District Health Board
Anaesthetist, Dr A

A Report by the
Deputy Health and Disability Commissioner

(Case 19HDC02233)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report highlights the importance of obtaining a consumer's informed consent before administering particular medication during surgery, particularly where that consumer has previously expressed concerns about the medication and there is documented evidence of the patient's past adverse reactions to it in the clinical notes.

2. On 12 September 2019, the woman underwent a hysterectomy. Prior to the surgery, the woman made her concerns regarding morphine administration known to DHB staff and the anaesthetist, including her understanding that morphine could cause her heart rate to slow to an abnormally low rate.

3. During surgery, the anaesthetist gave the woman 3mg of morphine, but had not obtained her informed consent for this prior to surgery. Post-surgery, the woman was informed that morphine had been administered, which she advised was "a big shock".

Findings

4. The Deputy Commissioner found that the anaesthetist breached Right 7(1) of the Code by failing to obtain the woman's informed consent for the administration of morphine prior to surgery.

5. The Deputy Commissioner found that the DHB did not breach the Code, as the errors that occurred did not indicate broader systems issues, and appropriate policies had been in place. However, the Deputy Commissioner considered that DHB staff could have done more to advocate on behalf of the woman to prevent the use of morphine during surgery.

Recommendations

6. The Deputy Commissioner recommended that the anaesthetist undertake further education and training on informed consent, and report back to HDC on completion of the training.

7. The Deputy Commissioner recommended that the DHB use an anonymised version of this case for the wider education of its staff; consider streamlining its process of pre-operation checks; and take steps to ensure that its staff are able to advocate for patients in theatre when and as required.

Complaint and investigation

8. The Health and Disability Commissioner (HDC) received a complaint from Mrs B about the services provided by the district health board (DHB) and Dr A. The following issues were identified for investigation:

- *Whether Dr A provided Mrs B with an appropriate standard of care from 28 February 2019 to 12 September 2019.*

- *Whether the DHB provided Mrs B with an appropriate standard of care from 28 February 2019 to 12 September 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:

Dr A	Provider/anaesthetist
Mrs B	Consumer
DHB	Provider

11. Also mentioned in this report:

RN C	Anaesthetic technician/nurse
Ms D	Anaesthetic technician

12. Independent expert advice was obtained from a consultant anaesthetist, Dr Alexander Khrapov (Appendix A).

Information gathered during investigation

Introduction

13. This report considers the care provided to Mrs B by the DHB and consultant anaesthetist Dr A[1] when Mrs B underwent a hysterectomy on 12 September 2019.[2] Dr A's involvement in Mrs B's care was limited to the day of her surgery.

Background

14. Mrs B (aged in her forties at the time of events) was admitted to hospital for elective surgery to remove her uterus, both ovaries, and both fallopian tubes[3] because of abnormal uterine bleeding and pelvic pain. Mrs B's Mirena[4] intrauterine device (IUD) was also to be removed at the same time.

15. Mrs B told HDC that at the time of these events she wore a medical alert bracelet that stated: "bradycardia [slow heart rate] with morphine and codeine".

[1] Dr A qualified as a doctor and completed his specialist training in anaesthetics. He has a vocational registration with the Medical Council of New Zealand as a consultant anaesthetist.
[2] Surgical removal of the uterus.
[3] A laparoscopic hysterectomy and bilateral salpingo-oophorectomy.
[4] A hormonal IUD that is inserted into the uterus for long-term contraception and to reduce heavy periods.

Pre-assessment patient questionnaire

16. On 28 February 2019, Mrs B completed a pre-assessment patient questionnaire at another hospital. On the questionnaire, Mrs B stated that she had an allergy to adhesives (sticking plasters) and a number of opioid medications — specifically codeine, morphine, and pethidine. Mrs B was transferred to the public hospital for her surgery.

17. On 11 July 2019, Mrs B completed another pre-assessment questionnaire. On this questionnaire she noted the same allergies to codeine, morphine, and pethidine, and added that these caused "severe bradycardia/hypotension [abnormally low blood pressure]".

Pre-assessment clinic appointment

18. On 30 August 2019, Mrs B was seen by a registered nurse (RN) in the pre-assessment clinic. The notes from this consultation list codeine, morphine, and pethidine as causing "hypotension and bradycardia (severe)". There was also a note about heart palpitations, which had been investigated by the cardiology clinic in 2018. Mrs B was found to have a normal heart rhythm and no evidence of any other concerns.[5]

Preoperative checklist

19. A preoperative checklist was completed by a nurse at the public hospital's Day Unit on 11 September 2019. The nurse recorded that Mrs B was allergic to codeine, morphine, and pethidine, which caused low blood pressure[6] and severe bradycardia. There was also a note about her allergy to sticking plasters, which caused blisters.

Surgery

Morning of surgery

20. On 12 September 2019, the preoperative checklist (which had been completed the previous day) was checked by a nurse when she admitted Mrs B. The preoperative checklist included that Mrs B was allergic to codeine, morphine, and pethidine, which caused low blood pressure and severe bradycardia.

21. An anaesthetic technician/nurse, RN C, also met with Mrs B prior to the surgery to check the preoperative checklist and confirm Mrs B's name, NHI, allergies/adverse reactions, consent, and site marking, and to check for any other information of note. In relation to this and in response to the provisional report, Mrs B also told HDC: "A red alert band was applied to my wrist as all jewelry had to be removed, which included my medic alert bracelet." On this day, RN C was working with anaesthetic technician Ms D. The DHB told HDC that the anaesthetic technician/nurse completes the second check of the preoperative checklist in theatre and also becomes the patient's advocate in theatre.

[5] The investigation into Mrs B's heart palpitations was unrelated to her adverse reactions to morphine.

[6] The clinical documentation recorded that Mrs B was allergic to codeine, morphine, and pethidine, which caused "HTN" and severe bradycardia. Commonly "HTN" stands for "hypertension" (high blood pressure). However, for consistency with the rest of the clinical documentation, "HTN" has been changed to "hypotension".

Pre-surgery appointment

22. On 12 September 2019, consultant anaesthetist Dr A met with Mrs B at the Day Unit for her preoperative assessment. Dr A recorded that Mrs B did not have any allergies but "does not like morphine [because it causes] bradycardia [and] flushing[7]". Dr A discussed the findings from the cardiology clinic and told Mrs B that the cardiologist was not concerned about her heart rate. Dr A prescribed paracetamol, ibuprofen, and gabapentin[8] as pre-surgery medication. A "consent to anaesthesia treatment procedure" form was signed by Dr A and Mrs B, and listed "general anesthetic" as the anaesthesia procedure description. Dr A told HDC that he did not recall seeing, and was unaware of, Mrs B's medical alert bracelet,[9] and it was "not recorded on the preop nurse assessment or on [his] anaesthetic sheet".

