

Department of Corrections
Clendon Pharmacy Limited (trading as Clendon Pharmacy)
General Practitioner, Dr B

A Report by the
Deputy Health and Disability Commissioner

(Case 17HDC01348)



Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. This report concerns the care provided to a man by the Department of Corrections (Corrections), by a pharmacy, and by a general practitioner (GP). In particular, the report focuses on the management of the man's clopidogrel medication, which was stopped in error on several occasions. The Deputy Commissioner considered that systems and processes failed the man on multiple occasions and in multiple ways. There was inadequate communication and documentation, a lack of critical thinking, and poor compliance with policy by a number of different providers.
2. The man was prescribed long-term clopidogrel after he was admitted to hospital following a stroke. However, he received the medication for only a month before it was stopped in error. It was not until he was re-admitted to hospital after suffering a heart attack and having four stents placed in his heart that he began receiving clopidogrel again. However, again the clopidogrel was stopped incorrectly after two months. The man did not receive clopidogrel again until after he had been hospitalised a further three times.
3. The Deputy Commissioner noted that in addition to the responsibilities under the Code, under the Corrections Act 2004 Corrections is required to provide prisoners with medical treatment that is "reasonably necessary", and the "standard of health care that is available to prisoners in a prison must be reasonably equivalent to the standard of health care available to the public". The Deputy Commissioner further highlighted that prisoners do not have the same choices or ability to access health services as a person living in the community. They do not have direct access to medication or to a GP. They are entirely reliant on the staff at Corrections' health services to assess, evaluate, monitor, and treat them appropriately.

Findings

Department of Corrections

4. The Deputy Commissioner found Corrections in breach of Right 4(1) of the Code. In his view, a number of failures by a number of Corrections staff represented a pattern of poor compliance with Corrections' policy and a concerning lack of critical thinking, and contributed to the man not receiving his clopidogrel medication as intended.

Pharmacy

5. The Deputy Commissioner found the pharmacy in breach of Right 4(1) of the Code. In his view, a number of deficiencies in the services provided by the pharmacy represented a pattern of suboptimal care that put the man at risk.

GP

6. The Deputy Commissioner found the GP in breach of Right 4(1) of the Code for incorrectly transcribing hospital prescriptions for clopidogrel and aspirin. The Deputy Commissioner considered that this error suggested that the GP did not read the discharge summary with sufficient care.

Recommendations

7. The Deputy Commissioner recommended that Corrections provide a written apology; arrange for an independent external review of the level of GP cover provided at the prison; report to HDC on its project to implement an electronic medication administration system at the prison's health centre; report to HDC on its new process for medication self-administration signing sheets; review a sample of recent discharges from hospital to the prison to ensure that appropriate care plans are in place; and report to HDC on the medical officers' review of medication charts.
8. The Deputy Commissioner recommended that the pharmacy provide a written apology; undertake a random audit of dispensing to the prison health centre to confirm that there was a current chart and prescription to support the dispensing; develop an anonymised case study based on this report and use the case study as the basis for training for staff; and share its anonymised case study with HQSC.
9. The Deputy Commissioner also recommended that Corrections and the pharmacy meet to discuss this report and any further issues identified, and report back to HDC.

Complaint and investigation

10. The Health and Disability Commissioner (HDC) received a complaint from Mr A about the services provided to him at the prison. The following issues were identified for investigation:
 - *Whether the prison provided Mr A with an appropriate standard of care between June 2016 and March 2017 (inclusive).*
 - *Whether Clendon Pharmacy Limited provided Mr A with an appropriate standard of care between June 2016 and March 2017 (inclusive).*
 - *Whether Dr B provided Mr A with an appropriate standard of care between June 2016 and March 2017 (inclusive).*
11. This report is the opinion of Kevin Allan, Deputy Commissioner, and is made in accordance with the power delegated to him by the Commissioner.
12. The parties directly involved in the investigation were:

Mr A	Consumer
Dr B	General practitioner (GP)/provider
Clendon Pharmacy Limited	Pharmacy/provider
Department of Corrections	Provider

13. Further information was received from:

Dr C	GP
District health board	

Also mentioned in this report:

Dr D	GP
RN E	Registered nurse
RN F	Registered nurse
Mr G	Pharmacist
RN H	Registered nurse

14. Independent expert advice was obtained from Registered Nurse (RN) Barbara Cornor (**Appendix A**) and from a pharmacist, Ms Sharynne Fordyce (**Appendix B**). In-house clinical advice was obtained from GP Dr David Maplesden (**Appendix C**).

Information gathered during investigation

Introduction

15. This report discusses the care provided to Mr A between June 2016 and March 2017 by the Department of Corrections, Clendon Pharmacy (the Pharmacy), and GPs Dr B¹ and Dr C,² while Mr A was an inmate at the prison and a patient of the prison's health centre. In his complaint, Mr A told HDC that a cardiologist at the public hospital told him that the health centre had inappropriately stopped his supply of clopidogrel,³ and that this cessation had caused the stents in his heart to become blocked, and put him in a life-threatening situation.

Corrections Health Service

16. Corrections provides primary healthcare to inmates, including GP services, nursing, and basic dentistry. The health centre is staffed by registered nurses who are employed by Corrections. Doctors are contracted by Corrections to provide medical care.

Clendon Pharmacy

17. The Pharmacy signed a contract with Corrections in 2015 to provide pharmacy services to several Corrections facilities, including the prison.

¹ Dr B was contracted by Corrections to supply medical practitioner services at the prison on a part-time basis. Dr B told HDC that he no longer provides these services at the prison.

² Dr C was contracted by Corrections to supply medical practitioner services at the prison on a part-time basis. Dr C told HDC that he still provides these services at the prison and he is still providing care for Mr A.

³ An antiplatelet medication used to reduce the risk of heart disease and stroke.

18. The Pharmacy told HDC that health centre staff order medication from the Pharmacy by faxing or emailing the Pharmacy an inmate's medication chart that has been signed by a medical practitioner. The Pharmacy stated:

"When the drug chart is forwarded to the pharmacy, it is accompanied by an order form which specifies which medications are to be dispensed; we then generate a prescription from these details for the prescriber to sign. At that stage the medication is released to the facility to allow it to be administered to the patient.

... The usual procedure is that we send the medications we process to the nurses so that they are checked against the charts before they are administered to patients. ... If there is any error or a medication change or any missing medication, then the pharmacy gets informed and the medications get redone accordingly and supplied as an urgent supply."

19. The Pharmacy also told HDC that it "supplies signing sheets to accompany all blister packs that are sent to [the prison]. Each time a blister pack is made, a new signing sheet is created to reflect the medications inside each pack along with the administration details." Signing sheets allow health centre staff or prison custodial staff to record the administration of medication to an inmate.

Mr A

20. Mr A became a patient of the health centre in April 2016. At the time, he had a history of chronic pancreatitis⁴ and gout.⁵ His regular medication included allopurinol⁶ and colchicine.⁷

Relevant policies and procedures in place at the time of events

21. Corrections' Health Services Health Care Pathway (the Corrections Pathway) stated:

"10.1 Policy on Creating Treatment Plans or a Plan of Care

- All patients who have health needs that are significant and/or complex in nature ... must have a Treatment Plan
- Patients who don't need a Treatment Plan must have a plan of care ... if they need clinical interventions"

22. The Pathway further provides that when a consumer is transferred to a Corrections facility from inpatient admission, then a plan of care must be developed if a treatment plan is not necessary (i.e., if the consumer does not have significant and/or complex health needs). Plans of care and treatment plans are to be completed in partnership with the consumer.

⁴ Inflammation of the pancreas.

⁵ A metabolic disease marked by a painful inflammation of the joints, deposits of urates in and around the joints, and usually an excessive amount of uric acid in the blood.

⁶ A medication that decreases high blood uric acid levels and is specifically used to prevent gout.

⁷ A medication used in the treatment of gout.

The Pathway states that interventions identified in the plans include health promotion and education.

23. Corrections' Health Services Medicines Policy and Procedure (Corrections' Medicines Policy) states:

"6.1.2 Recording Prescriptions

- All patients receiving medication must have a Health Services approved medication chart ...
- Prescriptions/medication charts must meet all legislative and professional requirements which include:
 - (i) being legible, indelibly printed, signed ...
 - (ii) Medication charts must be re-charted by the Medical Officer, if the medication chart is full, illegible, unclear, ambiguous or incomplete
 - (iii) Nurses must present the medication chart to the Medical Officer for re-charting if it is full, illegible, unclear, ambiguous or incomplete"

24. Corrections' Medicines Policy further states that if medication is given to an inmate to hold for self-administration, this must be recorded on the signing sheet.

25. The prison's Health Services Local Operating Manual (LOM) provides the following procedure for ordering medications:

"28-day Cycle Medications

- All medication charts with newly charted medications which need to be blister packed will be faxed to the pharmacy by the nurse on the day when the new medications are prescribed
- Pharmacy has records of all the Patient[s] and what blistered medications they are currently on.
- The pharmacy will regenerate prescriptions every four weekly for all long-term medications, until being noted about the stopping date.
- ...
- Delivered cycle medications and signing sheets will be checked against the current medication charts by the nurses
- ...
- Stopping of a medication, dose changing of a medication, Patient transfers and released is noted on the Pharmacy Ordering Sheet and is faxed to the pharmacy on a daily basis to ensure the 28-cycle information is updated daily.
- ...

Review and Signing of the repeated scripts

- The regenerated scripts will be sent in an envelope to the health centre.
- They are placed in the Health officer's folder for checking and signing against patients current medication chart.
- Signed scripts will be returned to the pharmacy."

26. Corrections also advised HDC that after a nurse has checked delivered medication and signing sheets against current medication charts:

"If the medication delivery is incorrect, the RN is obligated to immediately contact the pharmacy (via email) regarding the incorrect blister pack and send the incorrect medication back (via courier)."

Mr A's first hospital admission

27. On the morning of 17 June 2016, Mr A became dizzy while mopping. He then experienced sudden sharp chest pain and collapsed, hitting his head on the floor. Mr A lost consciousness for two to three minutes. After Mr A regained consciousness, prison guards noticed that he had weakness and facial droop on his right side, and slurred speech. At 11.30am he was seen by Dr C, who noted that Mr A had right-sided weakness and numbness, and slight right facial droop. Dr C gave Mr A glyceryl trinitrate⁸ (GTN) and aspirin.
28. An ambulance was called, and it arrived at the prison at 11.50am. Mr A was admitted to the public hospital at 12.51pm. He was diagnosed with a left middle cerebral artery⁹ subacute stroke,¹⁰ with secondary diagnoses of type 2 myocardial infarction¹¹ and triple vessel coronary artery disease.¹²
29. Mr A was discharged from the public hospital on 24 June 2016. The discharge summary advised Mr A to take aspirin for three weeks and clopidogrel long term. He was given a discharge prescription for a one-month supply of clopidogrel, among other medications.
30. The Pharmacy told HDC that it received the public hospital's prescription via fax on 24 June 2016, as well as an order form, which stated that Mr A had returned to the prison. The Pharmacy said that shortly after it received the fax, the health centre called requesting that the prescription be filled urgently. Later that day, the Pharmacy dispensed 28 tablets of clopidogrel.

⁸ A medication that relaxes the muscles surrounding blood vessels and so helps more blood and oxygen reach the heart.

⁹ This artery is one of the three major arteries that supply blood to the brain.

¹⁰ A stroke occurs when a blood vessel that carries oxygen and nutrients to the brain bursts or becomes blocked by a clot.

¹¹ A heart attack.

¹² A disease where the three main vessels in a person's heart are blocked.

June 2016 — prescription transcribing error

31. Mr A was seen by Dr B on 27 June 2016 for a post-discharge check. Dr B noted that Mr A was experiencing no further chest pain, and the weakness in his face and arm was settling, although the right side of his face was still slightly droopy. Dr B also recorded that Mr A was to receive “DAPT¹³ 1/12,¹⁴ then aspirin alone”. Dr B prescribed one month of clopidogrel for Mr A, along with long-term aspirin.
32. Mr A’s medication chart showed four entries dated 24 June 2016 with Dr B’s signature. Allopurinol, atorvastatin,¹⁵ and aspirin were entered as long-term medications, but clopidogrel was entered as a short-course medication for the period 24 June 2016 to 24 July 2016.
33. Dr B told HDC that when transcribing the prescription, he mistakenly transposed the lengths of time Mr A was to take aspirin and clopidogrel. Dr B stated:

“I have taken this prescribing error very seriously and have reflected upon how this happened. ...

I was unaware that a recent change had taken place in the recommendations for antiplatelet treatment. I was very familiar with the previous protocol where aspirin was continued and clopidogrel was prescribed in a short course. Therefore I believe that when I read the discharge summary I misread the instructions.”

July 2016 — clopidogrel dispensed

34. At 11.37am on 9 July 2016, the Pharmacy received a faxed order form from the health centre, which included a note stating that “clopidogrel [had been] crossed out on med chart in error” and requesting that the Pharmacy dispense the clopidogrel as per the hospital prescription. The public hospital’s discharge prescription dated 24 June 2016 was included with this fax. The medication chart, also sent with the order form, included clopidogrel as a short-term medication, as charted by Dr B on 24 June 2016. However, the medication chart also showed the clopidogrel entry struck out by hand, with the handwritten annotation “ERROR crossed out by mistake”. The annotation was undated and the writer was not identified.
35. At 12.19pm that day, the Pharmacy dispensed 28 clopidogrel tablets to the health centre for Mr A.
36. Along with the medication, the Pharmacy also provided a medication signing sheet to the health centre on 9 July 2016. The signing sheet was subsequently filled in by health centre staff, who recorded that Mr A was given his medication (allopurinol, atorvastatin, clopidogrel, and aspirin) daily during the period 11 July 2016 to 7 August 2016. The signing

¹³ Dual antiplatelet therapy, i.e., the combination of aspirin with a second antiplatelet medication such as clopidogrel.

¹⁴ For one month.

¹⁵ A statin medication used to lower lipid levels in the blood.

sheet also included a handwritten note that clopidogrel was “stopped 24/7/16”. The annotation was undated and the writer was not identified.

August 2016 — clopidogrel stopped

37. On 1 August 2016, the Pharmacy dispensed to the health centre 28 tablets of clopidogrel and other medication for Mr A. HDC has not been provided with a copy of the order form that the Pharmacy received from the health centre to order medication on this date.
38. On 5 August 2016, the Pharmacy received a faxed order form from the health centre that included a note in relation to Mr A that stated: “clopidogrel 75mg stopped on 24/7/16 THX”. The writer of the note is not identified. The medication chart that was sent to the Pharmacy along with this order form was the same medication chart sent to the Pharmacy on 9 July 2016.¹⁶ The Pharmacy told HDC that the health centre did not provide a new medication chart to confirm the stop that was requested in the order form.
39. On the same day, the Pharmacy dispensed to the health centre Mr A’s atorvastatin, aspirin, and colchicine, but no clopidogrel.

September 2016 — clopidogrel not dispensed

40. On 4 September 2016, the Pharmacy dispensed to the health centre Mr A’s atorvastatin, aspirin, colchicine, and allopurinol, but no clopidogrel.
41. On 14 September 2016, Mr A signed a contract with Corrections that allowed him to self-administer his medication. Under the contract, Mr A was able to hold up to seven days of his medication for self-administration. The contract listed Mr A’s medications as colchicine, allopurinol, atorvastatin, aspirin, and clopidogrel. The agreement was also signed by Dr D¹⁷ and RN E.

