HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

A Decision by the Aged Care Commissioner

(Case 21HDC02084)

Introduction

1. This report is the opinion of Carolyn Cooper, Aged Care Commissioner.

2. On Month2, YearA this Office received a complaint from Mrs A about the care provided to her grandmother, Mrs B (aged 92 years at the time) while she was a resident at Clutha Views Lifecare and Village (Clutha Views). Mrs A's main concern, and what was investigated by HDC, relates to the management of Mrs B's fentanyl patches and the discovery of two fentanyl patches applied to Mrs B at the same time, resulting in an overdose.

3. The following issues were identified for investigation:

- *Whether Heritage Lifecare (operating as Clutha Views Lifecare and Village) provided Mrs B with an appropriate standard of care between 28 Month1 Year A and 5 Month2 YearA inclusive).*
- *Whether Registered Nurse (RN) C provided Mrs B with an appropriate standard of care between 28 Month1, YearA and 5 Month2, YearA (inclusive).*

Background

4. Mrs B had longstanding chronic sciatic pain[1] (among other co-morbidities) and was on regular pain relief that included fentanyl transdermal[2] (skin) patches, along with as required (PRN) OxyNorm[3] capsules. Mrs B's regimen to manage her pain was paracetamol 1g three times a day, and fentanyl patches one 12.5mcg and one 25mcg to be changed every 72 hours. The fentanyl regimen was not synchronised, and so the patches were changed on different days (for example, the 12.5mcg patch was replaced on 20, 23, and 26 Month1, YearA, and the 25mcg patch was replaced on 21, 24, and 27 Month1, YearA).

[1] Pain that travels along the sciatic nerve. The sciatic nerve travels from the buttocks and down each leg.
[2] A medicated adhesive patch that is applied to the skin for absorption of a time-released dose of medicine into the bloodstream.
[3] An opioid medication used to treat moderate to severe pain.

5. According to Medsafe,[4] fentanyl is a medicine used to 'relieve chronic or long-lasting pain, which requires strong painkillers' and is an opioid.[5]

6. Regarding the use of transdermal patches, Medsafe notes that '[t]he old patch should be removed before the new patch is applied'.

Timeline of events

20 Month1 YearA

7. In order to establish what information was noted in Mrs B's Medi-Map relating to the administration of her fentanyl patches, the date range of 20 Month1, YearA through to 30 Month1, YearA was used as a sample. A table summarising the administration of Mrs B's fentanyl patches, as noted in Medi-Map and in Mrs B's progress notes, is included as Appendix C.

8. As reflected in the table, out of the nine times Mrs B was administered her fentanyl (over 20–30 Month1, YearA), multiple nurses administered the patches, but none noted the location, date and time (including removal) of the patches in Medi-Map, the progress notes, or on the patch itself.

28 Month1 YearA

9. Dr D, general practitioner (GP), told HDC:

> 'On 28 Month1 [YearA, Clutha Views] phoned me at the local health centre requesting an increase in Mrs B's regular pain relief due to frequent use of prescribed PRN [as required] analgesia.[6] At the time, I verbally confirmed that I would make the change to the fentanyl prescription and then changed the prescription on the Medi-Map electronic prescription format which [Clutha Views] has electronic access to and uses to refer to for medication dispensing.'

10. Mrs B's progress notes do not record who rang Dr D on 28 Month1, YearA to request an increase in her pain relief.

11. Mrs B's old prescription of 12.5mcg and 25mcg fentanyl patches was cancelled by Dr D on 28 Month1, YearA and replaced with the new prescription of 50mcg/hr fentanyl patches. The prescription to the pharmacy read: *'Fentanyl 50mcg/hr Transdermal patch — 1 changed every 3 days.'* However, Dr D erroneously recorded the prescription into Mrs B's Medi-Map as: *'Fentanyl 50mcg/hr Transdermal patch — 1 patch to be changed daily.'*

[4] The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) is responsible for the regulation of medicines and medical devices in New Zealand and the safe use of medicines. Its role is to ensure that medicines have acceptable efficacy, quality, and safety.
[5] A medicine used to relieve moderate to severe pain.
[6] Pain relief.

12. According to Mrs B's Medi-Map, she was started on the new 50mcg patch on 28 Month1, YearA, and it was administered to her at 8.53am.

29 Month1 YearA

13. Mrs B was given OxyNorm for pain in her back and hips, and it is documented that she was eating and drinking well, and mobilising with her walking frame.

30 Month1 YearA

14. On 30 Month1, YearA, a caregiver, Ms E, documented that Mrs B did not eat morning tea 'due to feeling sick from the medication she is on' and instead returned to bed to sleep.

31 Month1 YearA

15. At 5.35am on 31 Month1, YearA, RN F recorded that Mrs B '[r]efused any pain relief as she verbalised it makes her feel sick'.

16. At 4.42pm on 31 Month1, YearA, the Clinical Services Manager, RN C, recorded that she spoke to Mrs B at around 8–9am, and Mrs B told her that she was still nauseated from the increase in fentanyl from 12.5mcg one day, 25mcg the following day to a 50mcg patch. RN C told HDC that she checked Mrs B's skin for a new place to apply the 50mcg fentanyl patch that was due to be administered.

17. RN C documented in the clinical record:

> 'On checking charting for anti-nausea medication and rechecking charting of the Fentanyl Patch 50mcg discovered this was a daily patch change. Removed other 50mcg patch leaving a 50mcg patch in place.'

18. RN C told HDC that she removed the other 50mcg fentanyl patch and left only the one 50mcg fentanyl patch before she contacted the GP. Given the passage of time, RN C no longer recalls whether there was a 12.5mcg and/or 25mcg fentanyl patch left on Mrs B. However, RN C believes she would have recorded this in the progress notes.

19. Heritage Lifecare (Heritage) told HDC:

> 'The note also seems to suggest that Mrs B had two 50mcg patches in place when this was realised on 31 Month1. If that is correct, then the patch that was placed on Mrs B on 30 Month1, YearA did not involve removing the other patch. It therefore appears that two medication errors have been made. First, the GP has incorrectly prescribed the fentanyl patches as once daily, and also that a medication error was made on the 30th Month1 by not removing a fentanyl patch as would have been expected.'

