# Medical Centre General Practitioner, Dr B

# A Report by the Health and Disability Commissioner

(Case 15HDC00207)



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# **Executive summary**

- This opinion concerns the services general practitioner (GP) Dr B provided to Ms A, who had been under Dr B's care since 1993. Ms A, aged 74 years at the time of these events, presented to Dr B at a medical centre on 19 May 2014 and 13 June 2014 with abdominal pain.
- On 19 May 2014, Dr B examined Ms A and commented that her pain might be caused by bowel cancer. He told Ms A that a colonoscopy would help to confirm his clinical suspicion but, given the lack of other contributing symptoms, Ms A would not meet the criteria for a public referral. Dr B suggested a private referral for a colonoscopy, which Ms A declined. Dr B did not conduct any laboratory investigations regarding the cause of Ms A's pain, and instead prescribed medication in case her symptoms were caused by constipation.
- On 13 June 2014, Ms A presented to Dr B again with abdominal pain, and asked whether he would refer her to a specialist. Dr B stated that given Ms A's presentation, her symptoms would not meet the guidelines for a public referral. Dr B did not conduct any laboratory investigations at this consultation, and continued with his plan to trial constipation medication. Dr B also asked Ms A to report any rectal bleeding.
- On 11 July 2014, Ms A presented to GP Dr C with acute abdominal pain. Dr C examined Ms A and conducted laboratory investigations including blood tests. Upon receiving the results of the blood tests, Dr C immediately referred Ms A to the public hospital, where she underwent surgery for suspected appendicitis. During surgery, a tumour was found and a hemicolectomy was performed.

# **Findings**

- There were failings in the care Dr B provided to Ms A in May and June 2014. Dr B should have ordered laboratory investigations following both consultations on 19 May 2014 and 13 June 2014 to rule out his clinical suspicion that Ms A had bowel cancer. The results of this testing could have provided Dr B with evidence regarding whether or not Ms A required a specialist referral and/or a colonoscopy. By failing to conduct appropriate investigations, Dr B did not provide services to Ms A with reasonable care and skill, and so breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).
- Dr B's clinical note-taking did not comply with the relevant professional standards, and so Dr B also breached Right 4(2) of the Code.<sup>2</sup>
- Adverse comment is made about Dr B's communication with Ms A.
- The medical centre was found to not be in breach of the Code.

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

<sup>&</sup>lt;sup>2</sup> Right 4(2) of the Code states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

# **Complaint and investigation**

- 9. The Commissioner received a complaint from Ms A about the services provided to her by Dr B. The following issues were identified for investigation:
  - Whether Dr B provided an appropriate standard of care to Ms A between 1 May 2014 and 31 July 2014.
  - Whether the medical centre provided an appropriate standard of care to Ms A between 1 May 2014 and 31 July 2014.
- 10. An investigation was commenced on 16 July 2015.
- 11. The parties directly involved in the investigation were:

Ms A (dec) Consumer/complainant

Medical centre Provider Provider Dr B

Also mentioned in this report:

Dr C General practitioner Dr D General practitioner

- 12. Information was reviewed from the above parties and also from the District Health Board.
- 13. Independent expert advice was obtained from general practitioner Dr Penny Warring (Appendix A).

# Information gathered during investigation

# **Background**

14. Ms A (dec) was aged 74 years at the time of these events, and had been a registered patient of general practitioner (GP) Dr B since 1993.<sup>3</sup>

# First consultation with Dr B — 19 May 2014

- 15. On 19 May 2014, Ms A presented to Dr B with lower right-sided abdominal pain, which she thought could be appendicitis. Dr B documented that Ms A had experienced right iliac fossa (lower right) abdominal pain, lasting a minute at a time, three times a day, in the five weeks prior to the consultation.
- 16. Dr B documented that, on examination, Ms A's abdomen was soft and no masses were felt, and told HDC that there were no signs of peritonism (no guarding or

<sup>&</sup>lt;sup>3</sup> Dr B is vocationally registered in general practice and a Fellow of the Royal New Zealand College of General Practitioners.

- rigidity). Dr B's recorded "diagnosis" was abdominal pain, and he wrote a prescription for the laxative lactulose. Dr B told HDC that he prescribed lactulose in case Ms A's pain was caused by constipation. Dr B did not record his clinical impression or plan, the reasons for his diagnosis, or any differential diagnoses.
- 17. Dr B told HDC that other than abdominal pain, Ms A had no history or symptoms of note. More specifically, there was no change in bowel habit, and no weight loss or rectal bleeding.
- 18. Dr B further stated that during the consultation, Ms A asked whether she might have appendicitis. Owing to the short-lived nature of the episodes of pain she was experiencing, Dr B told HDC that he did not think appendicitis was indicated. However, he stated that Ms A's abdominal pain did cause him to consider the possibility of bowel cancer, which he mentioned to Ms A, and told her that a colonoscopy would help to rule out this clinical suspicion.
- 19. Dr B told HDC that he explained to Ms A that given her lack of symptoms, other than abdominal pain, a referral to the public hospital's Gastroenterology Department was unlikely to be accepted. However, a colonoscopy could be accessed in the private sector. Dr B told HDC that Ms A declined a private referral but did accept Dr B's prescription for lactulose. Ms A told HDC that she has no recollection of Dr B discussing a private referral with her, but does remember him telling her that a specialist referral was not possible. There is no record of Dr B discussing a specialist referral (public or private) in Ms A's clinical notes on 19 May 2014.
- 20. Dr B stated that he did not conduct any further investigations, such as a rectal examination or blood tests, owing to the absence of symptoms.<sup>4</sup>
- 21. Ms A told HDC that she did not feel that Dr B listened to her, and that he treated her in a "very casual manner". More specifically, Ms A stated that Dr B disregarded her query in regard to appendicitis, and told her that the cause of her pain could be bowel cancer. Ms A said that she found this news daunting, and the way Dr B communicated the information was upsetting and made her feel unsupported.

#### Second consultation with Dr B — 13 June 2014

- 22. On 13 June 2014, as Ms A's abdominal pain had not settled, she returned to see Dr B. Dr B documented that Ms A's pain had improved but that she had experienced one further episode of abdominal pain. Dr B also recorded Ms A's request for a public referral for a colonoscopy, which he recorded she was unlikely to get. Dr B's "diagnosis" was abdominal pain, and his documented clinical plan was to "trial lactulose" and Ms A was to report any bleeding. A public referral for a colonoscopy was not made during this consultation.
- 23. Dr B told HDC that while he did not document it at the time, Ms A had no rectal bleeding, change in bowel habit, or weight loss, and that he asked Ms A to report

<sup>&</sup>lt;sup>5</sup> Subsequently, Dr B stated that writing "trial lactulose" was an inaccurate description for continuing lactulose, which was his intended meaning.



<sup>&</sup>lt;sup>4</sup> More specifically, no change in bowel habit, and no weight loss or rectal bleeding.

these symptoms should they occur. He also stated that he intended to continue (not start) to trial lactulose and told Ms A to make an appointment should she have any further concerns. No further investigations were conducted. Dr B told this Office that he regrets not ordering blood tests at that time, as the tests may (or may not) have provided information that could have led to an earlier referral.<sup>6</sup>

# First consultation with Dr C — 11 July 2014

- 24. Ms A told HDC that her pain persisted, and that on 9 July 2014 she was in severe pain. In light of her pain, she telephoned an accident and medical centre, as she did not wish to see Dr B again, but she was unable to get an appointment that day. Ms A told HDC that, on 11 July 2014, she was in extreme pain, and so telephoned the medical centre for an appointment with Dr B. Ms A was informed that Dr B was away, so instead she made an appointment with Dr C.
- 25. Dr C documented that Ms A reported that she was experiencing low abdominal pain that had started in her right iliac fossa and had spread across her abdomen. Dr C also documented that Ms A "ha[d] dysuria<sup>7</sup> and [urine] frequency the last few days" and that her pain had been present intermittently in the previous two days (since 9 July 2014) and had disrupted her sleep. Dr C queried a urinary tract infection and/or a renal stone and made a plan to order "urine dipstick and review".

# Second consultation with Dr C — 11 July 2014

- 26. Dr C recorded the urine dipstick result as "urine dip large leucocytes no blood" and documented that Ms A's pain was the worst episode she had experienced "but is getting better". Dr C assessed Ms A again and recorded her abdomen as soft with guarding, and queried a urinary tract infection, constipation or an underlying mass or bowel problem. Dr C's plan was to conduct further investigations, and she ordered urine and blood tests.
- 27. Later that day Dr C telephoned the laboratory and received Ms A's test results, which showed an elevated C-reactive protein and iron deficiency. Dr C then telephoned Ms A to check on her. Ms A reported copious vomiting and said that she was feeling cold and shaky. Dr C told Ms A to go to the public hospital's Emergency Department (ED), and recorded: "[S]poke to [the] General Surgical registrar who will see [Ms A] in ED, [Ms A] will phone her son and get him to take her up."
- 28. At 6.30pm, Ms A presented to ED with abdominal pain and, after assessment, she was admitted to the general surgical ward at 12.22am on 12 July 2014.

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<sup>&</sup>lt;sup>6</sup> Dr B told HDC that carrying out a complete blood count and iron study may have helped to achieve acceptance of a referral to the DHB's Department of Gastroenterology, but would not have expedited the treatment.

<sup>&</sup>lt;sup>7</sup> Pain during urination, or difficulty urinating.

<sup>&</sup>lt;sup>8</sup> Leucocytes are also called white blood cells and help protect the body against infection.

<sup>&</sup>lt;sup>9</sup> C-reactive protein (CRP) is a protein found in blood plasma; CRP levels rise in response to inflammation

<sup>&</sup>lt;sup>10</sup> Dr C recorded Ms A's CRP as 127 and "iron 3 sats 6% ferritin 180".

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# Admission & surgery at the public hospital — 12 July 2014

29. On 12 July 2014, Ms A underwent surgery to remove her appendix. During surgery a tumour, suspected to have originated from the appendix, was found growing outside of the bowel wall. The tumour was confirmed as grade 1 colon carcinoma. It was surgically removed and a hemicolectomy<sup>11</sup> was performed. Ms A was then referred to the Oncology Department at the public hospital, where it was recommended she start chemotherapy. Sadly, despite treatment, Ms A's cancer progressed and she died in early 2016.

