MidCentral District Health Board

A Report by the
Deputy Health and Disability Commissioner

(Case 20HDC00962)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a woman who presented to an emergency department with pain in her upper legs. The woman presented to the public hospital during a very busy period and, without being reviewed by a medical practitioner, was administered an off-label sedative (droperidol) for pain relief by a registered nurse. The woman did not provide consent to receive the off-label sedative, and was not monitored, and she experienced an adverse reaction. HDC's investigation has been unable to identify the prescriber of the medicine.

2. This case highlights the importance of ensuring that even during busy periods, emergency departments provide information to consumers and obtain informed consent for medication given. Additionally, it highlights the importance of observing and monitoring a patient after administering medication.

Findings

3. The Deputy Commissioner found MidCentral DHB in breach of Right 4(1) of the Code for the inadequate monitoring the woman received after the administration of the sedative.

4. The Deputy Commissioner considered that the DHB failed to provide the woman with information that a reasonable consumer in her circumstances would expect to receive, including that droperidol had been approved for use as a sedative and was being prescribed off label to treat her pain. As such, the Deputy Commissioner found MidCentral DHB in breach of Right 6(1) of the Code. Consequently, as the woman was not in a position to make an informed choice about her treatment, the Deputy Commissioner found that MidCentral DHB also breached Right 7(1) of the Code by administering droperidol without the woman's informed consent.

5. Adverse comment was made about the wait time at the emergency department, as the woman waited for one hour and 45 minutes without analgesia or a medical assessment.

6. The Deputy Commissioner also made adverse comment about a registered nurse for the lack of monitoring of the woman after the droperidol had been administered.

Recommendations

7. The Deputy Commissioner recommended that MidCentral DHB provide a written apology to the woman; undertake an audit of the emergency department waiting times; provide an updated plan to improve waiting times; amend the medication charting guidelines to include a requirement for doctors' Medical Council of New Zealand (MCNZ) number to be entered on medication charts; undertake an audit of medication charts to check compliance of doctors entering MCNZ registration numbers into the medication chart; ensure that all staff are aware of the requirement to enter the MCNZ number in the medication chart; and consider incorporating guidelines for droperidol use in the analgesia protocol.

Complaint and investigation

8. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided to her by MidCentral District Health Board (MidCentral DHB). The following issue was identified for investigation:

- *Whether MidCentral District Health Board provided Mrs A with an appropriate standard of care in November 2019.*

9. This report is the opinion of Deputy Commissioner Deborah James, and is made in accordance with the power delegated to her by the Commissioner.

10. The parties directly involved in the investigation were:

Mrs A	Complainant/consumer
MidCentral DHB	Group provider

11. Further information was received from:

Registered Nurse (RN) B	Registered nurse
RN C	Registered nurse
RN D	Registered nurse

12. Independent expert advice was obtained from an emergency medicine specialist, Dr Stuart Barrington-Onslow (Appendix A), and a registered nurse, Michael Geraghty (Appendix B).

Information gathered during investigation

Introduction

13. This report discusses the care provided to Mrs A (in her thirties at the time of events) at the emergency department (ED) of a public hospital in November 2019. While in the crowded ED, she was prescribed and administered off-label droperidol (see paragraphs 16–21) for pain relief. Mrs A reports that she experienced an adverse reaction to the medication, and that this was not noticed.

ED capacity at the public hospital

14. The ED has 28 bed spaces. In 2018–2019 the ED experienced difficulties because of overcrowding. When the ED exceeds 28 patients, overflow bed spaces in the corridor are utilised. MidCentral DHB explained that the overflow space is a temporary solution until bed capacity can be managed back to 28, and every attempt is made to move patients out of corridor beds as soon as appropriate bed spaces become available. MidCentral DHB said that the overflow space is located in clear line of sight from the ED workstation.

15. At the time of Mrs A's presentation, the number of patients in ED outnumbered the bed spaces available. Patient numbers increased from 36 to 49 during her stay.

Medication approval

16. At the time of events, medicines were approved by the Minister of Health, after recommendation from the Medicines and Medical Devices Safety Authority (Medsafe). An approved medicine has been through a regulatory process and is considered safe to prescribe under the conditions set out in the Medicine Data Sheet. If the medicine is a prescription medicine or a restricted medicine, a medicine data sheet outlines the approved use of the medicine for prescribers.

17. Doctors can still prescribe unapproved medicines or prescribe medicines for an unapproved use, but there are certain requirements and safeguards for doing so, particularly around documentation and consent.[1]

Approved use of droperidol

18. The Medsafe Data Sheet states that in New Zealand, droperidol is approved for use:

a) "[As anaesthesia] to produce tranquilisation and to reduce the incidence of nausea and vomiting in surgical and diagnostic procedures. It can also be used for premedication, induction, and as an adjunct in the maintenance of general and regional anaesthesia …"; or

b) "[In psychiatry] in the management of severe agitation, hyperactivity, or aggressiveness in psychotic orders …"

19. Therefore, in New Zealand, any use of droperidol outside of these two approved uses is classified as "off label" or "unapproved" use.

20. Droperidol is not approved for use as pain relief (analgesia) but, when administered in conjunction with narcotic analgesia,[2] it can aid in producing tranquillity and in decreasing anxiety and pain. Using droperidol for pain relief is an unapproved, or off-label use.

21. The Medsafe Data Sheet for droperidol stipulates that vital signs should be monitored "routinely", although no further guidance is provided about what "routinely" entails.

Prior admissions to ED

22. On 28 and 29 October 2019, Mrs A presented to ED with pain in her left leg, and she was assessed, investigated, treated, and discharged.

Arrival at ED — 15 November 2019

23. On 15 November 2019, Mrs A was experiencing severe upper leg pain and was transported to the ED by ambulance at 3.41pm. The ambulance notes state that prior to arriving at the

[1] See section 25 of the Medicines Act 1981, and the Medical Council of New Zealand statement, "Good Prescribing Practice" (March 2020).
[2] A group of medications of the opioid class that have painkilling qualities, such as fentanyl.

hospital, Mrs A had taken paracetamol, Norflex,[3] and 600mg of ibuprofen, and during her ambulance transport she was given 200mcg of fentanyl.[4]

24. At 3.46pm there were 36 patients in the ED (eight more patients than available beds). At the time, the ED staff included five consultants and five resident medical officers (RMOs[5]).

25. At 3.48pm, Mrs A was triaged by RN D as category three[6] (which indicates that medical assessment and treatment should commence within 30 minutes) and assessed as having a pain level of 4–6 (moderate). RN D documented that Mrs A had a three-week history of worsening left sciatic back pain and had seen her general practitioner (GP) and been to ED previously, and was awaiting an orthopaedic appointment. RN D noted that Mrs A had taken analgesia but the pain could not be controlled.

26. Mrs A told HDC that she spent one hour and 45 minutes in the corridor with a pain level of 9–10/10.

27. Mrs A was not assessed in person by a doctor at any point during her stay.

28. Mrs A was placed in one of the overflow beds in the corridor at 4.00pm. MidCentral DHB told HDC that Mrs A would have been observed directly by ED medical and nursing staff.

29. The clinical notes show that at 5.20pm RN B, a staff nurse,[7] took Mrs A's observations and noted that her pain level was 10/10 and documented that she was alert and distressed.[8] RN B recorded that Mrs A was alert but was crying and distressed, with pain in her left lower back radiating down her left leg.

30. RN B told HDC that she has no recollection of Mrs A. However, on viewing the nursing documentation, she told HDC that after taking a history from Mrs A, she would have presented Mrs A's history (past history, pain level, allergy status, medications self-administered by Mrs A, and medication administered by paramedics) to a member of the medical staff, who charted further medication. RN B does not recall who charted the medication.

Charting of droperidol

31. Droperidol and ibuprofen were charted (prescribed) by an unknown doctor. HDC's investigation has been unable to identify the clinician who charted droperidol for Mrs A.

[3] A muscle relaxant.
[4] An opioid drug used in the treatment of severe pain.
[5] RMOs are doctors who have yet to complete the speciality training required to become an emergency medicine consultant. Two consultants and two RMOs completed their shift at 5.00pm.
[6] New Zealand EDs use the Australasian triage scale, which has five triage categories. For each triage category there is a specified maximum clinically appropriate time within which medical assessment and treatment should commence.
[7] In response to the provisional opinion, RN B told HDC that her assigned role for the shift was coordinator support, and in this role she triaged many of the ambulance arrivals and assisted with patient flow, and her role was not to give direct patient care.
[8] In response to the provisional opinion, RN B told HDC that she documented that Mrs A was alert at 5.28pm.

32. MidCentral DHB has also been unable to identify who prescribed the droperidol, as the signature on the front of the medication chart cannot be identified, and there is no Medical Council of New Zealand (MCNZ) registration number. MidCentral DHB told HDC that it circulated the medication chart and no one was able to identify the signature on the chart. All ED consultants working on 15 November 2019 confirmed that it was not their signature.

