Waitematā District Health Board

A Report by the
Health and Disability Commissioner

(Case 19HDC00159)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns a surgical instrument (specifically, an Alexis wound retractor (AWR) — a tool for holding open a surgical wound) being left in a man's abdomen inadvertently following surgery. The report discusses the care provided to the man when he re-presented to hospital with abdominal pain, and the subsequent investigations that led to the discovery of the AWR. The Commissioner reinforces the importance of routine safety checks during surgery, and highlights the risks in assuming that a highly unlikely event — in this case, the retention of a large surgical instrument — would not occur.

2. The man underwent emergency surgery at Waitematā District Health Board (WDHB) to treat a perforated colon. An AWR used to retract the surgical wound was not included in the surgical count, which was the usual practice at the time. During the surgery, the AWR was pushed fully into the man's abdomen and was not noticed or removed at the end of the procedure. The surgical count was documented as correct.

3. Over two weeks later, the man was admitted to hospital with abdominal pain and nausea. Imaging identified a retained instrument, thought to be a surgical drain. Four days later, the man underwent surgery to remove the retained instrument, which was found to be an AWR.

Findings

4. The Commissioner found several failures by a number of WDHB's staff and systems. Specifically:

- There was a collective failure by the surgical team to recognise the initial displacement of the AWR and, subsequently, that the AWR remained in the man's abdomen.
- The practice of AWRs being excluded from the count was very risky, and was reinforced by the surgical count policy not providing sufficiently clear guidance.
- There was an apparent lack of understanding by some WDHB staff as to the purpose of the surgical count policy, and a lack of critical thinking by some staff as to the risks of not counting all surgical items that enter the sterile field.
- The operation note was deficient in that it did not record the use of the AWR.
- There was poor communication by the surgical team who provided care to the man after he re-presented with the retained instrument.

5. The Commissioner considered that, cumulatively, these omissions represent systemic issues for which ultimately WDHB is responsible. Accordingly, WDHB was found in breach of Right 4(1) for failing to provide services to the man with reasonable care and skill.

Recommendations

6. The Commissioner recommended that WDHB provide evidence to HDC that all of the recommendations arising from its Serious Adverse Event Report have been implemented; establish a process for ensuring that the list of countable items in the surgical count policy

remains current; undertake a random audit of documentation for ten surgical procedures to assess compliance with the updated surgical count policy; provide training to staff on the importance of vigilance and challenging assumptions, using the anonymised version of this report as a case study; and provide a written apology to the man's family.

Complaint and investigation

7. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided to her husband, Mr A, by Waitematā District Health Board (WDHB). The following issue was identified for investigation:

- *Whether Waitematā District Health Board provided Mr A with an appropriate standard of care during November 2018 to February 2019.*

8. The parties directly involved in the investigation were:

Mr A	Consumer/complainant
Mrs A	Consumer's wife/complainant
Waitematā District Health Board	Provider

9. Further information was received from:

Dr B	Colorectal fellow/provider
Dr C	Registrar/provider
Dr D	Registrar/provider
Dr E	Colorectal senior medical officer/provider
Dr F	General and colorectal surgeon/provider
Registered Nurse (RN) G	Registered nurse/provider
RN H	Registered nurse/provider
RN I	Registered nurse/provider
RN J	Registered nurse/provider

10. Also mentioned in this report:

Dr K	Senior surgical registrar
Dr L	Junior registrar
Dr M	House officer

11. Independent expert advice was obtained from a general surgeon, Dr Christoffel Snyman (Appendix A), and RN Rosalind Jackson (Appendix B).

Information gathered during investigation

Introduction

12. This report discusses the care provided to Mr A (aged in his forties at the time of events) at a public hospital. In particular, the report discusses surgery that took place in December 2018, in which an Alexis wound retractor[1] (AWR) was inadvertently left inside Mr A's abdomen, and the post-surgical care provided.

13. On 25 November 2018, Mr A presented to the Emergency Department (ED) with severe abdominal pain. Imaging (a CT scan) showed a large mass obstructing Mr A's sigmoid colon. On 27 November 2018, he underwent a flexible sigmoidoscopy[2] and stenting[3] to relieve the colon obstruction and to obtain a biopsy. Subsequently, Mr A was diagnosed with bowel and liver cancer,[4] and was discharged on 30 November 2018 with a plan to commence chemotherapy on 15 January 2019.

27 December 2018 — return to public hospital

14. At approximately 3am on 27 December 2018, Mr A experienced sudden and severe abdominal pain. He then vomited a brown foul-smelling fluid.

15. An ambulance was called and Mr A arrived at the public hospital ED at 5.38am. He was reviewed by surgical registrar Dr C, and an abdominal scan suggested possible migration and perforation of the colonic stent that was placed during the surgery on 27 November 2018.[5] At 9.50am, the decision was made to proceed to surgery.

Emergency surgery

16. Mr A underwent surgery at 11.45am. Dr B, a colorectal fellow, was the operating surgeon, assisted by Dr C and registrar Dr D. In WDHB's Serious Adverse Event Review report (the SAER Report),[6] it was noted that colorectal Senior Medical Officer (SMO) Dr E was "operating in the theatre next-door and was available to provide opinion and review".

17. The nursing staff assisting in theatre were RN G (as anaesthetic nurse), RN H (also as anaesthetic nurse), RN I (as scrub nurse), and RN J (as circulating nurse).

Initial count

18. Before the surgery commenced, RN I and RN J completed the initial surgical count. Included in the count were all the swabs, sharps (blades, hypothermic needles, and atraumatic needles), and instruments on RN I's scrub trolley. RN J told HDC that she recalls

[1] An item used to retract surgical wounds, to maintain moisture at the incision site and protect the wound from infection. It is a double-ring polyurethane retractor, consisting of two plastic rings joined by a flexible plastic sleeve. One ring is placed inside the incision; the other ring sits outside against the skin.
[2] Inspection of the sigmoid colon (the end part of the bowel that connects to the rectum).
[3] Placement of a hollow tube.
[4] Specifically, adenocarcinoma, which is a malignant tumour that originates in the gland cells of the body.
[5] Perforation is a known complication of colonic stenting, and was noted as a risk on the consent form Mr A signed before the procedure on 27 November 2018.
[6] Completed on 1 April 2019.

seeing several AWRs on the bench, but that an AWR had not been opened onto the sterile field[7] at that time. RN J stated that AWRs are not part of WDHB's surgical count policy (the relevant parts of the policy are set out at paragraph 49 below).

Progress of surgery

19. During the surgery, it was confirmed that Mr A had a perforated sigmoid colon.[8] Mr A was also found to have peritonitis[9] and signs of ischaemia[10] in his descending colon.[11]

20. WDHB told HDC that the planned surgical procedure was a laparoscopically assisted[12] anterior resection[13] and washout. However, during surgery the decision was made to perform a Hartmann's procedure,[14] as the length of healthy bowel was insufficient for a resection. The SAER Report noted that this decision was made in consultation with Dr E.

21. During the Hartmann's procedure, an AWR was used to retract the Pfannenstiel incision[15] and to protect the wound from infection. RN I told HDC that when the AWR was requested, she unwound it and passed it to one of the surgeons, but she cannot recall which surgeon. RN I said that when surgery was coming to an end, often a surgeon would discard an AWR into her paper rubbish bag or the swab bucket, and she would not always notice it, as she could be focussing on the procedure or beginning the first surgical count.

Closure of surgical wound

22. In the SAER Report, it was noted that Dr D, supervised by Dr B, performed the closure of the surgical opening. Dr D told HDC that it is his usual practice to check the abdominal cavity before closing the wound, and to check with the scrub nurse that the count is correct, but he has no strong recollection of performing the closure or undertaking these steps. Dr D acknowledged that if the routine check of Mr A's abdomen did take place, then "clearly" it was inadequate.

23. Dr B told HDC that he does not recall closing the surgical wound himself, but is certain he was present when it occurred. Dr C told HDC that during the operation he became unsterile while cleaning the distal rectum, and therefore he left to re-scrub. He said that when he returned:

> "[Dr B] and [Dr D] had already begun closing the pfanennstiel wound … I was therefore absent from the operating table at the point where the [AWR] would have normally been removed and discarded."

[7] An isolated area that holds sterile instruments and other items required during surgery.
[8] A hole in the wall of the end portion of the bowel.
[9] Inflammation of the membrane that lines the abdomen.
[10] An inadequate supply of blood to a part of the body.
[11] The last portion of the large bowel.
[12] The operation is performed using small incisions and specialised equipment.
[13] Removal of diseased parts of the bowel and re-joining of the healthy ends of the bowel.
[14] Removal of diseased areas of the bowel and joining of the bowel to a temporary or permanent bag outside the body (a colostomy) to collect the bowel contents.
[15] A long, horizontal abdominal incision made below the line of the pubic hair.