# Dr B's changes to practice

- 30. Dr B told HDC that he discussed Ms A's case with colleagues, including Dr C. If presented with the same or a similar scenario, where he had clinical suspicion but an absence of grounds for a referral to be accepted, Dr B has stated that he would now undertake the following actions:
  - Perform a rectal examination and order blood testing.
  - Be less constrained and make telephone contact with a specialist regarding his patient.
  - Invite the patient back for review.
- 31. Prior to Ms A's death, Dr B also told HDC:
  - "I am sorry that [Ms A] feels I did not listen to her."
  - "With the knowledge of [Ms A's] diagnosis and the benefit of hindsight I do wish that I had taken blood tests, but at the time there did not seem to be an indication for this. I would certainly act differently in the future when presented with a patient with a similar history and concerns."
  - "I am sorry that [Ms A] felt unsupported by me."
  - "I am sorry that I have not contacted [Ms A] directly. [Ms A] has chosen to see another doctor, which I understand completely, and I felt that she did not want to talk to me and might be upset further by contact but I regret now that I have not contacted her. I am happy to talk to [Ms A] if she does wish to speak to me."
- 32. In his response to HDC, Dr B also included an opinion from GP Dr D. Dr D commented that, in his view, ideal practice would have been to perform haemoglobin and possibly ferritin testing (ie, blood tests) on Ms A if Dr B suspected colorectal cancer, but that currently it is not standard practice to do so. Dr D concluded that Ms A's presentation meant she was difficult to diagnose and, in his opinion, the care Dr B provided to Ms A on both 19 May 2014 and 13 June 2014 was of a reasonable standard.
- 33. Dr D further commented that whilst Dr B's record-keeping was brief, Ms A's clinical notes would be clear to another GP who read them.

<sup>&</sup>lt;sup>11</sup> Procedure to remove one side of the colon.

# The medical centre's response

34. The medical centre told HDC that no formal internal investigation has been conducted into the care provided to Ms A, but that "individual practitioners will be mindful of [Ms A's] case when managing similar situations, with non-specific symptoms but a level of clinical concern".

# Responses to the provisional opinion

35. 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.

#### MsA

36. Ms A supplied information to HDC during the investigation of her complaint. However, she died before the "facts gathered" section of the provisional opinion was available to her.

#### Dr B

37. Dr B submitted that the reports of Dr D and Dr Warring (HDC expert) "are opposed on all salient points". Dr B requested that the conclusion of the provisional opinion be reviewed, and that the final report contain further analysis of the evidence gathered during the investigation and an explanation as to why HDC "prefers" Dr Warring's report.

#### The medical centre

38. The medical centre made no comment in response to the provisional opinion.

# **Relevant guidelines**

# The DHB's Guidelines<sup>12</sup>

# *Gastroenterology*

Constipation and diarrhoea:

• [If there has been a recent change in bowel habit which is suspicious of malignancy (patient age >50, bleeding, iron deficiency), refer a patient to gastroenterology clinic].

# Ministry of Health, Referral Criteria for Direct Access Outpatient Colonoscopy (2012)

Criteria for direct access to colonoscopy:

# "Two week category

• Known or suspected CRC [colorectal cancer] (on imaging, or palpable, or visible on rectal examination), for preoperative procedure to rule out synchronous pathology.

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<sup>&</sup>lt;sup>12</sup> These Guidelines were current at the relevant time.

- Unexplained rectal bleeding (benign anal causes treated or excluded) with iron deficiency anaemia (haemoglobin below the local reference range). (Refer to Comments for Services section items 1 & 2).
- Altered bowel habit (looser and/or more frequent) > six weeks duration plus unexplained rectal bleeding (benign anal causes treated or excluded) aged ≥ 50 years.

# Six week category

- Altered bowel habit (looser and/or more frequent) > six weeks duration, aged ≥ 50 years.
- Altered bowel habit (looser and/or more frequent) > six weeks duration plus unexplained rectal bleeding (benign anal causes treated or excluded), aged 40–50 years.
- Unexplained rectal bleeding (benign anal causes treated or excluded) aged ≥ 50 years.
- Unexplained iron deficiency anaemia (haemoglobin below local reference range). (Refer to Comments for Services section items 1 & 2).
- New Zealand Guidelines Group (NZGG) Category 21 Family History plus one or more of altered bowel habit (looser and/or more frequent) > six weeks duration plus unexplained rectal bleeding (benign and anal causes treated or excluded), aged ≥ 40 years.
- NZGG Category 31 Family History plus one or more of altered bowel habit (looser and/or more frequent) > six weeks duration plus unexplained rectal bleeding (benign and anal causes treated or excluded), aged ≥ 25 years.
- Suspected/assessment inflammatory bowel disease (consider FSA).
- Imaging reveals polyp > 5mm.

For patients falling outside these criteria, referral for a first specialist assessment (FSA) may need to be considered.

Patients with atypical presentations outside these criteria may require colonoscopy, usually following specialist referral."

# Ministry of Health/New Zealand Guidelines Group, Suspected Cancer in Primary Care: Guidelines for investigation, referral and reducing ethnic disparity (2009)

"Recommendations

Colorectal cancer: urgent referral (within two weeks)

- A person aged 40 years and older reporting rectal bleeding with a change of bowel habit towards looser stools and/or increased stool frequency persisting for 6 weeks or more should be referred urgently to a specialist. ...
- A person presenting with a palpable rectal mass (intraluminal and not pelvic), should be referred urgently to a specialist, irrespective of age. Note that a

pelvic mass outside the bowel should be referred urgently to a urologist or gynaecologist. ...

• A non-menstruating woman with unexplained iron deficiency anaemia and a haemoglobin of 100g/L or below, should be referred urgently to a specialist.

# Good practice points

Colorectal cancer: urgent referral (within two weeks)

A person presenting with a right-sided abdominal mass, should be referred urgently for a surgical opinion. ...

#### Recommendations

Colorectal cancer: referral/investigation

- For a person with equivocal symptoms, a complete blood count may help in identifying the possibility of colorectal cancer by demonstrating iron deficiency anaemia. This should determine if a referral is needed and whether the person should be urgently referred to a specialist. ...
- For a person where the decision to refer to a specialist has been made, no examinations or investigations other than an abdominal and rectal examination, and a complete blood count should be undertaken as this may delay referral. ...

# Good practice points

Colorectal cancer: referral/investigation

• A person at low risk of colorectal cancer with a significant symptom (rectal bleeding or change in bowel health) and a normal rectal examination, no anaemia and no abdominal mass, should be managed by a strategy of treat, watch and review in three months. ..."

# **Standards**

# Medical Council of New Zealand, Good Medical Practice (2013)

"Keeping records

- 5. You must keep clear and accurate patient records that report:
- relevant clinical information
- options discussed
- decisions made and the reasons for them
- information given to patients
- the proposed management plan
- any drugs or other treatment prescribed.

6. Make these records at the same time as the events you are recording or as soon as possible afterwards."

# **Opinion:** Dr B — Breach

# Introduction

- 39. This opinion concerns the care Dr B provided to Ms A, a 74-year-old woman who had been a patient of Dr B since 1993. Ms A went to see Dr B in May and June 2014 complaining of abdominal pain.
- 40. Dr B told Ms A that the cause of her pain might be bowel cancer, and that a colonoscopy was required to rule out that possibility. However, given her lack of symptoms, Dr B did not make a public referral for a colonoscopy. Dr B also did not conduct laboratory investigations to ascertain the cause of Ms A's abdominal pain, at either the May or June consultations.
- 41. In July 2014, Ms A presented to Dr C, again with abdominal pain. Dr C conducted appropriate laboratory tests and, upon receiving the results, made an immediate referral to the public hospital. Ms A underwent surgery for suspected appendicitis and, upon discovery of a tumour, received a hemicolectomy.
- 42. As noted above, Dr B submitted a report from Dr D, who stated that, in his opinion, the care provided to Ms A on 13 June 2014 and 19 May 2014 was of a reasonable standard. When forming my opinion, I considered both Dr D's report and my independent expert advisor GP Dr Penny Warring's response to his report. I note that Dr Warring is an independent expert advisor, whereas Dr D's report was provided as part of Dr B's submission to HDC. I have taken both opinions into account, and my reliance on each reflects a number of factors, including the context of their provision to HDC.

# Clinical care provided by Dr B

Consultation one — 19 May 2014

- 43. On 19 May 2014, Ms A presented to Dr B with pain in the lower right side of her abdomen. Dr B documented Ms A's right iliac fossa abdominal pain, the frequency with which it occurred, and its duration. He also conducted a physical examination and recorded that Ms A's abdomen was soft and no masses were evident.
- 44. While not documented, Dr B told HDC that Ms A had not had a change in bowel habit, there was no rectal bleeding, and she had not experienced any weight loss. He also stated that he told Ms A that the cause of her pain might be bowel cancer, and that a colonoscopy was required to confirm or allay his clinical suspicion. However, Dr B stated that, given that Ms A's presenting symptoms did not meet the DHB's criteria for a public referral, he suggested a colonoscopy in the private sector, which he said Ms A declined. Ms A does not recall Dr B discussing a private referral with her.

45. The cause of Ms A's pain was left undiagnosed, and Dr B prescribed lactulose. He did not carry out a rectal examination or laboratory tests due to the absence of other symptoms.

# Consultation two — 13 June 2014

- 46. On 13 June 2014, Ms A returned to see Dr B as her abdominal pain had not settled. Dr B documented that Ms A's pain had improved, and that she had experienced one further episode of abdominal pain. Dr B also documented that he discussed with Ms A a public referral for a colonoscopy, and explained that her symptoms still did not meet the DHB's criteria for a referral. Dr B's clinical plan was recorded as "trial lactulose and report bleeding".
- 47. Dr B told HDC that Ms A again reported no rectal bleeding, and no change in bowel habit or weight loss, and that he asked Ms A to report these symptoms, particularly rectal bleeding, should she experience them. He also clarified that on 13 June 2014 he intended to continue, not start, to trial lactulose. No further investigations were conducted at this consultation.

# Laboratory investigations and clinical plan

- 48. My independent expert advisor, GP Dr Penny Warring, advised that irrespective of the later diagnosis of colorectal cancer, Ms A, a woman over the age of 50 years, presented to her GP with new onset abdominal pain, and so laboratory investigations would have been appropriate in the circumstances. More specifically, Dr Warring stated that accepted practice "would be to perform, at the minimum, a full blood count and serum ferritin [test]". 13
- 49. Dr Warring further advised that the purpose of such laboratory investigations would be "to test for and hopefully exclude a number of causes of abdominal pain in the older patient, for example ... [a] full blood count [is] looking for a raised white count in infection [and is] not simply to screen for colorectal cancer". <sup>14</sup>
- 50. Dr Warring was critical of the fact that such testing was not ordered following either consultation, and stated that Dr B's lack of appropriate laboratory investigations represented a moderate departure from the accepted standard of care. In the report provided to HDC by Dr B, Dr D states that it is ideal practice to perform a haemoglobin and possibly a ferritin test if colorectal cancer is suspected, but it is not standard practice to do so. Notwithstanding Dr D's comments, I agree with Dr Warring that testing should have been done to investigate the cause of Ms A's abdominal pain, whether that cause was cancer or something else.
- 51. Dr B stated that on 19 May 2014 Ms A did not report any change in bowel habit, and I note that Ms A's clinical records do not state that she was experiencing constipation. Dr Warring was critical of Dr B's decision to prescribe a laxative to a patient who was

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<sup>&</sup>lt;sup>13</sup> A ferritin test measures the amount of ferritin in the blood. Ferritin is a blood cell protein that contains iron. A ferritin test indicates how much iron a person is storing.

