General Surgeon, Dr D A District Health Board

A Report by the Health and Disability Commissioner

(Case 13HDC00538)



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Executive summary

- 1. In late 2011, a general practitioner referred Mr A to the public hospital because of a change in Mr A's bowel habits, and because he had rectal bleeding. On 5 October 2011, Mr A was seen by surgeon Dr D, at the public hospital's outpatient clinic. A CT (computed tomography) scan of Mr A's large intestine found a 17mm polyp in the sigmoid colon, and diverticulosis.
- 2. On 30 January 2012 Dr D performed a colonoscopy. A large polyp was removed. Histological examination indicated cancer within the stalk of the polyp with invasive tumour present at the diathermy margins.
- 3. Dr D concluded that the best option for Mr A was surgery. He did not inform Mr A of other options or of the risks of surgery for him. He did not discuss Mr A's case with his colleagues or at a multidisciplinary meeting.
- 4. On 1 March 2012 Dr D removed a section of Mr A's sigmoid colon and performed a primary stapled anastomosis (join). Mr A stayed in hospital for 18 days postoperatively and he was discharged on 19 March 2012.
- 5. Later in 2012 surgeon Dr F performed ileostomy reversal surgery. Following the surgery, Mr A deteriorated, and surgeon Dr H decided to conduct a laparotomy to exclude any anastomotic leak. Dr H recorded that he had discussed the high risk with the family, and that Mr A was likely to need intensive care and might not survive the surgery.
- 6. Mr A's wife, Mrs A, consented to the laparotomy, but there is no evidence that she was Mr A's legal representative or that he was incompetent to consent himself.
- 7. Following the surgery, Mr A was returned to the High Dependency Unit for on-going supportive care. Despite medical intervention, Mr A failed to respond and continued to deteriorate until, sadly, he died.
- 8. The colectomy specimen from the operation on 1 March 2012 did not show any residual tumour, and Mr A's lymph nodes were negative for carcinoma.

Findings

9. Mr A had the right to the information that a reasonable consumer in his circumstances would expect to receive, including an explanation of the treatment options available and an assessment of the expected risks, side effects, benefits and costs of each option. Dr D did not provide this information to Mr A following his diagnosis. Accordingly, Dr D breached Right $6(1)(b)^1$ of the Code of Health and Disability Services Consumers' Rights (the Code). Without this information, Mr A was not in a



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¹ Right 6(1)(b) states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including —

⁽a) An explanation of his or her condition; and

⁽b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option ..."

position to give informed consent to the surgery on 1 March 2012. Accordingly, it follows that Dr D also breached Right $7(1)^2$ of the Code.

10. Adverse comment is made about a number of shortcomings in the care provided to Mr A by the district health board (the DHB).

Complaint and investigation

- 11. The Commissioner received a complaint from Mrs A regarding the services provided to her late husband, Mr A. The following issues were identified for investigation:
 - Whether the DHB provided Mr A with an appropriate standard of care between October 2011 and his death in 2012.
 - Whether surgeon Dr D provided Mr A with an appropriate standard of care.
- 12. The parties directly involved in the investigation were:

Mrs A	Complainant
Ms B	Consumer's daughter
Ms C	Consumer's daughter
The DHB	Provider
Dr D	Provider/general surgeon

13. Information was reviewed from the above parties and from:

Dr E Dr F	General surgeon General surgeon
Coroner	0
New Zealand Police	
Also mentioned in this report:	
Dr G	House surgeon
Dr H	Locum surgeon

14. Independent expert advice was obtained from consultant surgeon Dr Elizabeth Ritchie (Appendix A).

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 $^{^2}$ Right 7(1) states: "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise."

Information gathered during investigation

Background

- 15. Mr A lived independently at home with his wife, Mrs A. Mr A had multiple coprostatectomy,³ morbidities including a previous radical appendectomy,⁴ cholecystectomy,⁵ femoral hernia⁶ repair, varicose veins, high blood pressure, atrial fibrillation,⁷ moderate mitral regurgitation,⁸ and early dementia. His medications included metoprolol,⁹ cilazapril,¹⁰ citalopram,¹¹ warfarin¹² and furosemide.¹³
- 16. In late 2011 Mr A's general practitioner (GP) referred him to the public hospital because of a change in his bowel habits and rectal bleeding. On 5 October 2011 Mr A was seen by surgeon Dr D at the public hospital's outpatient clinic. A CT (computed tomography) scan of Mr A's large intestine found a 17mm polyp in the sigmoid colon,¹⁴ and diverticulosis.¹⁵
- 17. On 19 December 2011 Dr D performed a colonoscopy,¹⁶ but the polyp was not seen because the bowel preparation was poor and there was significant stool present. The plan was to repeat the colonoscopy in mid-January 2012 after full bowel preparation. Dr D noted that Mr A would require Clexane¹⁷ cover for four days prior to the procedure.
- 18. On 30 January 2012 the colonoscopy was repeated. A large polyp was seen in the sigmoid colon amongst diverticulae, and was removed. Histological distal examination of the polyp indicated adenocarcinoma¹⁸ within the stalk of the polyp, with invasive tumour present at the diathermy margins.

Further consultation with Dr D

19. On 15 February 2012 Dr D saw Mr A again at the outpatient clinic to discuss the results and treatment. Dr D stated that, at the consultation, his "goal was to advise the



³ Removal of the prostate gland and surrounding tissue.

⁴ Removal of the appendix.

⁵ Removal of the gall bladder.

⁶ A bulging located near the groin and thigh that occurs when a small part of intestine pushes through the wall of the femoral canal.

⁷ Abnormal heart rhythm.

⁸ A disorder in which the mitral valve does not close properly when the heart pumps out blood.

⁹ Metoprolol is used alone or in combination with other medications to treat high blood pressure. It also is used to prevent angina. ¹⁰ Cilazapril is used in the treatment of hypertension and heart failure.

¹¹ Citalopram is used to treat depression by correcting a chemical imbalance in the brain.

¹² Warfarin is an anticoagulant used to prevent heart attacks, strokes, and blood clots.

¹³ Furosemide is a diuretic used in the treatment of congestive heart failure and oedema.

