

National Cervical Screening Programme

Public consultation feedback for updated *Clinical Practice Guidelines for Cervical Screening in New Zealand*

As part of the transition to primary screening for human papillomavirus (HPV), the National Cervical Screening Programme (NCSP) is updating the *Clinical Practice Guidelines for Cervical Screening in New Zealand* (the guidelines). As part of this process, the draft guidelines were released for public consultation for six weeks in late 2016. A copy of the consultation document is available by going to: <https://www.nsu.govt.nz/health-professionals/national-cervical-screening-programme/cervical-screening-guidelines/updated>

Please note, the guideline is a living document and may be subject to further changes prior to implementing HPV primary screening.

33 submissions were received in total. These were generally supportive of the proposed guideline updates. Responses came from a variety of sources including clinicians, health and non-governmental organisations, and from members of the public. Feedback is available to view in appendix one which contains the raw submission responses for each section of the guidelines. Two individual respondents requested the NCSP not to publish their submission.

A number of submissions included feedback on topics outside the scope of this consultation such as addressing cervical screening equity gaps, and the NCSP's policy decision to cease screening in women aged 20 to 24 years. This feedback has been noted, however the issues raised have already been considered as part of previous consultation, or are being considered in parallel with the development of new guidelines.

Key points raised in submission feedback are listed below.

- Submissions supported the inclusion of the equity section within the guidelines, and respondents strongly encouraged the NCSP to continue implementing strategies to improve the participation of Māori, Pacific and Asian women in the programme.
- Several submitters suggested that the NCSP incorporate recommendations to help clinicians appropriately care for female to male transgender people along the cervical screening pathway.
- Some submitters did not support screening women aged over 75, or felt that greater clarity could be provided around when this may be appropriate.
- Several respondents voiced concerns about the impact of the updated pathway on colposcopy referral volumes, and encouraged the NCSP to begin work with colposcopy services early to manage the transition to primary HPV screening. Some detailed feedback was received about specific guidelines in the colposcopy section, and this can be found in the attached appendix.

- In general submitters did not support the proposed guidance for cytological grades of atypical glandular cells (AG1-5) being separated into a lower and high risk with the lower risk (AG1-3) not being referred directly to colposcopy (Australia has adopted this 2 tier pathway). They preferred that AG1-3 continue to be managed in the same way as AG 4-5 with all being referred directly to colposcopy
- Submitters welcomed additional clarity provided in the updated guidelines to support clinicians to care for women following a total hysterectomy, during pregnancy, and for women who are immune deficient.
- Responses to the guidance on screening for women who experienced early sexual activity were mixed, suggesting further work may be required in this area.
- Several submitters requested greater clarity about the clinical care of women with abnormal vaginal bleeding and others questioned whether this should be included in cervical screening guidelines.
- Submitters encouraged the NCSP to provide clear and detailed guidance to relevant stakeholders as part of the transition to HPV primary screening. This should include education packages and clear guidance about how to manage cervical screening under the new pathway.
- Some respondents raised concerns about reference in the document to the incidence of cervical cancer in a global context, and suggested that incidence should refer to New Zealand cervical cancer incidence.

The feedback received during this consultation process has been considered by the Clinical Guidelines Development group, the Primary HPV project's technical reference group, NCSP advisory group and amendments made accordingly.

Next steps

The guidelines remain in draft format and will not be widely disseminated until closer to the implementation of HPV primary screening. This is to avoid confusion with the current clinical pathway and to enable the NCSP to incorporate any new evidence into the guidelines, and to work with women, clinicians and others caring for women along the screening pathway so that introduction of the new pathway runs smoothly.

Individuals who would like a copy of the draft guidelines can obtain a copy by emailing:

primaryhpv@moh.govt.nz

Updated Guidelines for Cervical Screening in New Zealand: collated raw submissions Oct 2016

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SECTION 1: Equity and screening for priority group women		
Name / Title	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Māori Health, Lakes District Health Board	From a non-clinical perspective they are very high level and there are no implementation processes to ensure that priority group women (Māori) will be screened earlier or at a level close to non-Māori. The Treaty of Waitangi component does not state how these principles will be implemented into practice and monitored.
Dr Vicki Robertson, Lead Colposcopist	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson, Education Nurse	Well Women & Family Trust	Should Pacific women still be a priority group? Other evidence/information to consider: June '16 NSU stats for coverage
Respondent's name redacted at request.	Waikato DHB	Pleased to see the focus on equity. Other evidence/information to consider: P2 amendment: HPV 6 and 11 responsible for most transient low grade lesions and genital warts. Funding for a nine-valent vaccine will be included in the immunisation schedule in 2017. The new vaccine will be funded for males and females up to the age of [25 years] and will provide protection against HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58. Including other high-risk Comment [JM1]: 26 years, not 25
Amanda Tristram, SMO Gynaecological Oncology	Health Practitioner	Would it be helpful to have direct referral from the laboratory to colposcopy for all women? This would remove inequities in provision of service for women having cervical smears taken by different providers. The system works very well in other countries- for example many places have adopted this in the UK. In Wales (similar size population) there is a direct referral system as well as call and recall.
Michael Thorn, Manager Strategic Policy	Royal NZ College GPs	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

		<p>develop cervical cancer is realised. We consider that achieving high screening coverage is just as important as offering an effective and acceptable test.</p> <p>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 <i>National Policy and Quality Standards</i> are highly relevant to the Equity section of the Guideline.</p> <p>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.</p>
Pip Egerton, Rural Practice Nurse (smear taker), Primary Care representative Otago / Southland NCSP regional multidisciplinary team	Tuatapere and Otautau Medical Centre	<p>Other evidence/information to consider:</p> <p>Would like to see an integrated team approach to improve coverage. The improved coverage, over a period of time, for immunisation, has occurred due to a team approach. That is the development of immunisation coordinators, immunisation outreach, data sharing, overdue reports shared with practices (particular to primary care practice ,is that these teams do the “list making” i.e. recalls for practices and relay this information which is time effective management for a practice nurse-who can do a phone recall- this known to be the most effective recall approach). Possibly this approach vs NCSP doing letter recalls themselves, will assist in improved screening uptake. Employing outreach nurses would also improve uptake. Having worked in Southland 13 years and been involved in woman’s health for the most part. I have noticed (again in primary care) since Otago / Southland have had clinical and management persons involved in their regional team and Otago and Southland based, the connection between NCSP and Primary Care (where most providers are situated) has improved with professional health education, updated information and data sharing. Now is a good time to review NCSP information resources (I am aware this is happening).The NZ public need simple health literate information available and most importantly demystify the role HPV has in cell change. Very important to move away from it being seen as a sexually transmitted infection (disease) – as it is presently portrayed in NCSP literature. Suggest cost effective move would be for health literature reviewers’ to work with HPV immunisation teams and the NZ Sexual Health Society in establishing consistent, simple health literate information.</p>

Fiona Moscrop – on behalf of Clinical Quality Board	Compass Health	<p>Consider supporting <i>enhanced access</i> rather than <i>equal access</i> – this acknowledges these priority women need more support.</p> <p>Partnership – consider adding PHO/General Practice/NSU etc as engagement required as every point of the health system. This is particularly pertinent for vulnerable groups.</p> <p>Consider using Whare Tapu Wha as a framework as an engagement model for equity access.</p>
Respondent's name redacted at request.	Member of the public	<p>Firstly, I feel it necessary to clarify; under the title Cervical screening in New Zealand (Updated Guidelines for Cervical Screening in New Zealand pg1, 4), it states “Cervical cancer is the fourth most common cancer for women; internationally 266, 000 women worldwide die from cervical cancer each year.” These are international figures and are not relevant to the New Zealand situation.</p> <p>It is important to note that, in New Zealand, cervical cancer is the 11th most common cancer for women and the 19th most common cause of cancer death in women. In 2014 there were 142 new cases of cervical cancer and in 2013 there were 54 deaths. This is an age standardised rate of 1.4 / 100,000 non Maori and 4.0 / 100,000 for Maori. [An overview of cervical cancer, Naomi Brewer The control of cervical cancer in New Zealand : Achievements and future prospects Auckland, 5 August 2016]</p> <p>It should also be noted that approximately 85% of cervical cancer cases occur in the developing world. [Epidemiological Studies of Cervical Cancer Survival in New Zealand, Naomi Brewer 2011]</p> <p>‘Around 80% of women who develop cervical cancer in New Zealand have either never been screened or have been screened infrequently’, (Updated Guidelines for Cervical Screening in New Zealand pg 8, 1.1). This suggests that lack of screening is the main factor in women developing cervical cancer. There are many factors that are implicated in the development of cancer. Smoking, low socio economic status, parity, oral contraceptives etc. [Epidemiological Studies of Cervical Cancer Survival in New Zealand, Naomi Brewer 2011]</p> <p>In the past because of the huge push for women to undergo screening, those who didn't may have been women who were indulging in other risky behaviours in their lives. Dr Margaret McCartney a Scottish GP mentions this in her book “The Patient Paradox”. Suggesting that lack of screening is a significant cause of cervical cancer over simplifies the issue. To date, the Pap smear and, latterly, the Liquid Based Cytology test LBC, have been used mainly to identify squamous cell carcinoma. “Other malignant tumours of the cervix (including adenosquamous carcinoma, glassy cell carcinoma, adenoid cystic carcinoma, adenoid basal carcinoma, carcinoid tumour, small-cell carcinoma, and undifferentiated carcinoma) remain less common. [Epidemiological Studies of Cervical Cancer Survival in New Zealand, Naomi Brewer 2011]</p>

		<p>It is important that women are told and understand that they can still get cervical cancer in spite of attending screening. This will still be the case even when we change to primary HPV testing. Infection by certain high risk HPV subtypes is necessary but not sufficient to cause cervical carcinoma. I note that self-sampling for primary HPV testing is being trialled to see if it is acceptable to Maori women. The Australian Draft clinical guidelines for cervical screening, show that they are introducing self-sampling for women in their screening programme in 2017. There is extensive collaboration between the NSU and the Australian screening programme so why is our screening programme not doing this? .My personal opinion is that the Australian programme is using self-sampling earlier to capture those women who are not part of their screening programme, as they have lower coverage rates than we do. In the new Australian programme women are only allowed to self-sample once and they are then directed to a clinician collected sample via the speculum once enrolled in the programme, very sneaky.</p> <p>[http://wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Prevention]</p> <p>I hope that in trying to achieve equity for priority group women you do not intend to further override the legal and ethical necessity to provide informed consent. It seems to be acceptable to offer cash incentives to smear takers to capture those women who have not screened or are not screening regularly. [Innovative approach increases cervical screening number, Screening Matters, August 2014]. Are women being told about these incentive payments? This is a conflict of interest and must be declared to the woman. I have also seen offers of Pak 'n Save supermarket vouchers used as a bribe to get women to have smear tests. I find this abhorrent. Our GPs are already incentivised via the IPIF to push screening. These incentives will drive smear takers to pay lip service to informed consent at best. If a woman refuses a smear test her wishes must be respected. It makes no difference whether that woman is from a priority group, she must be provided with sufficient information to give informed consent.</p> <p>To date, women who have not screened have been perceived as being in minority groups, having low health literacy, cultural barriers etc. As women learn more about the harms of screening there will be an increase in the group of intelligent, informed women who are already actively declining screening.</p>
Maria Poynter, Public Health Medicine Specialist	HQSC	<p>The Health Quality & Safety Commission (the Commission) is pleased to see the inclusion of equity recommendations in the clinical guidelines. Specific consideration of equity is an important aspect of health care quality improvement, as outlined in the Triple Aim for New Zealand (1). We have limited our feedback to comments on this section, which fits within our expertise.</p> <p>The Commission considers that these recommendations could be more explicit. Our experience is that many health professionals and health providers are aware of inequities, and support measures to reduce them. However, there is</p>

		<p>uncertainty and lack of knowledge about <i>how</i> to create change towards equity. Some examples of how the current recommendations could be more explicit include:</p> <ul style="list-style-type: none"> • Recommendation 1.01. Change “additional effort” wording, to concentrate on ‘different ways of working’. This would help to reduce any perceptions that pro-equity actions are time-consuming and cumbersome, and require ‘more of the same’ action. Such a perception is unhelpful, and incorrect. Evidence tells us that pro-equity actions are most effective when they are flexible enough to be responsive to sub-populations’ needs (2). • Recommendation 1.01. We suggest including guidance and examples of “evidence-based strategies”. This links to our comment above about a lack of knowledge about <i>how</i> to decrease health inequities. Detailed examples could be given in an appendix or a link to an on-line document. • Recommendation 1.03. Again, we suggest that the guidelines explicitly state what “an environment that respects the culture and the dignity and autonomy of women” looks like. Photos and examples could be provided in an appendix or an on-line document. There are plenty of examples available, but our experience is that health professionals and providers may not be aware of how simple innovations can lead to improved screening coverage. <p>References</p> <ol style="list-style-type: none"> 1. Health Quality & Safety Commission. The New Zealand Triple Aim for Quality Improvement [cited 2016 6 September]. Available from: www.hqsc.govt.nz/about-the-commission 2. Wyatt R, Laderman M, Botwinick L, Mate K, Whittington J. Achieving Health Equity: A Guide for Health Care Organizations. Cambridge, Massachusetts.: Institute for Healthcare Improvement, 2016.
CWH – Colposcopy Service: Drs Helene MacNab (Lead), Sharron Bolitho, Emma Jackson, Nurse Specialist Jill Lamb. Gynaecological Oncologists A/Prof Peter Sykes and Dr Bryony Simcock. CHL - Kirsten Beynon (General Manager), Dr	Collaborative feedback from staff at Christchurch Womens' Hospital (CWH) and Canterbury Health Laboratories (CHL).	<p>Practice Points 1.01-03 need expansion and elaboration <i>into actual methods that have been shown to work</i> to improve coverage within each of the Priority Groups. These Practice Points are light on “how” these recommendations may be achieved within each Priority Group.</p> <p>We fully agree with the statement “18. Achieving equitable access to and through the cervical screening pathway for all population groups is a key priority for the NCSP. Māori, Pacific and Asian women have lower rates of screening coverage than women of European/other ethnicities, and are a priority group for the programme.”</p> <p>Other evidence/information to consider: We are unaware of many/any studies into the <i>perceptions of HPV positivity</i> amongst different population groups within New Zealand, particularly within under-screened Priority populations. Such studies should look at both male and female perceptions. If the NZ Compass Study has some robust results regarding these perceptions, then the key findings should have been included in the Background information regarding Equity and Screening for Priority Group </p>

Anja Werno (Medical Director Microbiology) A/Prof Lance Jennings (Virologist), Drs Andrew Miller and Rachael van der Griend (Anatomical Pathologists).		<p>Women (1.1) in the Consultation document. Such studies will be very useful to those working on ensuring high uptake of primary HPV screening, particularly amongst under-screened Priority populations. We expect that his data will be crucial to inform “how” the aims listed in Practice Points 1.01-03 can be realised.</p> <p>Some oversight group, probably the NCSP, needs to collate, investigate and disseminate the innovative ways that can be used to reach target groups – these are likely to be different between the different under-screened Priority populations. However, the NCSP should be able to provide a “Toolbox” of the methods that have been shown to be most effective within a particular population/ethnic group. The NCSP should facilitate sharing of these methods for those involved in improving uptake of cervical screening within each of these Priority Groups. We do not see any plans for this in the Consultation document and would welcome any updated information in this key priority focus.</p> <p>Self sampling may be a useful adjunct for improving screening in some of the Priority populations – again, there needs to be targeted research into each group – including the <i>several different</i> Asian populations in NZ. We would like to be convinced about the effectiveness and acceptability of this potential sampling technique amongst different Priority groups. <i>We expect that self-sampling for most women will need to be in a supervised location to ensure adequate labelling of the request form and sample, to ensure adequate identification of such samples.</i></p> <p>There are <i>key opportunities in the lead up to implementation in 2018 for education</i> in multiple settings (schools, community groups, etc) to improve understanding regarding HPV and how primary HPV screening works.</p>
Pam Hewlett (Planning and Funding Portfolio Manager) Lucina Kaukau (Cervical Screening Nurse Specialist) Jane Grant (Cervical Screening Nurse Specialist)	Auckland & Waitemata DHBs	Good.

Barbara Holland & Barbara Robson, Co-Convenors	Federation of Women's Health Councils Aotearoa	<p>Agree with the broad-brush principles & practice points for priority group women. Culturally relevant information/education needs to be provided as well. Different cultures have different histories, understandings, and priorities. It is not just a matter of translating brochures that have been printed for NZ European or <i>pakeha</i> women.</p> <p>This information must relate to/explain the NZ context in terms of cervical cancer incidence and the success of cervical screening in reducing incidence and mortality from cervical cancer in NZ. Continuing to discuss cervical cancer in the international context as the 4th most common cancer for women makes little sense to priority women who have commented in qualitative research that cervical cancer lacks importance because they weren't hearing about it in their own lives; that they didn't know anyone or of anyone in their networks who had cervical cancer or had died of cervical cancer.</p> <p>Asian women (noting the significant subsets within this current broad ethnic classification) will no doubt also benefit from different approaches to invitation to screening and ongoing screening programme participation from Maori and Pasifika women. Where does this feature within current Support to Services contract and reporting services?</p> <p>1.02 – Participation: add - and monitoring & evaluation</p> <p>Other evidence/information to consider:</p> <p>Cost is still a barrier to cervical screening for many low-income women defined as 'Other'.</p>
Dr Gillian Gibson, Fellow RANZCOG, NZ committee Executive member and RANZCOG Council representative	On behalf of RANZCOG NZ Committee	The RANZCOG Maori Womens Health Committee Chair Dr Leigh Duncan (<i>He Hono Wahine</i>) agrees with the recommendations.
Annette Davis, Team Leader Population Screening	Hawke's Bay DHB	Agree.
Rae Duff, National President Ailsa Stewart, Convenor, Health Standing Committee	National Council of Women of NZ Health Standing Committee	We appreciate that New Zealand has one of the most successful cervical screening programmes in the world, with a clear series of tests and treatments to ensure women in this country are given the best chance of survival. However, as the document states, the scheme is not equally distributed to all population groups. We note that Maori, Pacific and Asian women are poorly represented in present statistics and have a higher cervical cancer rate.

