# Endoscopy Clinic

# Endoscopist, Dr B

## A Report by the

## Health and Disability Commissioner

## (Case 15HDC00043)

Health and Disability Commissioner
*Te Toihau Hauora, Hauātanga*

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## Executive summary

1. Mrs A was aged 69 years at the time of these events and had a family history of colorectal cancer. On 29 October 2014, general practitioner Dr I sent a referral for a screening colonoscopy to a gastroenterologist and endoscopist, Dr B, at his private rooms. In her referral letter Dr I stated that Mrs A was allergic to midazolam and fentanyl. A letter from Dr J, a general surgeon who had performed a colonoscopy on Mrs A previously, was also attached, and stated that Mrs A was allergic to a number of sedatives, and that "a general anaesthetic is advised".

2. On 29 October 2014, Mrs A's referral was forwarded directly to a colonoscopy clinic (the clinic) where he also worked. Dr B told HDC that he did not review Mrs A's referral personally before it was sent to the clinic. On 27 November 2014, Mrs A was sent an email from administrative staff informing her of the procedure date (2 December 2014). On the same day, on an online form sent to her by the clinic, Mrs A recorded that she had "allergies/known sensitivities" to midazolam and fentanyl.

3. The clinic's booking protocol in place at the time of these events stated that any problems arising with patient preparation for a procedure should be directed to the "appropriate person", which included nursing staff or the relevant specialist. The clinic stated that there is no record of its staff having notified Dr B of Mrs A's sensitivities to midazolam or fentanyl, or that she was on clopidogrel, prior to the day of her procedure.

4. On 2 December 2014, Mrs A presented to the clinic for her procedure. RN E completed a pre-procedure form and a consent form. Next to the "allergies/known sensitivities" on the pre-procedure form, she wrote "midazolam and fentanyl". The consent form was signed by Mrs A, RN E, and Dr B. A drug reaction sticker was affixed directly below the signature section of the form, with "midazolam and fentanyl" handwritten onto the sticker.

5. Dr B and Mrs A had a conversation regarding the sedation to be used; however, there are conflicting accounts about what was discussed. Mrs A stated that she recalls Dr B telling her once she was in the procedure room that they did not have an anaesthetist on that day, and that, when she experienced pain, she asked Dr B to stop the procedure, but he did not do so.

6. Dr B told HDC that he spoke to Mrs A in the pre-procedure area to explore her potential allergy further with her. Dr B stated that after talking with Mrs A it was apparent to him that she did not have an anaphylactic reaction to the drugs. Dr B said that he discussed with Mrs A how best to proceed, and that she agreed to start the colonoscopy examination initially without sedative drugs, but that if the examination became uncomfortable then small doses of midazolam and fentanyl would be administered. Dr B stated that he does not recall Mrs A asking him to abort the procedure.

**Findings**

7. The clinic breached Right 4(1) of the Code[1] by failing to have in place adequate systems to ensure that Dr B was notified of salient aspects of Mrs A's medical history, as required by its booking protocol.

8. Comment was made regarding Dr B's discussion with Mrs A on the day of the procedure.

**Recommendations**

9. It was recommended that the clinic use an anonymised version of this case to provide education to its staff and the endoscopists who use its facilities on topics including informed consent, advocacy for the consumer, and when it would be appropriate to notify the endoscopists of salient aspects of a patient's history prior to the day of the procedure. It was also recommended that education be provided to endoscopists on how they can access their patient's information held by the clinic.

10. It was recommended that the clinic review its protocols and policies and develop a protocol for the identification and escalation of patient allergies to senior nursing staff and the endoscopist; develop a protocol that clearly outlines the steps endoscopists are expected to have performed prior to forwarding a referral to the clinic; and consider whether the review of the patient's history and booking information by a registered nurse should be done earlier than the day before a procedure.

11. It was recommended that the clinic provide an apology to Mrs A for its breach of the Code.

## Complaint and investigation

12. The Commissioner received a complaint from Mrs A about the services provided to her by Dr B and the clinic. The following issues were identified for investigation:

- *Whether Dr B provided an appropriate standard of care to Mrs A between October and December 2014.*
- *Whether the clinic provided an appropriate standard of care to Mrs A between October and December 2014.*

13. The parties directly involved in the investigation were:

| | |
|---|---|
| Mrs A | Consumer/complainant |
| Dr B | Endoscopist |
| Endoscopy clinic | Endoscopy provider |

[1] Right 4(1) of the Code of Health and Disability Services Consumers' Rights states: "Every consumer has the right to have services provided with reasonable care and skill."

14. Information was reviewed from:

| | |
|---|---|
| Dr C | Endoscopist |
| RN D | Registered nurse/hospital Manager |
| RN E | Registered nurse |
| RN F | Registered nurse |
| RN G | Registered nurse |
| RN H | Registered nurse |
| Medical Council of New Zealand | |

Also mentioned in this report:

| | |
|---|---|
| Dr I | General practitioner |
| Dr J | General surgeon |

15. Independent expert advice was obtained from consultant gastroenterologist Dr Richard Stein (**Appendix A**).

## Information gathered during investigation

### Background

16. At the time of these events Mrs A was aged 69 years. She had a family history of colorectal cancer,[2] adenomatous polyps,[3] and atrial fibrillation.[4] In light of her family history of colorectal cancer she received periodic colonoscopies.[5]

17. Dr B is a physician, gastroenterologist,[6] and endoscopist.[7] He works in both public and private practice, and has consultation rooms. Dr B has worked at the clinic for many years. The clinic is a private company. It provides specialist endoscopy[8] services, including colonoscopies. Endoscopists use the facilities at the clinic, and it employs a number of registered nurses to assist with the procedures.

[2] Colorectal cancer is cancer of the colon.
[3] A polyp is a projection (growth) of tissue from the inner lining of the colon into the lumen (hollow center) of the colon. An adenoma is a polyp made up of tissue that looks much like the normal lining of the colon. In some cases a cancer can start in the adenoma.
[4] Atrial fibrillation is a type of irregular heart rhythm that causes poor blood flow to the body.
[5] Colonoscopy is a procedure in which a trained specialist uses a long, flexible, narrow tube with a light and tiny camera on one end, called a colonoscope or scope, to look inside the rectum and colon. Colonoscopy can show irritated and swollen tissue, ulcers, polyps, and cancer.
[6] Gastroenterology is a subspecialty of internal medicine. A gastroenterologist is a physician who specialises in diseases of the digestive system/gastrointestinal tract.
[7] An endoscopist is a doctor trained in the use of an endoscope (a long, flexible, narrow tube with a light and tiny camera on one end).
[8] An endoscopy is a procedure in which a doctor (endoscopist) uses specialised instruments to view and operate on the internal organs and vessels of the body. It allows surgeons to view problems within the body without making large incisions.

### 2014 GP referral

18. On 29 October 2014, general practitioner (GP) Dr I referred Mrs A to Dr B for a screening colonoscopy. In her referral letter, Dr I stated that Mrs A was asymptomatic but did have a history of adenomatous polyps and a family history of colorectal cancer. Dr I also noted that Mrs A had been putting off getting a colonoscopy because of a previous "unpleasant experience".[9] Dr I recorded Mrs A's allergies as follows:

> "ALLERGIES:
> 05 Mar 2012 aspirin — stomach upset
> 06 May 2009 midazolam[10] and fentanyl[11]"

19. Dr I's letter was addressed to Dr B's rooms.

20. Dr I also supplied Dr B with a letter and endoscopy report dated 8 February 2011 from general surgeon Dr J, which detailed the findings of the colonoscopy he performed (on the same day), and a pathology report dated 11 February 2011.

21. In his letter, Dr J stated:

> "I would strongly recommend, in view of [Mrs A's] family history and the polyp found today, that [she] undergo a surveillance colonoscopy in three years time rather than five years and once again it would appear that she is allergic to a number of the sedatives and a general anaesthetic is advised."

22. On the endoscopy report, Dr J circled "sedation" under the anaesthesia heading of the report.

### Receipt and transfer of referral to the clinic

23. Dr B explained that in 2014, it was "routine practice" for administrative staff at his rooms to redirect any GP referrals to either the clinic or another local endoscopy unit. Dr B told HDC that he did not review Mrs A's referral personally prior to it being forwarded to the clinic. Dr B further explained:

> "[Mrs A's] referral was [classed as] an open access referral. That is, a direct referral for endoscopy without an expectation for formal consultation prior to the day of the endoscopy procedure. The majority of patients referred for endoscopy fit into this category and the usual process is to obtain details of any pertinent issues via the Patient Information Sheet … and the doctor with whom the patient is booked would be contacted prior to the procedure if any issues were identified regarding allergies or if they were on anticoagulants etc."

[9] Mrs A told HDC that she was referred to a specialist in the main centre because she had had a bad experience during a colonoscopy in her home town, where she had a shaking fit as a result of the drugs administered to her.
[10] Midazolam is a benzodiazepine (class of psychoactive drugs). It works in the central nervous system (brain) to cause sleepiness, muscle relaxation, and short-term memory loss, and to reduce anxiety. It is commonly used to produce sedation before a medical procedure or surgery.
[11] Fentanyl is an opioid medication analgesic that is similar to morphine and typically is used to treat patients with severe pain or to manage pain after surgery.

24. Mrs A's referral was forwarded directly to the clinic on 29 October 2014.

25. The clinic's Hospital Manager, RN D, told HDC that once a referral is received by the clinic, the patient is added to an endoscopist's patient list. If the referring specialist is also going to perform the procedure, then the patient is added to the specialist's list. Dr B referred Mrs A to the clinic, and then Mrs A was added to Dr B's list at the clinic.

26. Once a patient has been added to an endoscopist's list, the patient is contacted by the administrative team to arrange a booking.[12] On 29 October 2014, a member of the administrative team contacted Mrs A and posted her patient instructions.

27. On 30 October 2014, a member of the clinic's administrative team completed an "Anti-coagulant instructions" form and recorded that Mrs A was on clopidogrel. That staff member also documented: "GP advised [to] stop x2 days prior + restart x2 days post procedure." It was also documented that Mrs A was advised of these instructions.