¹⁴ The sigmoid colon (pelvic colon) is the part of the large intestine that is closest to the rectum and anus.

¹⁵ Diverticulosis is the formation of numerous tiny pockets (diverticula) in the lining of the bowel.

¹⁶ Colonoscopy (or colposcopy) is the endoscopic examination of the large bowel and the distal part of the small bowel with a camera on a tube passed through the anus. It can provide a visual diagnosis (eg, ulceration, polyps) and grants the opportunity for biopsy or removal of suspected colorectal cancer lesions.

¹⁷ An anticoagulant used to prevent and treat deep vein thrombosis or pulmonary embolism.

¹⁸ A type of cancerous tumour that has glandular origin, glandular characteristics, or both.

patient on [his] treatment plan and also to ascertain [Mr A's] ability to satisfactorily progress through that plan and to obtain his informed consent for the procedure".

- 20. Dr D considered that there were several possible options for Mr A's management, but concluded that the best option was to prepare Mr A for surgical removal of the diseased part of the bowel, provided Mr A was physiologically well enough. Dr D said that his preference for surgery was based on the histology result, as he considered there to be approximately a one in four chance of residual tumour being present in the colon.
- 21. Dr D advised HDC that an alternative plan was to adopt a "wait and see" approach by doing nothing and repeating a full colonoscopy in the months ahead. He stated that there were two risks to that approach. The first was that the colon was known to be heavily involved with diverticulae, and invasive tumour might have been missed by the colonoscopy. The second was that Mr A might have deteriorated clinically in the intervening period should surgery eventually have become necessary. Dr D stated that there was also a third option of "doing nothing", which he did not consider appropriate for Mr A because he gave no evidence of being physiologically unstable.
- 22. The record of the consultation contains a list of Mr A's medications, and notes: "Large Sigmoid polyp on CTC eventually retrieved = Ca[carcinoma]." It also notes, "Sigmoid Colectomy¹⁹ 1 March", and "CT chest/abdo", and indicates that Mr A was given a treatment information pamphlet regarding colectomy, which includes sections on the indications for, and complications of, colonic resection. Dr D said that he also discussed with Mr A the probable need for a protective ileostomy,²⁰ because he believed it was prudent in case Mr A's anti-coagulation treatment caused problems with bleeding.
- 23. There is no record of any assessment of Mr A's cognitive function, but Dr D stated: "[Mr A] did not give any indication to me at the time of the consenting process of being demented, although I note that dementia is not of itself, necessarily a contraindication to surgery." Dr D stated that Mr A did not complain of any current symptoms and, "from his answers to [Dr D's] questions and explanations during the informed consent process and discussion of the management options, [Dr D] formed no concerns regarding [Mr A's] level of cognitive function". Dr D said that he was aware of Mr A's comorbidities, as he had also reviewed Mr A's last medical outpatient report from November 2011, which noted his medical status at that time, and that he was still able to play nine holes of golf.
- 24. Mrs A said that she attended the preoperative appointments with Mr A. She stated that Dr D showed them the scans, initially said he thought there were polyps shown, but then told them they were cancerous. When asked whether Dr D talked to them about any treatment options other than surgery, she said he did not, and that she and Mr A



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¹⁹ Surgical excision of part or all of the sigmoid section of the colon.

²⁰ A stoma (surgical opening) constructed by bringing the end or loop of the small intestine out onto the surface of the skin, and the surgical procedure that creates this opening. Intestinal waste passes out of the ileostomy and is collected in an artificial external pouching system, which is adhered to the skin.

understood that the only option was surgery. As noted, the record of this consultation is short and does not refer to any discussion of alternative treatment options.

- 25. Dr D stated that he cannot recall who was present at the consultation on 15 February 2012, nor can he recall the details of the discussion. However, he said: "I believe I did discuss the option of doing nothing with him but my opinion was that surgery was his best option so that was discussed in detail." In response to the provisional opinion, Mrs A said she was adamant that Dr D did not offer alternatives, and stated that he stressed the need for removal of part of Mr A's bowel, and that it was vital that the perceived diseased region was removed.
- 26. On 16 February 2012 Dr D reported to Mr A's GP that Mr A would "require a sigmoid colectomy but he has a heavily diseased bowel with diverticulitis", and that the surgery was scheduled for 1 March 2012.
- 27. In response to the provisional opinion, Mr A's daughter, Ms C, stated that the family all read the information about the operation, and said: "[B]eing led by [Dr D's] discussion with our parents we were convinced the operation was the only option."

Pre-anaesthetic assessment

- 28. Mr A was referred to the Pre-Anaesthetic Assessment clinic and, following a review, it was planned to change him from the oral anti-coagulant warfarin to a short-acting version (Clexane) prior to surgery.
- 29. Dr D said that, despite Mr A's known cardiac pathology, no negating factors were flagged by the anaesthetist. Dr D stated: "While I always endeavour to obtain a comprehensive medical background of all my patients, I rely on the expertise of the anaesthetists to determine the absolute risk profile of any patient going for surgery." He stated that anaesthetists are best placed to decide whether a high or moderately high risk patient should be transferred to another hospital for management. Dr D stated that he was not subsequently advised of any concerns from Mr A's preoperative workup, and he next met Mr A on the day of his surgery, 1 March 2012.
- 30. Dr D stated that, between that appointment and the surgery, Mr A could have asked for further information or clarification of the planned procedure and the risks. Dr D said: "All patients are encouraged to contact the medical staff if they have any questions or concerns." In response to the provisional opinion, Mr A's family said that, having read the information pamphlet, they "were not concerned for [Mr A] with respect to the operation in and of itself".

Multidisciplinary team consideration

- 31. Multidisciplinary team (MDT) meetings allow health practitioners of different specialities (eg, nursing staff, oncologists, surgeons, radiologists, physiotherapists and social workers) to meet and discuss cases with a view to forming a comprehensive treatment plan which takes into account the different elements of care required, and the different treatment options available.
- 32. Dr D acknowledged that there is "undoubtedly" a benefit to discussing colorectal cases in a multidisciplinary setting. However, he confirmed that Mr A's case was not



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discussed at a colorectal MDT meeting because the public hospital did not have such meetings at the time of these events. However, he recalls that colorectal MDT meetings had recently been initiated at a larger hospital (Hospital 2) also operated by the DHB where pathology and radiology input was available. Dr D stated that the DHB does not have a registered colorectal surgeon, but general surgical colleagues discuss their patients and, at times, he had discussed problem colorectal cases with them and had sent more challenging cases through to Hospital 2 for surgery. However, Dr D stated that he did not consider that the operation he proposed for Mr A needed the surgical input of other colleagues, as Mr A "did not present as a very difficult problem".