		<p>It is imperative that these groups of women are specifically targeted, that every effort is made to ensure their communities and social networks are included in the education for the need for immunisation and for cervical screening and that women of their own ethnicities are trained to provide these services in their language and in their own environments.</p> <p>Because of stark ethnic health disparities in New Zealand, it is imperative that every effort is made to connect with Maori, Pacific Island and the various ethnic communities through their whanau, local churches, ethnic associations and community leaders to ensure the desired increase in the number of vaccinated and screened women. Achieving equitable access to and through the cervical screening pathway for all population groups is a key priority.</p>
Leanne Manson, Policy Analyst Māori	On behalf of NZNO (submission endorsed by The College of Nurses Aotearoa Inc)	<p>Equity and screening for priority group women</p> <p>Māori women are over-represented in cervical cancer statistics, and under-represented in cervical screening participation - we do not agree that such inequalities are acceptable*, in Aotearoa New Zealand in 2016. We strongly advocate for equitable funding to address health outcomes for those with the greatest need, in particular Māori, Pacific and Asian women rights to access good health services. We also strongly advocate for culturally appropriate services that support an environment that respects the culture and the dignity and autonomy of women.</p> <p>* Human Rights Commission. (2012) A fair go for all? Rite tahi tātou katoa? Addressing Structural Discrimination in Public Services. Human Rights Commission: Wellington.</p>
Howard Clentworth, SMO Lead Colposcopist & Gynaecologist	CCDHB	<p>Equity in terms of screening is largely a primary care issue. Cost is the largest barrier. Education second. We may have views but in general they relate to access issues to care in general.</p>
Mary Webster, Cytology Screener (Scientist)	CHL	<p>Good - Jane O'Hallahan presentation of Changes to cervical screening had a section on self-sampling.</p> <p>Other evidence/information to consider:</p> <p>Metro Auckland Cervical Screening Advisory Group (MACSAG). HPV Self Testing Dr Karen Bartholomew paper 4 June 2015.</p> <p>A major advantage of transition to primary HPV testing this is the option for self-sampling for wahine ma and other low participation groups in New Zealand. The above referenced paper concludes that self- collected (self-sampled) is as good as physician collected. "... HPV testing on self-sample can be suggested as an additional strategy to reach women not participating."</p>

		<p>In addition from the CDHB Māori Health Action Plan 2016/17</p> <p>Statistics: In Canterbury</p> <p>Cervical Cancer vaccination Māori are 20% less likely than non-Māori to be vaccinated against HPV</p> <p>Cervical Cancer screening Māori are 40% less likely than non-Māori to have had a cervical smear in the last 3 years</p> <p>Cervical cancer diagnosis Māori are 4.2 times more likely to be diagnosed with cervical cancer than non-Māori</p> <p>Canterbury needs to pilot HPV self-sampling study and I would be more than happy to be part of the research group in a technical capacity, and with my Māori ancestry (Ngāi Tahu, Ngāti Māmoe, Waitaha and Ngati Kahungunu descent). Member of the Rapaki Māori Women's Welfare League.</p>
Lynda Williams, Co-ordinator AWHC	On behalf of Auckland Women's Health Council	<p>There is no evidence that the change to primary HPV screening will achieve equitable access to cervical screening for priority group women. Maori, Pacific and Asian women will benefit from being invited to participate in cervical screening by using approaches that are culturally appropriate. Access to publicly-funded screening will achieve a great deal more than changing the primary screening test.</p>
Lynere Wilson, Branch Secretary	Rapaki Maori Women's Welfare League	<p>We are pleased to see the opportunity for self-sampling. We hope that it will improve the participation of women who can be hard to reach and see it as complementary to an 'assertive' outreach approach. We note that Māori participation in cervical screening is low in Canterbury. (http://www.cdhb.health.nz/About-CDHB/corporate-publications/Documents/CDHB-Final-Maori-Health-Plan-2016-17.pdf). Therefore we strongly encourage you to fund research (both qualitative and quantitative) that seeks to understand the barriers to participation in cervical screening in Canterbury and then use this as the basis to make changes to practice.</p>
Dr Sandra Hall, Policy Analyst	On behalf of the Cartwright Collective	<p>Cost has been repeatedly shown to be a factor in not being screened and /or being underscreened. The guidelines need to address this issue in regards to providing equity and access. It would also be helpful for the guidelines to provide information about underscreened groups and the likely impact of moving to HPV testing is likely to have on their rates of screening.</p> <p>Other evidence/information to consider:</p> <p>There have also been a number of successful locally based programmes that have been successful in engaging underscreened groups of which you are aware.</p> <p>In addition the move to HPV testing may mean some groups believe they do not require testing (eg. women who only have sex with women, an already underscreened group) or others to afraid to have the test because of the personal</p>

		implications of a positive HPV result (eg. women from particularly male dominated cultures or religions or those in abusive relationships).
Individual respondent	Self-employed midwife CMH region	<p>Sensible and includes multiple opportunities for women to have screening.</p> <p>Other evidence/information to consider:</p> <p>Please look at MOH section 88 and please reinforce to GP's who mostly undertake the Non LMC payments for the first 12 weeks of pregnancy that they need to do the smear screening. I work in high deprivation communities where by smears are often not done, never had one or overdue. The GP should be proactive to do smear when the preg test is undertaken. Take the time then – opportunistically – so the smear is undertaken. They are paid the non LMC payment and basic health screening is part of that module.</p>
Dr Debra Graves, CEO	RCPA Australasia	The College believes equity issues are important as evidenced by the data of poorer screening coverage and higher incidence of disease. The recommendations however appear to make no practical suggestions as to how to increase screening coverage.

SECTION 2: Invalid and unsatisfactory cervical screening results

Name / Title	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	Non applicable from a non-clinical perspective.
Dr Vicki Robertson, Lead Colposcopist	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson, Education Nurse	Well Women & Family Trust	Good.
	Waikato DHB	<p>Good to give time frame for repeat testing and great to see recommendation for use of vaginal oestrogen in post-menopausal women – Need to ensure there are no CONTRA-INDICATIONS before prescribing (eg history of oestrogen sensitive tumours – such as breast cancer).</p> <p>Other evidence/information to consider:</p> <p>P10 amendment:</p>

		<p>2.04 Use of vaginal oestrogen for postmenopausal women <i>before</i> a cervical sample is taken</p> <p>Practice point</p> <p>It is recommended that postmenopausal women apply vaginal oestrogen every day for three weeks before the repeat testing, to improve the quality of cervical sample taken. They should be tested within two weeks of discontinuing treatment.</p>	<p>Comment [JM2]: and trans men on testosterone</p> <p>Comment [JM3]: and trans men on testosterone</p>	
Pip Egerton, Rural Practice Nurse (smear taker), Primary Care representative Otago / Southland NCSP regional MDT	Tuatapere and Otautau Medical Centre	<p>Good to see 2.04 included.</p> <p>Other evidence/information to consider: Good to see this removed as a Quality measure for cervical smear takers</p>		
Fiona Moscrop – on behalf of Clinical Quality Board	Compass Health	Acceptable.		
Respondent's name redacted at request.	Member of the public	In my opinion postmenopausal women should be offered self HPV testing in the first instance rather than vaginal oestrogen when a test is invalid.		
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	Support recommendations.		
Pam Hewlett (P&F Portfolio Manager) Lucina Kaukau (Cervical Screening Nurse Specialist) Jane Grant (Cervical Screening Nurse Specialist)	Auckland & Waitemata DHBs	<p>2.1 suggest changing the word cervibroom to “clinically appropriate sampling device</p> <p>2.6 There is a risk that less care may be taken collecting adequate cells if all positive type 16 &18 HPV tests are seen at colposcopy. We suggest monitoring of unsatisfactory rates as part of programme evaluation.</p> <p>2.03 Is there a clinical reason for waiting 3 months to repeat the sample? If the sample can be taken within 3 months then recommend stating this.</p> <p>2.04 Good to see documented guidance on use of vaginal oestrogen. Thank you.</p>		
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Service	<p>Other evidence/information to consider:</p> <p>2.04 We suggest a recommendation that all postmenopausal women use vaginal topical oestrogen for 3 weeks before any cervical sample is taken, not just those women who have had an unsatisfactory sample previously. This would have</p>		

		two benefits; firstly if reflex cytology was required the result would not be confounded by atrophy and secondly the examination would be more comfortable for the woman thereby reducing the decline rates for future screening.
Barbara Holland & Barbara Robson, Co-Convenors	Federation of Women's Health Councils Aotearoa	<p>2.03 Why not just repeat the smear instead of automatic referral to colposcopy? If the LBC sample is unsatisfactory how will the colposcopist be sufficiently informed to make an accurate diagnosis?</p> <p>Given that NSU is still to undertake modelling on the likely increase in colposcopy referrals and their impact on existing colposcopy capacity, it may be that screening test results with hrHPV detected (16/18) will need to be triaged using LBC results</p> <p>2.04 We note use of vaginal oestrogen cream is a recommendation. Will this be routinely recommended / offered to postmenopausal women when they make their appointment for a smear? Will the reasons be explained? Presumably this will be presented as an option? What are the likely additional costs? (cost of prescription for the cream and co-payment at the pharmacy). Could these additional costs and effort likely to be a barrier to some women participating in screening, especially the priority women and women on low incomes?</p> <p>How will women who make appointments via their patient portal be informed about this recommendation?</p>
Dr Gillian Gibson, Fellow RANZCOG, NZ committee Executive member and RANZCOG Council representative	On behalf of RANZCOG NZ Committee	<ol style="list-style-type: none"> 1) What is the evidence base for cervibroom as compared to spatula and in particular cytobrush- if co testing how important is it to ensure sampling from the endocervix? There is reference to combibrush and cytobrush in recommendation 10.11 later in document. 2) For postmenopausal women is it important for HrHPV testing to pretreat with estrogen (in case of need for co-testing) or could this be considered an advantage of the HPV primary screening that this group of women will no longer need to use topical estrogen?
Annette Davis, Team Leader Population Screening	Hawke's Bay DHB	<p>Agree.</p> <p>Other evidence/information to consider:</p> <p>Adding a flowchart, it's a quick way to check what is required.</p>
Individual respondent	Self-employed midwife CMH region	Ok.

SECTION 3: Management of HPV test results

Name / Title	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	Non applicable from a non-clinical perspective.
Dr Vicki Robertson, Lead Colposcopist	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson, Education Nurse	Well Women & Family Trust	<p>Good except I think testing women over 75 years is unnecessary.</p> <p>Other evidence/information to consider:</p> <p>Testing women over 75 years will increase the volume of smears and as cervical cancer is very slow moving I think there will be a lot of unnecessary testing.</p>
Respondent's name redacted at request.	Waikato DHB	Great to get much clearer guidance around some common cervical screening scenarios e.g. after hysterectomy and for immunodeficiency/immunosuppression.
Michael Thorn, Manager Strategic Policy	Royal NZ College GPs	See comments under Section 15 regarding transition.
Pip Egerton, Rural Practice Nurse (smear taker), Primary Care representative Otago / Southland NCSP regional multidisciplinary team	Tuatapere and Otautau Medical Centre	<p>I have concerns with the proposed change to starting cervical screening aged 25 yrs and the five year recall for certain woman. In reference to the later group, particularly women with a previous high grade history, who like most of us are likely to experience low levels of immunity through general ill health. It is good to see women with low immunity due to reasons other than HIV being recognised as requiring a 3 year recall still.</p> <p>Other evidence/information to consider:</p> <p>Feel big conflict of statements in the Public Consultation Paper for National Cervical Screening Programme: changing the laboratory test.</p> <p>I refer to Pg.11 in regards the Age Range. Reference is to the Australian data ‘...that has shown that cervical screening of women aged between 20-24 years has had no effect on the rates of cervical cancer cases’...Yet the next paragraph shows NZ project team identify total 23 women over a five year period 2008-2013 diagnosed with cervical cancers. “With 74 percent of the 19 squamous cell cancers were micro-invasive”.</p> <p>Has it been considered what a smear takers response will be to those in this age group who request an HPV test...will the laboratory have the ability to reject this request?</p>

		<p>Would it still not be cost effective with known four cases per year of invasive cancers in this age group to offer HPV testing in this age group?</p> <p>Is the fact we presently screen from aged 20 yrs (compared with other countries in the modelling process) possibly part of the reason "...New Zealand has one of the most successful cervical screening programmes in the world" NCSP public consultation paper Pg. 1</p> <p>Do have opinions on when the 5 year recall is questionable but will advise in appropriate sections</p> <p>Feel the change to HrHPV testing is a progressive move do feel however some of the less academic decisions. For example starting age and certain groups for 5 year recall should be discussed further. The opportunity to do this individually and indeed at regional level in 2015 through the discussion paper was noticeably "well controlled", in that the Otago /Southland regional NCSP multidisciplinary team was only aware of the consultation paper one week before submissions closed.</p>
Fiona Moscrop – on behalf of Clinical Quality Board	Compass Health	<p>Clinically acceptable.</p> <p>Consider referencing at a high level eg RNZCGP management of laboratory results re: process.</p>
Respondent's name redacted at request.	Member of the public	<p>Testing for high risk HPV types was introduced in New Zealand in October 2009. Adjunct HPV testing has been used as a reflex test to triage women aged 30 years and over with primary ASC-US/LSIL results. Women under 30 were not offered HPV testing unless they had a previous high grade (HSIL/ASC-H) lesion. [Guidelines for Cervical Screening in New Zealand. Guidance on HPV Testing Update 1: April 2010]</p> <p>Women under 30 years should not have an HPV screening test in this situation because HPV infection is very common in this age group and usually goes away. For younger women, including an HPV test along with a smear test provides no real health benefit and might lead to too many tests and unnecessary treatment. [https://www.nsu.govt.nz/national-cervical-screening-programme/frequently-asked-questions/frequently-asked-questions-about-0#Why is HPV testing not recommended for women under 30 years who have a mildly abnormal smear result?]</p> <p>It is already known that HPV testing in women under 30 leads to over diagnosis, over treatment and psychological harm yet it is being introduced anyway. The NCSP is gearing up for the 1% increase in colposcopy referral for vaccinated women and 15% for the unvaccinated. (Updated Guidelines for Cervical Screening in New Zealand pg2,11)</p> <p>All of this could be avoided if primary HPV testing was done at age 30 and above, and if the aim of the NSU was to protect women, not the screening programme.</p> <p>All women with hrHPV detected 16/18 will be referred to colposcopy even if the LBC report is negative. This will be women in the age group 25-29 predominantly as after the age of 30 only approx. 5% of women are HPV positive. I note</p>

		<p>that the NCSP has screening support providers who will, no doubt, ensure that these women go for colposcopy particularly if they are from a priority group.</p> <p>‘Women with persistent infection (or with any type of hrHPV infection) identified at the 12-month repeat HPV test will be referred to colposcopy, regardless of the LBC result’ (Updated Guidelines for Cervical Screening in New Zealand pg13, 3.13).</p> <p>You suggest that 67% of non hrHPV infections clear within 12 months. Other data I have seen suggests that HPV infections generally clear within 6-24 months. Unfortunately, those poor young women who don’t clear their HPV within a year will be heading to colposcopy.</p> <p>I really feel that this programme is excessive and we could learn from those Nordic countries that do not screen women before the age of 30 ie the Dutch and the Finns.</p> <p>With regard to exit testing, those women who are postmenopausal and wish to continue screening should be offered self HPV tests. In my opinion many postmenopausal women on realising that they are HPV negative following the introduction of primary HPV testing, will realise they are low risk and discontinue screening.</p>
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	<p>Recommendations make sense given the current high prevalence of HPV 16 in particular. However, we recommend research/monitoring of non16/18 genotypes in high grade lesions in NZ over the next 5 – 10 years. This essential given the known, higher proportions of HPV 52 and 31 in HSIL NZ currently. Surveillance should cover a proportion of the non 16 and 18 genotype cohort as the data regarding these genotypes is limited. Such extended genotyping should be done in a proportion of women with HSIL, high grade glandular lesions and cancers within several regions of NZ. Otherwise we support recommendations.</p> <p>Other evidence/information to consider:</p> <p>As above – there needs to be on-going <i>prospective research/monitoring of non16/18 genotypes</i> over the next 5 – 10 years in NZ. There should be a strategy to do extended genotyping on a proportion of women with non 16/18 HrHPV positivity detected on screening.</p>
Pam Hewlett (P&F Portfolio Manager) Lucina Kaukau (Cervical Screening Nurse Specialist)	Auckland & Waitemata DHBs	<p>We support the simple algorithm and especially like the risk colour coding. We support the changes to HPV primary screening.</p> <p>Supportive of reflex cytology for women who test positive for hrHPV.</p> <p>3.01 is a consensus based recommendation – preference would be if this was an evidence based recommendation. Is the evidence still emerging?</p> <p>3.11 where it is appropriate to delay referral to colposcopy we suggest that it states for 12 months.</p>

Jane Grant (Cervical Screening Nurse Specialist)		<p>3.19 Will there be an implementation plan with areas of responsibility for implementation identified. If so will this plan be available to regional coordinators and DHB's for feedback. This may take significant planning in the Metro-Auckland region.</p> <p>3.22 Could 'support to services' be clearly defined? Our experience is that many sample takers are unaware of this terminology. A link to NSU website could be inserted here. We recommend a health literacy approach to developing resources for women with abnormal results – that include links to NSU online information.</p> <p>3.23 The group that the guidelines apply to is not clearly defined. We suggest a front section of the guidelines that clearly states to whom they apply to.</p> <p>We support the concept of exit testing but have some questions:</p> <p>Will there be a catch up programme of exit testing for women aged 70-74 years? The section reads as if this may happen. Primary care will need support to do this.</p> <p>Will there be an official discharge notification from the NCSP register to women and their primary care provider?</p> <p>3.24 Women over 75. This recommendation seems confusing in its wording – are these recommendations for screening or guidance on HPV testing for those outside of the programme?</p> <p>Recommendation 3.13 may be interpreted in such a way that it could apply to all women over 75. If a woman exits the NCSP with a negative HPV test at age 71 for instance by age 77 she would not have had a test in the previous five years and therefore be eligible.</p> <p>We think there should be a separate section to these guidelines entitled 'Guidance on HPV testing outside of routine screening.' Guidance on testing women older than 75 years and under 25 years could be included in this section.</p>
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Service	<p>Generally very good.</p> <p>Other evidence/information to consider:</p> <p>Recom: 3.05 The term experienced colposcopist is recurrent throughout this document. Does NCSP intend to further define this. In most cases 'the referrer' is a GP or GP's practice nurse [as the smear taker] and they will simply be referring to their local DHB colposcopy service. They, of course, have little idea of the experience of the colposcopist and in most situations will not be able to refer to specific consultants anyway. Perhaps this is a point to be addressed to DHB triage i.e. pt should be seen by a senior consultant rather than a registrar.</p> <p>Recom 3.07. Will the NCSP standards change wrt timeframes for colposcopy? This statement contradicts 14.05 which suggests referral to gynae oncology or do you suggest only symptomatic women go directly to gynae onc? Will gynae onc accept them directly from smear takers?</p>

		<p>3.08: and 3.09 ‘Triage as higher risk’? Will there be time frames in which patients must be seen attached to these to these statements or is that only to be in the Operational Standards. Current standards dictate ‘must be seen within 4 weeks’.</p> <p>3.12: All postmenopausal women. [Incidentally in our experience daily use is unnecessary, twice weekly is sufficient and more acceptable to the patient.]</p>
Barbara Holland & Barbara Robson, Co-Convenors	Federation of Women’s Health Councils Aotearoa	<p>3.8 is not currently supported by FWHC. We do not have sufficient confidence that a primary HPV test has been adequately proven in a real world screening programme. Reports to date have been based on specific cohort modelling assumptions. NZ modelling by Cox (2016) for the whole NZ cervical screening programme, and taking note that the majority of currently enrolled women are unvaccinated, has shown a different benefit/risk profile for primary HPV testing alone compared with co-testing (HPV + cytology). Ref: Brian Cox. 2016. <i>‘The HPV screening policy’</i>. Paper presented at the 2016 Cartwright Forum: The Control of Cervical Cancer in NZ.</p> <p>3.01 FWHC recommends co-testing (HPV and cytology) as a staged testing process within the programme until further evidence confirms the value and safety of a primary HPV test alone.</p> <p>It is essential that an audit of all cancer cases is immediately undertaken to establish a baseline benchmark benefit of the NCSP, and for future assessment of the benefit/risk of any proposed programme pathway changes. We note this activity is long overdue for the current programme, the last report being published in 2004.</p> <p>hrHPV detected (not 16/18)</p> <p>3.13 third dot point is strongly supported.</p> <p>3.05 ‘should be referred to an experienced colposcopist <2 weeks’ – if the LBC result is ‘suspicious of’ or ‘invasive cancer’ why isn’t this a <u>must</u> be referred situation?</p> <p>‘What will be the process for referring to an ‘experienced’ colposcopist, and especially within a 2 week timeframe? There needs to be provision for the sample taker to add comment to the referral note based on their clinical/visualisation of the cervix.</p> <p>Not everyone will have rapid access to an ‘experienced colposcopist’ in their area and may be required to travel to another DHB. Might the woman be seen by a less-experienced colposcopist within her local DHB and a digital image immediately sent to an ‘experienced’ colposcopist for review and further direction? Otherwise the woman would have</p>

to be referred out (by whom?) and given another appointment. What is the likelihood of this then becoming another DNA case?