28. On 27 November 2014, Mrs A was sent an email from the administrative staff informing her that she was to have a colonoscopy with Dr B at 1.20pm on 2 December 2014. The email also contained a link to an online form, and instructed Mrs A to click the link, complete the form, and submit it to the clinic three days before her appointment.[13]

29. Mrs A completed the online form on the same day (ie, 27 November 2014). Under the "Allergies/Known Sensitivities" section of the form, Mrs A recorded: "Yes midazolam, fentanyl, digoxin, flecainide."

30. With respect to how this online form is processed, RN D told HDC that it is received into an email inbox and printed out by a member of the administrative staff, and then filed in an appropriate folder. Three days before the procedure the administrative staff start "data entry", and a patient's file is made up the day before the patient's procedure. A registered nurse also reviews the patient's file the day before the procedure.

31. The booking protocol in force at the time of these events (detailed below) stated that on the day prior to a procedure, all patient charts were to be checked by a senior nurse, who would confirm that patient details were correct and that pre-existing conditions were noted on the endoscopist's list schedule. The nurses responsible for checking the charts were required to initial the top right-hand corner of the list.

32. The clinic told HDC that it is "confident" that Mrs A's file would have been checked by a nurse on the day before the procedure, "in line with its requirements of staff".

[12] RN D also advised that referring specialists who work for the clinic also have the ability to make bookings at the clinic "from their end" (ie, without having to make a booking through the administrative team).

[13] The email also contained pre-procedure instructions, payment information, and a brochure which provided information on what to expect when receiving a colonoscopy, and the risks of the procedure. A separate email was sent containing a prescription for medications to take before the procedure.

However, it is unable to locate the endoscopist's list or identify the nurse who conducted the check on the day prior to Mrs A's procedure.

33. Dr B stated that it was his understanding that the endoscopist would be contacted by staff at the clinic prior to the procedure if any issues such as allergies, or if the patient was on anticoagulants, were identified on the patient information sheet. Dr B told HDC that he did not have access to the online patient information sheet that Mrs A completed on 27 November 2014. He also said that he was notified of Mrs A's allergies/sensitivities on the day of the procedure.

34. With respect to Mrs A's use of clopidogrel, Dr B stated that in 2014 he would not have been informed routinely that Mrs A was on clopidogrel, and "cannot recall with any certainty" whether he was notified of this fact prior to the day of the procedure.

35. The clinic told HDC that there is no record of its staff having notified Dr B of Mrs A's sensitivities to midazolam and fentanyl, or that she was on clopidogrel, prior to the day of the procedure.

36. Dr C, an endoscopist, told HDC: "[W]hile all patients go through our standard booking in and admission procedures those referred from individual practices are expected to have already gone through an assessment process by individual specialists." RN D told HDC that once the online form has been completed and put into the patient's notes, those notes "are available to the clinic staff and the endoscopists".

**The colonoscopy process at the clinic**

37. RN D explained that patients receiving a colonoscopy at the clinic present to the reception desk and are directed to the waiting room area. Adjacent to the waiting room are two smaller rooms, where a registered nurse takes the patient. The registered nurse then goes through a pre-procedure assessment form (called the "the pink" because of its colour) with the patient. The form contains a section that requests details about "allergies and known sensitivities". The registered nurse also goes through the patient's medical history and discusses the risks of the procedure and "what to expect from start to finish". The patient is then given an opportunity to ask any questions.

38. Once this process has been completed, the patient is transferred to a large room called "recovery". The recovery room is divided into a pre-procedure section and a post-procedure section. With respect to where the doctor completes the consent process, RN D stated that the doctor would not see the patient in the admission rooms, but would "possibly" see the patient in the recovery room. She further explained:

> "If an issue comes up that requires discussion, it is flagged to the procedure room staff by the admitting nurse. If it needs further discussion with the endoscopist, they often come to the pre-procedure area of recovery to discuss with the patient. They may or may not be accompanied by a nurse."

39. RN D confirmed with HDC that if the doctor did not see the patient in the recovery section of the room, the doctor would complete the consent process in the procedure room where the colonoscopy is conducted.

40. Dr C told HDC that doctors performing procedures would go through the patient's paperwork on the day of the procedure, unless the patient had been referred from that doctor's own private practice. Once the doctor had reviewed the relevant paperwork, the doctor would then talk with the patient and obtain consent. Dr C further explained:

> "When a patient comes into the [procedure] room, the doctor talks to them again and ensures that they are who they are and this is the procedure that they are expecting and get a history of their complaint and why they are there and that is a good chance for the patient to ask questions and talk about the wide ranging questions about their symptoms and conditions or the procedure and what to expect, and it is a very open discussion and if there are any concerns, like a drug concern it is very much discussed at that time, and options discussed."

41. Once the procedure has been completed, the patient is then transferred back to the post-procedure area of the recovery room. After the patient has recovered sufficiently from the sedation administered during the procedure, the patient is walked through to a separate room called "stage two recovery". Following an appropriate period of time, the doctor who performed the procedure then takes the patient into a side room, where the doctor discusses the findings. The patient is then discharged from the clinic's care.

**Events of 2 December 2014**

42. On 2 December 2014, Mrs A travelled with her husband to the main centre from her home. She presented to the reception area of the clinic with her husband, who left before any of the paperwork regarding her procedure was started.

*Consent process*

43. Mrs A was taken from the reception area to the patient waiting room. Mrs A told HDC that once she was in the patient waiting room, a nurse started asking her questions and filling in a form on a clipboard while other patients were present.

44. The clinic supplied HDC with a pre-procedure assessment form and a consent form, both of which had been completed by RN E. On the pre-procedure assessment form, RN E recorded Mrs A's arrival time as being "13.10/13.15". RN E also documented Mrs A's bowel preparation, patient history, and current medications. Next to the "allergies/known sensitivities" check box, RN E recorded a number of medications, including midazolam and fentanyl.[14]

45. A consent form entitled "Request for procedure", dated 2 December 2014, was also completed and signed by Mrs A, RN E, and Dr B. A drug reaction sticker was affixed

[14] The other medications RN E recorded were metoprolol, sotalol, asprin, digoxin, and flecainide.

directly below the signature section of the consent form, with midazolam and fentanyl handwritten onto the sticker.[15]

*Mrs A's recollection of the consent process*

46. With respect to the consent process, Mrs A stated:

> "I … took copies of my [medical] notes to give to the nurse for my procedure on 2 December 2014. I was interviewed by a nurse when I arrived and we went through all the questions etc. again. I asked what sedation was to be used on account of my previous experience with midazolam and fentanyl. The nurse stated she didn't know. I told her that I needed something, it was important. I was not heeded. I asked her if she wanted to read the reports that I had brought with me; she stated that I would see the doctor before the procedure. I didn't see him before going to theatre and no one seemed to be interested in looking at my notes."

47. Mrs A told HDC that she remembered signing some papers in the patient waiting room but did not specifically remember signing a consent form. Mrs A stated that she consented to the procedure "but did not consent to the use of the medication I advised I was sensitive to". Mrs A also said that she was not given an opportunity to ask questions about the drugs which were to be administered and did not understand she had consented to the use of midazolam and fentanyl. Mrs A stated that she was then taken to the pre-procedure section of the recovery room, where she got changed into a gown, and two nurses came and pushed her bed into the procedure room. Mrs A stated that when the two nurses came to get her in the pre-procedure area:

> "I was getting a bit worried now because I didn't talk to the doctor and I thought that was very important and I was worried about nobody reading my notes but I tried to calm myself by saying well the doctor has sent this all through and they should know."

48. Mrs A said that she asked the two nurses who wheeled her into the procedure room "what was going to be done for me by way of anaesthetic", and remembers the nurses telling her that they did not know. Mrs A further stated:

> "When I got into the procedure room there was a group of chaps at the end of the room, must have been three or four and I thought, 'Oh well that must be the anaesthetist hopefully' and then I said to [Dr B] 'Are you going to read my notes?' but he was already getting ready and doing everything and he said 'Oh we haven't got an anaesthetist on today'. So he began and put a thing on the inside of my right arm."

49. Mrs A told HDC that she does not remember any check-in process occurring before the procedure. She stated that Dr B "was in such a hurry and [the procedure] happened so quickly, but I don't remember anything like [a check-in process]

[15] RN E also wrote the following drugs on the drug reaction sticker: metoprolol, sotalol, aspirin, digoxin, and flecainide.

happened". Mrs A subsequently told HDC that her sensitivities were not discussed during the "sign-in" period.

*RN E's recollection of the consent process*

50. RN E told HDC that she cannot recall every detail about the consent process she conducted with Mrs A on 2 December 2014, but remembers that Mrs A's reported sensitivity/allergy to midazolam and fentanyl stood out to her as being unusual. RN E further stated:

> "In [Mrs A's] case, her sensitivity to midazolam and fentanyl were significant, and I told her that the doctor performing the procedure would discuss the issue of her sensitivities with her as those were the usual medications that were used for sedation during the procedure."

51. RN E told HDC that she was unable to recall "in any detail" what happened after she had spoken with Mrs A in the side room, including any discussions with Dr B or other staff at the clinic. However, she said that she would not have signed the form or let Mrs A sign the form if she had felt that Mrs A had not provided informed consent for the procedure.

*RN F's recollection of the consent process*

52. RN F was one of the nurses who assisted Dr B with the colonoscopy (more details below). RN F stated that before Mrs A came into the procedure room, there was a discussion with RN G, Dr B, and herself about Mrs A's sensitivities to midazolam and fentanyl, which had been recorded by RN E. RN F further commented:

> "During this discussion, it was decided that [Dr B] would commence the colonoscopy without sedation in the first instance. Only if sedation was required, would there be any sedative used. I recall that following this discussion [Dr B] went out to see [Mrs A] and make sure that she was fully informed."

53. RN F also noted that Mrs A's sensitivities were recorded on a sticker attached above where she ticked the sign-in box on the procedure form. RN F stated that Mrs A's sensitivities to midazolam and fentanyl would have been discussed during the "sign in" process,[16] for which Mrs A would have been present.