<sup>&</sup>lt;sup>14</sup> Dr Warring also noted that a serum ferritin test would have identified whether Ms A was iron deficient, and said that an unexplained iron deficiency "in a women aged over 50 years would also meet the Gastroenterology Department [DHB] ... criteria for a referral and colonoscopy".

experiencing undiagnosed abdominal pain and an acute abdomen,<sup>15</sup> as such drugs increase peristalsis<sup>16</sup> of the bowel and the possible risk of bowel perforation. Dr D submitted that this is not substantiated in any evidence-based literature. However, Dr Warring has since provided references to the literature and confirmed her advice that there is no evidence to support the use of lactulose in patients with undiagnosed abdominal pain. Dr Warring considered that the prescription of lactulose on 19 May 2014, and Dr B's plan to continue lactulose on 13 June 2014, were a moderate to severe departure from the accepted standard of care.

52. In my view, further diagnostic testing should have been conducted to investigate the cause of Ms A's abdominal pain, on both 19 May 2014 and 13 June 2014. Testing would have aided Dr B to either confirm, or allay, his initial clinical suspicion that Ms A might have bowel cancer. The results of such investigations may have provided Dr B with sufficient evidence to contact the public hospital's Gastroenterology Department and, if necessary, advocate for a referral for Ms A were her results below the guideline thresholds.<sup>17</sup>

# **Record-keeping**

- 53. As I have stated in previous opinions, the importance of good record-keeping cannot be overstated. 

  18 It is the primary tool for continuity of care, and it is a tool for managing patients. A patient's clinical record must therefore be dated, legible, and accurate, and comprehensively document all the relevant aspects of a patient's symptoms, signs, diagnosis and treatment.
- 54. The Medical Council of New Zealand in *Good Medical Practice* (2013) requires doctors to keep clear and accurate patient records that include relevant clinical information, options discussed with the patient, decisions made and the reasons for them, the proposed management plan, and any drugs or other treatment prescribed.
- 55. Dr Warring considered that Dr B's clinical notes on 19 May and 13 June 2014 were brief, and advised that accepted practice would be to document the presence and absence of relevant signs, symptoms, clinical information and drugs prescribed, as well as the options discussed, information given to the patient, and the proposed management plan. Accordingly, Dr Warring considered that Dr B's clinical note-taking represented a mild to moderate departure from expected standards.
- 56. After reviewing Ms A's clinical notes for 19 May 2014 and 13 June 2014, I consider Dr B's record-keeping inadequate and not consistent with his professional responsibilities. More specifically, I note that Dr B did not record that he was

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<sup>&</sup>lt;sup>15</sup> "Acute abdomen" refers to acute conditions arising within the abdomen associated with severe abdominal pain, requiring fairly immediate management and often requiring surgery.

<sup>&</sup>lt;sup>16</sup> Peristalsis is a series of wave-like muscle contractions that move food to different processing stations in the digestive tract.

<sup>&</sup>lt;sup>17</sup> I note that the Ministry of Health's *Referral Criteria for Direct Access Outpatient Colonoscopy* (2012) allows primary care providers to make a specialist referral for a patient with an atypical presentation. However, when such a patient should be considered for a referral is a matter of clinical judgement.

<sup>&</sup>lt;sup>18</sup> See, for example, Opinion 14HDC01100; Opinion 13HDC00482; Opinion 12HDC01483, available at www.hdc.org.nz.

considering bowel cancer or constipation as differential diagnoses. Nor is there any record of Ms A's symptoms, or absence of symptoms, other than pain, or any indication of Dr B's clinical reasoning. Lastly, I also note that Dr B recorded "trial lactulose" on 13 June 2014, when in fact it was already being trialled following the consultation on 19 May 2014.

### Conclusion

- 57. Ms A presented to Dr B on two occasions in May and June 2014. I am of the view that Dr B missed opportunities to investigate Ms A's abdominal pain. I consider that Dr B should have conducted tests to investigate the cause of Ms A's abdominal pain and rule out his clinical suspicion of bowel cancer on both 19 May 2014 and 13 June 2014. The results of this testing could have provided evidence to assist Dr B in advocating for Ms A to receive a specialist referral and colonoscopy. Accordingly, I am of the view that Dr B did not provide services to Ms A with reasonable care and skill, and so breached Right 4(1) of the Code.
- 58. Dr B's clinical record-keeping can at best be described as brief. As stated above, the importance of comprehensive clinical notes cannot be overstated, and is a legal and professional obligation. Dr B's notes should have outlined all relevant aspects of Ms A's symptoms, signs, diagnosis and treatment, but did not do so. Accordingly, I am of the view that Dr B did not provide services to Ms A that complied with professional standards, and so breached Right 4(2) of the Code.

# **Opinion:** Dr B — Adverse comment

- 59. Ms A stated that she felt that Dr B did not listen to her, and provided her with no support upon being informed of the possibility that she might have bowel cancer. Dr B confirmed that he did raise the possibility of cancer, but said he told Ms A that he did not think it was likely. I accept that Dr B told Ms A that she might have bowel cancer but offered no further follow-up guidance upon informing her that she did not meet the District Health Board's referral criteria.
- 60. With respect to patient–doctor communication, previously I have stated as follows:
  - "Given the amount of trust that individuals put in their GPs, it is very important for GPs to facilitate effective communication. GPs should be very aware of the need to ensure their patients feel heard and understood, and that issues which concern them should be addressed." <sup>19</sup>
- 61. I note that GPs operate within constrained timeframes, and that lengthy discussions with patients regarding diagnostic possibilities are not always possible. However, I expect effective communication to be well within the capabilities of GPs practising in New Zealand. Dr B told his patient that she might have bowel cancer a distressing

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<sup>&</sup>lt;sup>19</sup> Opinion 12HDC01483, page 14.

prospect for most patients. When advising patients that they may have cancer, I expect GPs, including Dr B, to outline the steps they intend to take to test their clinical suspicion, and to listen to their patient's concerns. I also expect GPs to deliver such information with due care and regard for their patient.

# **Opinion: Medical centre — No Breach**

- 62. Under sections 72(2) and 72(3) of the Health and Disability Commissioner Act 1994 (the Act), an employing agency may be held vicariously liable for any actions or omissions of its employees and/or agents who have been found to be in breach of the Code, whether or not the actions or omissions occurred with the employing authority's knowledge or approval. Pursuant to section 72(5) of the Act, it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the acts or omissions leading to an employee's breach of the Code. In addition to vicarious liability, the medical centre may also be held directly liable for the services it provides.
- 63. In my view, Dr B's failure to order the appropriate testing, and his inadequate record-keeping, were matters of individual clinical judgement and practice. There is no evidence that the medical centre's policies or practices contributed to Dr B's errors of clinical judgement. Therefore, I find that the medical centre is not vicariously liable for Dr B's breaches of the Code, or directly liable for any breach of the Code.

# Recommendations

# 64. I recommend that:

- a) Dr B provide a written apology to Ms A's family for his breaches of the Code. The apology should be sent to HDC for forwarding to Ms A's family within three weeks of the date of this report.
- b) Dr B conduct an audit of his patients' clinical records within the last two years from the date of this report to ensure that any patients with undiagnosed abdominal pain have been identified, and, if necessary, have received the appropriate testing. Within three months from the date of this report, Dr B should provide evidence to this Office of this audit and its outcome.

# Follow-up actions

- 65. a) 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 District Health Board, and the Royal New Zealand College of General Practitioners, and they will be advised of Dr B's name.
  - b) 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's website, www.hdc.org.nz, for educational purposes.

# **Appendix A: Independent advice to the Commissioner**

The following expert advice was obtained from general practitioner Dr Penny Warring:

# **Expert Opinion Report One:**

"Complaint: [Dr B] at [the medical centre]

My name is Dr Penny Warring. I am a vocationally registered general practitioner practising in Auckland, New Zealand. My qualifications are MB ChB (Auckland University 1995), Dip Com Em Med (2002), FRNZCUC (2002), and FRNZCGP (2010).

Thank you for the request that I provide clinical advice to the Commissioner in relation to the complaint from [Ms A] about the care provided to her by [Dr B]. In preparing the advice on this case I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. To the best of my knowledge I have no personal or professional conflict of interest.

#### 1. Documents reviewed

- 1.1. Letter of complaint [Ms A]
- 1.2. Provider Response [Dr B]
- 1.3. Clinical records from [the medical centre] covering the period 19 May 2014 to 12 July 2014
- 1.4. Clinical Records from [the] District Health Board covering the period 11 July 2014 to 21 July 2014

# 2. Background of Complaint

[Ms A] complains about the care provided by [Dr B] on the 19 May 2014, and on the 19 June 2014.

On the 19 May 2014 [Ms A] presented to [Dr B] with lower right sided abdominal pain which she felt could be appendicitis. [Ms A] states that [Dr B] told her that it was not appendicitis, but 'probably bowel cancer' and that she would need a colonoscopy. [Ms A] does not think that the clinical examination and investigations on that day were adequate. She does not believe that [Dr B] sent a referral for a colonoscopy on this date.

On the 19 June 2014, [Ms A] returned to see [Dr B] with worsening of her abdominal pain symptoms. [Ms A] advises that she requested a referral to see a specialist, but that [Dr B] stated that she would not meet the criteria for a publically funded colonoscopy and that seeing a specialist would not lead to undergoing a colonoscopy.

In [Dr B's] absence, [Ms A] saw [Dr C] on the 11 July 2014, this time with more severe abdominal pain. [Dr C] examined [Ms A], and organised urine and blood tests. The tests showed evidence of infection/inflammation, low iron stores and a high C-reactive protein. [Dr C] referred [Ms A] to the public hospital as an acute admission

under the general surgeons with probable appendicitis. She underwent surgery to remove the appendix, a tumour, presumed to be of appendicular origin, was found to be growing on the outside of the bowel wall and was presumed to be perforated, this tumour was surgically removed and a hemi colectomy was performed. The histology confirmed a low grade adenocarcinoma. [Ms A] is undergoing chemotherapy.

The Commissioner would like the clinical documents to be reviewed and brief advice provided on [Dr B's] assessment and treatment of [Ms A's] condition, in particular:

- 1. Regarding the first presentation on 19 May 2014:
  - a. Do you agree that [Ms A] would have been unlikely to meet the criteria for public referral for colonoscopy?
  - b. In those circumstances, what is accepted practice?
  - c. Was [Dr B's] plan reasonable in the circumstances?
- 2. Regarding the second presentation on 19 June 2014:
  - a. What is accepted practice in these circumstances?
  - b. Was [Dr B's] plan reasonable in the circumstances?
  - c. [Dr B] has indicated that in hindsight he should have ordered blood tests at this stage. What might those have shown? How might that have altered the treatment plan?
- 3. Are you able to comment on whether or not an earlier diagnosis (on 19 May or 19 June 2014) of metastatic bowel cancer would have altered [Ms A's] subsequent treatment?

