Dear All

As you may be aware, the National Cervical Screening Program Renewal (‘the Renewal’) is underway to ensure that all Australian women continue to have access to a screening program that is based on current evidence and that is safe, acceptable, effective, efficient.

The first phase of the Renewal is being undertaken through the Medical Services Advisory Committee (MSAC) process for reviewing the evidence for the safety, effectiveness and cost-effectiveness of new medical technologies and procedures. It will inform policy, including cervical cancer tests and screening pathways.

The draft Review of Evidence is now available for public comment on the Department of Health and Ageing’s website (www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/ncs-p-renewal). A summary of the review is attached to this letter and provides an overview of the key findings.

The NHMRC Clinical Trials Centre, University of Sydney has been engaged to undertake the review in line with the Decision Analytic Protocol (DAP)\(^1\). The aim of this review is to enable MSAC to make an informed assessment of the evidence. A separate report will model the comparative effectiveness and cost-effectiveness of the screening pathways outlined in the DAP. The Lowy Cancer Research Centre at UNSW has been engaged to undertake the effectiveness and cost-effectiveness modelling.

The release of this draft Review of Evidence for public consultation is not an MSAC requirement, but the Renewal Steering Committee is genuinely interested in seeking input from stakeholders. Specifically, we are seeking feedback to assist with identifying any additional substantive literature that has not been identified in the draft review document, prior to the evidence being considered by MSAC.

If you have feedback on the draft Review of Evidence, please provide it on the attached form to the Renewal Secretariat (CervicalRenewal@health.gov.au) by Friday, 28 June 2013.


Please contact the Renewal Secretariat at CervicalRenewal@health.gov.au if you have any queries or wish to sign up to receive regular email updates on the Renewal.

Yours sincerely

[Signature]

Professor Ian Hammond
Chair, Renewal Steering Committee
June 2013

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\(^1\) A copy of the Decision Analytic Protocol is available on the MSAC website (www.msac.gov.au/internet/msac/publishing.nsf/Content/FD36D6990FFAA639CA25799200058940/$File/1276-NCSP-FinalDAP.pdf)
Background
In Australia there are two programs designed to prevent cervical cancer, the National Cervical Screening Program (NCSP) and the National Human Papilloma Virus Vaccination Program (NHPVVP). The NCSP was introduced in 1991, and since then the incidence and mortality of cervical cancer among Australian women has halved.

Since the introduction of the NCSP there have been significant developments in the science and understanding of the causes of cervical cancer including; the development of a vaccine for HPV; new technologies; and new international and local evidence for cervical cancer prevention and screening.

In 2007, Australia was the first country to implement a fully funded national HPV vaccination program, directed at preventing up to 70% of cervical cancers.

The National Cervical Screening Program Renewal (‘the Renewal’) is underway to ensure that all Australian women continue to have access to a screening program that is based on current evidence and that is safe, acceptable, effective, efficient.

Most of the evidence in this review relates to population groups who have not been vaccinated for HPV. Data integration and modelling will be undertaken to apply this evidence to Australian context where the national HPV vaccination program has been in place for six years.

This MSAC Review of Evidence summarises the assessment of current evidence for screening tests and pathways; and the screening interval, age range and commencement, for both vaccinated and non-vaccinated women. A separate report will address the comparative effectiveness and cost-effectiveness of cervical screening in the Australian context.

Approach to assessment
The Decision Analytic Protocol (DAP) proposes the examination of the safety, effectiveness and cost-effectiveness of following three pathways:
1. Conventional cytology (that is, Pap smear), using the International Agency for Research on Cancer (IARC) recommendations for age range and interval\(^2\).
2. Liquid Based Cytology (LBC), using the IARC recommendations for age range and interval for cytology.
3. HPV testing for women aged 25 to 65 years undergoing screening every five years.

The conventional cytology (Pap smear), LBC and HPV tests all involve the same technique of taking a sample of cells from the cervix. The differences relate to how the cervical samples are prepared in the laboratory and the tests conducted.

Safety
The Review of Evidence notes that conventional cytology (Pap smear), LBC and HPV testing are considered safe procedures.