Mr A’s second hospital admission

42. At 3am on 17 September 2016, Mr A began to experience chest pain. He was seen later that morning by RN F. RN F documented that Mr A was experiencing sharp chest pain on his left side, shortness of breath, and mild dizziness. RN F performed an ECG¹⁸ and recorded his interpretation that the ECG showed a possible inferior myocardial infarction.¹⁹
43. RN F contacted Dr B, who advised that Mr A should be transferred to ED. RN F arranged for an ambulance, which arrived at 9.05am.

¹⁶ The medication chart included clopidogrel as a short-term medication, and also included the striking out of clopidogrel and the handwritten annotation “ERROR crossed out by mistake”.

¹⁷ At the time of events, Dr D was contracted by Corrections to supply medical practitioner services at the prison on a part-time basis.

¹⁸ An electrocardiogram, a medical test that detects heart problems by measuring the electrical energy generated by the heart as it contracts.

¹⁹ A heart attack. An inferior myocardial infarction specifically affects the inferior muscular tissue of the heart.

44. Mr A was admitted to the public hospital at 9.48am and diagnosed with ischaemic heart disease²⁰ alongside the pre-existing triple vessel coronary artery disease. He underwent percutaneous coronary intervention,²¹ and four drug-eluting stents²² were placed in his heart.
45. Mr A was discharged on 22 September 2016. The discharge summary advised that Mr A was to “continue both blood thinners (clopidogrel and aspirin) for 12 months followed by aspirin only”. The public hospital also provided a discharge prescription for clopidogrel for three months, as well as prescriptions for GTN, aspirin, and atorvastatin.
46. On 23 September 2016, Mr A was seen by Dr C. Dr C documented that Mr A had been prescribed “clopidogrel for 12/12”. Dr C told HDC that he added clopidogrel to Mr A’s existing medication chart²³ as a regular medication for a period of one year from 23 September 2016 to 23 September 2017. Dr C also noted that Mr A was to take aspirin long term.
47. On 23 September 2016, the Pharmacy dispensed to the health centre eight tablets of clopidogrel for Mr A. According to the Pharmacy, ten tablets should have been dispensed to cover from 23 September to 4 October 2016 (the start of the next medication cycle). The Pharmacy was unable to explain why only eight tablets were dispensed, as the order was processed by a staff member who had since left the Pharmacy.
48. The medication signing sheet that accompanied the clopidogrel showed lines through the dates 23 September to 30 September 2016, ostensibly to indicate the administration of medication. Corrections told HDC that Mr A self-administered clopidogrel between 24 and 30 September. However, there is no indication on the signing sheet that Mr A self-administered his medication.

November–December 2016 — Clopidogrel stopped again

49. On 4 October 2016, the Pharmacy dispensed to the health centre 28 tablets of clopidogrel for Mr A.
50. On 27 October 2016, the Pharmacy received a faxed order form from the health centre that included the typed annotation “Clopidogrel 70mg stopped on 23/9/16. Pls send a new whole blister cycle. Needs colchicine in mane²⁴ pack. Thx.” The writer of the note is not identified on the form, but Corrections told HDC that RN F signed the form to confirm

²⁰ Ischaemic heart disease is a condition where a waxy substance called plaque builds up inside blood vessels and restricts the normal flow of blood.

²¹ Percutaneous coronary intervention (formerly known as angioplasty with stent) is a procedure that uses a narrow tube called a stent to open up blood vessels in the heart that have narrowed as a result of plaque build-up.

²² A drug-eluting stent has been coated in medicine to prevent the blood vessel from forming scar tissue and closing around the stent.

²³ This medication chart included clopidogrel as a short-term medication as charted by Dr B, and also included the striking out of clopidogrel and the handwritten annotation “ERROR crossed out by mistake”.

²⁴ Morning.

receipt of the ordered medications. However, RN F was unable to advise who sent the order to the Pharmacy. Corrections told HDC that it appears that the charted stop date for clopidogrel of 23 September 2017 was misread as 23 September 2016.

51. On 3 November 2016, the Pharmacy dispensed to the health centre 28 tablets of clopidogrel for Mr A.
52. The medication signing sheet for October 2016 showed lines through the dates 3 October 2016 to 23 October 2016. The medication signing sheet for November 2016 showed lines through the dates 31 October to 27 November 2016. Corrections told HDC that Mr A self-administered clopidogrel from 3 to 23 October 2016, and from 31 October to 27 November 2016, but the signing sheets do not explicitly record this. There is also no record of medication administration for 1 and 2 October 2016, or for 24 to 30 October 2016.
53. Mr G, a pharmacist from the Pharmacy, told HDC that sometime in November 2016, the Pharmacy received a telephone call from someone at the health centre informing the Pharmacy that clopidogrel for Mr A had been stopped. Mr G said that following the telephone call, he raised a note²⁵ in the Pharmacy's electronic dispensing system recording that clopidogrel had been stopped for Mr A. Neither Mr G nor Corrections has been able to identify the person to whom Mr G spoke. In a statement to HDC, Corrections said that a nurse from the health centre recalled having a conversation with the Pharmacy about Mr A's colchicine, but does not recall a conversation about clopidogrel.
54. On 5 December 2016, the Pharmacy dispensed to the health centre Mr A's aspirin, atorvastatin, allopurinol, and colchicine, but no clopidogrel. The Pharmacy's dispensing records show that Dr D signed the prescriptions for these medications. In relation to clopidogrel not being dispensed on 5 December 2016, the Pharmacy stated:

"It is again accepted that there has been a deviation from the chart, which ought to have been detected by the Pharmacy. However (and without lessening the Pharmacy's error) it was reasonably expected that [the health centre] would also check dispensed medicines against the chart. This is part of their standard protocol ... As a result, when the December cycle of medications were not complete, it was expected that the Pharmacy would have been notified. This did not occur."

55. On 5 December 2016, RN H recorded on Mr A's signing sheet²⁶ for December 2016: "Awaiting clopidogrel order pharmacy 5/12/17 ordered." Corrections told HDC that RN H is unsure why she dated the note December 2017, when the record was for December 2016. RN H was unable to recall whether she ordered clopidogrel for that cycle from the Pharmacy and, if so, whether the clopidogrel arrived at the prison. Corrections told HDC that there is no documentation to confirm that clopidogrel was ordered past the end of November 2016.

²⁵ The pharmacy has been unable to provide HDC with a copy of the note or the exact date on which it was created.

²⁶ A copy of which was provided to HDC by Corrections.

56. The Pharmacy told HDC that after learning of these events in 2017, it obtained from Corrections a copy of the signing sheet for December 2016. The Pharmacy provided HDC with this copy, which is the same as that provided to HDC by Corrections, except that the Pharmacy's copy does not include the note from RN H about the clopidogrel order. The Pharmacy commented that this indicates that the signing sheet may have been altered subsequently.

Mr A's third hospital admission

57. On 7 December 2016, Mr A felt dizzy while in the yard at the prison. He was seen by Dr D, who documented that Mr A was taking clopidogrel, atorvastatin, aspirin, and allopurinol. Dr D undertook an ECG and noted: "Abnormal ECG — no chest pain." Dr D referred Mr A to ED at the public hospital.
58. Mr A was discharged from the public hospital on the same day with a diagnosis of "Presyncope²⁷ — potentially exacerbated by hot working conditions".

January–February 2017 — clopidogrel not dispensed

59. On 5 January 2017, the Pharmacy dispensed to the health centre Mr A's aspirin, atorvastatin, allopurinol, and colchicine, but no clopidogrel. The Pharmacy's dispensing records show that Dr D signed the prescriptions for these medications.
60. On 14 January 2017, the Pharmacy received a medication chart from the health centre that included clopidogrel as a long-term medication, as charted by Dr C, for the period 23 September 2016 to 23 September 2017. The chart still showed clopidogrel as a short-term medication, as charted by Dr B, and included the striking out of clopidogrel and the handwritten annotation that clopidogrel had been crossed out by mistake.
61. On the same day, the Pharmacy dispensed to the health centre for Mr A nine tablets each of aspirin, atorvastatin, and allopurinol, but no clopidogrel. The Pharmacy's dispensing records show that Dr D signed the prescriptions for these medications.
62. Mr G told HDC that the 14 January medication chart was sent to the Pharmacy to request that colchicine be stopped.²⁸ He added that the Pharmacy did not supply clopidogrel to the health centre after receiving this chart because "[clopidogrel] was not ordered and the Pharmacy only supplies medications that are ordered by the nurses at the Health Centre". Mr G also told HDC that "if a medication is missed due to any reason ... then the nurses notify [the Pharmacy] immediately and the Pharmacy remedies the problem and the missing medication is sent out urgently". Mr G said that this did not happen at this time.
63. On 3 February 2017, the Pharmacy dispensed to the health centre Mr A's aspirin, atorvastatin, allopurinol, and colchicine, but no clopidogrel. The Pharmacy's dispensing records show that Dr D signed the prescriptions for these medications.

²⁷ Feeling of light-headedness and faintness.

²⁸ HDC has not been provided with evidence that the health centre requested that colchicine be stopped on this date.

64. Corrections told HDC that on 11 February 2017, RN H noticed that clopidogrel was missing from Mr A's medication pack. According to Corrections, RN H faxed an order form to the Pharmacy to request that clopidogrel be restarted. However, neither Corrections nor the Pharmacy have provided HDC with a copy of this order form. Corrections also told HDC that RN H did not alert her manager or any colleagues that clopidogrel was missing.

Mr A's fourth hospital admission

65. At approximately 1.10pm on 21 February 2017, Mr A began to experience chest pain. He was seen by a health centre nurse at approximately 2.20pm. The nurse undertook an ECG and noted an inferior myocardial infarction. An ambulance was called and arrived at approximately 3pm. Mr A was admitted to the public hospital at 4.03pm.
66. While Mr A was in the public hospital, a pharmacist noted that Mr A had not received clopidogrel since 3 December 2016. Mr A was discharged on 22 February 2017 with a diagnosis of chest pain. The discharge summary noted: "[Mr A] has been provided with a script for [clopidogrel] (3 months supply) as he should have been on dual anti platelet therapy until 23/09/2017."
67. The health centre's clinical notes show that a pharmacist from the Pharmacy rang the health centre on 22 February 2017 to say that the Pharmacy had received a call from the public hospital asking why Mr A had not received clopidogrel for several months. The clinical notes also record: "Pharmacist [said] they didn't receive any notification that [Mr A] is on clopidogrel. As per the medtech notes and drug chart [Dr C] charted clopidogrel on 23/9/2017".²⁹
68. Later that day, the Pharmacy received the public hospital's prescription for clopidogrel and an order form from the health centre requesting urgent delivery of clopidogrel. The Pharmacy dispensed to the health centre 25 tablets of clopidogrel for Mr A.

Mr A's fifth hospital admission

69. At approximately 3.25pm on 24 February 2017, Mr A was seen by RN E regarding complaints of left-sided chest pain, shortness of breath, and "4 episodes of black outs since this morning". RN E undertook an ECG and noted a possible inferior myocardial infarction, and an ambulance was called. The ambulance collected Mr A from the prison at 4.40pm, and he was admitted to the public hospital at 6.03pm.
70. A medication history form completed while Mr A was in the public hospital recorded a comment that clopidogrel for Mr A "was last dispensed 03/11/2016 (1 month supply) then stopped in error — medication chart misread by community pharmacy".

²⁹ This date should read 23/9/2016.

71. An angiogram undertaken at the public hospital revealed significant coronary artery disease,³⁰ and Mr A underwent a balloon angioplasty³¹ to his right coronary artery. He was discharged from the public hospital on 28 February 2017.

Further information

Mr A

72. Mr A told HDC that in February 2017, the health centre told him that it was investigating the cessation of his clopidogrel. He said that he did not receive information about the outcome of the investigation, and it was not until he contacted and obtained support from the Nationwide Health and Disability Advocacy Service that the health centre provided him with a written response outlining the investigation into the matter.

Corrections

73. In a statement to HDC, Corrections said:

“We do wish to extend an apology to [Mr A] with regard to the lack of prompt communication with him in regard to this error and we recognise that the seriousness and the potential consequences of this error could have resulted in a vastly different outcome for [Mr A].”

74. Corrections accepted that the level of care provided to Mr A between June 2016 and March 2017 “fell short of [its] expected standards”. It also acknowledged that the medication charts used do not meet the expected standard. Corrections told HDC that as a result of these events, it is making, or has made, the following changes to the services provided at the health centre:

- A new medication filing system was introduced in May 2017.
- All correspondence between the Pharmacy and the prison is now via email, with all charts scanned and emailed to ensure a suitable audit trail.
- Clinical Governance meetings have been established and are held every six weeks at the prison to discuss any practice issues or current challenges.
- Work has commenced on moving to electronic prescribing.
- All patient medication charts are being reviewed and refreshed by medical officers so as to meet legislative requirements.
- A revised Healthcare Pathway policy has been implemented, and the expectations from health staff in relation to care plans have been clarified. Training on the new Healthcare Pathway policy is being provided to staff.

³⁰ A condition that reduces the blood flow through the coronary arteries to the heart muscle and typically results in chest pain or heart damage.

³¹ A procedure to open narrowed or blocked arteries caused by deposits of plaque.

- A new process is being implemented for nursing staff to be able to clearly identify and annotate on medication signing sheets when a medication is provided to a patient for self-administration.
- An audit schedule is being implemented that comprises weekly audits of a random sample of medication charts to check whether medication charts are compliant with legislative requirements and the health centre policy. It is also providing health centre staff with peer-led in-service training sessions on the top ten commonly prescribed medications.
- Further training relating to medication management will be implemented based on the findings of the above audit schedule.
- A monthly clinical quality meeting has been implemented where the health centre incident reports are discussed and reflected on as learning opportunities.
- A training session on Corrections' Incident Reporting Policy will be delivered to staff.
- It is exploring the options available to allow for electronic prescribing at the health centre.
- Work is being undertaken to secure permanent employment in the role of Assistant Health Centre Manager at the health centre.

Clendon Pharmacy

75. The Pharmacy stated that at the time of these events, it met with Corrections several times, and raised concerns about a number of matters, including unclear charts, messy order forms, and disorganised ordering processes. The Pharmacy told HDC that the supply contract with Corrections did not provide any framework for the processing of orders. The Pharmacy said:

“From the start of our contracted term with the Department of Corrections until June 2017, [health centre] Staff relied a lot on Phone and fax for communicating orders, changes, requests and urgent deliveries. This created endless problems as we could not trace some of these requests. ... We have always emphasised to [the health centre] the need to document all communication, and that emailing would be ideal ...”

76. As a result of the issues with Mr A's medication, the Pharmacy created its own standard operating procedure (SOP) for dispensing orders to the health centre. The SOP was implemented in May 2017. The Pharmacy also implemented a strict “No chart – No supply” policy.
77. The Pharmacy told HDC that for many months it had been requesting that any changes to medications be made in writing via email and signed by the prescriber. The Pharmacy stated:

“While not always best practice, the Pharmacy's actions were in accordance with Health Centre instructions. While this does not excuse their errors, the authority of the Health Centre when giving these instructions provides a clear explanation for the

Pharmacy's conduct. The Pharmacy must be able to rely on the instructions of the Health Centre to ensure prisoners are able to get their medication when required.