While it may be outside of the scope of these guidelines, what expectations should there be regarding the timeframe for any necessary treatment?

We note the various distinguishing references to ‘a colposcopist’ and ‘an experienced colposcopist’ throughout this guidelines document. What does this mean in practice and how is it assessed and monitored? How will women be advised that they need to be seen by an ‘experienced colposcopist’ as opposed to a ‘colposcopist’ when they are first offered a referral to colposcopy?

hrHPV detected (16/18)

3.18 If cytology is negative, how will this help guide the colposcopist in their clinical management? If the woman has recently contracted 16/18 – but we don’t know this, although –ve cytology may be a useful steer - a referral to colposcopy at this point seems over the top.

3.20 The sample taker could make an offer to refer the woman to a colposcopist (even though we can see the potential to add further pressure to colposcopy waiting times and would be triaged accordingly).

3.21 Presumably the woman still has the right to make an informed choice to defer the referral to colposcopy, and have follow up HPV/LBC tests in 6? 12? months. Wouldn’t this be a better option than being referred to colposcopy against her wishes and then her being a DNA?

3.22 Women can’t be forced to attend colposcopy. After all, “cervical screening services must be provided in an environment that respects the culture and the dignity and autonomy of women” (Guideline 1.03) and the HDC Code of Rights. The NCSP-Register should be configured to accommodate a variation to the pathway if this is the woman’s informed decision. She may well be put off by constant reminders and undue pressure/nagging (which we have anecdotal evidence of).

3.07 define ‘urgent’ – 2 weeks as per 3.05?

3.08 The woman might prefer to have another cervical sample taken before agreeing to colposcopy.

		<p>Exit testing</p> <p>Changed wording needed here: The HPV test is more sensitive than LBC (remove detecting) <u>in predicting the risk/liability of cervical abnormalities caused by HPV infection.</u></p> <p>3.23 FWHC recommends to continue with co-testing as an interim measure until evidence is conclusive that a single HPV test with an ‘hrHPV not detected’ is adequate.</p> <p>3.12 – is this really ‘treatment’ or more about comfort during sampling? Refer to previous comments (under 2.04).</p> <p>3.13 – correction or have not have had one.....</p>
Dr Gillian Gibson, Fellow RANZCOG, NZ committee Executive member and RANZCOG Council representative	On behalf of RANZCOG NZ Committee	<p>Agree - there will be fewer false negatives with HrHPV testing with the added safety of co-testing reflex LBC.</p> <p>What are the timeframes for women to be seen for colposcopy 3.03 and 3.04?</p> <p>What is the magnitude of expected false negatives /invalid test results eg. 0.1% or 10%?</p> <p>The nomenclature for what is currently HrHPV “other” is open to confusion in the Guideline as there are 2 possible descriptors “any type” and “not 16/18”. Should “any type” be replaced with ‘all types’?</p>
Annette Davis	Hawke's Bay DHB	Agree.
Dr Stephen Child, NZMA Chair	On behalf of NZMA	<p>Testing for women older than 75 years</p> <p>We note the potential for inconsistent interpretation between the statement that “screening for women aged over 75 years is not recommended where they have been in the NSCP screening pathway” and the practice point 3.13 which recommends that women aged 75 years or older who request an HPV test may have one if they have never had a cervical screening test or not had one in the previous 5 years. We also have some concerns that a request should influence optimal medical practice, and seek clarification on these concerns.</p>
Howard Clentworth, SMO Lead Colposcopist & Gynaecologist	CCDHB	<p>Management of HPV results.</p> <p>The unvaccinated population will initially present an upsurge in numbers of young women with high risk HPV many of whom will have no lesion and most of whom will clear the virus without pathology. Clearly that leads to an imperative about increasing the vaccination rate.</p> <p>The second doubt arising from the recommendation is the age of 25.</p> <p>The program ought to collect data specifically to the 25 to 30-year-old cohort that should be assessed by an independent investigator. We fear that will increase the worried and over serviced vulnerable group.</p>
Lynda Williams, Co- ordinator AWHC	On behalf of Auckland Women's Health Council	The AWHC recommends that all women should get an automated letter from the register with their test results, not just when they have a positive result.

		<p>The AWHC is concerned that this section assumes that women present for a cervical screening test every three years when this is not the case.</p> <p>The AWHC does not support women with an initial screening test result of 'hrHPV not detected' being re-screened in five years. It is not safe to leave priority women for five years. There is not sufficient evidence in a real world screening programme to prove that this is safe.</p> <p>The AWHC recommends co-testing as a staged testing process within the programme until further evidence confirms the value and safety of a primary HPV test alone.</p>
Individual response	Self-employed midwife CMH region	Need to explain results in the women's language whereby English is their second language. This could be asked about at the time of smear.

SECTION 4: Colposcopy		
Name / Title	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	Non applicable from a non-clinical perspective.
Dr Vicki Robertson, Lead Colposcopist	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson, Education Nurse	Well Women & Family Trust	Good.
Respondent's name redacted at request.	Waikato DHB	Good clinical practise points incorporated now – great for trainees and new colposcopists.
Amanda Tristram, SMO Gynaecological Oncology	Department Gynaecology Oncology, Wellington Hospital	<p>4.26 “Practice point</p> <p>Predicted or histologically confirmed AIS should be treated by a type 3 excision (usually a cold-knife cone biopsy) performed in an operating theatre, under general anaesthesia, by a gynaecological oncologist or gynaecologist competent in the technique.”</p> <p>Does this mean that all women with an abnormal glandular smear should have a cone biopsy done in theatre? It seems to be overkill! For many, a LLETZ performed in clinic would suffice.</p> <p>4.34 Some colposcopists may also perform a post-excision endocervical curettage at the time of the excision.³⁶</p> <p>There is no evidence for endocervical curettage. Perhaps it is done so that an additional charge code can be made?</p> <p>The two sections below are not consistent:</p> <p>4.10 Histological confirmation before treatment Consensus-based recommendation</p> <p>Treatment should be reserved for women with histologically confirmed HSIL (CIN2/3) or AIS, except for women requiring diagnostic excisional biopsy.</p> <p>In some circumstances it may be appropriate to take a ‘see and treat’ approach.</p>

		<p>A woman may be suitable for ‘see and treat’ if:</p> <ul style="list-style-type: none"> <input type="checkbox"/> she has been fully informed and is prepared for possible treatment <input type="checkbox"/> her cytology and colposcopic appearance are concordant and HSIL <input type="checkbox"/> the lesion and TZ are completely visible <input type="checkbox"/> a return visit after diagnostic biopsy may not be possible or may cause hardship for the woman. <p>4.33 Treatment at the first visit may be appropriate if women meet the following criteria.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Referral LBC result is HSIL. <input type="checkbox"/> Colposcopic impression is high-grade disease. <input type="checkbox"/> TZ is completely visible (type 1 or 2). <input type="checkbox"/> Invasive cancer has been excluded. <input type="checkbox"/> The lesion is suitable for treatment under local anaesthetic. <p>I cannot see why a return visit needs to “cause hardship” for a woman to have a see and treat.</p> <p>Other evidence/information to consider:</p> <p>The NCSP website states: “The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) has commenced the certification process for doctors who wish to register as a practising colposcopist. Please note: The NCSP will be amending the colposcopy standards to meet the requirements set by RANZCOG for practising colposcopists, in line with their time frame.”</p> <p>I cannot find any reference in the guidelines to the training or registration of colposcopists.</p>
Pip Egerton, Rural Practice Nurse (smear taker), Primary Care representative Otago / Southland NCSP regional multidisciplinary team	Tuatapere and Otautau Medical Centre	<p>I am not qualified to comment in this area of recommendations.</p> <p>Other evidence/information to consider:</p> <p>Do have concerns, as seems to be a constant occurrence in health in the last thirty years, where there will be an obvious increase and strain on our colposcopy services and staffing, yet the indication is, this obvious potential strain, will be “reviewed” after the changes are implemented. During which time staff will become overworked and stressed. Would like to see an innovated NSCP address this BEFORE implementation as we are all aware of the infinite research in regards this very situation. Be pro active.</p>

Fiona Moscrop – on behalf of Clinical Quality Board	Compass Health	Acceptable.
Respondent's name redacted at request.	Member of the public	<p>I find it perturbing that it is considered acceptable for an inexperienced colposcopist to perform a biopsy on a low grade lesion when it is not medically required. Surely the colposcopist should have access to a more senior colleague. (Updated Guidelines for Cervical Screening in New Zealand pg 19, 4.9)</p> <p>At the very least the woman must be informed that she is potentially having an unnecessary biopsy.</p> <p>Do all colposcopy staff know that “the random four quadrant biopsy technique will cause more discomfort, is not usual practice, and is not acceptable to the majority of women”? (Updated Guidelines for Cervical Screening in New Zealand pg19, 4.10)</p> <p>In my opinion offering a “see and treat” approach is not generally acceptable because there is a significant risk of over treatment without a diagnostic biopsy to inform the decision. Will women be told about the risk of overtreatment? Will they be given significant information about the obstetric complications associated with LLETZ or LEEP procedures ie premature rupture of membranes in the third trimester, increased rates of Caesarean section etc? I would also argue that a woman undergoing colposcopy is in an extremely stressful situation and unable to really give proper informed consent if a “see and treat” approach is adopted.</p>
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	<p>Most are fine, but 4.24 shouldn't be so prescriptive, many of our Consultants see a place for a “top hat excision” in women who have completed their family , or are medically unfit for a cone bx in a type 3 TZ , or if the initial depth seems insufficient.</p> <p>4.37 – recommend this should be a clinical judgement based on the clinical findings versus a hard pathway.</p> <p>4.12 – wording needs to be consistent with section 5. Discordant results should go via a MDM meeting and meet the standards as per 5.3. As per the Recommendations, we strongly favour the formal, minuted, MDM Meeting, rather than informal multidisciplinary consultation.</p>
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Service	<p>We have a few suggestions from a practical colposcopy viewpoint.</p> <p>Other evidence/information to consider:</p> <p>4.2 We are concerned that systematic examination not be interpreted as colposcopic examination of the entire lower genital tract. Incidentally examination of the perianal skin is accepted but not the anal canal and this should be specified.</p> <p>4.3 Surely it is not essential to record consultations electronically but it is essential to submit the data to the NCSP register.</p>

4.4 We strongly believe it is NOT essential to include a history of sexually transmitted infections and feel, in fact, that it is contraindicated. It will not alter management in any way and is seen as unnecessarily intrusive by the patients.

4.5/6 Inspecting the vagina as the speculum is withdrawn should not be regarded as a full examination of the vagina and no reassurance of normality should be gained from such.

4.8 Suggest that colposcopists should ask about symptoms pertaining to the anal canal and if present refer to an appropriate specialist.

Recommendations:

4.02 We suggest Lugol's iodine should be used if no obvious lesion is found with the application of Acetic Acid.

4.04 We suggest adding the following indicatios:

- . if the cytology was ASCUS or ASC-H
- . BV noted on the referral smear
- . Woman was breastfeeding when the smear was taken,
- . Patient has an IUD

We also suggest taking out the 'self collected' point as it is not part of the current programme. It assumes self collection will become part of the programme and therefore implies a bias in assessing data yet to come.

4.9 We question the statement that random 4 quadrant biopsies are not acceptable to the majority of women. Is this based on opinion? If so it is not our opinion.

4.10. We disagree with this statement and feel it will encourage colposcopists, especially those less experienced to not biopsy. It is our feeling [and the PRINcess trial may help to clarify this], that non16/18 HPV types do not necessarily display typical HSIL colposcopic patterns.

Recommendations :

4.06 We would always biopsy an abnormality regardless of the TZ type. It may be very helpful if there is a later discordance.

4.08 Upper genital tract imaging 'may be appropriate'.....

4.12 In section 5.02 it states that this type of discordance must be part of an MDM review.

4.15 Is MDM only for complex cases with discordance or does discordance per se make the case complex. This is particularly important when MDM's can only be held 2 monthly.

TREATMENT:

4.15 should read complete excision or ablation of the 'entire TZ' [not just the abnormal part of the TZ.]

		<p>4.17 How is the extent of the excision to be measured.</p> <p>4.18. We suggest this should be the first point in the Treatment section.</p> <p>4.12 Is this measurement the depth of the excision crater or the depth of the specimen measured in the histopathology laboratory. There is, at least, a 2mm difference.</p> <p>Recommendation.</p> <p>4.22 Should read general or regional anaesthesia.</p> <p>4.27 Should read. The loop size should be determined at the time of the treatment colposcopy.</p> <p>Recom 4.24: An explanation of why this is not acceptable should be given in the points above.</p> <p>Recom. 4.26 Suggests Type 3 excision but the statement above in 4.36 says a type 2 excision in under 35yr old women may be acceptable.</p> <p>Do you suggest all AIS is referred directly to gynae oncology.</p> <p>Again GA or regional anaesthesia.</p>
Barbara Holland & Barbara Robson, Co-Convenors	Federation of Women's Health Councils Aotearoa	<p>4.1 The wording of this para needs to be reviewed. The word 'abnormal' is problematic - it suggests just one screening test and it assumes there will be an abnormality.</p> <p>What about the HPV+ve, cytology –ve, and colposcopy –ve outcome?</p> <p>Or will the temptation be to biopsy an area even if it appears normal, as has been suggested?</p> <p>4.3 wording change needed here ...document the woman's <u>relevant medical history</u> (if it's a record it already has been documented)</p> <p>4.04 need to be consistent and change cervical smears to cervical samples throughout the document</p> <p>Although routine self-sampling is not policy it is greatly concerning to FWHC to note the suggestion that women who have tested +ve for hrHPV might be referred directly to colposcopy because an LBC sample would not be available. We contend the first follow-up action should be to seek a cytology sample.</p> <p>Biopsy</p> <p>4.10 So do women in the know ask for an experienced colposcopist? How else do less experienced colposcopists learn? Colposcopists need to be honest about their experience/skill level and tell the women what they are proposing to do, or not, and why. Then the women can make an informed partnership decision regarding the proposed activity.</p> <p>4.07 Would a less experienced colposcopist get a second opinion before proceeding?</p>

		<p>Ablation</p> <p>4.19 This needs to be highlighted, as does recommendation 4.17 first sentence</p> <p>Cold-knife cone biopsy</p> <p>4.25 should be highlighted</p>
Dr Gillian Gibson, Fellow RANZCOG, NZ committee Executive member and RANZCOG Council representative	On behalf of RANZCOG NZ Committee	<p>Electronic records are more challenging for private practitioners as the outlay/investment in a programme for this purpose is not insignificant for a solo practitioner who may already be paying for a practice management system.</p> <p>4.19 The option for ablation for suspected high grade dysplasia is somewhat surprising given the accepted practice is for excisional treatment.</p> <p>4.03 Is there a case for recommending vaginoscopy for all women having colposcopy to avoid unnecessary treatment?</p> <p>4.04 quote ‘post oestrogen treatment is being given’ is this a typo and should read “postmenopausal”?</p>
Annette Davis, Team Leader Population Screening	Hawke's Bay DHB	Agree.
Rae Duff, National President Ailsa Stewart, Convenor, Health Standing Committee	National Council of Women of NZ Health Standing Committee	<p>Para 11 (p2)</p> <p>Because there will be an increase in Colposcopy referrals, a well-planned and adequately funded structure underpinning the proposed changes, must be established and with on-going funding guaranteed.</p>
Howard Clentworth, SMO Lead Colposcopist & Gynaecologist	CCDHB	<p>The two sections are inconsistent.</p> <p>Section one remarks about diagnostic biopsies 4.33 says see and treat is only suitable if invasion is excluded.</p> <p>In an ideal world where everyone was regularly screened the only cancers that would present would be 1A1 and the majority of these are diagnosed on biopsies that are excisional with the intent to cure premalignant disease. That section needs amending perhaps to say that obvious cancers have been excluded.</p> <p>The guidelines should also add that colposcopists should be certified by RANZCOG or equivalent as is documented on the College website.</p> <p>Other evidence/information to consider:</p>

		NCSP statement “The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) has commenced the certification process for doctors who wish to register as a practising colposcopist. Please note: The NCSP will be amending the colposcopy standards to meet the requirements set by RANZCOG for practising colposcopists, in line with their time frame.”
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SECTION 5: Management of a discordant LBC report, colposcopic impression, and histopathology results		
Name / Title	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	Non applicable from a non-clinical perspective.
Dr Vicki Robertson, Lead Colposcopist	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson, Education Nurse	Well Women & Family Trust	Not in my area of expertise.
Clare Coles, Manager Screening Services	Waikato DHB	Is it not clear from flow diagram, or reading with the “repeat HrHPV test’ is done by smear taker or in colp clinic– can this be clarified please. Great to see guidance for clinicians on how to manage discordant cases.
Dr Peter Fitzgerald, Medical Director	Southern Community Laboratories	Figure 2, Page 29 HrHPV positive (any type) LBC negative/ASCUS/LSIL women. What is the plan after 2 colposcopy visits? Will these women continue to be recalled to colposcopy indefinitely until the HrHPV test is negative? What will these women be told.
Pip Egerton, Rural Practice Nurse (smear taker), Primary Care representative Otago / Southland NCSP regional multidisciplinary team	Tuatapere and Otautau Medical Centre	Health professionals will need to be well educated in the reasoning. Other evidence/information to consider: Have some concerns around the nature of any virus that can reoccur without reintroduction. Do have concerns with the 5 year recall even for LBC results. Have under the present guideline had 1 st annual follow up smear with no HrHPV detected yet the second year result to have HrHPV detected. Should these women be at the very least 3 year recall? Am I correct in saying the new guidelines seem to indicate for this group of women only one 12 month review then 5 yr recall?