23. Mrs B said that on the day of the surgery, she had a discussion with the anaesthetist. She stated: "[The anaesthetist] said he would not give me morphine, as I told him and my surgeon it caused bradycardia and hypotension if given to me." In response to the provisional report, Dr A stated that he "respectfully disagrees with this recollection". He said that "[t]here was not anything as direct as a 'request that morphine not be used'," and that he "would never have told [Mrs B] that he would not give morphine and then proceed to do so".

Collection of anaesthetic drugs

24. The DHB's "Controlled Drug Policy for Use in the Operating Theatre" (included at Appendix B) states that "all controlled drugs are to be collected by the anesthetic tech/nurse from the drug cupboard as is the usual practice, [and] checked by another RN". The DHB explained that the anaesthetist requests the controlled drugs required for each patient in theatre, and the anaesthetic technician/nurse collects the drugs on behalf of the anaesthetist. The DHB noted that often the drug request is made prior to the patient being seen, as the drugs requested are those used regularly by the anaesthetist for that type of procedure.

Surgery

25. The DHB told HDC that once Mrs B was in the theatre, as part of the Surgical Safety Checklist "Sign-In", Dr A would have asked her to confirm her name, date of birth, surgery and site, and allergies/adverse reactions, for the circulating nurse. Dr A would have used the consent/preoperative checklist to confirm Mrs B's NHI and any request for the return of tissue.

26. The DHB explained that the circulating nurse would also have used the Surgical Safety checklist, alongside the preoperative checklist and consent forms, during the "Time Out" procedure to confirm the patient's name, NHI, date of birth, procedure site, allergies/

[7] In response to the provisional report, Mrs B stated: "I never at any time said I experienced flushing. I am still unsure where this came from as it has been repeated a few times but it was actually never said by me as it has never been a symptom."

[8] Gabapentin is a type of pain medication used to treat some types of nerve pain and epilepsy, and to prevent migraine headaches.

[9] As already noted and in response to the provisional report, Mrs B confirmed that the medical alert bracelet had been removed earlier on the morning of surgery during a preoperative check.

adverse reactions, and any request for the return of tissue. There were two circulating nurses for Mrs B's surgery.

27. The operating theatre nursing notes dated 12 September 2019 again state Mrs B's allergies to morphine, pethidine, codeine, and adhesives.

28. Mrs B's surgery was performed by a consultant obstetrician and gynaecologist and a registrar. Mrs B's ovaries, fallopian tubes, uterus, and the Mirena IUD were all removed. Post-surgery, the procedure was documented as being "uncomplicated".

Anaesthetic during surgery

29. Dr A told HDC that the induction[10] at 8.40am was uneventful. He recorded the drugs used for the induction and for maintenance anaesthesia.[11] Dr A monitored Mrs B using various methods to track the oxygen levels in her blood (pulse oximetry), blood and airway pressure, temperature, carbon dioxide in exhaled breath (capnography), heart activity (using an electrocardiogram), and anaesthetic agent analysis.

30. Dr A gave Mrs B 3mg of morphine at 9.45am. He stated that Mrs B developed a sinus bradycardia[12] with a brief episode of junctional rhythm,[13] and her heart rate briefly dropped down to 22 beats per minute (bpm).[14] Dr A told HDC that he "noticed the bradycardia immediately and asked the surgeons to stop" while he administered appropriate medication.[15] Dr A said that shortly after this, Mrs B's heart rate "rapidly returned to normal", and he told the surgeons that they could continue. Dr A noted that Mrs B's blood pressure did not drop at the time of the bradycardia, and remained within the normal range.[16]

31. In response to the provisional opinion, Dr A told HDC that prior to administering morphine he had carefully considered Mrs B's "prior experiences and the potential for her not to be 'allergic' but rather to have experienced the known side-effect of bradycardia". However, Dr A accepted that the issue of whether morphine would be used or trialled was not properly dealt with as it should have been, and that Mrs B "must have gone into the surgery believing that morphine would not be used".

32. Dr A told HDC that the timing of Mrs B's bradycardia at 9.45am may have been related to the morphine, but it was possible that it was caused by a vagal response[17] to the surgery, as

[10] The transition from an awake state to an anaesthetised state.
[11] Dr A recorded the use of the following drugs for induction and maintenance: fentanyl, propofol, rocuronium, lignocaine, dexamethasone, phenylephrine, cefazolin, metronidazole, and desflurane.
[12] A heart rate lower than 60 beats per minute.
[13] A cardiac rhythm resulting from impulses coming from tissue in the right-hand area of the heart between the atrium and ventricle.
[14] A normal heart rate range for a healthy adult is 60–100bpm.
[15] Dr A administered glycopyrrolate.
[16] Mrs B's blood pressure was recorded as 118/80mmHg. The normal blood pressure range for a healthy adult is 90/60–120/80mmHg.
[17] A vagal response is excessive activity of the vagus nerve, causing slowing of the heart and a fall in blood pressure, which may lead to fainting.

the "surgeons were pulling on the broad ligament at the time and this can be a profound vagal stimulus". Dr A stated:

> "[I gave [Mrs B] morphine because] a hysterectomy is a painful surgical procedure … morphine is usually my preferred postop opiate because it has a longer duration of action than fentanyl. I thought that giving a small dose in theatre under anesthetic with continuous monitoring would allow me to establish that it was a safe drug for [Mrs B]. If I found the first 3mg dose to be safe, I intended to give a total of 10mg before the end of the surgery and this would have given her better postop pain control for the first few hours."

33. Dr A advised that he did not give any further doses of morphine, and instead gave Mrs B ketamine and oxycodone for analgesia. Dr A said that the rest of the anaesthetic and surgery proceeded uneventfully. At the end of the surgery he reversed the muscle relaxant[18] and extubated Mrs B in theatre.

34. At 10.30am on 12 September, Dr A noted on the acute pain service referral and treatment form: "[Mrs B had] severe bradycardia from morphine. To try oxycodone. Fentanyl is OK."

Post-surgery

35. After surgery, Mrs B was taken to the Post Anaesthetic Care Unit, where she received anti-nausea drugs,[19] and fentanyl and ketamine for pain management. Dr A noted that he prescribed atrophine if required for bradycardia, but this was not needed.