... The unfortunate event with [Mr A] has provided real impetus to making change. [Mr G] has noted this has required him to place the Prison under real pressure. He describes this as a 'turning point' in the relationship with Corrections. The communication issues which contributed to this incident will not be repeated."

Dr C

78. Dr C told HDC that from 23 September 2016, when he prescribed Mr A's clopidogrel, he "did not alter this medication or expect [Mr A] to miss any doses of this medication".

Dr B

79. Dr B told HDC that the main change he has made to his practice following these events is that he no longer works for the prison. He stated: "It was too much pressure of time trying to get as many prisoners seen as I could between lock-down periods [— it] was very difficult."

Responses to provisional opinion

80. Mr A, Corrections, Clendon Pharmacy, and Dr B were all given the opportunity to respond to the relevant sections of the provisional opinion.

Mr A

81. Mr A reiterated the enormous emotional and mental impact that these events had on him and his family.

Corrections

82. Corrections stated: "Corrections support your investigation and your provisional opinion." Corrections also acknowledged the proposed recommendations in the provisional opinion and provided an update on the work being undertaken to meet the recommendations.

Clendon Pharmacy

83. The Pharmacy accepted the provisional opinion and the proposed recommendations. It further stated:

"[T]he Pharmacy carefully considered its part in the event and [Mr G] has gone to significant lengths to ensure it does not occur again. Clendon Pharmacy has developed more comprehensive reporting methods and will continue to work on its systems, assisted by the recommendations proposed."

Dr B

84. Dr B did not wish to provide any further comment on the provisional opinion, but stated: "I am sorry for any problems [Mr A] may have suffered as the result of my misreading of the hospital letter."

Relevant standards

85. The Pharmacy Council of New Zealand (PCNZ) publication *Code of Ethics* (2011) (the PCNZ Code of Ethics) states that pharmacists must:

“1.2 Take appropriate steps to prevent harm to the patient and the public.

...

1.10 Where you have reasonable grounds to consider that a prescription contains any error, omission, irregularity or ambiguity or is not legitimate, or that a prescribed medicine could be detrimental to a patient’s health, consult with the prescriber and document the details and outcome.”

86. The Medical Council of New Zealand’s statement *Good prescribing practice*³² (the MCNZ Statement) provides:

“Preventing errors

9. When writing a prescription, avoid using abbreviations which might be misunderstood. A prescription must be legible, unambiguous and contain all the information necessary to ensure appropriate dispensing and compliance with all legislative and subsidy requirements...

13. There are often changes to a patient’s medicines when their care is transferred between health professionals or between care facilities. Transitions of care can result in medication errors and cause harm to the patient.”

Opinion: Introductory comments

87. Clopidogrel is an antiplatelet medication that is used in the prevention of stroke. It works by helping to prevent the formation of blood clots. As noted by my in-house medical advisor, Dr David Maplesden, at the time of these events, long-term clopidogrel was accepted first-line treatment for secondary prevention of stroke in patients without atrial fibrillation.³³ My expert nursing advisor, RN Barbara Cornor, noted that the risk of heart attack or stroke is increased if the consumer stops taking clopidogrel.
88. Mr A was first prescribed long-term clopidogrel by the public hospital after being discharged on 24 June 2016 with a primary diagnosis of stroke. He was incorrectly given this medication for only a month. It was not until Mr A was re-admitted to the public

³² November 2016 <https://www.mcnz.org.nz/assets/standards/eccbbf5a1/Statement-on-good-prescribing-practice.pdf>.

³³ Very rapid, uncoordinated contractions of the atria of the heart, resulting in a lack of synchronism between heartbeat and pulse beat.

hospital in September 2016 after suffering a heart attack, and having four stents placed in his heart, that he began receiving clopidogrel again. However, the clopidogrel was incorrectly stopped again after two months. Mr A did not receive clopidogrel again until February 2017, after he had been hospitalised a further three times.

89. Taking a step back from the details of this case, it is clear that systems and processes failed Mr A on multiple occasions and in multiple ways. There was inadequate communication and documentation, a lack of critical thinking, and poor compliance with policy by multiple providers. The care provided to Mr A fell well below the accepted standards.
90. The result of these failures was that Mr A did not receive the medication he needed to lower the risk of a heart attack or stroke and to help prevent his stents from becoming blocked. It is not possible to determine conclusively that Mr A's subsequent hospitalisations for blockages in his heart were a result of the incorrect cessation of his clopidogrel. It is nonetheless unacceptable that Mr A was unnecessarily exposed to a risk of harm. The failures that led to this exposure to risk are discussed below.

Opinion: Department of Corrections — breach

Introduction

91. The Corrections Act 2004 (the Act) states that “a prisoner is entitled to receive medical treatment that is reasonably necessary”. The Act requires that the “standard of health care that is available to prisoners in a prison must be reasonably equivalent to the standard of health care available to the public”. In addition, in accordance with the Code of Health and Disability Services Consumers’ Rights (the Code), Corrections has a responsibility to operate its health services in a manner that provides consumers with an appropriate standard of care.
92. As I have stated previously,³⁴ prisoners do not have the same choices or ability to access health services as a person living in the community. They do not have direct access to medication or to a GP. They are entirely reliant on the staff at Corrections’ health services to assess, evaluate, monitor, and treat them appropriately.

Nursing care

93. In my view, a number of failures by Corrections staff led to Mr A receiving care and treatment that was well below the acceptable standard of care. Many of the departures from the acceptable standard of care can be attributed to individual Corrections staff members. However, in my opinion these failures represent a pattern of poor care and were largely a result of broader systems issues at Corrections.

³⁴ 16HDC01922. Published February 2020.

94. Expert nursing advice was obtained from RN Barbara Cornor. Overall, RN Cornor commented that “serious communication, documentation [issues] and poor processes appear to be the downfall throughout this period”. For the reasons set out below, I agree with this comment.

No plan of care developed

95. Mr A was admitted to the public hospital on 17 June 2016 and discharged on 24 June 2016. Mr A’s diagnosis was left middle cerebral artery subacute stroke, with secondary diagnoses of type 2 myocardial infarction and triple vessel coronary artery disease. He was given a new prescription for clopidogrel and aspirin and was advised to take clopidogrel for a year.
96. Mr A was admitted to the public hospital again on 17 September 2016. While in the public hospital, four stents were placed in Mr A’s heart. He was discharged back to the prison on 22 September 2016, and was again given a prescription for clopidogrel and advised to take it for a year.
97. Mr A was admitted to the public hospital three more times between December 2016 and February 2017.
98. The Corrections’ Pathway provides that either a plan of care or a treatment plan be developed for all consumers who are transferred to a Corrections’ facility from inpatient admissions. A treatment plan is required for consumers with significant and/or complex health needs. A plan of care is required for consumers who do not require a treatment plan but do require clinical interventions. Both plans are to be developed in partnership with the consumer. HDC has not been provided with any evidence that either a treatment plan or plan of care was developed for Mr A after any of his hospital admissions between June 2016 and February 2017.
99. RN Cornor advised:
- “Following prescribing of clopidogrel, all clinical staff should be aware of and ensure a plan of care is implemented to support the observation of [Mr A], and/or ensuring he is aware of the consequences of this medication.”
100. In RN Cornor’s view, the failure to develop a plan of care for Mr A represented “a serious departure from Corrections Health policy and best practice”. In relation to the incorrect cessation of Mr A’s clopidogrel (discussed further below), RN Cornor also observed that if Mr A had been educated fully and had a good knowledge of his medicines, then he could have recognised the missing medication and reported it to staff.
101. I consider that following Mr A’s initial discharge from the public hospital in June 2016, he at least required a plan of care to ensure that the necessary clinical interventions (i.e., dual antiplatelet therapy with clopidogrel and aspirin) were carried out, and that his health needs were met appropriately. I therefore accept RN Cornor’s advice, and I am critical that no plan of care was created for Mr A.

102. Further, the Corrections Pathway required that the plan of care be developed in partnership with Mr A. This presented an important opportunity for health centre staff to educate Mr A about his health and the purpose and function of his medicines, and to empower Mr A to take an active role in managing his health. It is disappointing that this opportunity was missed owing to the failure to comply with the Corrections Pathway.

Documentation — medication chart

103. As noted above, clopidogrel was first prescribed for Mr A after he was discharged from the public hospital on 24 June 2016. Dr B (incorrectly) charted clopidogrel for a period of one month. At some stage after this, a health centre staff member struck out clopidogrel on Mr A's chart and then attempted to reinstate it by writing "ERROR crossed out by mistake".
104. The medication chart was the health centre's main record of the medications prescribed for Mr A. Corrections' Medicines Policy states that medication charts must be legible. It further states that the prescriber is responsible for completing a replacement medication chart when any medication chart is full, illegible, unclear, ambiguous, or incomplete. However, health centre staff are responsible for presenting any medication chart that is full, illegible, unclear, ambiguous, or incomplete to the prescriber for a replacement chart.
105. RN Cornor commented:

"[Mr A's] medication chart is at times illegible, untidy, has minimal recognizable names and signatures and is very difficult for the writer to understand. Medication charts provided contain an area of signing register which indicates the 'full name' or 'initial' of the signatory be provided. The majority of these do not contain a full name of the health professional, their status (MO³⁵ or RN) and/or are indecipherable and is a departure from local policy and/or legislative requirements."

106. In relation to the striking out and attempted reinstatement of clopidogrel, RN Cornor commented:

"This begins a process which has led to confusion and mixed messages, has never been queried and results in a serious departure of legislative [requirements], and local policy and a threat to the patient's health status."

107. RN Cornor further advised:

"The confusion and the risk put to the prisoner which followed after the original prescribing and cross out, sees all Registered Nurses at fault and responsible for a serious departure from expected practice for neither recognizing, reporting nor requesting an amendment. It is the responsibility of all Registered Nurses to ensure their own professional safety. Incorrect documentation causing confusion and/or mixed messages and putting a patient at risk is one of these."

³⁵ Medical officer.

108. I accept RN Cornor's advice. It is not possible to identify the individual responsible for the crossing out and reinstating of clopidogrel. However, given that Mr A had other medications that were being ordered from the Pharmacy even when clopidogrel was stopped, I consider it more likely than not that multiple health centre staff members would have seen Mr A's chart. Yet despite the ambiguity presented by the struck out and "reinstated" clopidogrel, and the overall illegibility of the chart as described by RN Cornor, apparently not one staff member thought to request a replacement chart. In my view, this failure shows a concerning lack of critical thinking about the risk to Mr A presented by the ambiguous and illegible medication chart. It also represents a widespread failure to comply with Corrections' Medicines Policy.

Documentation — administration of medication

109. Corrections provided HDC with medication signing sheets for the period July 2016 to March 2017. None of the signing sheets explicitly record whether Mr A was given medication to self-administer, or whether health centre staff administered the medication to Mr A. There were also several gaps, specifically 1 to 2 October 2016, and 24 to 30 October 2016, where there is no record of medication administered to Mr A.
110. I note that Corrections' Medicines Policy clearly requires that when medication is given to a consumer to hold for self-administration, this is recorded on the signing sheet.
111. RN Cornor advised that the lack of record of whether or not medication was given to Mr A to self-administer is "a departure from practice and if the medicines are signed as delivered to [Mr A's] unit, the signature needs to indicate that, rather than medication given".
112. I accept RN Cornor's advice. In accordance with Corrections' Medicines Policy, the signing sheets should clearly reflect how medication was given to Mr A. I am critical that the signing sheets are lacking this important detail, and also that there are gaps in the dates covered.

Communication with Clendon Pharmacy

113. When ordering medications, health centre staff sent both an order form and a medication chart to the Pharmacy. On 5 August 2016, four days after the Pharmacy dispensed clopidogrel to the health centre for Mr A, the Pharmacy received a faxed order form from the health centre. The order form included a note stating that Mr A's clopidogrel had been stopped on 24 July 2016. The writer of the note is not identified on the form. In response, later that day the Pharmacy dispensed Mr A's medications without clopidogrel.
114. After Mr A was re-admitted and discharged from the public hospital in September 2016, the Pharmacy dispensed clopidogrel for Mr A on 23 September 2016 and 4 October 2016. On 27 October 2016, the Pharmacy received a faxed order form that included a note stating that Mr A's clopidogrel had been stopped on 23 September 2016, and requesting a new blister pack of medications. The writer of the note is not identified on the form.

115. The Pharmacy dispensed clopidogrel for Mr A on 4 November 2016. Mr G told HDC that sometime in November 2016, the Pharmacy received a telephone call from someone at the health centre, informing the Pharmacy that clopidogrel for Mr A had been stopped. Following this call, Mr G noted in the Pharmacy's electronic dispensing system that Mr A's clopidogrel had been stopped. Neither Mr G nor Corrections has been able to identify the person to whom Mr G spoke. The Pharmacy did not dispense clopidogrel in December 2016.
116. According to the signing sheet for December 2016, RN H appeared to recognise that clopidogrel was missing from Mr A's medications. RN H's note on the signing sheet indicated that the missing clopidogrel was ordered, yet Corrections told HDC that there is no evidence to show that clopidogrel was ordered beyond the end of November 2016. I also note the Pharmacy's comment that the copy of the signing sheet it obtained from Corrections in 2017 did not include the note from RN H about the missing clopidogrel.
117. In relation to the process by which the health centre ordered medications from the Pharmacy, RN Cornor advised:
- "[T]his process has caused unnecessary confusion, frustration, and is time wasting for the health staff and the pharmacists. It is not normal practice for prescriptions provided by Medical Officers to be 'transcribed' to an 'Order Form'.
- ... The 'order form' was used to stop, restart and stop again the clopidogrel, [and] although some were signed, the signature is illegible ..."
118. I agree with RN Cornor's comments and I am critical of the poor standard of communication with the Pharmacy by health centre staff about Mr A's medications. Communication was inconsistent and poorly documented, and staff rarely identified themselves on the order forms. This made it difficult to determine who communicated with the Pharmacy and when. In my view, the poor communication unnecessarily created the risk for errors to be made when Mr A's medications were ordered.
119. For completeness, I note that it is not possible to determine when the note by RN H was added to the December 2016 signing sheet. However, the fact that the Pharmacy has a copy without the note does, in my view, raise the concerning possibility that it was added at a later stage.

GP care

120. As discussed below, there were also inadequacies in the GP care provided to Mr A. Specifically, there were issues with the charting and prescribing of clopidogrel for Mr A.
121. Mr A was discharged from the public hospital on 22 September 2016 with four newly placed stents in his heart. His existing medication chart was updated the next day to include clopidogrel as a regular medication for a period of one year from 23 September 2016 to 23 September 2017. At this stage, Mr A's medication chart included two entries for clopidogrel — the first entry was as a short-term medication, which was later struck

out and hand annotated with “ERROR crossed out by mistake”, and the second was as a regular medication.