Fiona Moscrop – on behalf of Clinical Quality Board	Compass Health	Acceptable.
Respondent's name redacted at request.	Member of the public	<p>When women with hrHPV detected (16/18) attend colposcopy will those over 50, those who have completed childbearing or whose future attendance is in doubt, be told that they are having potentially healthy tissue removed from their cervix when undergoing diagnostic excision of the TZ in the absence of high grade cytology or histology? (Updated Guidelines for Cervical Screening in New Zealand pg 34, Figure 5)</p> <p>Hopefully the colposcopist will discuss this fully with the woman in order to obtain informed consent.</p>
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	<p>Discordance should be discussed at a <i>formal, minuted MDT meeting (MDM)</i>, which meets the quality standards for MDMs.</p> <p>5.02 We suggest that women with + 16/18 HPV and normal colposcopy who are persistently positive, should they have to continue having colposcopy even if normal cytology.</p> <p>Other evidence/information to consider: Ongoing surveillance, non 16 and 18 genotypes. We suggest a cohort of women referred with non 16/18 HrHPV positivity should have more extended genotyping to correlate with clinical outcomes.</p>
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Service	<p>A few problems.</p> <p>Other evidence/information to consider:</p> <p>Recom 5.01 We are not sure what this means. Does it mean women should remain under a colposcopists care until an MDM recommendation for discharge is made is made?</p> <p>Recom 5.02 Inconsistent with 4.12</p> <p>Recom 5.03 We interpret this to mean that women with persistent HrHPV 16/18 and negative cytology and colposcopy will continue to have yearly colposcopy. Is it known how many women this will be?</p> <p>Recom 5.04 It is important to complete a full colposcopic examination of the vagina using acetic acid and lugols iodine before proceeding to excisional treatment of the TZ</p> <p>Recom 5.05 Treat BV, atrophy, IUCD effects etc before repeating the colposcopy.</p> <p>Figure 3: ASC-H smear LSIL BxRepeat Hrhpv 12 months. Shouldn't MDM review be included in this arm of the flow chart?</p>

		<p>Figure 4. Confirmed HSIL smear, colp negative Type 1 or 2 TZ ; should result in Excision but the flow chart says repeat HPV in 6 months</p> <p>Also in Fig 4 Type 1 or 2 TZ, Biopsy Lsil should go to MDM review</p> <p>Recom 5.16 We suggest adding. Remember that a negative result is not reassuring.</p>
Dr Gillian Gibson	On behalf of RANZCOG NZ Committee	Agree multidisciplinary meetings plan an important role and all colposcopists should have access to this either face to face or other means eg. teleconference, electronic submission.
Annette Davis	Hawke's Bay DHB	Agree.

SECTION 6: Management of histologically confirmed low-grade squamous abnormalities		
Name / Title	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	Non applicable from a non-clinical perspective.
Dr Vicki Robertson, Lead Colposcopist	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson, Education Nurse	Well Women & Family Trust	Not in my area of expertise.
Respondent's name redacted at request.	Waikato DHB	Great to see recommendation to NOT treat low grade.
Pip Egerton, Rural PN (smear taker), Primary Care rep Otago / Southland NCSP regional MDT	Tuatapere and Otautau Medical Centre	Feel not qualified to comment. Other evidence/information to consider: Feel need to explain to health professionals what "...expression of a productive HPV infection "means???
Fiona Moscrop	Compass Health	Acceptable.
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	Support recommendations.
Pam Hewlett (P&F Portfolio Manager) Lucina Kaukau & Jane Grant (Cervical Screening Nurse Specialists)	Auckland & Waitemata DHBs	6.11 We support reporting of HPV associated lesions with LSIL(CIN1) We would like to ask about plans to upgrade Primary care Practice Management system screening outcome codes to align with new guidelines and create a standardised set of codes. We request that this is done nationally by the PMS vendors. We think this will ensure a smoother transition and prevent inappropriate management of recall dates including early re-screening and ensure that test of cure occurs for those whom it is recommended for.
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Service	Good.
Dr Gillian Gibson	RANZCOG NZ	Agree.

Annette Davis	Hawke's Bay DHB	Agree.
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SECTION 7: Management of histologically confirmed high-grade squamous abnormalities

Name / Title	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	Non applicable from a non-clinical perspective.
Dr Vicki Robertson, Lead Colposcopist	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson, Education Nurse	Well Women & Family Trust	Not in my area of expertise.
Clare Coles, Manager Screening Services	Waikato DHB	Sensible practical advice – should comment be made about which treatment appropriate for Type 3 TZ?
Dr Peter Fitzgerald, Medical Director	Southern Community Laboratories	<p>Practice point 7.03:</p> <p>The proposed conservative management of CIN2 in older women is in my opinion unwise. What is the evidence base for such a policy? Is the data being extrapolated from the NZ U25 (PRINCES) conservative management study? While the majority of CIN2 and CIN3 lesions will not progress to invasive cervical cancer relying on a small biopsy to make the distinction between CIN2 and CIN3 is unreliable. This is not because of difficulties in histologic interpretation (which I will address) but because of issues of sampling.</p> <p>Based on my experience attending multi-disciplinary meetings in NZ over the last decade colposcopy cannot be relied upon to sample the worst area in a HSIL. That is to say many lesions called CIN2 on 1 or 2 diagnostic biopsies are under sampled CIN3 when the treatment specimen is processed and the cervical HSIL lesion more fully examined. In my experience LSIL or less index cytology is not a reliable marker of histology confirmed CIN2 versus CIN3. Is there some data/evidence to support this contention?</p> <p>I do not agree with the suggestion that P16 should be routinely used in this context “to stratify the diagnosis of possible HSIL (CIN2) or one of its mimics (LSIL or benign).” Block positivity for p16 maybe occasionally be seen in otherwise typical morphological LSIL. p16 may be negative in CIN3 and invasive carcinoma. Calling p16 positive LSIL focal CIN2 in</p>

		<p>CIN1 will inflate CIN2 rates but there is no evidence I am aware of to suggest that this is a lesion of increased risk for invasive cancer and treating such women is probably harmful.</p> <p>I think the 7.03/7.04 guidelines should be amended to read:</p> <p><u>7.03 HSIL (CIN2) and observation Practice point</u></p> <p>"It may be acceptable to offer a period of colposcopic observation to women who have a histological diagnosis of HSIL (CIN2) where they:</p> <ul style="list-style-type: none"> Have not completed child bearing. An experienced colposcopist should undertake this observation." <p>It should be self-evident that no colposcopist will elect to conservatively manage CIN2 with more than focal minor changes on colposcopy.</p>
Pip Egerton	Tuatapere and Otautau Medical Centre	<p>Other evidence/information to consider:</p> <p>High concern of a five year versus three year recall for this group of women after 2 consecutive "No HrHPV detected" years particularly in light of how virus can reoccur when immunity low.</p>
Fiona Moscrop	Compass Health	Acceptable.
Respondent's name redacted at request.	Member of the public	<p>"Although not all women with 'HSIL' will develop cervical cancer, the practice of treating all cases of 'HSIL (CIN2/3)' is a highly effective way of reducing a woman's risk of subsequent cervical cancer. A small number of women with 'HSIL' may be treated unnecessarily; however, it is not possible to identify these women in advance and the benefits of this practice outweigh the harms". (Updated Guidelines for Cervical Screening in New Zealand pg 37,7.6)</p> <p>This is totally disingenuous and paternalistic. Treatment of 'HSIL (CIN2/3)' leads to huge rates of over treatment. This is known by many clinicians. If "5% of 'CIN2' and 14-31% of' CIN3' are estimated to progress to invasive cancer" (Updated Guidelines for Cervical Screening in New Zealand pg 37,7.4) then obviously many women being treated are having unnecessary treatment.</p> <p>Associate Prof Peter Sykes has said, "With regard to younger women it is likely that a few of the thousands of women with CIN3 treated would have developed cancer if untreated". [Changing the Primary Laboratory Test Consultation, Submission 49]. This is hardly a small number.</p> <p>The Harding Centre for Risk literacy has produced an excellent graphic which outlines the level of over diagnosis with Cervical screening</p>

Cervical Cancer Early Detection

By Screening with the Pap-test for women aged 20 years and older. All numbers show benefits and harms per year

Benefits	100.000 without Screening	100.000 with Screening
How many women suffered from cervical cancer?	40	15
How many women died from cervical cancer?	6	3
How many women died from any type of cancer?	230	230
Harms		
How many healthy women were mistakenly classified as being at high risk or incorrectly diagnosed with cervical cancer due to screening*?	-	4950

* This can result in the repetition of the test, biopsies, operations such as cervical conization (which can affect later pregnancies), and can have psychological impact such as fear.

Sources: Gesundheitsberichterstattung 2009 des Statistischen Bundesamtes; Mühlhauser, Filz (2008) Arznei-Telegramm, 39; Neumeyer-Gromen, Bodemer, Müller, Gigerenzer (2011) Bundesgesundheitsblatt, 54; Siebert et al. (2003) http://portal.dimdi.de/de/hta/hta_berichte/hta067_bericht_de.pdf; Siebert et al. (2006) Eur J Public Health 16.

Associate Professor Brian Cox has said of Cervical screening “It works but it also has the highest ratio of over diagnosis. Almost all the positive results found are pre-invasive disease rather than cancer, and about 80% would resolve by itself. You don’t know which ones will and won’t; therefore you have to treat it all” [New Zealand Listener, Sept 19-25, 2015].

Angela Raffle, Public Health Consultant in England, has stated “1000 women have had to be screened for 35 years to prevent one death. Put in context, a nurse performing 200 tests each year – the workload for two general practitioners’ lists – would prevent a death once in 38 years.” She goes on to say, “For each death prevented, over 150 women have an abnormal result, over 80 are referred for investigation, and over 50 have treatment” [A E Raffle, B Alden, M Quinn, P J Babb, M T Brett, Outcomes of screening to prevent cancer: analysis of cumulative incidence of cervical abnormality and modelling of cases and deaths prevented, BMJ Volume 326, 26 April 2003].

Unfortunately most women have absolutely no idea about over diagnosis and over treatment and the NCSP seems keen to keep it that way.

From Ministry of Health Provisional Statistics;

Number of cervical cancer registrations for females by year of registration, ethnic group and age group.

Year	Ethnic group	Age group (years)																Total		
		0-4	5-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84		
2012	All	0	0	0	0	5	7	15	19	26	17	17	15	15	9	4	5	7	5	166
	Māori	0	0	0	0	1	1	3	7	9	7	4	4	3	1	0	0	0	40	
	Non-Māori	0	0	0	0	4	6	12	12	17	10	13	11	12	8	4	5	7	5	126
2013	All	0	0	0	0	5	24	17	17	19	13	7	14	9	8	8	4	5	8	158
	Māori	0	0	0	0	2	4	3	3	2	9	2	4	5	1	1	0	2	1	39
	Non-Māori	0	0	0	0	3	20	14	14	17	4	5	10	4	7	7	4	3	7	119
2014	All	0	0	0	0	3	15	11	18	22	14	16	5	6	7	8	10	2	5	142
	Māori	0	0	0	0	1	3	4	6	4	4	7	3	1	2	1	0	1	0	37
	Non-Māori	0	0	0	0	2	12	7	12	18	10	9	2	5	5	7	10	1	5	105

		From the above information it is clear to see that the absolute number of women developing cervical cancer in the 25-29 age group, is small, yet this is the group that will no doubt suffer the most over diagnosis and consequently, over treatment. While I appreciate that a diagnosis of cervical cancer is devastating at an individual level, it is inappropriate to over treat young women without telling them that this is a big risk of screening, particularly as over treatment can cause obstetric complications.										
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	Support recommendations but Colposcopists should have a discretion to offer continued colposcopic surveillance in women for whom they may be concerned about completeness of excision. If they see this person back at Colp clinic it would be necessary to perform cytology and/or HR HPV, which can become negative well before 12 months.										
Pam Hewlett (P&F Portfolio Manager) Lucina Kaukau & Jane Grant (Cervical Screening Nurse Specialists)	Auckland & Waitemata DHBs	<p>7.1 We support reporting of HPV associated lesions with HSIL (CIN2) HSIL (CIN3). We would like to ask about plans to upgrade Primary care Practice Management system screening outcome codes to align with new guidelines and create a standardised set of codes.</p> <p>We request that this is done nationally by the PMS vendors. We think this will ensure a smoother transition and prevent inappropriate management of recall dates including early re-screening and ensure that test of cure occurs for those whom it is recommended for.</p> <p>7.3 great definition of HSIL.</p> <p>7.12 typo – this practice is not evidence-based, but may reassure to both the patient and clinician (should read may provide reassurance to).</p>										
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Service	<p>Other evidence/information to consider:</p> <p>7.6 Based on the figures quoted in 7.4. 30- 50% will be treated unnecessarily. This is not a small number. We are not disagreeing with the recommendation just with the term 'small number'.</p> <p>Recom 7.03 Is there a suggested time frame for review colposcopy?</p>										
Dr Gillian Gibson	RANZCOG NZ	Agree - see comment 5a.										
Annette Davis	Hawke's Bay DHB	Agree.										
Rae Duff, National President Ailsa Stewart, Convenor, Health Standing Committee	National Council of Women of NZ Health Standing Committee	<p><i>Para 17, Table 1 (p3)</i></p> <table border="1"> <thead> <tr> <th>Section</th> <th>Comment</th> </tr> </thead> <tbody> <tr> <td>Section 7. Guideline 9.</td> <td>Colposcopy 6 – 12 months</td> </tr> <tr> <td><i>Relates to 7.07</i></td> <td><i>Agreed</i></td> </tr> <tr> <td>Section 7. Test of Cure</td> <td>Should continue to have annual co-tests</td> </tr> <tr> <td></td> <td><i>Agreed</i></td> </tr> </tbody> </table>	Section	Comment	Section 7. Guideline 9.	Colposcopy 6 – 12 months	<i>Relates to 7.07</i>	<i>Agreed</i>	Section 7. Test of Cure	Should continue to have annual co-tests		<i>Agreed</i>
Section	Comment											
Section 7. Guideline 9.	Colposcopy 6 – 12 months											
<i>Relates to 7.07</i>	<i>Agreed</i>											
Section 7. Test of Cure	Should continue to have annual co-tests											
	<i>Agreed</i>											

		<i>Relates to 7.11</i>
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SECTION 8: Management of glandular abnormalities		
Name / Title	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	Non applicable from a non-clinical perspective.
Dr Vicki Robertson, Lead Colposcopist	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson, Education Nurse	Well Women & Family Trust	Good.
Clare Coles, Manager Screening Services	Waikato DHB	Great practical, clinical guidance.
Amanda Tristram, SMO Gynaecological Oncology	Department Gynaecology Oncology, Wellington Hospital	I think it is a shame not to take this opportunity to harmonise the pathological terms used. For example: Why AIS, but CIN or HSIL? AIS is often confused by clinicians and patients as being a cancer. It is in fact, HGIL or CGIN. I can understand that there is a desire to make it stand out, but could it not be done without the use of "carcinoma" in the term? “ 8.16 Role of hysterectomy in AIS - Consensus-based recommendation. Where women have been treated for AIS by excision with clear margins, there is no evidence to support completion hysterectomy. In this situation, hysterectomy is not recommended.” This could be clarified, does this mean it is not routinely recommended, or that it is never recommended to do this?
Pip Egerton, Rural PN (smear taker), Primary Care rep Otago / Southland NCSP regional MDT	Tuatapere and Otautau Medical Centre	Good to see indefinite annual review for this group of women.

