Human Papillomavirus (HPV) Surveillance Plan – an integrated approach to monitoring the impact of HPV vaccine in Australia

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Prepared by the HPV Surveillance Working Group of the Communicable Diseases Network Australia (CDNA)
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Background

Australia was the first country to implement a fully funded comprehensive national population based human papillomavirus (HPV) vaccination program. The program aims to prevent HPV infection, which if persistent can cause cervical cancer, anal cancer, other anogenital cancers and a subset of head and neck cancers.

In November 2006, the Australian Government announced the National HPV Vaccination Program. Between 2007 and 2009, all females aged 12-26 years were offered vaccination against HPV using a three-dose course of the quadrivalent HPV vaccine (Gardasil®). Delivery occurred through schools and a community based program. The routine program of vaccination for 12-13 year old girls delivered in schools commenced in 2009.

From 2013, the program was extended to include 12-13 year old males through school based programs with a 2-year catch up vaccination program for males aged 14-15 years.

Two HPV vaccines are available in Australia, Gardasil® and Cervarix®. The vaccine used in the National HPV Vaccination Program to date is the CSL/Merck quadrivalent vaccine, Gardasil®, which protects against the two most important oncogenic HPV types, 16 and 18, and two non-oncogenic HPV types, 6 and 11. Types 16 and 18 cause 70% of cervical cancers worldwide, while types 6 and 11 are responsible for over 90% of genital warts.1,2 HPV types 16 and 18, more predominantly type 16, also account for approximately 90% of all HPV-attributable cancers in men.3 The bivalent vaccine, Cervarix®, was listed for use in the National Immunisation Program in October 2008 and it is possible that the vaccine, which protects against types 16 and 18, will have a role in the National HPV Vaccination Program in the future. Current evidence suggests that both vaccines may provide some degree of protection against infection and/or disease with HPV types closely related to types 16 and 18.

Australia has a very effective secondary prevention program for cervical cancer, the National Cervical Screening Program (NCSP). The NCSP provides organised cervical screening through regular (every second year) Pap testing, targeting women aged 20 to 69 years. Papanicolaou (Pap) test screening is effective when used regularly, as it enables the early identification of cytological changes and the treatment of precancerous cervical lesions, before invasive cancer develops. Between the commencement of the NCSP in 1991 and 2008, the incidence of cervical cancer in women of all ages decreased from 13.3 to 7.0 per 100,000 per annum.

HPV vaccination aims to reduce the incidence of HPV infection and in so doing prevent cervical cancer and other HPV related cancers. Vaccination of males will also provide indirect protection for unvaccinated females against sexually transmitted HPV. By preventing HPV transmission, vaccination will also reduce the incidence of high grade dysplastic and, to a lesser extent, low grade dysplastic cervical lesions. A reduction in other HPV related anogenital (and perhaps oropharyngeal) disease is also anticipated. Both available vaccines may result in reductions in other genital cancers (for example, vulval, vaginal and penile cancers), while the use of the quadrivalent vaccine should result in a reduction in genital warts and recurrent respiratory papillomatosis (RRP), both largely caused by HPV types 6 and 11.

As the current HPV vaccines do not protect against all oncogenic HPV types, vaccinated women need to continue to participate in the NCSP for the most effective protection against cervical cancer.
The HPV Surveillance Working Group

The Communicable Diseases Network Australia (CDNA) established the HPV Surveillance Working Group in December 2007 to develop recommendations for a national HPV surveillance program following the introduction of the National HPV Vaccination Program for females under the National Immunisation Program.

In November 2009, CDNA endorsed the HPV Surveillance Plan – an integrated approach to monitoring the impact of HPV vaccination in Australia.

In August 2012, the Working Group reconvened following the Australian Government’s announcement of the extension of the National HPV Vaccination Program to include males.

The Working Group is comprised of experts in disease surveillance, vaccine research, immunisation programs, sexually transmitted infections, virology and cancer screening. The Membership of the Working Party is listed in Appendix A.

Purpose of this document

The aim of the HPV Surveillance Plan is to outline key HPV surveillance objectives and in so doing provide guidance that will assist in monitoring the implementation of the National HPV Vaccination Program and evaluating its impact on circulating HPV types and HPV related disease. This document updates the 2009 HPV Surveillance Plan to include surveillance activities as at 2013 and to reconsider surveillance objectives given the expansion of the program to include males. A summary of changes to the 2009 HPV Surveillance Plan is at Appendix B.