24. Dr B dictated the operation note at the end of the surgery, and acknowledged to HDC that the note did not mention the use of the AWR.

Surgical count

25. RN I told HDC that when the surgeons were ready to begin closing the surgical site, she began the first count with RN J. RN J said that normally the swabs and sharps count would be completed when the bowel was being closed, followed immediately by a full surgical count (including swabs and sharps again) when the surgeons closed the abdomen. However, she said that when she and RN I finished the initial swabs and sharps count, the surgeons had already begun closing the abdomen, so "the first count blended into a full surgical second count".

26. All of the instrument counts were documented as correct. Both RN I and RN J said that the AWR was not included in the count, and that, in their experience, AWRs were never included in the count. RN G told HDC that reusable wound retractors are included on the count sheet, whereas AWRs, being disposable wound retractors, are included only on the surgeon's preference sheet, not the count sheet. RN H, who normally worked in the public hospital's separate Elective Surgery Centre (ESC), told HDC that at ESC, AWRs were routinely included in the count. She said that on that day she was told that in the main operating theatres the AWRs were not included in the count.

27. Dr B and Dr C both told HDC that at the time they were unaware that AWRs were not included in the surgical count. Dr D said that his understanding was that AWRs were included in the count.

Post-surgical care

28. Mr A was transferred to a surgical ward on 28 December 2018. His pain level was 6/10 on transfer to the ward, and he received ketamine as well as patient-controlled analgesia (oxycodone) and intravenous (IV) tramadol as required.

29. On 31 December 2018, Mr A's surgical drains and catheter were removed, and the nursing notes record no issues with this.

30. On 5 January 2019, Dr B reviewed Mr A and noted that his surgical wound was healing well. Mr A was discharged home that day.

14 January 2019 — return to hospital

31. At approximately 7pm on 14 January 2019, Mr A re-presented to the ED. He reported two days of worsening abdominal pain and associated nausea. X-rays of his abdomen and chest were performed at 9.03pm. At 12.11am on 15 January 2019, Mr A was admitted to the surgical ward under the care of general and colorectal surgeon Dr F.

32. Dr F told HDC that he first met Mr A at 8.30am on 15 January 2019 during his ward rounds. Dr F said that he noted Mr A's persistent abdominal pain and raised inflammatory

markers,[16] and planned for a CT scan of his abdomen and for him to be kept nil by mouth (NBM) in case surgery was required. Dr F told HDC that he also recommended that Mr A be administered antibiotics.

33. The results of the X-rays performed on 14 January 2019 were reported by a consultant radiologist at 11.13am on 15 January 2019. The radiologist noted that the X-ray showed a "circular low density rim overlying the lower abdomen, this is likely to represent a post-surgical catheter and clinical correlation suggested". Dr F told HDC that this was not conveyed to him at the time.

34. The CT scan was performed at 11.00am and reported by a consultant radiologist at 11.37am. The radiologist's report concluded:

> "There is a coiled drain lying within the anterior abdomen which is surrounded by mildly rim enhancing fluid, in keeping with a foreign body reaction. The fluid surrounding the drain is likely infected."

35. At 5pm, a house officer discussed the results of the CT scan with Mr A. The house officer's plan was to continue IV antibiotics and keep Mr A NBM.

36. Dr F told HDC that he was made aware of Mr A's CT results that evening after his elective surgery list. He said that later that evening he was also told that there was no external component to the surgical drain, and therefore it was presumed that Mr A had a retained surgical drain, or a drain that had broken upon removal. Dr F stated:

> "Ordinarily this would have prompted surgery, though because [Mr A] had metastatic colorectal cancer I considered it necessary to first seek advice from oncology. I felt it more than likely that [Mr A] would require return to theatre, however due to the fact he was stable and had an improving inflammatory count we had time to ensure there were no other potential non-surgical options."

37. Dr F told HDC that he advised his team that it was highly likely that Mr A would need surgery.

16 January 2019

38. Dr F said that on 16 January 2019 he had a rostered public endoscopy list at Waitakere Hospital, and was unable to meet with Mr A that day. Dr F stated:

> "I arranged for my team to meet with [Mr A] in my absence with a plan that I could see him the following day with the benefit of input from oncology and a clearer picture of his treatment options."

39. At 7.30am on 16 January 2019, Mr A was seen by senior surgical registrar Dr K, junior registrar Dr L, and house officer Dr M during morning ward rounds. Dr M documented that

[16] A set of biomarkers including C-reactive protein, erythrocyte sedimentation rate, and plasma viscosity, which can indicate the presence of an infective disease, among other conditions.

Mr A was reporting 7/10 pain. The clinical notes record that Mr A was told that the scans showed either a foreign body (the tip of a drain) or an anomaly in the scan. The documented plan was to continue with IV antibiotics and keep Mr A NBM. WDHB told HDC that the team also planned for further discussion with radiology to identify the likely material of the foreign body.

40. At 12.30pm, Mr A met with Dr L, along with a junior registrar and the Charge Nurse Manager. WDHB told HDC that this team had discussed with Dr F "a radiology opinion that reinforced the assumption that the retained foreign body … was most likely a drain that had remained in the abdomen after the external section of the drain had been removed". Dr L documented that she advised Mr A of Dr F's recommendation "to leave [the] drain [in place] due to the high risk of doing harm in taking [the] drain out with an operation". WDHB told HDC that Mr A felt that it was unlikely that the retained foreign body could have been a drain, as a "long length of drain had been removed". Dr L documented that Mr A accepted Dr F's recommendation but was concerned that he was in a lot of pain and was nauseous.

41. At 1.38pm, Dr L also documented that she had spoken with the oncology team, and that they had told her that Mr A would be seen in clinic on 22 January 2019 and might still commence chemotherapy. She also recorded having discussed Mr A with Dr F, and that Dr F advised that Mr A was not for surgery but would possibly be seen by Dr E in clinic on 21 January 2019.

17 January 2019

42. At 7.30am on 17 January 2019, Mr A was seen by Dr K, along with Dr L and a house officer during morning ward rounds. WDHB told HDC that Mr A reported ongoing pain and nausea, and wanted the foreign body removed. Mr A told HDC that at this point Dr K told him that the size of the retained drain was small, "about 2cm long only". Mr A stated that Dr K also suggested that he be discharged and "put on tramadol as the body is good at encapsulating these small foreign bodies". Mr A said that he told Dr K he was not going home.

43. At 12.50pm, Mr A was seen by Dr F, along with Dr K. Dr F told HDC that he had decided to spend some time with Mr A to talk about the options, because he had been made aware that "there had been an uncomfortable interaction" during the morning ward round, and that Mr A "had been advised that there was only a small portion of drain left in-situ". Dr F stated:

> "At no point did I want [Mr A] to be discharged home. I wanted [Mr A] to be aware of the potential issues that come with operating at the 3–4 week mark post complicated surgery, the increasing metastatic burden and the potential that surgery may cause a delay to chemotherapy. I advised [Mr A] and his wife that I would support them with whatever decision they made, at which point they understood the potentially serious nature of the re-operation and they were quite keen, as I was, to think about it for the evening and night before coming to a final decision."

44. Mr A told HDC that he was impressed with how Dr F admitted, at this meeting, that it was not a small piece of drain. Mr A further stated: "I instructed [Dr F] to surgically remove it. He said he will consider this and let me know."

Surgery to remove retained instrument

45. On the morning of 18 January 2019, the clinical notes record that Mr A was "feeling very sore" and "really want[ed] the drain out". Mrs A told HDC that at that point her husband demanded that the drain be removed because his pain was intolerable.

46. The decision was made to remove the retained object laparoscopically, and Mr A went to theatre at 2pm on 18 January 2019. During the procedure, the surgical team found that the retained instrument was an AWR, not a surgical drain. They found adhesions to the AWR from the peritoneum, small bowel, and colon, but the AWR was removed successfully. Dr F told HDC that had he known that the retained instrument was an AWR, he would have recommended surgery on the first day.

47. Mr A told HDC: "It most certainly was not a small piece of drain it was [an AWR] the size of a bread and butter plate." Photos of the AWR removed from Mr A were provided to HDC. Several of the photos show the AWR being held by two hands. The diameter of each of the plastic rings at either end of the AWR appear to be equal to or larger in size than one of the hands.

Subsequent events

48. On 21 January 2019, Mr A met with Dr E, who apologised to Mr A for the event and took over Mr A's care. Mr A was discharged home on 25 January and began chemotherapy on 29 January.

Relevant policies

49. At the time of events, WDHB's Theatre Count — Surgical Unit Policy (the Count Policy) provided:

> "This document is intended to ensure patient and staff safety by appropriately accounting for all countable items used (swabs, needles, and instruments) on and off the surgical field."