- 33. The DHB confirmed that there were no formal MDT processes in place at the public hospital at the time of events. However, the DHB noted that there was a regular sequence of radiology, pathology and inter-clinical pathological correlation meetings, at which time patient management discussions were held, but there was no formal reporting from those meetings. The DHB advised that the first gastrointestinal MDT meeting at Hospital 2 was held on 10 February 2012. The DHB advised that if a consultant was referring a patient and questioning whether preoperative radiation or other treatment was required, typically the consultant telephoned or referred to an MDT meeting at a hospital in a main centre.
- 34. The DHB stated that, although there were no policies in place at the time regarding MDT discussions:

"MDT meetings and the MDT process, both formal and informal, are an extended form of practice applied to management of patients across health continuum settings within primary and secondary care. Doctors and other health professionals are expected to operate in this capacity and [Dr D] would have been aware of the [the DHB's] expectations in this regard."

Surgery — 1 March 2012

- 35. Mr A presented for surgery on 1 March 2012. The "Patient Admission Information" form, dated 1 March 2012, states the reason for admission, but not Mr A's past medical history, medications, functioning level and examination findings.
- 36. Dr D completed the informed consent treatment form. The form records the procedure as "sigmoid colectomy and ileostomy". The reasons for, and risks of, the procedure are noted as "bleeding/infection/stoma/anastomosis leak". Dr D recalls that "operative consent was signed uneventfully".
- 37. During the operation, Dr D attempted urethral catheterisation, but that failed owing to a tight phimosis,²¹ so Dr D inserted a suprapubic catheter.²² He then performed a sigmoid colectomy. Dr D stated that the surgery was made slightly more challenging than usual by the continual tissue ooze (associated with Mr A's Clexane medication)

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²¹ Phimosis refers to the inability to retract the distal foreskin over the glans penis.

 $^{^{22}}$ A suprapubic catheter (tube) drains urine from the bladder. It is inserted into the bladder through a small hole in the belly.

and the presence of numerous large fatty appendix epiploicae²³ around the colon. The sigmoid section was removed and a primary stapled anastomosis (join) performed. Dr D fashioned a defunctioning proximal ileostomy and placed a drain into Mr A's pelvis to evacuate the anticipated blood and ooze.

38. Dr D recorded in the clinical note that it was a difficult sigmoid colectomy. Following the surgery, Mr A was admitted to the high dependency unit (HDU).

Hospital stay

- 39. Mr A's postoperative stay in hospital was 18 days, and the only complication of note was a wound infection. However, Mrs A noted that Dr D had led them to expect a stay of three to five days, and said that they were surprised by the length of the admission.
- 40. On 15 March the notes record that Mrs A had requested staff help with emptying the stoma bag, and that she felt she was not confident and would not be able to cope at home. It is noted that Mr A was confused.
- 41. On 16 March it is recorded that Mrs A's management of the stoma was improving but she needed more supervision to gain confidence. On 18 March the notes record that Mr A was "not managing ileostomy → relying on wife to learn this". Mr A was discharged on 19 March 2012.
- 42. Mr A was re-admitted with dehydration and acute renal impairment on 24 March 2012 and discharged on 26 March 2012. However, from the clinical records, it does not appear that the surgical team or stoma therapist saw him during that admission.

Outpatient review

- 43. On 10 April 2012 Dr D saw Mr A in the outpatient clinic and ordered a contrast study to assess the anastomosis. This was performed on 9 May 2012 and showed a small contained anastomotic leak, so a delay of a month was recommended before the stoma was closed. The plan was then that the stoma was to be closed in early June. Dr D had no further contact with Mr A.
- 44. On 21 June 2012 Mr A was seen in the outpatient clinic by surgeon Dr F, to discuss further surgery to reverse the ileostomy. A second scan was requested, which showed no further evidence of an anastomotic leak.

Reversal of ileostomy

45. Several weeks later, Mr A signed an informed consent to treatment form stating the reasons and risks for the procedure as "laparotomy, leaks, infection & bleeding". Dr F performed the ileostomy reversal surgery on Day 1²⁴. The operation note completed by Dr F states that no major adhesions were noted through the small incision, and the ileostomy was easily dissected off the surrounding tissue and a space created intraabdominally. Dr F advised the DHB that the surgery was uneventful.



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²³ Small pouches of the peritoneum filled with fat, situated along the colon.

²⁴ Relevant dates of Mr Å's second admission are referred to as Day 1 – Day 5 to protect privacy.