33. MidCentral DHB said that it also reviewed the medication charts used by all junior doctors working in ED and in the Medical Administration Unit, and the signatures on file in the Pharmacy, and it has been unable to identify the signee.

34. MidCentral DHB told Mrs A that droperidol is given as analgesia when standard opioid treatment is not effective, and that because of her continued pain level, the treating physician authorised the administration of droperidol. MidCentral DHB explained to Mrs A that there is evidence that droperidol assists with pain and has antiemetic[9] properties, and as nausea and vomiting are common side effects of opioid therapy (being the fentanyl Mrs A had been administered by paramedics), this was an added benefit.

35. MidCentral DHB told HDC that the clinical indication for the use of droperidol was likely Mrs A's severe pain, which had not been controlled by Mrs A's own medications of tramadol, paracetamol, ibuprofen, Norflex, and diazepam, or by the 200mg of intravenous (IV) fentanyl she received by paramedics on the way to the ED.

36. MidCentral DHB stated that although the use of droperidol for management of pain is not listed by the New Zealand formulary,[10] the use of droperidol or similar medications for intractable pain is well documented in international literature. MidCentral DHB provided HDC with an article that concluded that droperidol is an important adjuvant for patients who are tolerant to opioid analgesics.[11]

Administration of droperidol

37. The medication chart indicates that RN B administered 2.5mg of IV droperidol to Mrs A at 5.28pm. This was checked and co-signed by a nurse. The nursing notes state "IV droperidol 2.5mg given" but no further details about the droperidol or a plan for monitoring Mrs A are documented. In response to the provisional opinion, RN B told HDC that she documented at 5.28pm that Mrs A was alert.

38. Also in response to the provisional opinion, RN B told HDC that having seen Mrs A in distress, she stepped out of her assigned role (as coordinator support) and attempted to alleviate her distress by administering the prescribed medication.

[9] Antiemetic drugs are prescribed to help with nausea and vomiting, which can be side effects of other drugs.
[10] An independent resource providing healthcare professionals with clinically validated medicines information and guidance on best practice, enabling healthcare professionals to select safe and effective medicines for individual patients.
[11] Richards, JR, Richards, IN, Ozery, G, and Derlet, RW, "Droperidol analgesia for opioid-tolerant patients". *Journal of Emergency Medicine*. 2011, 41(4): 389–96.

39. Between 5pm and 6pm, 49 patients were present in the ED (21 patients over capacity), of whom several were deemed as high acuity and six were waiting for inpatient beds.

40. Although she cannot remember the events,[12] RN B explained that as droperidol is used infrequently, she would have had to access the *Notes on Injectable Drugs* 7th Edition handbook to obtain information about the administration, dosage, monitoring/observation, and cautions regarding the use of droperidol. RN B said that she consults the handbook regularly when preparing drugs for administration.

41. The *Notes on Injectable Drugs* handbook states:

> "[M]onitor for signs and symptoms of hypersensitivity/anaphylaxis [13] /electrolyte imbalances including hypokalaemia and hypomagnesaemia. Monitor ECG at baseline and periodically during therapy in patients susceptible to QT-interval prolongation."

42. Mrs A told HDC that she recalls a nurse approaching her and asking if she had heard of droperidol, and she told the nurse that she had not. Mrs A remembers the nurse telling her that "the drug needed to be administered over two minutes and that it should resolve some of her pain". She stated that she did not receive any explanation of what droperidol is, and she thought that it was a pain relief medication.

43. RN B told HDC that she would have administered the droperidol over three to ten minutes. She said that when an intravenous drug is given over a longer period of time, she always explains this to patients, as she likes them to understand why she is doing it. RN B told HDC that her standard practice when administering drugs is to ask the patient about their allergies, and inform the patient about the medication she is administering and its intended effect.

Reaction to droperidol

44. Mrs A told HDC that RN B left once the droperidol had been administered. Mrs A recalls that RN B did not look at her before she left, but looked only at her watch. In response to the provisional opinion, Mrs A told HDC that she recalls the nurse looking at her watch, and that after two minutes she left. Mrs A said that she remembers this as "clear as day", and that the nurse did not take her bloods after she gave her the medication.

45. RN B disagrees that she left straight after administering the droperidol. It is documented that a full blood sample was taken by RN B at 5.40pm, and RN B submitted that this indicates that she stayed with Mrs A from the time of administering the droperidol at 5.28pm until the bloods were taken at 5.40pm. Although RN B does not recall the events, she explained that after the administration at Mrs A's bedside, she would have taken Mrs A's blood and made notes in the records, and this would have involved verbal interaction with Mrs A. RN

[12] In response to the provisional opinion, RN B told HDC that she has worked as a registered nurse for many years in the ED and she has developed a style of care that is consistent, and this is why in her statement she could give an indication of what her actions would have been, without having any specific memory of the case.
[13] An acute allergic reaction to an antigen (a toxin or other foreign substance) to which the body has become hypersensitive.

B said that she may have completed the paperwork on top of the blood-taking trolley, as she sometimes does this. RN B stated that during her interactions with Mrs A after the administration of droperidol, she did not document that any adverse/dystonic reaction[14] was observed. RN B's nursing assessment notes document: "EWS=1. BP 107/70. IV Droperidol 2.5mg given. PO Ibuprofen 600mg given."

46. Mrs A told HDC that one minute after the droperidol was administered, she experienced an adverse reaction. Mrs A remembers that two women sitting across from her were looking at her, and she was unable to talk or move, and she felt completely helpless. She said that her tongue was folded inside her mouth and her mouth "did not work", she was "stuck inside" her body, she experienced involuntary muscle spasms, she could not control her thumbs and arms, her back arched involuntarily, and then she became unconscious.

47. RN B told HDC that RN C was the nurse assigned to the overflow section, and was Mrs A's primary nurse. RN B said that she was working outside of her assigned role, as co-ordinator support, when she administered droperidol to Mrs A. RN B stated that her usual practice when she carries out an intervention outside of her assigned area is to advise the patient's nurse. RN B said that although she cannot recall whether she did this, she believes that she would have. RN C told HDC that she does not recall RN B telling her that she had administered droperidol to Mrs A.

48. MidCentral DHB told HDC that Mrs A was not connected to a machine that would have monitored her vital signs remotely, and it is not documented that she had anyone with her.

49. Mrs A told HDC that when she woke up, her watch recorded that her heart rate had dropped to 38 beats per minute, and at this point she realised that something was wrong. Mrs A stated that she felt scared and traumatised, and thought that she would die in the hospital if she stayed.

50. Mrs A told HDC that once she was able to move, she asked a different nurse to help her, but the nurse did not hear her, so she removed the intravenous line and a nurse "told her off". Mrs A said that the nurse's attitude was rude and disrespectful and made her feel unsafe and unwelcome.

Subsequent events

51. Mrs A said that she contacted her husband and asked him to pick her up. She told HDC that she did not tell the nurse about the reaction she had experienced because of the nurse's attitude. Mrs A stated that she felt that she had been treated as if she did not matter, that the staff did not have time for her, and that the nurse had not realised that she had had a seizure in front of her.

52. MidCentral DHB told Mrs A that the "seizure" she reported having experienced was not witnessed or reported by the nursing staff, and was not documented. MidCentral DHB told

[14] A dystonic reaction is an involuntary contraction of muscles of the face, arms, abdomen, pelvis, and back. It can prevent speech and fine motor control.

HDC that as Mrs A was in full view in the centre of the ED, if she had experienced a serious adverse reaction, it would have been observed.

53. RN B told HDC that she is familiar with dystonic reactions as she has seen them during her time working as a registered nurse, and these types of reaction are very memorable.

54. MidCentral DHB told HDC that it is not certain that Mrs A's vital signs would have become abnormal during her dystonic reaction, and that most practitioners would have seen people having dystonic reactions who have completely normal vital signs.

55. MidCentral DHB confirmed that Mrs A did not report her adverse reaction and it was not witnessed by the nursing staff.

56. At 6.40pm, the ED went into "Red" status, which meant that there was a critical care capacity deficit, i.e., the service was operating in a critically degraded state with negative consequences apparent. The ED shift report noted: "ED in RED for 6.40pm but had been escalating from 5pm."

57. Mrs A's medical records outline that she self-discharged at 7.22pm. At this time, there were two ED consultants, 12 registered nurses, a clinical nurse specialist, a nurse practitioner, an associate charge nurse, and a healthcare assistant working in the ED.

58. The ED reduced to "Yellow" status at 8pm, and the ED was "under control" by 9.30pm.

ED Variance Response Management tool and wait times

59. MidCentral DHB uses a Variance Response Management (VRM) tool for the assessment of demands on staff in each area. The VRM tool uses a colour code to indicate the current status of each area. When in the "Green" status, an area is "business as usual", "Yellow" status signals that an area has an early variance on capacity, "Orange" signals that the area has a significant care capacity deficit or high risk, and "Red" signals that an area has a critical care capacity deficit. The VRM outlines that when the ED is in the "Red" category, the following protocol applies:

> "
> - Maintain close liaison with Duty Nurse Manager and Senior Medical Officer (SMO).
> - Notify the on-call SMO.
> - Consider contacting Charge Nurse after hours if a prolonged red period for extra advice and to notify of risk.
> - Allocate a senior doctor to triage/waiting room if able.
> - Consider contacting [ambulance service] to inform them of possible delays and ramping issues."