20. On 30 Month1, YearA (the previous day) RN C had been the second checker when Mrs B was administered her fentanyl patch by another nurse.

21. RN C told HDC that she contacted the GP clinic (the local health centre) twice — first in the morning, and again in the afternoon before 4.29pm. RN C recorded in the progress notes: '[T]here had been an error in the charting of the patch on Medi-Map [and] it should have

been [changed every] 72 [hours] not daily.' The local health centre triage nurse documented:

> 'I spoke with RN C at [Clutha Views] — appears [Mrs B] Medi-Map charting of Fentanyl patches has been incorrect — new 50mcg patch charted as daily and RN C understood this was to be every [3 days] and old Fentanyl patches of 12.5mcg [and] 25mcg was to come off and be replaced with just the 50mcg. She has had all three patches on ? total of 87.5mcg — has been nauseated ++, no vomiting and not eating much … RN C asking if Medi-Map can be adjusted and if antinausea medication can be charted [as required] …'

22. RN C cannot recall this and does not believe she said that Mrs B had 'all three patches on ? total of 87.5mcg' or whether that was the triage nurse's interpretation of her explanation.

23. The situation was referred to the on-call GP, who recharted the 50mcg/hr fentanyl patch every 72 hours as initially intended. The previous daily charting of the patch was discontinued on the same day.

24. RN C said that she informed Mrs B's daughter and Mrs B of the medication error. Of note, Mrs B was deemed competent at the time, and her Enduring Power of Attorney (EPOA)[7] had not been activated.

25. RN C completed an incident form regarding the fentanyl patch prescribing error.

2 Month2 YearA

26. On 2 Month2, YearA caregiver Ms E recorded that Mrs B was not feeling well and that Mrs B thought it was because of a change in medication.

3 Month2 YearA

27. At 3.13am on 3 Month2, YearA, RN G recorded that Mrs B said that she 'was experiencing a feeling of intense heat throughout her body especially in her legs … She said she had not slept well last night and felt she was going to be the same tonight.'

28. At 11.33am, Ms E documented that Mrs B was 'not feeling that great and feeling sick'.

29. At 4.20pm, another caregiver, Ms H, recorded that Mrs B told them that she was not feeling well and had a 'burning sensation' over her body and had been unable to sleep for the last two nights. This was escalated to enrolled nurse (EN) I and RN J.

30. RN J contacted Dr D regarding Mrs B's concerns. Dr D's notes record:

> '[E]mail from rest home, [Mrs B is] more "shakey" Obs today: temp 36.8, hr 90, sats 97 % RA, BP 146/111, … [W]ill check infection markers and renal, advised to monitor — if

[7] A legal document in which a person appoints another person (the attorney) to make decisions on their behalf if the donor becomes incompetent. A doctor is required to provide a medical certificate outlining the consumer's mental capacity in order to invoke or 'activate' the EPOA.

> more unwell change in obs they are to contact to arrange review — as very short staffed here, may need [to] assess at [tertiary hospital].'

31. At 10.16pm, caregiver Ms K recorded that Mrs B was transferred to tertiary hospital for 'test[s]'.

Ambulance transfer notes — 3 Month2 YearA

32. The ambulance summary recorded the presenting complaint as '[g]enerally unwell ? fentanyl patch toxicity'. The summary noted:

> '[Mrs B has] [l]ong term back and hip sciatica pain. Uses Fentanyl patches last [two months], along with [as required] oxynorm. On Saturday new patch applied that was 50mcg increased from her usual 25mcg by GP for breakthrough pain. Since then, restlessness, nausea, insomnia, shakiness, loss of appetite.'

Admission to tertiary hospital — 3 Month2 YearA

33. Mrs B presented to the Emergency Department (ED) with nausea, leg spasms, and back pain.

34. Dr L, an emergency medicine specialist, provided the following statement:

> 'Regarding Mrs B's Emergency Department attendance on 3rd Month2, YearA she had difficulty in sleeping … spasms in her right leg following what was reported to me as an accidental increase in her fentanyl dose. These have been reported as side effects of fentanyl (although they are rare). Due to the timing and the absence of any other reported precipitating factor it is my view that on balance it was the increase in fentanyl that led to her symptoms.'

35. Dr M, an internal medicine senior medical officer, also provided a statement regarding Mrs B's stay at the tertiary hospital. She noted that Mrs B's symptoms of insomnia, nausea, and right leg spasms 'improved with decreasing the fentanyl dose'. Dr M stated that on admission to the hospital, Mrs B's fentanyl dose was decreased to 25mcgs every 72 hours, and her symptoms of fatigue and confusion resolved with the lower dose of fentanyl, and she was able to be discharged back to Clutha Views on 5 Month2, YearA.

5 Month2 YearA

36. On 5 Month2, YearA, RN N documented that Mrs B said that she 'fe[lt] better' following her hospital stay.

Further information

Response from Dr D

37. Dr D suggested to HDC that 'the nursing staff had inadvertently continued to apply (or more likely had left in-situ) the discontinued 12.5mcg and 25mcg patches supplementary to the revised prescription for the 50mcg/hr fentanyl patch'.

Response from Heritage Lifecare

38. Heritage told HDC:

> 'It … appears that two medication errors have been made. First, the GP has incorrectly prescribed the fentanyl patches as once daily, and that a medication error was made on the 30th of Month1 by not removing a fentanyl patch as would have been expected.'

39. Heritage told HDC that no incident form was created regarding the two fentanyl patches being discovered on Mrs B, and no root cause analysis was conducted in relation to the incident, and therefore, no corrective actions were implemented.

40. Heritage told HDC:

> 'Heritage also considers that a primary issue in this case that led to care falling below an acceptable standard were the actions of the Clinical Services Manager present at Clutha Views at that time.'