Fiona Moscrop – on behalf of Clinical Quality Board	Compass Health	Acceptable.
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	<p><i>We disagree with Recommendation 8.02 which states, “Where women have a test result of ‘hrHPV detected (any type)’ with ‘AG1, AG2 or AG3’ LBC results confirmed on cytopathological review, and normal colposcopy, they can be offered repeat co-testing (HPV and LBC) at 6–12 months.”</i></p> <p>Colposcopy is not sensitive for the detection of cervical AIS (nor for glandular neoplasia elsewhere in the upper genital tract). LBC cytology reports of AG1 and AG3 are not infrequently the index smears for women subsequently found to have AIS (and/or adenocarcinoma) and/or HSIL. Recommendation 8.02 may lead to the potential delay of 6-12 months in the detection and treatment of AIS. Therefore, we recommend that serious consideration should be given to diagnostic excision for a woman with HrHPV positivity and confirmed cytology of AG1 or AG3 at a MDT meeting (MDM). Multidisciplinary review at a MDT meeting should occur as soon as possible following colposcopy. In <i>exceptional circumstances</i> conservative management may be considered in these women following a consensus in a minuted MDT Meeting.</p> <p>Follow-up of Atypical endocervical cells (AG1) and Atypical endometrial cells (AG2) should have clearly differentiated pathways and separate flow charts. We favour the AG1 and AG3 follow-up pathway to be the same.</p> <p>What is the evidence behind the 5mm margins for cone excision of ACIS?</p>
Pam Hewlett (P&F Portfolio Manager) Lucina Kaukau & Jane Grant (Cervical Screening Nurse Specialists)	Auckland & Waitemata DHBs	These recommendations are sensible. Consideration will need to be given to ensure women are offered annual co-testing, standardised screening outcome codes for primary care will help ensure this group of women are screened appropriately.
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Service	<p>Good.</p> <p>Other evidence/information to consider:</p> <p>Table 3: no mention is made of assessing the upper genital tract.</p> <p>In the flow charts no guidance for the situation of confirmed LBC glandular abnormality Type 1 or 2 TZ and an LSIL bx is given.</p>

		8.16 We suggest if a woman has been under screened before her diagnosis of AIS or she will have difficulties presenting for follow up co testing she should be offered hysterectomy on completion of her family.
Dr Gillian Gibson	On behalf of RANZCOG NZ Committee	A high risk and challenging group - agree with recommendations. Will there be funding to ensure women can travel within a region to access specialist colposcopy expertise which for example may not be available in provincial areas?
Annette Davis, Team Leader Population Screening	Hawke's Bay DHB	Agree.
Rae Duff, National President Ailsa Stewart, Convenor, Health Standing Committee	National Council of Women of NZ Health Standing Committee	<i>Para 17, Table 1 (p3)</i> <u>Section 8. Guideline 12. Observe & repeat HPV test in 12 month</u> <u>Agreed</u>
Howard Clentworth, SMO Lead Colposcopist & Gynaecologist	CCDHB	The nomenclature of AIS remains the only pre-invasive abnormality that retains the word cancer. It could be tidied. The role of hysterectomy should be clarified on the basis of HPV negativity and not clear margins on histology. After excisional treatment assessment of the transformation zone may be extraordinarily difficult and the option should be discussed on an individual basis. Equally the screening guidelines post treatment should match those of the other proof of cure guidelines. There is no evidence for annual contesting for life making a difference. Annual co testing does have harm, not in the context of normal but in every screen has yes, no and indecisive. The indecisive creates enormous angst.

SECTION 9. Screening after total hysterectomy

Name	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	Non applicable from a non-clinical perspective.
Trish Solomon	Lakes DHB	Supported.
Dr Vicki Robertson	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson	WWFT	Confusing.
Respondent's name redacted at request.	Waikato DHB	Good advice – will the reference in point 9.08 be hyperlinked to relevant document on line?
Amanda Tristram	Gynae Onc CCDHB	<p>9.4 “Evidence is insufficient evidence to support a change to recommendations for women with a history of AIS. These women should continue to have annual co-tests indefinitely. The potential harms of indefinite co-testing are minimal, especially in view of the greater safety women gain by continuing screening.⁸⁴”</p> <p>I am unable to access this reference – “access denied”. This seems like a huge burden of screening on the woman – based purely on “the evidence of harm is minimal”.</p>
Pip Egerton	Tuatapere and Otautau Medical Centres	Good to see annual review in this group of women.
Fiona Moscrop	Compass Health	Straightforward re: recommendations for a case by case basis.
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	<p>Support recommendations.</p> <p>Table 4 doesn't mention screening after previous or current LSIL, just no cervical pathology or HSIL.</p> <p>Figure 10 mentions unexpected LSIL but not known LSIL.</p>

Pam Hewlett, Lucina Kaukau & Jane Grant	Auckland & Waitemata DHBs	Thank you for the clarity around guidelines for screening after total hysterectomy. 9.3 will be a welcome change for many women.
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Services	Good.
Barbara Holland and Barbara Robson	Federation of Women's Health Councils	9.4 Amend wording: There is insufficient evidence ... We agree with this para. 9.08 – strongly agree with this practice point.
Dr Gillian Gibson	RANZCOG	Agree that this provides clarification for this group who have potentially been subjected to ongoing screening unnecessarily in the past
Annette Davis	Hawkes Bay DHB	Agree, there is no flowchart to outline the process if a woman has a LG hx prior to a hysterectomy.
Howard Clentworth	CCDHB Gynaecology Dept.	9.4 "Evidence is insufficient evidence to support a change to recommendations for women with a history of AIS. These women should continue to have annual co-tests indefinitely. The potential harms of indefinite co-testing are minimal, especially in view of the greater safety women gain by continuing screening. ⁸⁴ " I am unable to access this reference – "access denied". This seems like a huge burden of screening on the woman – based purely on "the evidence of harm is minimal".

SECTION 10: Screening in pregnancy		
Name	Organisation	Feedback
Aroha Morgan et al	Lakes DHB	Non applicable from a non-clinical perspective.
Dr Vicki Roberston	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson	Well Women and Family Trust	10.2 I think health professionals won't screen pregnant women after 12 weeks even if they are overdue, even when they should.
Respondent's name redacted at request.	Waikato DHB	Good practical advice. Great not to see low-grade as they often don't come for colposcopy – good recommendation to repeat post-partum.
Pip Egerton	Tuatapere and Otautau Medical Centres	Improved education around cervical screening and in particular in pregnant women is required. Most midwives I have dealings have been advising their pregnant women NOT to have a cervical smear. Would indeed like to see more midwives as cervical screening professionals but at the very least am aware there is a need for better education to our new and present midwifery fraternity.
Fiona Moscrop	Compass Health	Useful to have a definite comment re: prioritising/ proceeding with cervical screening ideally pre-conception to prevent the difficulties in managing screening process and abnormalities during pregnancy. Definitive statement around 2 nd and 3 rd trimester screening where the woman's smear is due – is there any occasion where it would be acceptable to delay until the pregnancy completed?
Respondent's name redacted at request.	Member of the public	Offering cervical screening to women in pregnancy would seem to me to be inappropriate. It is suggested that 5% of pregnant women will have abnormal cervical cytology and, as a result, some may be referred for colposcopy. The recommendation is that treatment is not carried out during pregnancy because it is associated with an increased risk of obstetric complications. Sending a woman to colposcopy and the suggestion of cervical abnormality must be hugely stressful for a pregnant woman. Hopefully the woman's GP or LMC would put her welfare first and suggest postponing a cervical screen until after the pregnancy. As the guidelines suggest, changes to the cervix during pregnancy are common and CIN may regress postpartum.

		<p>In my opinion it is not acceptable to use pregnancy, as a time to capture an unscreened or under screened woman for the cervical screening programme, to increase coverage.</p> <p>This is advice that the NHS in the UK give to women.</p> <p>Cervical screening and pregnancy</p> <p>In most cases, it is not recommended that a woman has a cervical screening test while she is, or could be, pregnant. This is because pregnancy can make the result of your test harder to interpret.</p> <p>If you're planning a pregnancy, it's a good idea to ask your GP if you are up to date with your cervical screening. This means that any tests or treatment can be arranged around the pregnancy.</p> <p>If you are already pregnant, and are due for a cervical screening test, the test will usually be postponed until three months after your baby is born. Tell your GP or clinic that you are pregnant when you are invited for your test.</p> <p>However, if you have previously had an abnormal result from a cervical screening test, or if you are not up to date with your screening (you have not had a test in the last three to five years, depending on your age), you may need to be screened while you are pregnant. Your GP or midwife may ask you to have a cervical screening test at your first antenatal appointment. This test will not interfere with your pregnancy.</p> <p>In my opinion it is not acceptable to use pregnancy, as a time to capture an unscreened or under screened woman for the cervical screening programme, to increase coverage.</p>
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	<p>10.07 biopsy is safe in pregnancy, and knowing the histology of a LSIL or HSIL lesion is useful in considering when next to do follow-up. Also it must be remembered that a biopsy may not show a cancer when it is present, and referral to an experienced colposcopist should be considered if there is a concerning appearance.</p>
Pam Hewlett, Lucina Kaukau & Jane Grant	Auckland & Waitemata DHBs	<p>Good to see greater clarity around screening in pregnancy.</p> <p>10.2 Is there a reference or could a reason be included for the recommendation that LBC samples are taken before 12 weeks. There is potential that this could be misinterpreted and unscreened women may not be offered opportunistic screening in pregnancy.</p> <p>If a clinician is taking swabs at 14 weeks in an unscreened woman it would be appropriate for an LBC sample to be taken at the same time.</p> <p>10.11 'Routine antenatal care should include review of women's cervical screening history' clarity on what is meant by this statement would be helpful. Is it just identifying the date of the last screen or is it a more detailed assessment, with</p>

		a consideration of referral to a specialist? If the expectation is that Midwives are responsible this should be clearly communicated to the College of Midwives.
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Services	<p>Good.</p> <p>Any other evidence/info to consider:</p> <p>Recomm 10.10 Twice weekly seems adequate and women will be less likely to worry about their milk supply.</p>
Barbara Holland and Barbara Robson	Federation of Women's Health Councils	<p>10.10 – some women who are breastfeeding are likely to have reservations about using vaginal oestrogen. Reasons for recommending its use need to be carefully explained and if a woman makes an informed decision not to use it this should be respected. Earlier comments under 2.04 also apply.</p> <p>Use consistent language – 10.12 self-sampling (not self-collection).</p>
Dr Gillian Gibson	RANZCOG	<p>Consider resource to allow access to expert colposcopist if not available in women's DHB.</p> <p>Statement 10.3 is at variance with recommendation 10.01 - non 16/18 and low grade screening to have repeat test 12 months, not immediate colposcopy.</p>
Annette Davis	Hawkes Bay DHB	Agree.
Howard Clentworth	CCDHB Gynaecology Dept.	The evidence for a single screen is overwhelming. In a pregnant patient who has not been screened the opportunity for a captive population should be grasped.
Adrienne Priday	Self-employed midwife CMH region	<p>Please look at MOH section 88 and please reinforce to GP's who mostly undertake the Non LMC payments for the first 12 weeks of pregnancy that they need to do the smear screening. I work in high deprivation communities where by smears are often not done, never had one or overdue. The GP should be proactive to do smear when the preg test is undertaken. Take the time then – opportunistically – so the smear is undertaken. They are paid the non LMC payment and basic health screening is part of that module.</p> <p>Other evidence/information to consider:</p> <p>Resource midwives separately if they undertake this screening as it's time consuming and not respected in the current Section 88 modular system. Same for GP's too. Resource for this work.</p>

SECTION 11. Screening for women who experienced early sexual activity

Name	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	<p>Support this recommendation.</p> <p>Other evidence/info to consider:</p> <p>More research into cancer in under 25 women.</p>
Dr Vicki Robertson	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson	WWFT	Not good having to ask 20 to 25 year olds if they have been sexually active under 14 years old. Most young women will not disclose to a male GP I think.
Respondent's name redacted at request.	Waikato DHB	Good practical advice.
Michael Thorn	RNZCGPs	<p>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.</p> <p>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.</p>
Pip Egerton	Tuatapere and Otautau Medical Centres	<p>Previous expressed concerns with increasing screening commencement age to 25 yrs from 20 yrs - regardless of previous sexual history. In particular the particular strain of HPV mainly 16 /18 is not necessarily determinant on previous sexual history but the "luck of the draw "which strain anyone can come across. Cannot see how ones history should be that which determine this point of discussion, which is to offer this particular group of women, early screening opportunity.</p> <p>Again I reiterate 23 NZ women 2008-2013 with cervical cancer, is 23 to many.</p> <p>PLEASE think very carefully about changing the screening age. In today's age of a need to "blame" we need to be very confident in the decisions that are made for our next generation.</p> <p>Other evidence/info to consider:</p> <p>Think carefully why we have "...one of the most successful screening programmes in the world".</p>

Respondent's name redacted at request.	Massey University	<p>These recommendations acknowledge that some women may have had a persistent high risk HPV infection and therefore higher risk of disease before age 25. When a history of sexual abuse is known I believe these recommendations are fair. However, generally it is not known to the smear/sample taker when a woman became sexually active. Questioning this also risks the woman feeling stigmatised which may in turn impact on her use of screening services. Studies have shown that recent birth cohorts tend to have an early onset of sexual activity, and a greater number of sexual partners [1]. The number of sexual partners, not only the early onset of sexual activity is a risk factor for cervical cancer, as is the presence of other sexually transmitted infections [2].</p> <p>Other evidence/info to consider: Studies on university aged women have shown histologically confirmed CIN2/3 can develop within two years of incident HPV infection [3, 4]. Although increasing the screening age may not result in a significant increase in the number of cervical cancer cases in those aged under 25, it is likely to have an impact on the number of cases of histologically confirmed high grade lesions in younger women. The combination of earlier sexual debut and an increased number of partners, with an older first screening age and longer screening interval will further add to this. It is possible the lesions diagnosed in younger women may be larger than those currently seen with three yearly screening from age 20. It is widely accepted that overtreatment for cervical lesions can lead to adverse fertility and pregnancy outcomes. However, the treatment of larger lesions also risks these outcomes.</p> <p>A possible consideration could be the expansion of these guidelines to further incorporate known risk factors for the development of cervical cancer, particularly in non-vaccinated women. The use of surrogate markers for sexual activity could be considered. For example if a non-vaccinated woman aged 20-24 has a history of a sexually transmitted infection, or has had two or more children, a test could then be offered.</p> <p>References</p> <ol style="list-style-type: none"> 1. Chaturvedi AK. Epidemiology and clinical aspects of HPV in head and neck cancers. Head and neck pathology 2012; 6 Suppl 1:S16-24. 2. Moscicki AB, Schiffman M, Kjaer S, Villa LL. Chapter 5: Updating the natural history of HPV and anogenital cancer. Vaccine 2006; 24 Suppl 3:S3/42-51. 3. Trottier H, Mahmud SM, Lindsay L, et al. Persistence of an incident human papillomavirus infection and timing of cervical lesions in previously unexposed young women. Cancer epidemiology, biomarkers & prevention : a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology 2009; 18:854-62. 4. Winer RL, Kiviat NB, Hughes JP, et al. Development and Duration of Human
Fiona Moscrop	Compass Health	Quantify increased risk of women (or a better steer – slight increased risk, moderate...etc) who have had early sexual intercourse to enable clinician decision making.

		<p>Other evidence/info to consider: Note consensus as assumingly lack of evidence in this area.</p>
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	<p>The single reference provided in the Consultation document may not be representative enough for the whole New Zealand population. We would recommend seeking more information and more recent data from a range of groups within New Zealand. There is anecdotal evidence that age of first intercourse (sexual debut) in some NZ populations is particularly young. We recommend further robust investigation within NZ, as it will inform decisions about screening for those populations in which early sexual intercourse is particularly common (and particularly early).</p> <p>We would strongly encourage development of a comprehensive awareness program for women under 25 who are symptomatic and the importance of seeking medical assistance immediately. This should be integrated with education about the rising STD rates in young women – if cervical screening is not routinely performed in this age-group, then there will be less regular sexual health checks in this key age group; this may have major impact on detection and treatment of STDs, with downstream consequences.</p> <p>All women under 25 that are tested for HPV or have a cervical smear should be part of the register.</p> <p>Other evidence/info to consider:</p> <p>Has comparative economic modelling been performed of the cost due to increased percentage of invasive cancers in the age group 20- 29 years compared to cost of screening under 25 years?</p> <p>Has consideration been given to other asymptomatic STDs in the under 25 years that may be missed in this population due to the loss of opportunity with patients presenting for a smear. Some monitoring of this population may be warranted with the changes of the screening program. STD surveillance is particularly important in the era of increasing antimicrobial resistance of these common organisms.</p>
Pam Hewlett, Lucina Kaukau & Jane Grant	Auckland & Waitemata DHBs	<p>We are concerned that these guidelines may further stigmatise this group of women.</p> <p>We think these recommendations are outside of routine screening. There is a risk that age of first sexual intercourse could become a routine question that serves little purpose and further traumatises women who have been sexually assaulted.</p>

		<p>11.01, 11.02 11.03 We think there should be a separate section to these guidelines that provides guidance on HPV testing outside of routine screening. Guidance on testing women who experienced early sexual intercourse and guidance on testing for women who experience abnormal vaginal bleeding could be included in this section.</p> <p>We suggest that such guidance be distributed to sexual health clinics and other organisations that work with young people in this situation.</p> <p>We suggest that guidelines recommend referral to appropriate sexual health service.</p>
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Services	<p>Good.</p> <p>11.7 Should be the second bullet point, not way down the list at 7.</p>
Barbara Holland and Barbara Robson	Federation of Women's Health Councils	<p>11.1 We are pleased to see this in these updated guidelines.</p> <p>11.02 FWHC recommends co-testing for these women.</p>
Dr Gillian Gibson	RANZCOG	The only limitation is that early sexual debut may not be known or disclosed or the young woman aware of the significance- informing women of the importance of disclosing this information should be considered in any patient information about cervical screening.
Annette Davis	Hawkes Bay DHB	Agree.
Lynda Williams	Auckland Women's Health Council	The AWHC supports the recommendation to perform a cervical screening test in women aged under 25 years if they have a history of sexual abuse or became sexually active before the age of 14 years.
Dr Sandra Hall, Policy Analyst	On behalf of the Cartwright Collective	<p>The pathway for women who have experienced early sexual activity is vague and does not give enough information about at risk groups or how practitioners can deal testing in the context of other serious related issues such as sexual abuse.</p> <p>We think this section requires more information and clear definitions of what 'sexually active' means in the context of HPV infection and what patients will be told so they can make a decision about sharing information about their sexual histories.</p> <p>Other evidence/info to consider:</p> <p>There is very little information to guide clinicians in this section. It would be good if this part of guideline produced some evidence about what age young people in NZ become sexually active enough to be infected with HPV.</p> <p>The possibility that women who are sexually active early may have been abused is also mentioned as a topic that may be difficult for clinicians to discuss and which may be traumatising for the woman. This type of information needs to be carefully referenced.</p>

		The guideline needs to be much clearer in this area and we are concerned that women who acknowledge 'early sexual activity' are not subjected to judgement or moralising or assumptions that they have been (or not been) sexually abused.
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SECTION 12. Screening for immune-deficient women

Name	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	Non applicable from a non-clinical perspective.
Dr Vicki Robertson	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson	WWFT	Good.
Respondent's name redacted at request.	Waikato DHB	<p>Great practical advice.</p> <p>Other evidence/info to consider:</p> <p>Page 62 – amendment</p> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p>[12.13] Guidance for immune-deficient women and their health care professionals</p> <p>Practice point</p> <p>It is important that a clinical immunology specialist guides immune-deficient women and their health care professionals who are using these guidelines.]</p> </div> <div style="border: 1px solid black; background-color: #f0f0ff; padding: 5px; width: fit-content; margin-left: 20px;"> <p>Comment [JM4]: presumably 12.11-12.13 refer to women who are immuno-deficient for reasons other than outlined in 12.08, 12.09 & 12.10. Suggest clarify a bit more to ensure smear takers do not think all immuno-deficient & immunosuppressed women need clinical immunology input, as per 12.13.</p> </div>
Michael Thorn	On behalf of RNZCGPs	We support the development of further guidance for GPs when providing care to women who are immune-deficient.
Pip Egerton	Tuatapere and Otautau Medical Centres	<p>Have concerns with women who have history of HrHPV 16/18 going onto 5 year recalls....all women will experience low immunity at times with potential for reoccurrence of this virus.</p> <p>Other evidence/info to consider:</p> <p>Like the 12.12 and 12.10 practice points.</p>
Fiona Moscrop	Compass Health	Useful to have a 3 year screening steer in this area.
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	Support recommendations.

