Ministry of Health (National Screening Unit)

A Report by the
Health and Disability Commissioner

(Case 18HDC01371)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided by the Ministry of Health National Screening Unit (NSU).

2. In October 2013, a woman received a cervical smear test and the results were reported as normal. She was then discharged back to her GP for annual smear screening at 12 months (October 2014) and 24 months (October 2015). In October 2014, the woman had her scheduled smear test and the result was negative. However, instead of scheduling her for another test in October 2015, the NSU IT system recommended that she return to routine three-yearly cycles. As a result, her next smear test was scheduled for October 2017.

3. Guideline 4 of the NSU's National Cervical Screening Programme (NCSP) states that if a smear test result is normal for a woman with ASC-US/LSIL, she should be referred back for two annual smear tests and, if tests are negative, then she should return to routine three-yearly screening. NSU told HDC that there was a misalignment in the NCSP system, and it took into account the woman's first smear test in 2013 as the first of the two annual smear tests, as per Guideline 4.

4. In July 2017, the woman had vaginal bleeding, and histology revealed that she had cervical cancer.

Findings summary

5. The Commissioner found NSU in breach of Right 4(2) of the Code, as the misalignment in NCSP's system meant that some patients who had undergone a colposcopy assessment for ASC/US/LSIL were not being recalled as per Guideline 4.

Recommendation

6. The Commissioner recommended that NSU apologise and report back to HDC regarding the result of its audit and the progress of the changes it is implementing.

Complaint and investigation

7. The Health and Disability Commissioner (HDC) received a complaint from Ms B about the services provided by the Ministry of Health National Screening Unit. The following issue was identified for investigation:

- *Whether the Ministry of Health provided Ms B with an appropriate standard of care in 2013 and 2014.*

8. This report is the opinion of the Commissioner.

9. The parties directly involved in the investigation were Ms B (consumer/complainant) and the Ministry of Health.

10. Further information was received from the medical centre.

Information gathered during investigation

Introduction

11. This opinion concerns the care Ms B, in her sixties at the time of these events, received from the Ministry of Health National Screening Unit[1] (NSU) regarding the scheduling and timing of her cervical smear tests.

12. Since her enrolment in the national cervical screening programme in 1994, Ms B had participated on a regular and on-time basis. She is reported to have had all negative cervical screening results until 2013.

Smear tests in 2013

13. On 6 August 2013, Ms B had a smear test[2] at her medical centre. The laboratory reported that low-grade ASC-US[3]/LSIL[4] and HPV subtype 16[5] had been detected. On 16 August 2013, the medical centre discussed the result with Ms B and made a referral to the Colposcopy[6] Clinic.

14. Ms B was seen at the Colposcopy Clinic on 10 October 2013. A gynaecologist performed a cervical examination and another smear test. The results of both the colposcopy and the smear test were reported as normal. Ms B was discharged back to the medical centre for annual smear screening at 12 months and 24 months from that date. Accordingly, Ms B required further smear tests in October 2014 and October 2015.

Smear test in 2014

15. On 13 October 2014, Ms B had the first of the two recommended annual smear tests at the medical centre. The smear test result was negative. However, instead of scheduling Ms B for another test in October 2015, it was recommended by the NSU IT system that she return to routine three-yearly cycles (which meant that her next smear test appointment was in October 2017).

[1] The National Screening Unit is within the Ministry of Health, and is responsible for the development, management, and monitoring of nationally organised population-based screening in New Zealand.
[2] A test for human papillomavirus using a small sample of cells taken from the surface of the cervix.
[3] Atypical squamous cells of undermined significance (ASC-US means that changes in the cervical cells have been found).
[4] Low-grade squamous intraepithelial lesion means that the cervical cells show changes that are mildly abnormal.
[5] Human papillomavirus (HPV) type 16 is a high-risk HPV that may cause cervical cancer.
[6] Colposcopy is a close examination of the cervix, vagina, and vulva for signs of disease.

16. The report on Ms B's cervical smear stated: "[The laboratory has] reviewed this result and everything appears in order." The NSU IT system scheduled the recommended date for Ms B's next smear test cycle.