Response from RN C

41. RN C told HDC:

> 'There was no need to do a further incident report. The error was made by the GP, and he was notified of it. I followed up with staff regarding the identification of the error and to remind them to [be] alert to significant changes in medication charting and to critically review any changes.'

42. RN C said that following the incident she was on leave (from 2 Month2, YearA to 5 Month2, YearA), and she returned to work on 6 Month2, YearA.

Relevant policies

Medication Management Policy and Procedure (issued 2014)

43. The purpose of the Medication Management Policy and Procedure is to 'ensure medications are managed and administered safely and in line with legislation, standards and guidelines …'

44. The policy states that registered nurses are to '[m]aintain good knowledge of the medications' they administer and their function, side effects, and dosage levels.

45. Regarding controlled drugs, the policy directs that they should be administered by 'employees who know how to monitor residents for potential adverse effects'.

46. The policy provides that only prescribers can make changes to medications, and the changes are to be made in Medi-Map, and the pharmacy is to be contacted. The policy notes that controlled drugs are to be checked and signed out by two employees, who are to go to the resident together when administering the medication.

47. The section of the policy regarding medication incidents and adverse reactions states: 'The reporting and monitoring of medication incidents is an essential element of our quality management system and helps to protect our residents from harm.' The policy describes an

adverse medicine reaction as any 'unexpected, unintended, undesired or excessive response to a medication' that necessitates an acute admission to hospital.

48. The policy states that the Clinical Services Manager will '[a]ssist with ensuring all medication incidents are reported and investigated' and '[u]ndertake a root cause analysis in the event of a medication incident and provide this to the [Care Home Manager]'. In the event of a prescribing incident, the GP is to be contacted and informed of the issue. The policy states that '[e]very effort needs to be made to determine the actual cause of the incident …'.

49. Regarding transdermal patches, the policy directs staff to '[r]emove all used patches when a new one is applied, as accumulation of the medicine can cause over-dosage'. The policy notes that the day, date, and time of when the patch was applied is to be written on the back of the patch. In addition, the day, date, time, and location of the patch is to be recorded on the resident's medication chart. The policy requires that when a patch is removed, the day, date, and time is to be recorded on the resident's medication chart. In Medi-Map, a comments box is available to record information such as the day, date, time, and location when a patch is applied to a resident.

Open Disclosure Policy and Procedure (issued January 2014)

50. The purpose of the Open Disclosure Policy and Procedure is to 'actively promote a transparent consistent approach to full and open disclosure during the course of any aspect of resident service provision and where there is an instance of actual or potential adverse effect and or harm to the resident'.

51. The policy provides that 'adverse events' may include incidents, accidents, an unexpected change in the resident's health status, or a complaint or concern expressed by a resident.

52. The policy states that '[t]he objective of open disclosure is to provide information with sensitivity and empathy, including arrangements for further support and ongoing care if required'.

53. The policy directs that whenever a harmful incident occurs, the resident and their family must be informed, and states that '[e]ven though no harm is immediately apparent, an ongoing safety risk may be present …'.

54. The policy directs that any adverse event shall be reported to the resident and their family as soon as possible and within 24 hours of the event occurring. Following this, the care home will initiate open disclosure. As noted in the policy, '[a] disclosure should include acknowledgement of the incident, an explanation of what happened, how it happened, why it happened and … what actions have been taken to prevent it happening again'.

55. The policy directs that '[d]etails about the incident and any harm, the disclosure, and any subsequent action/s is to be recorded on the incident/accident form, reportable event sentinel investigation form and in the resident's progress notes' while also providing the resident and their family with documentation throughout the process.

Position description — Clinical Services Manager

56. The Clinical Services Manager role is a senior position, and part of the role is to provide 'high level clinical leadership and support to clinical and care staff'.

Responses to provisional opinion

Mrs A

57. Mrs A was given the opportunity to respond to the 'information gathered' section of the provisional opinion.

58. Mrs A said that she was told by staff at the tertiary hospital that when the second fentanyl patch was found on Mrs B, she should have been transferred to the tertiary hospital immediately. Mrs A stated:

> 'The fact it took from the 31st Month1 to the 3rd Month2 for them to seek appropriate care for my 92-year-old grandmother haunts me to this day. I will never forget what it was like to see [Mrs B] having withdrawals from this drug and lack of care.'

59. Mrs A noted:

> 'The response by RN C saying that there was no need to do a further incident report as the error was made by the GP feels like they are shifting the blame … The GP did not put these [patches] on her or was meant to remove them.'

60. Mrs A told HDC:

> 'Heritage Lifecare had in their care our most loved family member — our mother/ grandmother/great grandmother and to see her endure this pain and suffering was most distressing … [T]his could have easily ended a patient's life.'

Heritage Lifecare

61. Heritage Lifecare was given the opportunity to respond to the provisional opinion, including the proposed findings and recommendations. Heritage Lifecare advised that it accepted the Aged Care Commissioner's findings and had no additional comments to make.

RN C

62. RN C was given the opportunity to respond to the provisional opinion, including the proposed findings and recommendations. RN C submitted that there is no evidence to support the view that she had found two 50mcg fentanyl patches in place. She said that in her opinion, there is insufficient evidence to support the view that she alone would and should have been responsible for conducting an investigation.

63. RN C told HDC that on 31 Month1, YearA she was working two roles as Clinical Nurse Manager and registered nurse 'on the floor' to cover staff absences. She stated: '[P]art of the challenge we faced at the time was that we were very short staffed through a pandemic and had a number of junior nurses employed by Clutha Views Lifecare in YearA.'

64. RN C also told HDC that she recalls reporting the prescription error to another registered nurse, who was going to report back.

65. RN C's legal representative stated:

> 'Other information relevant to any assessment of what the appropriate actions might have been in the circumstances has been overlooked, including the fact of pandemic lockdowns, influenza lockdowns , chronic staff shortages evident in Heritage records and in the Ministry of Health audits, the equivocal nature of relevant clinical records, and the fact that RN C acted promptly to contact Mrs B's GP and conducted an immediate investigation to identify the cause of the prescription error.'