60. MidCentral DHB told HDC that on 15 November 2019 when the ED went into the "Red" status, contacting an on-call SMO was not an appropriate action because ED SMOs were already working (one of whom was the Clinical Lead for the ED). In response to the provisional opinion, MidCentral DHB clarified that notifying the on-call SMO is only

applicable during the hours of 1am to 8am, when the ED SMO is on call and only RMOs and nursing staff are present. MidCentral DHB stated that the SMOs working did not allocate a senior doctor to the triage or waiting room and did not document the reason why not. In response to the provisional opinion, MidCentral DHB clarified that it is assumed that the SMOs considered this, but VRM and duty manager reports identify only the actions taken, rather than what was considered (such as assigning a senior doctor to triage/waiting room) but not actioned. MidCentral DHB told HDC that a medical nurse and a children's nurse were provided to assist in the ED.

61. MidCentral DHB said that within 70 minutes the acuity had settled, and five of the six patients who were waiting for beds had moved, and there were nine fewer patients in the ED.

62. MidCentral DHB told HDC that it recognises that patients may present to ED with acute pain or vomiting and need immediate relief of their symptoms, but may have been determined safe to wait to be interviewed and examined by an ED physician.

Informed consent

63. Mrs A told HDC that she later discovered that droperidol is a sedative, and that at the time she did not know that she was being given a sedative. She stated that if she had been told that the drug is a sedative, she would not have given consent, as she is a busy mum and she knows that sedatives force you to sleep, and she would never have been "ok with this". Mrs A told HDC that she feels as though she was not given an option to refuse.

64. RN B told HDC that if a patient expresses any concerns, she attempts to answer their questions or seek further information. RN B stated: "I would not administer a medication against a patient's wishes in these circumstances."

65. Mrs A's medical records do not document any conversation about the risks and benefits of droperidol or any possible adverse effects, and do not record Mrs A's consent to the administration of droperidol.

66. MidCentral DHB told HDC that when the nurse explained to her that she was going to administer the medication over a two-minute period, Mrs A allowed the nurse to proceed, and that because of this, Mrs A's consent was presumed.

67. MidCentral DHB told HDC that when obtaining consent prior to administering a sedative medication, best practice is to provide patients with the risks, benefits, and alternatives, and for the patient, their guardian, or a family member to sign a consent form. MidCentral DHB said that usually consent in relation to sedation takes place to facilitate a painful procedure such as a fracture manipulation. However, in Mrs A's case, droperidol was administered for its analgesic benefits rather than for its sedative, antiemetic, or antipsychotic properties.

68. MidCentral DHB told HDC: "[O]ne could consider that there was implied consent for treatment as the visit on 15 November 2019 was her third presentation for the same complaint."

69. MidCentral DHB stated that it does not obtain informed consent when administering analgesic medication to patients who present with acute pain — they make the presumption that these patients want their pain relieved. MidCentral DHB told HDC that it does not have a "usual practice" for obtaining informed consent from a patient when administering medication for "off label" use. MidCentral DHB stated that usually staff will tell patients what medication they are administering and why, and inform patients about the potential side effects.

70. However, MidCentral DHB's policy on the use of medicines for unapproved indications ("Off-label Use of Medicines" — see Appendix C) outlines that the prescriber is responsible for ensuring that informed consent has been obtained. It states that "[p]atients must be provided with information at an individualised level to enable informed, freely given consent", and that "[e]ffective communication, including frank information disclosure, are essential to fulfilling these requirements". The policy requires written consent to be obtained prior to the provision of an unapproved medicine/unapproved indication.

Further information

71. MidCentral DHB told HDC that both MidCentral DHB and the ED team offer their sincere apologies for Mrs A's poor experience and the lack of communication during her visit on 15 November 2019. MidCentral DHB stated that its staff are expected to treat all patients with dignity and respect, and it apologises that this did not occur during Mrs A's visit. MidCentral DHB told HDC that it will continue to remind staff about communicating in a manner that makes patients feel welcome and supported in the ED.

72. MidCentral DHB said that the adequacy of Mrs A's medical assessment and documentation is accepted as being non-existent and completely inadequate.

Investigation

73. MidCentral DHB told HDC that during a review of Mrs A's medical records, it was identified that there was a lack of documentation by medical staff in relation to Mrs A's visit to ED on 15 November 2019.

74. MidCentral DHB stated that all ED medical staff undergo training as part of their orientation to the ED, to ensure that they understand clinical documentation expectations.

75. Mrs A told HDC that she does not feel that the hospital took her traumatic experience seriously, and she feels that the hospital staff think that she should accept what they told her.

Responses to provisional opinion

MidCentral DHB

76. MidCentral DHB was given the opportunity to respond to the provisional opinion. Where appropriate, changes have been incorporated into the report. MidCentral DHB accepted that it did not provide services to Mrs A in accordance with the Code of Health and Disability Services Consumers' Rights (the Code), and accepted the report's findings. MidCentral DHB stated:

> "M[idCentral] DHB is committed to listening to its consumers and their whānau to improve consumers' experience and outcomes. We have discussed the events surrounding [Mrs A's] care at length and given careful consideration to improvements that we can make. Improving the services that we provide through our ED is a priority for MDHB and initiatives are underway (across the organisation) to support this."

RN B

77. RN B was given the opportunity to respond to the relevant sections of the provisional opinion. Where relevant, her response has been incorporated into this report. RN B told HDC that she has taken on board the reminder to undertake appropriate nursing practice when administering drugs. She stated that she thought she had met her obligations, and that she always observes a patient for adverse reactions when administering intravenous medications, and she always believed that a handover of care back to the primary nurse concluded her relationship with the patient.

78. RN B told HDC that her attempt to alleviate Mrs A's distress ultimately caused her harm, as she had an adverse reaction, and that this was the exact opposite of her intention. RN B said that she absolutely acknowledged that Mrs A had an unacceptable experience, and she has made every endeavour in her practice to prevent this happening to anyone else in the future.

Mrs A

79. Mrs A was given an opportunity to respond to the "information gathered" section of the provisional opinion, and her response has been incorporated into this report where relevant.

80. Mrs A said that she felt that MidCentral DHB did not grasp how distressful the event was for her. She explained that she was diagnosed with a slipped and herniated disc that was putting pressure on her sciatic nerve. She felt that medical staff just wanted her to "shut up" because they were so busy. Mrs A explained how traumatic the experience was for her, as she thought she was going to die. She said that after the incident she felt that she did not want to attend hospital again.

Opinion: MidCentral District Health Board — breach

Introduction

81. District health boards are responsible for the operation of the clinical services they provide. They have a responsibility for ensuring that their staff adhere to relevant policies, and an organisational duty to provide an appropriate standard of care to consumers of their services.

82. To assist my consideration of the care provided, I obtained emergency medicine advice from Dr Stuart Barrington-Onslow.

Droperidol

83. As explained at paragraphs 18–19 above, droperidol is approved for two uses in New Zealand — as anaesthesia in surgical procedures, and to treat psychotic disorders. Any use outside of these two indications is classed as unapproved or "off label". Mrs A was prescribed and administered droperidol as analgesia (pain relief). I am satisfied, with reference to MidCentral DHB and Dr Barrington-Onslow's consensus, that the use of droperidol in this situation was off label.

84. The question remains whether off-label prescription of droperidol for pain relief was appropriate in Mrs A's circumstances. MidCentral DHB told HDC that droperidol is given as analgesia when standard opioid treatment is not effective. The DHB stated that because of Mrs A's continued pain level, the treating physician authorised the administration of 2.5mg droperidol. MidCentral DHB said that although use of droperidol for management of pain is off label, it is well documented in international literature.

85. MidCentral DHB told Mrs A that there is evidence that droperidol assists with pain and vomiting and nausea, and that this was an added benefit, as nausea and vomiting are common side effects of opioid therapy.[15] MidCentral DHB's analgesia protocol refers to use of droperidol only for management of nausea.

86. Dr Barrington-Onslow advised that although some clinicians may use droperidol for pain relief, the majority would not.

87. Having regard to MidCentral DHB's statements and Dr Barrington-Onslow's advice, I am not critical of the off-label use of droperidol to treat Mrs A's pain. My primary concern lies with the information provided to Mrs A prior to its administration, and the monitoring of Mrs A after the administration, as outlined below.

Information provided and consent

88. Mrs A told HDC that she was not told that droperidol is a sedative, and she received no explanation other than being told by RN B that it would assist with her pain and that it would be administered over two minutes.

89. MidCentral DHB told HDC that its usual practice is to tell patients what medication they are to be administered and why, and to tell patients about the potential side effects. MidCentral DHB said that it does not obtain informed consent when administering analgesic medication to patients who present with acute pain — it makes the presumption that these patients want their pain to be relieved. MidCentral DHB stated: "[O]ne could consider that there was implied consent for treatment as the visit on 15 November 2019 was her third presentation for the same complaint."

