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Dear Ms Rae

Updated Guidelines for Cervical Screening in New Zealand

Thank you for the opportunity to comment on the Ministry of Health's consultation document, *Updated Guidelines for Cervical Screening in New Zealand* (the Guidelines). The Royal New Zealand College of General Practitioners (the College) commends the National Screening Unit on its work on this important area of health care.

General practice and the College

General practice is the range of values, knowledge, skills, and practices required to provide first level medical services in both community practice and hospital settings. General practice includes the provision of both first contact and continuing care for all ages and both sexes that is comprehensive, person-centred, and takes into account the roles of family, whānau, community and equity in achieving health gains.

GPs comprise almost 40 per cent of New Zealand's specialist workforce and their professional body, the College is the largest medical college in the country. The College provides training and ongoing professional development for GPs and rural hospital generalists, and sets standards for general practice. The College is committed to achieving health equity in New Zealand through:

- A greater focus on the social determinants of health.
- A greater focus on measures to reduce smoking and to increase healthy food options for low-income families.
- Better integration of health and social services.
- Ensuring the funding model for primary care is targeted towards the most disadvantaged.

The Guidelines

We understand the National Screening Unit is updating the Guidelines as part of the proposed change to primary testing for human papilloma virus (HPV). Further, that the Guidelines aim to provide high–level clinical guidance to those providing health care to women in the cervical screening pathway.

We understand the key changes to the National Cervical Screening Programme (NCSP) include:

- The primary screening test will change from liquid based cytology (LBC) to HPV and the age of first screening will increase from 20 to 25 years. (These matters were the subject of public consultation in October 2015).
- The screening interval will change from three to five years.
- Partial HPV genotyping will distinguish high-risk HPV (hrHPV) types 16 and 18 from other high-risk types, with LBC testing for all samples when any type of hrHPV is detected.
- Women with hrHPV (16/18) test results will be referred directly for colposcopy regardless of the LBC result.
- LBC will be used to triage women with hrHPV (not 16/18) to colposcopy or to observation with a repeat HPV test in 12 months.
- Exit testing will be available to women up to the age of 74 years.

The College's response

The College supports updating the Guidelines to ensure clinical guidance reflects current clinical evidence and internationally recognised best practice. We acknowledge the growing body of scientific evidence for cervical screening with primary hrHPV testing, and the demonstration of an improved sensitivity for detecting cervical cancer precursor lesions compared to the current testing method using cytology.

The College's response to the sections particularly relevant to general practice are set out in the attached submission form.

We hope you find our comments helpful. If you would like any further information or clarification please do not hesitate to contact the College's policy team (policy@rnzcgp.org.nz).

Yours sincerely

Michael Thorn
Manager – Strategic Policy

Updated Guidelines for Cervical Screening in New Zealand

Submission form

To finalise the updated *Guidelines for Cervical Screening in New Zealand*, the National Screening Unit (NSU) needs your feedback.

You can provide feedback by making a written submission using this form and emailing it to primaryhpv@moh.govt.nz

If you are emailing your submission in PDF format, please also send us the Word document.

Your details

This submission was completed by:	*(name)*	Michael Thorn
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	(town/city)	Wellington 6143
Email:		policy@rnzcgp.org.nz
Organisation *(if applicable)*:		The Royal New Zealand College of General Practitioners
Position *(if applicable)*:		Manager – Strategic Policy

Additional information

I am, or I represent an organisation that is, based in:

✓ New Zealand ☐ Australia ☐ Other *(please specify)*:

I am, or I represent, a: *(tick all that apply)*

☐ District health board ☐ Private health provider

✓ Professional body ☐ other institution, eg, university

☐ Health practitioner ☐ Member of the public

☐ Other *(please specify)*:

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Closing date for submissions

The closing date for submissions is **Friday 28 October 2016.**

Consultation questions

Please provide us with your feedback on the draft updated *Guidelines for Cervical Screening in New Zealand*.