Opinion: Heritage Lifecare — breach

66. First, I acknowledge the distress that these events caused Mrs B's family. I understand that during HDC's investigation, Mrs B passed away, and I offer my condolences for the loss of their loved one.

67. I have undertaken a thorough assessment of the information gathered regarding the concerns raised. In order to determine whether the care provided by Clutha Views — Heritage Lifecare was appropriate, I considered in-house clinical advice from RN Hilda Johnson-Bogaerts (Appendix A) and GP Dr David Maplesden (Appendix B).

Management of Mrs B's fentanyl patches

68. RN Johnson-Bogaerts advised:

> 'On 31 Month1, YearA Mrs B had two … patches in place. It would appear that the nurses had continued the previous routine of replacing one of the "two patches" in place instead of changing over to the one patch. Or alternatively the error involved the placement of a new patch without removal of the previous "one patch" in place. The provider concluded in their letter of response that it appears that two medication errors were made. Firstly the incorrect prescribing by the GP of a fentanyl patch each day and secondly that the patch of the previous day was not removed. However at the time no incident report or investigation was completed.'

69. RN Johnson-Bogaerts stated:

> 'It would appear that the prescription of the fentanyl patches involved a complex routine of fentanyl patches of different doses and different days of replacing which may have contributed to the medication error … In terms of change from the complex routine to the one patch routine on 28 Month1, YearA, this would have been the responsibility of the nurse who received the change in prescription to then document in the clinical notes, implement and communicate the change.'

70. Taking the above into account, RN Johnson-Bogaerts advised that this amounted to a moderate departure from the accepted standard of care due to the staff relying solely on the prescription on Medi-Map, instead of this change being documented and communicated by the nurse who received the prescription change. RN Johnson-Bogaerts said that '[b]ecause no investigation in the cause was completed it is unclear if the change was communicated to administering nurses'.

71. Dr Maplesden advised:

> '[Although Dr D] made an error in the Medi-Map prescribing by recording the 50mcg patch as a daily dose rather than every three days … the correct prescribing directions were provided to the pharmacy, [and] I do not believe the error represents a deficiency in clinical knowledge.'

72. Dr Maplesden said that assuming that the accepted practice of removing the existing patch prior to replacing it was followed, there would be no expectation of Mrs B receiving higher than the intended hourly dose of fentanyl, but there was unnecessary wastage.

73. Dr Maplesden advised:

> 'I believe Mrs B's existing patch application regime was unnecessarily complex with different strength patches being applied on different days, and this made the regime more prone to error.'

74. Dr Maplesden stated:

> 'I would expect registered nursing staff to have identified the daily prescribing of a fentanyl patch to be a departure from usual practice and to have discussed this with Dr D rather than proceeding with daily application of the patch.'

75. I accept RN Johnson-Bogaerts's and Dr Maplesden's advice. While there was an initial error in which the 50mcg patch was recorded into Medi-Map as a daily dose instead of every three days, in my opinion, staff should have identified the change in prescription and queried this with Dr D prior to administering the medication, especially as fentanyl is a controlled drug. I consider that a registered nurse should be aware of accepted practice with respect to the use of fentanyl patches (ie, removal of the existing patch before the application of a new patch). This information is also included in the Medication Management Policy, as noted above. I acknowledge that both advisors noted that the original prescription was unnecessarily complex, which may have contributed to the errors.

Adequacy of documentation in relation to Mrs B's fentanyl patches

76. RN Johnson-Bogaerts advised:

> 'Heritage Lifecare's Medication [Management] Policy and Procedure includes a comprehensive section on "Transdermal Patches" which asks for the nurse to record the day, date, time and location of the applied patch on the medication chart and also to record day, date and time on the medication chart when the patch is removed. The medication administration record or the clinical records do however not include the location of the applied patch …'

77. The above is reflected in the table (at Appendix C), which shows that out of the nine times Mrs B was administered her fentanyl patch (between 20 and 30 Month1, YearA), multiple staff did not document the location, date and time (including removal) of the patches in Medi-Map or in Mrs B's progress notes.

78. Taking the above into account, RN Johnson-Bogaerts advised that this amounted to a mild to moderate departure from the accepted standard of care, as the documentation around the placement and removal of Mrs B's fentanyl patches was inadequate, and staff did not adhere to the advice in the Medication Management Policy and Procedure.

79. I accept RN Johnson-Bogaerts's advice. I am concerned that a controlled opioid drug was not managed in a safe manner, in that the required information (location of the patch, and the date, day, and time) was not documented in either the comment section of Medi-Map or in Mrs B's progress notes. Accurate documentation is a basis for delivering continuous and appropriate care.

80. In my opinion, this directly contributed to Mrs B being found with two patches in place on 31 Month1, YearA, as staff would not have been aware of when the patches were applied and when they were to be removed.

Conclusion

81. I accept that the departures from an appropriate standard of care (as outlined by RN Johnson-Bogaerts and Dr Maplesden) are attributable to Clutha Views. While there is individual accountability for these omissions (discussed later in the report), in my view the continued repeated omissions of several staff responsible for the incorrect fentanyl administration and documentation from 20–30 Month1, YearA is to some extent a systemic and organisational issue, for which ultimately Clutha Views is responsible. I also acknowledge RN C's statement that she was working two roles during this time, and that she had reported the prescription error to another registered nurse.

82. In summary, I find that Clutha Views did not provide an appropriate standard of care to Mrs B between 28 and 30 Month1, YearA (inclusive), as the documentation regarding when Mrs B's patches were administered to her was inadequate — details such as the location of the patch, and the date and time on which it was applied and removed, were not recorded either on the patch itself, in Medi-Map, or in Mrs B's progress notes. Due to the poor documentation, the exact dose of each of the fentanyl patches found on Mrs B is not clear.

83. Accordingly, I consider that Clutha Views failed to provide services to Mrs B with reasonable care and skill and breached Right 4(1)[8] of the Code of Health and Disability Services Consumers' Rights (the Code).