# 3. Provider's Response

[Dr B] advises that [Ms A's] presenting symptoms on the 19 May 2014 were a 5 week history of intermittent abdominal pain localised to the right iliac fossa. This pain lasted 1 minute and occurred three times per day. He states that there were no other features in her history that would suggest bowel cancer. He states that her abdomen was normal to examine. He confirms [Ms A's] statement that her particular presentation did cause him to consider the possibility of bowel cancer and that he did mention this to [Ms A] at that time. He also concurs that he did advise [Ms A] that colonoscopy would be the best investigation, but that he felt that her referral would not reach the threshold to be accepted in the public system and that she could consider a private consultation to rule the possibility of cancer out. [Dr B] advises that [Ms A] did not wish to go privately, and that he prescribed lactulose in case her symptoms were caused by constipation. [Dr B] advises that he did not carry out a rectal examination or any blood tests at this stage because of the absence of symptoms.

[Dr B] advises that when he saw [Ms A] again on the 19 June 2014 she stated she had only one episode of pain since he last saw her and that her symptoms had settled. Again she had no other features suggestive of colorectal cancer. Consequently, he did not think a public referral for colonoscopy would be accepted.

[Dr B] also states that he has discussed [Ms A's] symptoms with [Dr C] and will present her case for discussion at his peer group. [Dr B] also says that [Ms A's] case will undoubtedly influence his management of patients with a similar presentation in the future: in the same clinical scenario he would perform a rectal examination and

carry out blood testing. He would now also be more likely to make phone contact with the hospital if he wants to refer a patient who does not meet the referral criteria having carried out these investigations.

# **4.** Review of Clinical Records 19 May 2014 [Dr B]

# 'Subjective

has had 5 week hx of three times per day rif (right iliac fossa) abdo pain lasting a minute at a time.

# Objective

abdo soft no masses.

Dx (diagnosis) Abdominal pain type

Rx (treatment) Lactulose 10/15ml Oral Soln 10 mls once daily.'

# **Clinical Opinion**

Firstly, the documented clinical notes are brief. The accepted practice is to keep accurate patient records that clearly document the presence and absence of relevant signs, symptoms, clinical information and drugs prescribed, as well as options discussed, decisions made and the reasons for them, information given to the patient, and the proposed management plan. <sup>1,4</sup> I consider the clinical note keeping to represent a mild–moderate departure from the expected standards of care. I believe that my peers would agree with this view.

**a.** Do you agree that [Ms A] would have been unlikely to meet the criteria for public referral for colonoscopy?

Based purely on the consultation notes above, it would be difficult to provide accurate comment, as any negative symptoms or signs are not documented. Taking into account the additional statements of [Ms A] and [Dr B], it is possible to comment further.

Based on the [DHB's] Gastroenterology Service Referral criteria<sup>8</sup>, the Ministry of Health Publication, Referral Criteria for Direct Access Outpatient Colonoscopy — Final (5 December 2012)<sup>2</sup> and the Suspected Cancer in Primary Care. Guidelines for investigation, referral and reducing ethnic disparities. New Zealand Guidelines Group. Ministry of Health 2009<sup>3</sup> I agree that [Ms A's] clinical presentation as documented by [Dr B] on the 19 May 2014, would not have met the criteria for public referral for colonoscopy.

Background and Rationale: Firstly, a timely diagnosis of colorectal cancer in primary care is difficult<sup>6,11,12</sup>. There is no one symptom, sign or test available for use in primary care that has sufficient discrimination to provide the basis for referral decisions. The decision to refer for investigation is largely based on the treating practitioner's estimated risk of an underlying colorectal cancer taking into account the secondary care criteria for referral.

Many symptoms have been described as being attributable to bowel cancer, with the main symptoms being rectal bleeding, diarrhoea, or constipation — collectively sometimes called a 'change in bowel habit' — loss of weight, abdominal pain, bloating and anaemia. However, these symptoms are also common with benign conditions, so the general practitioner needs to have a reliable method to select patients at higher risk for investigation<sup>6</sup>.

Much research has been done to establish which symptoms should be considered 'significant', and should alert the GP to seriously consider the possibility of colorectal cancer and therefore instigate appropriate referral. Significant symptoms include rectal bleeding, and/or blood mixed with stool, accompanied by weight loss or a change in bowel habit greater than 6 weeks duration; and unexplained iron deficiency, particularly in a person aged greater than 50 years. <sup>2,3,6,7,11</sup>

According to the New Zealand Colorectal Cancer Surveillance Guidelines<sup>3</sup> patients who have any factors which would infer a moderate or high risk of colorectal cancer should be monitored using Colonoscopy. Such patients include those with:

- i.A family history of colorectal cancer or an inherited colorectal syndrome ii.A history of colorectal polyps
  - iii. Inflammatory bowel disease

It is unclear from [Dr B's] notes whether [Ms A] had a moderate or high risk of colorectal cancer. She is a lifelong smoker, a known risk factor for colorectal cancer<sup>3</sup>, but this is not documented in the clinical notes provided.

In terms of referral, [the DHB's Guidelines]<sup>8</sup> state that the GP is to refer to Gastroenterology Services [if there has been a recent change in bowel habit which is suspicious of malignancy (patient age >50, bleeding, iron deficiency)]

Based upon the Ministry of Health Publication, Referral Criteria for Direct Access Outpatient Colonoscopy — Final (5 December 2012)<sup>2</sup>, [Ms A's] symptoms would not have met either the 2 week or 6 week criteria for direct access to colonoscopy, due to the lack of:- rectal bleeding and/or blood mixed with stool, unexplained iron deficiency, and/or persistent change in bowel habit greater than 6 weeks duration. The criteria clearly state that patients with abdominal pain alone without any 'six week category' features<sup>2</sup> are not accepted for direct access colonoscopy. In other words her presentation was insufficient to meet the guideline criteria, the caveat being that [Dr B] had not tested for iron deficiency anaemia. Furthermore, the guideline also clearly states<sup>2</sup>:-

- For patients falling outside these criteria, referral for a first specialist assessment (FSA) may need to be considered, and
- Patients with atypical presentations outside these criteria may require colonoscopy, usually following specialist referral.

According to the Suspected Cancer in Primary Care. Guidelines for investigation, referral and reducing ethnic disparities. New Zealand Guidelines Group. Ministry of Health 2009<sup>3</sup>, [Ms A's] presentation, as documented by [Dr B], would still not meet the criteria for urgent assessment/colonoscopy — but for a person with equivocal symptoms, accepted practice would be to perform a complete blood count, which may help in identifying the possibility of colorectal cancer by demonstrating iron deficiency anaemia. The result of this test should then determine if a referral is needed, establish whether the person should be urgently referred to a specialist<sup>3</sup>, and assist with the secondary care triage process.

This recommendation is also consistent with: Referral Guidelines for Suspected Cancer. NICE Clinical Guideline 27, 2005.

# **b.** In those circumstances, what is accepted practice?

High suspicion of cancer is defined as a person presenting with clinical features typical of cancer, or has less typical signs and symptoms but the clinician suspects that there is a high probability of cancer.<sup>2</sup>

As outlined above, [Ms A] had less typical signs and symptoms of cancer, yet [Dr B] had sufficient clinical suspicion that he raised the possibility of this diagnosis with [Ms A]. In this case, accepted practice would be to check and document vital signs — for example, a fever may be a presenting symptom on right sided colon cancer<sup>3</sup>. Accepted practice would be to perform, at the minimum, a full blood count and serum ferritin.<sup>2, 3, 11</sup> A liver function test and a renal function test to assess for liver metastases and assess the patient's fitness for surgery would also be accepted practice.<sup>11</sup>

Following the results of blood test investigations, accepted practice would be to consider referral for a first specialist assessment.<sup>2, 3, 11</sup>

Faecal Occult Blood Testing (FOBT) and carcinogenic embryonic antigen (CEA) testing are of little value in a person with symptoms suggestive of colorectal cancer and should not be performed, as a negative result does not exclude colorectal cancer. <sup>10, 11</sup>

A rectal examination may have been helpful directly prior to specialist referral<sup>3</sup>, but in the absence of symptoms suggestive of a rectal or left sided colonic lesion, would have added little value to the clinical examination.

Rectal examination is seldom contributory, and, in the absence of symptoms such as rectal bleeding and tenesmus, may be postponed until colonoscopy.<sup>7</sup>

I consider the lack of appropriate laboratory investigation on the 19 May 2014, to represent a moderate departure from the expected standards of care. I believe that my peers would agree with this view.

c. Was [Dr B's] plan reasonable in the circumstances?

[Ms A's] symptoms have not been fully investigated. The clinical examination is incomplete, including that vital signs have not been recorded. A decision is made to prescribe lactulose for undiagnosed abdominal pain. The rationale is not given for the prescription of lactulose. There is no indication in the clinical notes that [Ms A] was experiencing constipation.

Rationale, options, follow up arrangements, and management plan are not documented.

Drugs for constipation should not be given to a patient experiencing undiagnosed abdominal pain or acute abdomen, as these drugs will increase peristalsis of the bowel and the risk of bowel perforation. Bowel perforation is a life threatening surgical emergency.

I consider that the prescription of lactulose in a patient with undiagnosed abdominal pain on the 19 May 2014, represents a moderate to severe departure from the expected standards of care. I believe that my peers would agree with this view.

# 2. Regarding the second presentation on 19 June 2014:

# 'Subjective abdo pain has improved

but had 1 episode

request colonoscopy thru public services suggest unlikely to get it trial lactulose and report bleeding

# Objective

abdo soft no masses.

Dx (diagnosis) Abdominal pain type'

# a. What is accepted practice in these circumstances?

The 19 June 2014 clinical notes indicate that [Ms A] has persistent abdominal pain symptoms, and that she would like further investigation. As described in 1b, accepted practice would be to investigate with a full blood count, serum ferritin, and possibly renal function and liver function tests, followed by referral for specialist assessment/colonoscopy.

[Dr B] appears to have felt constrained by the [DHB's] referral criteria but it is the responsibility of the GP to advocate for his patient and as such, accepted practice would be to contact the hospital Gastroenterology Service and ask for advice and referral.

As outlined above, the referral guidelines are not absolute<sup>2</sup>:-

- For patients falling outside these criteria, referral for a first specialist assessment (FSA) may need to be considered, and
- Patients with atypical presentations outside these criteria may require colonoscopy, usually following specialist referral.

I consider that the lack of laboratory investigation and communication with secondary care services on the 19 June 2014, represents a moderate departure from the expected standards of care. I believe that my peers would agree with this view.

# b. Was [Dr B's] plan reasonable in the circumstances?

[Dr B] has asked [Ms A] to trial lactulose and report bleeding. He again provides a diagnosis of 'Abdominal pain type', in other words undiagnosed abdominal pain. He has not investigated her symptoms further.

[Ms A's] presentation was atypical for the more common *left* sided colon or rectal cancer in the sense that her only symptom was intermittent right iliac fossa abdominal pain. [Dr B] did consider a cancer diagnosis but did not consider investigation by means of a serum ferritin and full blood count (FBC).