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Deterioration

- 46. During the evening, a house surgeon noted that Mr A had not passed urine since the operation. At 7.10am on Day 2, Mr A was reviewed by the night house surgeon and administered furosemide for fluid overload. The night house surgeon noted that Mr A was wheezy, that he had had four litres of intravenous (IV) fluid since surgery, but only a 300ml urine output and an empty bladder when scanned. Bladder catheterisation was attempted, but it failed because of Mr A's bladder neck stricture. Later that morning Mr A was showing signs of improvement, but he developed sudden chest pain and, at 11.40am, was reviewed by house surgeon Dr G, who noted that Mr A was in obvious distress. In response to the provisional opinion, Ms C stated that she was with her father that morning, and he told her that he was in immense pain. She said he was extremely distressed and was experiencing waves of pain.
- 47. At 3pm on Day 2, Dr F reviewed Mr A and inserted a small urethral catheter to allow monitoring of Mr A's urine output and prescribed intravenous fluids. Later that day, Mr A developed abdominal pain and signs of peritoneal irritation in his abdomen. Ms C said that Dr F told her and her sisters that, after the surgery Mr A had undergone, the level of pain he was experiencing could reasonably be expected.
- 48. On Day 3 at 1.30am, the catheter was found to be blocked. Multiple attempts to flush the catheter were unsuccessful and, subsequently, the catheter was removed. During the day, Dr F inserted a suprapubic catheter under local anaesthetic and sedation. He consulted the on-call urologist at Hospital 2 who was happy with the management plan.
- 49. Mr A was returned to the ward with instructions on the management of the catheter and IV fluids. His care was handed over to the locum surgeon on call for the weekend, Dr H.
- 50. Mr A's condition deteriorated overnight, and house surgeon Dr G administered haloperidol 2mg to treat his delirium, and also IV fluids. On Day 4 at 3.15am, Dr G called Dr H to review Mr A.
- 51. Dr H began treatment with two antibiotics for presumed urinary tract sepsis, and increased the intravenous fluids. At 8.20am, Mr A was assessed by the house surgeon. Mr A's blood pressure had decreased (level not recorded), his pulse and respiration had increased (levels not recorded), and he was noted to be wheezy with crackles in his right chest. A chest X-ray was ordered, and Mr A was transferred to the HDU.
- 52. In response to the provisional opinion, Mrs A said that she was not advised that her husband had deteriorated, or that he had been transferred to the HDU.
- ^{53.} Dr H was contacted, and he reviewed Mr A at 11.30am. Mr A's blood tests showed acidosis,²⁵ renal failure and a low white cell count. Dr H recorded that the chest X-ray showed free air under the diaphragm. A decision was made to conduct a laparotomy to exclude any anastomotic leak. Dr H recorded that he had discussed the high risk with the family, and that Mr A was likely to need intensive care and might not survive the surgery.

²⁵ Acidosis is an increased acidity in the blood and other body tissue.



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Surgery — Day 4

- 54. The informed consent to treatment form indicates that Mrs A consented to the laparotomy on Mr A's behalf. However, there is no evidence that Mrs A was Mr A's legal representative, nor is there any clear record of any assessment of Mr A's competence to consent on his own behalf. In response to the provisional opinion, Mr A's family said that Mr A was "essentially in a coma" and could not consent for himself at this point.
- 55. The operation note states that the surgeon was Dr H assisted by Dr F. It further states that there was peritonitis²⁶ within the small intestine, and a small necrotic²⁷ hole at the site of the ileostomy reversal surgical join. It notes that there were also extensive adhesions from Mr A's previous laparotomy. Two ends of the small bowel were brought out through the old ileostomy site and formed a functional loop ileostomy.

Subsequent events

- 56. Following the surgery, Mr A was returned to the HDU for on-going supportive care. Mr A required ventilation, inotropic support, intravenous fluids, hydrocortisone and antibiotics. Despite medical intervention, Mr A failed to respond and continued to deteriorate until, sadly, he died.
- 57. Following Mr A's death, the DHB recorded a reportable event to the Coroner. However, the event was not considered an "unusual serious or sentinel event", so no internal review or investigation followed.

Histology

58. The colectomy specimen from the operation on 1 March 2012 did not show any residual tumour, and Mr A's lymph nodes were negative for carcinoma. The ileostomy specimen from the operation on Day 1 was assessed histologically, and the findings were consistent with an anastomotic leak.

Responses to provisional opinion

59. The response received from the family has been incorporated into the "information gathered" section of the report. In addition, the following submissions were received.

Dr D

60. Dr D stated that he has no further comments to make and confirmed that he will provide an apology letter to the family.

The DHB

61. The DHB stated that it agrees with the recommendations and comments about the MDT process (below).



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²⁶ Peritonitis is an inflammation of the peritoneum, the thin tissue that lines the inner wall of the abdomen and covers most of the abdominal organs. Peritonitis may result from infection (often due to rupture of a hollow organ, as may occur in abdominal trauma or appendicitis) or from a non-infectious process.

²⁷ Necrosis is death of body tissue. It occurs when there is insufficient blood flowing to the tissue.

Opinion: Dr D

Preoperative assessment — adverse comment

- 62. Mr A was seen at the outpatient clinic by Dr D on 15 February 2012. The record of the consultation contains a list of Mr A's medications, and notes: "[L]arge sigmoid polyp on CTC eventually retrieved = Ca[rcinoma]." It also notes, "Sigmoid Colectomy 1 March", and "CT chest/abdo", and indicates that Mr A was given a treatment information pamphlet regarding colectomy.
- 63. Dr D said that he was aware of Mr A's co-morbidities, as he had reviewed Mr A's last medical outpatient report from November 2011, which noted his medical status at that time, and that he was still able to play nine holes of golf. Dr D said that Mr A appeared asymptomatic when examined, did not complain of current symptoms, and "from his answers to [Dr D's] questions and explanations during the informed consent process and discussion of the management options, [Dr D] formed no concerns regarding his level of cognitive function". Dr D stated: "[Mr A] did not give any indication to me at the time of the consenting process of being demented, although I note that dementia is not of itself, necessarily a contraindication to surgery."
- 64. The clinical record contains no information about Mr A's medical diagnosis, his level of functioning, or any reasons for the medication he was taking. My expert advisor, surgeon Dr Elizabeth Ritchie, noted: "[T]his information is important when discussing possible treatment options with patients and their families and the likely outcomes of those options."
- 65. Dr D acknowledges that his notes "could have been fuller". On the basis of what was recorded in the clinical notes, it appears that Dr D did not assess Mr A's functional status (either physical or cognitive) appropriately, despite his co-morbidities and dementia being clearly recorded elsewhere in Mr A's records. Both Mr A's physical and cognitive status were relevant to any decision to operate. Given Mr A's age and other health factors, I am critical that the preoperative evaluation did not assess these issues appropriately.

Multidisciplinary team discussion — adverse comment

- 66. Dr Ritchie advised that the Ministry of Health publication "Management of Early Colorectal Cancer", published in May 2011 by the New Zealand Guidelines Group,²⁸ recommends that "all people with colon cancer should be discussed at a Tumour Board meeting", and that "every health practitioner involved in colorectal cancer care should actively participate in a multidisciplinary team".
- 67. Dr D acknowledged that there is "undoubtedly" a benefit to discussing colorectal cases in a multidisciplinary setting. However, he stated that there were no colorectal MDT meetings at the public hospital, although he recalls that such meetings had recently started at Hospital 2, where pathology and radiology input was available. Dr

²⁸ <u>http://www.health.govt.nz/system/files/documents/publications/early-management-colorectal-cancer-guideline.pdf</u>.