Opinion: RN C— adverse comment

Actions taken following discovery of medication error on 31 Month1, YearA

84. I acknowledge RN C's submission that there is no evidence to support that she found two 50mcg patches on Mrs B. Whilst I acknowledge her submission, I also consider that the clinical note she recorded is ambiguous and can be interpreted in several ways. 'Removed other 50mcg patch leaving a 50mcg patch in place' can be read as removing one of two

[8] Right 4(1) of the Code states: 'Every consumer has the right to have services provided with reasonable care and skill.'

50mcg patches or replacing one 50mcg patch with another. In my view, RN C's documentation of what patch/es she found, left in situ, or replaced should have been clearer. I also note that the interpretation of the telephone call with the GP practice was that Mrs B had had three patches in place.

85. RN Johnson-Bogaerts advised:

> 'Heritage Lifecare Medication Management Policy and Procedure includes that "every effort needs to be made to determine the actual cause of the [medication] incident and investigate all medication incidents". The provider response includes that this was not completed at the time by the Clinical Services Manager.'

86. RN Johnson-Bogaerts also stated:

> 'No incident form was found to have been completed. I did not find evidence of a detailed documentation or investigation as would be expected with a medication error involving a controlled drug.'

87. RN Johnson-Bogaerts advised:

> 'The Clinical Services Manager's job description explicitly outlines the responsibility to monitor care provision and maintain the highest standards. This role actively participates in the facility's Quality and Risk Management Program, seeking continuous improvement.'

88. RN Johnson-Bogaerts noted:

> 'While communication occurred with Mrs B and her family about the medication incident, there is no evidence of subsequent communication regarding resolution for affected parties, debriefing, or implementation of service improvements. This lack of follow-up violates the Open Disclosure Policy and Procedure.'

89. Taking the above into account, RN Johnson-Bogaerts advised that this amounted to a serious departure from the accepted standard of care because the Clinical Services Manager did not produce a second incident form and did not instigate a follow-up investigation to ensure that this high-risk and high-impact error would not be repeated.

90. However, whilst I acknowledge the departure from the accepted standard of care (as outlined by RN Johnson-Bogaerts), and I am critical that an investigation was not conducted either prior to RN C's leave or on her return, I acknowledge that RN C took immediate steps following the error, and that during this time she had to work two roles while there were staffing shortages and a lockdown, and that RN C was not the only staff member involved in Mrs B's care.

91. In summary, for the reasons outlined above, I find that RN C did not breach the Code, but I am critical of her documentation of the incident, and that further action was not taken to investigate the incident fully.

92. I have also considered the relevant policies in place at the time Mrs B was a resident at Clutha Views, and I note that the Medication Management Policy and Procedure stated that the Clinical Services Manager is to '[a]ssist with ensuring all medication incidents are reported and investigated' and '[u]ndertake a root cause analysis in the event of a medication incident and provide this to the [Care Home Manager]'.

93. While I acknowledge that RN C stated that she was on leave following the incident, in my opinion the investigation could have commenced on 31 Month1 or 1 Month2, YearA, prior to her leave, and been handed over to the Care Home Manager (or another responsible person), or continued upon her return. I am concerned that RN C may not have appreciated the severity of the incident and the serious impact it had on Mrs B. In addition, as this incident involved a controlled drug with multiple staff not adhering to the correct documentation of the patches (in terms of placement, noting time, date, and day of application and removal), this should have warranted further investigation. I note that RN C herself did not document the patches correctly. As per Appendix C, she administered and checked on the patches on three occasions.

Changes made since events

94. Heritage Lifecare stated that it is using this incident in an anonymised way across its sites for educational sessions.

Recommendations

95. I recommend that Clutha Views Lifecare and Village — Heritage Lifecare:

a) Provide evidence that this incident has been used in educational sessions, within three months of the date of this report.

b) Provide training for staff on how to manage fentanyl transdermal patches, with a review of the Medication Management Policy and Procedure, and understanding the importance of documenting the location, date, day, and time of patch placement and removal, and provide evidence of this training to HDC within three months of the date of this report.

c) Conduct an audit of Medi-Map to assess compliance with the Medication Management Policy and Procedure, in particular in documenting fentanyl patch placement and removal with sufficient details and report the results of the audit to HDC within six months of the date of this report.

d) Update the Medication Management Policy section in relation to 'Medication Incidents', specifically by including that the activated EPOA, welfare guardian, or designated representative is to be informed of any medication incident in which the resident is involved. Please provide HDC with evidence of any changes, within three months of the date of this report.

96. In the provisional opinion, I recommended that Clutha Views Lifecare and Village provide a written apology to Mrs B's family for the issues identified in the report. Clutha Views Lifecare and Village has provided this apology to HDC, and it will be forwarded to the family.

97. I recommend that RN C:

a) Provide a written apology to Mrs B's family for the issues identified in this report. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to the family.

b) Reflect on her practice in light of the findings in this case and report back to HDC on her learnings, within three months of the date of this report.

Follow-up actions

98. A copy of this report with details identifying the parties removed, except Clutha Views Lifecare and Village — Heritage Lifecare and the advisors on this case, will be sent to HealthCERT, Health New Zealand|Te Whatu Ora, and the Nursing Council of New Zealand and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

99. The Nursing Council of New Zealand will be provided with relevant sections of the final report.

Appendix A: In-house clinical advice to Commissioner

The following advice was obtained from RN Hilda Johnson-Bogaerts:

> 'Thank you for the request that I provide clinical advice in relation to the complaint about the care provided by Clutha Views Lifecare & Village (Heritage Lifecare). In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors.
>
> I am asked to review the provided information and advice on a medication error that occurred involving fentanyl patches. Specifically I am asked to comment on the appropriateness of placement of a second fentanyl patch without removal of the initial patch and, provide details of what would be standard practice when changing a fentanyl patch.
>
> i. The appropriateness of placement of a second fentanyl patch without removal of the initial patch, and details of what would be standard practice when changing a fentanyl patch.
> ii. The adequacy of documentation for the placement of the patches.
> iii. The adequacy of the rest home's medication management policy.
> iv. Actions taken following discovery of the over-medication and whether this was adequate.
> v. Any other comments you wish to add.
>
> 1. **Documents reviewed**
> - Heritage Lifecare letter of response dated 24 Month4, YearB
> - Provider's Medication Management Policy and Procedure
> - Medication administration record 19 Month1, YearA to 31 Month1, YearA
> - Clinical progress notes
> - GP notes
>
> 2. **Review of clinical records and clinical advice**
> Fentanyl is a strong opioid often prescribed for chronic pain. The transdermal patch is a long-acting formulation with delayed onset of effect initially and prolonged duration of action. They are most useful when oral opioids cannot be used for a variety of reasons. Because of a delayed onset and prolonged duration of action adverse reactions may be difficult to control. It is advised to replace patches every 3 days (72 hours) and not earlier and apply a new patch to the skin at a different place. The patch releases a continuous amount of fentanyl that is absorbed through the skin in contact with the patch. Nurses need to be aware of the safe use and disposal of fentanyl patches and monitor for potential side effects. Used patches contain still high quantities of residual fentanyl (60% of the intended dose). Common opioid adverse effects include nausea, vomiting, constipation, drowsiness and hypotension.

i. The appropriateness of placement of a second fentanyl patch without removal of the initial patch, and details of what would be standard practice when changing a fentanyl patch.

The Medsafe Consumer Medicine Information[1] includes that one should not use more than one patch at a time, unless authorised by the prescriber and only when a specific dose cannot be obtained otherwise by a single patch. The guidelines also include that "*the old patch should be removed before the new patch is applied".* The Information sheet specifies how to apply and change a patch and how to dispose of a used patch.

The provider response includes that on 31 Month1, YearA the clinical service manager realised that fentanyl patches were charted in error by the GP to be administered 50mcg each day and were administered each day in the last 3 days.

The prescription before involved the combination of two different doses to be changed every 72 hours on a three-day cycle, i.e. the first day a change of the 12.5mcg patch, the next day a change of the 25mcg patch and the third day no changes. In this scenario Mrs B would have two patches in place at the same time, as prescribed by the GP.

On 31 Month1, YearA Mrs B had two 50mcg patches in place. It would appear that the nurses had continued the previous routine of replacing one of the "two patches" in place instead of changing over to the one patch. Or alternatively the error involved the placement of a new patch without removal of the previous "one patch" in place.

The provider concluded in their letter of response that it appears that two medication errors were made. Firstly, the incorrect prescribing by the GP of a fentanyl patch each day and secondly that the patch of the previous day was not removed. However, at the time no incident report or investigation was completed.

In conclusion it would appear that the prescription of the fentanyl patches involved a complex routine of fentanyl patches of different doses and different days of replacing, which may have contributed to the medication error. I would like to refer for medical advice on the appropriateness of the prescription of this complex routine involving multiple doses and patches.

In terms of change from the complex routine to the one patch routine on 28 Month1, YearA, this would have been the responsibility of the nurse who received the change in prescription to then document in the clinical notes, implement and communicate the change. Because no investigation into the cause was completed it is unclear if the change was communicated to administering nurses. If there had been a sole reliance on the prescription on Medi-Map to communicate the change in routine this would be seen in this situation as a moderate deviation from accepted practice.

ii. The adequacy of documentation for the placement of the patches.

[1] https://www.medsafe.govt.nz/Consumers/cmi/f/fentanylsandoz.pdf

The medication administration record includes the administration of a 50mcg fentanyl patch on 28, 29 and 30 Month1, YearA and the time applied. The record does not include the placement of the patch and does not include when and which patches were removed.

Heritage Lifecare's Medication Managing Policy and Procedure includes a comprehensive section on "Transdermal Patches" which asks for the nurse to record the day, date, time and location of the applied patch on the medication chart and also to record day, date and time on the medication chart when the patch is removed. The medication administration record or the clinical records do however not include the location of the applied patch, and I did not find a record of removed patches. This could be documented in the "Comments" section within Medi-Map or alternatively within the clinical progress notes.

In conclusion the documentation was inadequate and did not follow the provider's Medication Management Policy and Procedure relating to documentation of placing and removing of a patch. Not documenting the placement and removal of a fentanyl patch would be seen by my peers as a mild to moderate deviation from accepted practice.

iii. The adequacy of the rest home's medication management policy.

Reviewing Heritage Lifecare's Medication Management Policy and Procedure, I found that the policy section relating to Medication Incidents could be updated to better reflect the Medicine care guides for residential aged care's [2] chapter relating to Medication Incidents. Specifically, this section of the policy should include that the resident or activated EPOA, welfare guardian or designated representative is to be informed of any medication incident the resident is involved in.

iv. Actions taken following discovery of the over-medication and whether this was adequate.

Actions taken included:

- The GP was contacted, who changed the prescription to fentanyl patches to be administered every 72 hours. The GP notes include a clinical triaging at 31 Month1, YearA at 16.30hrs of the situation and prescription of anti-nausea medication as required. Nurses documented symptoms in the clinical notes and administered anti-nausea medication as required.
- Mrs B and her daughter were informed. It is noted by the provider that Mrs B was deemed competent and at the time the EPOA was not activated. The communication notes include that "*Mrs B remains alert and conscious and has been fully informed regarding the error. Message left with family - daughter Ms O"* and further on 31 Month1, YearA as recorded by the Clinical Services Manager

[2] https://www.health.govt.nz/system/files/documents/publications/medicines-care-guides-for-residential-aged-care-may11.pdf

"*daughter Ms O rang back to inquire about medication incident, explained"* and "*On talking to Mrs B this morning she was still nauseated from the increase of fentanyl patch from 12.5mcg one day and 25mcg the following day to 50mcg … removed the other 50mcg patch leaving a 50mcg in place"*.