[Ms A] had pain in the lower right side of her abdomen. [Dr B] thought this pain may represent right sided colon cancer. [Dr B] did not test for iron deficiency anaemia but instead asked her to look for bleeding. Fresh blood per rectum is associated with lesions of the rectum or lower (left) descending colon/sigmoid colon. An ascending (right sided) colon cancer is highly unlikely to produce rectal bleeding per rectum, as explained below.

Colorectal cancers present differently depending upon their location. Right sided colon cancers represent the minority of colorectal cancers at approximately 1 in 5 colorectal cancers. Due to the somewhat vague presentation of tumours in this location, delayed diagnosis is not uncommon. 11, 12

The right, ascending, portion of the colon is the first part of the large bowel. It has a larger diameter, and the contents are predominantly liquid, as the contents have just passed through from the small bowel. Therefore, tumours of the right side of the colon are unlikely to cause any alteration in bowel habit or any obstructive features that may lead to pain until the tumour is relatively large and advanced, in other words the tumour has now grown into the lumen of the gut or adjacent structures. Whilst right sided colon cancers have a rich blood supply, and like all colorectal cancers tend to bleed, as the colon is 1.5 metres in length, any bleeding on the right side of the colon remains undetected, as it effectively dries up by the time it reaches the outside world. Therefore, patients with right sided colon cancer do not present with frank bleeding per rectum or blood mixed in with the stool. In other words bowel habits and motions may remain largely unchanged, and the patient does not see or experience any bleeding when they go to the bathroom.

Right-sided lesions are typically larger, while left-sided lesions are more likely to cause partial or full obstruction, resulting in constipation, overflow diarrhoea, narrowed stool, bloating and cramps. Lesions of the lower colon or in the rectum often cause brighter red blood in the stool and occasionally tenesmus (a feeling of constantly needing to pass stools or that the bowel is not completely empty).

This explains why the typical presentation of a patient with a right sided colon cancer may be non-specific, for example, the patient with right sided colon cancer may present with lethargy or fatigue due to iron deficiency anaemia. This would then lead to investigation and a finding of unexplained iron deficiency anaemia. Accepted practice would be to refer for gastroenterology assessment and diagnosis, particularly in a post-menopausal female where there is no other reasonable explanation for the blood loss. <sup>2, 3, 6,7,11</sup>

I consider that the lack of laboratory investigation, continued prescription of lactulose, and asking to 'report bleeding' in a post-menopausal patient with undiagnosed right sided abdominal pain on the 19 June 2014, represents a moderate to severe departure from the expected standards of care. I believe that my peers would agree with this view.

c. [Dr B] has indicated that in hindsight he should have ordered blood tests at this stage. What might those have shown? How might that have altered the treatment plan?

Iron deficiency anaemia would be an expected finding in right sided colon cancer. Liver function tests may also be abnormal due to metastatic spread. An unexplained iron deficiency anaemia would have met the 6 week criteria for direct access to outpatient colonoscopy. Unexplained iron deficiency anaemia in a woman aged over 50 years would also meet the [DHB Gastroenterology Department's] criteria for referral and colonoscopy.

I note that at the time of diagnosis, on 11 July 2014 [Ms A's] haemoglobin was normal at 119 g/dL. She was iron deficient with a serum ferritin of 3. With a normal haemoglobin and unexplained iron deficiency she would have met the 2009 criteria for referral to a specialist<sup>3, 6, 7</sup>. However, without anaemia (a haemoglobin below the normal range) she would not have been accepted for a direct access colonscopy<sup>2</sup>. In this circumstance, accepted practice would be to communicate with and discuss her presentation with a specialist and then make the referral<sup>2</sup>.

3. Are you able to comment on whether or not an earlier diagnosis (on 19 May or 19 June 2014) of metastatic bowel cancer would have altered [Ms A's] subsequent treatment?

In my view, an earlier diagnosis may have possibly led to a slightly faster start to cancer treatment, as per the MOH guideline below, but probably no difference in the type of treatment. My understanding as a General Practitioner is that low grade adenocarcinomas are very slow growing, in other words, the cancer would have been present for and slowly growing for some time, usually several years. Due to the inherent nature and function of the right side of the bowel, the right sided colon cancers typically present later than the left sided or rectal cancers<sup>11, 12</sup>, at which stage they are generally larger and quite advanced. An oncologist may be best placed to answer this question.

According to the MOH Referral Criteria for Direct Access Outpatient Colonoscopy — Final (5 December 2012)<sup>2</sup>, only patients who, at referral, have high suspicion of cancer are covered in the 'two week category' and included in the following Ministry of Health faster cancer treatment indicators.

Therefore, if [Ms A's] metastatic bowel cancer met the criteria for 'high suspicion' in the 'two week category' on 19 May or 19 June 2014, then in her particular case she would have had to have known or suspected colorectal cancer (on imaging, or palpable, or visible on rectal examination)<sup>2</sup>; and then may expect to<sup>2</sup>:-

- i. have her first specialist assessment within 14 days
- ii. receive her first cancer treatment within 62 days

Patients whose diagnosis is incidental, or as a result of 'six week category' investigation, are included in the following indicator<sup>2</sup>.

iii. Length of time taken for a patient with a confirmed diagnosis of cancer to receive their first cancer treatment from decision-to-treat (best practice maximum 31 days). <sup>2</sup>

If you have any further questions regarding this opinion please do not hesitate to contact me.

Dr Penny Warring

**Independent Clinical Advisor** 

#### References

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- Referral Criteria for Direct Access Outpatient Colonoscopy Final (5 December 2012)
  - http://www.health.govt.nz/system/files/documents/pages/referral\_criteria\_for\_direct\_access\_outpatient\_colonoscopy.pdf
- 3. Suspected Cancer in Primary Care. Guidelines for investigation, referral and reducing ethnic disparities. New Zealand Guidelines Group. Ministry of Health 2009 <a href="http://www.health.govt.nz/publication/guidance-surveillance-people-increased-risk-colorectal-cancer">http://www.health.govt.nz/publication/guidance-surveillance-people-increased-risk-colorectal-cancer</a>
- 4. New Zealand Medical Council Statement on *The maintenance and retention of patient records* New Zealand 2012 guidelines (www.nzgg.org.nz): Guidance on Surveillance for People at Increased Risk of Colorectal Cancer <a href="http://www.health.govt.nz/publication/guidance-surveillance-people-increased-risk-colorectal-cancer">http://www.health.govt.nz/publication/guidance-surveillance-people-increased-risk-colorectal-cancer</a>
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- 7. [The District Health Board Guidelines].
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  Surveillance of people at increased risk of colorectal cancer
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- 12. Stebbing GF, Nash AG. Avoidable delay in the management of carcinoma of the right colon. Ann R Coll Surg Engl. 1995 January; 77(1): 21–23."

# **Expert Opinion Report Two:**

# "Complaint: [Dr B] at [the medical centre]

My name is Dr Penny Warring. I am a vocationally registered general practitioner practising in Auckland, New Zealand. My qualifications are MB ChB (Auckland University 1995), Dip Com Em Med (2002), FRNZCUC (20002), and FRNZCGP (2010).

Thank you for the request that I provide further clinical advice to the Commissioner in relation to the complaint from [Ms A] about the care provided to her by [Dr B]. In preparing the advice on this case I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. To the best of my knowledge I have no personal or professional conflict of interest.

This opinion is to be read in conjunction with my first opinion dated 21 June 2015.

# 5. Documents reviewed

- **I.** Letter of complaint [Ms A] [date]
- II. Provider Response [Dr B] 19 May 2015 and 27 July 2015
- **III.** Clinical records from [the medical centre] covering the period 19 May 2014 to 12 July 2014
- **IV.** Clinical Records from [the DHB] covering the period 11 July 2014 to 21 July 2014
- V. [Dr B's lawyer's] Letter 10 August 2014
- VI. [Medical centre] Response and various Policies 8 August 2015
- VII. Opinion [Dr D] 27 June 2015
- VIII. Opinion Dr Penny Warring 21 June 2015

# 6. [Dr B's] second letter dated 27 July 2015

1. a. [Dr B] accepts that carrying out a complete blood count and iron studies may have helped achieve acceptance of a referral.

He proposes that an earlier test may have been normal. However the chance of a 'normal' test result is not a valid reason to decide against performing a test where clinical suspicion is raised or a serious diagnosis needs to be ruled out.

1b. [Dr B] has now recalled that [Ms A's] abdominal pain sounded to be of a colicky nature, and this was his rationale for considering constipation. This is not documented in the contemporaneous clinical notes or [Dr B's] first letter.

[Dr B] does not appear to have sought to exclude more sinister pathology in a 74 year old woman presenting with abdominal pain. More serious pathology should be excluded first through adequate history, examination and investigation.<sup>6</sup>

Lifestyle modification would have been the first treatment option before prescribing laxatives.

A rectal examination for faecal impaction would have been appropriate before prescribing laxatives.

Appropriate follow up should have been arranged.

1c. [Dr B] states he would take more detailed notes for patients with positive symptoms.

It is equally important to document negative findings.

According to *Coles Medical Practice in New Zealand* it is important that medical records are kept clear and accurate.

According to RNZCGP Aiming for Excellence, medical records must contain information to identify the patient and to document the assessment, management process and progress, and outcomes sufficiently for another team member to carry on the management. Records need to be sufficient to meet legal requirements to describe and support the management of health care provided.

1d. On the second appointment, [Dr B] decided to continue with lactulose. He advises that he did not intend to use the word 'trial'. He advises that he did not document the dose.

1e. The referral to [the public hospital] on the 11 July 2014 states that [Ms A] is both smoker and ex-smoker in the Current Problems category. The Social Worker, Occupational Therapist and Physiotherapist report dated 15 July 2014, states that [Ms A] is a current smoker. The [DHB's] Discharge Summary dated 28 July 2014, states that [Ms A] is a smoker. The report written by [an] Oncologist, dated 18 August 2014, states that [Ms A] is a lifelong smoker and that she is currently smoking 5–6 cigarettes per day. She has tried to stop smoking in the past. [Dr B] does not appear to be aware that [Ms A] was a current smoker. Instead [Dr B] states that [Ms A] stopped smoking in 2012.

[Dr B] says that it is not impossible for right sided colon cancer to cause rectal bleeding. This is in the context of his decision to continue [Ms A] on the lactulose, at which point he asked her to report rectal bleeding. However if [Dr B] was sufficiently concerned about the possibility of colon cancer and/or gastrointestinal bleeding then this does not explain why he did not order a laboratory test for FBC and ferritin, to exclude iron deficiency anaemia, nor why he did not consider contacting the gastroenterology service regarding his concerns.

I do not believe that [Dr B] should have been able to diagnose colorectal cancer or 'metastatic bowel cancer' on the 19<sup>th</sup> May or the 13<sup>th</sup> June, but that he should have listened to [Ms A's] concerns, and undertaken a process of adequate history taking, examination and investigation to look into the cause of these symptoms and concerns.

[Ms A's] history of abdominal pain and probable iron deficiency would have met the Referral Criteria for Direct Access Outpatient Colonoscopy to be seen within 6 weeks, and also to be seen by [DHB's] gastroenterology service. The gastroenterologists, who are experts in their field, would have decided on the most appropriate type of investigation for her, based on her presenting symptoms, past medical history and her 74 years of age. [Ms A's] age would not be a limiting factor to being seen and investigated by the service.