50. It further stated that "[a]ll items in the sterile field are counted", and that the count is conducted "[w]henever countable items are added to the sterile field". The following items were listed in the policy as being included in the initial count:

- Small swabs
- Large swabs
- Blades, atraumatic needles, hypodermics, diathermy tips, ligature reels, tapes, vessel loops, liga-clip cartridges
- Instruments
- Extras

Further information

Mrs A

51. In her complaint, Mrs A told HDC:

> "We cannot stress enough, the impact of this error on our family. [Mr A] is angry, frustrated, and again in post-surgical pain. … We are also extremely concerned about the avoidable delay to his chemotherapy when he has aggressive liver tumours. Furthermore, the second surgery and his significant weight loss in hospital may lessen the efficacy of his chemotherapy given that his body is in poorer condition than after his first surgery in December [2018]."

WDHB

52. WDHB sincerely apologised to Mr A and his family for the distress that this incident caused, and for any impact on his treatment as a result. WDHB told HDC that its team reflected on the incident and also expressed their concern for Mr A and the distress this event has caused him.

53. WDHB noted that the following factors may have contributed to the retention of the AWR:

- The operation on 27 December 2018 was challenging and required surgeons to alternate between laparoscopic and open approaches, which may have caused the AWR to become displaced.
- The AWR was not on the surgical equipment or final count sheets. WDHB's theatre count policy (set out below) did not list specific items to be counted, and it was not custom and practice to include AWRs in the count.
- Performing a thorough abdominal washout via a Pfannenstiel incision requires vigorous pushing through the wound, which may have caused the AWR to become displaced.
- The operation was long, possibly resulting in staff fatigue, which may have contributed to the failure to recognise that the AWR had become displaced.

<u>Changes made</u>

54. Following these events, WDHB amended its Count Policy to define "Countable Items" as including "[s]ingle use items/equipment e.g. wound protector/retractor, specimen bags".

55. In addition, the SAER Report recommended the following actions:

- Regular auditing of compliance with the revised Count Policy to be undertaken.
- Simplification and standardisation of theatre tray lists.
- Formal discussion of this incident at the General Surgical Audit Meeting.
- Setting aside "safe time" for commencing the count prior to closure of the cavity.
- A rolling multi-disciplinary education programme to include case studies and simulation-based training.

- This incident to be provided as a case study for use as part of WDHB's house officer orientation and teaching programme.

Responses to provisional opinion

56. Mrs A and WDHB were both given the opportunity to respond to the relevant sections of my provisional opinion.

57. Mrs A told HDC that she felt as though they never received an appropriate apology from the start. She stated that had WDHB staff owned up immediately and properly apologised for the error straight away, she and Mr A would have been fine. She also said that these events had a significant impact on Mr A, and that his mental health declined following this.

58. WDHB told HDC that it fully accepts the report and its findings.

Opinion: Waitematā District Health Board — breach

Introduction

59. District health boards are responsible for the services they provide. This includes a responsibility for the actions of their staff, and an operational responsibility to ensure that appropriate systems are in place to encourage a culture of safety and to support clinicians to carry out their roles safely and effectively.

60. As noted by my expert surgical nursing advisor, Rosalind Jackson, a number of assumptions were at play in this case:

> "Responsibility for the Alexis retractor was assumed to be the surgeon's (insertion, use and removal), assumed to have been placed in the rubbish by either the surgeon or scrub nurse, assumed that it would not be able to be retained due to its size and assumption and surprise that not all instruments were part of the count (surgical team)."

61. This case highlights the risks in assuming that a highly unlikely event — in this case, the retention of a large surgical instrument — would not happen. It also reinforces the importance of routine safety checks during surgery.

Initial surgery

Retention of AWR

62. As has been outlined above, during emergency surgery on 27 December 2018, an AWR was left in Mr A's abdomen. The AWR was not included in the surgical count. It was discovered on 18 January 2019 following Mr A's readmission for worsening abdominal pain and associated nausea.

63. I note the comments from my general surgeon advisor, Dr Christoffel Snyman:

> "Although the only possible verdict regarding this procedure must be that of severe deviation from standard of care, I am careful not to callously label it as negligent. It is, however, indefensible as there is no doubt that an instrument of any sort should not be left in the abdomen.
>
> … It is difficult to appreciate that the Alexis retractor, based on its size would have been missed had a routine check been performed. Regardless, the Alexis retractor was left in situ and this constitutes a severe deviation from standard of care."

64. Plainly, the retention of the AWR was a significant failure and I accept Dr Snyman's advice in this respect. I consider that there was a collective failure by WDHB's surgical team to:

- Recognise when the AWR became displaced and was pushed fully into Mr A's abdomen; and
- Check the abdomen adequately prior to closure of the surgical wound and, therefore, to recognise that the AWR had been retained.

65. In my view, this failure reinforces the need for vigilance during surgery, and the risks of not completing standard safety checks.

Surgical count and Count Policy

66. Both RN I and RN J, who together performed the surgical count, as well as RN G, told HDC that the AWR was not included in the surgical count. RN H told HDC that AWRs were counted in the public hospital's separate Elective Surgery Centre. Dr B, Dr C, and Dr D were either unaware that the AWR was not included in the count, or assumed that the AWR was included. WDHB also told HDC that it was not custom and practice to include AWRs in the count.

67. WDHB's Count Policy at the time of events did not explicitly include AWRs in the list of items included in the surgical count. The Count Policy did state that "[a]ll items in the sterile field are counted", but subsequently provided for the count to be conducted "[w]henever countable items are added to the sterile field". There was no definition of what was included as a "countable item".

68. RN Jackson noted:

> "The RNs stated that it is their understanding that all items in the surgical field are accounted for and that all wound retractors are a countable item. However, they consistently went on to qualify that this only applied to reusable retractors and 'countable items' and that the Alexis was not included in this description and therefore not counted. … [I]t was contradictory to not have included the Alexis wound retractor simply because it was a single use item, only found on the surgeon's preference list and not previously included in the surgical count."

69. While noting that Dr Snyman's advice that the Count Policy was adequate, I also note RN Jackson's comment that the Count Policy emphasised "countable" items, which would have reinforced the nurses' practice of excluding the AWR. RN Jackson advised:

> "Given the risk and consequences to a patient of a retained object, and disconnect between policy interpretation and practice, inadequacy of the policy to inform practice would have to be considered a severe departure from accepted standards."

70. RN Jackson also advised that while responsibility for the surgical count rested with RN I and RN J as the scrub and circulating nurses, retention of the AWR can be attributed to a systems failure. I agree, and accept RN Jackson's advice. In my view, the culture of excluding AWRs and other items from the surgical count was very risky, and was reinforced by the fact that the Count Policy did not provide sufficiently clear guidance on whether AWRs should be included in the count.

71. As RN Jackson noted, this failure suggests that some WDHB staff did not fully understand the purpose behind the Count Policy. In my view, it also demonstrates a concerning lack of critical thinking by some staff as to the risks of not counting all surgical items that enter the sterile field, and that WDHB had not adequately maintained a culture of safety amongst its staff with respect to surgical counts.

Documentation

72. As acknowledged by Dr B, I note that the operation note did not refer to the use of the AWR. While this may be a relatively minor oversight, it is unfortunate that there was no record of the AWR being used. Had the operation note included this information, potentially it could have guided the subsequent decision-making relating to the identification of the retained item after Mr A re-presented to the public hospital on 14 January 2019 (as discussed below).

Mr A's re-presentation to hospital

73. On 14 January 2019, Mr A re-presented to hospital with worsening abdominal pain and nausea. A CT scan completed the following day showed what was thought to be a retained surgical drain. This finding was discussed with Mr A by a house officer at 5pm, and Dr F was made aware of the finding later that evening. On 16 January 2019, Mr A was told by registrars that Dr F had recommended leaving the retained instrument in situ. On 17 January 2019, Mr A was seen again during morning ward rounds. Dr K told Mr A that the retained drain was small, and suggested that he could be discharged home.

74. At 12pm on 17 January 2019, Dr F met with Mr A and discussed management of the retained item. The following day, Mr A underwent surgery and it was discovered that the retained item was an AWR.

Team communication

75. Dr Snyman noted that Dr F's intention was always to remove the retained object surgically. However, Dr Snyman also noted:

> "The registrar ward round on the morning of 17 January 2019 suggested that [Mr A] could go home with the 'drain' in situ. [Dr F] then had to meet with [Mr A] later on the 17 January 2019 to clarify matters. [Dr F] states that at this meeting it was clarified that [Mr A] was not for discharge and that it was likely that [Mr A] required theatre. This does not sound like a cohesive team approach where everyone is following the same thought line."

76. Dr Snyman considers that Mr A was given mixed messages and, at times, conflicting information from the team. Dr Snyman commented:

> "This was at a time when [Mr A] and his family were at their most vulnerable, the future uncertain and [Mr A] in desperate need of a unified clear message. From my review, this unified message and clear communication did not happen."