Subsequent events

17. In July 2017, Ms B had vaginal bleeding overnight. Initially, she saw a nurse at the medical centre. However, she remained concerned and attended an accident and medical clinic for a medical examination, and was referred for a colposcopy. The results confirmed cervical cancer, and subsequently Ms B was referred to the Gynaecology Oncology Department for treatment.

Guidelines for Cervical Screening in New Zealand

18. The Ministry of Health NSU is established pursuant to Part 4A of the Health Act 1956. Its statutory objectives include "to promote the regular recall of women who are enrolled in the NCSP for screening tests[7]".

19. The NSU utilises the Guidelines for Cervical Screening in New Zealand (2008) (the Guidelines) to determine appropriate screening pathways for women who are enrolled in the National Cervical Screening Programme (NCSP). The Guidelines state:

> "The colposcopic assessment and management of women with a cytology result of ASC-US/LSIL should comply with the guidelines published by RANZCOG[8] and the Australian Society of Colposcopy and Cervical Pathology …
>
> Guideline 4: Colposcopic assessment of women with ASC/US/LSIL (See Flowchart 2)

COLPOSCOPIC ASSESSMENT	GUIDELINE	EVIDENCE
Satisfactory and normal	Refer back to the smear-taker for 2 annual smears. If either smear is abnormal, refer for repeat colposcopy. If both smears are negative, resume routine screening."	Grade C

13. The Guidelines also provide a flowchart, which states that if the colposcopic assessment is "satisfactory and normal -> Refer back to Smear-taker -> Repeat smear at 12 months -> Repeat smear at 12 months -> Routine 3 yearly screening", and that if there are any abnormal smears then the patient is to receive a new colposcopic assessment.

[7] Section 112D (c).
[8] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

14. Ms B's colposcopic assessment in October 2013 was satisfactory and normal. As per Guideline 4, Ms B should have been referred for a further smear test at 12 months (October 2014) and at 24 months (October 2015) following her colposcopic assessment.

NSU review report

15. Following this complaint, NSU conducted a review of Ms B's screening journey from August 2013 to 2017, along with an analysis of the screening journey in comparison to the requirements under the Guidelines (the review report). The review report noted that Guideline 4 was not followed, and that Ms B's care did not follow the assigned pathway to the Guidelines' recommended conclusion. The review report stated:

> "The first recall occurred and was attended for a smear in October 2014. The second recall should have occurred in October 2015. However, the consumer was recalled to attend routine three year screening in 2017."

16. It appears that the NCSP took into account Ms B's first smear test following her colposcopy in October 2013, and regarded it as the first of the two annual smear tests as per Guideline 4. The review report stated:

> "If the October 2014 smear was taken as first of the two annual smears after discharged from colposcopy, it would have followed that the second recall at 24 months should have occurred in October 2015. This appears to be where there is variation for this consumer when compared to Guideline 4.
>
> It appears the specimen taken for cytology at the colposcopy assessment in October 2013 with a negative result was taken to be the first of the two annual smears outlined in Guideline 4 Flowchart 2."

17. The report also stated:

> "It appears the reporting function within the laboratory information system (IS) counted two negative cytology results that were not aligned to the required timeline of these being 12 and 24 months after discharge from colposcopy as per Guideline 4. The process did not identify the initial negative cytology as being taken at colposcopy and not after discharge."

Further information from the medical centre

18. The medical centre told HDC: "I do believe that this case is cause for a broader review of the NZ recommendations for recalls, and secondary care management."

19. In August 2018, the medical centre wrote to a gynaecologist consultant at the district health board. The letter stated:

> "The providers within our practice have reviewed this case, discussed it with a pathologist and with the patient in an attempt to try and see if there was anything omitted in this patient's care … Following our review of the patient's medical records, we did not feel that anything was omitted with regard to following cervical smear

recommendations. However, we still feel concerned with regard to the fact that somehow this patient 'slipped through the cracks' and ended up with cervical cancer requiring major management."

Further information from NSU

20. NSU told HDC:

> "For clarity there was no error in the NCSP register IT system … The NCSP IT system business rules that guide the NCSP register tasks and reporting flags operated as they were set up to work."