36. When Mrs B woke up in recovery post-surgery, she was told that she had been given morphine during the surgery, which she said she was told had caused her heart rate to drop to 22bpm. Mrs B said that she was told that "it was alright due to the fact [she] had been in a controlled environment". In response to the provisional report, Mrs B told HDC: "It was actually a big shock when still coming around after surgery to be told I had been given morphine." In relation to this aspect of care, Dr A stated in response to the provisional report: "The inference [regarding Mrs B's recollection of what she was told following surgery] is that [I] was dismissive of what happened." Dr A said that after he took Mrs B to the recovery room, he advised the recovery room nurse of the events that had occurred during surgery, and as he had been called back to theatre for surgery, the nurse conveyed the above information to Mrs B.

37. Mrs B was transferred to the surgical ward, and was discharged on 14 September 2019.

Subsequent events

38. On 23 October, the surgeon saw Mrs B in the gynaecology clinic and noted that she was keeping well following the operation. The surgeon told Mrs B that the histology report had confirmed a normal uterus, cervix, and ovaries.

[18] Dr A used neostigmine and glycopyrrolate to reverse the muscle relaxant.
[19] Mrs B received ondasetron and cyclizine for nausea.

Further comment

39. Mrs B is concerned about the care provided to her, and told HDC that she does not "want other people to be ignored when they say don't give those drugs to me".

40. Dr A has provided an apology to Mrs B for having given her "morphine under anaesthetic after [she] had clearly indicated that [she had] previously experienced bradycardia in association with morphine". Dr A noted that "the bradycardia and flushing that [Mrs B] described did not seem to be an allergy. This is a side effect not an allergy." Dr A accepted that "[he] did not discuss [his] plan to give her morphine under anesthetic during the pre-op consultation and [so] gave the drug without her consent".

41. Dr A told HDC that following these events he completed "further reading on the side effects of morphine … and [has] had the opportunity to share [his] new knowledge with other anaesthetists at [the public hospital]". Dr A said that he now "pays closer attention to patients who report adverse effects from drugs and wherever possible [he] avoid[s] these drugs" and, if he feels that there is a good indication to use any such drug, he does "not use it without having a good discussion of the advantages and disadvantages and obtaining [the patient's] consent".

42. The DHB mirrored Dr A's response and noted that following this event staff were made more aware of the possibility of small doses of morphine causing severe dangerous bradycardia.

Responses to provisional report

43. Mrs B, Dr A, and the DHB were all provided with the opportunity to comment on the relevant sections of my provisional report, and their comments have been incorporated into this report where relevant.

44. Mrs B stated:

> "There seems to be much discussion around the word 'allergy' but I don't think whether it is an allergy or an adverse reaction is the point. [Dr A] had every intention of giving me the morphine no matter what was said, as he has stated [above], even though he told me he was not going to. If [Dr A] had come to me while I was still in the hospital and apologized I wouldn't have laid a complaint. But post surgery I never saw him again. I feel he put my life at risk because I feel that he thought he knew better, even though he said he wouldn't give me the morphine and then proceeded to do so anyway."

45. Dr A accepted the provisional decision. He submitted that in this case he responded responsibly to what happened, and reiterated that he disclosed the events to Mrs B following her surgery and apologised to her again in an earlier response to this Office, expressing regret for his actions. As noted above, he told HDC that he "would never have told [Mrs B] that he would not give morphine and then proceed to do so". Dr A stated that this was an isolated error, and he has made appropriate changes to his practice.

46. The DHB said that it believes this matter to be a singular event and that it has no other concerns around Dr A's practice. It further stated that Dr A will be arranging time with his head of department to discuss how to improve informed consent processes at the DHB.

Opinion: Dr A — breach

Informed consent

47. Mrs B had advised clinicians on six occasions that she was allergic to morphine and had experienced a reaction in the form of hypotension and bradycardia. As my anaesthetist expert advisor, Dr Alex Khrapov, has highlighted: "There were well-documented notes of bradycardia and hypotension with these medications [morphine, pethidine, and codeine]." Mrs B told HDC that on the day of the surgery: "[The anaesthetist] said he would not give me morphine, as I told him and my surgeon it caused bradycardia and hypotension if given to me." Dr A disputes that he told Mrs B he would not administer morphine. During the surgery, he administered morphine to Mrs B and she experienced an episode of bradycardia. Dr A did not discuss with Mrs B his intention to give her a trial of morphine during her surgery, or obtain her consent to this.

48. The principle of informed consent is at the heart of the Code of Health and Disability Services Consumers' Rights (the Code). Pursuant to Right 7(1) of the Code, services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. If the consumer will be under general anaesthetic, the Code provides an additional safeguard that consent must be in writing. This is also reflected in the DHB's Informed Consent Procedure, discussed further at paragraph 53 (relevant excerpts are included at Appendix B).

49. Dr Khrapov advised that it is a departure from accepted practice not to follow a patient's request not to use a particular drug, to avoid known side effects of the drug. He noted that in addition to Mrs B's request not to be given certain drugs:

> "[Dr A] was aware of [Mrs B's] increased risk of adverse reaction to opioids: Morphine, Pethidine and Codeine as noted in anaesthetic records and preadmission clinic as well as Medical Alert Bracelet. There were well-documented notes of bradycardia and hypotension with these medications."

50. Dr A does not accept that he was aware of the medical alert bracelet, or that a direct request that morphine not be used was made to him.

51. I note that Dr A stated that at the time he wanted to trial morphine in a safe environment, and that it could have been the surgery that caused the bradycardia. While Dr A's decision to administer morphine may have been with the best intentions, it is the consumer's right to decide and, in the absence of an emergency or certain other legal requirements, clinical judgement regarding best interests does not apply. It would have been a different situation if Mrs B had consented to the trial following a discussion with Dr A about her documented

risk of experiencing bradycardia. However, this trial was carried out without Mrs B's consent while she was vulnerable under general anaesthetic.

52. I acknowledge that Dr Khrapov considers that the administration of morphine by Dr A was a minor departure from accepted clinical practice because of the fast response by the doctors involved and because there were no further side effects and the consequences were not significant. I accept that in this case the consumer did not suffer significant harm, but, with respect, I do not accept that the subsequent events mitigate against the decision made by Dr A to administer morphine when he was aware of Mrs B's knowledge that she could have an adverse reaction to morphine, and her notes documented her previous reactions to morphine, pethidine, and codeine.

