Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 22HDC00014)

Introduction

1. This report is the opinion of Dr Vanessa Caldwell, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

2. The report discusses the care provided by Health New Zealand | Te Whatu Ora (Health NZ) Counties Manukau (formerly Counties Manukau District Health Board) at the Manukau SuperClinic.[1] In particular, it concerns the inadvertent retention of a surgical swab inside a woman after she had an elective laparoscopy,[2] bilateral salpingectomy,[3] and total hysterectomy[4] on 2 December 2021.

3. A complaint was received from the woman on 29 December 2021, and the following issue was identified for investigation:

- *Whether Health NZ Counties Manukau provided the woman with an appropriate standard of care on 2 December 2021.*

4. The parties directly involved in the investigation were:

Consumer
Health NZ Counties Manukau — Provider

5. Further information was received from ACC and an urgent care clinic.

Information gathered during investigation

6. On 2 December 2021 the woman had an elective laparoscopy, bilateral salpingectomy, and total hysterectomy at the Manukau SuperClinic hospital. Health NZ told HDC that the woman had an 'uncomplicated recovery' and, following a medical review, she was discharged home on 4 December 2021. Health NZ said that when the woman was

[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 (now Health New Zealand | Te Whatu Ora). Whilst the woman received care from Counties Manukau District Health Board at the time of events, all references in this report now refer to Health NZ Counties Manukau.
[2] A surgical procedure to access the inside of the abdomen and pelvis without making large incisions in the skin.
[3] Surgical removal of both fallopian tubes.
[4] Surgical removal of the uterus and the cervix.

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discharged, she was experiencing 'scant vaginal bleeding which is normal following this type of procedure'.

7. In the days after her discharge from hospital, the woman noticed a malodourous vaginal discharge and experienced lower abdominal pain, hot flushes, and a reduced appetite. On 18 December 2021 she presented to an urgent care clinic, where she was given antibiotics. The woman did not have an internal examination during this visit as she advised that the pain was too extreme.

8. The pain worsened overnight, and after self-examining using a mirror, she spotted what looked like a yellow cloth protruding from her vagina. When the woman tried to pull this out, she suffered significant umbilical pain,[5] so she stopped. The woman then telephoned Healthline[6] and was advised to go straight to the hospital to be assessed as to whether she was suffering from an infection.

9. On 19 December 2021, 17 days post-surgery and having experienced symptoms for one week, the woman presented to the public hospital. A vaginal speculum examination was completed in the Emergency Department. During the examination, the gynaecologist found and removed a surgical swab that had been retained inside the vagina. The woman was re-admitted to hospital for observation, was given antibiotics for vaginitis,[7] and had an abdominal X-ray to exclude any further foreign bodies.

10. A member of the gynaecology team visited the woman the day after she presented to the Emergency Department and apologised for the complication that had occurred. During her admission, a computed tomography (CT)[8] scan was performed and did not identify any further foreign body. However, it did identify a pelvic collection[9] above the vaginal stump.[10] On 21 December 2021, the woman was reviewed again and, as she had improved clinically, she was discharged home with oral antibiotics.

Surgery

11. Health NZ told HDC:

> '[A laparoscopic bilateral salpingectomy and total hysterectomy involves] very small instruments being inserted into the abdomen to perform the salpingectomies and to cut the ligaments that support the uterus, and then the uterus is removed vaginally. The vaginal vault is then sutured via the vagina.'

[5] Umbilicord pain, also known as 'bellybutton pain', can occur for many reasons such as infection, an umbilical hernia, pregnancy, or a problem with the digestive system.
[6] Healthline is a free 0800 phone line that provides 24 hours a day, 7 days a week over-the-phone health advice, information, and treatment from a healthcare professional.
[7] An inflammation of the vagina that can result in discharge, itching, and pain.
[8] A medical imaging technique used to obtain detailed internal images of the body.
[9] A collection of fluid.
[10] The upper portion of the vagina that is sutured shut after the removal of the cervix and uterus.

