Health and Disability Commissioner
*Te Toihau Hauora, Hauātanga*

# A Decision by the Health and Disability Commissioner

# (21HDC01479)


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## Complaint and investigation

1. This report discusses the care provided to a woman by Auckland District Health Board (ADHB) (now Te Whatu Ora Te Toka Tumai Auckland[1] (Te Whatu Ora)).

2. The woman made a complaint to HDC in 2021 after it was discovered that a wound retractor had been retained in her abdomen following a Caesarean section in 2020. The following issue was identified for investigation:

- *Whether Auckland District Health Board (now Te Whatu Ora Te Toka Tumai Auckland) provided the woman with an appropriate standard of care in 2020.*

3. This is the final opinion of Commissioner Morag McDowell.

4. I thank the woman and her family for taking the time to bring their concerns to my office.

## Background

5. The woman's complaint raises concerns around the standard of care provided to her by ADHB. In 2020, the woman, who was in her twenties, underwent a scheduled Caesarean

[1] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Te Whatu Ora|Health New Zealand. All references in this report to ADHB now refer to Te Whatu Ora.



*Names have been removed (except ADHB/Te Whatu Ora Te Toka Tumai Auckland and Auckland City Hospital) to protect privacy.*

section (C-section) at 36 weeks plus 3 days' gestation. The C-section was planned because of concerns about placenta previa[2] and placenta accreta.[3]

6. An Alexis wound retractor (AWR), a device used to draw back the edges of a wound during surgery, was left in her abdomen following her C-section. This resulted in the woman suffering chronic abdominal pain until the device was discovered incidentally on an abdominal CT scan.[4] In 2021, approximately 18 months after the woman's C-section, the AWR was removed from her abdomen.

## Information gathered

### C-section in 2020

7. In 2020, the woman underwent a C-section at Auckland City Hospital. In response to the complaint, Te Whatu Ora told HDC:

> "[T]he C-section was known in advance to be a complex case due to anterior placenta previa overlying a caesarean scar from previous delivery, as well as elevated maternal body mass index (>50 at time of surgery) … Therefore [the woman] was planned for delivery at early gestation (36+3 weeks)."

8. In response to the concerns raised in the complaint, ADHB completed a Retained Item Case Review (the Case Review), which was provided to HDC along with statements by some of the surgical team who were directly involved in the surgery.

9. The following theatre staff were present at the C-section: a surgeon, a senior registrar, an instrument nurse, three circulating nurses, two anaesthetists, two anaesthetic technicians, and a theatre midwife.

10. In the surgeon's summary of the case provided to HDC, she stated that all potential challenges were discussed with all theatre staff involved at a briefing meeting in theatre prior to the surgery. The procedure was explained step by step, with an anaesthetic plan outlined. It was during this discussion that the surgeon requested an AWR.

11. The surgeon performed a midline laparotomy,[5] and initially used a large-sized AWR. However, the surgeon stated that this was too small for the incision, so it was removed and replaced with an extra-large AWR. The senior registrar also referred to the replaced AWR. She stated: "A midline incision was made and an Alexis retractor was inserted, however it was too small for the incision." This was therefore removed and replaced with a larger Alexis retractor, which provided the visualisation required. The Case Review found that it was this second AWR (size XL) that was retained. It should be noted that the retractor, a round, soft tubal instrument of transparent plastic fixed on two rings, is a large item, about the size of

[2] A problem during pregnancy when the placenta completely or partially covers the opening of the uterus (cervix).
[3] A condition in which the placenta grows too deeply into the uterine wall, which may cause severe bleeding.
[4] A series of X-ray images taken from different angles around the body.
[5] A surgical incision into the abdominal cavity.

a dinner plate. Usually, it would be removed after closing the uterine incision (and before the skin is sutured).

12. At the time of the surgery in 2020, AWRs were not included as part of the surgical count. This understanding of not including AWRs in the surgical count was confirmed by the nursing staff involved in the woman's surgery. A nurse told HDC:

> "[A]s far as I am aware, in our department no one ever recorded the Alexis Retractor on the count board and/or included in the count. This may have been due to the fact that the Alexis Retractor doesn't go into the wound completely as half of the retractor needs to remain outside the patient and so it would not be at risk of being retained."

13. Two of the nurses present have no recollection of the case. However, one of the nurses recalls opening a second AWR. She noted that this was very unusual, and they had never had to do so before or since. She stated:

> "I remember being asked by the scrub nurse to open another Alexis wound retractor … [W]e had none in the prep room, so I quickly fetched one from the sterile stock room. I opened this to the scrub nurse and left it at that. I do not remember telling circ 1 nurse that I opened it and I did not write this with the count, as at this time this item was not part of our count routine."