53. The DHB's Informed Consent Procedure sets out:

> "[If the] procedure is experimental, or the consumer will be under general anaesthetic, or there is a significant risk of adverse effects on the consumer, information in the health record should include: what information was given to the patient/ representative, when this was done and by whom, the name and designation of the person obtaining consent, any timeframe discussed with the patient, the name and or designation of the person/s who will carry out the treatment (where this is known), and a statement of agreement/consent from the patient."

54. There is no evidence to suggest that Dr A provided any information to Mrs B about trialling morphine during the surgery. The DHB's Informed Consent Procedure also explicitly states that "when an anaesthetist is involved in [a] patient's care, it is the anaesthetist's responsibility (not that of the surgeon) to seek consent for anaesthesia … having discussed the benefits and risks with the patient". Again, no risks about the use of morphine were discussed with Mrs B.

55. It is unacceptable that Dr A did not discuss with Mrs B the possibility of a trial of morphine during surgery, or obtain her consent to this. I am concerned that Dr A did not follow the DHB's informed consent policies, and that Mrs B was particularly vulnerable, as she was under anaesthetic. It was Mrs B's right to decide, and she was deprived of this. I am critical of Dr A's actions and find that by giving Mrs B morphine when she had not only not agreed to the trial, but had also stated on multiple occasions that she is allergic to morphine, and where there was documented evidence of adverse reactions in her notes and on her medical alert bracelet, Dr A breached Right 7(1) of the Code.[20]

56. I acknowledge that Dr A has now apologised to Mrs B for going against her wishes, and has accepted that he gave morphine to her without her consent.

[20] 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."

Opinion: DHB — adverse comment

57. As a healthcare provider, the DHB is responsible for providing services in accordance with the Code. In this case, I consider that the errors that occurred did not indicate broader systems or organisational issues at the DHB. Therefore I consider that the DHB did not breach the Code directly.

58. In addition to any direct liability for a breach of the Code, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any acts or omissions of its employees. A defence is available to the employing authority of an employee under section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the acts or omissions.

59. From 28 February 2019 to 12 September 2019, Dr A was an employee of the DHB. Accordingly, the DHB is an employing authority for the purposes of the Act. As set out above, I have found that Dr A breached Right 7(1) of the Code for failing to obtain informed consent prior to using morphine on a patient who had disclosed an adverse reaction to the medication, and where this adverse reaction was well documented in the patient's notes.

60. The DHB has in place informed consent policies and procedures to ensure that services are provided to consumers only where they have made an informed choice and given informed consent. Staff fill out multiple forms where they ask consumers to detail their adverse reactions/allergies (the pre-assessment and preoperative forms). The anaesthetist also meets with patients prior to surgery to fill out a separate anaesthetic consent form. These forms are checked twice during the surgical process. On this occasion, Dr A failed to follow the DHB's Informed Consent Procedure, which requires staff to provide information to consumers if the procedure is experimental, and also the risks of anaesthesia.

61. Based on this information, I am satisfied that the DHB had in place the appropriate policies as were reasonably practicable to prevent the act and omission that occurred. Accordingly, I do not find the DHB vicariously liable for Dr A's breach of the Code.

62. However, I take the opportunity to note that there were many opportunities for multiple clinicians at the public hospital to advocate for Mrs B prior to the surgery and when she was under anaesthetic and vulnerable. Mrs B's documented adverse reaction to morphine was noted multiple times and checked twice by different staff in the theatre — during the "Sign-In" by Dr A for the circulating nurse, and during the "Time Out". I believe these were two missed opportunities to advocate for Mrs B given that all the paperwork had been filled out about the previous adverse reactions, and that these would have been mentioned during the two additional checks.

63. RN C and anaesthetic technician Ms D were also present during the surgery and were aware of Mrs B's adverse reaction to morphine, as they completed the preoperative checklist and a second check of the form prior to surgery. RN C and Ms D were Mrs B's advocates in theatre. I believe this was another missed opportunity to advocate for Mrs B.

64. The DHB's Informed Consent Procedure reflects the shared responsibility of the DHB clinicians regarding informed consent. The Informed Consent Procedure states that if "anyone involved in the care or treatment of a patient, who believes the patient is not adequately informed, must convey this to the person responsible for obtaining the consent". In my view, if staff had communicated and raised the issue of the use of morphine in surgery, this situation may have been prevented.

Changes made

65. This case was presented at the departmental morbidity and mortality meeting on 17 December 2019, where the following was discussed:

a) The danger of morphine possibly causing severe bradycardia;

b) The misuse of the term "allergy"; and

c) The need to have a good discussion with the patient and obtain their consent before using any drug to which the patient has noted an adverse response.

66. Dr A told HDC that he instructed all the anaesthetists and nurses in the preoperative assessment clinic to record any medical alert bracelets being worn by patients. Other changes to Dr A's practice have been noted at paragraph 41.

Recommendations

Dr A

67. I recommend that Dr A undertake further education and training on informed consent, and provide evidence of this to HDC within three months of the date of this report.

68. I acknowledge that Dr A has provided an apology to Mrs B.

DHB

69. I recommend that the DHB:

a) Use an anonymised version of this case for the wider education of its staff. Topics should include informed consent, advocacy of the consumer, and the importance of following and checking the preoperative checklist, as highlighted by my expert advisor, Dr Khrapov. Evidence of this should be provided to HDC within three months of the date of this report.

b) Consider streamlining the multiple layers of pre-operation checks and ensure that the notes recorded are read by all relevant parties and that relevant actions are taken and recorded accordingly.

c) Clarify the anaesthetist process during surgery to ensure that staff are able to advocate for the patient in theatre (as discussed at paragraphs 62–64).

70. The DHB should report back to HDC on the steps taken to achieve recommendations b) and c) within six months of the date of this report.

Follow-up actions

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

72. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from Dr Alexander Khrapov, a consultant anaesthetist:

"Thank you for providing an opportunity to help your investigation with expert advice to the Health and Disability Commissioner (HDC) on the care provided by [the DHB] to [Mrs B] in September 2019.

I don't have any personal or professional conflict in this case. I have read and agreed to follow the Commissioner's Guidelines for Independent Advisors.

I am a Specialist Anaesthetist, vocationally registered in New Zealand since 2002. I have worked as a Senior Medical Officer in Anaesthetics and Intensive Care at Timaru Hospital since 2002 having worked in the speciality for more than 30 years in different hospitals in New Zealand and overseas. I am involved with Acute Pain Services in Timaru and with Chronic & Persistent Pain Services on occasion.