90. I accept that there may be some limited circumstances where consent to treatment can be implied, but I consider that this was not one of those occasions. MidCentral DHB's policy (Appendix C) and relevant professional and legal standards are clear that informed consent must be obtained from the patient for off-label prescribing. MidCentral DHB's policy on the

[15] Mrs A was given fentanyl in the ambulance.

use of medicines for unapproved indications states that patients must be provided with information at an individualised level to enable informed, freely given consent, and that effective communication, including frank information disclosure, are essential to fulfilling these requirements. The policy requires written consent to be obtained prior to the provision of an unapproved medicine or for an unapproved indication.

91. Mrs A should have been told what was being prescribed (droperidol), the primary use of that medication (as a sedative), its primary side effects, why it was being prescribed for her (to relieve her pain), and that such a use was not an approved use of the medication. This was information that a reasonable consumer in Mrs A's circumstances would expect to receive, and needed to receive to give informed consent.

92. I accept that Mrs A was told that she was being given droperidol and that it was intended to relieve her pain. However, this information in and of itself was insufficient for Mrs A to give informed consent.

Monitoring

93. Mrs A told HDC that one minute after RN B administered the droperidol, she experienced an adverse reaction. She described that she could not move, her tongue folded inside her mouth and her mouth "did not work", she was "stuck inside" her body, she experienced involuntary muscle spasms, she could not control her thumbs and arms, her back arched involuntarily, and then she became unconscious. Mrs A said that before she lost consciousness, she recalls RN B looking at her watch and leaving without looking at her.

94. RN B told HDC that she would not have left Mrs A straight away, and that after the administration of droperidol she would have waited to take Mrs A's bloods and to make notes in the records. However, RN B also said that she does not recall the events. RN B's notes record that an initial nursing assessment took place at 5.20pm. The medication chart indicates the administration of IV droperidol at 5.28pm, and bloods were collected at 5.40pm. RN B told HDC that she would have administered the droperidol over three to ten minutes. There are no further notes after the administration of droperidol.

95. I acknowledge Mrs A's memory of events is that RN B walked away after the droperidol was administered. However, I also acknowledge that RN B's contemporaneous documentation leaves open the possibility that she did not leave immediately. Due to the paucity of evidence, I cannot make a finding of fact regarding the timing of Mrs A's reaction and whether or not RN B stayed with Mrs A after administering the droperidol at 5.28pm until she took bloods at 5.40pm. There is no documented evidence that RN B observed Mrs A's vital signs when droperidol was administered, or that any staff member observed or monitored Mrs A after 5.40pm.

96. MidCentral DHB told HDC that as Mrs A was in full view in the centre of the ED, if she had experienced a serious adverse reaction, it would have been observed. Mrs A told HDC that when she woke up, she saw that her watch had recorded that her heart rate had dropped to 38 beats per minute. She said that she did not inform any nurses retrospectively that she had suffered an adverse reaction.

97. I acknowledge that Mrs A's experience was traumatic. Her account of her reaction is detailed and, in my opinion, there is no basis on which to discount her experience, as it is conceivable that Mrs A's adverse reaction went unnoticed owing to the busyness of the ED and because she was not being monitored. Although I am unable to conclude exactly what kind of reaction Mrs A experienced, as there is no documentation outlining a description of the adverse reaction Mrs A experienced, this is not material to my findings.

98. The *Notes on Injectable Drugs* 7th Edition handbook states that a patient should be monitored for signs and symptoms of hypersensitivity/anaphylaxis[16]/electrolyte imbalances including hypokalaemia[17] and hypomagnesaemia,[18] and that a baseline ECG should be undertaken and repeated periodically during therapy in patients who are susceptible to QT-interval prolongation.[19] The Medsafe Data Sheet explained that vital signs should be monitored "routinely". Similarly, the Medical Council of New Zealand's guidance on good prescribing of unapproved medicines outlines that the prescriber must take responsibility for overseeing the patient's care, including monitoring and any follow-up treatment.

99. Dr Barrington-Onslow advised that the prescriber should have directed the nursing staff to perform regular vital signs, especially as Mrs A was already taking Norflex, which when combined with droperidol can cause marked depression of the level of consciousness. Dr Barrington-Onslow said that the dystonic reaction that Mrs A reported having experienced would have been picked up by a vital sign assessment, which she did not have. Dr Barrington-Onslow considers that this was a severe departure from the accepted standard of care.

100. My independent nursing advisor, Michael Geraghty, was also concerned at the lack of nursing care following the administration of droperidol. He advised that Mrs A should have been monitored to see whether she experienced any benefits from the medication.

101. I accept my advisors' advice. Despite a clear expectation that Mrs A should have been monitored after droperidol was administered, there is no evidence that the prescriber gave any instructions regarding the need to monitor Mrs A, or that any staff member thought to observe her regardless of any instructions. I am critical that Mrs A was not monitored after droperidol was administered, which meant that her adverse reaction went unnoticed.

102. MidCentral DHB's questioning of whether Mrs A in fact experienced an adverse reaction has caused her unnecessary distress. I remind MidCentral DHB of the importance of acknowledging the patient's experience, and of reflecting and taking learnings from such experiences, to identify any areas for improvement.

[16] An acute allergic reaction to an antigen (a toxin or other foreign substance) to which the body has become hypersensitive.
[17] A lower than normal potassium level in the blood, which can cause muscle twitches, muscle cramps, or weakness, paralysis, abnormal heart rhythms, and kidney problems.
[18] A lower than normal level of magnesium in the blood, which can cause vomiting, lethargy, weakness, and tetany (flexion of the wrist and thumb).
[19] The heart's electrical system takes longer than normal to recharge between beats.

Conclusion

103. There is individual accountability on the prescriber for failing to provide Mrs A, or ensure that she was provided, appropriate information before administering droperidol, and for failing to ensure that she was monitored adequately afterwards. The Medical Council standards are clear that this responsibility falls on the individual doctor.[20]

104. I am critical that MidCentral DHB's investigation did not identify the individual responsible, and in the absence of an individual clinician being identified, it must take responsibility for the failures of the individual.

105. For the failure to provide Mrs A with information that a reasonable consumer in her circumstances would expect to receive, including that droperidol was approved for use as a sedative and was being prescribed off label to treat her pain, I find that MidCentral DHB breached Right 6(1) of the Code.[21] Consequently, Mrs A was not in a position to make an informed choice about her treatment, and I find that MidCentral DHB also breached Right 7(1) of the Code[22] by administering droperidol without her informed consent.

106. For the failure to ensure that Mrs A was monitored appropriately after droperidol was administered, I find that MidCentral DHB breached Right 4(1) of the Code.[23]

ED capacity and wait time — adverse comment

107. Mrs A arrived at ED at 3.41pm and was assessed as category three, which meant that a medical assessment should have taken place within 30 minutes. At this point, the ED was eight patients above capacity. At 4pm, Mrs A was transferred to an overflow bed located in the corridor. Mrs A told HDC that she remained in the corridor for one hour and 45 minutes and was not assessed by a doctor during that time. At 5.20pm, Mrs A was assessed by RN B, and at 5.28pm Mrs A received droperidol. Between 5pm and 6pm, the ED was above capacity by 21 patients.

108. MidCentral DHB uses a VRM tool when there is overcrowding in the ED (see paragraph 59 above) and, at 6.40pm, the ED went into "Red" status. In response to the over-capacity, a children's nurse and a medical nurse were sent to the ED to assist. The on-call SMO was not contacted because ED SMOs were already working (one of whom was the Clinical Lead for the ED), and a senior doctor was not allocated to the triage or waiting room.

109. Dr Barrington-Onslow highlighted that if the issue of overcrowding is not addressed, then this problem will recur, and he is aware of many similar situations of medications being given before a patient has been assessed adequately, so that the patient does not wait in distress.

[20] See Medical Council of New Zealand "Good Prescribing Practice — Prescribing unapproved medicines" (Appendix D).
[21] Right 6(1) states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive."
[22] Right 7(1) states: "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise."
[23] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

Dr Barrington-Onslow advised that the reaction to overcrowding by MidCentral DHB was a major departure from expected standards. He suggested that the staff involved were trying their best to ease the pain of a patient who they knew would be waiting quite a while before being assessed appropriately. Dr Barrington-Onslow also advised that it was inappropriate for a patient with a pain score level of 10/10 to wait for the amount of time that Mrs A did without analgesia, and he would have expected there to have been a rapid assessment of the patient and for analgesia to have been prescribed.

110. I acknowledge that Mrs A's wait of one hour and 45 minutes without analgesia or a medical assessment would have been very distressing. Whilst I acknowledge Dr Barrington-Onslow's advice that this was a major departure from accepted standards, overcrowding in this ED is a well-known longstanding issue to MidCentral DHB. MidCentral DHB has advised HDC previously that it has completed work in an attempt to minimise wait times, including renovation work on the waiting area and triage area (which was completed in February 2019) and the introduction of an acute care nurse who is present at all times. In addition, a new Acute Services rebuild is forecast to take place in 2027. However, I remind MidCentral DHB of the impact that ED wait times have on the quality of care provided.

