Moving to HPV primary screening

Information for laboratories reporting cervical histopathology for the NCSP

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Time to screen
National Cervical Screening Programme

New Zealand Government

Content

1. Clinical Practice Guidelines 2023
2. The new NCSP Register
3. Request forms, histopathology reports and coding
4. NCSP Policies and Standards Section 5
5. Workload modelling for cervical histology

Reorganisation of NCSP laboratory services

From July 2023, there will be three laboratories reporting cervical cytology and HPV testing

- APS in Auckland
- Pathlab in Tauranga
- SCL in Dunedin

Colposcopy clinics need to send their cytology and HPV tests to one of these laboratories.

Colposcopy units decide where to send their histology for reporting - this has not changed

Clinical Practice Guidelines for Cervical Screening in Aotearoa New Zealand 2023

- screening age and interval
- HPV primary screening algorithm

- post-treatment management of AIS
- screening after hysterectomies

Screening age and interval

Anyone with a cervix or vagina who has ever been sexually active should be offered an HPV primary screening test from age 25 to age 69.

If the HPV screening test result is negative (HPV: Not detected) the next screening test should occur in 5 years, or in three years for those who are immune deficient.

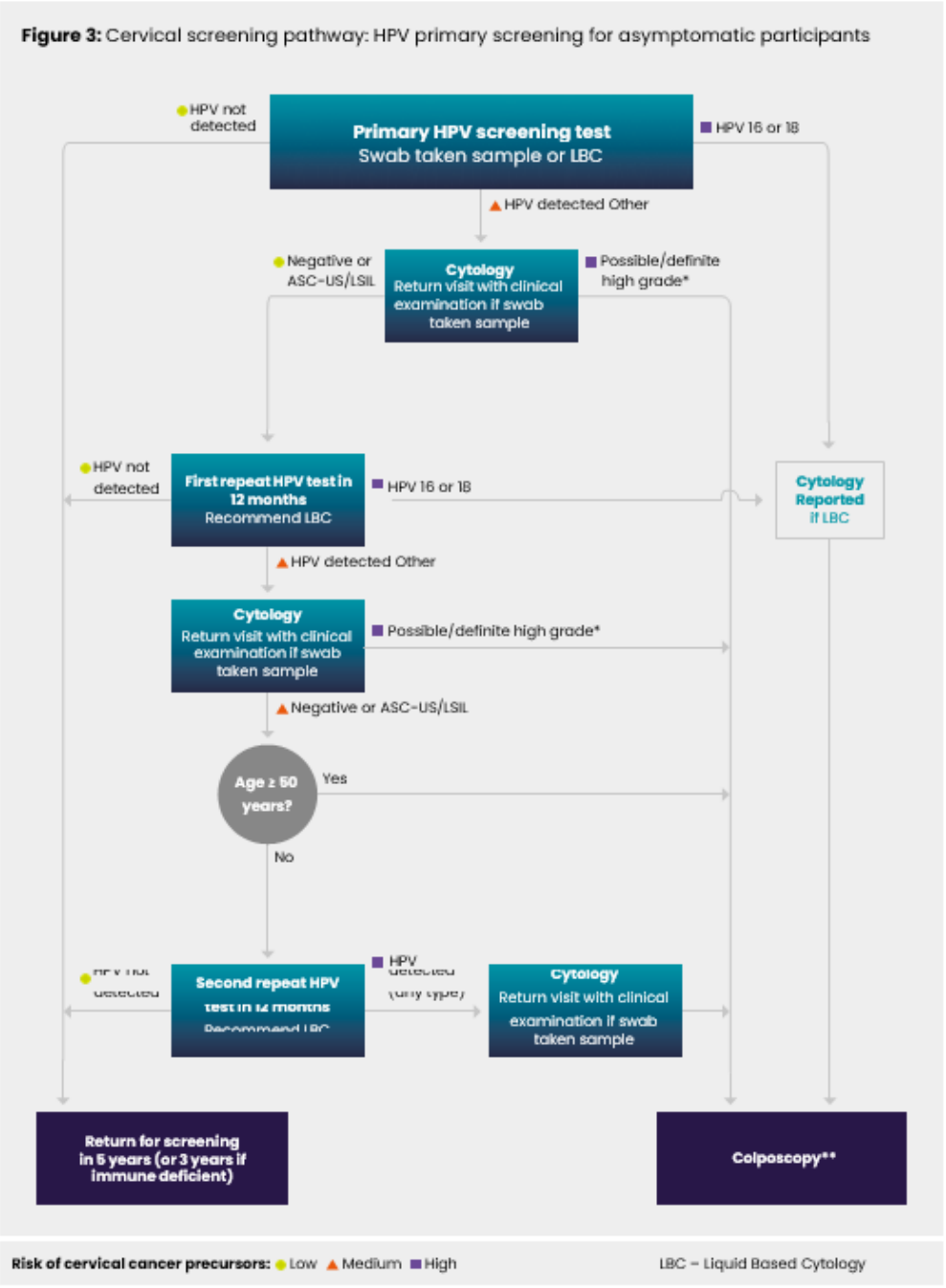
All participants should have an HPV: Not Detected test result before exiting screening