*RN G and RN H's recollection of the consent process*

54. RN G assisted Dr B during the colonoscopy procedure, and was also training RN H at the time. RN G stated that she does not recall Mrs A's colonoscopy, but commented that the procedure "would have stood out had there been any issue around consent". Similarly, RN H stated that he could not remember Mrs A's procedure "at all".

*Dr B's recollection of the consent process*

55. With respect to the consent process, Dr B told HDC:

[16] RN F explained that the sign-in process is where the patient details are discussed, including whether the patient has any allergies or sensitivities.

> "In [Mrs A's] particular case, the admitting nurse informed me that she had a potential allergy to midazolam and fentanyl. I specifically spoke to [Mrs A] in the pre-procedure area to explore this potential allergy further with her. The admitting nurse was present during this discussion … After talking to [Mrs A] it was apparent that her stated adverse reaction to midazolam/fentanyl was not of an anaphylactic reaction such as rash or difficulty in breathing (that would preclude the use of midazolam and fentanyl) but rather that of her 'body shaking'. It was at that stage that we discussed how best to proceed and [Mrs A] agreed for me to initially try to perform her colonoscopy examination without sedative drugs but that if the examination became uncomfortable then we would cautiously administer small doses of midazolam/fentanyl as required.
>
> Whilst I can no longer recall exactly what was said to [Mrs A], in accordance with my normal practice in this situation I would have informed her that she would be closely monitored with respect to her level of pain and for any adverse effects to the sedation, if it was given, and that the colonoscopy examination would be aborted if any significant adverse event occurred or if I felt that [a] colonoscopy could not be performed safely. It was after this discussion that she consented and signed the [consent] form.
>
> I would not have proceeded with the examination had she not given her consent. Her consent was later confirmed in the endoscopy suite immediately prior to starting her colonoscopy examination during the 'sign-in' period."

56. Dr B told HDC that during the sign-in (also known as "timeout") period, Mrs A's identity, indication for a colonoscopy, relevant medical history, and her informed consent for the procedure were confirmed.

57. There is no record of any conversation between Dr B and Mrs A on the consent form, procedure record, or any other clinical documentation. However, as stated, Mrs A, Dr B, and RN E signed the consent form, and a drug reaction sticker with midazolam and fentanyl handwritten on it was affixed directly beneath the signature section of the form.

*General anaesthetic and reading of notes*

58. As stated, Mrs A told HDC that Dr B did not read her notes prior to the procedure. She also stated that she was always under the impression that a general anaesthetic was going to be arranged as discussed with her GP and Dr J. She told HDC that she was assuming that she would receive a general anaesthetic up until the point she was informed that there was no anaesthetist available.

59. Dr B told HDC: "[I]t is incorrect that I did not read [Mrs A's] notes prior to the procedure and that I did not speak with her before [the procedure occurred]." Dr B further stated:

> "On the day of the procedure the admitting nurse reviews the patient's medical history and medications and goes over the procedure again with the patient. The admitting nurse advised me that [Mrs A] may have had an adverse reaction to midazolam/fentanyl in the past. This was the first I became aware of her potential

> adverse reactions to these specific drugs. There was no suggestion that she had an 'allergic' i.e. anaphylactic reaction to either midazolam and/or fentanyl, indeed this would be extremely rare.
>
> …
>
> I did read the notes prior to seeing [Mrs A]. There was no mention in these notes of a previous adverse reaction to midazolam or fentanyl. I assumed that having had the bowel prep and travelled down from [her home town] that [Mrs A] would not want to return at a later date to have a general anaesthetic. In hindsight I should have also discussed this option."

60. Regarding why a general anaesthetic was not arranged, Dr B commented:

> "In [Dr J's] colonoscopy report dated 8 February 2011 he states that the procedure was under general anaesthesia and general anaesthesia was recommended for future colonoscopies although in his handwritten note anaesthesia was stated to have been with sedation … [Mrs A's] GP did not specifically request that [Mrs A's] procedure be undertaken under general anaesthesia nor to my knowledge did [Mrs A] request this. Her pre-operative queries were in relation to her 'drug allergies'. The presumption is that colonoscopies are undertaken under conscious sedation.
>
> This is documented in the clinic's [patient information sheet] together with [an instruction sheet regarding colonoscopy bowel preparation] sent out to patients once their appointment has been scheduled. [Mrs A] received this information in advance and I proceeded on this basis."

61. Dr C also stated that "despite there being no specific request for general anaesthesia in the referral, in hindsight [the clinic] could have picked up on the suggestion that this would have been [Mrs A's] preference and contacted her before she travelled from [her home town]". However, Dr C also told HDC that he disagreed that the clinic should have arranged a general anaesthetic for Mrs A, as it was not specifically requested by Mrs A, Dr I (GP), or Dr B's rooms, and also because the referral came through Dr B's rooms.

*Colonoscopy procedure*

62. The clinic provided HDC with a "procedure record" form (PRF), which had been completed by RN F and documented the steps taken during Mrs A's colonoscopy. RN F had ticked the box confirming that a "sign in" had occurred, and a sticker labelled "drug reaction" was affixed to the top left-hand corner of the PRF, with midazolam and fentanyl handwritten onto the sticker.

63. The colonoscopy is recorded as starting at 1.50pm and finishing at 2.20pm. Dr B is documented as being the endoscopist, RN F as the patient nurse, and RN H and RN G as the scope nurses. "N/A" is written under the visitors section of the form. As the patient nurse, RN F was responsible for monitoring Mrs A's vital signs and caring for her directly. As the scope nurse, RN G was responsible for assisting Dr B with the

scope during the procedure. At the time of these events, RN H was being trained as a scope nurse.

64. RN F recorded that the following drugs were administered during the procedure:

| Drug | Time | Dose | Route |
|---|---|---|---|
| Midazolam | 1.58pm | 1mg | IV |
| Fentanyl | 1.59pm | 100mcg | IV |
| Glucagon | 1.54pm[17] | 1mg | IV |
| NaCl 0.9%[18] | – | 4ml | IV |
| Fentanyl | 2.00pm | 50mcg | IV |
| Midazolam | 2.01pm | 1mg | IV |
| Midazolam | 2.02pm | 1mg | IV |
| Zofran | 2.02pm | 4mg | IV |

65. Under the comments section of the PRF, RN F contemporaneously recorded:

> "Changed to long paediatric scope during [the] procedure due to pain/diverticular. Very painful procedure despite using paediatric scope. Given midazolam and fentanyl despite ? Allergies. No reaction observed. Respirations satisfactory. No shaking observed."

*Mrs A's recollection of the colonoscopy procedure*

66. Mrs A told HDC that Dr B informed her that there was no anaesthetist, and that he attempted to insert a cannula into the inside of her right arm unsuccessfully before inserting it into her right hand. Mrs A said that she was not told what drugs were going to be administered to her, but was told "this is something to relax you".

67. Mrs A further stated:

> "[Dr B] did not read my notes prior to the procedure commencing. The remark made by [Dr B] as he began the procedure 'we'll know in a few seconds' became all too clear to me what he meant when the awful pain began. I didn't appreciate the joke.
>
> A relaxing hormone, glucagon, was given to me. This did nothing for the pain and when the procedure started I was shocked, nothing was done for me and I was in terrible pain which got worse and worse. I asked [Dr B] to stop when I

[17] Sequence of timing per medical records.
[18] NaCl stands for sodium chloride (salt).

> couldn't bear it anymore. Why didn't he stop? He took no notice of me and began giving me what was stated as one of my allergies! What gave him the right to give me medication without my consent? Where was the informed consent? It was fortunate that I didn't have a reaction to add to my distress.
>
> It is obvious that the procedure continued to be very painful as he continued to administer the medication and because of this the rest of the procedure is blurry which was convenient for the staff but bad for me. It was distressing and insulting to be 'shushed' by the nurses when in so much pain."

*Dr B's recollection of the colonoscopy procedure*

68. With respect to his recollection of the procedure, Dr B told HDC:

> "IV glucagon, an anti-spasmodic, was given immediately prior to the colonoscopy commencing. I started the procedure with the standard sized colonoscope, and when I got to the sigmoid colon [Mrs A] started experiencing pain. I noted that the lumen of the sigmoid colon was narrowed and angulated due to diverticular disease. I then stopped the procedure and removed the scope. I then inserted a narrower, paediatric colonoscope, while at the same time administering 25µg fentanyl followed by another 75µg fentanyl analgesia. This was followed by 1mg of midazolam. No adverse reaction occurred to either medication based on direct observation by myself, nursing staff and continuous pulse oximetry monitoring.
>
> [Mrs A] experienced mild to moderate pain during the passage of the scope up the bowel. Each time she experienced pain we stopped and gave more analgesia and sedation, waiting until her pain had settled before proceeding. Once the scope was able to advance beyond the diverticular disease in the sigmoid colon she was pain free. The total amount of medication given was midazolam 3mg and fentanyl 150µg.
>
> Although I was ultimately able to perform a complete colonoscopy examination, following the cautious administration of incremental dose of sedation/analgesic drugs together with switching the standard colonoscope for a narrower paediatric colonoscope to facilitate passage through a narrowed sigmoid colon resulting from moderately severe diverticular disease, I fully acknowledge that [Mrs A] was very uncomfortable at times during the examination until appropriate sedation/analgesia was administered. [Mrs A] had no adverse reaction to either the midazolam or fentanyl administered."

69. Dr B stated that Mrs A was informed of the medication that would be given. He does not recall the nurses "shushing" Mrs A during the procedure in response to her reports of pain.

70. Dr B told HDC that he does not recall Mrs A asking him to abort the procedure, and that had she done so he would have recorded it in the colonoscopy report. He also said that he would never joke about a patient's pain and whether analgesia would work or not. Dr B stated: "I would like to unreservedly apologise for any behaviour or attitude that caused offence to [Mrs A]."

*RN F's recollection of the colonoscopy procedure*

71. RN F told HDC that she does not recall Mrs A's colonoscopy in any detail, as she is involved in so many procedures and "[Mrs A's] colonoscopy did not stand out in any way". With respect to the notes she recorded on the PRF, RN F stated that it was not unusual to describe colonoscopy procedures as being "very painful".