I have been asked to provide advice to the Commissioner regarding the care provided to [Mrs B] by [the DHB].

More specifically I have been asked to provide advice and comments on the following:

1. Whether the decision by [Dr A] to administer 3 mg of Morphine during [Mrs B's] Hysterectomy was appropriate in the circumstances;

2. Whether the decision by [Dr A] to administer Oxycodone as analgesia during [Mrs B's] Hysterectomy was appropriate in the circumstances;

3. The reasonableness of [Dr A's] explanation that he had never previously experienced or heard of Morphine causing 'dangerous bradycardia';

4. Any other matters which would be considered as departure from accepted standards of care or warrant comment.

This report is based on information provided by HDC, including copies of clinical records, preassessment questionnaires, different tests, surgical letter, follow up, cardiology report and responses from [Dr A], [the DHB] and various persons involved in the care of [Mrs B] and subsequent investigations.

Background/Key points:

[Mrs B] is a reasonably healthy [person in her forties] with few medical and gynaecological problems. She doesn't take regular medications. [Mrs B] underwent a laparoscopic hysterectomy and bilateral salpingo-oophorectomy + Mirena removal at [the public hospital] on 12 of September 2019 for abnormal uterine bleeding and pelvic pain problems. She completed her preassessment adult patient questionnaire at [another hospital] on 28/02/2019 and the same preassessment questionnaire at [the

public hospital] on 11/07/2019 in both forms mentioning adverse reaction to Codeine, Morphine and Pethidine. All of those produced severe bradycardia and hypotension. [Mrs B] wears the Medical Alert Bracelet with printed allergy to Morphine and Codeine. She also develops blisters to sticking plasters. [Mrs B] had occasional palpitations but was cleared by Cardiologist as having a normal sinus heart rhythm and rate without abnormalities. No atrial fibrillation, brady-tachycardia arrhythmias or SVT episodes were found on extended ECG monitoring. [Mrs B] had two previous laparoscopic surgeries under general anaesthetic without significant problems other than nausea and vomiting postop. She was checked at the public hospital preadmission clinic by [the] admitting registered nurse and mentioned her allergies to opioid drugs one more time. Her medical history, physical examination and laboratory results were normal before surgery and she was graded as ASA 1 — healthy person with good exercise tolerance.

[Dr A], consultant anaesthetist met [Mrs B] on the day of surgery 12/09/2019. He took her medical and anaesthetic history, checked preadmission notes and examined her before procedure. They have discussed the previous side effects of opiates on [Mrs B]: bradycardia and hypotension, as well as her cardiology exams for missed heart beats, palpitations and flushing.

I have checked an anaesthetic record provided by [the DHB] and signed by Anaesthetist [Dr A].

[Mrs B] had a routine inhalational anaesthesia with intravenous induction at 08:40: Fentanyl 75+75+50 mcg and Propofol 130 mg. Neuromuscular blocking agent Rocuronium was used for intubation and myorelaxation during the surgery. She had a standard monitoring including ECG, blood pressure, pulse oximetry, NMB monitoring, temperature, capnography, oxygen and volatile anaesthetic control. I have noticed that Fentanyl a synthetic opioid analgetic pharmacologically similar to Morphine didn't produce significant bradycardia on anaesthesia induction. Severe sinus bradycardia down to 22 beats per minute with short episode of junctional rhythm developed after 3 mg of Morphine administration at 09:45 without notable changes in blood pressure. It was corrected with 200 mcg of Glycopyrrolate almost immediately. It was at the same time as the surgeon pulling the uterus broad ligament and most likely presented as a vagal response due to either Morphine or uterine ligament traction. The surgery briefly stopped. The fast return of the normal heart rate with anticholinergic drug in five minutes and no changes in rhythm could support the likelihood of event. [Dr A] used Ketamine and 10 mg of Oxycodone i.v. later on and no more Morphine for the pain relief during the surgery. The further anaesthesia and surgery progressed uneventfully. [Mrs B] regained consciousness, was extubated in theatre and transferred to post-anaesthesia recovery unit (PACU) without any problems.

[Dr A] prescribed Fentanyl PCA, Oxycodone, Ketamine, Paracetamol, NSAIDs and Gabapentin for pain relief after surgery for [Mrs B]. I have noticed that Atropine was prescribed as well in case of any bradycardia event with opioids but not required. She had antinausea drugs given in PACU and her pain control was adequate. She was transferred to surgical ward without any issues later on.

Opinion/Comment:

This is a sad case of miscommunication and not following patient's concern and advice.

1. **The decision by [Dr A] to administer 3 mg of Morphine during [Mrs B's] hysterectomy was inappropriate in the circumstances provided.**

The anaesthetic management and care provided to [Mrs B] by [Dr A] was within the standards of care and acceptable acute pain management practice during laparoscopy and laparotomy. There were no departures from the accepted practice protocols and standards of care. Morphine and other opiates are widely used during the surgery and for postoperative pain relief and control. It is a safe and well-established practice within anaesthesia and pain medicine.

Unfortunately, [Dr A] didn't follow the patient request not to use Morphine, Pethidine or Codeine during the surgery or for postoperative pain relief. It is a departure of accepted practice not to consider patient request to avoid known side effects of drugs to the individual. Such complex and unusual severe bradycardia with above mentioned opioids is most likely a vagal response with or without histamine release as it was successfully treated and cured with anticholinergic drugs. Similar cases and patients are rare but described in anaesthetic and pharmacology literature. Individuals vary by as much as 10-fold in their sensitivity to different opioid analgesics. This is due to difference in plasma concentration needed to produce a given effect, and therefore is due to rather pharmacodynamic than pharmacokinetic variability. It is mostly related to mu-opioid receptor gene polymorphism (Ikeda et al. 2005). Genotyping could be used to identify opioid resistant individuals as well as unusual autonomous (sympathetic or parasympathetic) response to opioids.

We have discussed this case with our Anaesthetists and Pain Specialists anonymously without names, hospitals and services involved, few details missed due to non-disclosure. We all viewed it as a very rare event in clinical practice. We use Morphine but not Oxycodone in our protocols and anaesthetic management.

The only recommendation for improvement and prevention of the similar occurrence and complaints would be advice to strictly follow an allergy warning and repeated checking (WHO 'time out' the surgical team protocol) before any procedure involving surgery, anaesthesia, proper communication within the team.