Those aged between 70 and 74 years who were unscreened or inadequately screened prior to age 70 should have an HPV test before ceasing screening.

Clinical Practice Guidelines 2023

HPV primary screening with partial genotyping and cytology triage

Figure 3: Cervical screening pathway: HPV primary screening for asymptomatic participants



*Possible/definite high grade cytology includes ASC-H, HSIL, SCC, atypical glandular cells, AIS and adenocarcinoma.

Post-treatment management of AIS

Test of Cure: two co-tests (HPV and cytology) reported 12 months apart – if all 4 results are normal, TOC is completed

- is now approved for use after completely excised HPV-positive (pre-treatment) AIS
  - since 2020 all cases of AIS should have had an HPV test prior to treatment
  - recent classification of AIS cases as HPV-associated or HPV-independent
  - historic cases will be a challenge
- Those with HPV-negative AIS* will have to remain on annual co-testing for life
- This will also apply for those whose pre-treatment HPV status is unknown

*except those who have had a total hysterectomy

Determining the HPV status for historic AIS cases

- Many cases of AIS have been/are treated by hysterectomy. This group do not have residual endocervical glandular epithelium so do not need annual co-testing
- Options for cases of AIS treated by local excision without a pre-treatment HPV test:
  - histology review with p16 and amended reports
  - processing tissue through the Onclarity HPV test technology at Pathlab

Hysterectomy histology

1. Has all of the cervix been removed? Report as a subtotal hysterectomy if it hasn't been. Screening will then continue.

There are cases of cervical cancer that have occurred in a cervical remnant after a hysterectomy: any remaining cervical epithelium is at risk of being infected with HPV.

2. Where there is residual/unexpected HSIL or AIS in the hysterectomy specimen, excision margins will be reported to the NCSP Register (with SNOMED CT)

- if completely excised, will have a test of cure

- if incompletely excised will go to colposcopy

Situations where the cervix should be coned

- the hysterectomy is done wholly or in part to treat the cervical abnormality (eg, a woman with adenocarcinoma in situ (AIS) who proceeds to hysterectomy, a woman with a high-grade squamous intraepithelial lesion (HSIL) and another gynaecological issue such as large fibroids and menorrhagia proceeds to hysterectomy to deal with both issues)

- an identified high-grade abnormality has not been treated or resolved (eg, previous HSIL without successful completion of a test of cure)

- an identified low-grade abnormality has not resolved (the woman had not returned to regular interval screening before hysterectomy) and there is a concurrent hrHPV Detected test result (any subtype) or hrHPV status is unknown.