72. RN F further stated that her record, "[G]iven midazolam and fentanyl despite ?allergies. No reaction observed. Respiration satisfactory. No shaking observed," reinforced to her that there was a discussion about Mrs A's recorded sensitivity to midazolam and fentanyl before these medications were administered. With respect to Mrs A's statement that she was "shushed" during the procedure, RN F stated: "I have never said that to a patient, and never will. That allegation is totally incorrect."

*RN G and RN H's recollection of the colonoscopy procedure*

73. RN G stated that she does not recall the events of Mrs A's procedure, but said that she would "speak up" if she witnessed a patient being administered a medication without consent, and would refuse to take part in the procedure. RN G stated that if Mrs A had been "shushed" during the procedure it would have stood out to her, and "I would have taken issue with it". RN G also stated that "it would be totally out of character" for Dr B to make a joke during a colonoscopy procedure.

74. RN H told HDC that he cannot recall Mrs A's colonoscopy "at all". He stated that had he been aware that a patient was being administered medication to which the patient had not consented, that would have prompted him "to raise a concern".

*Post-procedure events*

75. At 2.22pm, Mrs A was transferred to the post-procedure section of the recovery room. It is documented that Mrs A was awake and was experiencing "a bit" of discomfort in her abdomen. At 3.25pm, Mrs A was transferred to the second stage recovery room, and the "seen by endoscopist" box on the discharge form was ticked. At 3.45pm, Mrs A was recorded as leaving the clinic with her husband.

76. With respect to her time in recovery, Mrs A told HDC that she was angry that she had been given drugs she had specifically asked not to have, and that Dr B did not stop the procedure when she asked him to. She stated that Dr B was very reluctant to speak with her. Mrs A stated that when Dr B did speak with her, he told her that she had "a distorted memory of the procedure".

77. Dr B told HDC that he apologised immediately after the procedure with respect to the pain that Mrs A experienced, and again in a letter to Mrs A (more details below). Dr B further commented:

> "I do not recall telling [Mrs A] that she 'had a distorted memory of the procedure'. It is worth noting however that midazolam can certainly cause both retrograde and antegrade amnesia even though the patient is awake."

*Dr B's colonoscopy report and letter to Mrs A*

78. On 2 December 2014 (the same day as the procedure) Dr B wrote to Mrs A's GP, Dr I, and stated:

> "[Mrs A] was said to be allergic to various medications including midazolam and fentanyl which caused uncontrollable shaking. General anaesthesia had not been arranged and attempt was initially made to undertake the procedure with no sedation but with IV glucagon but this was not tolerated due to moderately severe sigmoid diverticular disease with a relatively narrowed sigmoid colon.
>
> …
>
> The patient will not require repeat colonoscopy until at least five years. If she requires a repeat colonoscopy, propofol based sedation would be required. She did not appear to have any significant reaction to the midazolam or fentanyl on this occasion so I think these can be safely used in the future."

79. On 4 December 2014, Dr B wrote to Mrs A regarding the colonoscopy, and apologised for a "difficult and very uncomfortable procedure". He explained to Mrs A that her discomfort was "partly because we were uncertain as to exactly what drugs we could give you as you had stated you had reactions to both midazolam and fentanyl in the past".

*Subsequent events*

80. On 11 December 2014, Mrs A wrote a letter of complaint to the clinic.[19] Upon receipt of the complaint, and following a telephone call with Mrs A, RN D wrote to Mrs A on 23 December 2014, stating:

> "I agree that your concerns re the sedation should have been noted prior to admission and potentially a deeper sedation/anaesthetic considered. In retrospect we have discussed that you would have preferred to have been cancelled and rebooked on another day with an anaesthetist despite you having completed the bowel preparation and having travelled [some distance]."

81. RN D further stated that she had raised Mrs A's concerns directly with Dr B, and that her case would be discussed with other specialists at the clinic at their next meeting. RN D also apologised to Mrs A and said that the way the clinic reviewed referrals would be assessed "to ensure this doesn't happen again".

82. RN D told HDC that the clinical meeting referred to in her letter occurs twice annually. She stated that she was unable to make the March 2015 meeting, and that Dr B was unable to make the September 2015 meeting. Mrs A's complaint was discussed at the next clinical meeting on 28 April 2016. The minutes of that meeting state:

> "Colon referral — previous polyp with propofol. Was a specialist referral on [Dr B's list]. [Mrs A] arrived prepped from [home]. 'Allergies' to fentanyl and midazolam (shaking). Following discussion between [Dr B] and patient — colon without sedation … In hindsight could have arranged anaesthetist or rescheduled. [Mrs A] had not requested propofol on referral. Discussion that what had been done was very reasonable. Anaesthetists commented extremely rare to have true

[19] Relevant aspects of Mrs A's complaint letter have been incorporated into the factual account detailed in this report.

allergy to fentanyl and midazolam. This patient was clearly not allergic and had these drugs without reaction."

83. With respect to the timeliness of this meeting, Dr C acknowledged that "a special meeting could have been convened to discuss [Mrs A] specifically".

*The clinic's Informed Consent Policy*

84. The clinic's Informed Consent Policy at the time of these events stated:

> "All patients shall have an adequate explanation of the procedure by registered nursing staff/Endoscopist/specialist to enable informed consent. Explanation will include benefits, risks and expected outcome of the procedure. Patients will receive an explanation of the sedative used. The Endoscopist will take final responsibility for patient consent.
>
> Discussion will include sedation to be used during the procedure. If patient requests no sedation, this must be documented and discussed further with the Endoscopist/specialist.
>
> The patient will sign a request for procedure form prior to the procedure (during the admission).
>
> …
>
> Opportunity is provided for questions between patient and specialist before commencing administration of sedative and procedure.
>
> The request for procedure form will be signed by the Endoscopist/specialist performing the procedure."

*The clinic's Booking Protocol*

85. The clinic's Booking Protocol at the time of these events stated:

> "*Pre-admission patient information*
>
> After identification of patient and procedure, required patient information can be collected either by: [the] patient completing the patient particulars form at the clinic, posting in [the] form, faxing or by phone whichever is appropriate and acceptable to the patient.
>
> Medical history and current medications will be clearly identified at the time of the booking as this may affect admission time, date and preparation instructions.
>
> …
>
> *Preparation instructions*
>
> Appropriate preparation instructions, including [a] brochure, will be given to the patient by the clinic staff, or specialists.

> Any problems that may arise with preparation or preparation instructions will be directed to the appropriate person ([the clinic's] administration and/or nursing staff or specialists) depending upon the problem.
>
> …
>
> *Pre-admission*
>
> All patient charts are checked [the] day prior to [the] procedure by senior nursing staff. Correct patient details are confirmed. Any pre-existing conditions are noted on list schedule. Nurses responsible for checking charts are to initial top right corner of list."

*Further information from the clinic*

86. Dr C told HDC that the "vast majority" of the endoscopies performed at the clinic every year are performed using midazolam and fentanyl sedation. The remainder are performed without sedation, and approximately 1% of procedures are performed under general anaesthesia by an anaesthetist using propofol. Dr C further stated:

> "My staff, [Dr B] and, indeed, I are distressed by the fact that [Mrs A] has had such a negative experience and I apologise unreservedly on the part of the clinic for this. I believe there was a series of events leading to this poor experience and in retrospect and knowing [Mrs A's] negative experience, it would have been appropriate to send her away and re-book [Mrs A] for another day when an anaesthetist could be arranged."

87. With respect to changes to practice at the clinic, Dr C stated:

> "[We] have addressed the issue with both administration and nursing staff to increase vigilance for clues in referrals to suggest that general anaesthesia might be appropriate, [we] have reiterated to all specialists that we can certainly attempt to make urgent special arrangements such as general anaesthesia at short notice."

88. The clinic's "Blood Thinning Medication" protocol now states that where a patient is on clopidogrel, staff are to complete an antiplatelet agents form and provide this information to the relevant endoscopist for instructions.

89. Dr C also told HDC that patients who travel from outside the area are now contacted by telephone prior to their appointment, to identify any issues including whether they require a general anaesthetic. Dr C further stated that staff at the clinic have learned to "document any unusual discussions in case there is a dispute concerning the facts".

*Further information from Dr B*

90. Dr B told HDC that following these events he now reviews the referrals sent directly to him so that he can "identify potential problems including drug allergies, concurrent use of anticoagulant and antiplatelet agents, [the] possible need for propofol-based sedation or general anaesthesia and have them addressed prior to sending the referral to the appropriate endoscopy unit for actioning". Dr B also stated that he now documents more fully any discussions or actions that fall outside of routine practice, "particularly as it relates to consent issues". Lastly, Dr B noted that propofol-based

sedation, which requires anaesthetic assistance, is now used more routinely, and "thus we should be in a position to offer patients such as [Mrs A] access to a higher degree of sedation at short notice if required".

### Responses to provisional opinion

91. The parties were given an opportunity to comment on the relevant sections of the provisional report. These responses have been incorporated into the report where appropriate. Further responses have been outlined below.

*Mrs A*

92. Mrs A stated that she did everything possible to ensure that she was not given midazolam and fentanyl. She said that she felt ignored at many points during her visit, and that her allergies/sensitivities were not taken seriously. Mrs A also stated that she felt that the staff at the clinic and Dr B were under pressure to process patients quickly.

*Dr B*

93. Dr B stated that "at all times" he endeavoured to act with Mrs A's best interests in mind. Dr B told HDC that he was conscious that Mrs A would have to undergo further bowel preparation and travel from home again, if the procedure did not go ahead, and that these factors influenced his clinical decision-making. Dr B stated that, in retrospect, a better course of action would have been to reschedule Mrs A's procedure to another day, but he does not consider that the failure to do so represented a departure from the standard of care. Dr B also stated that he will ensure that he documents more fully any discussions or actions that fall outside of routine practice, "particularly as it relates to consent issues".

*The clinic*

94. Dr C responded on behalf of the clinic that propofol sedation (general anaesthetic) was never formally requested by Mrs A, Dr I, or Dr B. Dr C considers that the finding that the clinic breached the Code is "harsh". He also noted that Mrs A is not allergic to midazolam and fentanyl, and stated that it is important that Mrs A's surveillance colonoscopies continue.