122. Corrections’ Medicines Policy provides: “Medication charts must be re-charted by the Medical Officer, if the medication chart is full, illegible, unclear, ambiguous or incomplete.” Similarly, the MCNZ Statement requires that a prescription must be unambiguous.
123. In my view, having two different entries for clopidogrel meant that Mr A’s chart was ambiguous and confusing, and created the very real risk that Mr A’s medication needs could be misinterpreted. The risk of misinterpretation was compounded by the first clopidogrel entry being struck out and “reinstated” with the handwritten annotation.
124. In my opinion, the GPs should have acted to address the risk of misinterpretation of Mr A’s medication needs. As required by Corrections’ Medicines Policy, a replacement medication chart should have been completed. This step may have mitigated the risk of harm to Mr A.
125. In addition, after the supply of clopidogrel was again incorrectly discontinued in December 2016, the Pharmacy continued to send prescriptions to the health centre for Mr A’s other medications, for signing by the medical officers. Specifically, prescriptions were signed in December 2016, and in January and February 2017, for medications not including clopidogrel.
126. The LOM requires medical officers to check prescriptions received from the Pharmacy against the consumer’s current medication chart before signing. It is not clear whether the GPs adhered to this requirement, but the fact that there was no recognition that prescriptions for the charted clopidogrel were missing suggests that they did not. This apparent lack of care taken with Mr A’s prescriptions is concerning.
127. I also note that there were missed opportunities for doctors to identify that Mr A had not been receiving clopidogrel. On 14 September 2016, Mr A signed a contract with Corrections that allowed him to self-administer his medication. The contract included clopidogrel as one of Mr A’s regular medications. However, he was not receiving clopidogrel at this point, as Dr B’s prescription was for a one-month period only (24 June to 24 July 2016). The contract was also signed by a second GP and a registered nurse. It is disappointing that the medications listed in the self-administration contract were apparently not checked against Mr A’s current prescriptions, as this would have revealed the clopidogrel inconsistency. This may well have led to Mr A receiving clopidogrel again.
128. The GPs are responsible for the care they provided to Mr A. However, at the time of these events they were contracted by Corrections to provide GP services to prisoners at the facility and, ultimately, Corrections was responsible for the medical care provided to Mr A.

Conclusion

129. As set out above, there were a number of failures by a number of Corrections staff:

- There was no plan of care developed for Mr A following any of his hospital admissions.

- Mr A's medication chart was ambiguous and at times illegible and difficult to follow, and Corrections staff failed to present his chart for replacement.
- The signing sheets for Mr A's medications did not record whether Mr A was given medication to self-administer, and there were gaps in the dates covered.
- There was a poor standard of communication with the Pharmacy in respect of Mr A's medications.
- There were inadequacies in the care provided to Mr A by a number of GPs, for which Corrections was ultimately responsible.

130. In my view, the above failures also represent a pattern of poor compliance with Corrections' policy and a concerning lack of critical thinking, which contributed to Mr A not receiving his clopidogrel medication as intended.
131. Mr A had no control over his access to medication, which he was prescribed to reduce his risk of suffering a stroke. Mr A was reliant on the staff at Corrections to provide him with adequate care. It is unacceptable that they did not do so. Ultimately, Corrections was responsible for the delivery of services to Mr A by its staff. I consider that Corrections failed to ensure that Mr A was provided services with reasonable care and skill, and, accordingly, that Corrections breached Right 4(1) of the Code.

Information about outcome of the health centre investigation — adverse comment

132. Mr A told HDC that in February 2017 the health centre told him that it was investigating the cessation of his clopidogrel. However, it was not until Mr A contacted and obtained support from the Nationwide Health and Disability Advocacy Service that the health centre provided Mr A with a written response outlining its investigation.
133. Corrections acknowledged and apologised to Mr A about the lack of prompt communication with him.
134. Given the significance of the incorrect cessations of Mr A's clopidogrel, it is disappointing that the health centre was not more forthcoming in communicating with Mr A about the error.

Opinion: Clendon Pharmacy Limited — breach

August 2016 — dispensing without confirmation from medication chart

135. On 24 August 2015, the Pharmacy contracted to provide pharmacy services to the prison.
136. On 24 June 2016, the Pharmacy received via fax a copy of Mr A's public hospital prescription for one month's supply of clopidogrel. The Pharmacy dispensed clopidogrel to the health centre for Mr A later that day.

137. On 9 July 2016, the Pharmacy received a faxed order form from the health centre. The form included a note stating “clopidogrel crossed out on med chart in error” and requesting that the clopidogrel be dispensed as per the public hospital’s prescription (which was for one month of clopidogrel). The medication chart sent with the order form included clopidogrel as a short-term medication, as charted by Dr B on 24 June 2016. The medication chart also showed the clopidogrel entry struck out, with the handwritten annotation “ERROR crossed out by mistake”. Later that day, the Pharmacy dispensed clopidogrel for Mr A.
138. On 1 August 2016, the Pharmacy dispensed to the health centre 28 tablets of clopidogrel and other medications for Mr A. HDC has not been provided with a copy of the order form that the Pharmacy received from the health centre to order medication on this date.
139. My expert pharmacist advisor, Sharynne Fordyce, noted that the last charted supply of clopidogrel, signed by Dr B, ended on 24 July 2016. Ms Fordyce advised:
- “The standard of care/accepted practice would therefore be to confirm the stopping of the medication with the prescriber. Confirmation of continuation of the medication should also come from the prescriber, with a copy of an up to date chart, to confirm continuation of supply.”
140. In Ms Fordyce’s view, the Pharmacy’s dispensing of clopidogrel on 1 August 2016 unsupported by a current medication chart is a severe departure from accepted practice. I accept Ms Fordyce’s advice. I acknowledge that the intention of the public hospital’s treatment plan was that Mr A would take clopidogrel long term, and that by dispensing further clopidogrel, the Pharmacy was giving effect to that intention. However, the Pharmacy did not have a medication chart to support the dispensing of clopidogrel beyond 24 July 2016, and the public hospital prescription that was provided to the Pharmacy was for one month only.
141. I therefore accept Ms Fordyce’s advice. I am critical that the Pharmacy dispensed clopidogrel without a current medication chart or other confirmation from the prescriber that this medication should be supplied.

December 2016 — discontinuation of clopidogrel supply

142. After Mr A’s hospital admission in September 2016, Dr C charted clopidogrel as a long-term medication for a period of one year from 23 September 2016 to 23 September 2017. The Pharmacy dispensed clopidogrel for Mr A on 4 October 2016. On 27 October 2016, the Pharmacy received a faxed order form from the health centre that included a note stating that Mr A’s clopidogrel had been stopped on 23 September 2016, and requesting a new blister pack of medications. The writer of the note is not identified on the form.
143. Nonetheless, the Pharmacy dispensed clopidogrel for Mr A on 4 November 2016, in accordance with the medication chart. Mr G told HDC that the Pharmacy received a telephone call sometime in November 2016 from someone at the health centre, informing the Pharmacy that clopidogrel for Mr A had been stopped. Mr G said that following the

call, he noted in the Pharmacy's electronic dispensing system that clopidogrel had been stopped for Mr A. Neither Mr G nor Corrections has been able to identify the person to whom Mr G spoke. The Pharmacy did not dispense clopidogrel in December 2016.

144. Ms Fordyce advised:

"Given the importance of the medication ... and the previous misunderstandings about its supply, written or spoken authority from the prescribing doctor would be required, and a new chart supplied to reflect the change.

... There has been a severe departure from providing the correct standard of care in this scenario ... No action should have been taken without consulting the prescribing doctor, and being supplied with the appropriate chart indicating the date for the medication to be stopped."

145. The PCNZ Code of Ethics requires pharmacists to consult with prescribers to clarify potentially ambiguous prescriptions, and to take appropriate steps to prevent harm to a consumer. In my view, the discrepancy between the charted clopidogrel and the orders from health centre staff to discontinue clopidogrel created sufficient ambiguity. I also consider that stopping clopidogrel in these circumstances, without clarifying this with the prescriber, created a risk of harm to Mr A.

146. I therefore accept Ms Fordyce's advice and I am critical that the Pharmacy stopped dispensing clopidogrel for Mr A and failed to consult with the prescriber. I acknowledge the Pharmacy's comment that it should be able to rely on the instructions of health centre staff, and I accept that there were issues with the standard of communication from the health centre's staff to the Pharmacy (discussed above). However, I do not consider that these issues absolve the Pharmacy of its responsibility for taking appropriate steps to prevent harm to Mr A.

January 2017 — not dispensing clopidogrel

147. The Pharmacy told HDC that on 14 January 2017 it received a medication chart along with a request that Mr A's colchicine be stopped. The medication chart included clopidogrel as a long-term medication, as charted by Dr C, and also included clopidogrel as a short-term medication, as charted by Dr B. The Pharmacy said that the health centre did not order clopidogrel when it sent this chart, so clopidogrel was not dispensed.

148. Ms Fordyce advised:

"Despite the lack of provision of an order form specifying clopidogrel, the Pharmacy did have a medication chart, signed and dated by a doctor requesting (among others) clopidogrel. This alone, given the repetitive and contentious nature of the supply of this medication, should have been enough to prompt an enquiry from the Pharmacy to the prison service for confirmation of what medication was needed. This was not done."

149. In Ms Fordyce's view, the failure of the Pharmacy to enquire as to what medication was needed was a severe departure from accepted practice. In mitigation, I note the Pharmacy's comments that it would have expected to be told by health centre staff if any medications were missing from an order. I also note that Corrections has confirmed that if a medication delivery is incorrect, the nurse who checks the delivery is obligated to contact the Pharmacy immediately. It was therefore reasonable for the Pharmacy to expect to have been told that clopidogrel was missing from its previous deliveries.
150. However, I nonetheless share Ms Fordyce's view that it was unwise for the Pharmacy not to make further enquiries with the prescriber when it received the medication chart on 14 January 2017, given the historical issues with this medication for Mr A.

Lack of policy

151. The Pharmacy told HDC that it did not have a specific protocol or policy in place to guide the service it was providing to the health centre. However, since this incident, the Pharmacy has developed a dedicated standard operating procedure (SOP) for its dispensing to the health centre.
152. Ms Fordyce considered that the Pharmacy's lack of an SOP at the time was a severe departure from accepted practice. She commented that the lack of policies in place for the health centre "increases the pressure on [Mr G] and his staff to provide an accurate professional service, and increases the likelihood of such incidents occurring".
153. I note the Pharmacy's comments that the supply contract with Corrections did not provide any framework for the processing of orders, and that it had met with Corrections several times to discuss concerns about the disorganised processes. However, in my view, the Pharmacy should have acted earlier to ensure that it had the appropriate internal procedures in place for processing orders from Corrections, so as to address the increased risk of errors created by the lack of formalised arrangements with Corrections. I therefore accept Ms Fordyce's advice and I am critical of the Pharmacy's lack of procedures at the time.
154. However, I commend the Pharmacy for having since developed a detailed and dedicated SOP for the service it provides to the health centre. In my view, this change was necessary and appropriate to ensure that similar issues do not happen again.

Conclusion

155. As set out above, there were a number of deficiencies in the services provided to Mr A by the Pharmacy:
- Clopidogrel was dispensed in August 2016 without a current medication chart or other confirmation from the prescriber that this medication should be supplied.
 - The Pharmacy discontinued clopidogrel in December 2016 despite clopidogrel being charted until 23 September 2017.

- The Pharmacy did not make further enquiries with the prescriber when it was sent a medication chart in January 2017 that showed clopidogrel charted until 23 September 2017.
- At the time of these events, the Pharmacy had no internal procedure in place for processing orders from Corrections.

156. In my view, these deficiencies represent a pattern of suboptimal care, which put Mr A at risk. I therefore consider that the Pharmacy failed to ensure that Mr A was provided services with reasonable care and skill, and, accordingly, that the Pharmacy breached Right 4(1) of the Code.

Opinion: Dr B — breach

157. Mr A was discharged from the public hospital on 24 June 2016 with a diagnosis of left middle cerebral artery subacute stroke, and secondary diagnoses of type 2 myocardial infarction and triple vessel coronary artery disease. The discharge summary advised Mr A to take aspirin for three weeks and clopidogrel long term.

158. Three days later, Dr B saw Mr A for a post-discharge check-up. Dr B documented that Mr A was to receive dual antiplatelet therapy for one month, and then aspirin alone. Dr B prescribed one month of clopidogrel for Mr A, along with long-term aspirin.

159. Mr A's medication chart at the time shows that clopidogrel was entered as a short-course medication for a period of one month from 24 June 2016 to 24 July 2016. Dr B's signature accompanied this entry.

160. Dr B told HDC that when transcribing the public hospital's prescription, he mistakenly transposed the lengths of time Mr A was to take aspirin and clopidogrel.

161. My in-house clinical advisor, Dr David Maplesden, advised that "[Dr B] was responsible for ensuring the medication he was prescribing for [Mr A] was appropriate". Dr Maplesden further commented:

"I believe that a clinician reading [Mr A's] discharge summary dated 24 June 2016 should have no doubt that DAPT was being prescribed for secondary prevention of stroke in the first instance, and that clopidogrel was to be continued long-term with aspirin stopped after three weeks (one month total treatment).

... I think the prescribing error would be regarded as at least a moderate departure from accepted practice given the instructions in the discharge summary and accepted practice for secondary prevention of stroke at the time."

162. I note the MCNZ Statement to which Dr Maplesden refers:

“There are often changes to a patient’s medicines when their care is transferred between health professionals or between care facilities. Transitions of care can result in medication errors and cause harm to the patient.”

163. I am critical that Dr B incorrectly transcribed the public hospital’s prescriptions for clopidogrel and aspirin. This error suggests that he did not read Mr A’s discharge summary with sufficient care. As noted in the MCNZ Statement, transitions of care between clinicians can result in medication errors and, consequently, harm to consumers. In my view, Dr B needed to be alert to the risk of a medication error in these circumstances, and to take care when transcribing the prescription for Mr A.
164. I accept Dr Maplesden’s advice that Dr B’s prescription transcribing error represents at least a moderate departure from accepted practice. His error contributed to the fact that Mr A did not receive clopidogrel for as long as was intended. I therefore find that Dr B failed to provide services to Mr A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.
-

Recommendations

165. I note the significant actions taken by Corrections to improve medication management since the time of these events. I welcome these actions. My recommendations below are made taking into account these actions.
166. In response to the recommendation in my provisional opinion, Corrections provided a written letter of apology to Mr A for the failures identified in this report. The apology has been forwarded to Mr A.
167. I recommend that Corrections:
- a) Arrange for an independent external review of the level of GP cover provided at the prison to advise on whether it is adequate and meets the requirements of section 75 of the Corrections Act 2004, and whether any changes are necessary. Corrections is to provide HDC with a report with the result of the review, and any actions taken or agreed as a result of it, within six months of the date of this report.
 - b) Report back to HDC on its project to implement an electronic medication administration system at the health centre, within nine months of the date of this report.

- c) Provide a report to HDC on:
- (i) its implementation of the new process for nursing staff to clearly identify and annotate on medication signing sheets when a medication is provided to a patient for self-administration (referred to in paragraph 74 of this report); and
 - (ii) its consideration of whether the new process should involve consumers signing the medication signing sheets to confirm that they have received their medications.

The report is to be provided to HDC within six months of the date of this report.

- d) Review a sample of recent discharges from hospital to the prison over the previous six months, to confirm that the appropriate plans of care or treatment plans are in place. Corrections is to report back to HDC on the results of its review, and any further improvements identified, within six months of the date of this report.
- e) In response to the recommendation in my provisional opinion, Corrections has advised HDC that the review of medications by medical officers has been completed. Corrections is to provide HDC with a random selection of three audit reports from the previous three months of its audit schedule of medication charts within six months of the date of this report.

168. In response to the recommendation in my provisional opinion, Corrections has advised HDC that it appointed a permanent assistant manager for the health centre in 2019.