Heritage Lifecare Medication Management Policy and Procedure includes that "every effort needs to be made to determine the actual cause of the [medication] incident and investigate all medication incidents". The provider response includes that this was not completed at the time by the Clinical Services Manager and that they could not follow up on the detail with the Clinical Services Manager at the time of writing the response. No incident form was found to have been completed. I did not find evidence of a detailed documentation or investigation as would be expected with a medication error involving a controlled drug.

In conclusion I have found the actions taken to have been a moderate to significant deviation from accepted practice. I have come to this conclusion because the Clinical Services Manager did not follow the organisation's policy and procedure in terms of documenting the incident, completing an in-depth investigation into the cause of the incident, and putting measures in place to prevent such incidents from happening again.

Addendum 16 Month5 YearC

After reviewing additional information provided, I have adjusted my initial conclusion regarding the actions taken following the over-medication incident. Initially, I categorised these actions as a "moderate to significant" departure from accepted practice. However, upon further consideration and examination of relevant documents, I now deem it a "significant" departure.

Key Points:

- **Job Description and Responsibilities:** The Clinical Services Manager's job description explicitly outlines the responsibility to monitor care provision and maintain the highest standards. This role actively participates in the facility's Quality and Risk Management Program, seeking continuous improvement.
- **RN C's Response:** RN C's statement, dated 30 Month4, YearC, acknowledges the incident but emphasises that the error was solely the GP's fault. However, my review indicates multiple mistakes beyond the prescribing error.
- **Communication and Open Disclosure:** While communication occurred with Mrs B and her family about the medication incident, there is no evidence of subsequent communication regarding resolution for affected parties, debriefing, or implementation of service improvements. This lack of follow-up violates the Open Disclosure Policy and Procedure.

Conclusion: Considering all aspects and the additional information provided, I have adjusted my initial advice and conclude that the incident management by the Clinical Service Manager fell short and deviated significantly from accepted practice for such a high-risk and high-impact error.

Hilda Johnson-Bogaerts, BNurs RN MHSc PGDipBus
Nurse Advisor (Aged Care)
Health and Disability Commissioner'

Appendix B: In-house clinical advice to Commissioner

The following in-house advice was obtained from GP Dr David Maplesden:

'I have reviewed the information on file.

1. Mrs B (age 92 years) is a resident of Clutha Views Lifecare & Village (CVL). Her medical history includes: previous metallic aortic valve replacement (on warfarin); hypertension; previous upper GI bleed; rectal prolapse; chronic sciatic pain. Mrs B's regular analgesia regime on 19 Month1, YearA was paracetamol 1g TDS and fentanyl patches 12.5mcg + 25mcg every 72hrs. However, the application of the patches did not coincide so that, for example, the 12.5mcg patch was replaced on 20, 23 and 26 Month1, YearA and the 25mcg patch replaced on 21, 24 and 27 Month1, YearA. Oxynorm 5mg capsules were prescribed for breakthrough pain and these were administered 2–3 times daily with consistent requirement for 3 capsules daily from 26–28 Month1, YearA because of persistent musculoskeletal pain. Administration records show a single 5mg dose was administered on 29 and 20 Month1, YearA following the medication changes discussed below.

2. On 28 Month1, YearA (Wednesday) CVL staff contacted the local health centre GP Dr D regarding Mrs B's ongoing pain issues and requesting an increase in her regular analgesia. GP notes include: *phoned by RN J, increase pain — needing 10–15mg oxynorm every day, has run out of pills, needs new Rx. Discussed will increase fentanyl dose — up from 12.5+25 to 50mcg patch.* The prescription generated for the pharmacy was for *Fentanyl 50mcg/1hr Transdermal Patch — 1 changed every 3 days.* Dr D states he accessed the Medi-Map prescribing module which was used by CVL staff and he cancelled the 12.5mcg and 25mcg fentanyl patch prescriptions and prescribed the 50mcg patch in their place (confirmed on review of Medi-Map image supplied — reason for cessation recorded as *increase dose*). However, the 50mcg patch was prescribed on Medi-Map erroneously as to be applied daily in contrast to the correct directions of the prescription going to the pharmacy. It is standard and expected practice to remove the old fentanyl patch when applying a new patch.

3. Medication administration records indicate there was no further application of the 12.5mcg patch after 26 Month1, YearA and no further application of the 25mcg patch after 27 Month1, YearA. However, the 50mcg patch is recorded as being applied daily on 28, 29 and 30 Month1, YearA. The CVL response notes that on 31 Month1, YearA … *it appears that the clinical services manager has realised that fentanyl patches have been charted by the general practitioner to be administered 50mcg each day. That prescription was different to Mrs B's previous prescription for fentanyl patches at a different dose changed every 72 hours. The note also seems to suggest that Mrs B had two 50mcg patches in place when this was realised on 31 July. If that is correct, then the patch that was placed on Mrs B on 30 Month1, YearA did not involve removing the other patch … When this issue was identified, the general practitioner was telephoned and this resulted in the general practitioner recharting the fentanyl to be administered every 72 hours. There was no other order given to address the fact that Mrs B could have been receiving additional fentanyl than prescribed.*

4. In the interim, Mrs B had become increasingly unwell with nausea and disturbed sleep although there is no reference to confusion or respiratory depression symptoms. On the afternoon of 31 Month1, YearA (Saturday) the local health centre was notified of the situation with triage nurse notes recording: *Spoke with RN C at CV — appears Mrs B's Medmap charting of Fentanyl patches has been incorrect — new 50mcg patch charted as daily and RN C understood this was to be every 3/7 and old Fentanyl patches of 12.5mcg + 25mcg was to come off and be replaced with just the 50mcg. She has had all 3 patches on ? total of 87.5mcg — has been nauseated ++, no vomiting and not eating much. Nausea has slightly reduced in the last hour. RN C asking if Medi-Map can be admitted* [should read "amended"] *and if anti-nausea medication charted PRN also.* The situation was referred to the on-call GP who has recorded: *Recharted fentanyl 50 mcg every 72 hrs and metoclopramide 10 mg tds for nausea prn.* I have confirmed this charting on Medi-Map noting the previous daily charting of the patch was also discontinued on 31 Month1, YearA.