## Opinion: Dr B

### Management of Mrs A's referral

95. GP Dr I's referral letter to Dr B stated that Mrs A was allergic to midazolam and fentanyl. A letter from Dr J, a surgeon who had performed a colonoscopy on Mrs A previously, was also attached, and stated that Mrs A was allergic to a number of sedatives, and that "a general anaesthetic is advised".

96. On 29 October 2014, Mrs A's referral was forwarded directly to the clinic. Dr B told HDC that he did not review Mrs A's referral personally before it was sent to the clinic.

97. Dr B stated that "the usual" process following the forwarding of a referral to the clinic was for the patient to complete a patient information form and, if there were any issues identified regarding allergies, he would be contacted prior to the day of the procedure. Dr B said that he was notified of Mrs A's allergies/sensitivities to midazolam and fentanyl, and the fact that she was on clopidogrel, on the day of the procedure.

98. Dr C stated that patients referred from individual specialists are expected to have been assessed by individual specialists prior to the referral. The clinic stated that there is no record of its staff having notified Dr B of Mrs A's sensitivities to midazolam or fentanyl, or that she was on clopidogrel, prior to the day of her procedure.

99. The clinic's booking protocol in place at the time of these events stated that "any problems that may arise with preparation or preparation instructions will be directed to the appropriate person", which included the administrator, nursing staff, or the relevant specialist. The protocol also stated that a patient's medical history and current medications were to be clearly identified at the time of the booking, "as this may affect admission time, date and preparation instructions".

100. My expert advisor, consultant gastroenterologist Dr Richard Stein, advised me that it is reasonable for a doctor working in a large endoscopy unit in New Zealand to expect to be contacted regarding a patient's allergies or if the patient is on anticoagulants, if the doctor considers that the endoscopy unit has a robust system in place to identify such issues. Dr Stein stated that in light of the clinic's booking protocol, it was reasonable for Dr B to expect to be notified by staff at the clinic of Mrs A's history of reactions to fentanyl and midazolam, as well as her use of clopidogrel, in advance of the procedure. I accept Dr Stein's advice.

101. In light of the clinic's booking protocol, I am not critical that Dr B did not review Mrs A's referral documentation before forwarding it to the clinic. However, I consider that this was a missed opportunity to identify Mrs A's stated allergies and current medication, and to discuss sedation and medication management options with her prior to the day of the procedure.

102. I note that Dr B has advised that he now takes care to review referrals sent directly to him to identify any issues, before they are forwarded to endoscopy units such as the clinic. I consider that this change to Dr B's practice is appropriate.

**Informed consent**

103. RN E was involved in the first stage of consenting Mrs A for the colonoscopy procedure, and completed a pre-procedure form and a consent form. Next to the "allergies/known sensitivities" on the pre-procedure form, she wrote "midazolam and fentanyl". The consent form was signed by Mrs A, RN E, and Dr B. A drug reaction sticker was affixed directly below the signature section of the form, with "midazolam and fentanyl" handwritten onto the sticker.

104. Mrs A told HDC that during her discussion with RN E, "I asked what sedation was to be used on account of my previous experience with midazolam and fentanyl." Mrs A remembers that RN E told her that she did not know, but that Mrs A would see Dr B

before her procedure. Mrs A stated that she did not see Dr B before going to the procedure room. RN E was unable to recall what happened after she spoke with Mrs A, including any discussions with Dr B or other staff at the clinic.

105. Mrs A told HDC that in the pre-procedure area of the recovery room, she asked the nurses wheeling her into the procedure room "what was going to be done for me by way of anaesthetic". Mrs A remembers that the nurses told her that they didn't know. Mrs A stated that she recalls Dr B telling her once she was in the procedure room that they did not have an anaesthetist on that day, and that he started the procedure by putting "a thing on the side of my right arm". Mrs A said that Dr B was in a hurry, and that she did not remember a "check in process" occurring before the commencement of the procedure.

106. Dr B told HDC that RN E informed him that Mrs A had a potential allergy to midazolam and fentanyl, and that he "specifically spoke to [Mrs A] in the pre-procedure area to explore this potential allergy further with her". Dr B stated that after talking with Mrs A it was apparent to him that she did not have an anaphylactic reaction to the drugs.

107. Dr B remembers discussing with Mrs A "how best to proceed", and that she agreed to start the colonoscopy examination initially without sedative drugs, but that if the examination became uncomfortable then small doses of midazolam and fentanyl would be administered. Dr B said that Mrs A then consented to the procedure. Dr B said that during the "sign-in" period, Mrs A's informed consent for the procedure was confirmed. Dr B also stated that he assumed that having had her bowel prepared for the procedure, and having travelled some distance, Mrs A would not want to return at a later date to have a general anaesthetic. However, Dr B said that "in hindsight [he] should have discussed this option".

108. RN F told HDC that she remembers that Dr B, RN G and herself had a conversation regarding Mrs A's stated sensitivities, which had been highlighted on the file by RN E. RN F remembers that Dr B made a plan to commence the procedure without sedation in the first instance, and that he left the procedure room to discuss his plan with Mrs A.

109. Upon review of the evidence presented to me, I accept that Mrs A and Dr B had a conversation regarding sedation. However, given the conflicting recollections, I am unable to make a finding as to the precise content of this discussion, or where it occurred.

110. Dr Stein advised me that Dr B's plan to commence the procedure was clinically reasonable, but that Mrs A should have been given the option of returning at a later date in order to allow for a general anaesthetic, and the failure to offer her this option represented a mild departure from the standard of care.

111. I note that Dr B acknowledges that he did not discuss with Mrs A the option of rescheduling her procedure in order to allow a general anaesthetic. I also note that Dr B does not consider that the failure to do so represents a departure from the standard of care. I accept Dr Stein's advice.

112. Dr Stein also advised me that Dr B met the standard of care for documentation in relation to the informed consent process. I note that Dr B told HDC that he now documents more fully any discussions or actions that fall outside routine practice, particularly where they relate to consent issues. I consider this change to Dr B's practice to be appropriate.

### Events during and after the procedure

113. As outlined above, there is conflicting evidence about various matters. Mrs A stated that Dr B did not read her notes prior to the procedure commencing, and made a joke regarding whether she would experience pain during the procedure. Mrs A further stated that when she experienced pain, she asked Dr B to stop the procedure. She said that after the procedure, Dr B told her that she had a distorted memory of events.

114. RN G, RN H, and RN F stated that they do not recall Mrs A's procedure. Dr B told HDC that he does not recall Mrs A asking him to abort the procedure, and stated that he would never joke about a patient's pain or whether analgesia would work or not. He also stated that he did read Mrs A's notes prior to the procedure. Dr B said that he does not recall telling Mrs A that she had a distorted memory after the procedure.

115. Dr B stated that when Mrs A started to experience pain, he stopped the procedure and removed the standard sized scope and replaced it with a narrower paediatric scope, whilst also administering small doses of fentanyl and midazolam. He noted that Mrs A experienced no adverse reaction to either medication. Dr B stated that each time Mrs A experienced pain, he stopped the procedure and administered additional doses of fentanyl and midazolam, and waited until her pain had settled before proceeding.

116. Dr Stein advised me that the steps Dr B took during the procedure, including the administration of medications and the use of colonoscopes, did not depart from the standard of care. I accept this advice.

117. In light of the conflicting recollections of events I am unable to make a finding regarding whether Dr B read Mrs A's notes prior to the procedure, joked during the procedure, or failed to stop the procedure on Mrs A's request. I am also unable to make a finding as to what was discussed in the post-procedure meeting.

## Opinion: The clinic — breach

### Management of referral

118. I note that the clinic's booking protocol in place at the time of these events stated that "any problems that may arise with preparation or preparation instructions will be directed to the appropriate person", which included the administrator, nursing staff, or the relevant specialist. The protocol also stated that a patient's medical history and current medications were to be identified clearly at the time of the booking, "as this may affect admission time, date and preparation instructions".

119. The booking protocol also stated that on the day before a patient's procedure, all patient charts were to be checked by a senior nurse, who would confirm that the patient's details were correct and that pre-existing conditions were noted on the endoscopist's list schedule. The nurses responsible for checking the charts were required to initial the top right-hand corner of the list.

120. Dr B told HDC that his understanding was that if there were any issues identified regarding a patient's allergies, he would be contacted by the clinic prior to the day of the procedure. Dr C stated that while all patients go through the clinic's standard booking and admission process, patients referred from individual practices are expected to have already gone through an assessment process by individual specialists.

121. RN D stated that once the online patient form had been put into the patient's notes, it was available to the clinic staff, including the endoscopists. Dr B said that he did not have access to the patient information sheet Mrs A completed, and that he was notified of Mrs A's allergies/sensitivities, and the fact that she was on clopidogrel, on the day of the procedure.

122. The clinic also stated that it is "confident" that Mrs A's patient file would have been reviewed by a nurse on the day prior to her procedure. However, the clinic was unable to provide HDC with supporting documentation. The clinic also stated that there is no record of its staff having notified Dr B of Mrs A's sensitivities to midazolam and fentanyl, or that she was on clopidogrel, prior to the day of her procedure.

123. Dr C also stated that despite there being no specific request for general anaesthesia in the referral, in hindsight the clinic "could have picked up on the suggestion this would have been [Mrs A's] preference and contacted her before she travelled from [her home town]". However, Dr C also stated that he did not consider that the clinic should have arranged a general anaesthetic for Mrs A because it was not specifically requested by her GP or Dr B's rooms, and also because the referral came through Dr B's rooms.

124. Dr Stein noted that the clinic's booking protocol does not specify that patients referred from a specialist are to be treated differently from other patients who have been referred directly to the company. Dr Stein also advised me that in light of the clinic's booking protocol, it was reasonable for Dr B to expect to be notified by staff at the clinic of Mrs A's history of reactions to fentanyl and midazolam, as well as her use of clopidogrel, in advance of the procedure.

125. Dr Stein stated that Mrs A's medical history should have been reviewed by an experienced endoscopy nurse or doctor shortly after the time of booking, and commented that administrative staff did not have the training to evaluate a patient's medical history and current medications. With respect to the booking protocol's requirement that a nurse review the patient's chart the day before the procedure, Dr Stein stated that he would consider this to be a "final double check for potential problems that may have been overlooked in the booking process".