21. However, NSU said that "the NSU review of the complaint found misalignment[9] in the NCSP register". NSU stated:

> "The issue highlighted in the review report is the NCSP register business rules are misaligned to clinical guideline 4 specifically, the requirement for two negative cytology results 12 and then 24 months post discharge from colposcopy.
>
> The NCSP register business rules and pathway tracking processes are complex. Any changes may lead to unintended consequences."

Changes made since incident

22. NSU told HDC that the following has resulted from this incident and NSU's subsequent review report:

a) A copy of the review report was provided to the laboratory.

b) A review of Guideline 4 was undertaken, and Guideline 4 was confirmed as evidence-based best practice. A review of all NCSP clinical guidelines will follow to ensure completeness of the review process.

c) NSU is working with urgency to ensure that the provider of the NCSP register will implement a new failsafe workaround mechanism that aligns register tasks to meet the requirement of Guideline 4.

d) A new cloud-based information system solution called National Screening Solution has been proposed to replace the NCSP register function from 2021.

e) NSU will communicate with all NCSP providers on the new failsafe workaround mechanism, i.e., NSU will inform all sample-takers, GPs, and screening laboratories, as well as the four regional NCSP coordinators.

f) NCSP has committed to a review of all clinical guidelines to ensure that they reflect best practice and that the advice is articulated clearly to guide individual clinical practice. NSU said that it cannot commit to a timeframe for this review until it has scoped the extent of the work.

[9] Business IT alignment is a process in which an organisation uses information technology (IT) to achieve its objectives.

g) NSU will conduct a sample clinical audit of the NCSP register for the past 3.5 years. NSU stated:

> "The purpose of the sample clinical audit is to check the screening history of all women where guideline 4 NCSP register business rules were applied to their recall to screen.
>
> The audit will assess if any women after a normal result from a low-grade colposcopy procedure has missed one or two screen tests within an acceptable time frame of 12 and 24 months. According to the finding:
>
> i. A plan of care will be implemented for any woman who has followed the recommended screening pathway including an offer of a smear to correct her pathway.
>
> ii. There will be a decision on the possibility to widen the clinical audit to other years.
>
> iii. Consideration of reviewing the cancer register from start of guidelines in 2008 for compliance."

h) NSU will conduct a root cause analysis review of the screening programme system enablers, process steps, and decision-making that led to a misalignment between the clinical guidelines and the NCSP register business rules. It is anticipated that this will lead to quality improvement action/s for the programme.

Response to provisional opinion

Ms B

23. Ms B was provided with an opportunity to comment on the "Information gathered" section of the provisional opinion. Ms B told HDC:

> "I can see how the problem arose with the scheduling of my repeat smears, which was unfortunate in my case … To conclude I am satisfied with the results achieved by the Commissioner in the report, and if my complaint brings about some changes … it is all worthwhile."

NSU

24. NSU was provided with an opportunity to comment on the provisional opinion. NSU stated that it "considered the Commissioner's provisional opinion and accepts the conclusion outlined in the letter". NSU also told HDC:

> "It is important to NSU to conclude this complaint with the outcome of the National Cervical Screening Programme (NCSP) register review. The review found no woman who missed the second follow up screen after low-grade colposcopy has been found to have cervical cancer.
>
> We sincerely regret [Ms B] had negative experience with the cervical programme and wish her the very best outcome with her cancer treatment."

Opinion: Ministry of Health (National Screening Unit) — breach

Introduction

25. This opinion concerns the care Ms B received from the Ministry of Health NSU — in particular the timing and scheduling of her smear tests as per the Guidelines.

Discussion

26. In August 2013, Ms B had an ASC-US/LSIL smear test result and, as per Guideline 4, she received a colposcopic assessment and also another smear test. Her results were reported as normal. Ms B was discharged back to her GP for annual smear tests at 12 months and 24 months. The referral was made as per the Guidelines' recommendations.

27. The Guidelines state that if the colposcopic assessment result is satisfactory and normal, the patient is to be referred to the smear-taker for two annual smears at 12 months and another 12 months following the colposcopic assessment. Accordingly, Ms B should have had further smear tests in October 2014 and October 2015.