14. Te Whatu Ora's response to HDC notes that the woman's intraoperative documentation shows that no relief staffing was documented, the count was recorded as routine and correct, and the Surgical Safety Checklist was recorded as having been completed.

**Subsequent events**

*Post C-section — 2021*

15. The woman presented to her GP a number of times in the 18 months after the C-section, and on one occasion she presented to the Emergency Department at Auckland City Hospital with severe pains in her abdomen.

16. On 30 May 2022, HDC sought internal clinical advice from GP Dr David Maplesden, to assess whether the retained AWR could have been identified sooner at the woman's presentations to her GP and Auckland City Hospital. Dr Maplesden commented on the primary care role in reviews of the woman's abdominal pain in the intervening period, together with the woman's assessment at Auckland City Hospital in the month following the C-section, and the role of an ultrasound in detecting such foreign bodies.

17. Dr Maplesden reviewed ADHB's response to HDC, and the woman's GP notes and clinical notes, and considers that the assessments completed during this period were largely consistent with accepted practice and timeframes.

18. ADHB's Case Review noted that an AWR is a non-radio-opaque item and thus is not able to be detected on an X-Ray.

*Case Review and response to HDC*

19. ADHB completed a formal review of the care provided and expressed its sincere apologies for the distress caused to the woman.

20. Te Whatu Ora told HDC that the process for ensuring that all surgical tools are accounted for following surgery is set out in Te Whatu Ora's Count Policy for Surgical Procedures (the Count Policy). Te Whatu Ora said that the Count Policy is based on international best practice guidelines of the Association of peri-Operative Registered Nurses (AORN) for the Prevention of Retained Surgical Items. The target audience for the Count Policy is identified as "all staff working in the perioperative area". However, ADHB's Case Review noted that neither surgeon involved in the surgery had read the Count Policy. At the time of the surgery, AWRs were not included as part of the Count Policy.

21. Te Whatu Ora told HDC that following the incident involving the woman, on 23 June 2021 a memo was sent to all perioperative staff directing that AWRs were to be included in the count going forward. However, there is some confusion regarding who received the directive, as the Case Review outlines that it was sent to "all nursing staff", rather than all perioperative staff.

22. The Case Review outlines three recommendations:

1. A review of the Count Policy by a working group formed with representatives from all stakeholder groups;
2. The development of an online learning tool on knowledge, use and application of the Count Policy; and
3. The Perioperative Directorate to review the induction process and ongoing mandatory learning of staff involved in the count process, including its frequency.

**Responses to provisional opinion**

23. The woman was given an opportunity to respond to the "information gathered" section of the provisional opinion and made no further comments.

24. In response to the provisional opinion, Te Whatu Ora submitted that the opinion was influenced by hindsight and outcome bias, and there was not sufficient basis to find that there was a failure to exercise reasonable skill and care. Te Whatu Ora pointed to a lack of expert evidence to support the conclusion that the Code of Health and Disability Services Consumers' Rights (the Code) had been breached and referenced known error rates — in particular a study where, despite swab counts being documented as correct, swabs had been retained. These and other submissions have been considered in the course of my discussion and conclusions below.

25. Te Whatu Ora accepted that the wording of the Count Policy could be improved to clarify which items should be included in the count, and accepted that at the time of this incident, there was no comprehensive framework in place to ensure that all key stakeholders present during surgical procedures were cognisant of the content and intent of the Count Policy. Te Whatu Ora said that it continues to take steps to remedy this.

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26. In 2020, an AWR was retained in the woman's abdomen during surgery. I acknowledge the stress that these events caused to the woman and her family. The woman experienced episodes of pain over a significant period of time following her surgery until the AWR was removed in 2021. I accept her concerns regarding the impact this had on her health and wellbeing and that of her family.

27. From the staff statements provided to HDC, it is also clear that the theatre staff involved in the surgery are genuinely concerned and were most apologetic upon hearing of the woman's experience.

28. As a healthcare provider, ADHB was responsible for providing services in accordance with the Code, and the woman had the right to have services provided to her with reasonable care and skill. ADHB was required to ensure that its systems provided her with safe care of an appropriate standard.

29. I have undertaken a thorough assessment of the information gathered in light of the woman's concerns, including information from the woman and ADHB, as well as clinical records. I have also considered other HDC opinions relating to the retention of surgical instruments, and in particular a recent opinion, 19HDC00159, which also involved the retention of an AWR. That opinion is particularly relevant as, factually, it is remarkably similar to the present case. Namely, an AWR was retained in the context of complex abdominal surgery, and in a situation where staff did not include the AWR in the surgical count. It is accepted that at the time of this event, Auckland Hospital staff were unaware of this case (which occurred in another DHB approximately one year earlier). Nevertheless, the principles determined in that case have direct application.