Pam Hewlett, Lucina Kaukau & Jane Grant	Auckland & Waitemata DHBs	<p>12.01 Thank you it is excellent to see recommendations aligned to WHO recommendations.</p> <p>12.04 Assessing entire lower anogenital tract is very sensible in this group of women.</p> <p>12.08 Thank you for the clarity around immune deficient women. These guidelines are helpful.</p> <p>12.10 Thank you for this clarity.</p> <p>12.12 We think there should be a separate section to these guidelines that provides recommendations and guidelines HPV testing outside of routine screening.' Guidance on testing immune deficient young women could be included in this section.</p> <p>12.13 We would like to ask if there is a plan to inform specialists in secondary care and private practice of the changes regarding immune deficient women? It is common practice for specialists to recommend appropriate vaccination for immune deficient patients, it would be excellent to see appropriate cervical screening recommendations from specialists.</p>												
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Services	<p>Good.</p> <p>Other evidence/info to consider:</p> <p>If an immuno deficient woman is diagnosed with a histologiaclly confirmed abnormality should they be referred to a specialist practiced in anoscopy?</p>												
Dr Gillian Gibson	RANZCOG	<p>12.02 What does "informed by the result of the reflex LBC test" mean here?</p> <p>Other evidence/info to consider:</p> <p>HIV positive women may not be at increased risk if low viral loads – is there evidence to suggest this?</p>												
Annette Davis	Hawkes Bay DHB	Agree.												
Rae Duff, Ailsa Stewart	National Council of Women of NZ Health Standing Committee	<p><i>Para 17, Table 1 (p3)</i></p> <table> <tr> <td>Section 12.</td> <td>Guideline 16.</td> <td>Recommendations for immune-deficient women particularly organ transplant recipients.</td> <td>Agreed</td> </tr> <tr> <td></td> <td></td> <td>Routine screening interval for immune-deficient women is three years.</td> <td>Agreed</td> </tr> <tr> <td></td> <td></td> <td>We would prefer a case by case follow-up of immune-deficient women treated for high-grade lesions.</td> <td></td> </tr> </table>	Section 12.	Guideline 16.	Recommendations for immune-deficient women particularly organ transplant recipients.	Agreed			Routine screening interval for immune-deficient women is three years.	Agreed			We would prefer a case by case follow-up of immune-deficient women treated for high-grade lesions.	
Section 12.	Guideline 16.	Recommendations for immune-deficient women particularly organ transplant recipients.	Agreed											
		Routine screening interval for immune-deficient women is three years.	Agreed											
		We would prefer a case by case follow-up of immune-deficient women treated for high-grade lesions.												

Dr Sandra Hall, Policy Analyst	On behalf of the Cartwright Collective	We think information should be included about auto immune diseases which result in higher risk.
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SECTION 13. Cervical screening for women exposed to diethylstilbestrol		
Name	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	Non applicable from a non-clinical perspective.
Dr Vicki Robertson	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson	WWFT	This means we will have to ask every women born from 1940 to 1980 if their mother took DES. I am sure most women would have no idea – what then? Should we be co-testing all women born in those years?
Respondent's name redacted at request.	Waikato DHB	Good practical advice.
Pip Egerton	Tuatapere and Otautau Medical Centres	Was NOT aware of this group –had no knowledge that this group of women have an increased risk of clear cell carcinoma of the vagina and cervix. Would be interested to know how many other smear takers are aware. Other evidence/info to consider: How best to identify these women in our practice??? Especially considering they should be offered annual testing
Fiona Moscrop	Compass Health	Acceptable.
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	Support recommendations. This is a minority group.
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Services	Should the smear be from cervix only or should the vagina also be smeared?
Dr Gillian Gibson	RANZCOG	13.01 “and colposcopic examination of both the cervix and vagina indefinitely” is this annual colposcopy as well or just if an abnormal HPV test or co-test?
Annette Davis	Hawkes Bay DHB	Agree.

Howard Clentworth	CCDHB Gynaecology Dept.	The last time Diethylstilboestrol was used in pregnant women worldwide was 1971 and in New Zealand in 1968. All of those women have been screened multiple times they are now 50. The section is simply redundant.
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SECTION 14. Investigation of abnormal vaginal bleeding

Name	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	Supported.
Dr Vicki Robertson	West Coast DHB	<p>No additional comments. We support these recommendations.</p> <p>Other evidence/info to consider:</p> <p>Recommendation 14.07. Should there be a comment about urgent referral/HSC for this group of postmenopausal women?</p>
Beth Henderson	WWFT	Doesn't say whether co-testing will need to be ordered or reflex if IMB/PCB/PMB written on the lab form. As it is, hrHPV testing hasn't been requested by health professionals when it should be.
Respondent's name redacted at request.	Waikato DHB	<p>Good practical advice.</p> <p>Other evidence/info to consider:</p> <p>Page 65 amendment</p> <p>14.5 Health care professionals may remain concerned by the presence of postcoital bleeding, despite the reassurance of negative findings on co-testing, and [may continue to refer women with only one episode of postcoital bleeding and a clinically normal cervix.] Therefore, the education of health care professionals is of paramount importance to successful implementation of recommendation 14.03.</p> <div style="border: 1px solid black; padding: 5px; background-color: #f9e7ff;"> <p>Comment (JMS): this could be interpreted as meaning 'should continue to refer'; suggest clearly state recommendation 14.03 here, as well as in recommendation box, that 'Where pre-menopausal women have a single episode of postcoital bleeding, a clinically normal cervix, and 'hrHPV not detected' and negative LBC test results, they do not need to be referred for colposcopy'</p> </div>
Pip Egerton	Tuatapere and Otautau Medical Centres	<p>Like the guidelines very clear.</p> <p>Other evidence/info to consider:</p> <p>Increased strain potential / probability on colposcopy services and concerns as already expressed. Section 4</p>
Fiona Moscrop	Compass Health	Clear guidance here – which is very practically useful.

Respondent's name redacted at request.	Member of the public	The NHS have a document; "Clinical practice guidance for the Assessment of Young Women aged 20-24 with Abnormal Vaginal Bleeding".
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	We recommend some more clarity on how the under 25 years fit into this part of the pathway. Colposcopy is a useful first port of call for women with prolonged post coital bleeding and other menstrual problems, so that the cervical lesion can be diagnosed and treated at the same time as hysteroscopy and other investigations.
Pam Hewlett, Lucina Kaukau & Jane Grant	Auckland & Waitemata DHBs	<p>14.1 We would like to suggest that there is a separate section to these guidelines that provides 'Guidance on HPV testing outside of routine screening.' Guidance for investigation of abnormal vaginal bleeding could be included in this section.</p> <p>14.3 We would like to propose a national standardised laboratory request form which clearly states whether the test is routine screening, if it is investigation for abnormal vaginal bleeding, or other reasons outside of routine screening, and whether co-testing is requested.</p> <p>There are implications for nurse sample takers who may be considered to be working outside of their scope of practice if requesting co-testing for symptomatic women. This may require some thought as nurse sample takers who work outside of teams which include doctors may need to request both HPV and cytology, and refer if screening opportunistically. It would be a shame for this to deter opportunistic screening in symptomatic women.</p>
Drs Jay Sirisena, Anand Gangi, Jenny Blasingame, Kristy Wolff, Donna Hardie	Northland Colposcopy Services	We believe that section 14 should be at the beginning of this document. With the change to HPV screening we have an opportunity to stress the importance of taking a history at the time of screening. HPV screening, like cytology, will not detect some cancers but in our experience most of those cancers will be symptomatic. History taking by smear takers must be stressed during this change over. It is our experience that history taking by smear takers [and therefore education of women about the importance of symptoms] is not well done under the current screening programme and this is our opportunity to improve that aspect of the programme. Other evidence/info to consider: 14.2 Include STIs in the list of causes. 14.3 This reasoning suggests that women who are not bleeding at the time of sampling do not require co testing but we suggest women with unexplained abnormal bleeding should all have co testing. 14.5 Women with a single episode of PCB and negative findings on co testing do not require referral to colposcopy. Recom 14.05 This suggests smaertakers should refer directly to gynae oncology without assessment at local DHB level. Is that what is intended?

		Recom 14.07 Women with a single episode of PMB may be assessed by their GP with imaging or pipelle and if all is negative and only referred to gynae if there is recurrent bleeding.
Barbara Holland and Barbara Robson	Federation of Women's Health Councils	<p>14.1 It is good to have this section included in the Guidelines but it needs to be stressed that investigation of abnormal vaginal bleeding and other related symptoms belongs in a diagnostic pathway, not screening. We assume that referrals made under 14.03, 14.05, 14.06 and 14.07 may meet the criteria for the Faster Cancer Treatment programme but this needs to be clarified along with any fit within ESPI prioritisation tools and waiting time targets for FSAs and treatment.</p> <p>14.01 define 'urgent'</p> <p>14.03 has this been factored in to the colposcopy waiting times review?</p> <p>14.05 define 'urgent'</p> <p>14.06 & 14.07 where will this fit within waiting times prioritisation?</p>
Dr Gillian Gibson	RANZCOG	Agree education of primary care practitioners will be required.
Annette Davis	Hawkes Bay DHB	Agree.
Howard Clentworth	CCDHB Gynaecology Dept.	These patients should be referred to a general gynaecology clinic and not to colposcopy. Colposcopy clinics are overloaded with patients with bleeding and negative cytology and HPV testing.

SECTION 15. Transition to HPV primary screening

Name	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	Non applicable from a non-clinical perspective.
Dr Vicki Robertson	West Coast DHB	No additional comments. We support these recommendations.
Beth Henderson	WWFT	Involved but I guess that is how it is.
Michael Thorn	RNZCGPs	<p>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.</p> <p><i>Informing GPs and women</i></p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>

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.

		<p># 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.</p>
Pip Egerton	Tuatapere and Otautau Medical Centres	<p>Consistent sooner than later education to health professionals, especially primary care and midwifery, utilising a variety of communication avenues/venues. Be aware of the disseminated primary care service in NZ.</p> <p>Good simple, health literate information normalising the HPV virus and education around the transmission, (having worked in conjunction with NZ sexual health society and HPV programme educators and health promoter) which will ultimately assist in the uptake of the HPV vaccine alongside ideally improved screening uptake.</p> <p>Other evidence/info to consider:</p> <p>Need improved quality measurements in place – aware these are being reviewed. In order to ensure smear takers are well educated and updated to ensure consistency.</p> <p>Not to assume that every health professional utilises the NSU or Ministry of Health website on a regular basis...as implied when the initial public consultation paper 2015 was presented on the Ministry website, yet a NCSP multidisciplinary regional group managed to be unaware of the consultation paper until one week before submissions closed.</p>
Rebecca Lucas-Roxburgh	Massey University	<p>The transition presented in the document appears very quick and does not fully recognise the current split in New Zealand's screening population with regards to risk factors and vaccination status.</p> <p>Other evidence/info to consider:</p> <p>There will be three different groups with different risk profiles after the introduction of the nine-valent vaccine.</p> <p>The current screening population are older and unvaccinated (with the exception of those women who were vaccinated as part of the initial catch up program) and therefore based on both these factors have the greatest risk of developing cervical cancer.</p> <p>Those vaccinated with Gardasil are the second group who will begin to enter the screening program this year. These can be considered partially vaccinated, both in terms of the low vaccine coverage, and the inclusion of only HPV types 16 and 18 in this vaccine. The vaccine coverage of ~60% creates a subgroup with a higher risk i.e. those unvaccinated individuals. Data from the New Zealand prevalence study has shown that HPV 16/18 are responsible for 62.9% of</p>

		<p>confirmed CIN2/3 or CIS cases [5]. Therefore, this group are still at risk of the development of disease associated with other types.</p> <p>The third group will be those who will be vaccinated with the nine-valent vaccine as of 2017, and will therefore not enter the screening programme until around 2030. This group will have a significantly lower risk of the development of HPV related disease, and as new data emerges may benefit from an even longer screening interval.</p> <p>A longer term transition to primary HPV testing based on the women's risk / vaccination status could be considered. This could include co-testing for the current screening population (group one), and primary HPV testing as described in the consultation documents for those Gardasil vaccinated women (group two).</p> <p>Women who have been in the screening program for a while are used to three yearly screening, and many are aware of the issues cervical screening in New Zealand has had in the past. By slowly phasing in primary HPV testing (ideally until the nine-valent vaccinated population start screening) time for education of both medical staff, and the public is available. It also allows time to improve the current vaccination coverage. The approach also reinforces vaccination/primary prevention as the best option for the reduction of cervical cancer cases.</p> <p>Reference</p> <p>5. Simonella LM, Lewis H, Smith M, Neal H, Bromhead C, Canfell K. Type-specific oncogenic human papillomavirus infection in high grade cervical disease in New Zealand. <i>BMC Infectious Diseases</i> 2013; 13:1-10.</p>
Fiona Moscrop	Compass Health	Guidelines around advice to give women who are approaching 20 years now, when indeed the age is to be raised to 25 years in 2018. This age change is to reduce the risk of harm from unnecessary intervention and so some interim guidance would be useful at this stage.
Respondent's name redacted at request.	Member of the public	<p>Other evidence/info to consider:</p> <p>[Safety of extending screening intervals beyond five years in cervical screening programmes with testing for high risk human papillomavirus: 14 year follow up of population based randomised cohort in the Netherlands, BMJ 2016; 355 doi: http://dx.doi.org/10.1136/bmj.i4924 (Published 04 October 2016) Cite this as: BMJ 2016;355:i4924]</p> <p>Objectives To provide an early risk assessment of extending screening intervals beyond five years for a human papillomavirus (HPV) based cervical screening programme in the Netherlands.</p> <p>Design 14 year follow-up of a population based randomised cohort from the POBASCAM randomised trial.</p>

		<p>Setting Organised cervical screening in the Netherlands, based on a programme of three screening rounds (each round done every five years).</p> <p>Participants 43 339 women aged 29-61 years with a negative HPV and/or negative cytology test participating in the POBASCAM trial.</p> <p>Interventions Women randomly assigned to HPV and cytology contesting (intervention) or cytology testing only (control), and managed accordingly.</p> <p>Main outcome measures Cumulative incidence of cervical cancer and cervical intraepithelial neoplasia (CIN) grade 3 or worse (CIN3+). Associations with age were expressed as incidence rate ratios. In HPV positive women, reductions in CIN3+ incidence after negative cytology, HPV type 16/18 genotyping, and/or repeat cytology were estimated.</p> <p>Results The cumulative incidence of cervical cancer (0.09%) and CIN3+ (0.56%) among HPV negative women in the intervention group after three rounds of screening were similar to the cumulative among women with negative cytology in the control group after two rounds (0.09% and 0.69%, respectively). Cervical cancer and CIN3+ risk ratios were 0.97 (95% confidence interval 0.41 to 2.31, P=0.95) and 0.82 (0.62 to 1.09, P=0.17), respectively. CIN3+ incidence was 72.2% (95% confidence interval 61.6% to 79.9%, P<0.001) lower among HPV negative women aged at least 40 years than among younger women. No significant association between cervical cancer incidence and age could be demonstrated. CIN3+ incidence among HPV positive women with negative cytology, HPV 16/18 genotyping, and/or repeat cytology was 10.4 (95% confidence interval 5.9 to 18.4) times higher than among HPV negative women.</p> <p>Conclusions Long term incidences of cervical cancer and CIN3+ were low among HPV negative women in this study cohort, and supports an extension of the cervical screening interval beyond five years for women aged 40 years and older. HPV positive women with subsequent negative cytology, HPV16/18 genotyping, and/or repeat cytology have at least a fivefold higher risk of CIN3+ than HPV negative women, indicating that HPV based programmes with long intervals (>five years) should be implemented with risk stratification.</p> <p>Trial registration POBASCAM trial number ISRCTN20781131.</p>
CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	<p>The work-flow modelling needs to be well understood by all the key departments and those managing them, to inform workforce considerations in Pathology and Colposcopy in particular.</p> <p>A multi-disciplinary approach for those high risk patients progressing from screening to a diagnostic and treatment pathway is essential and needs to be set up in a robust fashion.</p>

Pam Hewlett, Lucina Kaukau & Jane Grant	Auckland & Waitemata DHBs	<p>15.01 On page 5 where key changes to the guidelines are discussed it reads differently to this section, there is room for misinterpretation, it states on page 5: Women under 25 years whose recommended routine recall falls before they are 25 will have an HPV test when they reach age 25. We read this to mean that if a women is screened at age 20 in 2017 her next test should be deferred until age 25. The recommendation in 15.01 is sensible.</p> <p>The transition to HPV primary screening is likely to cause some confusion in primary care and affect recall systems we would like to suggest that a detailed transition plan be developed to manage this.</p> <p>We would like to note that Practice Management System (PMS) vendors will need to change auto recall dates to reflect the guidelines.</p> <p>15.02 Suggest the words screening/follow up due date instead of next scheduled follow up appointment as this may apply to screening or colposcopy.</p>
Barbara Holland and Barbara Robson	Federation of Women's Health Councils	<p>15.01 Note that FWHC recommends co-testing as an initial transition pathway step.</p> <p>15.02 FWHC would want co-testing for this.</p> <p>15.07 We continue to disagree. We want to see co-testing on all samples until evidence confirms that HPV testing as the primary test is the best test in the real world screening programme setting.</p> <p>Other evidence/info to consider:</p> <p>We note the UK cervical screening programme maintains 3 yearly screening for younger women along with co-testing. Ref: Scientific Impact Paper No. 7 <i>Progress in Cervical Screening in the UK</i>.</p> <p>NZ should do the same – one size (both screening test and screening interval gap) does not best fit all women. We cannot ignore the current evidence of benefit for women arising from LBC testing who have non-HPV screening programme detected cancers.</p>
Dr Gillian Gibson	RANZCOG	Agree.
Annette Davis	Hawkes Bay DHB	Agree.