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D said that he did not consider that the operation he proposed for Mr A needed the surgical input of other colleagues.

- 68. The DHB stated that prior to February 2012 there was a regular sequence of radiology, pathology and inter-clinical pathological correlation meetings, at which time patient management discussions were held, but there was no formal reporting from those meetings. The first formal gastrointestinal meeting was held at Hospital 2 on 12 February 2012.
- 69. The DHB said that, at that time, if a consultant questioned whether preoperative radiation or other treatment was required, he or she typically telephoned or referred the case to an MDT meeting at a hospital in a main centre. The DHB advised that, at the time, there were no policies in place regarding MDT discussions. However, the DHB noted that MDT meetings and the MDT process, both formal and informal, are a standard form of practice applied to the management of patients across health continuum settings within primary and secondary care. The DHB stated that doctors and other health professionals are expected to operate in this capacity, and Dr D would have been aware of the DHB's expectations in that regard.
- 70. Given Mr A's co-morbidities, age, and the stage of his cancer, I am of the view that Mr A's case should have been discussed in a multidisciplinary setting to confirm whether surgery was a necessary and appropriate treatment method. This would have been in line with the relevant guidelines, which suggest that all early colorectal cancers should be discussed in a multidisciplinary setting. I am critical of Dr D for failing to do so in Mr A's case.

Information and consent — breach

- 71. Mrs A stated that she attended her husband's preoperative appointments with Dr D. She said that, on 15 February 2012, Dr D showed them the scans, initially said he thought the scan showed that Mr A had polyps, and then told them the polyp was cancerous. She said that the only treatment option they were given was surgery.
- 72. Dr D cannot recall who was present at the consultation, or the content of the discussions. He believes he discussed the option of doing nothing but that, as his opinion was that surgery was Mr A's best option, this was discussed in detail. Dr D accepts that there were several possible alternatives for Mr A's management. Dr D stated that an alternative plan was to adopt a "wait and see" approach and repeat a full colonoscopy in the subsequent months, but his conclusion was that the "best option for Mr A was to get him prepared for resection of the pathological section of bowel, provided he was physiologically well enough". In my view, all clinically appropriate management options should have been discussed with Mr A.
- 73. Dr Ritchie advised that a reasonable alternative was to repeat the colonoscopy within four to eight weeks, particularly in an elderly patient with co-morbidities. However, she noted that a repeat colonoscopy may have been difficult as there was significant diverticular disease affecting the bowel. Dr Ritchie advised that another alternative course of management would have been to watch and wait, possibly with a surveillance colonoscopy.



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- 74. There is no record of any options apart from surgery having been discussed with Mr A, and I accept Mrs A's account that no other option was discussed.
- 75. Mr A was given an information sheet on colectomy, which has sections on the indications for, and complications of, colonic resection. However, there is no record of a discussion with Mr A of likely complications such as postoperative confusion, or the postoperative management of his planned ileostomy. I agree with Dr Ritchie's comments that the information given to a patient must be specific to the particular patient, and take into account the particular circumstances and requirements of the patient. In this case, that would include the risks given Mr A's age, co-morbidities, and the outlook for his quality of life with and without surgery. I do not consider that standard information forms are a substitute for providing specific information to an individual patient.
- 76. Mr A had the right to the information that a reasonable consumer in his circumstances would expect to receive regarding the management of his cancer, including an explanation of the options available and an assessment of the expected risks, side effects, benefits and costs of each option. That was not provided to Mr A. Accordingly, I find that Dr D breached Right 6(1)(b) of the Code. Without this information, Mr A was not in a position to give informed consent to the surgical treatment plan. Accordingly, it follows that Dr D also breached Right 7(1) of the Code.

The DHB — Adverse comment

Introduction

77. District health boards are responsible for the operation of clinical services within public hospitals, and can be held responsible for any service level failures.²⁹ This responsibility includes district health boards ensuring that the systems and culture necessary for the safe operation of its hospitals are established, well understood and implemented. In this case, I am concerned that there were a number of suboptimal aspects to the care provided to Mr A at the DHB.

Multidisciplinary team meeting

78. The DHB told HDC that, at the time of Mr A's treatment, there were no policies in place regarding MDT discussions. However, it noted that MDT meetings and the MDT process, both formal and informal, are a standard form of practice applied to the management of patients across health continuum settings within primary and secondary care. The DHB stated that doctors and other health professionals are expected to operate in this capacity, and Dr D would have been aware of the DHB's expectations in this regard.

²⁹ See Opinion 10HDC00703 (September 2012) available at <u>www.hdc.org.nz</u>.



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- 79. In contrast, Dr D stated that there were no colorectal MDT meetings at the public hospital at the time of events, although he was aware that meetings had recently started at Hospital 2. Dr D said that the DHB does not have a registered colorectal surgeon, but general surgical colleagues discuss their patients and that, at times, he had discussed problem colorectal cases with his colleagues and had sent more challenging cases through to Hospital 2 for surgery.
- 80. Dr D stated that, in Mr A's case, he did not think he needed the surgical input of other colleagues, although he accepted that there was undoubtedly a benefit to discussing colorectal cases in a multidisciplinary setting.
- 81. I note that the Ministry of Health publication "Management of Early Colorectal Cancer" (May 2011) recommends that all people with colon cancer should be discussed at a Tumour Board meeting, and that "every health practitioner involved in colorectal care should actively participate in a multidisciplinary team". Dr Ritchie advised that had Dr D discussed Mr A's pathology and his clinical condition with colleagues, alternative avenues of treatment were more likely to have been considered. In my view, policies should have been in place to ensure the DHB's expectations of its staff were clear in this regard. I consider that the DHB's failure to make its expectations clear contributed to Dr D's choice not to discuss Mr A's care with other clinicians.