Overview of the document

Each surveillance objective includes the rationale for surveillance; history of surveillance; current surveillance in Australia; and recommended indicators.

A timeline for the surveillance objectives as they may be required post-implementation of the National HPV Vaccination Program is at Appendix C.

Further work will be undertaken to develop an agreed process for reporting against the surveillance objective recommended indicators. A summary of the indicators and availability of data for reporting is at Appendix D.
Surveillance objectives

1. **Program monitoring**
   1.1. Monitor HPV vaccine safety
   1.2. Assess age-specific HPV vaccination coverage achieved in the ongoing 12-13 year old program and the catch up program
   1.3. Monitor the uptake of cervical screening in the eligible population
   1.4. Monitor knowledge, attitudes and beliefs about HPV, HPV vaccination and cervical cytology screening

2. **Infection monitoring**
   2.1. Monitor the prevalence of HPV genotypes in the general female population
   2.2. Monitor the prevalence of HPV genotypes in the general male population

3. **Non-cancer disease endpoints**
   3.1. Monitor the incidence of genital warts
   3.2. Monitor the incidence of recurrent respiratory papillomatosis
   3.3. Monitor the prevalence of screen-detected cervical abnormalities
   3.4. Monitor the distribution of HPV genotypes detected in high grade cervical dysplasia lesions

4. **Cancer endpoints**
   4.1. Monitor cervical cancer incidence and mortality
   4.2. Monitor anogenital\(^1\) and oropharyngeal\(^2\) cancer incidence and mortality
   4.3. Monitor the distribution of HPV genotypes detected in cervical cancers.
   4.4. Monitor the distribution of HPV genotypes detected in anogenital\(^1\) and oropharyngeal\(^2\) cancers

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\(^1\)Includes anal, penile, vulval and vaginal cancers.
\(^2\) Includes base of the tongue and HPV related head and neck cancers.
1. Program monitoring

1.1. Monitor vaccine safety

**Recommended indicators**

- HPV vaccine related adverse events are routinely analysed and published in a timely manner, including rates derived from denominator data collected by the National HPV Vaccination Program Register and analysis by sex.

**Rationale for surveillance**

Vaccination has been repeatedly demonstrated to be one of the most effective interventions to prevent disease worldwide. Immunisation is a simple, safe and effective way of protecting people against harmful diseases before they come into contact with them in the community. The benefit of protection against the disease far outweighs the very small risks of immunisation. It should be acknowledged that there are always some risks associated with the use of any medicine or vaccine, and the decision to approve the use of medicines or vaccines in Australia is based on a positive benefits and risks balance. Serious reactions to vaccinations are rare.

While vaccine safety is investigated during pre-licensure clinical trials, these studies are insufficiently powered to detect rarer adverse events following immunisation (AEFI) (occurring at a frequency less than 1 in 10,000 vaccinees) and are unable to detect late-onset events.

It is important to closely monitor AEFIs after the introduction of new vaccines into population based immunisation programs. It is of particular importance to monitor the safety profile of the HPV vaccine as it is both a relatively new vaccine and is given in an older population group than most childhood vaccines, where a different range of coincidental events may be experienced.

**History of surveillance**

The Therapeutic Goods Administration (TGA) has regulatory responsibility for ensuring that vaccines and medicines continue to have an acceptable safety profile once they are registered for use in Australia. The TGA operates the Adverse Drug Reaction Reporting System (ADRS), which is the passive surveillance system to which reports of adverse reactions to both medicines and vaccines are submitted. AEFI are notified to the TGA via different routes. In most jurisdictions (except Tasmania), AEFI should be reported directly to the relevant state or territory health authority who then forward all reports to the TGA. Reports are also provided directly to the TGA by vaccine sponsors, health professionals and consumers. Each year, data on rates and patterns of AEFI reported to the TGA are published by the National Centre for Immunisation Research and Surveillance (NCIRS) in conjunction with the TGA. During the first year of the National HPV Vaccination Program, reporting to the ADRS showed some clustering of adverse events, however, there have been no confirmed safety signals associated with the vaccine.4

The need for improved vaccine safety monitoring was identified through the Horvath Review, which reported on the management of adverse events associated with the administration of Panvax® and Fluvax® in children during 2010. The Horvath Review recommended the development of mechanisms for more timely information flows between the TGA and jurisdictions and agreed templates for nationally consistent reporting of AEFI. The TGA has since implemented a number of changes which have resulted in more timely exchanges of information and a minimum dataset has been agreed. The TGA has also established the Advisory Committee on Vaccine Safety, which has a dual role in providing advice to both the TGA and the Office of Health Protection (OHP).