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12. Health NZ stated that it is usual process for a surgeon completing this type of surgery to routinely visualise the vaginal vault closure abdominally through the laparoscope before completing the hysterectomy.

13. Health NZ noted that during the surgery there was a slight complication,[11] which meant that the surgeons had to re-perform a certain part of the procedure, more specifically, the vaginal vault closure. When this was being completed and the surgeons were checking via the laparoscope, the woman began to bleed, so further steps were taken to control the bleeding.[12] Health NZ stated that during vaginal surgery it is common to use swab sponges (which includes surgical swabs) to visualise and assure haemostasis,[13] and 'it is possible that a sponge could have been used in this way and left for haemostasis while performing the re-look laparoscopically'.

14. In the woman's case, the surgical count (including swabs) was completed and documented as correct. The count sheets for both the top and bottom trolleys show that a collective total of 40 small swabs and 5 large swabs were used during the procedure.

Relevant policies and procedures

15. The 'Surgical Count Policy for Swabs, Instruments and Sharps at CM Health' (the Count Policy) specifies that a full surgical count must be completed at the following stages by the Scrub Nurse and Circulating Nurse:

> 'i. Initial count — prior to initial incision.
>
> ii. First closing count — prior to closure of any body cavity.
>
> iii. Second count — for a cavity within a cavity (if applicable).
>
> iv. Final closing count — at closure of skin.'

16. The Count Policy also specifies that when an item is placed into a wound temporarily during surgery and is intended to be removed before cavity closure or skin closure, it must be written on the whiteboard with the time in and out and the number of swabs and confirmed with the surgeon.

17. In relation to swabs that are placed into a patient's wound during surgery and are intended to remain within the patient,[14] these must be documented on the count sheet and the theatre record, and an incident report submitted. The operating surgeon decides whether any items are to be retained within the wound.

[11] One of the sutures appeared to have caught the serosa on the outside edge of the sigmoid colon.
[12] Additional sutures and FloSeal (a substance used to help to stop bleeding) were applied.
[13] Ensure that bleeding has stopped.
[14] Examples of swabs intentionally left within a patient include vaginal packs that absorb excess blood loss postoperatively, and swabs used on large abdominal wounds for patients who need to return to theatre later for wound closure.

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18. The Count Policy also states that it must be read in conjunction with the CM Health Surgical Count for Swabs, Instruments & Sharps Guideline. This guideline states:

> 'i. The surgical count must take place in the operating room prior to commencement of the surgical procedure.
>
> ii. The Scrub Nurse must initiate and lead the count. In the absence of a Scrub Nurse, the Circulating Nurse will initiate and leads the count (e.g. LAOP/D&C).
>
> iii. The count must be completed systematically; it must be audible, uninterrupted, in English and written legibly on the Count sheet.
>
> iv. Of the staff performing the count, one must be a Registered Nurse. Staff involved in the count should not be changed, except in cases which involve prolonged surgery, if a staff member becomes unwell, an emergency case, or staff on meal breaks.
>
> v. No more than 2 Scrub Nurses and 2 Circulating Nurses should be involved in a count; except for exceptional circumstances involving multiple teams or specialities combinations, and long procedures defined as more than 8 hours.
>
> vi. HCAs[15] and anaesthetic technicians may add to the count during the operative procedure, but may not perform the initial, first/second closing or final closing count.
>
> vii. A full handover must take place for permanent relief of the surgical count.'

Adverse event review

19. In accordance with Counties Manukau Health Policy and Procedure, an Incident Report was completed at the time the retained surgical swab was identified. Health NZ also completed an adverse event report on 29 July 2022. An adverse event report details the event that occurred, outlines the standard operating procedures in place at the time of the event, and makes several recommendations.

20. The adverse event review for the surgery could not explain or identify how the swab was retained, given the fact that the surgical count was recorded as correct.