169. I recommend that Clendon Pharmacy Limited:

- a) Provide a written apology to Mr A for the failures identified in this report. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mr A.
- b) Undertake a random audit of its dispensing to the health centre for 30 consumers to confirm that the dispensing was supported by a current chart and prescription. The Pharmacy is to report back to HDC with the results of its audit within six months of the date of this report.
- c) Develop an anonymised case study, based on this report, and use this case study as the basis of training for staff, including on the need for medication charts and prescriptions to support dispensing of medication. The Pharmacy is to provide HDC with a copy of the case study, and report back on the training it provided to staff, within six months of the date of this report.
- d) Share its anonymised case study with HQSC. The Pharmacy is to provide confirmation to HDC that it has satisfied this recommendation within six months of the date of this report.

170. I recommend that Corrections and the Pharmacy meet to discuss this report and to identify whether the report highlights any further issues and, if so, potential solutions to address these issues. Corrections and the Pharmacy are to provide a joint report to HDC outlining the result of this meeting, within six months from the date of this report.
-

Follow-up actions

171. The Department of Corrections will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken.
172. A copy of this report with details identifying the parties removed, except the Department of Corrections, Clendon Pharmacy Limited (trading as Clendon Pharmacy) and the experts who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name.
173. A copy of this report with details identifying the parties removed, except the Department of Corrections, Clendon Pharmacy Limited (trading as Clendon Pharmacy) and the experts who advised on this case, will be sent to the Office of the Ombudsman, the Pharmacy Council of New Zealand, and the Health Quality & Safety Commission, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.
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Addendum

174. Following negotiations with the Department of Corrections, the Director of Proceedings filed proceedings by agreement in the Human Rights Review Tribunal. The Tribunal issued a declaration that Corrections breached Right 4(1) of the Code by failing to provide services to Mr A with reasonable care and skill.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from RN Barbara Cornor:

“Barb Cornor

Registered Nurse, Masters Nursing

NZ Nursing Council 051169

Complaint: Care of [Mr A]

Ref: C17HDC01348

I have been asked to review enclosed documentation and advise whether I consider the nursing care provided to [Mr A] by [the prison] of the Department of Corrections was reasonable in the circumstances, and why.

Understanding Clopidogrel Medication

Clopidogrel is used to prevent blood clots especially in those with frequent chest pain, peripheral artery disease, heart attack or stroke. It may be used as part of a combination therapy and it may need to be taken with other medicines. It belongs to a class of medicines called platelet inhibitors. Platelets are blood cells that help blood clot normally. Clopidogrel helps prevent platelets from sticking together and forming blood clots.

Side effects: Clopidogrel oral tablet can cause mild or serious side effects. The more common side effects that can occur with clopidogrel include bleeding and itchy skin. Serious side effects can include unexplained bleeding or bleeding that lasts a long time. Bleeding can be seen in urine, stools, unexplained bruising, coughing up or vomiting blood. A blood clotting problem can occur called thrombocytopenic purpura (TTP) when taking Clopidogrel and can occur as early as two weeks after commencement. Symptoms of this are purplish spots on skin or gums, jaundice, tiredness or weakness.

Serious bleeding warning: This medicine can cause serious and sometimes fatal bleeding. Clopidogrel may cause bleeding and bruising more easily, eg nosebleeds, and it will take longer than usual for bleeding to stop. Patients should be advised to report any serious bleeding, such as unexplained, prolonged, or excessive bleeding, blood in the urine or stools immediately.

If the patient stops taking the medicine or doesn't take it at all: there is an increase in risk of heart attack or stroke. Stopping this medicine may increase the risk of serious heart conditions, stroke, or a blood clot in the legs or lungs. These conditions can be fatal.

Warning for surgery or procedure: Before having any procedures done, patients are advised to tell their doctor or dentist they are taking clopidogrel as it may need to be stopped for a short time before a procedure, to prevent bleeding. The doctor will advise when to stop Clopidogrel when it is used for long-term treatment. It comes with very serious risks if not taken as prescribed.

If the patient misses a dose or doesn't take the medicine on schedule: the medication may not work as well or may stop working completely. For this medicine to work well, a certain amount needs to be in the body at all times.

NATIONAL AND LOCAL NURSING STANDARDS, GUIDELINES, & POLICY RELEVANT TO THIS REVIEW

Nursing Council New Zealand Standards and Guidelines for Nurses

4.3.4 Documentation

All medicines administration must be documented in the medicines record or chart.

Such documentation should occur simultaneously with administration and be legible, accurate and meet legislative and organisational requirements, as well as any specific policy requirements of the facility.

The medicines chart should contain, at a minimum, the complete name and date of birth of the person. People with similar or the same names must have alerts written on their charts. Use of the NHI is also recommended.

The medicines chart should have a separate section for pro re nata (PRN) or 'as required' medicines; nurse-initiated medicines (see section 6.7); once only doses of medicines; medicines which are self-administered; any complementary, alternative or self-prescribed medicines being taken; and emergency telephone/facsimile/email instructions.

The medicines chart should also note any allergies or previous adverse drug reactions; and indicate when a review of the client's medicines is required.

If alternative methods of administering medicines are appropriate, eg crushing or dispersing tablets, this should also be indicated on the medicines chart.

Nurses should be aware of the medicines which can or cannot be reconstituted for administration.

4.2 Dispensing medicines

Dispensing is defined as the preparation of a medicine for sale to the public (whether in response to the issue of a prescription or a request by an individual to be supplied with the medicine) and the packaging, labelling, recording, and delivery of that medicine (Medicines Act, 1981).

4.2.1 Which health professionals can dispense?

The Medicines Regulations outline *'no person other than an authorised prescriber, veterinary surgeon, pharmacists, pharmacy graduate, a pharmacy technician, a [pharmacist] student, or dispensary technician may dispense a prescription medicine'* (Medicines Regulations 1984 42(1)).

Nurses must **NOT** tamper with a seal on a monitored dosage system between its closure by the pharmacist and time of administration.

Nursing implications

- Dispensing activities **must** be avoided by nurses.
- If a nurse is exposed to dispensing situations, s/he must alert the manager/employer. The manager/employer has a responsibility to determine protocols and provide resources to deal with dispensing activities and these.

5.3 The pharmacist

- Checks the prescription is written correctly (to avoid misunderstanding or error) and is signed by an authorised designated prescriber
- Refuses to dispense any medicine where the form of the prescription is incorrect
- Checks that any newly prescribed medicines will not have adverse interactions with current medicines
- Provides the medicine in a form relevant for administration to the particular client, in an appropriate container, and gives relevant information and advice on storage and security conditions.

5.3 The registered nurse

- understands the legislative and professional/ethical issues outlined in these guidelines, including the standards outlined in appendix one
- must report concerns about risks in the medication process to management and the prescriber
- is aware of, and complies with, agency policies regarding the preparation and checking of medicines

6.5 Monitored dosage dispensing

- Monitored dosage systems (also known as compliance packaging aids, i.e. blister packs, dispensing boxes, dosette boxes, and sachets) are systems for supplying and dispensing medicines prepared by a community pharmacist.
- These systems involve dispensing a client's medicine into a special container, with sections for days of the week and times within those days.
- The supply of the medicines in a special container or blister packs must be accompanied by the appropriate prescription information to the hospital/ARC/ domestic residence.
- Systems must meet criteria established by Medsafe.

- To be acceptable for use in hospital/ARC/domestic residence, the containers for the medicine must:
 1. be filled by a pharmacist and sealed by them, or under their control and delivered complete to the medicine administrator or user;
 2. be accompanied by clear and comprehensive documentation which forms the authorised prescriber's prescription;
 3. be able to be stored in a secure place;
 4. have a structure that makes it apparent if the containers (blister packs, space within a container or sachets) have been tampered with between the closure and sealing by the pharmacist and the time of administration.

6.5.1 Nursing implications

- The introduction of a monitored dosage system transfers to a pharmacist the responsibility for being satisfied the container is filled and sealed correctly to comply with the prescription. This does not alter the fact the RN administering the medicines must still consider the appropriateness of each medicine at the time of administration.
- It is **not acceptable**, in lieu of a pharmacist-filled monitored dosage system container, for a health provider to transfer medicines from their original containers into an unsealed container for administration at a later stage. This is a dispensing activity (see section 5.3 for further detail).
- It is also **not acceptable** to interfere with a sealed section of a monitored dosage system at any time between its closure by the pharmacist and the scheduled time of administration, eg opening a sealed blister pack section, adding a charted antibiotic and taping over the section.
- Where it is not possible for the boxes to be filled and sealed before supplying to the client, the nurse should mark the container with the day and time the medicines are to be taken only, rather than with the name of the medicine.
- The client should be well instructed (preferably in writing in addition to verbal instructions) on the name of the medicine and should be given any information regarding taking it, side effects, and relevant contra-indications (Keenan, 2016, p.309).
- There are potential difficulties associated with individual medicine identification by staff in a monitored dosage system. For example, it may be necessary to withhold a specific tablet such as digoxin. The employer, nurses, doctors, and the liaison pharmacist need to establish a guideline for the management of such a procedure that ensures client safety.

6.6 Transcribing

- Transcribing is defined as the legitimate copying of prescription information from one source to another without any alterations or additions (NZNO 2016).
- **NZNO does not support transcribing as a routine practice**, however, NZNO believes transcribing is an appropriate activity within the scope of nursing practice

in certain circumstances (outlined in NZNO's Transcribing guideline). *NZNO guidelines do not include anything to match Corrections Department requirements.*

- **Note:** Photocopying/photographing a Medication Administration Record Chart **is not** transcribing.

6.11 Self-administration of medicines by clients

- Where self-administration is introduced for all or some clients, arrangements must be in place for the appropriate, safe and secure storage of the medicines. The people who will e-access these medicines will be determined by local workplace policy.
- For the long-stay client, whether in hospital, ARC or primary care, self-administration can help foster a feeling of independence and control. This can be facilitated by the nurse, via a self-administration policy.
- For the hospital client approaching discharge, who will continue on a prescribed medicines regime following return home, there are obvious benefits to self-administration while still having access to professional support.
- Health professionals need to be aware of maintaining the standards outlined in appendix one, if they are monitoring self-administration by a client.

6.15 Reporting adverse events (errors or incidents)

If an error is made in the administration of a medicine, the RN must take every action to prevent any potential harm to the client, and report the error as soon as possible to the prescribing health professional, the line manager or employer (according to local workplace policy).

The RN must document the incident and the action taken.

A reportable event form must be completed.

6.15.1 Implications for nursing

- The RN and EN are accountable for their actions in the administration of medicines to the Nursing Council.
- Any error or incident should be subject to an investigation; this may be internal or, if serious harm has occurred, external.
- NZNO supports a thorough, open and multidisciplinary approach to investigating adverse events. This will ensure improvements in practice can be discussed, identified and disseminated.
- An open culture is important to encourage the immediate reporting of errors or incidents in the administration of medicines.

6.17 New Zealand Formulary

- The New Zealand Formulary (NZF) is an independent resource providing health-care professionals with clinically validated medicines information and guidance on

best practice, enabling health-care professionals to select safe and effective medicines for individual clients.

- The NZF is a free resource for all health-care professionals prescribing, dispensing and administering medicines in community and hospital care. It aids decision-making and contributes to best practice through standardised and evidence-based information on medicines.
- Over time, the NZF will be fully integrated into the e-health environment, including prescribing and dispensing systems across primary and secondary care.
- It can be accessed electronically.

National medication chart

In 2011, a standardised national medication chart was rolled out across district health boards (DHBs) nationally. All nurses working in DHBs and the majority of health care facilities are familiar with the layout and design features of the chart, including the abbreviations used.

<https://www.hqsc.govt.nz/assets/Medication-Safety/NMC-PR/NMC-UserGuide-Oct2012.pdf>

Policy — Corrections Department ‘Medication Management’

8.9 Prescribing medications —

- the prescriber must be responsible to ensure all prescriptions comply with Regulation 41 of the Medicines Regulations 1984. Medication charts must be legible.
- all prescriptions must clearly show the medicine name, and the administration dose, route, time, and the amount supplied or length of supply for each medicine.

8.10 The prescriber is responsible for completing a replacement medication chart when any medication chart is full, illegible, unclear, ambiguous or incomplete. The replacement chart must be sent to the pharmacy.

8.11 Correction Health Services Staff are responsible to present any medication chart to the prescriber for replacement if it is full, illegible, unclear, ambiguous or incomplete.

8.14 The prescriber is responsible for reviewing medication charts every three months ...

8.21 To discontinue a medication the prescriber must draw a line through the prescription on the medication chart to delete the prescription and then sign and date the deletion. If any such deletion results in the chart being illegible, ambiguous, or incomplete the prescriber is responsible to replace the medication chart.

8.22 In the case that the prescriber dates and signs the medication chart to discontinue medication at a later date, the RN is permitted to draw a line through the medicine, initial and date the change, on the date the discontinuation takes effect.

13.14 Describes the RN responsibilities when administering medications which includes understanding the therapeutic purpose of the medicine.

Corrections Department Policy — ‘Health Care Pathway Policy/Procedure’

This Policy states

- Treatment plans or plans of care will be reviewed within an appropriate time frame.
- All clinical interventions in a treatment plan or a plan of care will be based on current practice standards.
- Any standardised treatment plan must be able to be personalised and varied according to individual patient’s health needs.
- Health services staff carrying out clinical interventions for a patient must create the treatment plan or plan of care for that patient.
- The health services staff member who starts the treatment plan is responsible for ensuring the treatment plan is completed.
- Any prisoner with ‘significant and/or complex needs’ eg ‘acute diseases, conditions or injuries that place the patient at significant risk (including mental illness)’ [is to be provided with a] treatment plan [that] must cover these.
- Health assessments will provide clinical assessments that are appropriate to clinical presentations, according to current good practice and provided in a timely manner. The plan of health care interventions should then be matched with assessed needs.

REVIEW FINDINGS

1. Documentation used by [prison] nursing staff to manage [Mr A’s] medication, including any changes to his medication.

WHAT IS THE STANDARD OF CARE/ACCEPTED PRACTICE?

Clinical documentation is a legal record of patient care. It is essential for good clinical communication and a core requirement of the Nursing Council of New Zealand (NCNZ) competencies for scope of practice. Good documentation helps to protect the welfare of patients by promoting:

- High standards of clinical care
- Continuity of care
- Better communication and dissemination of information between members of the multidisciplinary care team
- An accurate account of treatment, care planning and delivery
- The ability to detect problems, such as changes in the patient’s/client’s condition, at an early stage (Collins, Cato et al. 2013).

When documenting in the clinical record, it is important to remember many people are required to read the notes that are written. All health professionals who are involved in the planning, implementation and evaluation of care — from the time of admission through to discharge must complete documentation to meet the needs of all health professionals. External bodies in the case of an investigation e.g. NCNZ, MCNZ, Accident Compensation Corporation (ACC), Health and Disability Commissioner (HDC), Health Practitioners Disciplinary Tribunal (HPDT) or the Coroner are also required to read the written notes.

Documenting all relevant information ensures others know, including what clinical interventions were taken and what the result was. Documentation must show evidence of clinical judgement and escalation/referral as appropriate and evaluation of the care provided. There is an old saying which remains relevant to this day — *If care is not recorded, then it is assumed the care was not given.*

The treatment of a patient with medicines for therapeutic, diagnostic or preventive purposes involves prescribing, dispensing, administering, receiving and recording medicine/s, storage and handling. The nursing process including assessment, planning, implementation and evaluation also applies to medicine administration. Documentation should include any departure from the patients 'normal' progress and should include the reason why. When addressing changes in care delivery (medication), health professionals are advised to document the rationale for the decision. In this case, the information provided and the importance of continuing to take Clopidogrel is not documented as either part of the education for [Mr A] prior to self-administration or as an alert for the nursing staff.