NSS: National Screening Solution

- The IT system used for the Breast, Bowel and Cervical screening registers
- The NSS NCSP Register will go live when HPV primary screening is introduced
- Pathway Status: each person have a specific Pathway Status which will tell you where they are in the screening pathway algorithms
  - There are 20 statuses and the name tells you what the next expected event is

  e.g. Ist Test of Cure is a person who is due for the first co-test for a test of cure

  Under specialist care means a person who is at colposcopy

Using the Pathway Status in the laboratory

National Cervical Screening Programme
Screening History Report
As at 26-02-2023 14:26

NHI	ABC1234	**Full Name**	Test, Screening, A	**Pathway Status**	5 Year Recall
Date of Birth	15-10-1981	**Address**	123 Royal Street	**Next Expected Event**	HPV Screening Test
Ethnicity	Other European		Wallacetown	**Next Event Due Date**	24-02-2028
			9874		

NHI ABC12345 **Screening History**

Event Date	Event	Lab ID	Specimen ID	Site Code	Specimen Type	Adequacy	Rec	Interpretation Codes	Grade
24-FEB-23	HPV	G00014-C	XAJK128921		LBC		H8	16	D
24-FEB-23	CYT	G00014-C	XAJK128921	C	LBC	S1	H8	05	HG
21-SEP-16	HIST	G00014-C	XAJK128921	T83200	P11481	M09010		none	U

Those having biopsies and excision will be Under Specialist Care, some At Gynae Oncology

The transition period between the two registers

- Date xxx: The current NCSP Register is frozen: Data can still be viewed but no more results are entered

- Transition (10 days approx.)
  - Data is migrated across into the NSS Register
  - Results received are kept separately

- Go-live date 12 September 2023: New register is live with all past and recent results

Coding histopathology reports

SNOMED coding will be replaced with SNOMED CT

- is part of a large structured pathology reporting project run by Te Aho o Te Kahu (Cancer Control Agency)

- SNOMED CT codes are a string of numbers, often 10-12 numbers long

- the intention is to use drop-down menus for pathologists

The SNOMED CT codes are mostly selected but implementing them requires laboratory IT staff time

- this will not be implemented at the time of HPV primary screening

Request forms and reports

Request forms:

- Current forms will continue to be used
- the (pink) NCSP printable form will be updated on the NCSP Website
- electronic request forms are coming

Te Aho o Te Kahu (Cancer Control Agency) are developing the structured electronic requesting and reporting data standards

NCSP Policies and Standards Section 5

- Most of the updates for histopathology are in the current version of Section 5
- Reminders:
  - you are required to view the NCSP screening history when reporting cervical histology
  - hysterectomy specimens: need to cone the cervix under certain circumstances
  - sending slides overseas for those of Māori ethnicity: new NCSP policy

Sending Māori genetic material offshore: requirements

- Ensure that unless essential, all personal identifiers are removed from all slides, samples and accompanying documentation before being sent. Second opinions will require personal identifiers to be retained because of the clinical risk of removing them.
- notify the recipient if the slide/sample contains Māori genetic material, and send a printed instruction sheet identifying the specific requirements of Māori in relation to the material sent, to be signed and returned to the sender
- ensure that if samples are sent for educational or quality assurance reasons that the recipient provides a written statement before the material is sent, agreeing to adhere to the requirements
- have a tracking process in place to ensure that all material is signed out and signed back in at the laboratory when returned. If the material is not returned within a reasonable time frame, this must be actively investigated by the laboratory.

Resources

- Pack of information of final documents will be emailed to you soon:
  - Clinical Practice Guidelines 2023
  - Reporting to the NCSP: Coding information
  - NCSP Policies and Standards Section 5
  - Sending slides overseas NCSP policy

- the NCSP website will be updated soon
  - Training modules for primary/community care: https://learnonline.health.nz/course/view.php?id=587

- www.ncpts.co.nz *Training for HPV primary screening* on the homepage – don't need a login

  - short talks about the Clinical Practice Guidelines and the NSS NCSP Register

Predicted workloads in cervical histopathology

Factors that will increase histology volumes when HPV screening starts

1. HPV primary screening is a more sensitive test

   more lesions will be detected in the first three years among those already screening

2. Self-testing will be popular for those unscreened or underscreened as the speculum exam is a barrier

   Those unscreened/underscreened have a higher rate of cervical abnormalities and their lesions are often larger