The care that [Ms A] received in the hospital system is not in question.

4. [Dr B] has advised that he would order blood tests more readily in a similar situation, and where he had clinical suspicion but an absence of grounds for referral to be accepted, in addition to contacting the specialist, that he would also invite the patient back for review. He would be less constrained by the [DHB's] referral criteria and try to achieve referral around the criteria.

# 7. Opinion [Dr D] 27 June 2015

- 1. Regarding the first presentation on 19 May 2014:
- a. Do you agree that [Ms A] would have been unlikely to meet the criteria for public referral for colonoscopy?

# 'Subjective

has had 5 week hx of three times per day rif (right iliac fossa) abdo pain lasting a minute at a time.

# **Objective**

abdo soft no masses.

Dx (diagnosis) Abdominal pain type

Rx (treatment) Lactulose 10/15ml Oral Soln 10 mls once daily.'

I agree with [Dr D] when he states that 'His plan is brief'.

I do not agree that [Dr B's] notes on this occasion 'would be clear to another GP who read the medical record'.

[Dr D] refers to [Dr B's] 'trial of lactulose' as a 'Test of Treatment' 1.

The Heneghan article (2009) states that there is a poor evidence base informing 'test of Treatment' as an appropriate process.<sup>1</sup>

I note that the Heneghan article (2009) was a small prospective study and it was conducted only in the UK as follows:

In the pilot phase, a focus group composed of GPs and researchers in primary health care identified several possible diagnostic strategies, based on consensus opinion and the published literature. Use of these strategies was assessed in a consecutive series of 100 patients presenting with a new condition to one GP (CH). Strategies were recorded on a spreadsheet at the end of each consultation. The group of GPs then discussed these pilot results, and revised and refined the set of strategies.

We revised the data collection sheet and asked six GPs to record their diagnostic strategies for 50 new patients at the end of each consultation. The GPs were two partners (27 and 16 years' clinical experience), two registrars (8 and 4 years' experience), one part time assistant (29 years' experience), and one locum (7 years' experience). At a final focus session, the six GPs and one statistician reviewed data from these 300 consultations, using a consensus development approach, and clarified definitions used for the diagnostic strategies.'

This study also identifies selection and reporting bias:<sup>1</sup>

'The data we present have limitations: we cannot tell whether the difference in the use of strategies results from the case mix or the doctors. Both probably are a factor, with cases varying more than the individual GP's use of a given strategy. In addition, selective bias in the reporting of strategies may result from using the collection sheets and recall. During consultations the GPs tended to record the main problem only, leading to a selective under-reporting of secondary problems. Thus the doctors in our study may have under-reported using a second or third strategy.'

This article also clearly states 'Less than 50% of cases resulted in the certainty of a 'known diagnosis' without further testing'

The article describes how GPs use other strategies in the final stage of diagnosis, including ordering further tests, test of treatment, and test of time. In some cases the final diagnosis could not be given a label.

The article also states 'For the final diagnosis, tests of treatment and time were used on average for a quarter of consultations, despite there being a poor evidence base informing this process.'

In the article Heneghan<sup>1</sup> states that Researchers observed that diagnostic hypotheses are made early in the consultation and guide subsequent history and examination, in a process of 'hypothetico-deductive reasoning'.

There is no clear evidence of hypothetico-deductive reasoning in [Dr B's] clinical notes.

With reference to this article I propose that [Dr B] used a cognitive forcing strategy. 'Some GPs used a cognitive forcing strategy, whereby plausible alternative diagnoses were not considered once a diagnosis had been reached (a common cause of diagnostic error).'

The general practitioner needs to have a reliable method to select patients at higher risk for investigation<sup>3</sup>.

I agree with [Dr D's] statement 'could be criticised for not ruling out constipation' and in addition, it was important to consider other more sinister pathology, which is a particular concern in the older patient. Patients over 50 years of age should be considered to be different to younger patients and more carefully in this context. 8,12,15 I agree with [Dr D] that 'Constipation is one of the most common presentations of abdominal pain in general practice?'

In the STOOL Trial<sup>21</sup>, general practitioners considered that it is important to find the underlying cause of the constipation, and to be aware that constipation is a symptom and not a disease.

However, the first step is to establish that the patient is indeed suffering from constipation. In [Ms A's] case the clinical notes indicate that her primary complaint was abdominal pain. The notes do not state that she was experiencing symptoms of constipation.

The first step in establishing that the patient has constipation symptoms is by taking an adequate history, for example utilising the Rome III criteria <sup>8,11</sup>. The Bristol Stool Scale may also be used as a guide. An adequate physical examination must also be performed to rule out red flags. In the older patient the GP needs to be aware of and consider more serious causes. The GP needs to identify and treat reversible causes, and exclude medication as a potential cause. <sup>21</sup> If, after going through this process, constipation is considered to be of high probability, then the GP would institute lifestyle modification in the first instance, (ASCRS Grade B, Level II) also taking into account the patient's own unique circumstances and which interventions are safe for their particular patient. If the lifestyle modification intervention fails and constipation remains the most likely diagnosis, then the GP may consider initiating laxative therapy, and monitor efficacy and safety. Bulk forming laxatives are generally the first laxative of choice in the elderly. Lactulose may be chosen if bulk forming laxatives do not have the desired effect. Older adults with a history of electrolyte imbalances should use laxatives with caution. <sup>7,8,9,10</sup>

Constipation is a symptom and whilst it may simply be due to lifestyle factors such as a low fibre diet, inadequate fluids, and insufficient exercise, the GP must always bear in mind whether it may be an indicator of an underlying disease, particularly in the older patient ( $\geq 50$  years old). If a secondary cause is suspected the GP may consider performing a range of tests including complete blood count, serum electrolyte levels, blood sugar, thyroid function tests. <sup>8,12</sup>

During the process outlined above, the GP is looking out for 'red flags' or 'alarm signs'. [Ms A] had a relatively acute onset of bowel symptoms (5 weeks).<sup>8,10</sup> It is not clear whether she had other alarm signs because of the inadequacy of the history taken.

If alarm signs and symptoms are present (or patient is  $\geq$  50 years old), additionally consider complete blood count, serum ferritin, radiological investigations such as a plain film erect abdominal X-ray or ultrasound to rule out mass or obstruction, and referral to surgical department at the hospital for inspection of full length of colon.  $^{8,12,15,2}$ 

[Dr B] thought the abdomen was 'soft, no masses' yet [Ms A] was reporting pain severe enough to make her consider acute appendicitis. In the older patient reporting abdominal pain, pain out of proportion to the examination findings is a red flag, and is not benign or reassuring. Abdominal Examination has poor Test Sensitivity in the elderly. Peritonitis may be present with minimal abdominal exam findings in the elderly.<sup>6</sup>

[Dr B] has stated in his first letter that he indicated to [Ms A] that is was 'possibly bowel cancer'.

In the older patient it is important to exclude serious causes of Abdominal Pain before making a benign diagnosis. Early determination of diagnoses of exclusion (e.g. GERD, Constipation, and Gastroenteritis) should be avoided.<sup>6</sup>

[Dr D] states that [Ms A] had symptoms of 'bowel spasm', however this is not documented in the clinical notes. [Ms A] complained of intermittent abdominal pain.

It is not documented in the clinical notes that [Dr B] considered 'bowel spasm' in the diagnosis. Secondly, 'Bowel spasm' is a symptom and not a diagnosis. If [Dr B] considered 'bowel spasm' as a symptom then it is not apparent that he looked for an underlying cause.

If [Dr B] thought that [Ms A] had constipation then he should have performed a rectal examination for faecal impaction before prescribing laxatives. 8,9,10

Based on the Ministry of Health Publication, Referral Criteria for Direct Access Outpatient Colonoscopy — Final (5 December 2012)<sup>2</sup> I agree with [Dr D] that [Ms A] would not have met the criteria for public referral for colonoscopy because her presentation on this day was insufficient to meet the guideline criteria. In other words, this is based on her clinical presentation as documented by [Dr B] on the 19 May 2014, and also by taking into account the additional information provided by [Ms A] and [Dr B] in his first letter, and the lack of blood testing for iron deficiency anaemia.

# 1b. In those circumstances, what is accepted practice?

[Dr D] states that accepted practice in NZ has not been the subject of any audit.

In New Zealand there are several professional bodies that support medical practitioners by providing guidance and a framework that informs the accepted standards of practice. These professional bodies include The Medical Council of New Zealand, the various professional Medical Colleges, the New Zealand Medical Association (NZMA), and the Medical Protection Society. Examples of guidance documents include the MCNZ statements, Aiming for Excellence (RNZCGP), Coles Medical Practice in New Zealand, and the NZMA Code of Ethics.

The Royal New Zealand College of General Practitioners has CORNERSTONE accreditation. 'CORNERSTONE is a combined quality improvement and quality assurance process which allows a practice to measure themselves against a defined set of standards.'

The RNZCGP also expects General Practitioners to perform at least one audit per year. The audit process allows GPs to perform self-assessment of their level of performance in relation to accepted standards, one such audit is the audit of Clinical Records. This particular audit enables the GP to reflect and to implement ways to continuously improve their practice of medical record keeping.

When assessing accepted practice, it is worth considering how reasonable overall the practice was that was undertaken on the day, including how reasonable was the risk assessment, diagnosis and treatment on a matter of clinical judgement on that day. [Dr D] opines that [Dr B's] working diagnosis is constipation and therefore that lactulose is an appropriate treatment.

I agree that lactulose is one of the appropriate treatments for constipation. Lactulose 10–20 g/day may increase stool frequency and improve stool consistency. The dose may be increased to 40 g/day. (ASCRS Grade B, Level II)

However, lactulose is not the recommended first line treatment for constipation.

Dietary modification, including increasing fluids, dietary fibre and exercise are the first-line treatment choices for general practitioners once a diagnosis of constipation is established.<sup>7,16</sup>

If, on the second GP visit, it is determined that these lifestyle changes have failed to alleviate the constipation then a bulk forming agent is the usual first choice.

Lactulose is generally accepted as a second line choice for the pharmacological treatment of constipation.<sup>7</sup> In the stepped care approach for the elderly, lactulose is considered as the 4<sup>th</sup> step in pharmacological treatment.<sup>13</sup> Therefore it would be accepted practice to offer lactulose as a treatment for constipation on the third visit for the condition, when lifestyle modification followed by bulk-forming agents have failed.

Lactulose is becoming less favourable in New Zealand general practice since the introduction of Movicol, a newer osmotic laxative that was introduced several years ago. Lactulose is also prescribed less frequently as there are more cost effective laxative options available.