DEPARTURE FROM CARE

Medication Chart

[Mr A's] medication chart is at times illegible, untidy, has minimal recognisable names and signatures and is very difficult for the writer to understand. Medication charts provided contain an area of signing register which indicates the 'full name' and 'initial' of the signatory be provided. The majority of these do not contain a full name of the health professional, their status (MO or RN) and/or are indecipherable and is a **departure from local policy and/or legislative requirements.**

The Medicine Chart provided as evidence documents Clopidogrel in the 'Short Course Medication' template with a date of, indecipherable number, June, 2016. The entry is crossed out with lines through it, dated 24.7.16 and signed. Under this entry, in the date column, 'ERROR, crossed out by mistake' is handwritten. This begins a process which has led to confusion and mixed messages, has never been queried and results in **a serious departure of legislative, and local policy and a threat to the patient's health status.**

The discharge summary from [the public hospital] dated 24/06/2016 included a prescription for one month supply of his medications including Clopidogrel 75mg

tablets. The plan documents [Mr A] is to have 'dual antiplatelet therapy' as prescribed i.e. clopidogrel and aspirin.

The writer questions if the discharge summary is read by all health staff at [the prison], as it is not acknowledged in any further documentation or as part of a documented health plan.

Following prescribing of Clopidogrel, all clinical staff should be aware of and ensure a plan of care is implemented to support the observation of [Mr A], and/or ensuring he is aware of the consequences of this medication. Corrections policy states a 'health plan of care is developed for patients who do not need a Treatment Plan' and describes the needs in that plan and the interventions should reflect the specific needs of the patient, including health promotion and education. This is a **serious departure from Corrections Health Policy and best practice** as the reason for prescribing a medicine should be documented and a care plan implemented in the patient's health record to ensure their safety is maintained.

There is evidence medications provided to [Mr A] are signed for by the nurses on the medication administration chart. This chart 'Medication Administration Record (Signing Sheet)' is signed daily on earlier charts but later has a line through the week and is signed at the bottom of the box. The latter documentation, the writer cannot understand how this reflects medicines given but has assumed this is during the period of self-administration, so therefore has not been given by the signatory, and again the writer must assume this is when the medications are actually 'checked' and/or delivered to [Mr A]. This is a **departure from practice** and if the medicines are signed as delivered to [Mr A's] unit, the signature needs to indicate that, rather than medication given.

Prescribing/Charting of medications:

Entries on a medication chart must not be altered and any variation in dosage, frequency, form, route or time must be recorded as a new prescription (entry) and the previous prescription discontinued with a line through it and dated.

[Mr A] was discharged from the hospital on June 24, 2016 and prescribed a one-month course of Clopidogrel. A month's prescription is common practice for discharged patients from all hospitals. The hospitals advise their patients to follow-up with their General Practitioner (GP) in a month for further prescriptions and to ensure the patient is assessed.

- Clendon Pharmacy dispensed Clopidogrel from the hospital prescription, to [the prison] on June 24th.
- A further prescription completed by [Dr C] was dispensed from Clendon Pharmacy July 9th again for one month.

- An order form (unsigned) and faxed to Clendon Pharmacy July 9th states 'clopidogrel crossed out on medchart in error otherwise its exactly the same as Hosp script'.
- [Dr B] prescribed clopidogrel again for one month on 1st August, 2016 but an order form (again unsigned) and no date, documents 'Clopidogrel 75mg stopped on 24/7/16 THX'.
- [A doctor] prescribed x8 Clopidogrel 23rd September, 2016 and a further month supply 4 October, 2016.
- 28 October, 2016 an order form was sent to Clendon Pharmacy documenting 'Clopidogrel 70mg stopped on 23/9/16. Pls send a new whole blister cycle. Needs colchicine in mane pack. Thx.' This is signed and dated.
- A further month prescription for Clopidogrel is completed by [Dr D] and dispensed on 3 November 2016.

All the while the prescriptions are being generated, it appears the 'order form' is not reflecting this, neither is the medication being received by [the prison], or if it was, there are instructions to remove it from the pack. The writer finds the lack of process very confusing and difficult to determine if and when the medicine is given. The Medical Officers are prescribing as part of the 'ongoing cycle medication (monthly supply)' and some nurses are reflecting the poor medication chart documentation of discontinuing the medicine on the 'order form', others are requesting the medicine be dispensed. The writer shares the confusion of all providers and investigators in this process. **Serious communication, documentation and poor processes** appear to be the downfall throughout this period.

When discontinuing a medicine or rewriting a prescription, for example due to a dose change, the 'sign, date and time to cancel' box must be completed. The prescriber must draw a clear line through the order in both the prescription and record the reason in the patient's notes. Attempting to reinstate a medicine by documenting the cross out was an 'error' and/or 'mistake' is not accepted practice in any legislation or policy and a **severe departure from legislation and local policy**.

If the error and/or confusion associated was recognised and reported by any of the health staff, at the very early stages, this review would not be required. Knowledge by the nursing staff of the implications of taking or not taking the medicine appears to be limited, as there is no alarm or query as to why the medication was stopped (or not). If [Mr A] had been educated fully and had a good knowledge of his medicines he would have been aware of the missing medicine and would report to health staff. The documented 'ERROR crossed out by mistake' should have been identified and amendment requested immediately.

If there is concern in the administration of a medicine, the Registered Nurse must take any action to prevent any potential harm to the patient, and report it as soon as possible to the prescriber, the line manager or employer (according to local workplace policy). The General Practitioner is responsible for prescribing appropriate

medications for the patient and also it is the responsibility of the nurse to ensure they have a full understanding of the medication, its use, side effects and adverse reactions to ensure it meets the needs of that patient and to keep that patient safe. National guidelines and standards indicate the documentation **does not meet any legislative or local requirements**.

The prescribing of Clopidogrel re-commenced 23 Sept, 2016 as documented in a Discharge Summary from [the] District Health Board. The hospital discharge summary which is sent to the GP (addressed to '[Dr C] [the prison]') and a copy given to the patient clearly documents the 'Plan' from the hospital, 'Please continue both blood thinners (clopidogrel and aspirin) for 12 months followed by aspirin only' and a full medicines list.

23rd September 2016, [Dr C] has documented in [Mr A's] Medtech notes 'Clopidogrel for 12/12. Meds discussed with patient.' What was discussed should have been documented to ensure the information is further shared with all health staff. The other entry in Medtech reflecting [Mr A] being on Clopidogrel is 7th December, [Dr D] writes 'patient is on Clopidogrel'. Clopidogrel 75mg is charted and signed in the 'Regular Medication' section of the Medication Chart 23/9/16 with a discontinuation date of 23/9/17. This documentation is within legislative requirements but the medication is not documented correctly until four months after the original Clopidogrel was prescribed in June 2016.

Recommendations are made on Page 16.

2. The methods by which [prison] nursing staff ordered and checked medication for [Mr A] from Clendon Pharmacy

The writer finds this process has caused unnecessary confusion, frustration and is time wasting for the health staff and the pharmacists. It is not normal practice for prescriptions provided by the Medical Officers to be 'transcribed' to an 'Order Form'. The writer does not understand the reasoning behind this because in health facilities throughout New Zealand the use of prescriptions for patient specific medicines and bulk order forms for 'over the counter medicines' is all that is required and a very simple process.

In normal situations, any prescription generated by a GP and given to the patient is taken to the pharmacy for dispensing, without any further intervention or documentation. This personal delivery of prescriptions cannot happen in [the prison] but determining a quick and easy process to get that prescription to the pharmacy is required. The majority of general practices throughout New Zealand will fax patients' prescriptions to the pharmacy of their choice and have been doing so for many years.

If [the prison]ers are being supported to become more autonomous in their own health care they will have a good awareness of their medications, and will be aware of what is in the pack, its use and if anything is missing.

As the process of dispensing is the full responsibility of the pharmacist, why does it then become the responsibility of a nurse to check the 'blister packs' dispensed by the pharmacy on arrival at [the prison]? A Registered Nurse should not be requested to complete or be responsible for this process and the writer queries this reasoning. As this is not part of their scope of practice, nurses are not taught what a medication looks like, so the writer queries again, why is this required or are they just counting that the numbers match the label? This does not happen in normal practice and would be constructed as **a serious departure from normal practice** in any other health facilities.

Recommendations:

- A full review of the process of prescribing and blister packs within [the prison]
- Objective: why the process is required
- Outcome: the provision of a process which meets the objective and all legislation, ensures all staff (medical officers, pharmacists and nurses) are working within their scope of practice, and the safety of prisoners on medication is not compromised.
- Regular review of the new process following implementation between all parties.

3. The actions taken by [RN H] on 11 February, 2017 upon identifying that Clopidogrel was missing from [Mr A's] blister pack

If there is concern in the administration of a medicine, the Registered Nurse must take any action to prevent any potential harm to the patient, and report it as soon as possible to the prescriber, the line manager or employer (in accordance with local workplace policy).

The General Practitioner is responsible for prescribing appropriate medications for the patient and also it is the responsibility of the nurse to ensure they have a full understanding of the medication, its use, side effects and adverse reactions to ensure it meets the needs of that patient and to keep that patient safe.

Although this is a serious departure from expected practice by [RN H], the blame cannot be laid at her. The documentation error on the Medication Chart is of more concern to the writer and should have been recognised and amended (rewritten) immediately, not some months later! The confusion and the risk put to the prisoner which followed after the original prescribing and cross out, sees all Registered Nurses at fault and **responsible for a serious departure from expected practice** for neither recognising, reporting nor requesting an amendment.

It is the responsibility of all Registered Nurses to ensure their own professional safety. Incorrect documentation causing confusion and/or mixed messages and putting a patient at risk is one of these. The non-compliance to meet legislation on Medication Charts, the lack of a care plan and transcribing medications to an 'order form' are unsafe practice also. The leaders of the nursing staff at [the prison] are also responsible to ensure the maintenance of the required standards and the staff safety.

The non-compliance with required nursing standards is a severe departure of practice.

Recommendations:

- Training/education/audit of legislative and local requirements of prescribing medicines and nurses' responsibilities for documentation
- Training/education/audit of legislative and local requirements of prescribing and further documentation by Medical Officers
- Training /education/audit of local requirements of reporting incidents and errors all health staff.

4. The overall communication with Clendon Pharmacy by [prison] nursing staff regarding [Mr A's] medication

Again, if the error had been pointed out and amended immediately and/or there had been discussion between all health staff, the situation could have easily been resolved. The pharmacist phoned [the prison] to ask if the request to stop the medicine was correct and was told it was, although no-one seems to know who. The 'order form' was used to stop, restart and stop again the clopidogrel, [and] although some were signed, the signature is illegible to know if it was a nurse or a medical officer. This was confusion enough for the pharmacist who if perhaps, had requested a conversation with a Medical Officer or Nurse Leader, may have resolved the issue. Regular meetings with the pharmacist were being held and I wonder why it was not discussed at these.

Recommendations:

- **A new formal process** which is correct and medically managed/signed or led by a Nurse Leader is required to maintain consistency in communication and safety in prescribing and dispensing.
- The use of **either** an electronic prescribing process, scanning or faxing prescriptions must become custom practice by all medical officers and nursing staff. All these systems will provide the ability to audit prescriptions, stop transcribing to order forms, inform the pharmacist of the actual and specific prisoner needs and confirm delivery. The writer is aware a high number of Residential Care Facilities, General Practices and Pharmacies throughout New Zealand are now using electronic prescribing tools with success. All hospitals in New Zealand use the National medication chart.
- The use of bulk supply ordering for 'over the counter' medications.
- Any further review of pharmacy services and management of dispensed medicines should be formally conducted and any outcomes determined between both parties.

5. The adequacy of relevant policies and procedures in place at [the prison] for ordering, checking, distributing medications to inmates

Health Services Procedure, issued in 2008, and reviewed in October 2015, support Health Services staff to provide efficient and effective health care interventions

according to the clinical needs of individual patients. They also provide guidance for the delivery of health care at each stage of imprisonment.

Current guidelines and standards is provided in the latest dated and best practice policies available through the Corrections Department intranet (Corrnet). Others are found under the Health Services Manual as Ministry of Health NZ, Medsafe, New Zealand Guidelines Group and Cochrane Library with direct access to the websites provided. Policies and procedures were in place in [the prison] at the time of the reported event but these were under review at the time of the review. New Zealand Nursing Council Guidelines and Standards are the foundation of any nursing process and procedure and found on the Nursing Council website. **It appears there is inconsistency of knowledge in health standards including best practice and policy requirements especially around clinical documentation and the legitimacy of some processes at [the health centre].**

There also appears to have been a lack of auditing or leadership in the processes, policies or compliance of all health staff. Auditing and effective leadership may have reflected the lack or limited knowledge and skills and lack or limited compliance with processes within Corrections Department or Health regulations at a much earlier stage and perhaps have prevented this event.

The implementation of the Clendon Pharmacy contract for supplying medicines in 2015, appears to be informal and lacking systems, processes and procedures. This must be formalised and a process implemented to prevent any further errors. The responsibilities of all persons involved in the process of medications required for prisoners, from prescription to administration, must be determined and the process kept simple and within their scope of practice. **Quality processes to review and regular audit will ensure this continues.**

Recommendations:

- It is reported by [the General Manager] that following recommendations from two previous reviews a number of changes have been made, specifically relating to medication management, including regular audits and training. These changes were expected to be completed mid-2018.
- With well implemented policy through learning and regular audit, these changes should have a positive influence on [the prison], ensuring no potential harm to the prisoner and the safety of the health staff.
- It is also the responsibility of the national leadership/management team and the regional and local health leaders to ensure the implemented changes continue at the highest level and that these are audited and reported on a regular basis. This process will reflect the improvements are continued as business as usual, and professional practice will continue at a higher level.
- Strong leadership skills to implement and maintain the policy, procedures and standards at the highest level.

- The Corrections Health Services Medication Management Policy and Procedure underwent substantial review, was rewritten to reflect current legislation and best practice and implemented in April 2018.
- A programme of work, which will run for some time, will ensure the quality and effectiveness of training and upskilling of the health staff to deliver services in accordance with the new policy and procedures.
- Regular audit of all health policy and procedures and standards of practice is required following a programme of work which involves all health staff, is priority.
- Individual staff performance reviews will provide feedback and the opportunity to identify and meet learning deficits.

6. Other matters

The writer also notes in January 2017, [Mr A] ‘put in a chit’ and was seen by the dentist because he had toothache. This was resolved by a dental extraction. Nothing in his clinical notes reflected him taking Clopidogrel (or not) and the detrimental effects this procedure may have had on [Mr A]!”

The following further advice was obtained from RN Cornor:

“Addendum: May, 2019

I have received a copy of a documented response from Department of Corrections of my review and recommendations made in the case of [Mr A]. I have been asked to review that document and advise whether it causes me to amend the conclusions drawn in my initial advice, or make any additional comments. I have added additional comments as below.

I commend the Department of Corrections and [prison] Health Services on the progress made prior to and following my ‘findings’, ‘criticisms’, ‘notes’, ‘advice’ and recommendations.