You don't have to provide a response for all of the sections of guidelines. Please provide feedback on the sections you feel are most relevant.

If there is a specific recommendation you wish to comment on, please include the number of this in your feedback.

You are welcome to include or cite supporting evidence in your submission.

Section 1. Equity and screening for priority group women

1a. What do you think about this group of recommendations?

The College considers equity and screening for high priority women to be a crucial element of the NCSP and welcomes its inclusion as the first section of the Guidelines. It is vital the NCSP continues to identify women who are either not screened or infrequently screened so that the potential to further reduce the number of New Zealand women who develop cervical cancer is realised. We consider that achieving high screening coverage is just as important as offering an effective and acceptable test.

Recommendation 1.01 of the Guidelines states that providers are expected to use evidence-based strategies to support equal access and outcomes for priority group women. It would be useful to direct users to further guidance on such strategies relevant to screening. We note the details on cultural competency set out in the *National Policy and Quality Standards* are highly relevant to the Equity section of the Guideline.

We also note that it would be helpful to discuss health literacy in this section. For example, for Māori individuals and whānau, guidance for supporting them to develop their own health literacy about the NCSP.

1b. Are you aware of any other evidence/information you think we should consider?

Section 3. Management of HPV test results

3a. What do you think about this group of recommendations?

See comments under Section 15 regarding transition.

3b. Are you aware of any other evidence/information you think we should consider?

Section 11. Screening for women who experienced early sexual intercourse

11a. What do you think about this group of recommendations?

The College supports the recommendation that it may be appropriate for women who experienced early sexual activity to have a cervical screening test before the age of 25 because of a higher risk of cervical cancer precursors with persistent HPV infection. We note that although HPV vaccination has reduced the risk of high grade abnormalities in young women, not all young women have been vaccinated.

We also support the development of further guidance for GPs when providing care to women younger than 25 where screening may be appropriate. For example, women with symptoms, women who have experienced childhood sexual abuse or early sexual activity, and women who are immune–deficient.

11b. Are you aware of any other evidence/information you think we should consider?

Section 12. Screening for immune-deficient women

12a. What do you think about this group of recommendations?

We support the development of further guidance for GPs when providing care to women who are immune-deficient.

12b. Are you aware of any other evidence/information you think we should consider?

Section 15. Transition to HPV primary screening

15a. What do you think about this group of recommendations?

We note the recommendations in Section 15 focus on how women should be transitioned to the new cervical screening pathway in 2018. However, there is very little information in the document on the overall transition to the Guidelines – including to primary HPV screening.

Informing GPs and women

It is the College's view that the success of the updated programme relies on its successful implementation. Therefore, providing timely information and education to general practice teams and women on the changes and their safety are key.

The changes will have significant implications for GPs providing care to women. Therefore, the onus is on the Ministry of Health to ensure GPs are well supported and sufficiently informed about the changes so that women in the cervical screening pathway continue to receive high quality care. It is essential that GPs are able to continue to provide health care to women that is safe, appropriate, and does not create further health inequities.

Moreover, it is crucial that communication to the public about the changes is clear and appropriate so that women take up the screening offered. We acknowledge that the changes may create concern and anxiety, particularly for those women used to the current pathway, and wrong messages may damage existing GP–patient relationships.

The College considers it is important to put the NCSP in the context of the national HPV vaccination programme; highlighting that prevention by HPV immunisation is the first line of defence and cervical screening is second. Further, we note the evaluation of primary HPV testing for cervical cancer screening in New Zealand by Lew and colleagues* (ie the modelling informing the decision to move to primary HPV testing) took into account the national HPV vaccination programme. However, Lew and others had noted that the three-dose coverage in cohorts born in 1991-2000 was only about 48-56 percent nationwide. Therefore, it would help to provide reassurance around the safety of increasing the age of first screening to 25 years given herd immunity against HPV has not yet been achieved and that the three–dose course of HPV immunisations provides protection against only four strains of HPV.