**Current situation**

Since the introduction of the National HPV Vaccination Program in 2007, analysis of the adverse events following HPV vaccination has been reported in the Surveillance of AEFI in Australia annual reports.5 In June 2010, the TGA provided a summary update on its website, listing the most
frequently reported symptoms (headache, injection site reactions, nausea) and results of active safety investigations.6

The TGA updated the information on its website on 16 May 2013 and included a link to the publicly accessible Database of Adverse Events Notifications.7 The Australian and international experience to date has been reassuring with no safety issues identified.8 As at July 2013, over 116 million doses of the quadrivalent HPV vaccine have been distributed worldwide.

To support the extension of the National HPV Vaccination Program to include males, the Department of Health established the HPV Implementation Working Group as a time-limited Working Group of the Australian Technical Advisory Group on Immunisation in October 2012, to consider the need for enhanced monitoring of AEFI with HPV vaccination of males. The Working Group proposed a number of enhancements to the existing surveillance system, many of which have been implemented by the Department of Health. These include:

- communication activities targeted at immunisation providers, the public and media on the safety of the HPV vaccine and the importance of timely reporting of AEFI;
- rapid school based report of four acute significant AEFI following HPV vaccination to the TGA in all jurisdictions (applicable to first dose only);
- a regular teleconference held between members of the TGA, the Office of Health Protection (OHP) and Jurisdictional Immunisation Coordinators (JIC) to discuss HPV AEFI reports during administration of dose one;
- active surveillance of presentations to emergency departments following HPV vaccination (in NSW only);
- development of a Protocol for National HPV Vaccination Program Action and Communication to ensure a nationally consistent program response to a potential or confirmed safety signal after HPV vaccination is given; and
- Adverse Events Following Immunisation – Clinical Assessment Network (AEFI-CAN) HPV Pilot - a pilot project aimed at increasing collaboration and linkage between vaccine safety clinics across Australia to facilitate provision of more standardised information on significant/unexpected HPV AEFI following the expansion of the National HPV Vaccination Program to males.

The TGA has closely monitored the adverse events reported following HPV vaccination since the program was extended to males in February 2013 and no new safety concerns have been identified in males or females.

The Department of Health continues to consider vaccine safety plans to support the introduction of new vaccines, or the extension of an existing vaccine to a new cohort, on the National Immunisation Program. The feasibility of various methods for enhanced vaccine safety monitoring will need to be considered as part of each individual vaccine safety plan. Since July 2013, enhanced surveillance is also occurring through the introduction of monthly AEFI teleconferences between the TGA, OHP and JIC. An agreed core minimum data set for AEFI reporting will be implemented in 2014.
1.2. Assess age-specific HPV vaccination coverage achieved in the ongoing 12-13 year old program and the catch up programs

**Recommended indicators**

- HPV vaccination coverage by dose number and sex for:
  - The ongoing school based cohort (12-13 years).
  - Those turning 15 years of age in the year of report (World Health Organization recommended indicator).
  - The cohorts vaccinated in the female catch up program 2007-2009 (12-26 years).
  - The cohorts vaccinated in the male program 2013-2014 (14-15 years).

- Vaccination coverage by:
  - Indigenous status.
  - Area level socioeconomic status.
  - Remoteness classification of residence.
  - Geographical area:
    - National.
    - State and territory.
    - Smaller areas as determined by state and territory delivery mechanisms (e.g. Local Government Area/council or Health region).
    - By school level for program use (not published).

**Rationale for surveillance**

Vaccination coverage is a key component in evaluating a vaccination program. It indicates how successfully the program delivers the vaccine to the target group(s) and, therefore, whether strategies are required to improve coverage further. It allows identification of groups or areas with lower vaccine uptake, which can assist with targeted immunisation efforts. Regular monitoring of age-specific vaccination coverage allows assessment as to whether the program is actually delivering on its objectives and is a key outcome indicator to account for the large financial investment in the program.

The women predominately at risk of developing cervical cancer are those who do not fully participate in the National Cervical Screening Program and include women who: are Indigenous; are from certain culturally and linguistically diverse groups; live in rural/remote areas; and live in areas of low socioeconomic status, especially those with high population growth. High vaccination coverage in girls who belong to these population groups in particular is required for success, and coverage in these groups should be assessed early, regularly and throughout the life of the program. Men who have sex with men are at a higher risk than other men of developing HPV related cancers, particularly anal cancer with incidence more than 30 times that of other men.\(^3\) When boys vaccinated in the school program reach adulthood, it will be important to measure the coverage achieved amongst men who identify as men who have sex with men.