126. Dr Stein advised me that the clinic's failure to notify Dr B of Mrs A's prior adverse reactions to midazolam and fentanyl, and the fact that she was on clopidogrel, prior to the day of the procedure represented a moderate departure from the standard of care. With respect to Mrs A's use of clopidogrel, Dr Stein stated that an endoscopist needs to be made aware that a patient is on this medication, so that a decision can be made about whether or not it should be discontinued, and for how long.

127. Dr Stein recommended that the clinic consider having a nurse contact patients prior to their procedure to discuss the medications they are on and any concerns they may have, and to make sure they have a good understanding of what to expect. Dr Stein suggested expanding this telephone call to include all patients at the clinic, not just patients who are travelling from outside the area.

128. Upon review of the evidence provided to this Office, it is clear that there was a discrepancy between the expectations of Dr C and Dr B. Dr B expected to be notified of patient allergies prior to the day of the procedure. Dr C expected that patients would be assessed by the specialist prior to the referral being made. I also note that Dr B was unaware that he had access to Mrs A's online patient information form.

129. In light of the fact that the clinic's booking protocol stated that an appropriate person, including the specialist, would be notified of any problems that might arise with respect to preparation, I consider that it was reasonable for Dr B to expect that he would be notified of Mrs A's stated allergies. I note that Dr C advised HDC that the "vast majority" of procedures undertaken were performed using midazolam and fentanyl. I consider that any potential allergy to these medications was sufficiently unusual, and warranted escalation to Dr B.

130. I consider that the failure to follow the booking protocol and notify Dr B of these facts represented a missed opportunity for Dr B and Mrs A to have an informed discussion about sedation options prior to the day of her procedure. Accordingly, by failing to have in place adequate systems to ensure that Dr B was notified of salient aspects of Mrs A's medical history, as required by the booking protocol, I consider that the clinic did not provide services to Mrs A with reasonable care and skill, and breached Right 4(1) of the Code.

## Recommendations

131. I recommend that the clinic:

a) Use an anonymised version of this case for the wider education of its staff and the endoscopists who use its facilities. Topics should include informed consent, advocacy for the consumer, and when it would be appropriate to notify the endoscopist of salient aspects of a patient's history prior to the day of the procedure.

b) Review its current protocols and policies and:

i. Consider whether the review of the patient's medical history and booking information by a registered nurse should be done earlier than the day before the procedure, in order to allow sufficient time to arrange matters such as appropriate sedation options.

ii. Develop a protocol for the identification and escalation of patient allergies to senior nursing staff and the endoscopist.

iii. Develop a protocol that clearly outlines the steps endoscopists are expected to have performed prior to forwarding a referral on to the clinic. This protocol is to be distributed to all endoscopists who use the facilities at the clinic.

c) Provide education to endoscopists on how they can access their patient's information held by the clinic.

132. The clinic is to report back and supply evidence to HDC on the outcome of these recommendations within six months of the date of this report.

133. I recommend that the clinic provide a written apology to Mrs A for its breach 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.

## Follow-up actions

134. 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, the Royal Australasian College of Physicians, and the district health board. The Medical Council of New Zealand will be advised of Dr B's name.

135. 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 gastroenterology advice to the Commissioner

The following expert advice was obtained from gastroenterologist Dr Richard Stein:

## Report One

"I have been asked to provide an opinion to the Commissioner on case number 15/00043 and have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

I have reviewed all of the enclosed documents including:

[Mrs A's] letter of complaint to the HDC from [date]
Letter to [Mrs A] from the clinic from 23 December 2014
Letter from [Mrs A] to the clinic from 12 December 2014
Letter from [Dr B] to [Mrs A] from 4 December 2014
Letter from [Dr B] to [Dr I] dated 2 December 2014
Letter of Referral from [Dr I] to [Dr B] dated 29 October 2014
Letter from [RN D] to [Mrs A] dated 23 December 2014
Record of phone call to [Mrs A] by [HDC] 9 August 2016
Letter from [Dr C], [clinic director] to [HDC] 18 February 2015
[Dr J's] endoscopy report dated 8 February 2011
Letter from [RN D] to [HDC] dated 20 August 2015
Nursing records/procedure record from 2 December 2014
Consent form dated 2 December 2014
Anti-coagulant instructions dated 30 October 2014
Letter from [Dr C] to [HDC], dated 1 December 2015 *
Statement of [RN F] dated 26 November 2015 *
Statement of [RN G] dated 3 December 2015
Statement of [RN E] dated 1 December 2015*
Statement of [RN H] dated 26 November 2015
Letter from [RN D] to [HDC] dated 2 December 2015
Emails between [HDC] and [the clinic's lawyer] from August 2016
Minutes of the clinic specialists meeting 28 April 2016
Letter from [Dr B] to [HDC] dated 25 February 2015
Letter from [Dr B] to [HDC] dated 11 May 2015
Letter from [Dr B] to [HDC] dated 20 August 2015 *
Letter from [Dr B] to [HDC] dated 3 December 2015 *

I reviewed the background of the case that was provided by you and, after reviewing the above documents, I agree with what was reported in your letter of 9 May 2017.

I am a gastroenterologist who has been in practice since 1986. I have been living and practicing in NZ since 2007. I received my undergraduate degree from Columbia University in New York, my medical degree from the University of Illinois in Chicago, did my postgraduate training at University of Illinois Hospital (Internal Medicine) and Emory University in Atlanta (Gastroenterology Fellowship). I have academic appointments at Otago Medical School in Wellington (Lecturer) and at the

University of Washington in Seattle (Assistant Clinical Professor of Medicine). I have vocational registration in New Zealand, am a Fellow of the RACP, the American College of Gastroenterology, and the American Gastroenterological Association. I presently am a Consultant in Gastroenterology at Hutt Valley DHB (since 2010), and have a private practice at Boulcott Hospital and Specialty Centre in Lower Hutt. I also worked for eight years as a Consultant in Gastroenterology at Wairarapa DHB, two years as a visiting Consultant at Northlands DHB, and privately at Selena Sutherland Hospital in Masterton. I am the RACP representative to the NZ Conjoint Committee for Recognition of Training in GI Endoscopy and an active member of the quality committee at Hutt Hospital.

The following are my comments which were requested regarding the specific issues raised by you in your letter dated 9 May 2017.

1a. The appropriateness of [Dr B] reviewing [Mrs A's] medical notes on the day of the procedure.

[Mrs A's] referral from her GP was received 29 October 2014. [Mrs A] also gave information in advance of the procedure via an online questionnaire. There is documentation of 'allergies/sensitivities' to both midazolam and fentanyl as well as the fact that the patient was on clopidogrel. Both of these issues should have been brought to [Dr B's] attention prior to the date of the colonoscopy. There is mention that the GP 'advised stop (clopidogrel) 2 days prior and restart 2 days post procedure' on 30/10/14 (it is unclear who reviewed the information before the procedure. The anticoagulation instructions form was signed by '[…]', but it is unclear from the records if she is a nurse or the booking person). Stopping clopidogrel two days before the procedure is inadequate to reverse the effects of the medication.

It should be standard practice for a nurse to do a pre-assessment of the patient either face to face or by phone prior to the procedure date and bring any significant issues such as pertinent allergies or the use of anticoagulants to the doctor's attention in advance of the procedure date.

It was ultimately [Dr B's] responsibility to have knowledge of the patient's history beforehand, not that of the clinic. The initial referral of [Mrs A], including her list of medications and allergies, was sent to [Dr B's] office, not to the clinic. It was [Dr B's] staff who forwarded the referral to the clinic. He needs to have a system in place, either through his staff or the staff of the clinic to assure him that pertinent issues are addressed prior to meeting the patient on the day of their procedure. This represents a moderate departure from standard of care.

1b. Whether [Dr B] should have taken steps to arrange a general anaesthetic for [Mrs A] prior to her procedure on 2 December 2014 in light of [Dr J's] recommendation.

The decision whether to arrange a GA should have been made prior to the appointment date and after a full discussion with the patient. The outcome of that discussion would then determine whether to arrange to do the procedure under general anaesthesia or to proceed cautiously with fentanyl and midazolam. While the recommendation by [Dr J] should have been noted and taken into consideration, it would not dictate the final decision. That decision should have been made after a

discussion between the doctor and patient. It was a moderate departure from standard of care that this discussion did not happen prior to the procedure day.

1c. The appropriateness of [Dr B's] plan to proceed without sedation and trial small doses of midazolam and fentanyl if required in light of [Mrs A's] allergies.

[Dr B's] plan was very reasonable, assuming the patient had been informed of potentially having a similar reaction to the medications which she had in the past and informed of the expectation that the procedure would likely cause some discomfort if performed without sedation. The overwhelming majority of colonoscopies are performed with sedation and it is the expectation of both doctor and patient that sedation will be used. That being said, the procedure is, on rare occasion, attempted and usually successfully performed without sedation (in cases such as this where the patient may be intolerant to the medications, or in a situation where a patient specifically requests no sedation). However, these patients would be informed to expect some discomfort if no sedation was used.

[Mrs A] should have been given the option of returning at a later date in order to allow for a general anaesthetic if that was the decision after her discussion with [Dr B]. [Dr B] acknowledges that she should have been offered this option although he was concerned that the patient travelled a long distance for the procedure and had already undergone the vigorous pre-procedure prep. Under the circumstances, his plan to proceed with the procedure as per his plan showed no departure from standard of care. His failure not to offer her the option to return at a later date to have the procedure done under general anaesthesia represents a mild departure from standard of care.

1d. The Standard of [Dr B's] documentation in relation to the informed consent process.

[Dr B] met the standard of care for documentation in relation to the informed consent process. It is the practice at some centres, as apparently it is at the clinic, to have an experienced endoscopy nurse independently review the consent form with the patient, explain the risks, and answer the patient's questions. The nurse works under the supervision of the doctor and the doctor is immediately available if there are issues that are outside the nurse's expertise. It is the doctor who ultimately signs the consent and accepts responsibility that the process is complete. [Dr B] states that the nurse alerted him to the adverse reactions to midazolam and fentanyl, that he discussed this with [Mrs A] in the pre-procedure room and that they agreed on the aforementioned plan for cautious use of the medications if they were needed. While it would have been ideal if this discussion about medication was specifically documented, most doctors in this situation would not have specifically documented it. Hence there was no departure from standard of care.