Follow-up care

- 82. It is evident from the clinical records that during Mr A's admission in March 2012 he was unable to manage his ileostomy, and that Mrs A lacked confidence and was concerned about her ability to cope with managing the ileostomy at home. As at 16 March 2012, it is recorded that Mrs A required more supervision to gain confidence. On 18 March the notes record: "[N]ot managing ileostomy → relying on wife to learn this." Despite this, Mr A was discharged on 19 March 2012.
- 83. As noted by Dr Ritchie, there is little documentation of the level of education Mr and Mrs A received with regard to managing Mr A's fluid intake and output. Dr Ritchie notes that that would have been difficult for Mr and Mrs A to manage successfully, even with intensive support.
- 84. Mr A was re-admitted to hospital with dehydration and acute renal impairment on 24 March 2012. However, from the clinical notes, it does not appear that the surgical team or stoma therapist saw him during that admission. In my view, the level of support and assistance to Mr A in relation to postoperative care, particularly the management of his ileostomy, was inadequate, especially given his dementia and confusion.

Deterioration following surgery on Day 1

- 85. On Day 2 Mr A was noted to be wheezy, and to have had four litres of IV fluid but only a 300ml urine output and an empty bladder when scanned. Later that day, Mr A developed abdominal pain and signs of peritoneal irritation in his abdomen.
- 86. A CT scan was performed, and Dr H reviewed Mr A again that afternoon. Mr A was reviewed regularly, but the focus was on a possible chest infection and monitoring his



urine output, rather than a suspicion of an anastomotic leak. However, I note Dr Ritchie's advice that the diagnosis of an anastomotic leak following surgery is often not clear, and that manifestations of severe infection in elderly people may be subtle.

87. I accept Dr Ritchie's advice that the standard of care provided to Mr A following his surgery during his second admission in 2012 was satisfactory, but that if there had been greater suspicion of the possibility of an anastomotic leak and more awareness of the subtlety with which this complication may present, Mr A could have been returned to theatre sooner, before the sepsis was so advanced. However, I note Dr Ritchie's comment that if sepsis is already established, a patient may not recover, particularly if his or her physiologic reserves are limited by age and other illnesses.

Consent to surgery

- 88. The informed consent to treatment form for the laparotomy was signed on Day 4 by Mrs A. The form states that she was the person legally entitled to consent on Mr A's behalf. However, there is no evidence from the records that Mrs A was either Mr A's enduring power of attorney or welfare guardian, or that Mr A was incompetent. Accordingly, Mrs A was not legally entitled to consent to her husband's surgery, even in a situation where Mr A was not competent to consent on his own behalf. Instead, Right 7(4) of the Code³⁰ would have applied if Mr A was not competent to make an informed choice.
- 89. To be clear, I note that this is not a criticism of Mr A's family, or of Mrs A's decision to sign the consent form when it was presented to her. It is the health provider's responsibility to understand the legal requirements of consent where a consumer is incompetent. This is not the first time I have expressed concern about DHB staff lacking understanding of the legal requirements for consent. As I stated in a previous opinion: "the DHB should ensure that its staff are fully cognisant of ... the circumstances in which a person is legally entitled to consent on another person's behalf".³¹
- 90. As outlined, I consider that there were a number of shortcomings in the treatment Mr A received from the DHB, but I accept that overall his treatment by the DHB was adequate. Accordingly, I do not consider that the DHB breached the Code.

³¹ Opinion 11HDC00531 (published 20 October 2014) available at <u>www.hdc.org.nz</u>.



 $^{^{30}}$ Right 7(4) states: "Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where —

a) It is in the best interests of the consumer; and

b) Reasonable steps have been taken to ascertain the views of the consumer; and

c) Either, —

i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or

ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider."

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Recommendations

91. I recommend that Dr D:

- a) Provide a written apology to Mr A's family. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mr A's family.
- b) In the event that Dr D returns to practice, he should review his practice regarding operating on patients with severe co-morbidities, and advise the Commissioner of what changes he has made or intends to make.
- 92. I am aware that the Medical Council of New Zealand's processes are on-going in relation to Dr D, and I have asked the Council to keep me updated.
- 93. I recommend that the DHB, within three months of the date of this report:
 - a) Develop a policy to ensure that complex patients are discussed by a multidisciplinary team prior to undergoing surgery, and ensure that all relevant staff receive training in that policy.
 - b) Review its admission documentation to ensure that there is a clear admission record summarising a patient's medical conditions, medications, and examination findings, which is readily accessible by all clinicians.
 - c) Provide training to staff regarding the legal requirements of informed consent, particularly with regard to incompetent patients.
- 94. I recommend that the National Health Board review the implementation of changes six months after the amended arrangements are in place.

Follow-up actions

- 95. A copy of this report will be sent to the Coroner and the Police.
 - A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr D's name.
 - A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Royal Australasian College of Surgeons, and it will be advised of Dr D's name.
 - A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to DHBNZ (Shared Services) and the Health Quality and Safety Commission and placed on the Health and Disability Commissioner website, <u>www.hdc.org.nz</u>, for educational purposes.



Appendix A — Independent expert advice to the Commissioner

The following expert advice was obtained from Dr Elizabeth Ritchie:

"I have been asked to provide advice to the commissioner on case number 13/00538. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. My qualifications are MBChB (1995) and FRACS (2006). I hold vocational registration as a general surgeon with the New Zealand Medical Council. I have been employed as a General Surgeon by the Hawkes Bay District Health Board since 2009. My practice includes endoscopy and the management of colorectal cancer, as well as other areas of general surgery. I am not a specialist colorectal surgeon.

The purpose of the advice requested of me 'is to enable the Commissioner to determine whether, from the information available, there are concerns about the surgical care provided to [Mr A] at [the public hospital] that require formal investigation.' 'The commissioner is interested in whether you consider the care provided was reasonable in the circumstances.' I have been asked to ensure that my advice includes the following:

- the adequacy of care provided to [Mr A] prior to his surgery in March 2012, including
 - whether he was appropriately assessed;
 - whether the decision to operate was reasonable;
 - whether there were any reasonable alternatives; and
 - on the basis of the available information, the adequacy of the information provided to [Mr A] preoperatively.
- The standard of perioperative care provided in March 2012
- the adequacy of the follow-up care; and
- the standard of the perioperative care provided [in 2012], including the response to the deterioration in [Mr A's] condition following his surgery on [Day 1].