The conclusions drawn and documented in my initial response (2018) will not be amended but it is confirmed that the recommendations from that document have been embraced and have either been, or are currently being implemented in [the prison]. The support provided and changes being implemented, as evidenced in the Corrections Health Service response, is very positive and will, in time, build capability to provide a sustained and positive improvement to [the prison’s] Health Service.

1. Medication Chart

It is applauded that all the Medication Charts are being reviewed and amended by the Medical Officers to meet legislation.

Training and peer review is being undertaken on medications and new processes including self-administration.

The introduction of a Medication Chart and process that meets legislation and local policy for prescribing and administering of all medications will provide for a safer environment for prisoners and all staff.

2. Checking medication from the pharmacy

Corrections Department decision to continue prison nursing staff secondary assurance checks on blister packs but must become part of policy and have a procedure associated with it.

Legislation states a pharmacist will 'accurately dispense and label medicines according to prescriptions, legislation, regulations and guidelines'. The Registered Nurse is responsible for the administration of the prescribed and dispensed medication. To remain within their scope, the RN can check from prescription/medication chart to labelling of the blister pack/container and the number of tablets in the pack. Identifying the tablets/capsules in the blister pack is not within the RN's scope of practice.

The policy must identify who will be responsible/accountable if a medication error (of the wrong medicine being given) is made by a nurse administering, after the pack has been checked. The policy (to be included in the Medication Policy) will also include a process and training requirements for this task.

As a previous staff member of the Corrections Department Health Service I am very aware of the unique health environment, however, the process around self-administration is not unique and is used safely in many health facilities including Aged Residential Care. The framework for processes must remain the same. The Ministry of Health (2011) provided a Medicine Care Guide for Residential Aged Care Facilities which provides a framework for medicines checking and self-administration, including criteria for assessing the capacity to self-administer.

Conclusion:

Once again, I commend Corrections Department and [the prison] Health Services on their work so far.

I would anticipate that following the intensive and formal programme for change which includes performance management, education/training, regular audit and peer review currently underway, all new processes will be embedded as normal and best practice within the next six months to a year.

It is highly recommended these processes for improvement continue and therefore, strong effective leadership and continued Corrections Department support will be necessary to retain this.

Barb Cornor
30/05/2019"

Appendix B: Independent advice to the Commissioner

The following expert advice was obtained from pharmacist Sharynne Fordyce:

“C17HDC01348

27 March 2019

I, Sharynne Fordyce, have been asked to provide an opinion to the Commissioner on Case number C17HDC01348 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.

Given the complexity of this matter and the large volume of information involved, I have been provided with a chronology summarising the factual background giving rise to the complaint. Below I have included a summary of the case, in words, that I was also provided with.

The case is regarding an inmate at [the prison] (the Consumer) who was admitted to hospital several times. After being admitted to hospital for the first time, the Consumer was diagnosed with a left middle cerebral artery subacute stroke. The second time he was admitted to hospital, four stents were placed in his heart. Both times, the Consumer was prescribed an anti-platelet medication on discharge from the hospital. However, this medication was mistakenly stopped, and the Consumer went without it for approximately three months. As a result, the stents in the Consumer’s heart became blocked and he suffered a serious medical event.

Expert advice requested

Please review the enclosed documentation and advise whether you consider the care provided to [Mr A] by Clendon Pharmacy was reasonable in the circumstances, and why. In particular, please comment on:

1. the appropriateness of the action(s) taken by Clendon Pharmacy after receiving the order form from [the prison], which stated that Clopidogrel for [Mr A] had been stopped, on 5 August 2016;
2. the appropriateness of the action(s) taken by Clendon Pharmacy after apparently receiving a phone call from a nurse at [the prison] requesting that the medication blister pack for [Mr A] be resupplied without Clopidogrel in November 2016;
3. the appropriateness of the action(s) taken by Clendon Pharmacy after receiving the new medication chart for [Mr A], which included Clopidogrel, on 14 January 2017;

4. the adequacy of relevant policies and procedures in place at Clendon Pharmacy in relation to receiving, dispensing, and checking of prescriptions and orders received by Clendon Pharmacy from [the prison]; and
5. any other matters in this case that you consider warrant comment.

For each question, please advise:

- a. What is the standard of care/accepted practice?
- b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?
- c. How would it be viewed by your peers?
- d. Recommendations for improvement that may help to prevent similar occurrence in future.

If you note that there are different versions of events in the information provided, please provide your advice in the alternative. For example, whether the care was appropriate based on scenario (a), and whether it was appropriate based on scenario (b).

1. a. Clopidogrel is used after heart attacks to help prevent another one, and the consumer would expect to be on this medication for 12 months and then reviewed. The drug would only be stopped when it was being replaced by a similar drug that suited the customer better. The standard of care/accepted practice would therefore be to confirm the stopping of the medication with the prescriber. Confirmation of continuation of the medication, should also come from the prescriber, with a copy of an up to date chart, to confirm continuation of supply.
- b. Clendon Pharmacy followed acceptable practice by obtaining confirmation of continuation of supply, via an order form, but this confirmation was not supported by a current chart. The last charted supply of clopidogrel finished on 24/7/16, signed and dated by the doctor. No further supply was charted until 23/9/16. Clendon Pharmacy records a phoned prescription copy for clopidogrel processed on 1/8/16 for the next blister pack run, but unsupported by a current chart. This is a severe departure from accepted practice.
- c. Given the nature of the medication, and the seemingly arbitrary way the medication was requested to be stopped and then restarted, with no accompanying charting of the medication, this action would be viewed as unwise by my peers, and a severe departure from accepted practice.
- d. Recommendations to help prevent a similar occurrence in the future would include a comprehensive policy/SOP that dealt with medication stoppages and restarts, and included who was authorised to do this. A policy could also be needed to deal with the requirement for an up to date chart from which both the pharmacy and [the prison] service can confidently and accurately work from.

2.a. The accepted practice would be to confirm who was making the phone call, and on whose authority he/she was ordering a new medication blister pack, excluding the clopidogrel. Given the importance of the medication (see above 1.a) and the previous misunderstandings about its supply, written or spoken authority from the prescribing doctor would be required, and a new chart supplied to reflect the change.

b. There has been a severe departure from providing the correct standard of care in this scenario. As previously mentioned, this medication is normally prescribed for a year and, as charted on the medication chart, was not due to be stopped until 23/9/17, signed and dated by the doctor. No action should have been taken without consulting the prescribing doctor, and being supplied with the appropriate chart indicating the date for the medication to be stopped.

c. The actions taken would be viewed as being irresponsible and very unwise by my peers. Given the previous issues with supply of this medication, it would be expected to have a warning note in [Mr A's] computer records, reminding staff to be aware of the need for authority of supply. Not to have this, and to act in this way would be viewed as a severe departure from accepted practice and standard of care.

d. Recommendations to help prevent a similar occurrence in the future include a computer note or alert on patient's records regarding any near misses or errors. Also to have written into [the prison] Dispensing SOP the need to obtain permission from the prescribing doctor to cease supply of a medication.

3.a. The standard of care/accepted practice on receiving a new medication chart for [Mr A] (including clopidogrel) on 14/01/17 would be to compare it with the previous chart that was being used, note any differences, and make enquiries re these differences. This is to confirm exactly what is needed/being taken by the patient now, and to ensure no errors have occurred in the recharting of medications from the old chart to the new.

b. The actions taken by Clendon Pharmacy after receiving the new chart are a severe departure from accepted practice/standard of care. Despite the lack of provision of an order form specifying clopidogrel, the pharmacy did have a medication chart, signed and dated by a doctor requesting (among others) clopidogrel. This alone, given the repetitive and contentious nature of the supply of this medication, should have been enough to prompt an enquiry from the pharmacy to [the prison] service for confirmation of what medication was needed. This was not done.

c. This would be regarded by my peers as not following accepted practice, to be unprofessional and unwise, given the consumer's medication incident history.

d. Recommendations would include following industry standard SOPs for dispensing blister packs to institutions, and the requirement for a current and up to date chart for each patient. Also, as mentioned before creating, improving and following SOPs specifically for the provision of this service to [prisons].

4.a. The accepted practice when taking on a new service, such as the one offered to [prisons] by Clendon Pharmacy, would be to have a dedicated set of SOPs that deal

solely with all that service entails. Particularly with the client Clendon Pharmacy is dealing with, it is vital to have all aspects of the service detailed and covered. This ensures all staff are following the same procedures, and that all legal and contractual matters are dealt with.

b. There has been a severe departure from accepted practice, and a marked departure from standard practice. By [Mr G's] own admission, no specific SOPs were drawn up to deal with the new service provided to [prisons] until after these incidents took place. With few or no specific policies in place for this service, it also increases the pressure on [Mr G] and his staff to provide an accurate professional service, and increases the likelihood of such incidents occurring. [Mr G] does comment in a letter to the Department of Corrections, Tuesday March 7th 2017 that 'so far we've had no issues with the system.'

c. This would be viewed by my peers as bad business practice, very risky and unprofessional. With the need for comprehensive SOPs to meet all audit requirements, particularly for specific service contracts such as this one with [the prisons] the lack of documentation would be deemed foolhardy.

d. Recommendations to help prevent a similar occurrence in the future would be to ensure new professional, well presented SOPs are drawn up, in consultation with [the prisons]. These SOPs would cover all pharmacy's legal requirements, and include any points of practice peculiar to, or required by [prisons]. All pharmacy staff members involved in the provision of this service would need to read and sign these SOPs, and new staff would need to be trained in them. This would help ensure all processes and procedures are replicable and professional.

5. Any other matters that warrant comment. Dealing with an institution such as this is fraught with constant challenges. By [the prison's] own admission, many of their own processes dealing with medication also needed attention."

The following further advice was obtained from Ms Fordyce:

"Addendum for 17HDC01348

The changes that the pharmacy has made in its processes, and its confidence in dealing with [the prison] are very commendable. The pharmacy has implemented a much more comprehensive service with specific SOPs that enable the provision of an excellent service. That these SOPs were drafted in consultation with people with experience in dealing with dispensing to prisons, indicates the importance the pharmacy now places on these procedures. As stated in the letter from [Clendon Pharmacy] 'the pharmacy considers these events to have been a "turning point" in their relationship with [the prison], which includes the "no chart — no supply" policy.'

Partly because of pharmacies' highly regulated nature, when an error of this nature occurs, the pharmacy processes come under close scrutiny, and any failing put under the spotlight. While not having dealt with Corrections Facilities, I am very much aware of the pressure put on busy dispensaries to bend or ignore normal processes with very

similar statements to the ones quoted 'the last guy did it and didn't complain.' Therefore it is up to the pharmacy to set and maintain its own standards from the outset of any new venture.

It is for these reasons, but also because of our professional and ethical responsibilities, that I have made my comments.

Sharynne Fordyce

29/09/19"

Appendix C: In-house advice to the Commissioner

The following expert advice was obtained from Dr David Maplesden:

“Thank you for the request that I provide clinical advice in relation to the complaint from [Mr A] about the care provided to him in relation to prescribing of clopidogrel by [Dr B] at [the prison] on 24 June 2016. 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 have reviewed the following information:

- (i) Letter from [Dr B] dated 17 September 2018
- (ii) Transfer of care notes and discharge prescription from [the public hospital] dated 24 June 2016, and [the public hospital’s] general medicine clinic outpatient report dated 21 July 2016 (both reports addressed to [Dr C] at [the prison])
- (iii) Corrections Health Services medicine chart for [Mr A]
- (iv) Order form from [the prison] to Clendon Pharmacy (which supplies [the prison] with medications for its prisoners) dated 9 July 2016. This chart records that clopidogrel was crossed out on the medicine chart incorrectly and that clopidogrel should be supplied as per hospital prescription
- (v) Letter from [Dr C] dated 17 September 2018
- (vi) Clinical notes [prison health centre])

2. [Mr A] was an inmate of [the prison] on 17 June 2016 when he suffered chest pain and collapse. [Dr B] usually provided GP services to [the] inmates through a regular clinic service. At the time of [Mr A’s] collapse [Dr B] was not at [the prison] and the GP currently providing a service to [inmates] ([Dr C]) who was in attendance was called to provide emergency care to [Mr A]. [Dr C] assessed [Mr A] and arranged ambulance transfer to [the public hospital] with diagnosis of possible inferior myocardial infarction (MI) and arrhythmia. The referral letter was in [Dr C’s] name, but [Dr C] was not involved in providing day-to-day services for [Mr A].

3. According to the transfer of care summary, while in [the public hospital] [Mr A] was given a primary diagnosis of left middle cerebral artery (MCA) territory subacute stroke with secondary diagnoses of type 2 myocardial infarction¹ and triple vessel coronary artery disease. [Mr A] underwent thrombolysis for his stroke as per local protocol, and subsequent CT coronary angiogram revealed severe triple vessel

¹ Type 2: MI consequent to a mismatch between oxygen supply and demand. This includes a multiplicity of potential mechanisms including coronary dissection, vasospasm, emboli, microvascular dysfunction, as well as increases in demand with or without underlying coronary artery disease.

From: Reeder G et Kennedy S. Diagnosis of acute myocardial infarction. Uptodate. Literature review current through January 2019. www.uptodate.com

coronary artery disease (CAD). There was no percutaneous intervention (PCI) for the undertaken CAD during [Mr A's] admission.

4. [Mr A] was discharged back to [the prison] on 24 June 2016. A copy of the transfer of care summary was available to [health centre] staff on that date. The summary included the following points:

(i) In the section 'Advice To Patient':

Please take aspirin for the next three weeks

Please take clopidogrel long-term, unless otherwise advised by the cardiologists

We will see you in clinic in 2–3 weeks for a review. If you remain well in that time, we will book you for a treadmill test to investigate your heart and arrange an angiogram for your heart

(ii) In the section 'Plan':

1. Atorvastatin 80mg

2. Dual antiplatelet therapy as per stroke team as prescribed above

3. Gen med clinic Purple 1 reg, in 2–3 weeks — will review Echo then and if remains well and improving from stroke point of view, to arrange ETT ... and OP angio after ETT

(iii) The relevant portion of the section marked 'Medications' is reproduced below:

Medications			
Medications Prior to Admission (2)	Discharge Medications (6)	Change	Reason/Comment
-	Aspirin (Ethics Enteric Coated Aspirin) 100mg Enteric coated Tablets 1 tab po mane 3 weeks (Provide Script on discharge)	Started ▶	stroke
-	Atorvastatin (Zarator) 80mg Tablets 1 tab po mane 1 month (Provide Script on discharge) (Long term condition)	Started ▶	dyslipidaemia
-	Clopidogrel (Arrow Clopid) 75mg Tablets 1 tab po mane 1 month (Provide Script on discharge) (Long term condition)	Started ▶	stroke

5. [Mr A] was provided with a discharge prescription from the public hospital dated 24 June 2016. Medications prescribed were aspirin, atorvastatin, clopidogrel, paracetamol, allopurinol and colchicine. A supply of one month (*Mitte: 1 month*) was noted for atorvastatin, clopidogrel, and allopurinol. A three week supply (*Mitte: 3 weeks*) was ordered for aspirin, one week supply for paracetamol and three day supply for colchicine. I understand it is standard practice for a one month supply of regular medications to be provided to a patient on discharge. The specific instructions for aspirin and clopidogrel were:

(i) *Rx: Aspirin (Ethics Enteric Coated Aspirin) 100mg Enteric coated Tablets*

Sig: 1 tab po mane

Mitte: 3 weeks

(New — stroke)

(ii) *Rx: Clopidogrel (Arrow Clopid) 75mg Tablets*

Sig: 1 tab po mane

Mitte: 1 month

(New — stroke)

6. The transfer of care summary was addressed to [Dr C] as the referring clinician. The summary appears in the 'Inbox' section of the clinical record dated 24 June 2016 and is annotated as having been filed by [Dr C] (MXGP). [Dr C] states: *I reviewed [the transfer of care document] and ensured that the Dr's ... would follow up and review [Mr A] ... I read the discharge summary² and checked that [Mr A] was in [Prison Division]. I asked the nurses to book him in for GP review at the next [Prison Division] Medical clinic to ensure he received appropriate review.*

7. Nursing notes dated 24 June 2016 include a record of [Mr A's] observations and: *Returned from hospital at around 1330hrs. Seen in medical by [nurse]. Arrived with discharge letter. Obs checked and ok. Hospital script faxed to pharmacy. As per discharge summary request prisoner listed to be seen by [the prison] GP on Monday.* Medications were evidently supplied from the pharmacy in a blister pack as per the hospital prescription for administration to commence on 25 June 2016.