The Medical Council of NZ describes informed consent as 'an interactive process between a doctor and patient' (statement from MCNZ 11 March 2011). In most centres in NZ the consent process is the sole responsibility of the doctor who personally goes over the procedure, the risks, and answers any questions that the patient may have in a face to face encounter before the procedure, in a setting outside the procedure room (where a patient may feel vulnerable or under duress). It can be

argued that if the doctors routinely were the ones who obtained consents at the clinic, the patient may have felt more at ease and there would not be two different versions on where the discussion about medication took place.

If the discussion about sedation, as [Mrs A] asserts, took place in the procedure room, where patients may feel vulnerable, rather than in the pre-procedure room, that would have been inappropriate and a moderate departure from the standard of care.

1e. The adequacy and appropriateness of the steps taken during the procedure, the administration of sedation, whether [Dr B] responded appropriately in light of [Mrs A's] pain.

There are no issues with the types of colonoscopes that were used. Procedures are usually begun and successfully completed with the regular adult colonoscope, even in patients with pre-existing diverticulosis. While the paediatric colonoscope is sometimes needed to manoeuvre through an area of severe diverticulosis, using the paediatric colonoscope can sometimes make a procedure more difficult as the scope is quite thin and floppy and has a tendency to form 'loops' that stretch the colon. This can sometimes result in more discomfort for the patient.

[Dr B] attempted to perform the procedure initially without sedation due to the patient's history of having adverse reactions to the drugs. Fentanyl and midazolam were given within seven minutes of the start of the procedure which is not a particularly long time, but, from the patient's perspective, seven minutes of pain can seem very long. The medications could have been given sooner, at the first indication that the procedure was going to be a difficult one, but these judgements are difficult to make retrospectively.

I do not see any issues with how [Dr B] handled the procedure and there was no departure from standard of care.

1 f. The steps taken following the procedure, including [Dr B's] letters to [Mrs A] on 2 and 4 December 2014.

I thought [Dr B's] letter to the patient was thoughtful and sincere. He apologised that the procedure was uncomfortable for the patient twice in the letter.

1g Any other relevant matters

While [Dr B] met the standard of care and used good judgement in terms of performing the procedure on 2 December 2014, there was a moderate departure from standard of care in that he was unaware of the patient's history of adverse reactions to pertinent medications as well as her use of clopidogrel before [Mrs A] arrived at the clinic. The initial referral of [Mrs A], including her list of medications and allergies, was sent to [Dr B], not to the clinic. He needs to have a system in place, either through his staff or the staff of the clinic, to assure him that pertinent issues are addressed prior to meeting the patient on the day of their procedure.

****In short, I do not think [Dr B] operated outside the standard of care in his decision to perform the procedure as he did. I think he managed the situation to achieve the safest and best outcome for the patient. He was concerned that she

travelled a considerable distance for the procedure and had already taken the pre-procedure prep. There was a moderate departure of standard of care in that he was unaware of the patient's pertinent medication history (adverse effects from fentanyl and midazolam and use of clopidogrel) prior to the patient's arrival at the clinic on the date of the procedure.

The patient, however, irrespective of the fact that she signed the consent form, clearly did not have a good understanding of the plan for sedation and contends that she met [Dr B] for the first time in the procedure room and it was there that medications were first discussed. If that was the case, it would represent a moderate departure from the standard of care. ****

2a. In light of [Dr J's] recommendation and [Mrs A's] stated allergies to midazolam and fentanyl, should the clinic have to taken steps to discuss or arrange for a general anaesthetic for [Mrs A] prior to her procedure on 2 December 2014?

Yes. These issues should have been discussed beforehand with [Dr B]. Management of her clopidogrel should also have been discussed. This represents a moderate departure from standard of care.

2b. The adequacy and appropriateness of the clinic's informed consent process

The consent process seems adequate. I would suggest, however, that the clinic consider having the doctor personally conduct the entire consent process for the procedure. This is the practice in most endoscopy centres in NZ. This would prevent similar situations where there is a breakdown in communication between the doctor and the patient. However, there was no departure from standard of care.

I did not see a policy on pre-assessing the patient prior to the procedure date and what issues are brought to the doctor's attention in advance of the procedure. If no such policy is in place, it should be written. If one is in place, I would suggest that allergies to fentanyl and midazolam be added as well as any anticoagulant therapy (excluding aspirin). Peri-operative management of anticoagulants should be by the endoscopist as it is usually outside the realm of expertise of the GP.

Failure to have a pre-procedure discussion (either by phone or in person) between staff and patient of pertinent issues such as medications, prior medical history, and patient expectations and concerns represents a moderate departure from standard of care. This is based on my experience in five endoscopy units, both private and public, throughout NZ.

2c. Any other relevant matter

I think the hospital manager, [RN D], did an excellent job communicating with [Mrs A]. She responded to her initial letter of complaint promptly. She apologised for her experience and validated many of her concerns. However, despite the fact that she told [Mrs A] that a review would occur in January of 2015, that review did not happen until April of 2016. Waiting fifteen months to formally address this complaint was too long. The group of doctors meets semi annually. The manager could not be present for the first meeting and [Dr B] was out of the country for the second meeting. There

should have been a special meeting held between key personnel and [Dr B] soon after the event, followed by a discussion of the recommendations from that meeting with [Mrs A].

More importantly, the root issues of the complaint were not addressed, including:

1. Problems with communication. Despite the fact that the plan for sedation was discussed with [Mrs A], she clearly did not have a good understanding of that plan before going into the procedure room.

2. The fact that the doctor was unaware of the patient's significant medication history prior to her arrival on the date of the procedure.

Patient complaints are an opportunity for improving processes and showing where systems break down.

My recommendations:

1) Have a system in place either through the doctors' offices or through the clinic to identify pertinent allergies, anticoagulant therapy, or any other significant issues that could impact performing a procedure prior to the procedure date. If there is a written policy regarding this, there should be an investigation as to why it did not occur in [Mrs A's] case in order to prevent it from happening again.

2) To communicate directly with patients (particularly those who live a long distance away) to review medications and concerns, and to make sure they have a good understanding of what to expect.

3) Once potential problems are identified, there needs to be a system to notify the doctor and determine a plan to manage these situations. The plan needs to be discussed with the patient prior to the procedure date.

4) To consider having the consent process done directly by the doctor, face to face with the patient, rather than by nursing personnel.

5) To consider documenting discussions that fall outside the scope of the standard consent form.

6) Asking the doctors to meet with the staff to discuss the issues above. While it can be argued that the patient had a successful outcome and the procedure was done safely, the procedure should be looked at from [Mrs A's] point of view. Her chart was not reviewed prior to the exam date, she reasonably expected to have the exam done under a GA, her procedure was painful, and her recollection of the consent is different from that of the staff."

**Report Two**

"I have read [Dr B's] reply to my opinion to the Commissioner regarding case number 15/00043 and will address the following questions in light of [Dr B's] reply as well as the additional documents supplied by the clinic, specifically their anticoagulation and booking/preparation protocols:

1a. The steps taken by [Dr B] prior to the day of the procedure (2 December 2014)

[Dr B] was unaware of the fact that both [Dr I], who was the referring doctor, and [Mrs A] had listed midazolam and fentanyl as allergies prior to the procedure. He states that it was his expectation that 'the doctor with whom the patient is booked would be contacted (by the clinic) prior to the procedure if any issues were identified regarding allergies or if they were on anticoagulants'. I would agree that this would be the usual expectation of a doctor working in a large endoscopy unit in New Zealand if he/she thought a robust system was in place to identify problems. After reviewing additional documents, I think this expectation by [Dr B] was reasonable. The clinic's protocol states that 'any problems that may arise with preparation or preparation instructions will be directed to the appropriate person', which they note includes the administrator, nursing staff or specialist.

The clinic's booking protocol also mandates that 'medical history and current medications will be clearly identified at the time of the booking as this may affect admission time, date, and preparation instructions'. Since it is acknowledged that this information could have important implications in planning the procedure, it would be expected or implied that there would be a review of the information, such as by an experienced endoscopy nurse who would alert the doctor of pertinent issues prior to the procedure date. In this case [Mrs A's] history of reactions to fentanyl and midazolam, medications routinely used in the unit, as well as her use of clopidogrel, would clearly fall into the category of items in the medical history that would need to be addressed prior to the procedure. As [Dr B] stated, it was a reasonable expectation for him to be notified of this in advance.

In light of this additional information supplied in the booking protocol, I do not think [Dr B's] handling of any aspects of [Mrs A's] care fell outside the standard of care. He reasonably thought there was a robust system in place to identify pertinent issues such as [Mrs A's] reactions to fentanyl and midazolam as well as her use of clopidogrel prior to the procedure. While best practice would have dictated [Dr B's] review of the referral prior to forwarding it to the clinic and addressing these issues beforehand, many gastroenterologists would have simply forwarded the referral to the endoscopy unit, relying on the endoscopy unit's protocols to identify these issues and bring them to the endoscopist's attention prior to the date of the procedure.

In his letter [Dr B] notes that he has taken additional steps to avoid a similar situation by personally reviewing all referrals that come to his office, prior to forwarding them to the clinic. He also reiterated to the booking staff the importance of being notified of issues such as pertinent drug reactions and use of anti-platelet agents.

1b. [Dr B's] comments regarding the cessation and recommendation of clopidogrel prior to, and after, [Mrs A's] colonoscopy procedure.

My only point in raising the issue of clopidogrel was that [Dr B] should have been aware that [Mrs A] was on clopidogrel prior to the procedure, not whether it should have been discontinued or for how long. These decisions are made by the endoscopist, but they are decisions that need to be made prior to the procedure. For instance, if there was the expectation that a large polyp might be identified, few doctors would choose to continue clopidogrel unless the clinical situation mandated its continuation. As an aside, most endoscopists adhere to the American (ASGE) and European (ESGE) guidelines of withholding clopidogrel for at least five days for high risk procedures as most evidence shows that the anti-thrombotic effects take 5–7 days to

wear off once it is discontinued. I note that [Dr C], in his response letter, states that the clinic has a recently adopted a protocol 'consistent' with the current European guidelines.