77. Dr Snyman advised that the poor team communication constituted a moderate departure from the standard of care. I note that Dr F said that he made his team aware that it was highly likely that Mr A would need surgery; however, it appears that not all his team understood this. I therefore accept Dr Snyman's advice. In my view, given the significance of a retained surgical instrument, and Mr A's vulnerabilities as a patient recently diagnosed with cancer and awaiting further treatment, it was vitally important that the clinicians communicated clearly between themselves and with Mr A as to the management plan. This did not happen. Clear communication between all parties could have lessened the stress of this event for Mr A and his family.

Conclusion

78. In my view, a number of failures by a number of WDHB's staff and systems were evident in the care provided to Mr A. Specifically:

- There was a collective failure by the surgical team to recognise the initial displacement of the AWR and, subsequently, that the AWR remained in Mr A's abdomen.
- The practice of AWRs being excluded from the count was very risky, and was reinforced by the Count Policy not providing sufficiently clear guidance.
- There was an apparent lack of understanding by some WDHB staff as to the purpose of the Count Policy, and a lack of critical thinking by some staff as to the risks of not counting all surgical items that enter the sterile field.
- The operation note was deficient in that it did not record the use of the AWR.
- There was poor communication by the surgical team who provided care to Mr A after he re-presented with the retained instrument.

79. Individual staff members hold some degree of responsibility for their failings. However, cumulatively, these omissions represent systemic issues for which ultimately WDHB is responsible. I therefore find that WDHB failed to provide services to Mr A with reasonable care and skill and, accordingly, that it breached Right 4(1) of the Code.

Recommendations

80. I recommend that WDHB:

a) Provide evidence to HDC that all of the recommendations arising from its SAER Report have been implemented, within three months of the date of this report.

b) Establish a process for ensuring that the list of countable items in the Count Policy remains current and is updated when new surgical items and technology are introduced. Evidence of the new process is to be provided to HDC within three months of the date of this report.

c) Undertake a random audit of documentation for ten surgical procedures to assess compliance with the updated Count Policy. A documented report of the results of the audit, including remedial actions where there has not been 100% compliance, should be provided to HDC within three months of the date of this report.

d) Provide training to its surgical staff on the importance of vigilance and challenging assumptions, using the anonymised version of this report as a case study. Evidence of this training is to be provided to HDC within three months of the date of this report.

e) Provide a written apology to Mr A's family for the failures identified in this report. The apology is to be sent to HDC, for forwarding to the family, within three weeks of the date of this report.

Follow-up actions

81. WDHB will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken.

82. A copy of this report with details identifying the parties removed, except WDHB and the experts who advised on this case, will be sent to the Health Quality & Safety Commission, the Royal Australasian College of Surgeons, and the New Zealand Nurses Organisation, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Addendum

83. The outcome of the referral to the Director of Proceedings was a restorative settlement by way of negotiated agreement. No formal proceedings were taken by the Director.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from general surgeon Dr Christoffel Snyman:

> "I have been asked by the HDC to provide an opinion to the Commissioner on case number C19HDC00159.
>
> I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.
>
> My name is Christoffel Gerhardus Snyman. I hold an Australasian fellowship in general surgery (FRACS) since 2003. I am a full time consultant general surgeon in a medium sized public hospital. I perform acute and elective surgery. Colorectal surgery is a major part of my work load.
>
> I do not have a personal or professional conflict in this case.
>
> **Expert advice requested**
>
> Please review the enclosed documentation and advise whether you consider the care provided to [Mr A] by Waitematā DHB was reasonable in the circumstances, and why.
>
> In particular, please comment on:
>
> 1. The standard of care provided during the 27 December 2018 procedure;
> 2. The overall standard of care provided from [Mr A's] presentation on 14 January 2019 to 18 January 2019, when the retained instrument was removed;
> 3. Whether the theatre count policy in place at the time the care was provided was appropriate and in line with accepted standards of practice and the adequacy of the subsequent changes made to the theatre count policy (Additional question requested by email 31 July 2019);
>
> And
>
> 4. Any other matters that you consider amount to a departure from accepted standards of care.
>
> For each question, please advise:
>
> a. What is the standard of care/accepted practice?
> b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?
> c. How would it be viewed by your peers?
> d. Recommendations for improvement that may help to prevent a similar occurrence in future.

Documents provided

- Letter of complaint dated 22 January 2019
- Waitematā DHB's response dated 4 April 2019
- Clinical records from Waitematā DHB from December 2018 to January 2019
- Timeline of events provided by Waitematā DHB
- A copy of the surgical unit theatre count policy in place at the time the care was provided and a copy of the subsequent updated policy

Additional Resource

- Peri-operative standards and recommended practices. AORN, 2008, p 293–302
- Retained surgical items and minimally invasive surgery. V.C. Gibbs. World J Surg (2011) 35: 1532–1539
- Risk factors for retained instruments and sponges after surgery. Gawande et al. N Engl 1 Med 2003; 348: 229–235
- Retained surgical sponges, needles and instruments. Hariha ran et al. Ann R coil Surg Engl 2013; 95: 87–92
- Management of instruments, accountable items and other items used for surgery or procedures. NSW government health policy directive. December 2013. Document number PD2013_054.

Summary

On 27 November 2018, [Mr A] underwent a flexible sigmoidoscopy and stenting at [the public hospital]. On 27 December 2018, he re-presented with colonic stent perforation and underwent laparoscopically assisted Hartmann's procedure. On 14 January 2019, [Mr A] was re-admitted to [the public hospital] as he was experiencing pain in his abdomen. An X-Ray and CT scan showed the presence of a foreign body, which was initially believed to be a broken drain. On 18 January 2019, a procedure was undertaken to remove the object, which was discovered to be an Alexis wound retractor, retained since the 27 December 2018 procedure.

The standard of care provided during the 27 December 2018 procedure

Prospectively: No deviation from standard of care

My peers would be comfortable with the choice of procedure and decisions made during the procedure

Retrospectively: Severe deviation from standard of care

My peers would agree this is the only verdict possible

Education, vigilance and improved theatre process will minimise the risk of a recurrence.

1. Although the only possible verdict regarding this procedure must be that of severe deviation from standard of care, I am careful not to callously label it as negligent. It is, however, indefensible as there is no doubt that an instrument of any sort should not be left in the abdomen.

2. The management of [Mr A] surrounding his stent associated colon perforation was well within standard of care.

3. He was assessed, investigated and treated surgically within an appropriate time frame. The notes list him as arriving by ambulance at 05h30 in the morning. He was in theatre being anaesthetised according to the anaesthetic record by 11h45. The choice to decide to proceed with either an open or laparoscopic operation depends on the skill set of the surgeon and either would be appropriate.

4. The anaesthetic record lists the procedure finish time as 16h40. The dictated procedure note describes the procedure and decisions and reasons for them adequately. It is not always possible to restore bowel continuity at the end of a resection. In [Mr A's] case this resulted in a Hartmann's procedure. It is a very common end result of an emergency procedure to fix a perforated colon, whatever the cause. The surgery note lists the surgeon as being [Dr B], and notably, assisted by [Dr E]. [Dr B] was a colo-rectal fellow at the time. A colo-rectal fellow has usually already passed their general surgery specialist exams and is sub-specialising in colo-rectal surgery specifically. [Dr E] is a senior specialist colo-rectal surgeon. I would therefore consider the skill set involved in [Mr A's] surgery to have been adequate.

5. The literature states that the retention of a surgical instrument is a rare event with an incidence of between 1 in 8 000 to 1 in 19 000 operations. Often this can happen in patients who had complete instrument counts without deviation from standard theatre procedure at the time of closure. The most common retained surgical instrument is a swab (40%) followed by various retractors (20%).

6. Risk factors identified in the literature for retained instruments are:

   - Emergency procedure
   - Change in planned procedure due to unexpected findings at surgery
   - Change of staff
   - Different staff closing wound compared to primary surgeon
   - Prolonged operative time
   - Surgical team fatigue
   - Raised BMI

- Blood loss
- Female patient

Multiple of these risk factors were present during the case.

7. In the reply from Waitematā (point 11), the surgical team indicate that they are uncertain and do not recollect specifically checking the abdomen prior to closure. It is difficult to appreciate that the Alexis retractor, based on its size would have been missed had a routine check been performed. Regardless, the Alexis retractor was left in situ and this constitutes a severe deviation from standard of care.

8. The theatre process is covered by question 3.

The overall standard of care provided from [Mr A's] presentation on 14 January 2019 to 18 January 2019, when the retained instrument was removed

Moderate to severe deviation from standard of care.

My peers would agree that it could have been managed better.

Education in adverse event and full disclosure management will improve the management of any future major events.