'If in answering any of the above questions you believe that there has been a departure from accepted standards, it would be helpful if you could indicate whether the departure from that standard would be considered mild, moderate or severe.'

The sources of information, which I have reviewed, are:

- 1. Copy of the complaint letter to HDC from [the Coroner], enclosing reports by [Dr F] and [Dr E]
- 2. Response from [the DHB]
- 3. Report from [Dr D]
- 4. Clinical records
 - a. Laboratory
 - b. Correspondence
 - c. ED and outpatients notes

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- d. Admission 1 March to 19 March 2012
- e. Admission 24 March to 26 March 2012
- f. Admission [Days 1-5].
- g. Letter from [Dr E] dated 28 March 2014 with regard to Gastrointestinal Multidisciplinary Meetings in [Hospital 2]
- h. Record of telephone call from Mrs A to [HDC Investigator] 5/06/2013 (number C13HDC00538) and to Ms B by [HDC Investigator] on 24/05/2013 (number C13HDC00538)
- i. [the DHB] Bowel Surgery Pre-Admission Process Protocol.

I have also referred to:

- Ministry of Health, Management of Early Colorectal Cancer Guideline, published by the New Zealand Guidelines Group in May 2011.
- Australian Government, National Health and Medical Research Council Clinical Practice Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer 2005.
- Royal Australasian College of Surgeons Informed Consent Policy 2006

Further references are listed at the end of this document.

Factual Summary

[Mr A] presented to [the public hospital's] surgical service in October 2011, due to a change in bowel habit and rectal bleeding. General surgeon [Dr D] saw him. A CT scan of the large intestine found a 17mm polyp in the sigmoid colon, and diverticulosis. [Mr A's] medical background included mitral and tricuspid valve disease, atrial fibrillation, pulmonary hypertension, essential hypertension and early dementia. Regular medications included warfarin.

[Dr D] performed a colonoscopy on 19 December 2011, but the polyp was not seen due to poor bowel preparation. Colonoscopy was repeated on 30 January 2012, at which time the polyp was found and removed. Histological examination indicated adenocarcinoma within the stalk of the polyp, with invasive tumour present at the diathermy margins. On 15 February 2012, [Dr D] saw [Mr A] in outpatients to discuss the results and proposed treatment (surgery).

On 1 March 2012, [Mr A] underwent a sigmoid colectomy and ileostomy formation. There were some postoperative complications but he recovered from these and was discharged on 19 March 2012. He was readmitted on 24 March 2012 and treated for acute renal failure and dehydration, and discharged again on 26 March 2012. [Mr A] was reviewed in outpatients on 10 April, 9 May, and 21 June 2012.

On [Day 1], [Mr A] underwent an ileostomy reversal. General surgeon [Dr F] performed the surgery. [Mr A's] condition deteriorated postoperatively. On [Day 4], it was decided that a laparotomy should be performed, to exclude the possibility of anastomotic leak. The surgery revealed dense adhesions, peritonitis, and an anastomotic leak. The surgeons performed adhesiolysis, lavage, resection of the anastomosis and re-formation of an ileostomy. [Mr A] was transferred to



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the High Dependency Unit, where he required ventilation, inotropic support, IV fluids, hydrocortisone and antibiotics. [Mr A] did not respond and he died on [Day 5].

Opinion

- 1. The adequacy of care provided to [Mr A] prior to his surgery in March 2012.
- Whether he was appropriately assessed?

[Mr A] was seen by [Dr D] in the outpatient clinic on the 15th February 2012. The hand written note of this consultation lists his medications. There is no record of the medical diagnoses, which these were being prescribed for, or his level of functioning (either physical or cognitive) in this note or the typed letter to the GP. In my opinion this information is important when discussing possible treatment options with patients and their families and the likely outcomes of those options. 'It is important that preoperative evaluation include accurate assessment of the functional status of the surgical candidate in addition to the cognitive level of functioning. This ensures that operative intervention will not significantly impair the quality of life of an elderly surgical candidate'.

• Whether the decision to operate was reasonable?

The decision to operate appears, from the patient records and telephone conversation records, to have been made without discussion of any alternative options for treatment with [Mr A]. While surgical resection of the colon is a reasonable treatment for a malignant polyp, a wider assessment of the patient's fitness and performance status and discussion of other potential avenues of treatment may have led to another course of action being taken. Discussion of the pathology and the patient's clinical condition with colleagues may have also made consideration of alternative avenues of treatment more likely.

The Ministry of Health publication 'Management of Early Colorectal Cancer' published in May 2011 by the New Zealand Guidelines Group recommends that 'All people with colon cancer should be discussed at a Tumour Board meeting' and that 'Every health practitioner involved in colorectal cancer care should actively participate in a multidisciplinary team' (p13). 'Practitioners should provide people with colorectal cancer information about their diagnosis, treatment options (including risks and benefits) and support services' (p18). This publication quotes Australian Government 'Clinical Practice Guidelines the for the Prevention, Early Detection and Management of Colorectal Cancer' 2005 with regard to the management of malignant epithelial polyps. 'Malignant adenomas may be safely managed by endoscopic polypectomy provided strict criteria for patient selection and histopathological assessment are adhered to. In particular, malignant adenomas should be well or moderately differentiated and excision should be complete.'

• Whether there were any reasonable alternatives?

Repeat colonoscopy within 4–8 weeks to reassess the area of the polypectomy, and the completeness of the polypectomy, would have been a reasonable alternative, particularly in an elderly patient with co-morbidities. This may have

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been difficult as it was noted that there was significant diverticular disease affecting the segment of bowel. In the notes provided to me there is no record of whether the polypectomy site was marked, for example with a tattoo, to aid identification of the site at a later date for either endoscopy or surgery. I note that the pathology report on the resected specimen of sigmoid colon describes a 'residual soft tan pedunculated polyp 15mm maximum dimension.' This polyp had features in keeping with a polypectomy site. 'No residual adenomatous mucosa is present and no residual invasive malignancy is seen'. No lymph nodes were identified in the specimen.