1c. [Dr B's] comments regarding the informed consent process.

[Dr B] disagrees with my statement that 'in most centres in NZ the consent process is the sole responsibility of the doctor'. I disagree with his contention. The endoscopist obtains his own consent [in the hospitals where he works]. Of the nine DHBs with whom I checked [around NZ], only [one] has nurses obtaining consents for colonoscopy. The matter, however, is moot, since I did not state that a nurse-led consent was outside the standard of care.

However, I want to reiterate that the Medical Council of NZ in their statement on informed consent states that it is 'an interactive process between a doctor and patient'.

My suggestion to have the doctor obtain the consent was only a recommendation to avoid a breakdown in communication between the patient and the doctor performing the procedure. While it can be argued that a good nurse-led consent process has advantages, I think few people would argue that it is superior to a good consent process personally conducted by the doctor who will be doing the procedure.

1d. I think [Dr B's] changes to his practice are thoughtful and will likely prevent a similar situation in the future.

He notes that it is now his policy to have all referrals reviewed by the doctor prior to them being forwarded to the clinic. He also reiterated to the booking staff at the clinic that the Endoscopist needs to be notified of any pertinent issues such as medication reactions prior to the procedure date.

In short, in light of viewing the clinic's protocols, I think all of [Dr B's] actions were within the standard of care as it was reasonable for him to expect to have the issues of [Mrs A's] prior drug reactions and use of clopidogrel brought to his attention by the clinic prior to the day of the procedure. I think his performance of the procedure was also within the standard of care.

2a. The steps taken by the clinic prior to the day of the procedure including but not limited to whether the company should have arranged for a general anaesthetic for [Mrs A].

There is no question that [Mrs A's] medical history should have been reviewed shortly after the time of booking by an experienced endoscopy nurse or doctor. Presumably this is why the clinic requires that the medical history form and current medications be 'identified at the time of the booking as this may affect admission time, date and preparation instructions'. I do not think it can be argued that booking personnel have the training to evaluate this information.

Reading the policy, it would be my expectation that a nurse would be reviewing this information well in advance of the date of this elective procedure. It does not appear that a medically trained professional reviewed this information until the 'pre-admission' review that the clinic mandates in their policy on the day prior to the procedure. I would interpret this 'pre-admission' review to be a final double-check for potential problems that may have been overlooked in the booking process. In this

case, even if a pre-admission review was done the day prior to the procedure, [Dr B] was still not informed until the time of the actual procedure. This represents a moderate departure from standard of care.

If this information had been brought to [Dr B's] attention prior to the procedure date, it would be reasonable to assume that a meaningful discussion would have occurred between [Dr B] and [Mrs A] to determine how the procedure would be performed, either in the manner it was eventually done, or under general anaesthesia.

2b. The management by the clinic of [Mrs A's] medications including but not limited to clopidogrel.

As noted above, the issue of [Mrs A's] prior adverse experiences with fentanyl and midazolam should have been recognised and reported to [Dr B] prior to the day of the examination.

Regarding the use of clopidogrel, [Dr C] states that 'Dr Stein may be confusing clopidogrel, an anti-platelet agent, with anticoagulants such as warfarin. It is highly debatable how long patients should be off clopidogrel'. I would like to state that I am very familiar with these medications and am not confusing them. I maintain current Board Certification in Internal Medicine in the United States and have Vocational Registration in Internal Medicine in NZ. I have extensive experience with both medications, having worked as a general hospital based physician in New Zealand for over two and a half years and as a gastroenterologist in NZ for over ten years.

My point about clopidogrel was not whether, in this case, it should have been withheld or continued or, for that matter, for how long. My point was that the endoscopist needs to be aware that a patient is on clopidogrel prior to the procedure, not on the day it is to be performed. Regarding his statement that 'it is highly debatable how long patients should be off clopidogrel', it is well-established that, once discontinued, the anti-thrombotic effect of clopidogrel can take 5–7 days (not the two days that her GP advised) to reverse. [Dr C] states that the clinic's current protocol is 'consistent with the current European Society of Gastrointestinal Endoscopy Guidelines for the cessation of clopidogrel. Those guidelines specifically recommend holding clopidogrel for five days for high risk procedures such as polypectomy; while I agree that clopidogrel can be safely continued in many situations, there are few endoscopists who would knowingly continue it if, for instance, there was a possibility of identifying a large polyp needing EMR.

His unit's policy, adopted in 2015 for patients on clopidogrel, states 'The Endoscopist will then be contacted (if a patient is on clopidogrel) for orders and then the patient advised by administration staff'.

The ESGE's published guidelines regarding clopidogrel from 2016 are the same as they were in 2010, four years prior to [Mrs A's] procedure.

The clinic's failure to notify [Dr B] of these issues, i.e. [Mrs A's] prior adverse reactions to midazolam and fentanyl and the fact that she was on clopidogrel, prior to the procedure are a moderate departure from standard of care. It also does not appear that a nurse or other medically trained professional reviewed the records until the day prior to or on the day of the actual procedure. [Dr C] notes that 'all patients go through our standard booking in and admission procedures' whether they are from an

individual practice or directly referred to the clinic. While he states that 'those referred from individual practices are expected to have already gone through an assessment process by individual specialists' I cannot find reference to this expectation in the information provided to me. It was [Dr B's] expectation that he should have been notified of these medication issues , as noted by [Dr C], 'all patients go through our standard booking in process'. I think [Dr B's] expectation that a nurse would be reviewing the records and that he should have been contacted about the patient's history of adverse drug reactions and her use of clopidogrel well before the day of the procedure was reasonable and within the standard of care. Most gastroenterologists would have a similar expectation.

2c. [Dr C's] comments regarding the informed consent process including but not limited to the statement, 'I would strongly disagree that a phone or in person discussion prior to the day of the procedure for consenting in endoscopy is usual throughout New Zealand.'

[Dr C] misquotes me when he writes, 'Dr Stein states "in most centres the consent process is the sole responsibility of the doctor"'. While this is not what I said, I would state that in all centres the consent process is the sole responsibility of the doctor. What I wrote was 'I would suggest, however, that [the clinic] consider having the doctor personally conduct the entire consent process for the procedure. This is the practice in most endoscopy centres in NZ. This would prevent similar situations where there is a breakdown in communication between the doctor and the patient'.

[Dr C] then writes, 'This practice of obtaining consent is not at all unusual in New Zealand, e.g. that is standard practice at […] Hospital. Dr Stein's experience of endoscopy in this country would appear to be limited to centres where he has worked and I would disagree with his contention'. He further states that 'Once again Dr Stein incorrectly assumes that the doctor conducts the entire consent process in most endoscopy centres in New Zealand'.

As I noted above, the four private centres and the two DHBs in the […] region have doctors, not nurses, obtaining consents. I queried nine DHBs (roughly half of the DHBs in New Zealand) on this issue [list of DHBs]. Only at [one] DHB does the nurse obtain the consent. In addition seven of those nine DHBs do either a face to face or a telephone pre-assessment by an endoscopy nurse.

Finally, I would like to point out that the New Zealand National Bowel Cancer Screening Program, recently rolled out at my DHB, requires that a telephone or face to face pre-assessment be performed by an experienced endoscopy nurse.

3d. The appropriateness of the changes the clinic has made to its practice.

[Dr C] makes the following statements in his section 'Recommendations' and I will respond to each one:

1."We have robust systems to identify patient problems, sensitivities, allergies, and anticoagulant and anti-platelet therapy. This did occur in [Mrs A's] case …' He states, 'I believe two days off clopidogrel was entirely appropriate.'

While there may be a system for identifying patient problems, sensitivities, allergies, etc., I see no system in place to act on information that may impact the procedure, specifically who is reviewing this information. A booking clerk should not be the

person making decisions about what information needs to be brought to the Endoscopist's attention.

On the matter of clopidogrel [Dr C] states that the clinic recently adopted a protocol that adheres to the ESGE guidelines. Those guidelines specifically state that clopidogrel needs to be held for five days. I think adoption of those guidelines is very appropriate.

2. [Dr C] notes that he will put in place a phone call for patients travelling from outside [the main centre] for their procedures in order to address 'specific issues'. This is a very positive change in the clinic's practice. I would recommend that he consider expanding this to include all patients and would specify that this be performed by an experienced endoscopy nurse. While local patients do not travel as far, they still undergo a vigorous two day preparation for their procedures.

3. [Dr C] states 'We have a robust system for notifying the appropriate specialist of any significant issues for patients who are referred directly to the clinic'.

This statement does not mention patients who are referred from the Specialists' offices and runs counter to his previous statement that all patients, whether they are referred directly to [the clinic] or come from the Specialist's office undergo the same booking in and admissions procedures. In the clinic's protocol, under the heading 'Referral Criteria', it states that 'Attending the clinic specialists, general practitioners, and other medical specialists will refer all patients who attend the clinic.' If patients referred to [the clinic] by the Specialist are treated differently from patients referred, for instance, directly from a GP's office, [Dr B] was unaware of that fact and I have seen no policy to that effect in the documents provided to me. Additionally, any information that may have an impact on an impending procedure, when identified by the clinic, should always be brought to the Specialist's attention. This is a moderate departure from standard of care.

3. Any other matter you consider relevant to comment on:

After surveying nine DHBs in New Zealand as well as four private endoscopy units in the […] region, I identified two DHBs where a phone or face to face pre-assessment by a nurse is not performed. In my previous report I stated that the clinic's failure to do a phone or face to face nurse pre-assessment with the patient was a moderate departure from standard of care. In light of this information, I would amend my opinion that this is not a departure from standard of care. However, standard of care is not synonymous with best care and I would still recommend a formal nurse-led pre-assessment process for all patients. It likely would have resulted in a better outcome in [Mrs A's] case and might prevent similar situations in the future."