9. [Mr A] was readmitted with abdominal pain 14 January 2019. The admission documentation notes pain and tenderness in the abdomen. There is mention of X-Rays done as part of the admission. There is one instance noted of the chest and abdominal X-rays to be unremarkable. It is disappointing that the abnormality was not appreciated on the X-ray at this time.

10. There was a consultant led ward round on 15 January 2019 at 09h30 the next morning and the plan was to perform a CT scan. There is no mention in the notes to indicate the team was aware of the abnormal X-ray at this stage. The official report of the X-ray was not available until 11h13 (point 21) at which stage [Mr A] was already having a CT scan.

11. The CT was performed at 10h47.

12. The House Surgeon documented informing [Mr A] of his CT result at 17h00 on 15 January 2019. There is no documentation to indicate that this result was conveyed or known to the registrar or the consultant at this stage.

13. In Waitematā's reply (point 16) it is stated that [Dr F] and his team reviewed both the X-ray and the CT scan. They assumed that it was a surgical drain with an external component.

14. I find this difficult to believe.

At this stage [Mr A] was almost 3 weeks post-surgery with a routine discharge at the time. Surgical drains in the absence of known and continued complexity are long since removed at this stage. [Mr A] was admitted and assessed by the admitting surgical team on 14 January 2019, no mention of a drain was made. [Mr A] was seen by [Dr F] and team the next morning on the ward round. Although the documentation is sparse, the diagram and associated writing makes no mention of a drain in place. CT scans, being what they are, would have showed conclusively that there was no external component to the 'drain' seen on CT. I therefore can only conclude that the assessment of [Mr A] and his radiology investigations by [Dr F] and his team at that stage to be below the standard I would expect for a team review of the situation.

15. [Mr A] was seen by the registrar on 16 January 2019 and assessed to have continuing pain. The possibility of a retained foreign body is documented at the time. A further entry at 12h30 by the registrar indicates that [Dr F] had been informed of the diagnosis of retained drain and that the recommendation was to leave the drain in situ. This decision is reinforced at 13h38 after further discussion with [Dr F] and oncology.

16. Waitematā indicate in their reply the reasons for recommending this plan (points 17 and 18).

17. It is disappointing that at the time of discussing the possibility of a retained drain, [Mr A] was not listened to with more attention. Waitematā response (point 29) states that [Mr A] felt that a long length of drain had been removed. Although neither the X-ray nor the CT report mentions the measured length of the 'drain', both refer to a coiled or circular catheter or drain. This implies an object of some length to be able to coil. The original 2 drains were removed on 31 December 2018. The nursing note on 31 December 2018, 13h00, reports no concerns or difficulty regarding drain removal. This should have suggested that it is unlikely to be a retained drain. This should have alerted the team to the possibility of retained instruments other than drains. Had this been considered earlier, it may have swayed the team towards the decision to remove whatever it may be, sooner.

18. [Mr A] was reviewed by the registrar on 17 January 2019 at 07h30 and by [Dr F] at 12h50. This was the first time [Mr A] and his wife was seen by the consultant following his CT scan.

19. [Mr A] proceeded to theatre on 18 January 2019.

20. I find the management of the retained instrument to be below the standard I would expect from a surgeon in New Zealand. I have no doubt that my colleagues would agree.

21. As soon as a retained instrument or foreign body following surgery is diagnosed, the default approach should be to remove it. It was never meant to be there. Leaving the object in place exposes the patient to potential further harm. In highly selected cases, a conservative approach could be considered based on an incidental finding long after the procedure was done, and being asymptomatic at the time of discovery. It would appear from my review of the literature that even then, the preference is to remove it. [Mr A's] retained instrument was neither incidental nor asymptomatic or long after the procedure. [Mr A] presented with abdominal pain within 3 weeks of his surgery and specific investigations to determine a cause, found a retained instrument. It is my opinion that the response to that should have been a plan to remove it as soon as appropriate. Waitematā response (point 37) indicates that if they had been aware of the nature of the foreign body, they would have acted sooner. This does not make sense to me as [Mr A's] symptoms and presentation was not dependent on the type or size of retained instrument, but on the retained instrument itself.

22. I acknowledge that the holistic approach in [Mr A's] case took into consideration the potential delay to chemotherapy. However, this should have been considered in the context of timing the removal, not as a consideration for continued conservative management. It is unlikely that chemotherapy in the presence of a symptomatic retained instrument would have been successfully tolerated.

23. The discovery of a retained instrument or drain is a significant and traumatic event for all parties involved. This includes the patient, their family, the surgical team and the hospital. I acknowledge that as surgeons we are often required elsewhere and frequently will have competing engagements through the day. However, I do find it disappointing that after the team evaluated the results on the 15 January 2019, it took until the 17 January 2019 for [Mr A] to have an opportunity to see and discuss the results and options available to him with the consultant leading his care at the time.

24. It is worth reflecting that if a full disclosure meeting between senior staff and [Mr A] and his family had taken place earlier, a more definitive and consultant initiated plan would have resulted in clearer communication to [Mr A] (point 45).

25. Fundamentally I do not have a specific opinion on the time it took for [Mr A] to go to theatre. My concern centres round what translates via the notes and the complaint as a disorganised and lack of decisive senior initiated care. There appears to have been a disappointing lack of clarity in the communication between the surgical team and [Mr A] and his family.

Whether the theatre count policy in place at the time the care was provided was appropriate and in line with accepted standards of practice and the adequacy of the subsequent changes made to the theatre count policy (Additional question requested by email 31 July 2019)

The policy itself was adequate with no deviation from standard of care.

The interpretation of the policy was incorrect in relation to an Alexis retractor. This misinterpretation has directly contributed to the retained surgical instrument and therefore is a major deviation from standard of care.

The updated policy better clarifies and expands on what was already covered in the original policy.

26. A 'Count Policy' or similar has the simplified purpose of ensuring that no surgical instrument is unintentionally left in the patient. These policies have evolved and continue to evolve as procedures and instruments change.

27. The end of procedure count relies as much on the surgeon being satisfied that no instruments remain in the patient as it does on the nursing count to confirm no countable instruments remain in the patient. This incident is therefore a failure of the end of procedure process.

28. The Waitematā DHB theatre count policy (010805-20-002), April 2018, does not specifically state that Alexis retractors must be counted, nor does it list Alexis retractors as excluded from the count. The document mentions that the policy applies to 'all countable items' and references 'surgical instruments' as part of the count. An Alexis retractor is by definition a disposable surgical wound protector and retractor. Common sense would dictate that this would be included under those terms in the count.

29. The updated policy is more comprehensively explained with up to date examples of what is meant by the various headings and collective terms. This is without doubt a clarified and improved document.

Any other matters that you consider amount to a departure from accepted standards of care.

None."

The following further advice was obtained from Dr Snyman:

"I have been asked by the HDC to provide further comment to the Commissioner on case number C19HDC00159.

Amendment

15 July 2020: I have since this report been provided with the correct Adverse Events Management policy November 2018. I have amended point 21, and deleted my original point 22 to reflect this. My original point 29 has been deleted as it is no longer applicable.

Please note my previous two reports on the case.

I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

My name is Christoffel Gerhardus Snyman. I hold an Australasian fellowship in general surgery (FRACS) since 2003. I am a full time consultant general surgeon in a medium sized public hospital. I perform acute and elective surgery. Colorectal surgery is a major part of my work load.

I do not have a personal or professional conflict in this case.

Advice requested

Please review the enclosed documentation and advise whether it causes you to amend the conclusions drawn in your initial advice, or make any additional comments.

Documents provided

- Waitematā DHB's response dated 18 February 2020 and 12 enclosures.

Summary

On 27 November 2018, [Mr A] underwent a flexible sigmoidoscopy and stenting at [the public hospital]. On 27 December 2018, he re-presented with colonic stent perforation and underwent laparoscopically assisted Hartmann's procedure. On 14 January 2019, [Mr A] was re-admitted to [hospital] as he was experiencing pain in his abdomen. An X-Ray and CT scan showed the presence of a foreign body, which was initially believed to be a broken drain. On 18 January 2019, a procedure was undertaken to remove the object, which was discovered to be an Alexis wound retractor, retained since the 27 December 2018 procedure.

The standard of care provided during the 27 December 2018 procedure

Prospectively: No deviation from standard of care

My peers would be comfortable with the choice of procedure and decisions made during the procedure

Retrospectively: Severe deviation from standard of care

My peers would agree this is the only verdict possible

Education, vigilance and improved theatre process will minimise the risk of a recurrence.

1. My original opinion stands as that of severe deviation from standard of care regarding the retained instrument.
2. I have taken note of the reports and reflections around the procedure from the four surgeons, [Dr D], [Dr B], [Dr E] and [Dr C].