21. In response to my provisional decision, Health NZ noted that the adverse event review did identify that there was a possibility that staff removed a swab from the count trolley following the final count, and the review recommended reminding staff not to do this. On review of its current count policy, Health NZ identified that this may still occur, and it plans to update the count guideline to 'require staff to actively verbalise that they have removed an item off the sterile trolley after the final count has occurred, and to introduce a second final count should an item be removed from the trolley in such circumstances'. Health NZ reviewed the theatre records and identified that a vaginal pack was not left in situ

[15] Healthcare assistants.

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intentionally and that the swab count completed by the nursing team for the procedure was documented as correct for both the abdominal and vaginal procedure trolleys.

22. Furthermore, the operating surgeon does not recall leaving any swabs behind vaginally. The surgeon stated that this procedure was performed as per usual practice.

23. The scrub nurse recalled the events as follows:

> 'There were two trolleys used in the procedure, one trolley for laparoscopic/abdomen equipment and another for the vaginal procedure. The patients vaginal vault was re-opened (not fully) and re-sutured/closed because of bleeding and complications. Laparoscopic trolley was count[ed] off before the vaginal trolley at the end when surgeons had completed the laparoscopic re-look and they were happy with the surgical outcome.
>
> Following that, a final count of the vaginal trolley was completed and count was correct, surgeons were informed and check-out was completed.
>
> I do not recall how the swabs could have been left inside the patient as I am 100% sure that I did not give any swabs to surgeons after the final count was completed unless someone grabbed it off my trolley without my knowledge or without informing me while I was cleaning the patient's abdomen and vagina.'

24. The charge nurse of Gynaecology noted:

> '[A]s per the statement of the scrub and circulating nurse, and as per the record, they did one full count for both scrub trolleys at the very end of the procedure rather than doing it in between re-look laparoscopy and re-opening of the vaginal vault. This is because as per my experience, it is expected that during LAVH (laparoscopic assisted vaginal hysterectomy) with 2 scrub trolleys (top and bottom trolley) the surgeons are expected to go up on top (laparoscopy) and down (vaginal) to make sure that there is no bleeding and that sutures are all in place and the vaginal vault are totally closed.
>
> Performing [a] full count during this instance is not ideal because the series of this action is very fast.'

25. The circulating nurse for the case also recalled that the '[f]ull count was done during the closure of the vagina and another full count was completed for the abdominal closure'.

Subsequent events

26. On 2 February 2022, following admission to hospital and the discovery of a retained swab, the woman was seen at the Gynaecology outpatient clinic by a consultant and a manager to discuss the surgery and the retained swab. During the meeting they also discussed the investigation to be undertaken and informed the woman that they would be in touch. Following this, the woman and her husband met with clinical staff and were provided with a formal apology for the events that had occurred.

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27. The case was also discussed with the theatre and Gynaecology staff involved, and on 2 February 2022 the case was presented as a learning opportunity at the Gynaecology complications meeting.

Further information gathered

28. Health NZ provided the following additional information to HDC during the investigation.

29. The woman was concerned that she was not informed of any internal bleeding during her surgery and queried whether this was documented in her clinical records. Health NZ told HDC that some bleeding during a surgical operation like this is expected. The operation note for the surgery did record details of 'brisk bleeding' occurring, and Health NZ noted that gaining control of the bleeding was managed successfully and done in routine fashion. Health NZ said that the bleeding that occurred was not considered 'excessive' for this type of procedure.

30. Health NZ also told HDC:

> '[The Gynaecology service does not routinely discuss] finer details of the operation with the patient unless the patient enquires, but rather the service explains what was done and where any differences were required from the initial surgical plan or approach … and how the surgeon remedied any surgical issues at the time.'

31. Health NZ stated that the surgery and postoperative care were carried out in accordance with standard practice and that processes were followed in a standard fashion.