3. The NCSP Register: everyone will be notified when they are due for screening

   This will be a progressive notification rollout, based on risk priority

Factors that will decrease histology volumes

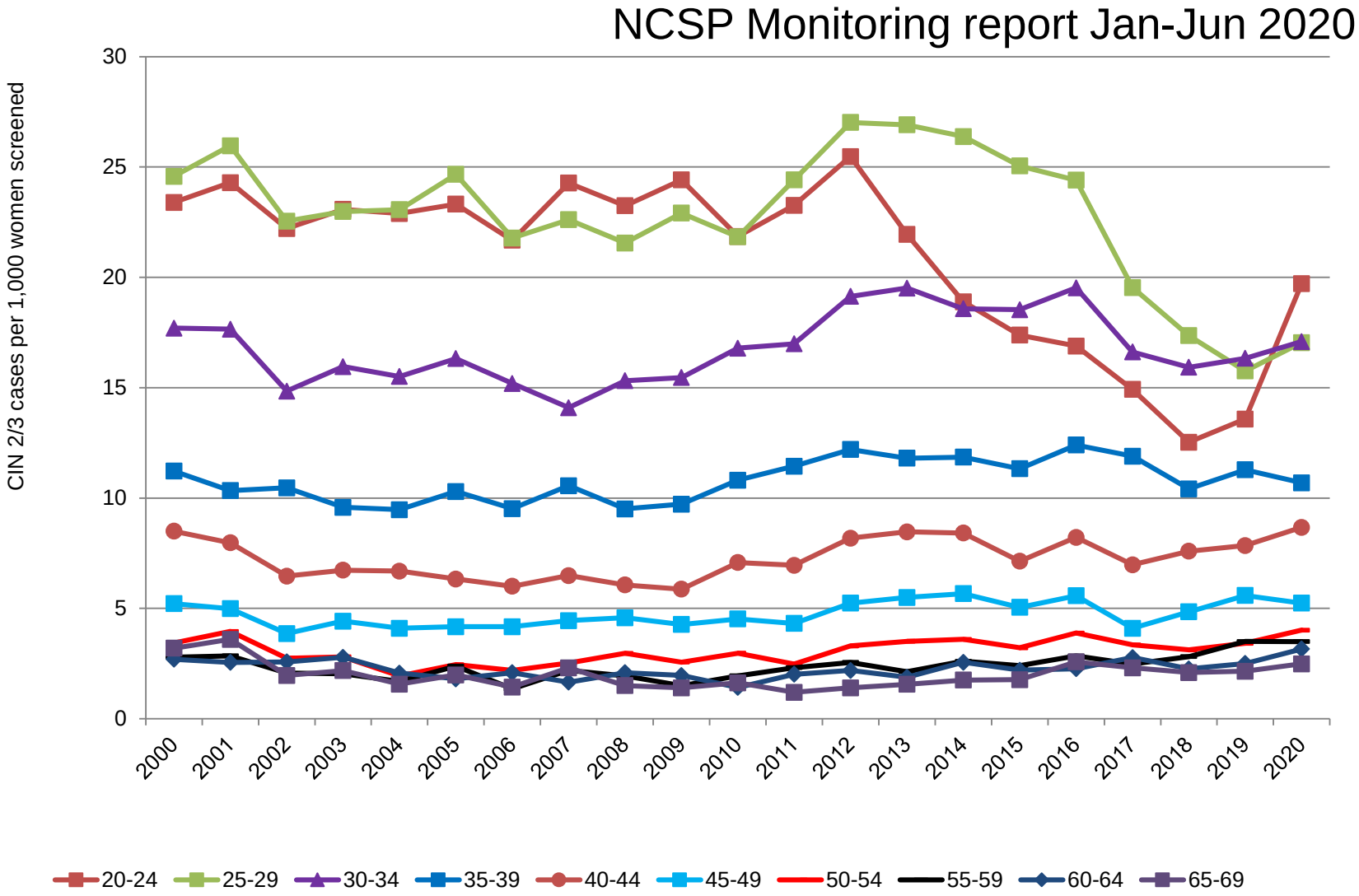
1. HPV vaccination significantly reduces the number of people who develop cervical lesions