The overall standard of care provided from [Mr A's] presentation on 14 January 2019 to 18 January 2019, when the retained instrument was removed

Moderate to severe deviation from standard of care.

My peers would agree that it could have been managed better.

Education in adverse event and full disclosure management will improve the management of any future major events.

3. I would change my opinion to overall **moderate deviation from standard of care**.

4. I have read [Dr F's] reply.

5. This opinion is based on:

   - Team communication,
   - Management of an adverse event
   - Management of a retained surgical foreign body.

Team Communication (Moderate deviation from standard of care)

6. My original report (07 August 2019) points 12, 15, 23, 24, 25.

7. [Dr F] states in his report that the team was always aware that [Mr A] will most likely need to go to theatre. I acknowledge that a lot of our thoughts and conversations within our teams are not always documented in the notes. However, the overriding impression from my review of the notes and the complaint is that neither [Mr A], nor the team as a whole, was made aware of this.

8. This impression is supported by [Dr F's] own statement.

9. A family meeting between the registrars, nursing staff and [the] family was held on 16 January 2019. [Dr F] states in his report that this was to get further information on non-surgical options prior to going to theatre. If the team were communicating the same consistent plan, then there would not have been confusion on the ward round the next day.

10. The registrar ward round on the morning of 17 January 2019 suggested that [Mr A] could go home with the 'drain' in situ. [Dr F] then had to meet with [Mr A] later on the 17 January 2019 to clarify matters. [Dr F] states that at this meeting it was clarified that [Mr A] was not for discharge and that it was likely that [Mr A] required theatre.

11. This does not sound like a cohesive team approach where everyone is following the same thought line.

12. My opinion is that the communication amongst the surgical team members and to [Mr A] fell below the standard of care.

Management of an adverse event (moderate deviation from standard of care)

13. I acknowledge [Dr F's] statement in his final paragraph that few surgeons have ever had to deal with a similar situation. I acknowledge that for most surgeons and their immediate colleagues this situation will be alien and difficult to deal with. I sincerely hope that no surgeon will ever have to deal with a similar situation.

14. It is worth noting that [Dr F] was not involved in any of the original decisions or surgical procedures.

15. However, as senior surgeons we have an obligation and a duty to acknowledge and manage adverse events and to acknowledge the patient at the centre of the event.

16. There are multiple policies and ways to deal with a serious adverse event. But in principle the steps are the broadly the same:

    a. Recognise and acknowledge the event.

    b. Ensure patient safety and no continued or worsening harm.

    c. Escalate and inform the senior clinicians and appropriate managers, Quality and Risk department.

    d. Inform the patient, and preferably their family, of the event and set a clear plan going forward.

    e. Usually within 24 hours.

    f. Investigation part of process to follow.

    g. Conclusions, reports and feedback.

17. [Dr F] stated in his reply that he was made aware of the CT result and likely retained surgical foreign body by the evening of 15 January 2019. He did not personally talk to [Mr A] until midday 17 January 2019.

18. I would expect that the consultant surgeon would be informing and explaining the diagnosis of a retained surgical foreign body to the patient within 24 hours of becoming aware of it. This would fit with most policies and guidelines around serious and sentinel events and full disclosure meetings.

19. It is worth reflecting that if a consultant had met with [Mr A] on the morning of the 16 January 2019, acknowledging the retained surgical foreign body, the plan to explore the impact on existing care plans and raise the high likelihood of surgery to remove it, most of the confusion as raised by the complaint and the review of the notes could have been avoided.

20. As a result, I feel this constitutes a moderate departure from standard of care.

21. Waitematā DHB has included their policy on Adverse Events. This supports in broad strokes my point in 16.

Management of a retained surgical foreign body (modified to No deviation from standard of care).

22. [Dr F] clarifies in his report that his opinion and intention were always to remove the object.

23. This would be in line with standard of care.

24. This opinion was not clear from my previous review of the case.

25. See my comments on team communication. See further points 21, 22, 23 my report 07 August 2019.

Whether the theatre count policy in place at the time the care was provided was appropriate and in line with accepted standards of practice and the adequacy of the subsequent changes made to the theatre count policy (Additional question requested by email 31 July 2019)

The policy itself was adequate with no deviation from standard of care.

The interpretation of the policy was incorrect in relation to an Alexis retractor. This misinterpretation has directly contributed to the retained surgical instrument and therefore is a major deviation from standard of care.

The updated policy better clarifies and expands on what was already covered in the original policy.

26. My opinion on this stands.

27. The updated policy — July 2019 — is a much improved version.

Any other matters that you consider amount to a departure from accepted standards of care.

28. Some concern with statements in [Dr F's] report: 'long standing' and 'acute on chronic' abdominal pain. Definition of chronic abdominal pain is taken as pain persisting beyond 3 months. [Mr A] was only 4 weeks post surgery. If these statements referred to general abdominal pain separate to [Mr A's] post-operative pain, then please ignore this comment."

The following further advice was obtained from Dr Snyman:

"I have been asked by the HDC to provide a further opinion to the Commissioner on case number C19HDC00159.

I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

My name is Christoffel Gerhardus Snyman. I qualified as a Fellow of the Australasian College of Surgeons (FRACS) in 2003. I am a full time consultant general surgeon in a public hospital. I perform acute and elective surgery. Colorectal surgery is a major part of my work load.

I do not have a personal or professional conflict in this case.

Please take note of previous reports:

07 August 2019 — Initial report

18 March 2020 — Second report

15 July 2020 — Amendment to second report

Original Expert advice requested

Please review the enclosed documentation and advise whether you consider the care provided to [Mr A] by Waitematā DHB was reasonable in the circumstances, and why.

In particular, please comment on:

1. The standard of care provided during the 27 December 2018 procedure;
2. The overall standard of care provided from [Mr A's] presentation on 14 January 2019 to 18 January 2019, when the retained instrument was removed;
3. Whether the theatre count policy in place at the time the care was provided was appropriate and in line with accepted standards of practice and the adequacy of the subsequent changes made to the theatre count policy (Additional question requested by email 31 July 2019);

And

4. Any other matters that you consider amount to a departure from accepted standards of care.

For each question, please advise:

a. What is the standard of care/accepted practice?

b. If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be?

c. How would it be viewed by your peers?

d. Recommendations for improvement that may help to prevent a similar occurrence in future.

Documents provided and reviewed

- Letter of complaint dated 22 January 2019
- Waitematā DHB's response dated 4 April 2019
- Waitematā response 18 February 2020
- [Dr F's] response dated 18 December 2019
- [Dr F's] response 27 July 2020
- Professor Frizelle's report

Updated Summary following review of documentation

1. The standard of care provided during the 27 December 2018 procedure.

Prospectively — No deviation from standard of care.

Retrospectively — Severe deviation from standard of care.

2. The overall standard of care provided from [Mr A's] presentation on 14 January 2019 to 18 January 2019, when the retained instrument was removed

Management of a retained surgical foreign body — No deviation from standard of care.

Management of adverse event — No deviation from standard of care.

Team communication — Moderate deviation from standard of care.

3. Whether the theatre count policy in place at the time the care was provided was appropriate and in line with accepted standards of practice and the adequacy of the subsequent changes made to the theatre count policy (Additional question requested by email 31 July 2019)

No deviation from standard of care

4. Any other matters that you consider amount to a departure from accepted standards of care.

None

Questions 1 and 3 have been covered in previous reports with no new changes.

The overall standard of care provided from [Mr A's] presentation on 14 January 2019 to 18 January 2019, when the retained instrument was removed

Management of a retained surgical foreign body — No deviation from standard of care.

Management of adverse event — No deviation from standard of care.

Team communication — Moderate deviation from standard of care.

1. I have chosen to answer this question under the above three subsections.

Management of a retained surgical foreign body

2. My original opinion of moderate to severe deviation from standard of care has been modified in subsequent reports to No Deviation from standard of care in relation to the management of a retained surgical foreign body. This is in response to clarification of intent in subsequent reports.

3. [Dr F] has clarified that it was always his intention to remove the retained surgical object. He has referenced several points that support this statement.

4. This intention was not originally clear to me from my review of both the notes and the reports at the time of my first report.

Management of adverse event

5. My original opinion of moderate to severe deviation of standard of care has been modified to No deviation from standard of care in relation to the management of an adverse event.

6. This change follows [Dr F's] last report, 27 July 2020, in answer to my second report, 18 March 2020, criticising the time it took for [Mr A] to be seen by a consultant.

7. In his last report [Dr F] states that the reason for not seeing [Mr A] earlier was the result of an endoscopy list at [another hospital] on 16 January 2019. This distant off site commitment would have made it impractical for [Dr F] to attend to [Mr A] personally on 16 January 2019.

8. I consider it appropriate under these circumstances to delegate the full disclosure meeting to a senior registrar, as [Dr F] had done on 16 January 2019.