Rae Duff, Ailsa Stewart	National Council of Women of NZ Health Standing Committee	<p><i>Para 17, Table 1 (p3)</i></p> <table border="1"> <thead> <tr> <th>Section 15.</th><th>Primary Screening</th><th>We agree with all listed updates particularly for annual co-testing for women treated for glandular abnormalities.</th></tr> </thead> </table>	Section 15.	Primary Screening	We agree with all listed updates particularly for annual co-testing for women treated for glandular abnormalities.
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Howard Clentworth	CCDHB Gynaecology Dept.	<p>The transition to primary HPV screening should be reviewed within 5 years. The present tests use HPV DNA which is not a particularly good surrogate for viral activity. The program should encourage and participate into research to interrogate whether HPV RNA is a better surrogate marker of disease and to trials of other markers of HPV activity. I see no vision in these guidelines about the obvious refining of what is measured.</p> <p>The final comment about AIS as the only Australasian terminology is simply inaccurate and relies on a single reference which is seriously flawed.</p>			
Mary Webster	CHL	<p>Definitely look at a pilot study of self-sampling HPV prior to transition to Primary HPV.</p> <p>Dr Margaret Sage presentation at Scientific Day 'Screening for cervical disease' Starting slide 26 - HPV testing and cytology for women with invasive cancer and slide 27 - Selective co-testing will be used for women who ...' is an improvement on earlier guidelines</p> <p>From the same event Dr Gary Fentiman regarding Safety of change slide – 10 Safety monitoring will be ongoing during transition.</p> <p>Other evidence/info to consider:</p> <p>The risks of HPV –Alone screening Pap + HPV Together http://papplushpv.hologic.com/why</p> <p>Evidence from the Quest Study publication</p> <p>6.0% CIN 3+ missed by HPV-Alone</p> <p>8.7% CIN3+ missed by Pap-alone</p> <p>1.2% CIN3+ missed by Pap+HPV together</p>			

Lynda Williams	AWHC	<p>The AWHC supports co-testing as an initial transition pathway step. For recommendations 15.01 and 15.02 and 15.07 we want to see co-testing on all samples until the evidence from real world screening programmes confirms that HPV testing is both safe and is the better test.</p> <p>The AWHC supports 3-yearly screening for younger women along with co-testing. A one size fits all – HPV primary screening at 5-yearly intervals – is not necessarily the best for all women. We are also aware of the current evidence demonstrating the benefits for women arising from LBC testing who have non-HPV screening programme detected cancers.</p>
Dr Sandra Hall, Policy Analyst	On behalf of the Cartwright Collective	<p>We think issues of informed consent to transition to the new HPV primary screening need to be included here. The possibility that some women may refuse HPV testing and some may request to continue with the current screening process should also be considered, as well as how this will be managed.</p> <p>Other evidence/info to consider:</p> <p>We have already made representations to the NSCP and the MOH in this regard. We will be submitting a number of questions raised by the NCSP Scientific meetings to you next week.</p>

OTHER COMMENTS		
Name	Organisation	Feedback
Aroha Morgan, Phyllis Tangitu and Trish Solomon	Maori Health, Lakes District Health Board	<p>The highly clinical and technical detail of these guidelines made it difficult for people with non-clinical experience to read, but who have a keen interest in Cervical Screening for the priority group women – Maori in particular.</p> <p>It is also noted that priority women include Maori, Pacific and Asian which from a population perspective is high and therefore the scope of the guidelines should be targeted at this grouping.</p> <p>Is there opportunity to establish an expert advisory group that can provide high level support to the implementation of these in a appropriate manner for Maori?</p>
Mr Mark Stegmann, Medical Director O&G	Whanganui DHB	<p>Thank you for giving us this opportunity. We note that the guidelines are extremely well researched and detailed. The treatment algorithms flow logically and appear to cover most, if not all, scenarios.</p> <p>Whanganui DHB has no other comments to make and looks forward to their implementation in due course.</p>
Dr Vicki Roberston	West Coast DHB	<p>Thank you for the opportunity to provide our feedback and for the extensive work that has gone into the development of these guidelines.</p>
Beth Henderson, Education Nurse	Well Women & Family Trust	<p>Great to be updating the guidelines. I have concerns about hrHPV testing only as it will miss the cervical cancers not caused by hrHPV and it won't pick up endometrial cancers.</p>
Respondent's name redacted at request.	Waikato DHB	<p>Pleased to see the references to the vaccines.</p> <p>Our Sexual Health Physician wanted to ensure the NSU and guidelines group is aware of the recent surge in the number of trans men receiving hormone treatment in NZ, in keeping with international trends around greater awareness of gender variance. A lot more presentations in the last 2-3 years around the country and the physician is already getting local queries about how best to approach cervical smear taking for trans males. That is, birth-assigned women with vaginal-cervical atrophy due to lack of oestrogen because they are taking testosterone, many of whom have not undergone hysterectomy due to of lack of publicly funded gender-related surgery in NZ. It would be timely, and help future proof this document, if NSCR included a comment about considering a short course of topical oestrogen before attempts at smear taking for this growing group. Ideally, a group that could be targeted for self-</p>

		<p>sampling for HPV too, as they are really reluctant to have genital examinations, although more evidence may be needed to substantiate this.</p> <p>We have ongoing concerns with the potential increase in numbers of patients referred for colposcopy in our unvaccinated population initially, and the ability of the service to see these patients in a timely manner. This will need to be taken into consideration during our Ministry Audit while we work through this potential problem.</p> <p>There are also concerns raised by health professionals in our community of women with high grade pathology (often seen in our MDM) and AIS cases that are HrHPV negative. Has there been any review of the potential number of patients that fall into this category?</p>
Amanda Tristram	Gynae onc CCDHB	<p>In the Appendix:</p> <p>'Adenocarcinoma in situ (AIS)' is the only currently recommended term in Australasia for glandular mucosal pre-invasive lesions.¹⁰⁹ The term 'glandular dysplasia' is not currently used in New Zealand, but has been used historically and is in use in the United Kingdom (where the synonym is 'low-grade cervical glandular intraepithelial neoplasia').¹¹⁰</p> <p>This is not accurate. In the UK, the equivalent term would be CGIN, not necessarily with the "low grade" in front of it. The reference given here is one single author, who gives his opinion on a number of descriptions.</p>
Michael Thorn	RNZCGPs	<p>The College acknowledges that the NCSP is currently updating the documents, <i>National Policy and Quality Standards – Section 3: Cervical screening services and Competencies for Cervical Screening Education and Training</i>. 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 <i>National Policy and Quality Standards</i> are highly relevant to the Equity section of the Guideline.</p> <p>The College also supports further work on the feasibility of options to increase screening uptake such as HPV self-sampling for those women who find it difficult to access screening services.</p>
Peter Fitzgerald	Southern Community Laboratories	If you believe the hypothesis that 5 yearly HPV screening with partial genotyping for HPV 16/18 will reduce cervical cancer mortality in NZ by 18% then the guidelines proposed in this consultation document are logical. I do not believe that this hypothesis is necessarily correct and remain of the view that co testing (HPV plus LBC) for the first 2 screening rounds is the safest way to proceed. Our organisation has made several offers to the NCSP to discuss co testing costs because the modelled cost assumptions are wrong. We have had no response from the NCSP to date.

		<p>I broadly agree with all the guidelines as written. I will make some specific comments in relation to specific clinical scenarios. (see other sections of feedback).</p> <p>Monitoring and evaluation:</p> <p>There is no detail given in the consultation document about the indicators being proposed “to monitor the quality of programme delivery and a high-level evaluation framework to ensure the benefits of the programme are realised.”</p> <p>From my perspective monitoring and evaluation of the new screening program is the most important consideration in all the consultation document. All the guidelines as suggested are logical based on the hypothesis that 5 yearly HPV screening with partial genotyping for HPV 16/18 will reduce cervical cancer mortality in NZ by 18%.</p> <p>Future monitoring and evaluation of the NCSP must be independent of the NCSP. The current monitoring and evaluation is not independent of the NCSP. NCSP staff and those paid directly or indirectly by the NCSP should not be employed to monitor and evaluate the NCSP.</p>
Pip Egerton	Tuatapere and Otautau Medical Centres	<p>I have more concern around the change to 25 yrs than I do in regards an exit test...would prefer at least 1 entry test under aged 25 yrs. Since first submission I have read further around this topic. I am well aware my concerns will not stop the already decided age change and this in itself concerns me. Public consultation in 2015, was completely inadequate and I wonder how many submissions were actually received for this paper. I know very few health professionals were aware of this paper so can only imagine the general public would have had NO idea of its existence. My concerns extend to the knowledge the process in which this consultation paper was presented indicates the Ministry of Health really did not want to know what the public (and indeed many ground level smear takers felt) on this very controversial topic . NZ Ministry will be very aware of the problems the UK, Scotland and Wales had when implementing the increased age. Please if nothing else stop referring to the “harms from over treatment outweigh benefits, including increased anxiety and trauma from colposcopy, and potentially future adverse pregnancy outcomes such as premature labour”...I am aware this is a research based statement but cannot find the same research for those women where the benefits of treatment outweigh the harm. There is a big difference in the “harms and anxiety, and indeed preterm labour” of screening, compared to the harm of potential death and harm by possibly not living long enough to become pregnant. It does not compare !So I encourage any future explanation in the next 15 months NOT to continue to undermine peoples intelligence and emotions like in the present typical Ministry approach by “scaremongering ”...as most recent statement read in the October 2016 Kai Tiaki Nursing magazine , Pg.9-where Jane O’Hallahan states” Harms of screening in this age group(referring to 20-24 yr olds) include over-diagnosis, increased</p>

		<p>stress and anxiety associated with additional tests and treatments, and unnecessary colposcopy, which is associated with heightened risk of future pre-term births".</p> <p>This approach by the Ministry will in itself, particularly due to the seeming closed Ministry process of consultation, will only incite some clinicians and general public concerns...perhaps the Ministry might like to consider the words of Dr Rosemary Fox, Director of the Screening Division of Public Health Wales, when Wales decided to increase the screening age, she said "Women should be reassured that these changes are based on the best available evidence about when screening should be undertaken". www.wales.nhs.uk. 'Cervical Screening Wales reminds women of smear test changes'. I am personally really annoyed the age change "consultation" was attached to the discussion around changing to HPV Primary testing. The later seems most appropriate without need for public consultation-I acknowledge the expertises of those suggesting this change to HPV Primary testing, the research around this, and of the need for the change in guidelines to reflect this , it is most appropriate.</p> <ul style="list-style-type: none"> 1- Do not feel NZ over treats women with abnormal screening results as our present pathways deal with the different types of HPV detected, especially in the last 3-4 years. We certainly do NOT rush into treatment (for CIN1) as we did in the recent past when most of the research data, in terms of assumed harm, stems from . 2- Do feel unless there is improved public information, simple and health literate around the changes expect a public outcry especially from the 19-23 women aged less than 25 yrs (2008-1013) in NZ , their families and friends and indeed communities-who have had insitu ca diagnosed and treated appropriately in NZ. They will not be swayed by statistics. 3- Has there been consideration by NZ Ministry of Health, in leading the way in future research, by waiting further 5 years before implementing the age change, so NZ has reliable data to relate to HPV vaccination after implementing NEW HPV Primary testing. i.e ease into the changes. 4- The Ministry needs to be transparent in the information about not screening younger women, particularly when it is already offered, in advising "...this reflects the natural tension when considering an individual patient versus the broader public health approach to minimising cancer risk ,when the overall harms and costs of a population wide intervention may become disproportionately high (Castle et al,2015)...and that cervical cytology screening is ineffective at preventing cervical cancer in women aged 20-14 years on a population basis. https://www.nsu.govt.nz/system/files/evidence-supportion-stop-cervical-screening-women-aged-20-24-sept16.docx 5- Need better health literate information from NCSP that HPV vaccination as better protection against invasive cancer than screening in this age group- "on best available evidence".
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6- Please also ensure clinicians and the public are well advised in regards of the abnormal vaginal symptoms (post coital bleeding, irregular bleeding, heavy vaginal bleeding, pain, mass) that should require a GP visit under the age of 25 to at least ensure in some small way this age group are **given individual** opportunity to prevent as much as possible not to become a cervical cancer mortality statistic.

How can I be sure my submission has been read?

How will I know when the submissions have been published on the Ministry's website?

I have just realised my 2nd submission was on last years 2015 submission form –which I imagine will not be taken into consideration so have elected to resubmit my original submission with the added comments made on the wrong form.

Further to my previous submission I would like to highlight the concerns of a 5 yr vs 3 yr (after x2 annual HrHPV not detected in women with previous CIN2/3 history-? Am I correct in saying it appears the 2 year clearance is also not in the future guideline)...I have experienced already x1 annual not detected only the 2nd annual (test of cure) to return a HrHPV detected result. Awareness of the nature of viruses that can reoccur without reintroduction brings concern in regard the 5 year recall of these women.

Need good education to providers and the public around the high risk groups ie those with low immunity states-and these women should be on 3 yr recall (after x2 annual HrHPV not detected results) vs 5 yr recall especially those with a CIN2/3 history

Perhaps self sampling could be implemented for the 20-14 year olds and any HrHPV 16/18 be followed up. Any HrHPV detected not 16/18 advised to have smear in 1 year's time. Then review the process through research to transition to changing screening recommendations. NZ is known to be the first to do many things perhaps this would be another proactive approach.

Phone contact recall appears to be the most effective recall method and team approach to recall with NCSP and Primary Care working together. Perhaps NCSP could look into phone contact recall and appt making by phone contact recalls then advising the practice who can then contact the woman and arrange an appointment. This would yield more appointments than an overdue letter. This would also help with time management for practice recall

Thank you for this opportunity to submit and the timeframe given in which to attend this submission.

Rebecca Lucas-Roxburgh	Massey University	Although general sexual health is outside the scope of the screening program's role, STI's, in particular Herpes simplex and <i>Trichomonas vaginalis</i> can be detected in a cervical smear. Although confirmation through other testing is normally required the detection in a cervical smear may be the first time these are picked up, and will lead to a confirmed diagnosis. Many women get a sexual health check-up at the same time as their cervical smear. As the age is increased to 25 it is possible some women will delay getting these check-ups. This benefit of LBC testing could possibly warrant a co-test being performed as part of a woman's first test at 25.																				
Respondent's name redacted at request.	Member of the public	<p>In my opinion the NCSP must update the information provided to women about the screening programme. This must include the harms of screening as well as the benefits. Without such information women are not able to give informed consent. Reading these guidelines it is clear to me that you avoid giving relevant statistical information, even to Health Professionals. Women should be told the true incidence and mortality rates for cervical cancer in New Zealand and those statistics appropriately framed. The harms of over diagnosis and over treatment are significant and must also be explained. Treatment to the cervix can result in obstetric complications. Many women who have been coerced into taking part in the screening programme have absolutely no idea about this. For an individual woman the benefit of taking part in the screening programme is small but the risk of over diagnosis is significant.</p> <p>The following table, taken from the BMJ, gives a clear visual indication of the chance of a woman surviving for 10 years if she does - or doesn't - have her routine Pap smears. It is apparent that to an individual woman the absolute benefit of having a Pap smear is small.</p> <table border="1"> <thead> <tr> <th>Age at start of 10 year period</th> <th>No of women alive at start of 10 year period</th> <th>Alive 10 years later if they attend NHSCSP</th> <th>Alive 10 years later if they do not attend NHSCSP</th> </tr> </thead> <tbody> <tr> <td>25</td> <td>10,000</td> <td>9963</td> <td>9962</td> </tr> <tr> <td>35</td> <td>10,000</td> <td>9863</td> <td>9859</td> </tr> <tr> <td>45</td> <td>10,000</td> <td>9713</td> <td>9708</td> </tr> <tr> <td>55</td> <td>10,000</td> <td>9457</td> <td>9450</td> </tr> </tbody> </table> <p>Table 1 - the benefit gained by women attending the NHS cervical cancer-screening programme [BMJ, 03 July 2000, Andrew Rouse, Senior Lecturer, Dept of Public Health, Birmingham University]</p> <p>All women need to know that any form of screening is a choice and women can choose to decline. It is not acceptable to be bombarded with letters or opportunistically pushed to have a smear test when visiting a health provider. Maori, Asian and Pacific women will be particularly vulnerable in the consultation room as they are to be heavily targeted. The new dumbed down consumer website, courtesy of advertising agency FCB, is set to "remove some of the barriers</p>	Age at start of 10 year period	No of women alive at start of 10 year period	Alive 10 years later if they attend NHSCSP	Alive 10 years later if they do not attend NHSCSP	25	10,000	9963	9962	35	10,000	9863	9859	45	10,000	9713	9708	55	10,000	9457	9450
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women have to screening" [Screening Matters March 2016]. Will this new website minimise the harms of screening to promote uptake and increase coverage? Any sensible woman would look to the NSU website and read the information for health professionals provided there.

In my view, self HPV testing must be introduced as soon as possible. This would be a much more acceptable screening tool than the invasive speculum for most women. There would be particular benefits for older women and any woman who chooses to accept an offer to screen but finds the speculum overly intrusive.

Home-testing for HPV, due to be introduced in the Netherlands next year, is a "surprisingly good idea", explains Peter Sasieni, a leading expert in cancer screening at the Wolfson Institute in London, since HPV is the first step in the development of cervical cancer. "It would involve women taking a simple vaginal swab and sending it off for tests," he says. Women found to be negative for HPV – which would be most of those over 50 – would not need the conventional smear test.

"A self-sampling kit would be convenient, less embarrassing, less intrusive, quicker and studies have shown it is very accurate at identifying HPV," says Mr Sasieni. "It is an efficient way of discriminating between women who need further tests and those who can safely be left alone." [The Telegraph 22nd June 2015].

Dr Karen Bartholomew, chair of the Metro Auckland Cervical Screening Advisory Group, lectured on HPV self testing in June 2015, see

http://nationalwomenshealth.adhb.govt.nz/Portals/0/Cervical%20Screening/HPV%20Self%20testing_Karen%20Bartholomew_June%202015.pdf

Summary

- HPV self-sampling is an acceptable alternative for never screened and underscreened women
- At least as accurate as cytology, slightly less sensitive than 'physician collected' sample (as sensitive if using new PCR tests)
 - PCR based tests most sensitive and preferred for self-sampling in a population
 - PCR test with partial genotyping allows triage of positive women for follow-up
- Ensuring follow up is critical
- Cost-effectiveness needs to be determined in Australian and NZ setting – but this approach is primarily about equity
- Still need to do quite a bit of pre-work including cultural and ethical discussions, discussions with communities of interest and consumers

Finally, I do applaud the NCSP for standing firm against pressure from women's health groups and Cytopathologists pushing the introduction of co-testing. Co-testing would lead to even more over diagnosis and over treatment for women. The primary HPV test must stand alone.

I also think the NCSP has done the decent thing by making it possible to opt off the screening register. The NHS are only now giving information on how to withdraw from screening in the UK.