   - Gardasil-4 prevents 70% of cervical cancers: the first age cohort offered widespread HPV vaccination approaching 30
   - Gardasil-9 prevents 90% of cancers; used since 2017
   - WHO 2022: one dose is enough

2. Women with low-grade lesions caused by low-risk HPV types will not be going to colposcopy

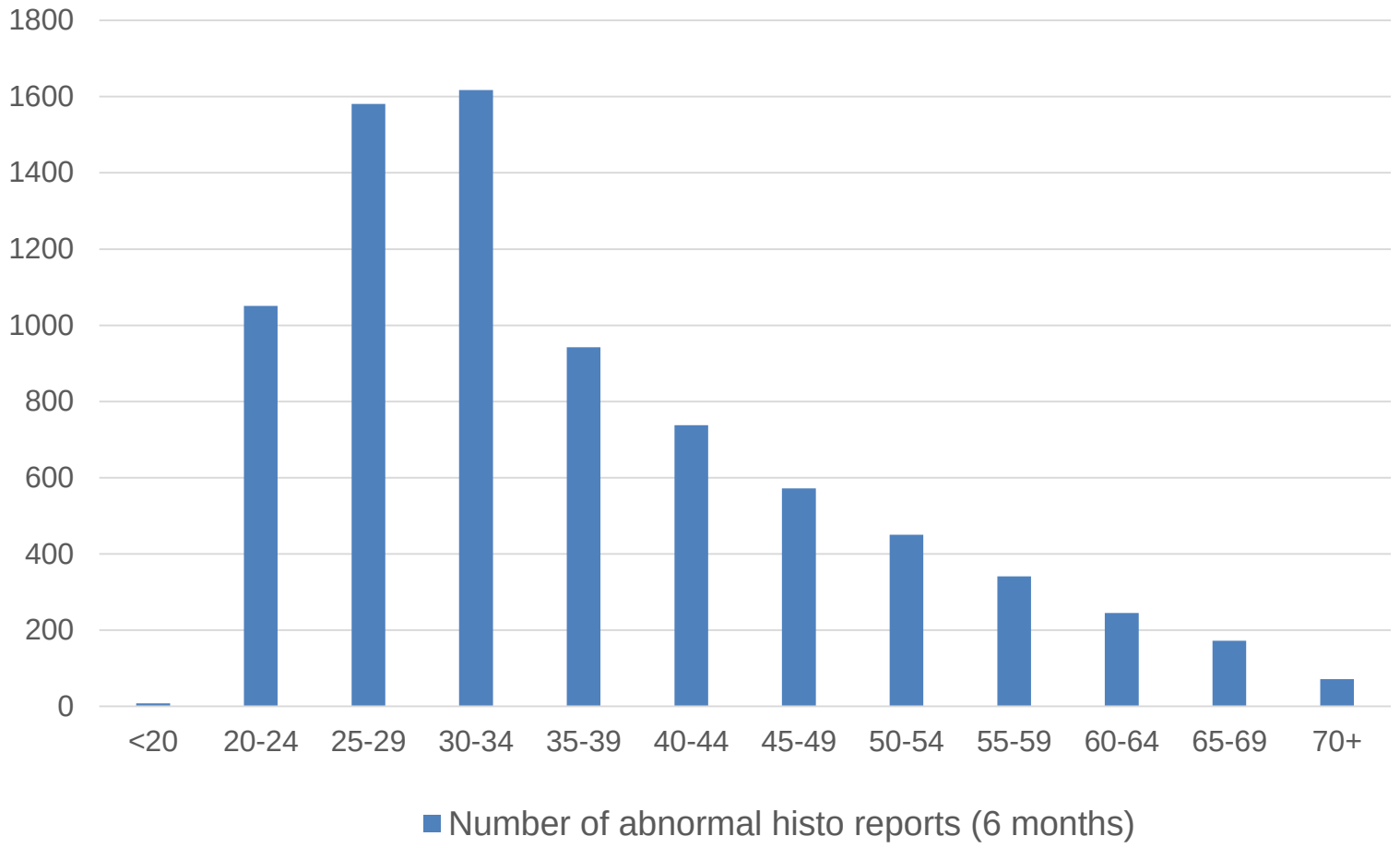
3. If more disease detection occurs in the first three years after implementation, there is less to detect in subsequent rounds of screening