Opinion: RN B

Monitoring — adverse comment

111. Mrs A recalls RN B leaving after the droperidol was administered at 5.28pm. However, the records show that RN B took Mrs A's blood at 5.40pm. Whilst RN B does not have a clear recollection of the events, she believes that she would have made notes in Mrs A's records after the administration, and at 5.40pm she took bloods, which meant that she did not leave straight away.

112. I acknowledge Mrs A's memory of events is that RN B walked away after the droperidol was administered. However, I also acknowledge that RN B's contemporaneous documentation leaves open the possibility that she did not leave immediately. Due to the lack of evidence, I cannot make a finding of fact regarding what occurred.

113. In response to the provisional opinion, RN B told HDC that she transferred the care of Mrs A back to RN C. However, it is not clear whether she told RN C that she had administered an off-label sedative or conveyed what monitoring was required. RN C told HDC that she does not recall RN B telling her that she had administered droperidol to Mrs A. RN B did not document her conversation with RN C. Due to the parties' lack of accurate recollection of the events, and the lack of documentation, I cannot make a finding as to whether or not RN B transferred Mrs A's care back to RN C or, if she did, what information and instructions were conveyed at the handover.

114. There are therefore two key areas of RN B's care that are ambiguous, due to a lack of contemporaneous documentation. My independent nursing advisor, Michael Geraghty, advised that the documentation indicates a lack of nursing care. In particular, there should

have been documentation about any benefits Mrs A experienced from the medication. He considers that the absence of any ongoing nursing documentation/evidence of nursing care following the administration of the droperidol represents a mild departure from the expected standard of care.

115. In any case, however, there is no evidence that RN B observed Mrs A's vital signs when droperidol was administered, or that any staff member observed or monitored Mrs A after 5.40pm. Notwithstanding whether RN B transferred the care back to RN C, as the administrator of the medication, RN B was responsible for ensuring basic nursing practices such as monitoring vital signs and any benefits experienced, which RN B did not do. In addition, if this was not completed by RN B, it was her responsibility to ensure that adequate handover to RN C was completed.

116. In my view, RN B should have been aware that droperidol was an unusual drug, and should have completed these basic nursing practices. However, I acknowledge that RN B was working in pressured circumstances and did not receive any instructions regarding monitoring from the prescribing doctor, and, for these reasons, I do not consider that her failings amount to a breach of the Code. However, I remind RN B of her obligations to ensure that she undertakes appropriate nursing practice when administering a drug prescribed for an off-label purpose, and for conveying in a handover that an off-label drug has been administered.

Informed consent — no breach

117. MidCentral DHB's policy on consent and the use of medicines for unapproved indications (Appendix C) outlines that the responsibility for providing information to the patient and obtaining consent is that of the prescribing doctor.

118. Mrs A told HDC that she was not provided with an explanation of what droperidol is, or that it was a sedative, and she thought that it was a pain relief medication. She stated that if she had been told that droperidol is a sedative, she would not have given her consent to receive it. RN B cannot recall the care she provided to Mrs A, but stated that when she administers a drug, it is her standard practice to inform the patient what medication she will be administering and its intended affect.

119. In the circumstances, I accept that the primary responsibility for obtaining informed consent to the administration of droperidol off label lay with the prescriber. I am satisfied that RN B made reasonable attempts to explain what the medication was (droperidol) and what it was intended for (pain relief), and that, in doing so, she met her duty of care.

Changes made

120. MidCentral DHB told HDC that work has been completed to attempt to minimise wait times, including renovation work on the waiting area and triage area (completed in February 2019), and the introduction of an acute care nurse who is present at all times. I further acknowledge that a new Acute Services rebuild is forecast to take place in 2027.

121. In addition, MidCentral DHB's ED Consultant Group has devised the following:

- A Medication Charting Guideline for patients waiting to be seen in the ED.
- A list of medications allowed to be given to patients who are waiting to be seen, including which medications are allowed to be given by RMOs and which areas of the ED are appropriate for administration of specific medications.

122. RN B told HDC that as a result of this incident, if she undertakes an intervention for a patient who has a different primary nurse, she now documents that she has returned the care to the primary nurse.

Recommendations

123. I recommend that MidCentral DHB:

a) Provide a written apology to Mrs A for its breaches of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs A.

b) Conduct an audit of the ED to identify waiting times over the past three months and whether these times correlate with the triage code ascribed to presenting patients. In addition, undertake a cross-reference of the new audit and the audit undertaken by MidCentral DHB in May 2020 and provide an update regarding the results of this. MidCentral DHB should provide this information to HDC within three months of the date of this report.

c) Provide HDC with MidCentral DHB's updated plan for improving waiting times in the ED, including the work that has been undertaken regarding patient flow from the ED to other departments within the hospital. MidCentral DHB should provide this information to HDC within three months of the date of this report.

d) Provide an update to HDC, within three months of the date of this report, on:

   i. The Work Programme status report including the Strategic Workforce Plan; and

   ii. Progress on the work undertaken with the Primary Opportunities in Acute Care programme.

e) Include in the MidCentral DHB's medication charting guidelines for patients waiting to be seen in the ED, a requirement for an RMO/SMO to enter their New Zealand Medical

Council registration number. Evidence that this has been completed is to be sent to HDC within three months of the date of this report.

f) Conduct an audit of ED medication charts over the past six months to check the compliance of doctors entering Medical Council of New Zealand registration numbers on the medication chart. This audit is to be provided to HDC within six months of the date of this report.

g) Ensure that all ED medical staff are aware that they should enter Medical Council of New Zealand registration numbers into the medication chart. Evidence that this has been completed is to be sent to HDC within three months of the date of this report.

124. I also recommend that if MidCentral DHB intends to use droperidol regularly in higher doses for augmentation of an opioid, the DHB consider whether to incorporate guidelines for this into the existing analgesia protocol (with accompanying comments or footnotes regarding consent for off-label use and the importance of excluding obvious QT-interval prolongation risk). MidCentral DHB should report to HDC on the outcome of its consideration within one month of the date of this report.

Follow-up actions

125. I consider that the systems issues highlighted in this report, in addition to the multiple severe departures from accepted practice identified by my independent advisor, cumulatively present a picture of very serious failures at a service level. As such, I have decided that MidCentral DHB 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.

126. A copy of this report with details identifying the parties removed, except MidCentral DHB and the experts who advised on this case, will be sent to the Ministry of Health and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

127. I will be writing to the Director-General of Health to highlight the capacity issues MidCentral DHB is facing in its ED.

Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from Dr Stuart Barrington-Onslow:

"April 2021

Independent advice to the Health and Disability Commissioner for case number 20HDC00962 by Dr Stuart Barrington-Onslow.

I have read and agreed to follow the guidelines for independent advisers provided by the office of the Health and Disability Commissioner.

I am an Emergency Medicine Specialist, qualifying as a doctor in 1988 at the University of London. I have been practising Emergency Medicine since 1997 and became a Fellow of the Australasian College for Emergency Medicine in 2007. I am currently employed as a full-time specialist at the Christchurch Hospital Emergency Department.

I have been asked to provide independent expert advice regarding the care provided to Mrs A in the Emergency Department of [the public hospital] on 15th December 2019. To aid me in my advice I have received documentation from the commissioner's office that includes:

Letter of complaint dated 5 June 2020.

Supporting letter from Advocacy Services dated 5 March 2020.

MidCentral's response dated 19 March 2020.

MidCentral's response dated 29 May 2020.

MidCentral's response dated 19 January 2021 with various policies and clinical records.

MidCentral's response dated February 2021.

Summary of Events

These are provided in the documentation I have received.

On the 15th November 2019, [Mrs A], at the time [in her thirties], presented for the third time to [the] Emergency Department with severe pain in her back, left buttock and upper left thigh. The prior presentations had been on 28th October 2019 and 29th October 2019 when she had been assessed, investigated, treated and discharged.

An ambulance was called at 15:00hrs on the 15th November 2019 because of uncontrolled pain [Mrs A] was experiencing in her back. The ambulance arrived at 15:07hrs, assessed [Mrs A] and transported her to [the] Emergency Department arriving at 15:41hrs. Between 15:22 and 15:46, she received a total of 200 micrograms of intravenous Fentanyl from the ambulance staff in four doses of 50 micrograms, with minimal improvement in her pain level. She went from a pain level of 10 out of 10 to 9.

[Mrs A] was triaged at 15:48 hours and given a category of 3 (to be seen within 30 minutes), with a set of acceptable observations. Her temperature was 37.3°C, heart rate of 71 bpm, blood pressure of 144/69 mmHg and a respiratory rate of 18 bpm. It was noted that she presented with a three week history of increasing back pain and left sciatica that was not responding to the analgesia she had at home. She was waiting for an Orthopaedic review as an outpatient, and had received 200 micrograms of Fentanyl that afternoon.