Responses to provisional opinion

32. The woman was provided with the 'Information gathered during investigation' section of my provisional report and given the opportunity to comment.

33. The woman remained concerned that the surgical swab was 'missed' by the team performing her surgery. Furthermore, she was concerned that after this error had been discovered, the relevant parties involved commented that 'the count was 100% correct at the end or don't remember leaving [a] swab … inside me'.

Health NZ

34. Health NZ was provided with a copy of my provisional report and given the opportunity to comment. Its comments have been incorporated into this report where relevant.

Opinion: Introduction

35. This case concerns a surgical swab being retained inside a woman's vagina following her surgery.

36. As a healthcare provider, Health NZ is responsible for providing services in accordance with the Code. This includes a responsibility for the actions of its staff, and an operational responsibility to ensure that systems are in place and adhered to, to ensure that consumers receive safe care of an appropriate standard. Somehow, during the surgery, the system failed, and a swab was retained inside the woman's vagina.

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Opinion: Health NZ — breach

37. According to Health NZ, the surgery was performed in accordance with the Gynaecology service's standard operating procedures. All relevant counts were performed and recorded as correct.

38. The event of a surgical swab being retained inadvertently is described as a 'Never Event' — something that should never occur and signifies an adverse event that is unambiguous, serious, and usually preventable. The Health Quality & Safety Commission has indicated that the retention of a foreign object in a consumer after a surgical/invasive procedure is an adverse event that should always be reported and reviewed.

39. From the information gathered during this investigation, I am unable to make a factual finding as to how and at what exact point the surgical swab was retained inside the woman. Health NZ told HDC:

> 'Our review of the theatre records for [the] procedure identified that a vaginal pack was not intentionally left insitu, it also identified that the swab count for the procedure was documented as correct for both the abdominal and vaginal procedure trolleys.'

40. Nevertheless, it is not disputed that a surgical swab was retained unintentionally. At some point in the surgery, a swab was placed into the woman's vagina and not accounted for. I consider this to be a clear demonstration of a systems failure, in that the surgical count process, which is designed to ensure that all surgical items used during a procedure are removed (unless intentionally left in situ, for example to manage postoperative bleeding) and accounted for, clearly failed in this instance.

41. I acknowledge that under the Count Policy, primary responsibility for the surgical count procedures lies with the scrub and circulating nurses. However, in my view, this error is the responsibility of all staff involved in the surgery, who were required to ensure that this did not occur, and it is also the responsibility of Health NZ, who provided the overall service. Even if the initial retention of the swab was a result of human error or an individual failing, the fact that the surgical count process did not identify the missing swab demonstrates that the system failed in this case. This event also likely represents a failure by staff to adhere to the Count Policy, although without knowing how the swab was retained, it is not possible to determine how, and to what extent, the Count Policy was not complied with.

42. In response to my provisional decision, Health NZ stated that there is 'an assumption that there was a failure by staff to adhere to the count policy'. I acknowledge this comment and, while the surgical counts were completed and documented fully, I consider the fact that the swab was retained is evidence that there was a failure in the system, which is designed to ensure that all items used during surgery are accounted for. I also note that the count policy states that when an item is placed into a wound temporarily during surgery and is intended to be removed before cavity closure or skin closure, it must be acknowledged and recorded, and it is possible that this aspect of the policy was not adhered to.

43. In any event, I am critical that this 'never event' occurred. I also acknowledge that it caused unnecessary harm to the woman and prolonged her recovery process.

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44. I consider that this incident highlights the need for hyper-vigilance during surgery, and the importance of strict adherence to surgical count policies and processes. In my view, the unintentional retention of the surgical swab constitutes a failure to provide services with reasonable care and skill. As such, I find Health NZ Counties Manukau in breach of Right 4(1) of the Code.[16]

45. However, I commend Health NZ on the actions taken once it became aware of the incident, such as extending apologies both in person and in writing and undertaking an adverse event review to try to identify the cause of the error. I am satisfied that Health NZ has demonstrated that due to the overall record of adherence to the surgical count protocols, this was a very rare but unfortunate event and is not indicative of a widespread systemic issue.