2. **[Whether] the decision by [Dr A] to administer Oxycodone as analgesic during the hysterectomy was inappropriate in the circumstances.**

[Dr A] was aware of [Mrs B's] increased risk of adverse reaction to opioids: Morphine, Pethidine and Codeine as noted in anaesthetic records and preadmission clinic as well as Medical Alert Bracelet. There were well-documented notes of bradycardia and hypotension with these medications.

Ketamine was added to control analgesia (PCA) Fentanyl pump intravenously in the ward to help with severe pain which is common in hospital practice.

We have discussed anaesthetic pain management of [Mrs B] with our Anaesthetists and Pain Specialists anonymously without names, hospitals and services involved, a few details missed due to non-disclosure. We all viewed the care provided to [Mrs B] as acceptable pain management according to the best available medical evidence practice and standards. We use similar protocols and treatment strategy but not Oxycodone in our Pain Clinic. Oxycodone is semi-synthetic opioid comparable to Morphine. It has better 60% oral bioavailability and twice as potent but has addiction potential. Oxycodone may provide alternative pain relief to Morphine peri-operatively. It has similar pharmacokinetic and pharmacodynamic profile with mostly the same side effects. Oxycodone shares the same drug interactions as other opioids but, in contrast to Morphine, the CYP2D6 and CYP3A4 are involved in the hepatic Oxycodone metabolism. Any drugs inhibiting those enzymes may increase its plasma concentration and side effects (bpac.org.nz, 2020). Oxycodone is not thought to have significant adverse effects on cardiac function but can cause vagus nerve-mediated bradycardia and hypotension. It has been associated with histamine release.

3. The reasonableness of [Dr A's] explanation that he had never previously experienced or heard of Morphine causing 'dangerous bradycardia'.

Hypotension and bradycardia occur with large doses of most opiates due to action on the medulla. With morphine and similar drugs, histamine release may also cause hypotension. Central neurally mediated mechanisms are the primary causes of opioid-induced bradycardia. Morphine has also a direct effect on the sino-atrial node and atrio-ventricular conduction (Kennedy et al, 1967; Tomichek et al, 1982; De Silva et al, 1978). Asystole may follow opioid-induced bradycardia and several case reports illustrate predisposing factors: presence of β-blockers or calcium entry blockers; premedication with benzodiazepines; muscle relaxants without vagolytic or with vagotonic properties; added vagal stimuli (laryngoscopy, surgical tractions); rapid administration of opioids. Periods of severe bradycardia or even asystole up to 10–20 seconds may resolve on their own but usually require Atropine 0.4–1.0 mgl.v. (R Miller Anaesthesia, 5th edition, pp299–300). I can accept [Dr A's] explanation of misuse of the term 'Allergy' which is complex pathophysiology and specific immune mediated response to antigens. [Mrs B] most likely has significant side effects with some opioids which should not be used in future to avoid any problems. I am also in agreement with [Dr A's] statement that for any painful surgical procedure such as hysterectomy the multimodal pain relief approach is the best with opioids included for severe pain as part of anaesthesia protocols peri-operatively. Bradycardia with Morphine or Oxycodone is a known phenomenon but rare event in routine clinical practice cardiac surgery excluded when large doses of Fentanyl are used sometimes. Some anaesthetists may never witness such severe bradycardia with small doses of opioids in their clinical practice. [Dr A] noticed his experience with dangerously slow heart rate during gynaecological surgery with vagal stimulation.

4. Other matters which need comments.

I am satisfied that [Dr A] has reacted immediately to dangerous intraoperative events (bradycardia) which may be related either to Morphine or surgical manipulations with

proper management and without significant consequences to [Mrs B's] health. It was well executed management of an anaesthetic crisis. The short (about one minute) bradycardia events didn't cause any significant harm to [Mrs B] and her blood pressure has not dropped. I can also commend [Dr A] for frank and prompt disclosure of events during anaesthesia and explanation to the patient what has happened and why. He regretted underestimation of [Mrs B's] bradycardia warning and missed discussion and consent with her for planned use of Morphine or Oxycodone during the surgery. [Dr A] has apologised to [Mrs B] for the misunderstanding, miscommunication and events during her surgery. I was surprised to hear that many of [the] anaesthetists had never heard of Morphine or other opioids causing severe bradycardia or experienced it and some of them will be happy to proceed with Morphine use in such circumstances. I agree that the term 'Allergy' might be misused in this case as it is most likely known severe side effects of opioids. The most important consequences of the Morbidity and Mortality meeting on 17 December 2019 at [the DHB] Anaesthetic Department were:

1. The danger of Morphine or other opioids causing dangerous bradycardia;
2. The need of a good discussion and obtaining a signed consent with patient before using any drugs with noted adverse or side effects to that patient;
3. Proper check in of any Medical Alert bracelet used and documented in preadmission and during 'Time Out' before any medical or surgical procedure.

[Dr A] has sent an email to all anaesthetists and nursing staff in the preassessment clinic to record any Medical Alert Bracelets being worn and any drugs allergy or side effects registered to patients.

I have no other matters on the case, which warranted any further comments. I am happy that my advice on the matter may be requested and disclosed under the Privacy Act 1993 and Official Information Act 1982. I am able to provide oral evidence in case of formal disciplinary or Tribunal hearing required. I am not sure it is necessary at the current stage.

I have no intention to enter into any discussion about my advice and expert review with any insurance, lawyers, health providers or media involved in the case.

I have no personal or professional involvement and have no conflict in this case.

Please do not hesitate to contact me should you have any additional questions or advice on the matter.

Sincerely yours,

Dr Alexander Khrapov, MD, PhD, FANZCA
Consultant Anaesthetist."