Trends in the rate of women with CIN 2/3 per 1,000 women screened, by age



Specimen numbers for preinvasive cervical lesions in histology reported nationally by age

NCSP Monitoring Report data July-Dec 2019



Modelling for the transition to primary HPV screening in NZ

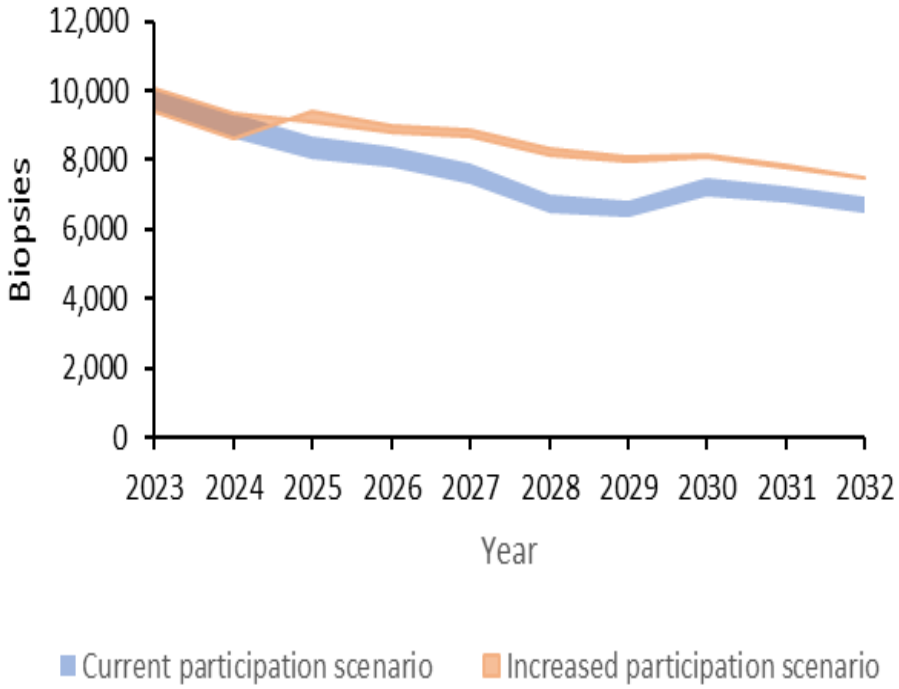
Draft report August 2022

A/Prof Megan A Smith, Dr Michaela T Hall, Ms Kay Rimalos and Prof Karen Canfell.
Cancer Council of NSW

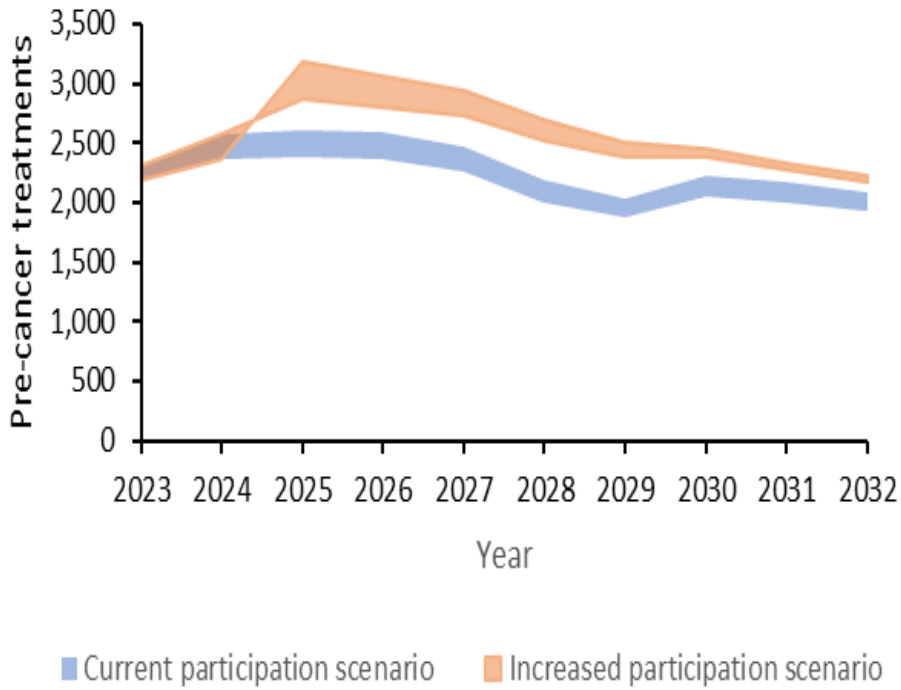
- A "current participation" scenario where current screening participation rates are maintained