Team Communication:

9. I apologise if my previous reports created the impression that I held [Dr F] solely responsible for the miscommunication of the team.

10. I maintain my opinion of Moderate deviation from standard of care.

11. I have reviewed all relevant documents again. One of the main themes in Mrs A's complaint on behalf of her husband is the team communication. Waitematā acknowledges this and apologises for this in their original response.

12. My review of the notes found evidence of communication that could have been better and more consistent between the surgical team and [Mr A]. It all

contributed and added complexity to what was already a difficult complication at the time of [Mr A's] admission in January 2019.

13. It is difficult to grade miscommunication. Others may have a different opinion on the grading. I do, however, feel that most of my peers would agree that the level of communication deviated from standard of care.

14. I base my grading of moderate on the following considerations:

    a. The mixed messages came at the end of what would have been a very traumatic and emotionally exhausting journey for [Mr A].

        i. He had been diagnosed in short order with metastatic bowel cancer, had a stent placed and was waiting to commence neo-adjuvant chemotherapy.

        ii. This plan then had to change twice prior to his January 2019 admission secondary to a stent perforation, surgery and deconditioning.

        iii. His admission in January 2019 presented yet another hurdle in his path of treatment. At this admission, the overriding concern for all was to get [Mr A] to Chemotherapy with as little delay as possible.

    b. Once the diagnosis of a retained surgical foreign body was made, I would have expected the plan communicated to [Mr A] to reflect clear concise steps in managing the retained foreign body and the options available to [Mr A].

    c. However, my review of the notes and the letter of complaint, shows that [Mr A] was given mixed messages and at times conflicting information.

    d. This was at a time when [Mr A] and his family were at their most vulnerable, the future uncertain and [Mr A] in desperate need of a unified clear message.

    e. From my review, this unified message and clear communication did not happen.

    f. I take note of the various reports provided explaining that the team was exploring and clarifying the options in the background.

    g. I acknowledge that some of the uncertainty may have been the result of multiple consults with other specialties and clinicians to get an appropriate plan for [Mr A].

15. I do not ascribe this deviation in communication to an individual, but to the whole surgical team involved.

16. I do not consider there to be any gain in individual reports from the individual members of the team around their communication. The event happened in January 2019 and whatever each individual may recall regarding their personal communication, there is ample evidence that the team's communication with [Mr A] was below the desired standard at the time.

Gerrie Snyman"

Appendix B: Independent advice to the Commissioner

The following expert advice was obtained from RN Rosalind Jackson:

"Thank you for the opportunity to provide opinion to the Commissioner on this case, number 19HDC00159. I confirm that I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. By reviewing this case I confirm that I have identified no conflict of interest.

My name is Rosalind Clare Jackson and I am a New Zealand trained Registered Nurse (NZRN comp, reg 120875) and hold a Master's Degree in Health Science. Since 2006 I worked full time as a Nurse Service Leader (Anaesthesia and Surgical Services) in a larger secondary district health board, with responsibility and accountability for operational management and professional leadership to nursing in the surgical setting including the Perioperative Department.

In November 2017 I was seconded to a programme manager role responsible for organisational development of our staff engagement and culture programme. In February 2019 I was appointed into the permanent role as Associate Director of Nursing which includes responsibility for the nursing practice development team, care capacity demand management, infection prevention control and occupational health services.

Other training that I have completed that is relevant to the role of an Independent Advisor includes,

- Institute for Healthcare Improvement (IHI) — Patient Safety Programme
- New Zealand Incident Management System — Root Cause Analysis Training (Clinical event/investigation review)
- IHI Open School (completed) — six modules on quality improvement methodology

1.0 Background

On 27 November 2018, [Mr A] underwent a flexible sigmoidoscopy and stenting procedure at [the public hospital]. On 27 December 2018, he re-presented with colonic stent perforation and underwent laparoscopically assisted Hartman's procedure. On 14 January 2018, [Mr A] was readmitted to [the public hospital] as he was experiencing pain in his abdomen. An X-ray and CT scan showed the presence of a foreign body, which was initially believed to be a broken drain. On 18 January 2019, a procedure was undertaken to remove the object, which was discovered to be an Alexis wound retractor, retained since the 27 December 2018 procedure.

The Commissioner is seeking my opinion on whether the care provided by Waitematā District Health Board (WDHB) to [Mr A] was reasonable under the circumstances, and why. In particular,

- The overall standard of care provided by the surgical nurses (from a systems perspective)

- Whether the theatre count policy in place at the time the care was provided was appropriate and in line with accepted standards of practice.
- The adequacy of the subsequent changes made to the theatre count policy.
- The appropriateness of the local practice of excluding certain items from the surgical count.
- Any other matters that I consider amount to a departure from accepted standards of care.

For each question I will consider and advise,

- What is the standard of care/accepted practice?
- If there has been a departure from the standard of care or accepted practice, how significant a departure do I consider this to be (mild, moderate or severe departure)?
- How would it be viewed by my peers?
- Recommendations for improvement that may help to prevent a similar occurrence in the future.

In forming my opinion on the matters requested I have reviewed the following documents provided by the Commissioner,

- Letter of complaint dated 22 January 2019
- Waitematā DHB's response dated 4 April 2019, including a timeline of events.
- Clinical records from Waitematā DHB covering late December 2018 to January 2019.
- Waitematā DHB's further response dated 18 February 2020, including:
  - A copy of the Theatre Count — Surgical Unit policy in place at the time of the events.
  - A copy of the updated Theatre Count — Surgical Unit policy.
  - Statements from [RN G], [RN H], [RN I] and [RN J]

On request, HDC provided part of Waitematā DHB's event investigation. This was the Action Plan (event number …) page to achieve recommendations against two key findings (not specified). The full investigation report was not provided.

2.0 The overall standard of care provided by the surgical nurses (from a systems perspective).

To clarify, focus of this review is on perioperative department 'surgical' nurses. I have not considered the surgical ward staff as no concerns have been raised by [Mr A] or HDC about care provided whilst an inpatient.

The substantive matter to consider is whether the actions of the perioperative nurses not to include the Alexis wound retractor in the surgical count was reasonable. Firstly, consideration is given to the RN statements, secondly framework of error and finally my opinion of reasonableness.

On review of the statements from Registered Nurses [RN G], [RN H], [RN I] and [RN J] I find the following themes,

Contradiction — The RNs stated that it is their understanding that all items in the surgical field are accounted for and that all wound retractors are a countable item. However, they consistently went on to qualify that this only applied to reusable retractors and 'countable items' and that the Alexis was not included in this description and therefore not counted. In my opinion there is a contradiction between 'all items' and a quantifiable list of items, i.e. the Alexis retractor entered the surgical field, was passed between the scrub nurse and surgeon and entered the abdominal cavity however,

> *'all the swabs, sharps and instruments that I am responsible for were all accounted for' ([RN I]).*

Emphasis has been placed on the fact that the count was correct however this would always have been the case because the Alexis retractor was never included as an instrument/item to count.

Focus on Equipment Lists — There appear to be a number of places for equipment, consumables and instruments to be identified including CSD instrument list, surgeon preference list, count sheet, and white board. The RN responses focused on where an item was documented and whether it qualified to be counted rather than thinking more broadly about what enters the surgical field and/or body cavity and the purpose of the count which is to protect the patient against risk of an item being unintentionally retained. For example,

> *'The Alexis retractor is only documented on a Consultant's preference sheet, which is NOT a count sheet (count sheet being a legal document)' ([RN G])*

This speaks to an interesting dynamic between a more rigid interpretation of the count policy vs practical application of managing equipment, instruments and consumables 'in the moment'.

Purpose — Whilst understanding is implied, the purpose of the surgical count is not explicit from the RN statements. There appears to be a disconnect between policy and purpose, for example, *'I counted what I was told to count' ([RN I]).*

Perioperative Experience — I can see that the RNs responded to specific questions put to them by the commission whereby all outlined their varied level of perioperative experience. Whilst some have stated they have less experience in large bowel surgery I don't consider that this was a significant contributing factor. This is because the matter of concern is a retained instrument and the RN's understanding of the process and interpretation of the policy — which appears to be consistent across specialities, i.e. reusable retractors are not included in the count. In addition, other than the surgery duration there was little else of note that would have suggested that surgical specific skills and knowledge was of concern.