The following further expert advice was obtained from Dr Khrapov:

> "The reason to advise on the first question regarding Morphine used in the case being inappropriate as it went against patient's warning and request not to use it. It could be considered as a minor departure from the clinical practice due to non-significant consequences for the patient and the fast response by doctors involved without further side effects.
>
> Advice on the second question regarding use of Oxycodone as being inappropriate has the same meaning. Oxycodone has the same pharmacological profile as Morphine. It is better to avoid it if Morphine is contraindicated. This is the same minor departure from accepted clinical practice. In both decisions [Dr A] tried to do his best for the patient to relieve the pain during and after the surgery.
>
> Departures from acceptable clinical practice might be considered minor due to non-anaphylactic reactions to opioids and mostly due to well known side effects of it. It was easily corrected in this case.
>
> Many Anaesthetists have never experienced significant bradycardia down to 22–28 beats per minute heart rate in their working life but such side effects are known and well described in Anaesthetic Literature.
>
> Please don't hesitate to contact me should you have any further questions.
>
> Sincerely,
>
> Dr Alex Khrapov"

The following further expert advice was obtained from Dr Khrapov:

> "Thank you for providing an opportunity to reply on [Dr A's] letter regarding your investigation and my expert advice to the Health and Disability Commissioner (HDC) on the care provided by [the DHB] to [Mrs B] in September 2019. As I mentioned before I do not have any personal or professional conflict in this case. I have read and agreed to follow the Commissioner's Guidelines for Independent Advisors.
>
> I am a Specialist Anaesthetist, vocationally registered in New Zealand since 2002. I have worked as a Senior Medical Officer in Anaesthetics and Intensive Care at Timaru Hospital since 2002, having worked in the speciality for more than 30 years in different hospitals in New Zealand and overseas. I am involved with the Acute Pain Services in Timaru and with Chronic & Persistent Pain Services on occasion.
>
> I have been asked to reply and comment on the letter by [Dr A] dated 29.03.2021, and response by [the DHB] dated 06.04.2021, regarding the care provided to [Mrs B] ([Mrs B]) by the [the DHB]. More specifically, I have been asked to review [Dr A's] response on the administration of Oxycodone to [Mrs B] as analgesic in view of her high sensitivity to Morphine.

I am satisfied with [Dr A's] response and explanation of the decision to administer Oxycodone as analgesic during [Mrs B's] hysterectomy. I can amend my advice as Oxycodone administration being appropriate in the circumstances. In the pre-assessment questionnaire at [the public hospital] on 11/07/2019, [Mrs B] mentioned adverse reaction to Codeine, Morphine and Pethidine. All of those produced severe bradycardia and hypotension. [Mrs B] wears a Medical Alert Bracelet with printed allergy to Morphine and Codeine. Oxycodone was not mentioned either in preadmission forms or on her Medical Alert Bracelet. [Mrs B] was checked at [the public hospital] preadmission clinic by [the] admitting Registered Nurse and mentioned her allergies to opioid drugs but not to Fentanyl or Oxycodone. [Dr A], Consultant Anaesthetist met [Mrs B] on the day of surgery 12/09/2019. He discussed the previous side effects of opiates with [Mrs B]: bradycardia and hypotension.

[Mrs B] had a routine inhalational anaesthesia with intravenous induction using Fentanyl 75+75+50 mcg. I have noticed that Fentanyl, a synthetic opioid analgetic pharmacologically similar to Morphine, did not produce significant bradycardia on anaesthesia induction. Severe sinus bradycardia down to 22 beats per minute with short episode of junctional rhythm developed after 3 mg of Morphine administration. It was corrected almost immediately. It was at the same time as the surgeon pulling the uterus broad ligament and most likely presented as a vagal response due to either Morphine or uterine ligament traction. The surgery briefly stopped. The fast return of the normal heart rate with anticholinergic drug in five minutes and no changes in rhythm could support the likelihood of event. [Dr A] used Ketamine and 10 mg of Oxycodone IV later on and no more Morphine for the pain relief during the surgery. [Dr A] explained his rational to use Oxycodone in his letter. He considered it as a safe alternative to Morphine. He didn't notice any side effect of Oxycodone in [Mrs B's] Anaesthesia, and surgery progressed uneventfully later on.

I have checked an anaesthetic record provided by [the DHB] and signed by Anaesthetist [Dr A]. I have also checked the Enhanced Recovery After Surgery (ERAS) Protocol supplied by [the DHB] and authorised by [the DHB] Department of Anaesthetics 28.06.2019. This protocol mentioned using Morphine (Sevredol) or Oxycodone (OxyNorm) for postoperative analgesia with Fentanyl and Morphine IV for breakthrough pain as well as PCA (patient-controlled analgesia) with the same opioids. Oxycodone is used in this protocol as a component of the multimodal analgesia and as an alternative to Morphine if the latter is not tolerated. I have noticed that [Dr A] prescribed opioids for pain relief after surgery: Fentanyl PCA, Oxycodone. Other drugs prescribed were Ketamine, Paracetamol, NSAIDs and Gabapentin. Ketamine was added to control analgesia with Fentanyl (PCA) pump intravenously in the ward to help with severe pain which is common in hospital practice. Atropine was prescribed as well in case of any bradycardia event with opioids but not required, and her pain control was adequate.

I can amend my previous letter as: **The decision by [Dr A] to administer Oxycodone as analgesic during the hysterectomy was appropriate in the circumstances of limited choice of strong analgesics available to [Mrs B] considering her allergy to Morphine and Pethidine.**

[Dr A] was aware of [Mrs B's] increased risk of adverse reaction to opioids: Morphine, Pethidine, and Codeine, as noted in the anaesthetic records and preadmission clinic, as well as Medical Alert Bracelet. There were well-documented notes of bradycardia and hypotension with these medications.

I have mentioned in my previous expert advice that we have discussed anaesthetic pain management of [Mrs B] with our Anaesthetists and Pain Specialists anonymously without names, hospitals and services involved, a few details missed due to non-disclosure. We all viewed the care provided to [Mrs B] as acceptable pain management according the best available medical evidence practice and standards. We use similar protocols and treatment strategy but not Oxycodone in our Pain Clinic. Oxycodone is a semi-synthetic opioid comparable to Morphine. It has better than 60% oral bioavailability and twice as potent but has addiction potential. Oxycodone may provide alternative pain relief to Morphine peri-operatively. This was the case for [Mrs B] as described by [Dr A]. Oxycodone has a similar pharmacokinetic and pharmacodynamic profile with mostly the same side effects. Oxycodone shares the same drug interactions as other opioids, but in contrast to Morphine, the CYP2D6 and CYP3A4 are involved in the hepatic Oxycodone metabolism. This might be the reason for lesser sensitivity to Oxycodone and its better safety profile in [Mrs B's] anaesthesia. Nevertheless, any drugs inhibiting those enzymes may increase its plasma concentration and side effects (bpac.org.nz, 2020). Oxycodone is not thought to have significant adverse effects on cardiac function but can cause vagus nerve-mediated bradycardia and hypotension. It has been associated with histamine release.