GPs should be provided with information about what the changes will mean for them. For example addressing:

- What changes to expect to laboratory reports, eg recommended action.
- If there are any changes to smear taking.
- The potential risk of not referring women with hrHPV (16/18) to colposcopy if reflex LBC is negative.
- The follow-up protocols in the NCSP–Register to ensure a referral has been made.
- Additional measures that will be put in place particularly for high risk women to ensure safety during early implementation of the changes.
- Providing exit screening for women older than 69 years.

- The safety of the move to primary HPV testing in relation to the proportion (albeit small) of cervical cancer not caused by HPV
- That the rates of colposcopy referral and histology evaluation may increase initially with the transition, but would be expected to drop as cohorts offered vaccination age and enter the new programme (noted by Lew et al)
- The existence of potential disadvantages. We note the American Interim Guidance Panel[#] discussed concerns about introducing primary hrHPV testing:
  - False negatives will continue to occur.
  - Specimen adequacy, appropriate internal controls, and the impact of potential interfering substances such as lubricants are important considerations.
  - There are different hrHPV tests and it is important that laboratories use an FDA–approved test.

GPs should also be well equipped with knowledge and tools to inform women what the changes will mean for them. For example:

- Whether a speculum examination is still required.
- That no additional visit is required for cytology.
- The need for colposcopy when reflex LBC is negative.
- How women will receive their results.
- What happens to their results such as where results will be recorded.
- Why routine screening will start at age 25 years.
- What a woman outside the screening age should do if she develops symptoms.
- The continued importance of screening despite the change to a five-yearly interval. The longer screening interval is also relevant in women who are difficult to follow up (eg transient patients).

It is crucial that educational material for GPs includes a clear, concise summary of the changes or a legible pathway which is relevant to the general practice audience. A one-page wall chart would be one option. The provision of local training on the new pathway and access to a hotline for smear takers may also be useful.

Clear, succinct messaging is also essential for consumer materials. The College would be happy to assist in the development and/or dissemination of educational material.

Sufficient lead–in time

The College is of the view that sufficient lead–in time is needed so that practice management systems can adapt to the changes and the changes are implemented into routine workflows. Invitation and recall can already be a time–consuming and frustrating for general practices. Therefore, practices will need to have an effective recall system in place to ensure follow-up in accordance with the updated NCSP policy and guidelines.

The College also requires sufficient lead-in time to ensure the College's quality standard and guidance are aligned to the new NCSP.

Monitoring and evaluation
The College also considers that it is essential to closely monitor and evaluate the performance of the new NCSP to ensure the quality, safety and effectiveness of cervical screening is improved. The changes need to achieve better outcomes for women. Further it is important to closely monitor the effect of the changes on women's behaviour to ensure update at the recommended five-yearly intervals.

* Lew J-B, Simms K, Smith M, et al. Effectiveness Modelling and Economic Evaluation of Primary HPV Screening for Cervical Cancer Prevention in New Zealand. Tornesello ML, ed. *PLoS ONE*. 2016;11(5):e0151619. doi:10.1371/journal.pone.0151619.

Huh WK, Ault KA, Chelmow D, et al. Use of primary high-risk human papillomavirus testing for cervical cancer screening: interim clinical guidance. Gynecol Oncol. 2015 Feb;136(2):178-82. doi:10.1016/j.ygyno.2014.12.022.

15b. Are you aware of any other evidence/information you think we should consider?

Other comments

The College acknowledges that the NCSP is currently updating the documents, *National Policy and Quality Standards – Section 3: Cervical screening services* and *Competencies for Cervical Screening Education and Training*. It would be helpful for the Guideline to clarify the relation between the documents. For example, as noted above, the details on cultural competency set out in the *National Policy and Quality Standards* are highly relevant to the Equity section of the Guideline.

The College also supports further work on the feasibility of options to increase screening update such as HPV self-sampling for those women who find it difficult to access screening services.

Thank you for taking the time to provide feedback.