Like all drugs, laxatives are not without adverse effects. Laxative enemas, for example, may cause perforation or serious metabolic derangement, particularly in the elderly<sup>17</sup>. There is a risk particularly with hyperosmotic laxatives in undiagnosed abdominal pain, or symptoms of appendicitis, as the hyperosmotic laxatives may cause pseudo obstruction of the bowel. <sup>18,19</sup>

In a double blind placebo controlled randomized study, 316 critically ill adults with multiple organ failure requiring mechanical ventilation, and who had not produced stools for 3 days were randomized to PEG vs. lactulose vs. placebo every 8 hours until defecation occurred or a maximum of 4 days had passed. 308 patients were analyzed. When comparing PEG vs. lactulose vs. placebo, lactulose may have impacted on a reduction in the median length of stay in the intensive care unit 190 hours vs. 156 hours vs. 196 hours (p = 0.001) but also had the higher rate of intestinal pseudo obstruction or Ogilvie's syndrome 1% vs. 5.5% vs. 4.1%.

Thus lactulose is not a 'benign' treatment.

Older adults with a history of electrolyte imbalance or bloating should use lactulose with caution. <sup>7,13</sup>

The NZ Formulary states that lactulose may cause nausea, vomiting, flatulence, cramps, abdominal discomfort, and electrolyte disturbances; and that lactulose is contraindicated in galactosaemia and intestinal obstruction (NZ Formulary NZF 39 01 September 2015).

Excessive amounts of lactulose may cause diarrhea with electrolyte losses. Physicians are instructed to avoid giving lactulose to patients with acute abdomen, fecal impaction, or obstruction.<sup>19</sup>

I note that [Dr B] did not perform a rectal examination to exclude faecal impaction before he prescribed lactulose to [Ms A].

I agree with [Dr D] that there is no evidence based literature that supports the use of lactulose in patients with <u>undiagnosed</u> abdominal pain.

Lastly, I note that [Dr B's] working diagnosis was not Constipation. [Dr B's] working diagnosis was Dx (diagnosis) Abdominal pain type.

# 1c. Was [Dr B's] plan reasonable in the circumstances?

I do not consider that [Dr B's] plan was reasonable in the circumstances. The history is inadequate, and the clinical examination is incomplete. Had [Dr B] thought that [Ms A] was experiencing functional constipation then it would have been appropriate to perform a rectal examination before treating with laxatives. A laboratory investigation was not performed. A decision was made to prescribe lactulose for 'abdominal pain type'. The rationale is not given for the prescription of lactulose. There is no indication in the clinical notes that [Ms A] was experiencing constipation. There is no follow up, monitoring or management plan in place.

I agree with [Dr D] that 'criticism might be directed at the lack of documentation'.

I note that [Dr D] states 'if he was thinking if excluding colon cancer then a history of a normal bowel habit is reassuring'. However there is no indication in the clinical notes that [Dr B] enquired about [Ms A's] bowel habit. The following sentence suggests he did not make the enquiry but instead 'guessed', in keeping with cognitive forcing strategy. 'In the event her pain might be caused by constipation I offered her a prescription.'

As outlined above, I do not consider that laxatives should be given to a patient experiencing undiagnosed abdominal pain or acute abdomen, as these drugs will increase peristalsis of the bowel and the possible risk of bowel perforation.

I agree with [Dr D] that referral to a surgical department or referral for radiological investigation at this stage might be reflex actions of an inexperienced GP.

However, I differ on [Dr D's] point regarding referral for blood tests. For reasons outlined above, I consider that it would have been appropriate to refer a 74 year old with new onset and undiagnosed abdominal pain for, at the least, a full blood count on this occasion.

I agree with [Dr D] that [Ms A] may have been given a low triage priority had she attended the Emergency Department at this point in time. I would anticipate that she would be provided with a level of care and treatment that addressed her presenting complaint, patient demographic, and individual patient factors.

Morbidity and mortality among older patients presenting with acute abdominal pain are high, and these patients often require hospitalization with prompt surgical consultation. In retrospective studies, more than one half of older patients presenting to the emergency department with acute abdominal pain required hospital admission, and 20 to 33 percent required immediate surgery.<sup>20</sup>

Acute abdominal pain is a common presenting complaint in older patients. Presentation may differ from that of the younger patient and is often complicated by coexistent disease, delays in presentation, and physical and social barriers. Older

patients tend to present later in the course of their illness and have more nonspecific symptoms.

In addition, a broader differential diagnosis must be considered in older patients with abdominal pain. Older patients may delay seeking care because they fear losing independence, lack health insurance, lack transportation, lack a secondary caregiver for their spouse or pet, or are afraid of hospitals or death.<sup>20</sup> As outlined above, the physical examination can be misleadingly benign.

The causes of abdominal pain in older patients are not greatly dissimilar from the causes in younger patients; however, certain disease processes occur more often in older patients. Causes include cholecystitis, appendicitis, diverticular disease, acute pancreatitis, peptic ulcer disease and perforation, small bowel obstruction, large bowel obstruction, abdominal aortic aneurysm, acute mesenteric ischemia, and constipation. Additional causes of abdominal pain in older patients include urinary tract infection, pyelonephritis, myocardial infarction (inferior wall), pulmonary embolism, congestive heart failure with hepatic congestion, pneumonia, constipation, urinary retention, or an abdominal muscle injury.<sup>20</sup>

[Dr D] states that [Ms A's] situation was considered low risk for colorectal cancer and performing screening tests for haemoglobin and liver function tests would by most doctors be considered inappropriate. However, [Dr B] raised the possibility of colon cancer with [Ms A] and it is not clear why he would have done this if he considered the possibility to be low risk.

[Dr D] has provided evidence based literature in support of his opinion that [Ms A] was low-risk for colorectal cancer. I do not dispute that patients with a low risk symptom will continue to be at risk of delayed diagnosis.

I agree that the only symptom or sign that [Ms A] had at that time as per the clinical notes on that day was intermittent right sided abdominal pain. But this may not be because [Ms A] did not have the prerequisite symptoms and signs. Since [Dr B] did not follow a process of taking an adequate history, performing an adequate physical examination or appropriate blood testing the level of colorectal cancer risk could not be determined.

Furthermore [Dr B] did consider a cancer diagnosis but then did not follow a process of adequate history taking, examination, investigation to exclude or include the possibility.

Whilst it is true that a right sided bowel cancer may present with non-specific symptoms, had [Dr B] taken an adequate history, he may have obtained that [Ms A] was still a smoker, and or had lethargy and or fatigue. This may have prompted him to test for iron deficiency anaemia. Such a finding would change the colorectal cancer risk that [Dr D] refers to. With a finding of iron deficiency anaemia, [Ms A] would have been seen within 6 weeks for a Direct Access Outpatient Colonoscopy<sup>2</sup> and also met the criteria to be seen [by Gastroenterology].<sup>22</sup>

Irrespective of the later diagnosis of colorectal cancer, [Ms A], a woman over the age of 50 years (age 74 years) presented to her GP with new onset abdominal pain. Laboratory investigations would be appropriate in this circumstance.

Laboratory investigations would be to test for and hopefully exclude a number of causes of abdominal pain in the older patient, for example liver function tests for biliary tract disease, full blood count looking for a raised white count in infection; and not simply to screen for colorectal cancer.

I consider that the prescription of lactulose in a patient with undiagnosed abdominal pain on the 19 May 2014, represents a moderate to severe departure from the expected standards of care. I believe that my peers would agree with this view.

# 2. Regarding the second presentation on 19 June 2014:

# a. What is accepted practice in these circumstances?

'Subjective
abdo pain has improved
but had 1 episode
request colonoscopy thru public services suggest unlikely to get it
trial lactulose and report bleeding

### Objective

abdo soft no masses.

Dx (diagnosis) Abdominal pain type'

[Dr D] says that the evidence that it would be accepted practice to perform a complete blood count on this occasion is not clear. I agree that the clinical notes are not clear. Yet, [Dr B] has asked his patient to report bleeding. This suggests [Dr B] is either considering or aware of a significant problem. Given the context of bleeding, and ongoing gastrointestinal symptoms, a full blood count is advisable. I agree with [Dr D] when he says that [Ms A] would not have received a colonoscopy based on her symptoms alone, but the referral might be stronger if she had iron deficiency anaemia. Therefore this provides support that it would have been appropriate for [Dr B] to perform the full blood count test on this day.

[Dr D] quotes the following study.

Raje D, Mukhtar H, Oshowo A, Ingham Clark C. What proportion of patients referred to secondary care with iron deficiency anaemia have colon cancer? Dis Colon Rectum. 2007 Aug; 50(8):1211-4.

The underlying consideration behind this study was whether the detection of iron deficiency may prevent a delayed diagnosis of right sided colon cancer. The authors compare the difference in presentation between right sided and more distal colon cancers. Unlike more distal colon cancers, the authors say that in right sided colon cancer, iron deficiency anaemia can be the first presentation.

'There is an impression that because this presentation is nonspecific it may be associated with a longer delay from referral to diagnosis compared with those patients with symptoms of change in bowel habit and/or rectal bleeding caused by more distal colorectal cancer.'

The purpose of this study was to determine the incidence of colon cancers in patients referred to the hospital with iron deficiency anaemia and to determine what proportion of these patients were referred and diagnosed urgently in line with cancer waiting time targets.

Of 513 (not 512) patients referred with iron deficiency anaemia in 2003, only 142 (28 percent) met the eligibility criteria.

Nine (6.3 percent) of these patients were found to have colon cancer. Eight out of nine (89%) of these cancers were in the right colon. Other patients with iron deficiency anaemia were found to have other types of benign upper or lower gastrointestinal disease (n = 125, 88%) or upper gastrointestinal cancer (n = 1, <1%). In seven patients (4.9%), no cause was found. Of the nine patients with iron deficiency anaemia who were found to have colon cancer, five had been referred urgently and four as routine. The mean delay from referral to diagnosis for these patients was 31 days for those referred urgently but 60 days for those referred routinely.

This study shows that testing for iron deficiency is a worthwhile test because in 95% of patients a treatable gastrointestinal cause will be found.

This study also shows that it is worth testing for iron deficiency anaemia in a patient with abdominal pain and/or bowel symptoms because the presence of iron deficiency anaemia is very likely to indicate that there is an underlying disease process or condition of the gastrointestinal tract.

This study shows that in the case of colon cancer, the presence of iron deficiency anaemia would suggest that the cancer is more likely to be right sided.

With reference to the following study quoted by [Dr D]:-

Damery S, Ryan R, Wilson S, Ismail T, Hobbs R; Improving Colorectal Outcomes Group. *Iron deficiency anaemia and delayed diagnosis of colorectal cancer: a retrospective cohort study.* Colorectal Dis. 2011 Apr; 13(4):e53–60

I do not believe that the take home message was that General Practitioners are not making a timely diagnosis of bowel cancer. The point of this study was that upon the diagnosis of iron deficiency anaemia, the GPs were referring to various specialties — surgical, medical, haematology etcetera. The timeline to diagnosis of the colorectal cancer depended on the specialty that the GP referred their patient to. This was not regarded as ideal, and it was expected that GPs would follow one pathway of referral.

The authors concluded 'Significant differences exist between referral specialties in time to CRC diagnosis following a primary care diagnosis of IDA. Despite NICE referral recommendations, a significant proportion of patients are still not managed within recommended care pathways to CRC diagnosis.'