8. [Dr B] reviewed [Mr A] at his [prison] clinic on 27 June 2016. He documented his assessment findings and *Discussed graduated exercise. DAPT [dual antiplatelet therapy — in this case aspirin and clopidogrel] 1/12, then aspirin alone.* Acute myocardial infarction was coded as a long-term condition but stroke was not coded. The prescribing chart has four entries dated 24 June 2016 and which I assume have been signed by [Dr B]. In the 'regular medication' section of the chart is allopurinol, atorvastatin and aspirin all prescribed as long-term medications (ie no stop date recorded). In the 'short course medication' section of the chart is clopidogrel charted as 75mg mane with a discontinuation date noted of 24 July 2016. The entry has been crossed out and there is a handwritten annotation '*error, crossed out by mistake*'. I am unable to confirm whether the discontinuation date was annotated on 24 June or 24 July 2016, and I cannot confirm the date on which the clopidogrel was crossed out and error message annotated. While the prescriptions in question are dated 24 June 2016, I presume these were retrospective entries actually made on 27 July 2016 (the

² Discharge summary is also referred to as Transfer of Care summary in this report

medication having been administered since 24 July 2016 on the basis of [the public hospital's] prescription).

9. [Dr B] includes the following points in his response:

- (i) *I documented that [Mr A] was on clopidogrel anti-platelet treatment for one month and then aspirin alone.*
- (ii) *In reviewing this case it is clear that I misread the discharge letter and stopped the clopidogrel after a month and carried on with aspirin. The hospital instructed to stop the aspirin after a month and continue the clopidogrel.*
- (iii) *I was unaware that a recent change had taken place in the recommendation for antiplatelet treatment. I was very familiar with the previous protocol where aspirin was continued and clopidogrel was prescribed in a short course. Therefore I believe that when I read the discharge summary I misread the instructions.*

10. I have interpreted the preceding point as confirmation by [Dr B] that he read the discharge summary (transfer of care) prior to prescribing for [Mr A]. I am unable to establish what he refers to as a recent change in recommendation for antiplatelet treatment. I have provided some historical and current references in this regard as Appendix 1. BPAC references are freely available to NZ GPs. In terms of secondary prevention of stroke (the primary indication in [Mr A's] case, but influenced by his concurrent CAD) I could not find any historical reference to short term use of clopidogrel in the clinical scenario he represented although the short term use of DAPT in the manner described (aspirin plus clopidogrel with aspirin then discontinued) appears to have been a recent change in practice. There may have been some specific situations where short term use of clopidogrel was being used as noted in Appendix 1 sections 3 and 5, but I do not think this could be described as a 'previous protocol' for secondary stroke prevention.

11. It appears [Mr A] was administered his clopidogrel and aspirin as prescribed by [Dr B] ie aspirin daily long-term and clopidogrel daily for one month, stopping on 24 July 2016. The prescribing error was not detected until [Mr A] was admitted to [the public hospital] on 17 September 2016 having suffered a further MI following which he had four stents inserted. In the interim, [Mr A] had been seen in [the public hospital's] general medicine outpatient clinic (21 July 2016) and was noted to be recovering from his stroke and no further chest pain experienced. There was no reference to his current medication regime and no changes made to that regime. I think it was reasonable for [Mr A's] [public hospital] clinicians to assume [Mr A] was receiving his medications as per the hospital discharge summary and prescription provided on 24 June 2016.

12. Comments

(i) [Dr B] was responsible for ensuring the medication he was prescribing for [Mr A] was appropriate. [Dr B] states he read [Mr A's] discharge letter. The letter states [Mr A's] primary diagnosis was stroke and, on the advice of the stroke specialists, clopidogrel was to be continued indefinitely with aspirin to be stopped after one month of treatment. Long-term clopidogrel was accepted first-line treatment for secondary prevention of stroke in patients without atrial fibrillation at the time of the events in question, and had been since at least 2011 although long-term aspirin monotherapy or aspirin plus dipyridamole were regarded as alternative treatments. [Mr A's] situation was complicated by his concurrent MI and finding of severe CAD although he did not undergo any percutaneous intervention which might have impacted on the DAPT prescribing. It is possible the annotation of one month supply on the clopidogrel prescription (written prescription and discharge summary) might have caused some confusion, but this same annotation was present on [Mr A's] other long-term medications (three weeks noted on the aspirin prescription as this was intended to be short term), and prescribing of one month of long-term medications on discharge was standard practice.

(ii) I believe that a clinician reading [Mr A's] discharge summary dated 24 June 2016 should have no doubt that DAPT was being prescribed for secondary prevention of stroke in the first instance, and that clopidogrel was to be continued long-term with aspirin stopped after three weeks (one month total treatment). The concurrent conditions of severe CAD with recent MI might have complicated the choice of DAPT regime, but unless the discharge summary was not reviewed I would not expect this to have influenced [Dr B's] prescribing. I note [Dr B] coded [Mr A's] myocardial infarction history but not the stroke history although the significance of this is unclear.

(iii) [Dr B] prescribed [Mr A's] clopidogrel in the 'short course' section of the medication chart. A one month supply was charted. The significance of the medication being crossed out in error is unclear but at no stage over the period in question was the clopidogrel charted as a 'long-term' medication. It appears [Dr B] interpreted the advice in [Mr A's] discharge letter as meaning clopidogrel should be stopped after one month and aspirin continued indefinitely, and his prescribing reflected this interpretation. The reason for this misinterpretation is unclear as I feel the information in the discharge letter, if adequately reviewed, was unambiguous. I think the prescribing error would be regarded as at least a moderate departure from accepted practice given the instructions in the discharge summary and accepted practice for secondary prevention of stroke at the time. If the discharge summary was not reviewed, and prescribing was undertaken on the basis of flawed assumptions (such as prescribing was for prevention of stent thrombosis), I would be somewhat more critical.

(iv) The fact medication transcribing errors are common might be regarded as a mitigating factor and this has been discussed in Appendix 2 section 1. At the same time, clinicians have an obligation to minimise harm to patients through such medication errors and relevant extracts from Medical Council of New Zealand guidance in this regard are presented in Appendix 2, section 2. I acknowledge that while DAPT (and aspirin alone) might reduce the risk of recurrent stroke or recurrent MI, it does not remove the risk entirely and it is not possible to unequivocally attribute [Mr A's] MI in September 2016 to premature cessation of clopidogrel. The main issue examined in this report is that the prescribing intended for [Mr A] (by his [public hospital] clinicians) was appropriate but there were deficiencies in [Dr B's] management of [Mr A's] ongoing care with respect to this prescribing.

Appendix 1

1. From: *BPAC. The use of antithrombotic medicines in general practice: a consensus statement. Best Practice Journal. 2011; Issue 39*

Secondary prevention of stroke – people without atrial fibrillation

Medicine	Dose	Duration	Comments
First-line: Clopidogrel	Loading dose of 300 mg followed by 75 mg daily	Lifelong	Although evidence and consensus opinion favours clopidogrel monotherapy first line, combination treatment with aspirin and dipyridamole or aspirin monotherapy remain alternative first-line choices
Second-line: Aspirin + dipyridamole	Aspirin 100 mg daily and dipyridamole 150 mg* twice daily	Lifelong	Consider for patients who cannot tolerate clopidogrel
Third-line: Aspirin alone	Aspirin 100 mg daily	Lifelong	Consider for patients who cannot tolerate clopidogrel or dipyridamole

Secondary prevention of acute coronary syndrome

Scenario	Medicine	Dose	Duration	Comments
After acute event: no stent	Aspirin and clopidogrel	Aspirin 100 mg daily and clopidogrel 300 mg loading dose followed by 75 mg daily	12 months	After 12 months stop clopidogrel
After acute event: bare metal stent	Aspirin and clopidogrel	Aspirin 100 mg daily and clopidogrel 300 mg loading dose followed by 75 mg daily	12 months (do not stop treatment in first 6 months)	After 12 months stop clopidogrel
After acute event: drug eluting stent	Aspirin and clopidogrel	Aspirin 100 mg daily and clopidogrel 300 mg loading dose followed by 75 mg daily	12 months (do not stop treatment in this period)	After 12 months stop clopidogrel
High risk patients: multiple events in more than one vascular territory, e.g. MI and stroke	Aspirin and clopidogrel	Aspirin 100 mg daily and clopidogrel 300 mg loading dose followed by 75 mg daily	Lifelong	Treatment for these high risk patients often requires secondary care input

2. From: *BPAC. Access to clopidogrel now widened. Best Practice Journal. 2010; issue 31.*

Indications for clopidogrel

There is insufficient evidence to support the use of clopidogrel for primary prevention of cardiovascular disease (CVD), and it is not licensed for this indication.

Clopidogrel is currently recommended for secondary prevention of CVD in the following situations:

1. People with established CVD
 - First choice – aspirin
 - Second choice – clopidogrel, continued indefinitely
2. Secondary stroke prevention
 - First choice – aspirin + dipyridamole combination
 - Second choice – clopidogrel, continued indefinitely
3. Acute coronary syndrome without ST-segment elevation (non-STEMI)
 - First choice – aspirin + clopidogrel combination
 - Second choice – clopidogrel
4. Post-revascularisation procedures e.g. cardiac stenting and angioplasty
 - First choice – aspirin + clopidogrel combination
 - Second choice – clopidogrel

N.B. for acute coronary syndrome without ST-segment elevation and post-revascularisation procedures there is currently no evidence to support the use of clopidogrel beyond 12 months.

3. From: *BPAC. The immediate management of acute coronary syndromes in primary care. Best Practice Journal. 2015; Issue 67*

Medicines frequently initiated following admission to a coronary care unit

- Most patients treated for an acute coronary syndrome will be offered dual antiplatelet treatment for one year following discharge to reduce current events, after which point aspirin alone is recommended. The majority of these patients will have undergone a coronary stenting procedure and dual antiplatelet treatment also reduces the likelihood of stent thrombosis.
- Patients who require anticoagulation to be initiated, e.g. patients who develop atrial fibrillation, may begin treatment with aspirin and clopidogrel or ticagrelor, plus warfarin or dabigatran. However, the patient's risk of bleeding is relatively high with this treatment combination and ticagrelor or clopidogrel is generally withdrawn at one month and treatment continued with aspirin plus warfarin or dabigatran.

4. From: Stroke Foundation of New Zealand and New Zealand Guidelines Group. *Clinical Guidelines for Stroke Management 2010*. Wellington: Stroke Foundation of New Zealand; 2010 (updated guidelines were released in 2017)

Recommendations	
Antiplatelet therapy	Grade
Long-term antiplatelet therapy should be prescribed to all people with ischaemic stroke or TIA who are not prescribed anticoagulation therapy (Antithrombotic Trialists, 2002).	A
Low dose aspirin and modified release dipyridamole or clopidogrel alone should be prescribed to all people with ischaemic stroke or TIA taking into consideration patient comorbidities (Sacco et al, 2008).	B
Aspirin alone can also be used, particularly in patients who do not tolerate aspirin plus dipyridamole or clopidogrel (Antithrombotic Trialists, 2002).	A
The combination of aspirin plus clopidogrel is NOT recommended for the secondary prevention of cerebrovascular disease in patients who do not have acute coronary disease or recent coronary stent (Diener et al, 2004; Bhatt et al, 2006).	A
Grade description A Body of evidence can be trusted to guide practice B Body of evidence can be trusted to guide practice in most situations C Body of evidence provides some support for recommendation(s) but care should be taken in its application D Body of evidence is weak and recommendation must be applied with caution ✓ Consensus-based recommendations (GPP)	

5. From: 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *Circulation*. 2011;124(23)

- In patients receiving BMS³ for a non-ACS⁴ indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks)

Appendix 2

1. From: Veo G et Minuz P. Medication errors: prescribing faults and prescription errors. *Br J Clin Pharmacol*. 2009 Jun; 67(6): 624–628

- Medication errors are common in general practice and in hospitals. Both errors in the act of writing (prescription errors) and prescribing faults due to erroneous medical decisions can result in harm to patients.
- Any step in the prescribing process can generate errors. Slips, lapses, or mistakes are sources of errors, as in unintended omissions in the transcription of drugs. Faults in dose selection, omitted transcription, and poor handwriting are common.

³ Bare metal stent

⁴ Acute coronary syndrome (including MI)

- Inadequate knowledge or competence and incomplete information about clinical characteristics and previous treatment of individual patients can result in prescribing faults, including the use of potentially inappropriate medications.
- An unsafe working environment, complex or undefined procedures, and inadequate communication among health-care personnel, particularly between doctors and nurses, have been identified as important underlying factors that contribute to prescription errors and prescribing faults.
- Active interventions aimed at reducing prescription errors and prescribing faults are strongly recommended. These should be focused on the education and training of prescribers and the use of on-line aids. The complexity of the prescribing procedure should be reduced by introducing automated systems or uniform prescribing charts, in order to avoid transcription and omission errors. Feedback control systems and immediate review of prescriptions, which can be performed with the assistance of a hospital pharmacist, are also helpful. Audits should be performed periodically.

2. From MCNZ statement 'Good Prescribing Practice'⁵

- Be familiar with the indications, adverse effects, contraindications, major drug interactions, appropriate dosages, monitoring requirements, effectiveness and cost-effectiveness of the medicines that you prescribe.
- Prescribe in accordance with accepted practice and any relevant best practice guidelines. Prescribing outside of accepted norms should only occur in special circumstances with the patient's informed consent. It might be useful to discuss the proposed treatment with a senior colleague before completing the prescription.
- There are often changes to a patient's medicines when their care is transferred between health professionals or between care facilities. Transitions of care can result in medication errors and cause harm to the patient. You should ensure that the health professional taking over the patient's care is supplied with the patient's current list of medicines, allergies and adverse drug reactions, and that any changes are documented, reconciled and explained.
- Where a patient's care is shared between clinicians, the doctor with the responsibility for continuing management of the patient has a duty to keep him or herself informed about the medicines that are prescribed and the monitoring required for patients on that medicine to ensure safe and effective use.
- If you are the doctor signing and issuing the prescription you bear responsibility for that treatment; it is therefore important that, as the prescriber, you understand the patient's condition as well as the treatment prescribed and can monitor any adverse effects of the medicine should they occur."

⁵ <https://www.mcnz.org.nz/assets/News-and-Publications/Statements/Good-prescribing-practice.pdf>

Accessed 6 February 2019