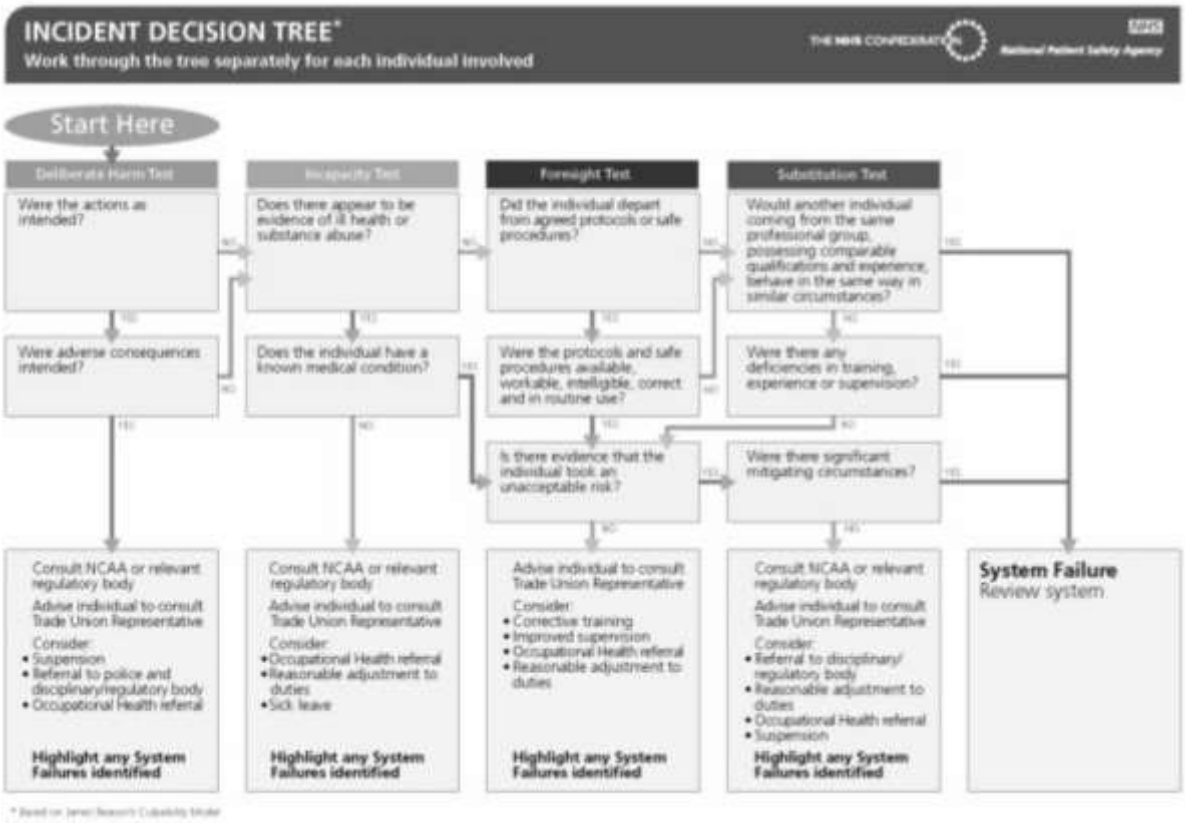
Assumption — Responsibility for the Alexis retractor was assumed to be the surgeon's (insertion, use and removal), assumed to have been placed in the rubbish by either the surgeon or scrub nurse, assumed that it would not be able to be retained due to its size and assumption and surprise that not all instruments were part of the count (surgical team). For example,

> *Surgical team stunned to discover the Alexis was not included in the count as 'had assumed that all instruments were part of the count' ([CMO] 4 April 2020)*

When conducting a case review one is reviewing information provided and looking for areas of inconsistency/concern and opportunities for improvement. It is acknowledged that this is often easier to do in hindsight. Therefore considering the RN statements and identified themes, was the standard of care provided by the perioperative nurses reasonable?

To help, I refer to an incident decision tree or culpability matrix. This is an evidence based framework (this one is a NHS version) to assessing adverse events. That is,

Whilst responsibility for the surgical count rests with the Scrub and Circulating nurses, [RN I] and [RN J], following the decision algorithm, retention of the Alexis retractor can be attributed to a systems failure, i.e. there is no evidence of intention to cause deliberate harm or employee incapacity, the staff acted within current policy and common interpretation, and it is likely that a comparable staff member would (and do) make a similar decision.



In conclusion, whilst retaining a foreign object in a patient is considered a 'Never Event' (ARHQ, 2019), and can never be considered 'reasonable' the actions of the RNs were understandable and of a reasonable standard consistent within the context of WDHB's practice and policy at the time of the event.

3.0 Whether the theatre count policy in place at the time the care was provided was appropriate and in line with accepted standards of practice.

The theatre count policy in place at the time was current and expected of policies/guidelines required in perioperative departments. Acknowledging the bias of reviewing the surgical count policy in the context of this case of retained foreign body, I make the following observations,

- The guideline purpose does not include any rationale.
- The guideline focuses on countable items and focuses narrowly on specific lists, e.g. whiteboard and CSSD instrument set check list.
- There is reference to 'Extras' but this is not elaborated on what they may be or how to manage the items when they enter the sterile field.

Referring to a guideline template (enclosed) available via AORN (2016), there is a more detailed process for managing (sharps and) miscellaneous items compared to what could be found in WDHB's 2018 count policy.

The policy current at the time of the event emphasised 'countable' items which would have reinforced RN practice.

- All RNs involved in the case stated they were familiar with the guideline and how to access it.
- The policy content would have informed orientation and education to staff in the department.
- The assumption that not all items were counted was reinforced because there were other items stated by [RN I], which entered the sterile field and were not included in the count, e.g. marking pens, ports and trocars, linas (liners) and syringes.

It is evident that there was rigour surrounding reusable (CSSD) instruments however rigour is less evident for reusable or miscellaneous items and this inadvertently increased the risk of error occurring. **Given the risk and consequences to a patient of a retained object, and disconnect between policy interpretation and practice, inadequacy of the policy to inform practice would have to be considered a severe departure from accepted standards.**

4.0 The adequacy of the subsequent changes made to the theatre count policy.

The revised policy (July 2019) reads well, is logical and well written. It is a comprehensive document that provides a more 'single point of reference' that informs policy purpose, rationale, staff roles and responsibilities as well as surgical count process and items to be included, and by speciality. The use of the count board for additional items and process for miscellaneous items is clear.

Whilst the 'list' of countable items is more comprehensive and inclusive of speciality preferences, there does not appear to be a process about how to be flexible when new items are introduced, e.g. new technology, item or surgeon/speciality preference change and how this is 'added' to the appendix during the controlled document 36 month currency period. [RN I] alludes to this about the previous guideline in her statement '… when this (Alexis) product was added to our sterile shelves, the WDHB policy was not updated to reflect this.' Therefore, I would offer the **recommendation that whilst the current policy is very 'adequate', a process is agreed how to maintain currency of those items listed in the July 2019 guideline and appendix.**

5.0 The appropriateness of the local practice of excluding certain items from the surgical count.

It would generally be agreed amongst peers that excluding certain items from the surgical count carries risk of them being unaccounted for and retained by the patient which occurred in this case. It has already been stated that it was contradictory to not have included the Alexis wound retractor simply because it was a single use item, only found on the surgeon's preference list and not previously included in the surgical count. Management of items in the surgical field are not solely bound by a list or a policy but reinforces the need to know about everything in the surgical field. I would expect that the staff would agree that whilst there are lists, all items on the surgical field would and should be accounted for. In the WDHB response of February 2020 this is agreed by the senior nursing and surgical team. The RNs directly involved in the case have learned a valuable but difficult lesson.

6.0 Any other matters for consideration.

I acknowledge the extent of regret and apology conveyed by WDHB and willingness to meet with [Mr and Mrs A], plus share the formal investigation report. In addition, in response letter of 18 February 2020 from [the CMO], WDHB accepts that this event constitutes a severe departure from accepted standards.

I note the actions included in the investigation action plan, i.e.

- Update of policy — provided and comments included in point 4.0
- Audit — example not provided
- Clarification that policy applies to all WDHB theatre sites
- Multidisciplinary learning/education
- Simplify and standardisation of theatre tray lists — example not provided
- Forcing function to protect time to count. I noted the statement that the surgeons had already begun closing the abdomen which compressed the time for the count to be completed.

7.0 Summary and Recommendations for Improvement

As an outcome of this review I have identified one area where a departure from accepted standards has occurred,

1. Given the risk and consequences to a patient of a retained object, and disconnect between policy interpretation and practice, inadequacy of the policy to inform practice would have to be considered a severe departure from accepted standards.

2. It is recommended that a process is agreed how to maintain currency of items listed in the July 2019 guideline and appendix.

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28 June 2020

References

Agency for Research, Healthcare and Quality (ARHQ). Never Events, Patient Safety Primer (Updated September 2019) https://psnet.ahrq.gov/primer/never-events

Meadows, S., Baker, J., Butler, J (2005). The Incident Decision Tree: Guidelines for Action Following Patient Safety Incidents. Advances in patient safety: from research to implementation (Vol 4). Programs, Tools and Products, Agency for Healthcare Research and Quality (US).

AORN Standards, Recommended Practices and Guidelines (2017)"