I do not consider that this study is relevant to the case of [Dr B] and [Ms A].

[Dr B] did not perform the necessary test to assess for iron deficiency anaemia in the first place.

[Dr D] quotes the following Scandinavian study:

Droogendijk J1, Beukers R, Berendes PB, Tax MG, Sonneveld P, Levin MD. Screening for gastrointestinal malignancy in patients with iron deficiency anaemia by general practitioners: an observational study. Scand J Gastroenterol. 2011 Sep; 46(9):1105–10.

This study demonstrates that less than a third of the patients whose primary care GPs identified iron deficiency anaemia (IDA) received appropriate investigation with

endoscopy by 4 months. Of those who underwent endoscopy 46% were found to have at least one lesion potentially responsible for the blood loss, and 17 out of 21 colon lesions were found to be malignant. The authors concluded that in general practice, IDA is investigated sub optimally, and interventions other than the issuing of guidelines are needed to change practice.

I do not consider that this study is relevant in the case of [Dr B] and [Ms A] because [Dr B] failed to perform the test to assess for iron deficiency anaemia in the first place.

It is speculation to propose that based on this study, if [Dr B] had tested and found iron deficiency anaemia in [Ms A] that he would not have made an appropriate referral for further specialist investigation such as endoscopy, because the majority of GPs in Scandinavia fail to do it.

[Dr D] advises that GPs use guidelines poorly.

The question may not be should GPs always follow guidelines, but rather, how reasonable overall was the practice that [Dr B] undertook on that day; including how reasonable was his risk assessment, diagnosis and treatment on a matter of clinical judgement.

I agree with [Dr D] that it would have been appropriate to perform a haemoglobin and possibly a ferritin on this day 'if *colorectal cancer was suspected*'.

I consider that colorectal cancer was suspected. I note the written record (letters) of the conversation between [Dr B] and [Ms A] regarding the suspicion of cancer on that day.

[Dr D] states it is not currently standard practice to perform a FBC and ferritin if colorectal cancer is suspected. I disagree with this statement. <sup>2,8,12,15,20,24,29</sup>

I do not agree with the statement that if [Ms A's] haemoglobin was normal <u>or abnormal</u> this would not necessarily cause concern in a referral service because the [DHB's] Gastroenterology referral guidelines and the Referral Criteria for Direct Access Outpatient Colonoscopy include iron deficiency as a reason for referral to be accepted.

I cannot see how either the UK experience with referrals for colonoscopy or the [grading criteria of another DHB] are more relevant to a person residing in the [DHB's] catchment area than the [DHB] Hospital guidelines and Referral Criteria for Direct Access Outpatient Colonoscopy.

I agree with [Dr D] that [Ms A's] ultimate care was acceptable; however I do not consider that the treatment she received from [Dr C] or the [DHB] is in question.

# 2b. Was [Dr B's] plan reasonable in the circumstances?

[Dr B] considered colonoscopy as a means of investigation for colon cancer.

He considered that [Ms A] would not be seen in the public hospital and suggested that the assessment was performed in private.

He did not offer to perform further investigation such as FBC and ferritin for iron deficiency anaemia, which if detected would have met the criteria for public referral. It is the GP's role to listen to and advocate for their patient and I do not think it is

reasonable to suggest to the patient that private care is the only available option when [Ms A] had said that she could not afford it.

Other options available to [Dr B] included performing laboratory tests such as FBC and ferritin, radiological investigations such as ultrasound or plain film abdominal X ray, and talking to a hospital gastroenterologist, or medical specialist for advice and direction on the phone.

Perhaps, as [Dr D] says it is a reality that New Zealand GPs do not necessarily follow 'the guidelines'. However, what is clear is that [Dr B] did not follow the accepted process of adequate history taking, examination and investigation, follow up arrangements, and documentation of that process. The clinical notes also indicate that he did not listen to and acknowledge [Ms A's] concerns, nor did he consider her unique situation (age 74 years, lifelong smoker). It appears that his clinical judgement may have been impaired on these two days by cognitive forcing strategy.

# 2c. [Dr B] has indicated that in hindsight he should have ordered blood tests at this stage. What might those have shown? How might that have altered the treatment plan?

[Dr D] agrees that based on evidence from the UK that these tests would have helped in the diagnosis of whether [Ms A] could have colorectal cancer, and if the IDA was present, would have reduced the waiting time to colonoscopy.

[Dr D] speculates that [Dr B] would have performed these tests when [Ms A] became acutely unwell, acting in the same way as [Dr C].

[Dr D] refers to [Dr B's] decisions and actions as reasonable. I do not agree with this statement, as outlined above.

[Dr D] states that [Dr B's] decisions and actions did not delay the treatment of [Ms A] outside a time seen as reasonable by the public health service.

If [Ms A] had been diagnosed with IDA on her first consultation on the 19 May she would have been seen in 6 weeks for a colonoscopy, as per the guidelines.

# 3. Are you able to comment on whether or not an earlier diagnosis (on 19 May or 19 June 2014) of metastatic bowel cancer would have altered [Ms A's] subsequent treatment?

I do not agree with [Dr D] when he states that an earlier diagnosis was not possible on the basis that 'Bowel cancer was considered but the symptomatology was not considered to be at a level for referral for colonoscopy'.

Bowel cancer was considered, but based on the contemporaneous clinical notes and the first letter by [Dr B], the history and symptomatology was not adequately explored, an adequate examination was not performed and appropriate investigations were not undertaken. Follow up arrangements were not made.

It is for these reasons that the possibility of bowel cancer was not considered to be at a level for referral for public colonoscopy.

However, [Dr B] appears to have been happy to refer for colonoscopy in private, provided that [Ms A] had the funds to pay for it.

I do not agree that early referral with IDA would have meant that [Ms A] was not seen and investigated any sooner, because this would fall outside the Referral Criteria for Direct Access Outpatient Colonoscopy — in which she would be expected to be seen in 6 weeks.

In addition, with a diagnosis of abdominal pain and IDA, [Ms A] would have been seen in the [DHB's] Hospital Gastroenterology Service. The gastroenterologists, who are experts in their field, would have decided on the most appropriate type of investigation for her presenting symptoms, past medical history and her 74 years of age.

[Ms A's] age would not be a limiting factor to being seen and investigated by the service as [Dr D] seems to suggest.

[Dr D] states that 'significant numbers of New Zealanders are missed by our referral criteria according to [one] study (24.7%). Fortunately, because of the actions of her primary care givers, [Ms A] was not one of these people.'

I agree with the second sentence with regards to the actions of [Dr C], but not in terms of the decisions and actions (or lack of actions) by [Dr B].

# 4. Opinion

# Did [Dr B] provide an appropriate standard of care to Mrs [Ms A] between 1 May 2014 and 31 July 2014?

I agree with [Dr D] when he says that [Dr B's] standard of care demonstrated some shortcomings in the recording of his medical record.

However, I do not accept that the level of 'seriousness' of the condition or patient dictates the quality of the medical note keeping.

I do not consider that [Dr B] had safely excluded more sinister pathology when he 'hoped that [Ms A] had a self-limiting condition'.

I do not consider that the treatment [Dr B] chose was one that could be considered 'low level and safe' in the context of inadequate history, examination, investigation and follow up arrangements. Laxatives were prescribed to a 74 year old woman with undiagnosed abdominal pain in the context of patient and general practitioner concern of colorectal cancer.

The risks associated with laxative use are outlined in the body of the document.

I am unable to find documented in the contemporaneous clinical notes that [Dr B] considered 'the significant risks and costs of exposing his patient to unnecessary diagnostic tests'.

In choosing to prescribe lactulose, [Dr B] did not consider a less costly option for his patient.

[Dr B] was willing to refer [Ms A] for private colonoscopy; this could not be because he considered private care to carry less risk or cost than publically funded colonoscopy.

I am unable to find documented in the contemporaneous clinical notes evidence that [Dr B] was acting cautiously.

I consider that [Dr B] failed to adequately listen to and investigate [Ms A's] symptoms and concerns.

[Dr D] states that the second consultation demonstrated a successful 'test of treatment', but I do not share this view. There is a poor evidence base informing 'Test of treatment'.

Instead [Dr B] appears to have used cognitive forcing strategy in his assessment.

I am unable to find documented in the contemporaneous clinical notes that he 'again resisted an invasive diagnostic test that could harm [Ms A]'.

The notes demonstrate that [Dr B] did not think that [Ms A] would meet the criteria for public referral.

The notes do not demonstrate that he was concerned that such a referral would do her harm.

I am unable to find documented in the contemporaneous clinical notes that he was concerned about 'overloading the public health system'.

My understanding is that every New Zealander should have an equal right and opportunity to be seen in the public health system.

If [Dr B] had done a FBC and ferritin, a simple non-invasive, low cost blood test, and it was shown that [Ms A] had iron deficiency anaemia then she would have been seen in the public hospital system for further investigation of her abdominal pain symptoms and iron deficiency anaemia.

I do not agree with [Dr D's] statement that 'There is strong evidence that [Dr B] took a reasonable approach to [Ms A's] care, not only from the literature discussed above but from the medical records of [Dr C]'.

I do not agree with [Dr D's] opinion that because [Dr C's] medical records on the day that she saw [Ms A] do not consider a diagnosis of colorectal cancer that this puts her level of medical practice on an equal footing with the medical practice of [Dr B].

[Dr C] went through a process of adequate history taking, examination and investigation. When [Dr C] suspected something sinister might be going on she appropriately referred to tertiary services.

Likewise I do not agree with [Dr D] that because the hospital doctors did not immediately diagnose [Ms A's] condition that this infers that [Dr B's] standard of practice was 'reasonable and acceptable'.

The hospital doctors followed a process of listening to and acknowledging [Ms A's] concerns, taking an adequate history, performing an adequate examination and following up with appropriate investigation. This process was followed and informed the decisions that were made regarding the most appropriate care, management and follow up arrangements for [Ms A]. Appropriate documentation was performed during this process. This is the accepted standard.

My opinion remains unchanged. I consider that the decisions and actions of [Dr B] on the 19 May 2014 and 19 June 2014 represent a moderate to severe departure from the expected standards of care. I believe that my peers would agree with this view.

If you have any further questions regarding this opinion please do not hesitate to contact me.

Dr Penny Warring Independent Clinical Advisor

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#### **Grades of recommendation**

Grade A — evidence of type I or consistent evidence from multiple studies of type II, III, or IV

Grade B — evidence of type II, III, or IV with consistent findings

Grade C — evidence of type II, III, or IV with inconsistent findings

Grade D — little to no empirical evidence

#### Levels of evidence

Level I — meta-analysis of > 1 well-designed randomized trials with high power Level II —  $\geq 1$  well-designed experimental study; randomized trials with low power Level III — well-designed, quasi-experimental studies (such as nonrandomized, controlled, preoperative vs. postoperative comparison, time, single-group, cohort, case-control)

Level IV — well-designed, nonexperimental studies (such as comparative, correlational, or case studies)

Level V — case reports and clinical examples"