**History of surveillance**

**National HPV Vaccination Program Register**

The National HPV Vaccination Program Register (NHVPR) was established as part of the vaccination program. Legislation was passed in 2007 and the register commenced operation in mid-2008.

**Current situation**

The NHVPR records details about HPV vaccinations administered in the school based programs (via upload from the state and territory programs) and from general practice and other community providers. During the community based catch up program from 2007 to 2009, the Australian Government paid general practitioners an incentive payment of $6 per dose to submit their HPV vaccination data. These payments ceased in June 2010. General practitioners are still encouraged to notify doses administered. In February 2013, in line with the extension of the program to males,
the NHVPR was expanded to accept data for males. The NHVPR supports vaccine recipients and providers to complete HPV vaccine courses by providing reports and statements. The register supports monitoring and evaluation of the program by providing operational and coverage reports and by maintaining a permanent record of vaccines administered. The legislation enabling the NHVPR provides for data linkage with state and territory cervical screening and cancer registers.

Immunisation coverage estimates for the catch up program have been published in the peer-reviewed literature and include coverage estimates by age, region, Indigenous status and socioeconomic status.9-12 Updated estimates are published on the Immunise Australia website and Department of Health and the jurisdictions are provided with quarterly coverage reports.

A population based mobile phone survey of young women eligible for the catch up program was undertaken by Victorian Cytology Services (VCS) and the Kirby Institute to obtain independent coverage estimates.13 Both this survey and other data10,14,15 indicate under notification to the register from general practice during the catch up program.
1.3. Monitor the uptake of cervical screening in the eligible population

**Recommended indicators**

- The percentage of women screened in a 2-year, 3-year and 5-year period for women aged 20 years and over and for the target age group 20–69 years.

- Stratified by age, location of residence and socioeconomic status of residence.

- Participation stratified by HPV vaccination status for women who were vaccine program eligible (DOB July 1980 or after).

- Participation stratified by Indigenous status.

*Note: The top two bullet points above are existing indicators from the National Cervical Screening Program (NCSP).*

**Rationale for surveillance**

Cervical cytology screening (Pap testing) is most effective when participants screen regularly. This is due to the limited sensitivity of cytology and the usually gradual nature of disease progression, meaning that if a lesion is missed at an initial screen, it is likely to be detected at a subsequent screen prior to development of cancer. Because current prophylactic HPV vaccines do not prevent all HPV types that can cause cervical cancer, and because some vaccinated women were already infected prior to vaccination in the catch up cohorts, women who are vaccinated still need to participate in cervical screening. Over the last decade participation in cervical screening has been gradually declining in young women both in Australia and in similar developed countries. Thus, monitoring participation in the screening program post vaccination is important to determine whether women continue to participate and that vaccination does not accelerate the fall in participation rates.

**History of surveillance**

Opt-off cervical screening registers operate in each state and territory. These registers use ABS population estimates, adjusted for hysterectomy rates by age, to determine the denominator for the calculation of participation rates. Registers regularly report upon participation within their state/territory. Additionally the Australian Institute of Health and Welfare (AIHW) publishes an annual report on the performance of the NCSP called *Cervical Screening in Australia*. There are seven performance indicators including participation. The state and territory cervical screening registers provide the data for this report.

**Current situation**

Participation in the National Cervical Screening Program (NCSP) has remained relatively stable, at around 60% of women aged 20-69 years, since national data collection began in 1999-2000. In recent years there has been a slight decline in participation, to around 57%, with minor peaks observed following the introduction of the National HPV Vaccination Program in 2007.

Currently, there is no ability for participation to be reported by HPV vaccination status because state and territory legislation governing the operation of the cervical screening registers do not allow for data linkage. States and territories are working to amend jurisdictional legislation to allow data linkage with the NHVPR in the future. Research based data linkage projects linking jurisdictional Pap test and vaccine registers are underway to assess participation by vaccination status.