30. In response to my provisional opinion, Te Whatu Ora submitted that the risk of an AWR being retained was not known by its staff, and that without the benefit of hindsight there is no sufficient basis to find that there was a failure to exercise reasonable care and skill in this case. I acknowledge that national count policies were similar, and that Te Whatu Ora was not aware of a risk that an AWR could be retained surgically. I also accept that my assessment of whether care was appropriate must not be unduly influenced by the eventual outcome.

31. However, I have little difficulty concluding that the retention of a surgical instrument in a person's body falls well below the expected standard of care — and I do not consider it necessary to have specific expert advice to assist me in reaching that conclusion. This is a consistent approach to the precedent cases, as well as the nursing and surgical advice in opinion 19HDC00159 (as reported in that opinion), which concluded that retention of the AWR, of itself, constituted a serious deviation from the standard of care. In reaching this conclusion, I have also formed the view that while individuals hold some measure of accountability in this respect, this is a systems failure for which Te Whatu Ora Te Toka Tumai Auckland holds responsibility. I therefore find Te Whatu Ora Te Toka Tumai Auckland in breach of Right 4(1) of the Code.

32. In addition, I have identified several other matters of concern to support this primary finding.

**Count Policy**

33. The Count Policy is an important tool to mitigate the risk of retention, and I am concerned that it did not provide adequate guidance to staff in order to meet this objective.

34. The Count Policy states that its purpose is to "account for all items used during the surgical procedure". It subsequently introduces the concept of "countable items" requiring the counting of "any item which moves from the main sterile trolley … onto the surgical field and has the potential to be lost in the wound". The policy states the following rationale alongside this requirement: "An item transferred to the surgical site has increased risk of being retained." A later section entitled "Count order" lists the items to be counted. Although retractors are not specifically listed, it refers to "any item … which enters a cavity". The rationale statement alongside this section states: "This list is not exhaustive and any item that has the risk of retention must be counted …"

35. As stated above, at the time of the surgery in 2020, AWRs were not included as part of the surgical count. While I accept the conclusion of ADHB's Case Review that it would be unrealistic for the policy to have specifically listed all instruments and items, it appears that ADHB relied on staff to identify those items "at risk of retention" (as per the policy). The Case Review identified that staff perceived the risk of an AWR being retained as low, leading to a culture of AWRs not being counted. It was also thought that the fact that the AWR was designed to be inserted into the wound with its edges on the outside of the wound contributed to this perception.

36. It is also relevant that there was an apparent disparity of understanding between the surgical team and the nursing staff about what was to be counted — again noted by the Case Review. The nursing staff had never counted AWRs, whereas the surgical team were under the impression that all sterile items were counted (although I note that neither surgeon in the case had read the Count Policy (an issue addressed below)). This suggests that there was a different understanding of managing and mitigating retention risk within the team. Furthermore, a Count Policy audit after this event identified inconsistent count practice not only between different departments, but within the same department (again illustrating a "disconnect" between policy and interpretation and practice).

37. Taking these matters into account, in my view the policy was flawed in allowing staff to apply their own interpretation as to what items "had the potential to be lost" or carried "the risk of retention". The policy could and should be clearer. While acknowledging the reasons for why nursing staff did not consider the AWR as needing to be counted, I do not accept Te Whatu Ora's submission that the risk "was not known". It is common sense that an AWR that not only enters the surgical field but is introduced into the wound and surgical cavity carries an inherent risk of retention — albeit rare. A degree of critical thought needed to be brought to that risk (noting that the actual purpose of the Count Policy is to reduce risk), and further guidance and clarity should have been provided to staff via the policy to reduce the likelihood of interpretation error.

**Medical staff not required to read Count Policy**

38. I am also concerned by Te Whatu Ora's inconsistent messaging surrounding the expectations of staff reviewing the Count Policy. In particular, I note that at the time of the woman's surgery, the surgeons involved had not read the Count Policy.

39. The Count Policy states clearly that the policy is to be used by "all staff working in the perioperative area", and that the risk of non-compliance "may result in significant harm to the patient/hospital". The Count Policy also outlines the role of the surgeon and surgical assistant, including: "[M]aintains an awareness of all surgical items and their location when on the surgical field."

40. All staff who perform procedures in an operating room at Te Whatu Ora have a responsibility to adhere to the policies and guidelines set down by their governing health body. However, this case demonstrates that while the Count Policy clearly sets out practice guidelines, the expectation that "all staff working in the perioperative area" are to review the policy does not appear to have been applied consistently.

41. In 2018, ADHB was found in breach of the Code for the retention of a swab in a patient's abdomen.[6] The findings from ADHB's review at the time included that all staff involved in surgery were required to adhere to the Count Policy, but only nurses were required to read it and be orientated to it.