I have no other matters on the case which warranted any further comments. I am happy that my advice and amendment regarding use of Oxycodone may be requested and disclosed under the Privacy Act 1993 and Official Information Act 1982. I am able to provide oral evidence in case of formal disciplinary or Tribunal hearing required. I am not sure it is necessary at the current stage.

I have no intention to enter into any further discussion about my advice, amendment and expert review with any insurance, lawyers, health providers or media involved in the case. I hope that will be enough to consider the case is well discussed, and apology from [Dr A] and [the DHB] are accepted by [Mrs B] I am satisfied that all corrective measures were reviewed, implemented and protocolised in the Department of Anaesthetics and [the DHB] Policies as revealed in your letter.

I have no personal or professional involvement and no conflict in this case. I will be happy to see this case resolved ASAP with apologies to [Mrs B] are accepted. I wish [Dr A] to continue to provide safe and high quality anaesthetic services for people of [the district].

Please do not hesitate to contact me should you have any additional questions or advice on the matter.

Yours sincerely

Dr Alexander Khrapov, MD, PhD, FANZCA
Consultant Anaesthetist."

Appendix B: Relevant standards

DHB Policy "Controlled Drug Policy for Use in the Operating Theatre"

The "Controlled Drug Policy for Use in the Operating Theatre" publication states the following:

"**4. Policy**

This policy covers all controlled drugs used in theatre, including all opioids.

- All controlled drugs are to be collected by the anesthetic tech/nurse from the drug cupboard as is the usual practice, checked by another RN.
- The controlled drugs logged against a particular patient should only be used for that patient.
- Controlled drugs for an individual patient should remain in the theatre being used for the procedure.
- All drug doses administered to that patient should be carefully charted in the anesthetic form.
- Any controlled drug not administered should be discarded into the sharps bin and amount discarded signed for by the anesthetist and anesthetic tech/nurse."

DHB Policy "Informed Consent Procedure"

The "Informed Consent Procedure" publication states the following:

"**5.4 Written and verbal consent**

1. Under the Code of Health and Disability Services Consumers' Rights written consent is required where:
   - the consumer is to participate in any research; or
   - the procedure is experimental; or
   - the consumer will be under general anaesthetic; or there is a significant risk of adverse effects on the consumer (Right 7(6)).
2. Written consent is also required in certain circumstances under the Mental Health (Compulsory Assessment and Treatment) Act (sections 59, 60, 61) and when taking a bodily sample under the Criminal Investigations (Bodily Samples) Act unless consent is given orally and recorded (section 9).
3. In addition, written consent on the appropriate [the DHB] consent form is mandatory at […] Hospital and the two rural health centres:

- for the administration of blood and blood products; or
- when the patient is to have an epidural or spinal anaesthetic; or
- when the patient is undergoing a procedure specified in clause 5.4 of this procedure; or
- when either party requests it.

4. Specifically, written consent is required by [the DHB] for the following treatments:

General treatments/procedures
Including but not restricted to:

- Abdominal taps
- Bronchoscopy
- Cardioversions
- Chest drain insertion
- Colonoscopy
- Electroconvulsive Therapy,
- Endoscopic retrograde cholangio pancreatography
- Endoscopy
- Epidurals
- Gastroscopy
- Ischaemic arm blocks
- Liver biopsy
- Lumbar punctures
- Manual removal of placenta
- Insertion of temporary pacemaker
- Pleural tap
- Suprapubic catheter insertion
- All surgical procedures.
- Any other invasive procedure …

5.5 Documenting information and consent

1. Documentation of consent must be on [the DHB's] Request for/consent to treatment/procedure Form or other approved consent forms (for example, those used by dental therapists in the School Dental Service).
2. Where the criteria in clause 5.4.1 of this procedure are satisfied, that is, the consumer is to participate in any research, or the procedure is experimental, or the consumer will be under general anaesthetic, or there is a significant risk of adverse effects on the consumer, information in the health record should include:
   - what information was given to the patient/representative, when this was done and by whom
   - the name and designation of the person obtaining consent

- any timeframe discussed with the patient
- the name and or designation of the person/s who will carry out the treatment (where this is known)
- a statement of agreement/consent of the patient.

5.6 Informed decision

1. A patient is unable to make an informed decision about treatment unless they receive all the information that is required to enable them to make a fully informed choice about their treatment. As a minimum the Health and Disability Consumers' Code of Rights requires:

   (a) The patient to be informed on the following matters:

   - an explanation of his/her condition; and the nature and purpose of the treatment, including a description of the procedure proposed; and
   - the explanation of the options available, including an assessment of the expected risks; side effects; benefits, and costs to be directly borne by the person concerned (if any) of each option; and
   - the estimated time within which the services will be provided; and
   - the results of tests; and
   - any other information requested by the patient.

   (b) The honest and accurate answers to questions relating to services, including questions about:

   - the identity and the qualifications of the provider providing the service; and
   - the recommendation of the provider; and
   - how to obtain an opinion from another provider; and
   - the results of research.

   (c) The patient to receive, on request, a written summary of the information provided.

   (d) The information is to be given:

   - in a language, style and form that can be readily understood by the patient. This may require trained interpreters to be available where necessary (contact the Telephonists or Customer Relations and Complaints Coordinator for access to approved interpreters); and
   - an environment which allows open, honest and effective communication, including ensuring physical privacy.

2. Where practical, time should be allowed for the patient to read written information and to reflect and seek support of family/whānau before making a decision. While

a written information sheet may be useful, simply handing out an information sheet by itself will not satisfy the requirement for informed consent.

3. Patients have the right to have a reasonable number of family, support persons, and/or patient advocates present during discussion of proposed treatment or procedure if they wish.

5.7 Responsibility for giving of information and obtaining consent

1. The person carrying out a procedure is responsible for ensuring that Informed Consent has been obtained, before proceeding.
2. It is sometimes impracticable for all information to come from the employee conducting the procedure. In these cases, the gaining of the patient's consent may be delegated to an appropriate health professional who is familiar with the treatment/procedure and the matters relating to the procedure or treatment as specified in the section 5.6.1 of this procedure on 'informed decision'. However, the responsibility for ensuring informed consent has been obtained remains with the health professional carrying out the treatment.
3. In situations where a team is involved in the management or treatment, the process of imparting information may be shared among various team members. If a team member feels they are unable to provide adequate information in obtaining informed consent they must arrange for consent to be obtained by another team member.
4. Anyone involved in the care or treatment of a patient, who believes the patient is not adequately informed, must convey this to the person responsible for obtaining the consent. This should occur prior to the treatment or procedure being performed."