynne Fordyce
12 July 2020"