28. Ms B had the first of the two annual smear tests in October 2014, and the result was normal. However, instead of being scheduled for another smear test in October 2015, it was recommended that Ms B return to routine three-yearly cycles, without receiving her second annual smear test as required under Guideline 4.

29. NSU conducted a review of Ms B's screening journey. It told HDC that it appears that the NCSP system took into account Ms B's smear test taken in October 2013, and deemed it to be the first of the two annual smear tests. As a result, the NCSP register IT system considered that Ms B had had two annual smear tests — in October 2013 and October 2014. This was incorrect, as the Guidelines required the first of the two annual smear tests to be at 12 months from the date of the colposcopic assessment. NSU acknowledged that Ms B should have had a second recall for a smear test in October 2015.

30. NSU told HDC that there was no error in the NCSP register IT system, and that the system operated as it was set up to work. However, NSU stated that "the NSU review of the complaint found misalignment in the NCSP register", and that "[t]he issue highlighted in the review report is the NCSP register business rules are misaligned to clinical guideline 4 specifically, the requirement for two negative cytology results 12 and then 24 months post discharge from colposcopy".

31. NSU confirmed that Guideline 4 is evidence-based best practice, and stated that it will conduct a root cause analysis review of the screening programme system that led to a misalignment between the clinical guidelines and the NCSP register business rules.

32. In my opinion, it appears likely that the misalignment between the NCSP IT system and Guideline 4 has been present since the system was implemented, as NSU has acknowledged that the system operated as it was set up to work. NSU also noted: "The NCSP register business rules and pathway tracking processes are complex. Any changes may lead to unintended consequences."

33. NSU has stated that a new system will replace the NCSP register function from 2021, and that it has implemented a new failsafe workaround mechanism and informed all providers about the issue.

Conclusion

34. NSU is within the Ministry of Health, and it has an organisational duty to provide services of an appropriate standard, including an organisational duty to ensure that its services are conducted in accordance with applicable Guidelines for Cervical Screening in New Zealand (2008). The NCSP IT register system should have complied with the Guidelines' flowchart, but there was an issue with the NCSP system regarding Guideline 4. I acknowledge that the system and pathways tracking processes are complex, and that an appropriate failsafe mechanism has been put in place. Nevertheless, NSU should have had in place a system to ensure that the IT register rules aligned with the Guidelines.

35. There was a misalignment of the NCSP's IT register system and Guideline 4, which had the effect that some patients who had undergone a colposcopy assessment for ASC/US/LSIL were not being recalled for repeat smears at 24 months after the colposcopy assessment. As a result, Ms B missed her second annual smear test in October 2015, as recommended by Guideline 4. Accordingly, I find that NSU breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code).

Recommendations

36. In response to the recommendation in my provisional opinion, NSU advised HDC of the progress of its register review and changes made. NSU stated:

a) All laboratories were required to review and confirm their report recommendation practice and ensure that it is aligned to the advised interpretation of Guideline 4 for the follow-up of women with previous ASC-US/LSIL results who have been referred and had a negative colposcopy. This action was completed, and advice and request for action provided to all laboratories on 10 February 2020;

b) A permanent failsafe workaround process has been implemented for the NCSP Register. Its purpose is to ensure that the register tracking aligns with the correct interpretation of Guideline 4. The workaround is run daily and managed by the NCSP Register Services provider. A monthly report is provided to the NCSP for ongoing monitoring. This action was completed, and NCSP has ongoing monitoring in place.

c) A clinical audit for the previous five years from the date of the implementation of the failsafe has been initiated. The audit is expected to be completed on 30 July 2020.

37. I also recommend that the Ministry of Health (National Screening Unit):

a) Provide a written apology to Ms B for its breach of the Code. The apology is to be sent to HDC, for forwarding to Ms B, within three weeks of the date of this report.

b) Report back to HDC on the results of the audit and progress of the other changes made by NSU, as stated at paragraphs 36(c) and 22 of this report, within six months of the date of this report.

Follow-up actions

38. A copy of this report with details identifying the parties removed, except the Ministry of Health National Screening Unit, will be sent to the Health Quality & Safety Commission.

39. An anonymised copy of this report with details identifying the parties removed, except the Ministry of Health National Screening Unit, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.