- • An "increased participation" scenario in which screening participation increases due to self-testing (assumed to be 25% increase)

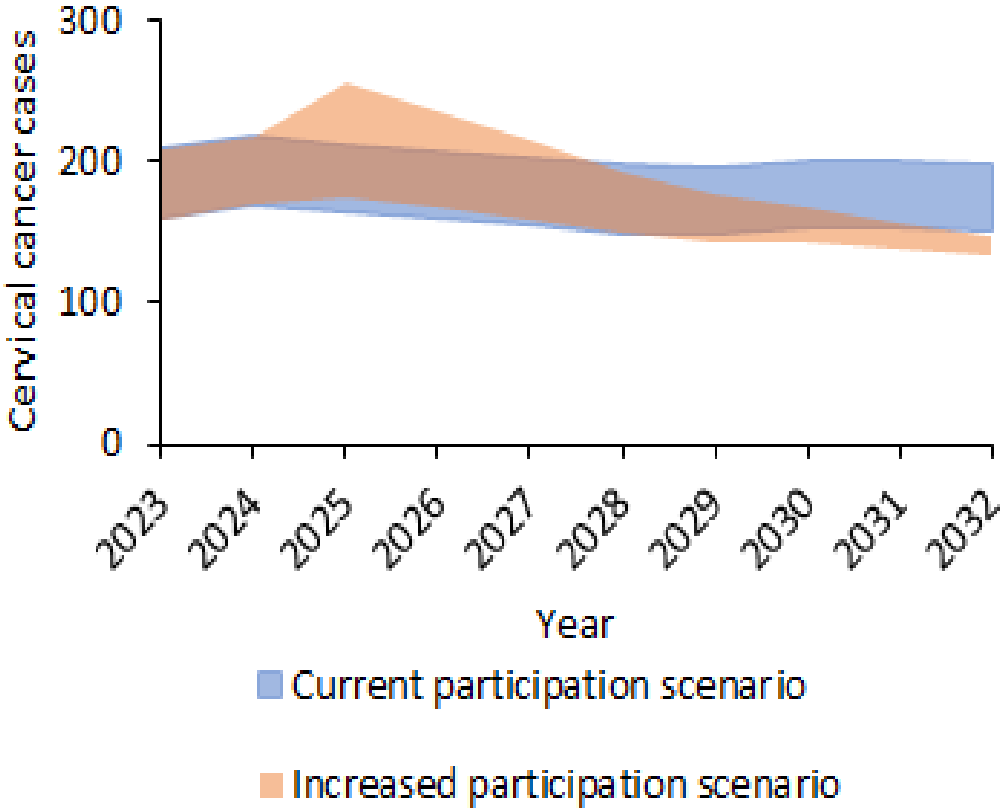
Cervical biopsies



Excision specimens



Cervical cancer cases



Expected number of cervical cancer cases, per year over 2023-2032. WHO standard population structure (2015).

Impact for registrars

- Histopathology reporting will continue as at present

- Training in cervical cytology is being considered at the RCPA Board of Education meeting in July: update awaited

Thanks for your time and interest

Questions can be directed to margaret.sage@health.govt.nz

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