5. Mrs B apparently remained non-specifically unwell with ongoing nausea and intermittent sleep disturbance. On 3 Month2, YearA she reported feeling more unwell with a "burning sensation" over her body and "shakiness" and Dr D was contacted for advice. GP notes read: *email form rest home, more "shakey" Obs today: temp 36.8, hr 90, sats 97 % RA, BP 146/111, is due her inr on blood round today — will check infection markers and renal, advised to monitor — if more unwell change in obs they are to contact to arrange review — as very short staffed here, may need assess at local tertiary hospital.* When local health centre staff were notified later in the day that Mrs B felt more unwell CVL staff were advised to have her assessed at a tertiary hospital. Mrs B spent three days at tertiary hospital with the clinician's view there that her symptoms of nausea, sleep disturbance and shakiness (transient clonus evident) were most likely due to transient fentanyl toxicity with symptoms resolving after the dose was reduced to 25mcg patch per 72hrs.

6. Comments

(i) Mrs B was not opioid naïve and her requirement for PRN analgesia in the days leading up to her medication adjustment was 15mg oxycodone daily (equivalent to 30mg oral morphine or 12.5mcg fentanyl patch[3]). I believe it was therefore reasonable to make an increase in her regular transdermal fentanyl dose from 37.5mcg (12.5 + 25) patches per 72hrs to a single 50mcg patch per 72hrs. While this was clearly Dr D's intention, he made an error in the Medi-Map prescribing by recording the 50mcg patch as a daily dose rather than every three days. While these prescribing directions were not consistent with accepted practice, assuming the accepted practice of removing the existing patch prior to replacing it was followed there would be no expectation of Mrs B receiving higher than the intended hourly dose of fentanyl, but there was unnecessary wastage. Dr D might review what factors led to the prescribing error (is there the potential within Medi-Map to avoid such an error in the future?) but noting the correct

[3] http://www.saferx.co.nz/assets/Documents/bb2a9d2d7a/Opioid_dose_conversion_guide.pdf Accessed 6 September 2022

prescribing directions were provided to the pharmacy, I do not believe the error represents a deficiency in clinical knowledge.

(ii) I believe there were several factors leading to the presumed but not clearly defined error regarding administration of the fentanyl patches. My comments are predicated on the assumption that a registered nurse should be aware of accepted practice with respect to use of fentanyl patches (ie removal of the existing patch before application of a new patch).

(iii) I believe Mrs B's existing patch application regime was unnecessarily complex with different strength patches being applied on different days, and this made the regime more prone to error. Effort should be made to ensure that when different strength patches are being prescribed, the patch change timing coincides. This may mean an extra day or so of regular oral analgesia is required to facilitate timing.

(iv) While the intended patch strength change authorised by Dr D on 28 Month1, YearA was quite reasonable, noting the rather complex pre-existing regime I believe it was important to convey quite explicit instructions to nursing staff that the existing 12.5 mcg and 25mcg patches required removal before application of the 50mcg patch event though the 25mcg patch had been applied only the previous day. However, as discussed above I would regard this as an additional "safety measure" noting the expected knowledge of registered nursing staff in this regard.

(v) Dr D states he did not forward a copy of his clinical note of 28 Month1, YearA to CVL although it is his usual practice to do so for more extensive notes. With the benefit of hindsight, had CVL staff had access to the note they might have observed the discrepancy between the fentanyl prescribing instructions recorded in the note and those recorded in Medi-Map. I recommend any local health centre consultation note in which clinical advice has been provided to CVL staff is forwarded in a timely manner.

(vi) As discussed previously, I would expect registered nursing staff to have identified the daily prescribing of a fentanyl patch to be a departure from usual practice and to have discussed this with Dr D rather than proceeding with daily application of the patch. Similarly, if there was pharmacist reconciliation of Medi-Map instructions with those on the GP prescription (and I am not sure how this process works at CVL) early detection of the prescribing error might have been expected.

(vii) When the prescribing/application error was brought to the attention of local health centre staff on 31 Month1, YearA the triage nurse acted appropriately in attempting to quantify the error and passing it on to the on-call GP with a degree of urgency. However, I am mildly critical that the re-prescribing of fentanyl at the originally intended dose of 50mcg patch per 72 hrs was not preceded by some more detailed enquiry into Mrs B's wellbeing or likely total opioid dose leading up to the current enquiry although I cannot state that had such information been clarified, this would necessarily have altered the prescriber's actions. The risk of abrupt withdrawal versus those of opioid toxicity needed to be considered when making this decision.

7. I have no further comments but I recommend Dr D is provided with a copy of the letter dated 22 Month3, YearA from tertiary hospital physician Dr M which provides some useful advice on use of fentanyl patches and potential sources of medication errors involving the patches.'

Appendix C: Table of fentanyl administration from 20–30 Month1, YearA

Medication — dose	Date and time of administration	Administrator	Second checker	Location, date & time of patch noted in Medi-Map ? (including removal?)	Location, date & time of patch noted in progress notes? (including removal?)
Fentanyl 12.5mcg patch	20 Month1, YearA at 7.16am	Ms H	RN C	No	No
Fentanyl 25mcg patch	21 Month1, YearA at 7.47am	RN J	Ms H	No	No
Fentanyl 12.5mcg patch	23 Month1, YearA at 7.29am	Nurse P	RN J	No	No
Fentanyl 25mcg patch	24 Month1, YearA at 7.42am	RN J	Nurse P	No	No
Fentanyl 12.5mcg patch	26 Month1, YearA at 11.14am	RN C	Nurse P	No	No
Fentanyl 25mcg patch	27 Month1, YearA at 7.56am	Person Q	RN J	No	No
Fentanyl dose increased on 28 Month1, YearA					
Fentanyl 50mcg patch	28 Month1, YearA at 8.53am	EN I	RN J	No	No
Fentanyl 50mcg patch	29 Month1, YearA at 7.23am	RN J	Nurse P	No	No
Fentanyl 50mcg patch	30 Month1, YearA at 7.18am	Nurse P	RN C	No	No