At 16:00 she was moved to an overflow space in the department, and it was documented that her care was delayed due to acuity in the department. It is documented that she was lying on her right side, 'teary' and 'on her phone'.

There is no further documentation until 17:26 when she is noted to be distressed with pain and crying. Vital signs remained acceptable with a blood pressure of 107/70 mmHg, heart rate of 71 bpm, a respiratory rate of 20 bpm, normal oxygen saturations, but a pain score of 10 out of 10.

She was prescribed 600mg of oral ibuprofen and 2.5mg of intravenous Droperidol which were given at 17:28 hours. The Emergency Department has been unable to ascertain the person who prescribed the drug.

[Mrs A], in her complaint to the Health and Disability Commissioner, describes what she experienced after receiving the drug. Namely, her tongue folding in her mouth, unable to use her fingers, and back arching. She initially thought she was having a seizure, and when she regained her faculties at 19:22 hours, she self-discharged from the department. What she describes is typical of a dystonic reaction, not a seizure.

A dystonic reaction is an involuntary contraction of muscles of the face, arms, abdomen, pelvis and back. It can prevent speech and fine motor control e.g. operating a telephone. It is thought to be due to the dopamine blocking effect of this drug and others in its group.

Finally, there are no notes made by a doctor during this visit to the Emergency Department.

Specific Questions

Firstly, I wish to answer the last question first. There are a number of issues I have with the experience of [Mrs A] on this presentation, but I feel the Commissioner needs to be aware of what policy the Mid Central DHB has for overcrowding in [the] Emergency Department, and what resources are available to a service that has almost twice its capacity in attendance. Also, what provision does the DHB make for sickness within the Emergency Department. Because if these are not addressed, then this problem will recur, as I am aware of many similar situations of medications being given before a patient is adequately assessed, so they do not wait in distress.

The appropriateness of the clinical assessments undertaken.

There was none apart from the triage assessment.

In my opinion, it is inappropriate for a patient with 10 out of 10 pain to wait the amount of time [Mrs A] had to wait without adequate analgesia.

This is a severe departure from standard of care.

How would it be viewed by your peers?

It would be viewed as an inappropriate level of care. Below accepted level.

My recommendations would depend on the response from the DHB regarding my above comments.

The appropriateness of the history taken.

Again, there was none.

The nursing assessments were appropriate, but there were none by a doctor.

I would expect a rapid assessment of the patient to be made and analgesia prescribed.

This is a severe departure from standard of care, being aware that some patients do not wait to be seen. This was not the case for [Mrs A] as she left because of the reaction she had had to the Droperidol given.

How would it be viewed by your peers?

This again would be below the expected level of care.

I would suggest a review of off label drug prescribing by the Emergency Department.

The appropriateness of the information provided to [Mrs A] prior to prescribing Droperidol.

This was inadequate.

The use of Droperidol in this situation is off label, i.e. it is not of standard practice in this indication, and as such the clinician who prescribed it should have explained their reasoning, and any potential issues, to the patient. However, in an overcrowded and understaffed ED, this is impossible to do.

The severe departure from standard of care, is that [Mrs A] appeared to have been left in a corridor with no documented review or vital signs taken after the administration of Droperidol.

How would it be viewed by your peers?

The use of Droperidol for pain, in my, and the literature's opinion is not a standard of care. There may be some clinicians who use it in this way, but the majority would not use it for pure pain relief.

It would be impossible to discuss all the potential side effects of all drugs given in the Emergency Department. But if a reaction occurs, it should be treated as soon as possible, and an explanation should be given to the patient.

The lack of explanation is acceptable, but the monitoring post was not. This is a severe departure from standard of care.

If the prescriber of Droperidol did not administer the medication, whether you would have expected any information and/or further steps should be taken.

The question is as above.

The use of Droperidol as an alternative to opiate pain relief is not standard of care.

The prescriber should have directed the nursing staff to perform regular vital signs, especially as [Mrs A] was already taking Orphenadrine, the combination of which can cause marked depression of conscious level.

The dystonic reaction that [Mrs A] experienced would have been picked up by a vital sign assessment, which she did not have.

This is a severe departure from standard of care.

How would it be viewed by your peers?

It would be viewed as below an acceptable standard of care.

The adequacy of the documentation for [Mrs A's] admission, in particular the adequacy of the documentation from the prescribing doctor.

There is none, so it is inadequate.

The doctor who prescribed the drug has not been identified. But I suggest the ED team at [the public hospital] look at the signature for the Droperidol on 15th November 2019 and compare it with the named signature on the drug chart of 29th October 2019. (Marked on two folded pages I have returned in section 5c).

This is a severe departure from standard of care.

How would it be viewed by your peers?

The drug charts used by this Emergency Department have a space for each prescribing doctor to identify their signature. This was not done in this case. Some colleagues would

not be too concerned about this whereas others would. Personally I feel it is important to be able to identify the prescriber of drugs.

The adequacy of the policy entitled 'Medication Charting Guideline for Patients Waiting to be seen in the ED'

The policy is good, but the person who prescribed the Droperidol has not followed it.

This is a severe deviation from standard of care.

How would it be viewed by your peers?

This would be viewed unfavourably by my peers.

The nursing aspect of this document is appropriate. They have not completed the reason/indication part of the policy, but in an overcrowded ED this has to be acceptable.

Any further comments on the policies in place at the time of events.

No.

Any other matters in this case that you consider warrant comment.

I have commented in the first paragraph above as I feel the institution needs to take more responsibility when issues occur in overstretched and understaffed departments.

Further Comments

I have received further information from the office of the Health and Disability Commissioner, and been asked to respond.

Response dated 8 April 2021

This is a comment on the policy of self-discharge and has no bearing on this case.

Response dated 28 April 2021

There is no specific plan to cover overcrowding. This is frankly inappropriate. And it appears the task is laid on the SMO. At a time when the department is overcrowded, the best use of an SMO is to perform tasks they are trained for, seeing patients, not running around making phone calls. It is not surprising that clinicians in this situation take short cuts that can cause problems. I am sure the physicians are doing their best for the patients, but in an environment and management structure that makes it impossible.

Regarding the information about cover for sick leave, there is a policy, but it does not appear to deal with the issue, so an overcrowded Emergency Department is left with inadequate support and staffing.

In my opinion, this would be seen as a poor response by the DHB by my peers and a major departure from expected. However, this situation tends to be the rule rather than the exception when Emergency Departments are understaffed and overcrowded. I suggest

this was the major issue as the staff involved were trying their best to ease the pain of a patient they knew would be waiting quite a while before being appropriately assessed.

Response dated 13 May 2021

I did investigate the use of Droperidol for acute and chronic pain during my original statement, as it is nothing I am experienced with and could find no literature. I have enclosed a Cochrane report regarding this issue. It is dated 2013, and suggests the use is not proven. I have not seen any subsequent, appropriate literature to alter my opinion.

Regarding the signatures, I am not an expert, but feel the signature for the droperidol is similar to the lower signature on the sample of prescribers dated 29th November 2019.

'It is also not certain that [Mrs A's] vital signs would have become abnormal during her dystonic reaction … Most practitioners would certainly ha[ve] seen people having dystonic reactions who have had completely normal vital signs.'

I agree that vital signs are usually normal, but the patient does not appear normal when they have such a reaction. Therefore, visualising, properly, is essential, not a quick glance as lying in a corridor. Again, overstretched staff in overcrowded situations cannot be expected to be as thorough as usual.

I am of the opinion that my peers would not use this medication for this role. Nevertheless, some departments may do so. As I have stated, there is no conclusive evidence in the Emergency Medicine literature that Droperidol has such a role. I would suggest this is a mild to medium departure from expected care.

'The guideline about medication charting is good, but is just a guideline. It is not a directive and clinical judgement can come into play; it does not need to be rigidly followed.'

That is correct, but what is the point of a guideline if it is not adhered to. And when it is not adhered to, can the person justify this if they cannot be identified.

My opinion is that a doctor who prescribes a medication, especially for an 'off label use' should be identifiable. This would be considered a severe departure from expected care.

'That using droperidol as an adjuvant to opiate pain relief is not standard of care is incorrect. There is international literature describing its use for pain relief.'

I stand by my original statement. I have discussed with colleagues, our departmental pharmacist confidentially, not mentioning the case. None have used droperidol in this way, and I feel this is confirmed by the literature.

Dr Stuart Barrington-Onslow"

Appendix B: Independent clinical advice to Commissioner

The following expert advice was obtained from MJ Geraghty in April 2021:

"HDC Case 20HDCCOO962

Personal Statement.

I am an Emergency Nurse Practitioner (NP) and currently employed at Auckland City Hospital, Adult Emergency Department (ADHB) and have been in this role since 2001. I hold a Masters of Nursing degree (University of Auckland); I am an Honorary Professional Teaching Fellow (University of Auckland) and an active member of the College of Emergency Nurses (NZNO) as well as their former journal Editor and regularly provide expert advice to the NZ Nursing Council and particularly in respect to advanced nursing practice. On an ad hoc basis I have provided expert advice to the HDC for the past eight years and at their invitation.