Currently there is no ability for participation to be reported by Indigenous status as the cervical screening registers do not routinely record this information. Jurisdictions are reviewing mechanisms to collect and record Indigenous status on the registers. Research based data linkage projects linking jurisdictional Pap test and other health databases are underway to assess participation by Indigenous status.
In October 2011, the Renewal of the NCSP commenced. The aim of the NCSP Renewal is to ensure that all Australian women, HPV vaccinated and unvaccinated, have access to a cervical screening program that is safe, acceptable, effective, efficient and based on current evidence. Participation will continue to need to be monitored if a new screening test, screening interval and/or starting age result from the Renewal program.
1.4. Monitor knowledge, attitudes and beliefs about HPV, HPV vaccination and cervical cytology screening

Rationale for surveillance
Knowledge, attitudes and beliefs about HPV infection and HPV vaccination may impact on the success of the HPV vaccination program and on participation rates in cervical screening.

Uptake of the HPV vaccine may be influenced by attitudes of vaccine providers and those at risk of infection and/or their parents. Physician and parental attitudes to HPV vaccines may differ from their attitudes to other routine childhood vaccines because the vaccine prevents a sexually transmitted infection. Strong support from health care providers and from professional organisations is essential for fostering the acceptability and uptake of HPV vaccines. Doubt about a vaccine can affect vaccination coverage rates achieved through immunisation programs. For instance, parental concerns over the sexual implications of HPV vaccination may reduce uptake of the vaccine, particularly where parents consider their children to be at low risk of infection. Publicity about adverse events associated with the vaccine can erode confidence in its safety and reduce uptake, especially in situations where the risk of disease is perceived to be low.

Screening participation may be impacted if vaccinated women believe the vaccine provides sufficient protection for them to no longer need to undergo regular screening.

Regular monitoring of the knowledge, attitudes and beliefs about HPV infection and vaccination among immunisation providers, parents, adolescents and young men and women could assist in developing immunisation and cervical screening program responses, such as revised educational and promotional materials, to ensure a continued high uptake of the vaccine and participation in screening.

Expanded qualitative research into knowledge, attitudes and beliefs should be undertaken if there is a significant fall in uptake of HPV vaccination or in participation in the screening program.

History of surveillance
There was research and program interest in HPV knowledge and attitudes prior to and at the time of vaccine delivery.\textsuperscript{16,19}

Current situation
Both vaccination and cervical screening programs across Australia regularly undertake quality improvement reviews and evaluations, which often include surveys of the population. These surveys provide highly relevant data for monitoring knowledge, attitudes and beliefs about HPV, HPV vaccination and cervical screening.\textsuperscript{14,20,21} Relevant research is also undertaken by other key stakeholders and research groups with an interest in HPV related disease, vaccination and cervical cancer prevention.\textsuperscript{22,23,24}
2. Infection monitoring

2.1. Monitor the prevalence of HPV genotypes in the general female population

**Recommended indicators**

- Prevalence of HPV by type in women with:
  - Comparisons over time and with sufficient power to detect significant changes.
  - Analysis by age cohort, vaccination status, Indigenous status and geographical area.
  - An estimate of the proportion of HPV infection attributable to vaccine preventable and non-vaccine preventable HPV types.

- Population prevalence of HPV antibody positivity in sera for types 6/11/16/18 over time by age group and sex.

**Rationale for surveillance**

Genotype-specific HPV surveillance is required for three main reasons:

- To monitor changes in the prevalence of both the high-risk (16 and 18) and low-risk (6 and 11) HPV genotypes included in quadrivalent HPV vaccine currently used in the National HPV Vaccination Program to determine vaccine impact. This will assess the effectiveness of the vaccination program in preventing vaccine preventable HPV infections and disease.

- To monitor changes in the prevalence of non-vaccine genotypes to evaluate what proportion of the disease burden is vaccine preventable over time. This will assess the effectiveness of the vaccination program in providing cross protection against infection and disease due to non-vaccine, but phenotypically related HPV genotypes. It is also important to guide further vaccine development and use, particularly with the next generation of vaccines (e.g. nonavalent vaccine).

- To monitor for genotype replacement, where a previously uncommon non-vaccine genotype becomes more common, "replacing" the common HPV genotypes present in the vaccine.

Serosurveillance may be an alternative or complementary mechanism to HPV DNA testing of patient samples for population based surveillance of HPV infections. The use of serological testing provides an opportunity to test of both sexes and all age for past and current HPV infections (although these infections cannot be differentiated) without collection of genital specimens. The major limitation of serology using currently available assays is its lack of sensitivity, with positivity correlating better with persistent HPV infection than with HPV exposure/any duration infections.

**History of surveillance**

There was, and is, no routine process for HPV genotyping of HPV found in normal or abnormal cervical smears or in other genital or urine samples in Australia.

