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## Self-sampling HPV testing versus mainstream cervical screening and HPV testing

comprehensive review of Australia's National Cervical Screening Program (NCSP), the Renewal, has been undertaken over the past few years.<sup>1</sup> This review recommended a number of changes, including that human papillomavirus (HPV) testing replace conventional cytology (ie, Pap tests) as the primary screening test, with 5-yearly screening commencing at age 25. The proposals have been endorsed by the Medical Services Advisory Committee (MSAC).<sup>2</sup>

The Renewal deliberations also considered the question of the recruitment of women who had never been screened or who were underscreened, a significant concern because it has been estimated that 80% of cervical cancers are diagnosed in these women.1 One proposed solution is to offer a separate self-sampling HPV testing pathway, as studies, both in Australia<sup>3</sup> and internationally,4 have shown self-sampling to increase recruitment and to be advantageous in underscreened women. The Renewal proposal is that the self-sampling option be organised by a clinician who also offers routine screening. It would be offered to women who have not been screened during the previous 6 years, or who have never been screened and have declined to participate in the mainstream screening pathway. The sample would be taken by the patient, possibly in the clinic, and sent to the laboratory for testing. If the sample is positive for HPV, the patient would be asked to return to give a cytology sample.

This edition of the *MJA* includes the report on a study by Smith and colleagues that compared the benefits of self-sampling HPV testing with the mainstream screening program.<sup>5</sup> One consideration for the NCSP was that offering two different screening options might cause confusion. Some women who normally undergo screening may even prefer the self-sampling option. Smith and colleagues, using a dynamic modelling approach, clearly established that self-sampling is associated with a lower risk of a cervical cancer diagnosis than not being screened. However, it also found that HPV testing as part of the recommended mainstream screening program has clear advantages over the self-sampling pathway, and that women should avail themselves of this option.

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The importance of education and communication is well illustrated by the self-sampling question. Self-sampling has already received quite significant publicity in mainstream media; however, there appear to be many misconceptions. Many of the reports, for example, imply that self-sampling was the only significant change recommended and that it is significantly beneficial. Headlines such as "Australian women will be able to do their own Pap smear"<sup>6</sup> and "You could soon be doing your own Pap smear<sup>77</sup> have appeared online. Such comments are confusing and misleading for both the general public and the medical profession. The study by Smith and colleagues is therefore important, as it clearly establishes that there are two different testing pathways to be preferred under different circumstances.

This difference in the two pathways also highlights how the test result can be affected by the nature of the sample and the type of HPV testing. At the last count, more than 500 different types of HPV testing are available worldwide. The technology of HPV testing is complex and variable, and, until the commencement of the new program, will have predominantly been used as a diagnostic rather than a screening test. Validated assays that assure high quality screening must be used. A recent article suggested that only HPV tests that have been subjected to large randomised trials with a long cohort follow-up be used.<sup>8</sup> The Netherlands has recently introduced HPV self-sampling as the primary screening test, but, unlike Australia, has designated one specific type of high risk HPV assay for use.<sup>9</sup>

The Australian Renewal recommends that any type of HPV test can be used, but that the test must meet certain quality criteria. The study by Smith and colleagues points out that, although self-sampling has been shown to be beneficial, it is dependent on the nature of the HPV assay. Specific quality standards for self-sampling HPV testing will need to be set. The National Pathology Accreditation Advisory Council (NPAAC) is in the process of setting quality parameters for HPV testing and will consider the criteria for the two pathways.<sup>10</sup> Laboratories will be left to choose which type of HPV test they perform, but the testing will have to fulfil the quality standards mandated by NPAAC.

The proposed changes to cervical screening are major and will need accurate and concise information to be distributed to both sample takers and women. The message from Smith and her colleagues is quite clear: self-sampling offers an alternative pathway for women who will not participate in routine screening, but it is significantly less beneficial than mainstream cervical screening. For both screening pathways, the quality of the HPV assay will be crucial to the success of the program and the safety of women.

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References are available online at www.mja.com.au.

- Australian Government, Department of Health. Renewal of the National Cancer Screening Program [website]. http:// www.cancerscreening.gov.au/internet/screening/publishing. nsf/content/renewal-ncsp-pres (accessed Jan 2016).
- 2 Australian Government, Medical Services Advisory Committee. MSAC outcomes. Application no. 1276 – Renewal of the National Cervical Screening Program [public summary document]. 2014. http://www.msac.gov.au/internet/msac/ publishing.nsf/Content/FD36D6990FFAA639CA25799200 058940/\$File/1276%20-%20Final%20MSAC%20PSD%20 -%20NCSP%20Renewal.pdf (accessed Jan 2016).
- **3** Sultana F, English DR, Simpson JA, et al. Rationale and design of the iPap trial: a randomized controlled trial of home-based HPV self-sampling for improving participation in cervical screening by never- and under-screened women in Australia. *BMC Cancer* 2014; 14: 207.
- 4 Arbyn M, Castle PE. Offering self-sampling kits for HPV testing to reach women who do not attend in the regular cervical cancer screening program. *Cancer Epidemiol Biomarkers Prev* 2015; 24: 769-772.
- 5 Smith M, Lew JB, Simms K, Canfell K. Predicted impact of integrating self-sampling testing into the Australian HPV screening program. *Med J Aust* 2016; 204: 194.el-194.e9.
- Australian women will be able to do their own Pap smears. Mamamia News 2015; 14 Oct. http://www.mamamia.com.au/ news/diy-pap-smear/ (accessed Jan 2016).
- 7 Nogrady B. You could soon be doing your own Pap smear. The Glow [website] 2015; 1 Mar. http://www.theglow.com. au/health/you-could-soon-be-doing-your-own-pap-smear/ (accessed Jan 2016).
- 8 Arbyn M, Snijder PJ, Meijer CJL, et al. Which high risk HPV assay fulfil criteria for use in primary cervical cancer screening? *Clin Microbiol Infect* 2015; 21: 817-826.
- 9 Rijksinstituut voor Volksgezondheid en Milieu. Population screening is about to change [Dutch]. 2015. http:// www.rivm.nl/Onderwerpen/B/Bevolkingsonderzoek\_ baarmoederhalskanker/Bevolkingsonderzoek\_gaat\_ veranderen (accessed Jan 2016).
- 10 Australian Government, Department of Health. Renewal of the National Cervical Screening Program. Partner Reference Group e-newsletter — December 2015. http://www.cancerscreening. gov.au/internet/screening/publishing.nsf/Content/52DF58 3BA30DCAD4CA257CED00801847/\$File/E-newsletter%20 December%202014%20%28D14-2854861%29.pdf (accessed Jan 2016).