Information reviewed.

This report was based on the following information provided by the Commissioner and in respect to the care provided to [Mrs A] in the Emergency Department, [the public hospital], MidCentral DHB (MDHB) on 15th November 2019.

1. Letter of complaint — 5th June 2020
2. Supporting letter from Advocacy Services — 5th March 2020
3. MDHB's responses — 19th March 2020, 29th May 2020 and January 2021 plus the documents listed below:
    1. Informed consent policy
    2. Clinical records and documents
    3. All documents relating to the previous investigation
    4. Adult IV opioid policy — April 2018
    5. Adverse Medications Reactions Notification — September 2017
    6. Documentation of nursing care in the ED — May 2019
    7. IV Therapy September 2015
    8. Use of medicines for unapproved indications March 2018
    9. Medication Charting Guidelines for patients waiting to be seen in the ED
    10. A copy of the a.m. and p.m. shift reports for the time period of the complaint
    11. Documentation on the use of Droperidol use in opioid tolerant patients
    12. MDHB's responses — 16th February 2021
    13. Statements from [RN C] and [RN B]
    14. ED Core schedule
    15. Initial triage assessment
    16. Administrations of Medicines Policy revised 17th April 2012
    17. Guideline Medico-legal responsibilities of ED staff — December 2006.

Information requested.

I have been asked to make particular comment, from a nursing perspective on the following:

1. The appropriateness of the information provided to [Mrs A] by nursing staff prior to administering Droperidol
2. The appropriateness of the administration of droperidol
3. The appropriateness of the nursing care following the administration of Droperidol.
4. The adequacy of the nursing documentation and notation of any inadequacies discovered.
5. Any other matters relating to the nursing care [Mrs A] received in this case that I may consider commenting on.

In acknowledging the above points this is contextualised further by addressing the following questions:

1. What is the standard of care/accepted practice?
2. If there has been a departure from this standard(s), how significant is this departure?
3. How would a peer group view this?
4. Recommendations for improvement that may help to prevent a similar occurrence in future.

Summary of events.

[Mrs A] was admitted to the emergency department via ambulance on 15th November 2019 at 15.46 hours. Her primary complaint was of severe pain in her upper leg (with a pain score of 10/10 noted by [the ambulance service]). This presentation was similar to two previous ones on 28th and 29th October 2019 and most likely an exacerbation of sciatica. She received a combination of oral and intravenous pain relief en route to hospital. She was given a triage code three and placed in corridor space 'overflow two' due to a lack of available cubicles (this is in an area of high foot traffic but not a dedicated treatment space). After an initial nursing assessment further analgesia was prescribed namely Ibuprofen and intravenous Droperidol 2.5 mg. She had no medical assessment during this visit and self discharged at 19.22. [Mrs A's] decision to leave centres around her perception that she was not treated with respect leaving her feeling unsafe and unwelcome, that she had an adverse reaction to the Droperidol which was neither acknowledged nor treated and that she was not given sufficient information about this drug prior to administration which she may have opted to decline.

Review

1. The appropriateness of the information provided to [Mrs A] by nursing staff prior to administering Droperidol.

As per [an SMO's] reply of 29th July 2020 consent to treat a patient in severe pain is implied, and the choice of medications at the discretion of the prescriber. It is hard to determine how much information a patient needs in order to accept treatment and also how much any one individual can digest when distracted by severe pain. In her letter of complaint to the HDC [Mrs A] acknowledges being asked if she knew of a drug called Droperidol, and being told it was to help her with pain. In her personal statement (12/02/2010) [RN B] acknowledges that Droperidol is not a drug she administers frequently and would have familiarised herself with its administration prior to injecting. [RN B] explained it had to be given slowly but it is not clear if she explained why or if she elaborated any further on the drug's side effects etc. It would not be an expectation that this level of detail would be recorded on a patient's notes.

I do not believe there has been any departure from an expected standard of care.

2. The appropriateness of the administration of droperidol.

I do not have any personal experience of using Droperidol in the context of pain management. It is not a drug that is commonly used in our ED for this but would be used as an antiemetic, an antipsychotic agent, for migrainous headaches and treating synthetic cannabinoid induced hyperemesis. Although the primary reason given for prescribing this drug was to manage her pain [Mrs A] had been given four incremental doses of intravenous Fentanyl prehospital which can induce nausea and vomiting, the droperidol would have been beneficial in this context. Most prescribing clinicians have personal preferences for the prescribing of certain medications and analgesia would be one of these groups where individual choice (and to some extent the culture of the department) would dictate the choice of one agent over another.

I do not believe there has been any departure from an expected standard of care.

The appropriateness of the nursing care of following the administration of Droperidol and the adequacy of the nursing documentation and notation of any inadequacies discovered.

There is good evidence to support the fact that the department was under a significant strain at the time she was admitted, placing [Mrs A] in a corridor space was clearly not ideal but equally a reasonable compromise given the fact that she was placed in an area of high visibility.

The initial nursing assessment is succinct and a full set of vital signs is recorded, including a pain score of 10/10, noting her to be 'crying and distressed'. There is no named nurse or signature recorded. The initial nursing assessment enables the nurse to further explore the initial triage complaint and act on any findings of note, in this case severe pain. The assessment took place at 17.20 hours and the Droperidol administered

soon after which is commendable. It would also have been reasonable to consider 'up-triaging' the patient which may have expedited a medical review.

There is no nursing documentation from 17.30 onwards (the time the droperidol was given), as such there is no tangible evidence of any nursing care occurring after this time period. The statements provided by [RN C] and [RN B] gives an honest account of their recollection of that time and reasonably draws on their experience and the care they provided would be of a standard they would routinely provide as registered nurses. The absence of any ongoing documentation however does not meet the standards set by MDHB's own ED nursing care guidelines (section 4.2) or that of the Nursing Council Code of Conduct (principle 4 — documentation). I would have expected some documentation on:

- Any benefits attained by [Mrs A] following the administration of the analgesia.
- Documentation of the patient's decision to leave without medical assessment and whether the IV luer had been removed prior to self discharge.

Any observations of the adverse reaction to the Droperidol described by [Mrs A].

To balance out the observations above the nursing documentation from [Mrs A's] second visit (29th October 2019) is exemplary and fulfills most of the expectations of a RN as outlined in the MDHB Documentation of Nursing Care in ED, Clinical Guideline. I believe this evidences the standard of care that would be their norm when functioning under optimum conditions.

MDHB has already apologised for any perceived slight experienced in her interactions with the nursing staff. The 'norm' of emergency departments is one of relentless busy-ness. Patients by virtue of being in the ED are stressed, in pain, anxious, nursing staff are often equally stressed and preoccupied by the demands during their shift and their attempts to be efficient can come across as uncaring, brusque. This should never be an excuse to not treat patients with respect and dignity.

The absence of any ongoing nursing documentation/evidence of nursing care following the administration of the Droperidol represents a mild departure from the expected standard of care provision and would be judged unfavourably but sympathetically by a group of peers.

4. Any other matters relating to the nursing care [Mrs A] received in this case that I may consider commenting on.

None.

References:

Code of Conduct. Nursing Council of New Zealand
https://www.nursingcouncil.org.nz/Public/Nursing/CodeofConduct/NCNZ/nursing-section /Code of Conduct.aspx

Guidelines on the implementation of the Australasian Triage Scale in Emergency Departments ACEM July 2016
https://acem.org.au/getmedia/51dc74f7-9ff0-42ce-872a-0437f3db640a/G2404 Guidelines on Implementation of ATS Jul-16.aspx

MJ Geraghty April 2021"

Appendix C: MidCentral Health relevant standard operating procedures

"Use of Medicines for unapproved indications ('Off-label Use of Medicines') dated 20 March 2018

1. Purpose

This policy provides information on unapproved medications and the use of approved medicines for unapproved indications in both inpatient and outpatient settings.

2. PREAMBLE

The process of safe provision of medication to patients is a complex multidisciplinary healthcare process, requiring input and involvement from numerous personnel. The professional groups involved include medical practitioners, dental practitioners, nurses, midwives and pharmacists, all of whom are duly registered by their respective regulatory authorities. The prescription and administration of medications is the culmination of the actions of those who prescribe the medication (authorised prescribers), those who dispense/supply the medications and those who physically administer the medication. There is a well-developed expectation that at any and every step of the process there is freely conducted consultation and questioning between and among (collectively and individually) the professional groups, especially so whenever any uncertainty may have arisen.

Pharmaceutical Corporations will in general only seek approval of a medication if it is a commercially sound decision to do so; thus the absence of approval does not necessarily indicate that the medication is unsafe — indeed there are multiple examples of medications that are not approved in NZ (or not approved for a specific indication) that have long track records of safe and efficacious use and may, for example, be approved in other comparable jurisdictions. In addition many patients groups (e.g. children; pregnant women) are frequently excluded from approval applications because of the paucity of data on hand that supports their inclusion. Again, this does not mean that the medications are not safe and beneficial in these groups.