Another alternative course of management would have been to watch and wait, possibly with surveillance colonoscopy.

• On the basis of the available information, the adequacy of the information provided to [Mr A] pre-operatively.

On the basis of the information available to me the information provided to [Mr A] preoperatively was not adequate. [Mr A] was given the RACS information sheet on Colectomy, which has sections on the indications for and complications of colonic resection. There is no record of any alternative avenues of treatment being discussed with him, or of the possibility that there would be no further malignancy found in a resection specimen. There is no record of any discussion of likely complications such as postoperative confusion or postoperative management of his planned ileostomy.

The Royal Australasian College of Surgeons Informed Consent Policy (2006) states: Section 5.3 'The way the surgeon gives information should help a patient understand the illness, management options and the reasons for any intervention. It may sometimes be helpful to convey information in more than one session, and sometimes to provide written material in addition to oral information.

When giving information, surgeons should encourage the patient to ask questions and should answer them as fully as possible. Such questions sometimes will help the surgeon to ascertain what is important to the patient.

The patient should be allowed sufficient time to make a decision. He\She should be encouraged to reflect on advice, ask more questions and consult with their family, or advisers. The Surgeon should assist in seeking other medical opinion where this is requested.' Section 5.8 'The use of standard "consent forms" and information sheets will not necessarily be sufficient to maintain "informed consent". Standard information forms are useful, but are no substitute for information to an individual patient. Under the requirements of "informed consent", the information to be given to a patient must be specific to the particular patient. It must take into account the particular circumstances, and requirements, of the patient.

Similarly, a simple form signed by a patient is not conclusive proof that valid consent has been obtained.



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Prepared consent forms and prepared information sheets certainly can have their place and can be used as an aid or educational tool, as well as a prompt or checklist for the discussion that must take place between doctor and patient. They are also useful for the patient to take away after the discussion as a reminder of some of the issues that have been considered. However, they are not, in themselves, adequate to ensure that informed consent has been obtained.'

2. The standard of perioperative care provided in March 2012

In the notes provided to me the clinical record for this admission begins with a nursing 'Theatre Summary' note. I have not been able to find an admission note detailing the patient's reason for admission, his past medical history, medications, functional level and examination findings. This summary of information should be readily available at the beginning of the clinical record, where those caring for the patient can refer to it easily throughout the time the patient is in hospital.

The standard of care following his surgery during this admission appears from the notes available to have been adequate, however [Mr A's] confusional state could have been investigated, and high ileostomy outputs could have been managed, more intensively.

3. The adequacy of the follow-up care

It is not clear from the notes provided to me what the plan for follow-up care with regard to [Mr A's] ileostomy management was. He had had problems with high ileostomy outputs on the ward and was on multiple medications including a diuretic at the time of discharge. He was not able to manage his ileostomy himself and his wife was to do this. Loperamide, to slow the bowel transit and reduce fluid losses was also prescribed, to be taken as needed. There is little documentation of the level of education [Mr A] and his wife received with regard to managing his fluid intake/output, from medical or stomatherapy staff. This would have been difficult for [Mr and Mrs A] to manage successfully even with intensive support. [Mr A] was admitted with dehydration, and acute renal impairment due to this, on 24/03/2012. It does not appear from the notes that the surgical team, or stoma therapist saw him during this admission.

The follow-up with imaging of the area of the anastomosis to check for healing before proceeding to ileostomy closure was appropriate.

4. The standard of perioperative care provided [during his second admission in 2012], including the response to the deterioration in [Mr A's] condition following his surgery on [Day 1].

The clinical record for this admission begins with information about the patient's 'Smoke free Status' and notes about his preoperative anticoagulation management. As in the admission for March 2012 I am not able to find a clear admission note summarising [Mr A's] medical conditions, medications, functional level and examination findings. This is important information for those caring for him to have ready access to during his stay in hospital following his procedure. On



the day following his procedure [Mr A] was noted to be wheezy and to have had 4 litres of IV fluid, only 300ml urine output and to have an empty bladder on scanning. Later in the day [Mr A] developed abdominal pain and signs of peritoneal irritation in the right upper quadrant of his abdomen. A CT scan was carried out and the operating surgeon reviewed [Mr A] again, that afternoon. Free Gas was noted within the abdominal cavity on CT and the report awaited. The report noted consolidation of the base of the right lung, free fluid below the diaphragm on the right side and extensive free gas in the peritoneal space. The impression was of 'Right basal consolidation. Evidence of previous surgery only in the abdomen, no complication identified.' During this time [Mr A] did not have a fever or a raised heart rate (his medication metoprolol would be likely to have reduced his ability to have an elevated heart rate) but his blood pressure was low 100–110 systolic. Close attention continued to be paid to [Mr A], mainly focused on a possible chest infection and attempting to monitor his urine output, as catheterisation was difficult. There was also concern about possible urinary sepsis.

If there had been greater suspicion of an anastomotic leak at the time of the CT scan and [Mr A] had returned to theatre on the day after his ileostomy closure he may have survived, but the mortality rate after an anastomotic leak is high. Reported rates range between 12 and 27%. Patient age and comorbidity have been identified as risk factors for mortality after an anastomotic leak. The diagnosis of an anastomotic leak following surgery is often not clear. Raised temperature and white cell count are a late finding. Imaging such as CT scans are often difficult to interpret soon after surgery as some amount of free fluid and free gas within the abdominal cavity is expected. In addition 'Manifestations of severe infection in elderly people may be subtle, such as anorexia, decrease in functional status and altered cognition. Due to physiological aging the elderly surgical patient may fail to show symptoms and signs that herald developing sepsis.'

In my opinion the standard of care provided to [Mr A] following his surgery [during his second admission in 2012] was satisfactory, however with a higher index of suspicion for the possibility of an anastomotic leak and greater awareness of the subtlety with which this complication may present, particularly in the elderly, [Mr A] could have returned to theatre sooner, before sepsis was so advanced. This could have altered his subsequent course, but if sepsis is already established the body's responses to it continue and the patient may not recover, particularly if their physiologic reserves are limited by age and other illnesses.

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Names have been removed (except the expert who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

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