\(^2\) IARC recommendation: cervical screening should cover women aged 25 to 65; and women should undergo screening once every three years up to the age 49, and every five years thereafter.
Effectiveness – Conventional Cytology (Pap smear) using IARC recommendations for age range and interval

The Review of Evidence notes that:
- Cervical cancer is very rare below the age of 25 years.
- HPV vaccination is anticipated to almost eliminate the risk of cervical cancer in young women.
- There are limited comparative data on the age at which to start and stop screening.
- The majority of cervical cancer cases in women aged 65 and over are in women who do not have a history of negative Pap smear results.
- Extending the screening interval from 2 to 3 years is unlikely to substantially alter cervical cancer incidence or mortality rates.

Effectiveness – LBC

The Review of Evidence supports conclusions previously made by MSAC, that is:
- LBC provides no statistically significant difference in the ability to detect high grade cervical abnormalities or to exclude women without high grade cervical abnormalities compared to conventional cytology (Pap smear).
- LBC reduces the rate of unsatisfactory smears in comparison with conventional cytology (Pap smear).
- Automation-assisted image analysis detects as many high grade lesions as conventional cytology (Pap smear), and may detect more.

Effectiveness – HPV testing

The Review of Evidence notes that:
- HPV based screening strategies detect at least as many high grade cervical abnormalities as cytology based screening strategies.
- HPV testing alone (without triage) for primary screening increases that number of women that are referred to colposcopy for further investigation.
- Among unvaccinated women, the balance between increased detection of precancerous cervical lesions and increased colposcopy referral for HPV testing alone is more favourable in women over 30 years.
- HPV and cytology co-testing does not demonstrate a clear advantage over HPV testing alone.
- The accuracy of HPV self-collection varies for different types of sampling devices and HPV tests. However HPV self-collection has a moderate to high ability to detect high-grade cervical abnormalities and comparably high ability to to exclude women without high-grade abnormalities compared to clinic HPV testing. Most importantly, HPV self-sampling increases screening participation rate for women who do not attend for cervical screening or who are under-screened and warrants consideration for women in these groups.

Cost-effectiveness

A separate report will model the cost-effectiveness of the proposed cervical screening pathways in the Australian context. The cost-effectiveness report will not be finalised until the Review of Evidence (safety and effectiveness), has been completed.
Renewal of the National Cervical Screening Program

Public Consultation: Feedback Form for the draft Review of Evidence

Please note: This is a draft report. It has not been subject to editing and is considered a work in progress. Minor editorial and data reporting errors will be rectified as the report is finalised. The purpose of the public consultation is to determine whether any significant literature has been omitted from the report.

If you wish to provide feedback on the draft Review of Evidence please complete and return this Feedback Form to the Renewal Secretariat by Friday 28 June 2013.

Renewal Secretariat
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CervicalRenewal@health.gov.au

Name:
Position:
Organisation:
Email:

Please note that all feedback will be provided to, and considered by, the Renewal Steering Committee, the Department of Health and Ageing, the NHMRC Clinical Trials Centre and the Lowy Cancer Research Centre.

1. Additional Evidence

Please list below under the relevant primary question any additional literature. Relevant studies are systematic reviews, health technology assessments or primary studies [original reports] addressing the research questions published from 2010 onwards.

Primary Question 1 – Additional Evidence
What is the comparative safety, effectiveness and cost-effectiveness of conventional cytology, using the International Agency for Research on Cancer (IARC) recommendations for age range and interval, compared with the protocol used in the current Australian cervical screening program?
Primary Question 2 – Additional Evidence
What is the comparative safety, effectiveness and cost-effectiveness of either filtration or cell enrichment liquid based cytology (LBC) (using the IARC recommendations for age range and interval for cytology), compared with the protocol used in the current Australian cervical screening program?

Primary Question 3 – Additional Evidence
What is the comparative safety, effectiveness and cost-effectiveness of HPV DNA testing as the primary screening test in women aged 25 to 65 years every 5 years, compared with the protocol used in the current Australian cervical screening program? (this would include information on partial genotyping HPV tests/stratifying by the highest risk HPV genotypes)

2. Additional Comments
Please provide any additional comments on the evidence in the draft Review of Evidence below.

Thank you for providing feedback.

Responses can be forwarded to the Renewal Secretariat via Email – CervicalRenewal@health.gov.au or by mail to MDP 702, GPO Box 9848, CANBERRA ACT 2601.