Given the nature of the process for medication approval in New Zealand, it is impractical and unrealistic to expect that all healthcare professionals will be intimately aware of every single legislative detail pertaining to the approval status (and approved indications) of each and every medication that may be prescribed. It is also clearly unacceptable to allow unfettered administration of any medication for any indication, and practitioners must have due regard to the medication status (i.e. approved versus unapproved) when prescribing, administering, dispensing or supplying medication.

The intention of this Policy is to provide broad categorisation and to conceptualise a practical real-world framework to guide the multidisciplinary team in the safe administration of medication to patients. It is NOT the intention of this Policy to populate (or maintain) indicative lists of specific individual medications.

…

The articles of the HDC Code of Rights and the principles of informed consent underpin all of these expectations.

3. Scope

This Policy provides information to prescribers, pharmacists and administrators of medicines.

This document outlines the process that must be followed before unapproved medicines/ unapproved indications may be used in the treatment of any patient under the care of MidCentral DHB.

Note:

- There are circumstances whereby it will be in the best interests of a patient receiving emergency treatment to receive one or more unapproved medicines. The principles presented in this policy should guide the prescriber, but it is accepted that professional judgement (including where appropriate, consultation with peers) should be the key determinant of treatment in these situations. Wherever possible, unapproved medicines that may have a role in emergency treatment should be prospectively identified.

- Investigational use of unapproved medicines (and therefore with low certainty of net benefit) fall outside the scope of this document. Such usage should be limited to clinical trials that have been approved by a Health and Disability Ethics Committee. In these circumstances patients must understand that the purpose of the investigational use is to generate data to improve medical care for future patients rather than to provide medically-indicated treatment, although the patient may benefit from the treatment.

DEFINITIONS

4.1 Approved Medicines and Supported Medicines*

A medicine which has been through the New Zealand regulatory process and can be considered appropriate to prescribe under the conditions (indications, dose, route of administration) set out in the Medicine Data Sheet has approved medicine status.

For the purpose of this Policy, and for the purpose of day-to-day practicalities, the Medicines Advice and Policy Committee considers that the following will also be regarded as having equivalent 'approved' status and for the purposes of this document are referred to as supported medicines:-

- Medications contained within the PHARMAC Hospital Medicines List
- Medications contained within the New Zealand Formulary
- Medications contained within the NZHPA 'Notes on Injectable drugs'
- Medications that are currently approved within other comparable jurisdictions, specifically Australia, UK, Canada, EU or USA.

- Extemporaneously prepared medicines (covered by Section 26 of the Medicines Act 1981), including parenteral nutrition, cytotoxic reconstitution, repacked medicines prepared by the Hospital Pharmacy.
- Medications whose use is endorsed by professional consensus (locally, nationally or internationally), and/or by professional guidelines (be they DHB-based, or generated by the likes of Vocational Colleges or Professional Societies).

Prescribers

- Where possible, approved and supported medicines/approved and supported indications will be used to treat patients.
- Unapproved medicines/unapproved indications for medicines will only be used where the approval process outlined in this policy has been followed.
- The prescriber is responsible for ensuring that informed consent has been obtained.

  Note: Obtaining written consent does not mean that the requirements of the Code have been complied with. Patients must be provided with information at an individualised level to enable informed, freely given consent. Effective communication, including frank information disclosure, are essential to fulfilling these requirements.
- The prescriber must ensure that there is appropriate and adequate information provided to all health professionals involved in the patient's care so that the unapproved medicines can be administered safely.
- Prescribers should be aware of (alert to) the availability of alternative approved medicines which become available and to information of any serious problems that have been published for unapproved medicines and/or unapproved indications.

Nursing Staff

- Nursing staff should seek clarification from the doctor or pharmacist if a prescription to administer a medicine is thought to be unapproved* with regard to dose, route of administration or any other aspect.

Nurses may refuse to administer medicines being outside the approved indications of the medicines if it is to be judged in the best interests of the patient.

Refusal to administer should not occur solely because a medicine is unapproved or the indication is unapproved.

POLICY

- Where possible, approved and supported medicines/approved and supported indications will be used to treat patients. That notwithstanding, any member of the multidisciplinary team involved in the provision of medication is obliged to question and seek clarification if, in their professional judgement, there is any uncertainty regarding the use of any given medication. It is anticipated that the majority of such situations can be resolved through collective consultation.

- It is recognised that the use of an unapproved medicine/unapproved indication is sometimes necessary to provide optimum treatment for a patient. To assist in managing the risk from the use of unapproved medicines/unapproved indications, the prescriber must seek and receive approval from Medicines Advice and Policy Committee before prescribing an unapproved medicine/unapproved application. A copy of the application form is set out in Appendix One.
- If prescriber is unclear as to the approval status of the medication, advice can be sought from professional peers, the multidisciplinary team, and the Hospital Pharmacy staff. Details regarding these discussions, and the reasons for any decisions, ought to be clearly documented in the patient's medical records.
- Prescribers are professionally accountable for their prescribing decisions and may be called upon to justify their actions.
- The prescriber is responsible for ensuring that informed consent has been obtained. Written consent must be obtained prior to the provision of an unapproved medicine/unapproved indication. Note: Obtaining informed consent is a process which involves effective communication, frank information disclosure and freely given consent. It also involves careful investigation of the clinical condition of the patient and maintaining a current knowledge of treatment options.
- Adverse drug/medicine reactions and medicine incidents must be reported in the same manner as for approved medicines.
- The Medicines Advice and Policy Committee shall provide a report to the Clinical Board every six months on the applications it receives.

Medication Charting Guideline for Patients Waiting to be Seen in the Emergency Department

Context

1. Patients waiting to be seen by ED Medical Staff will often have symptoms which can be, at least in part, relieved by the appropriate charting of simple medications. This must be a balance between the desire to manage patient symptoms in a timely manner vs doing so safely for both patient and staff.
2. The Triage Nurse or Primary Care Nurse will determine the need for such medications, and request an ED RMO or SMO to chart them in accordance with this guideline.

Rules

1. Specifically for patients still in the waiting room & S1–S4

   a. No IV/IM drug prescribing

   ie PO, inhaled, SL or PR medications only in the W/R & S1–S4

   b. Medications should only be charted as 'Stat' doses ie no prn option whilst in the waiting room & S1–S4

2. Only medications on the approved list may be charted prior to patient being seen. Exceptional circumstances may exist only at the discretion of the ED SMO.

3. The medication chart must be completed correctly and legibly

   ie front page, printed name, signed, patient labels

   Nursing Responsibility

   a. Patient observations to be completed and recorded
   b. Medication allergies asked and recorded
   c. Document the indication/reasoning for the medication request in nursing notes
   d. Apply patient ID labels to the medication chart

   RMO/SMO Responsibilities

   a. Check the above is completed — obs, allergies, indication
   b. Complete front page of drug chart legibly — your printed name is required.
   c. Consider ordering triage based tests/investigations at that time

      eg bloods, urine, x-ray etc"

Appendix D: Relevant standards

Medical Council of New Zealand Good Prescribing Practice

"1 Make the care of patients your first concern. You should only prescribe medicines or treatment when you have adequately assessed the patient's condition, and/or have adequate knowledge of the patient's condition and are therefore satisfied that the medicines or treatment are in the patient's best interests. To ensure that your prescribing is appropriate and responsible you should:

…

- Be familiar with the indications, adverse effects, contraindications, major drug interactions, appropriate dosages, monitoring requirements, effectiveness and cost-effectiveness of the medicines that you prescribe. Be aware that promotional and other information on medicines that are distributed by commercial interests are unlikely to be impartial; and independent expert sources of information (such as the New Zealand Formulary, and Medsafe Prescriber Update) are preferred where available.
- Take an adequate history of the patient, including: family history of the disease or condition, any previous adverse reactions to medicines; previous and current medical conditions; and concurrent or recent use of medicines (including non-prescription, complementary and alternative medicines).

…

Prescribing unapproved medicines[24]

17 You may prescribe unapproved medicines or prescribe medicines for a purpose for which they have not been approved. However, if you decide to do so, you must take responsibility for overseeing the patient's care, including monitoring and any follow-up treatment. You must make a clear, accurate and legible record of your reasons for prescribing any unapproved medicines and of the patient's consent. You must not prescribe medicines for an unapproved use if it is outside your scope of practice. You should discuss medicines for an unapproved use with a senior colleague before prescribing them. You should also inform the patient:

- whether there are any other options available
- of any risks, adverse effects, costs or benefits
- that the medicine being prescribed is for an unapproved use
- that pharmacies are not allowed to stock unapproved medicines and the medicines can only be ordered once a prescription is presented
- that details relating to the supply of the unapproved medicine will be supplied to the Director-General of Health."

[24] An unapproved medicine is a medicine for which consent has not been given by the Director-General of Health for sale, distribution or marketing in New Zealand. Such medicines have not undergone any Medsafe regulatory process.