Thank you for allowing feedback on the proposed Guidelines for Cervical Screening.

CWH & CHL - Refer Section 1	Collaborative feedback CWH and CHL	We have significant reservations about the decision to not screen women in the 20-25 age group, given our currently relatively low HPV vaccination rates. Some of us are opposed to the decision to not screen women under 25. In this age-group we do see invasive cancers, a significant proportion of whom have had microinvasive disease which was picked up on smears. This should be seen as a success of screening rather than a failure of the screening programme.
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	<p>With current HPV vaccination rates, we do not know how much the untreated high grade lesions, particularly CIN3, in young women will affect the increase in cervical cancer rates in women under 30. Our view is that stopping screening in women under 25 is a currently unquantified risk.</p> <p>We also have reservations about how the NCSP proposes to ensure high levels of uptake of cervical screening at 25, as this will be a particularly crucial age-group in which to get early, high recruitment rates for primary HPV screening, in order to minimise the numbers of unnecessary cervical cancers.</p> <p>With regard to such crucial decisions, we do not want to rely on high nationwide HPV vaccination rates in NZ until we achieve them.</p> <p>Everyone acknowledges that the success of the proposed HPV primary screening program is crucially linked to a successful nationwide HPV vaccination campaign. Therefore, messaging the right populations in a targeted fashion in relationship to vaccination is critical. The NCSP and HPV vaccination program need a strong integrated approach. The approach to vaccination needs to be a nationally consistent and based on methods that successful regions have ensured that vaccination targets are met. Education and health literacy in relation to HPV vaccination and screening go hand in hand.</p> <p>In the under 25 group, we recommend the consideration of a more holistic view of women's health in relationship to sexually transmitted infectious diseases. This would truly reflect the spirit of Hauora - taha tinana (physical wellbeing), taha hinengaro (mental and emotional wellbeing), taha whanau (social wellbeing), and taha wairua (spiritual wellbeing).</p> <p>For sustainable delivery of colposcopy and laboratory services sustained volumes and staffing are important for success. Teaching and education programs are needed to support workforces to ensure a successful and sustainable integrated services.</p> <p>The Laboratory Information System changes to support the NCSP Register can be costly and time-consuming and advanced planning is essential for seamless introduction.</p> <p>Access to data for regional and local decision making is important for good management.</p>
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Pam Hewlett, Lucina Kaukau & Jane Grant	Auckland & Waitemata DHBs	<p>Suggest an introducing statement about who the guidelines apply to for example: Asymptomatic women aged 25 to 74 years</p> <p>Suggest that a separate section is created that includes recommendations for special circumstances</p> <ul style="list-style-type: none"> - Investigation of abnormal bleeding - HPV testing for women over 75 - HPV testing for immune deficient women under 25 - HPV testing for women who have experienced early sexual intercourse - Co-testing for women who have had glandular abnormalities <p>Suggest a section for guidance on HPV testing for gender variant people.</p> <p>Suggest a section of recommendations for overseas HPV tests – we would like clarity on the issue of overseas HPV tests being added to the NCSP register, is that possible?</p> <p>Suggest some clear guidelines for nurse sample takers around requesting HPV and cytology for symptomatic women and subsequent referral.</p> <p>We would like to thank the group that worked on these guidelines, they represent positive changes for both New Zealand women and those working along the screening pathway.</p>
Sharon Mercer, Manager	NCSP Register Central Team	<p>The feedback is that they are very comprehensive and clear. A huge amount of work has obviously gone into them. We particularly liked the way that the Hysterectomy Guidance is much clearer than it was, along with management of Immunosuppressed women.</p> <p>Page 50, Paragraph 9.4 there is a tiny typo (repeated the word evidence), and should perhaps read ‘Evidence is insufficient to support....’</p> <p>Lastly, the flow charts used in the document could possibly be clearer and larger font as many clinicians will be printing this off rather than viewing online I expect. In the draft the quality of the font and size makes it pretty hard on the eyes!</p>
Drs Jay Sirisena, Anand Gangi, Jenny	Northland Colposcopy Services	Congratulations on a very thorough document.

Blasingame, Kristy Wolff, Donna Hardie		
Dr Gillian Gibson	RANZCOG	<p>RANZCOG fully supports the change to primary HPV screening for cervical cancer as this is based on international evidence as well as NZ modelling. More cancers will be prevented >15% and women will require fewer screening tests without compromising safety.</p> <p>The importance of primary prevention with HPV vaccination is key and an effective vaccination programme underpins the NCSP.</p>
Annette Davis	Hawkes Bay DHB	<p>The guidelines is very detailed it will be important to ensure that the flow charts are clear and easily readable. Its essential that sections are kept separate. This document is an important resource to clinicians and due to the detail that is in this draft version it could deter clinicians from getting familiar with the changes, if the document is not layed out in a manner that makes reading easy, and information is obtained efficiently.</p>
Dr Stephen Child, NZMA Chair	NZMA	<p>General comments</p> <p>We welcome the development of updated guidelines for cervical screening. We note this follows the decision to move to primary testing for human papilloma virus (HPV). While the NZMA is fully supportive of primary HPV testing in the screening pathway to prevent cervical cancer, we are very disappointed that we have not received responses to our requests for further information, particularly in relation to the extension of the age of first screening to 25 years.¹</p> <p>The provision of our feedback, in response to calls for sector feedback, is intended to assist policy development and is provided in good faith. We are concerned, therefore, that the failure to respond to requests for further information as part of this process diminishes the perceived value in participating in consultation and our confidence in the quality of the Ministry's decision making. We strongly believe there is a need to close the feedback loop in order to encourage and support ongoing sector engagement and ensure the Ministry is aligned with recognised good practice. For example, formal responses to questions arising from review are provided as part of the standard process of guideline development by the European Society of Cardiology – a copy of the standard operating procedures for the review process of guidelines is attached for your information.²</p> <p>We recommend that the Ministry adopt a policy for responding to questions raised during consultation, and we ask that the Ministry take immediate steps to establish this.</p> <p>Acknowledgements</p> <p>We suggest that the Acknowledgements section list the names of individuals involved in the development of the guidelines rather than merely refer to 'members of the New Zealand guidelines development group'.</p>

Introduction

We note that the intended audience of the guidelines is ‘those involved in caring for women along the cervical screening pathway’. The document appears, however, to be written largely for medical specialists. We submit that the guidelines as they stand are too long to be practically useful for GPs. We suggest the development and addition of a short summary guideline for GPs.

The ‘background’ section is light on data. We suggest it be expanded to include the numbers of new cases of cervical cancer before and after the introduction of the screening programme in 1990. A bar graph showing this information would be informative. We also suggest the addition of data for cervical cancer deaths, as well as screening and incidence rates in Māori, Pacific and Asian women.

We note that paragraph 15 states that “the decision to change the screening start age to 25 years is outside the scope of this consultation”. We reiterate our disappointment that we have not received responses to our requests for further information in relation to the extension of the age of first screening. Many GPs in New Zealand report seeing young women (eg, at 17 or 18 years of age) with CIN grades I, II and III. We would appreciate being apprised of research commissioned by the NSU on raising the starting age for screening. In the meantime, we note that guidelines are simply guidelines; they do not prevent clinicians deciding to test high-risk patients.

With respect to the section about ongoing and future research, we submit that there should be a planned assessment of the effects of the new screening programme. This should prospectively define both agreed key performance indicators and timeframes. The evaluation should also compare the effects of outcomes pre- and post-introduction of the new screening programme.

Figures

Many of the figures are not clear when the updated guideline is printed out. The font size is also too small, particularly for figures 2, 3, 4 and 6, where the text is extremely difficult to read.

We hope that our feedback has been helpful and look forward to learning the outcome of this consultation.

References

¹ NZMA submission on National Cervical Screening Programme: Changing the primary laboratory test. Paragraphs 4-5: 20 October 2015. Available from https://www.nzma.org.nz/_data/assets/pdf_file/0019/45325/sub-National-Cervical-Screening-Programme_Changing-the-primary-laboratory-test.pdf

		<p>² Standard operating procedures for the review process of guidelines. European Society of Cardiology. Paragraphs 9-10. A member of the NZMA Board / Specialist Council is Co-chairperson of the Taskforce for the of European Society of Cardiology Universal Definition of Myocardial Infarction, and is heavily involved with guideline development.</p>
Rae Duff, Ailsa Stewart	National Council of Women, NZ	<p>We support and applaud the Guideline focus being on accessibility, improvement of services, technologies and treatments. The programme strives to encourage women to be immunised and screened, supporting women who need further testing, treatments and follow up.</p> <p><i>Introduction Para 10 (p2)</i></p> <p><u>Key changes:</u></p> <ul style="list-style-type: none"> • Raising the age from 20 to 25 coincides with the age of the young women who have already received HPV immunisation and based on the testing and information collated. We believe this is an appropriate change. • We do not agree with the screening interval being extended from 3 to 5 years. We consider this time frame is too long and would prefer the screening interval to remain at 3 years. • We support the change from LBC to HPV for the primary screening test, as it appears anomalies are picked up more accurately. • We agree that the pathway for genotyping improves testing results and referral for colposcopy for women with hrHPV(16/18) results. <p><i>Introduction Para 13 (p2)</i></p> <p>Alongside the HPV programme, there also needs to be an education programme setting out the dangers of unprotected sex and the many possible consequences.</p> <p><i>Introduction Para 14 (p2)</i></p> <p>NCWNZ views the proposed option for self- sampling as a forward step towards an equitable outcome for all women. There is a diverse group of women, including those with disabilities, rural women and women whose cultural/religious beliefs discourage them from taking part in the current programme, who may be willing to self-sample if the option is available to them. We are very pleased to note that new data on self-sampling will continue to be assessed throughout the project.</p> <p><i>Other comments</i></p>

		<p>We applaud the research, evaluation, developments and actions that have been set out within the Clinical Guidelines for Cervical Screening in New Zealand and commend the thoroughness of the National Cervical Screening Programme.</p> <p>The reviewed and revised Guidelines demonstrate a determination for improving services, of providing best practice and for ensuring accessibility for all the women of New Zealand.</p> <p>Adequate, ongoing funding and support for the programme must be guaranteed, to ensure the implementation of the Guidelines and to ensure that all steps taken to improve the Cervical Screening services are implemented and provided for all population groups. Ensuring gender equity for all ethnicities throughout our country is imperative.</p> <p>On behalf of the National Council of Women Health Standing Committee we wish to thank you for the opportunity to submit feedback on the Clinical Guidelines for Cervical Screening in New Zealand and look forward to seeing them implemented.</p>
Leanne Manson, Policy Analyst Māori	On behalf of NZNO (endorsed by The College of Nurses Aotearoa Inc)	<p>In principle, we support the intent of a national standard and guidelines to improve the health and wellbeing of women's health in Aotearoa.</p> <p>We acknowledge that currently, Aotearoa continues to have low uptake of HPV vaccination by young women, with only 50% of those young women who are eligible opting to be vaccinated and young men not being eligible until 1st January 2017.</p> <p>We do wish to raise the following concerns:</p> <ul style="list-style-type: none"> • unintended consequences for the 20-25 year old group; • equity and screening for priority group women (refer Section 1) • clarification of the following queries. <p>Unintended consequences for the 20-25 year old group</p> <p>We believe that the changes to the vaccination schedule will benefit the cervical screening programme in the future only as long as improvements can be made to the coverage for those most at risk and a focus on improving screening and vaccination.</p> <p>We are however extremely concerned that the proposed changes may have unintended consequences for the 20-25 year old group, especially when micro invasion cancers are asymptomatic and only detected by cervical smear and miss some of the younger women who are sexually active and not vaccinated against HPV. The draft document (9) section 11 does not fully address how this group of women will be captured under the proposed schedule, especially when 10% of invasive cancers are found in women under 30 years (Ministry of Health Cancer Registry, 2012). We seek clarification</p>

		<p>on the Ministry's plan to monitor this group of women, especially with the instances of antimicrobial resistance in common sexually transmitted infectious disease (STDs).</p> <p>We recommend that a holistic focus (one that truly reflects the spirit of Hauora – taha tinana, taha hinengaro, taha whānau and taha wairua) of women's health in relationship to STDs in the under 25 group along with education, training and health literacy information on HPV.</p> <p>We strongly advocate for shorter interval (less than 5 years) between smears in this age group to mitigate potential risks.</p> <p>Seek clarification with the following:</p> <ul style="list-style-type: none"> • what are the plans to resource and improve access to screening and reduce inequalities to those women with greatest need; • how do you plan to screen for under 25 where there is early signs of early sexual activity or abuse; • the potential to reduce the number of unnecessary colposcopy's for those women who have a low grade viral infection; • what is the potential to link the immunisation register with the NCSP register to get a good cohort of screening data; • what is the modelling data undertaken for New Zealand based on and how will this fit with the New Zealand population with low vaccination coverage; • what modelling of costs of co-testing have been done? Co-testing would appear to be a sensible approach especially for higher risk women in this transition phase; • what cultural competency training is available to ensure that the workforce is culturally and clinically competent; and • what costs saving are predicted by implementing the increased age of screening and the decreased intervals.
Mary Webster	CHL	<p>The scientific data is impressive and the transition to HPV screening of women is a natural step forward in New Zealand together with offering Gardasil9 vaccination to both girls and boys.</p> <p>I hope the assumptions made in Lew JB et al PLoS ONE 2016 Discussions... "That the optimal strategy for primary HPV screening strategies would be both more effective and cost saving when compared to current screening practice, reducing cervical cancer incidence and mortality in New Zealand by a further 12–16% compared to current levels".</p> <p>All the best.</p>

Lynda Williams	Auckland Women's Health Council	<p>The AWHC objects once again to the NSU constantly referring to the incidence of cervical cancer in a global context which creates the misleading inference that cervical cancer is a big problem in New Zealand. Stating that cervical cancer is the fourth most common cancer for women and that over half a million women worldwide die from cervical cancer each year is exaggerating the facts as they pertain to women in New Zealand. All information provided by the NSU must use NZ data and state the diagnosis and mortality rates in New Zealand.</p> <p>In recent years, the AWHC has also become increasingly concerned about the role that the pharmaceutical industry is playing in pushing its own agenda for cervical screening programmes. We have no doubt that Roche's presence at last year's consultation meetings in Auckland indicated their influence and vested interests in the change to HPV screening.</p>
Lynere Wilson	Rapaki MWWF	<p>We are concerned at an apparent lack of engagement with Māori at the National level for the cervical screening programme. This has been drawn to our attention by two situations;</p> <ul style="list-style-type: none"> • Having been present at your meeting in Christchurch to discuss the scientific evidence for the changes to the screening programme, we were struck by the complete absence of tikanga in the meeting process. You appear to have no Kaumatua to guide you at a National level. We note from the minutes of your Advisory Group meeting that there no apparent representation of Māori at a National level to provide you with assistance in this area. This is very disappointing given your stated aim that the new guidelines will improve equity of access to health services. • This lack of engagement was also evidenced for us by the apparent lack of your presence at our recent National Māori Women's Welfare League Conference as a supporting sponsor. We did note that while there was an organisation there promoting cervical screening, they were about to lose their contract and would not be attending conference in 2017.
Dr Sandra Hall, Policy Analyst	On behalf of the Cartwright Collective	<p>Thank you for this opportunity to provide feedback on the Updated Guidelines for Cervical Screening in New Zealand.</p> <p>As you know, the Cartwright Collective continue to have a number of serious concerns about the move to primary HPV testing. In particular we question, on the basis of insufficient evidence, why we are moving from a programme in the forefront of screening programmes to an untried and untested situation when we could wait for the evidence from the Australian programme.</p>

	<p>We urge you to consider a delay to the introduction of primary HPV screening or to at least consider a period of contesting which by your own admission gives superior results. We also note the publication of the recent Felix study which demonstrates significant projected cost savings using a co testing regime ¹</p> <p>However, we do not feel our continued concern about move to HPV primary screening should prevent us from giving feedback on the updated guidelines. We have made some general comments first and then addressed some of the specific sections.</p> <p>General comments:</p> <p>In general the guidelines appear very focused on the mechanics of testing and the prescribed route of those requiring further investigations and tests. While this is obviously important we think not enough attention has been given to patient interactions, informed consent and allowing for women to make informed decisions about their screening and /or investigation pathway.</p> <p>We believe the sections on management of test results and equity and priority screening should also cover issues such as education and public perception of both the tests and the results and how health practitioners should manage these.</p> <p>In addition the process for informed consent for the changes to HPV testing should be defined. It should also be defined for the process of further screening and investigation. There should also be a process for women who wish to continue with LBC testing.</p> <p>The data management strategies that will be put in place are not described. How women will be informed about the changes to the register and what information will be retained on the register is not described. Nor is managing the possibility that some women may wish to withdraw and not be part of the register which could record a diagnosis of HPV. The document should contain more information about the changes to the register and what this will mean for women including what information will be held.</p>
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¹ Primary HPV Testing vs. Co-testing for Cervical Cancer Screening Outcome and Economic Support that Co-testing is Superior. Juan C. Felix, M.D. Professor of Clinical Pathology and Obstetrics & Gynecology Keck School of Medicine of USC
Los Angeles, CA.

		<p>We are particularly concerned about monitoring of the move to HPV primary testing as any issues with a new programme would need to be identified early and openly discussed. It appears the current data analysis driving the program monitoring is contracted to the same group who designed the HPV modelling that drove the decision to use HPV screening in NZ. We believe the Independent Monitoring Group needs to be independent and not composed of the proponents of the new programme. It should also be independent of any industry links. The guidelines should include information about how the composition of the monitoring and evaluation group will be determined, what consumer representation will be included and how unscreened and under screened groups be represented /included? Finally the guidelines should include a description of who will administer the screening register and how informed consent, data monitoring, auditing and confidentiality issue be dealt with.</p>
Dr Debra Graves, CEO	RCPA Australasia	<p>Thank you for asking the Royal College of Pathologists of Australasia (the College) to consider the above guidelines.</p> <p>With regard to the following question in particular, Section 1. Equity and screening for priority group women - 1a. What do you think about this group of recommendations? – Refer Equity section above.</p> <p>The remaining recommendations seem very clinically orientated.</p> <p>With regard to the histopathology (and cytopathology) The College presumes there are other documents and standards that address in greater detail the pre-test, test and post test quality issues, the laboratory standards (IANZ accreditation), diagnostic criteria and pathologist credentialing.</p> <p>One further comment is the lack of evidence based recommendations. There are plenty of practice points and consensus based recommendations. Does this reflect on the quality of data that has been collected over the many years of the screening programme or the poor state of academia with little time available for critical analysis of the cervical screening data collected to date?</p>