42. A recommendation from the 2018 breach finding was for ADHB to "[m]andate that all surgical staff read the Count Policy, and ensure that they keep up to date with any changes …" I note that Te Whatu Ora also referred to its revised Count Policy, and stated:

> "Te Whatu Ora noted that the Count Policy now clarifies staff responsibilities, including expectations about communication and documentation of items placed in wounds and cavities, noting that the responsibilities for the surgeon and surgical assistant now includes:
>
> a. Maintaining an awareness of all surgical items and their location when on the surgical field;
>
> b. Communicating the placement of items in the wound so that this can be written on the count board where all team members can visualise; and
>
> c. Communicating items intentionally left in the wound, e.g., packing."

43. I am disappointed that the former recommendation has not been implemented by Te Whatu Ora, with the review stating:

> "The current practice is that there is no expectation that medical staff have read the policy although there is the expectation that they have understanding of the accountability and responsibilities of the count."

[6] Opinion 18HDC02321.

**Conclusion**

44. Te Whatu Ora has submitted that there is insufficient basis to find that there was a failure to exercise reasonable care and skill in this case. Staff involved have no explanation for how the retractor ended up in the abdominal cavity, or why it was not identified prior to closure. In my view, it is self-evident that the care provided fell below the appropriate standard, because the AWR was not identified during any routine surgical checks, resulting in it being left inside the woman's abdomen. There is substantial precedent to infer that when a foreign object is left inside a patient during an operation, the care fell below the appropriate standard.[7] It is a "never" event.

45. In addition, ADHB's staff and systems failed in the care provided to the woman in the following ways:

- The Count Policy provided insufficient guidance to staff to enable them to determine what instruments should be included in the count, instead relying on them to apply their own interpretation of what instruments were "at risk of being retained", which led to a culture and practice where AWRs were excluded from the count.
- There were discrepancies surrounding ADHB's requirement for all surgical staff to read and stay updated on the Count Policy.

46. In my view, cumulatively these omissions represent systemic issues for which ultimately ADHB was responsible at a service level. ADHB had an operational responsibility to ensure that appropriate systems were in place to encourage a culture of safety and to support clinicians to carry out their roles safely and effectively.

47. For the retention of an AWR in the woman's abdomen during surgery, and the above failures in its system, I consider that ADHB failed to provide services with reasonable care and skill. Accordingly, I find Te Whatu Ora Te Toka Tumai Auckland in breach of Right 4(1) of the Code.

## Recommendations

48. I recommend that Te Whatu Ora Te Toka Tumai Auckland:

a) Provide a written apology to the woman for the breach of the Code identified in this report. The apology is to be sent to HDC, for forwarding to the woman, within three weeks of the date of this report. Te Whatu Ora is also to provide the woman and her kaīnga the opportunity to meet face to face, facilitated by Te Whatu Ora's Pasifika health services. The outcome of the meeting is to be provided to HDC within three weeks of the date of this report.

b) Confirm to HDC that the directive to include AWRs as part of the surgical count has been sent to all Te Whatu Ora perioperative staff as the target audience of the Count Policy. This confirmation is to be provided to HDC within three weeks of the date of this report.

[7] HDC Opinions 19HDC00159 and 18HDC02321. See also *MacDonald v Pottinger* [1953] NZLR 196 (SC).

c) Provide a copy of the Count Policy routine review to HDC within three weeks of the date of this report.

d) Provide HDC with an update on the online learning and assessment modules for all relevant Te Whatu Ora staff, with specific learning modules for surgeons and other stakeholders based on the Count Policy created. This update is to be provided to HDC within 12 months of the date of this report.

e) Implement the recommendations identified as part of its Case Review. Confirmation and a progress update are to be provided to HDC within three weeks of the date of this report.

49. I recommend that Te Whatu Ora|Health New Zealand ensure that all of its hospitals are aware of the risk of Alexis wound retractor retention, as evidenced by this case and case 19HDC00159, and include Alexis wound retractors as part of nationally consistent count policies. Evidence that Te Whatu Ora|Health New Zealand has done so is to be provided to HDC within three months of the date of this report.

## Follow-up actions

50. Te Whatu Ora Te Toka Tumai Auckland will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 to determine whether any further proceedings should be taken. As set out in my report, the care fell significantly below the appropriate standard in this case and resulted in a prolonged period of distress for the woman. Systems should have been in place to prevent this from occurring.

51. A copy of this report with details identifying the parties removed, except ADHB/Te Whatu Ora Te Toka Tumai Auckland and Auckland City Hospital will be sent to the Health Quality & Safety Commission.

52. A copy of this report with details identifying the parties removed, except ADHB/Te Whatu Ora Te Toka Tumai Auckland and Auckland City Hospital will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.