46. Furthermore, in relation to the woman's concern that she was not informed of any internal bleeding that occurred during her surgery, Health NZ stated that the Gynaecology service does not routinely discuss the finer details of procedures with consumers unless the consumer specifically requires this. Health NZ said, however, that the service does explain what was done and where any differences were required from the initial surgical plan or approach, and how the surgeon remedied any surgical issues at the time. I consider that this approach is reasonable. I also acknowledge that while complications did arise during surgery, ultimately they did not require any significant deviations from the planned surgical approach, and the bleeding that did occur was not excessive. As such, I am not critical of this aspect of the care provided to the woman, but I remind Health NZ of the importance of patients being made aware of what occurred during surgery and being given as full an explanation as possible.

Changes made since events

47. I am encouraged by the prompt response and thorough review of events by Health NZ by way of its adverse event review. Clearly, this event has been taken extremely seriously, with all surgeons and theatre teams being educated about the case. I note that several changes and recommendations have been made since this event to reduce the possibility of such an incident reoccurring. The recommended changes from the Adverse Event Review included:

a) Reminding Gynaecology surgeons not to use swabs or instruments after the final count is completed. If this is necessary, then a further count for each trolley is required.

b) Recommending that a vaginal sweep be performed by the surgeon at the conclusion of surgical procedures that include a vaginal component.

c) Completing a data review for the whole of Health NZ Counties Manukau to understand the prevalence of retained foreign objects during surgical procedures. The incident reporting data from 1 January 2017 to 1 August 2022 identified six episodes of retained swabs in the Division of Women's Health in Counties Manukau, two of which occurred in 2017 and 2018, and one that occurred in both 2019 and 2021.

[16] Right 4(1) states: 'Every consumer has the right to have services provided with reasonable care and skill.'

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48. In addition, Health NZ Counties Manukau recommended an investigation into medical device technology that will support the detection of retained surgical products via bedside scanning. Currently, only radiology imaging is available in New Zealand and, as such, is not used routinely, and the handheld scanner used widely in hospitals in the United States to mitigate the risk of retained swabs is not yet available.

49. As stated in paragraph 21, Health NZ told HDC that it plans to update the count guideline to 'require staff to actively verbalise that they have removed an item off the sterile trolley after the final count has occurred, and to introduce a second final count should an item be removed from the trolley in such circumstances'. Health NZ also stated that it will be making further changes to the formatting and wording used in the count guideline to aid clarity for the reader.

50. Health NZ told HDC that following this incident, the Count Guideline was updated to include the statement: 'For all laparoscopic gynaecological procedures a vaginal "sweep" must be completed at the end of the surgery.'

Recommendations

51. In light of the changes made above and the previous formal apologies offered, I recommend that Health NZ Counties Manukau:

a) Provide evidence to HDC that all recommendations arising from the Serious Adverse Event Review Report, as listed above, have been implemented, within three months of the date of this report.

b) Perform a random audit of 20 patients' records from the past three months, to identify compliance with the Gynaecology service's Count Policy. A documented report of the results of the audit, and any changes made, is to be provided to HDC within three months of the date of this report.

c) Conduct a refresher training session for existing staff on the Count Policy, incorporating the use of an anonymised case study based on this report, and provide HDC with a copy of the training materials used for this session and evidence that the session has taken place, within three months of the date of this report.

d) Provide HDC with evidence that new staff are being oriented to the Count Policy, and that this orientation includes the use of the anonymised case study referred to in recommendation c) above, within three months of the date of this report.

Follow-up actions

52. A copy of this report with details identifying the parties removed, except Health NZ Counties Manukau and Manukau SuperClinic, will be sent to the Health Quality & Safety Commission and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.