A research study, “Establishing the prevalence of HPV infection in Indigenous and non-Indigenous women in Australia, urban and rural: WHINURS - Women's - HPV - Indigenous - Non-Indigenous - Urban - Rural - Study” was initiated in 2004 and aimed to determine circulating HPV genotypes among Australian women to provide baseline data prior to the introduction of HPV vaccine. Consenting women agreed to have their routine cervical sample tested for type-specific HPV DNA. Of the 2,152 women, including 655 Indigenous participants, the prevalence of genotypes 16 and 18 (high-risk types), with genotype 16 the most prevalent, was similar between the Indigenous and non-Indigenous women. Compared with other HPV genotypes, other than HPV types 16 and 18, prevalence among Indigenous and non-Indigenous women did not differ in the younger age groups, but in the 31-40 year old age group HPV prevalence for other HPV types was higher for Indigenous women than non-Indigenous women (35% and 22.5% respectively).
Current situation

Following on from the WHINURS study, a post-vaccine cross-sectional study (Vaccine Impact in the Population [VIP] study) using WHINURS sentinel sites was undertaken sampling women aged 18-24 years who had attended Family Planning Clinics in 2010-2011 (these women would have been in the target vaccination group between 2007 and 2009) for cervical screening. The study found that there was an overall decrease in HPV prevalence (20%) and a significant decrease (77%) in HPV types targeted by the quadrivalent vaccine.27

In May 2013, the Department of Health commenced funding of a HPV genotyping study in Indigenous women (HPV Vaccine Impact in the Australian Population [VIP-I]). VIP-I will assess HPV genotype prevalence (including HPV vaccine-specific genotypes 6, 11, 16 and 18) among Indigenous women attending routine cervical screening, again using sentinel sites that participated in the WHINURS study. This study will be comparable with earlier studies and provide the first empirical evidence regarding the direct impact that the vaccination program is having on HPV types in cervical samples in young Indigenous women.

The most feasible method of undertaking type-specific surveillance in normal cervical smears is to use the sentinel sites used in WHINURS to prospectively collect suitable specimens for HPV genotyping on an ongoing basis.

Other countries have been able to opportunistically test other genital/urine samples, collected as part of national chlamydia screening programs, for HPV DNA for the purposes of HPV surveillance. A study in Sweden, using samples (such as urine, swabs from the vagina, cervix, rectum and urethra and combined genital swabs and urine) collected through a chlamydia screening program were found to be a convenient and effective way of undertaking HPV prevalence studies in the population. Using the infrastructure of the existing program enabled high coverage of sexually active adolescents (both males and females) and ease of sample collection as the swabs/urine had already been collected for the purposes of chlamydia testing.28 Other studies have also found urine testing, especially among women, a feasible method, for detecting HPV DNA provided further improvement and standardisation of tests are achieved.29 However, Australia does not have an established national chlamydia screening program or baseline urine samples in large volumes pre vaccination that could be tested retrospectively.

Serosurveillance

In 2005, the first study to determine HPV seroprevalence in Australia, using serum from all age groups in New South Wales, Victoria and Queensland, was conducted. This was the only feasible means of estimating the prevalence of HPV exposure across the population. The study used residual serum samples obtained from specimens submitted to diagnostic laboratories during 2005 and included specimens from 1523 females and 1247 males. HPV antibodies against types 6, 11, 16 and 18 were measured using a competitive Luminex immunoassay – a proprietary assay developed by Merck Laboratories, USA. Seropositivity was higher for HPV types 6 and 16 across the population, and was higher in females than in males. For females, seropositivity peaked in the 30-39 year age group for types 6 (22%), 16 (22%) and 18 (10.5%) and in the 40-49 age group for type 11 (11.8%). For males, the peak was in the 40-49 year age group for HPV types 6 (15.4%) and 11 (9.1%), and the 50-59 year age group for types 16 (14.3%) and 18 (8.2%). The finding that seropositivity began to increase after 10 years of age supported commencing vaccination in young adolescents, and concurred with findings from comparable countries.25,30-33 In June 2013, a serosurvey limited to 15-39 year old males was initiated (discussed under surveillance objective 2.2).
2.2. Monitor the prevalence of HPV genotypes in the general male population

**Recommended indicators**

- Prevalence of genital HPV by type in men:
  - Comparisons over time and with sufficient power to detect significant changes.
  - Analysis by age cohort, vaccination status, Indigenous status, sexual orientation and geographical area.
  - An estimate of the proportion of HPV infection attributable to vaccine preventable and non-vaccine preventable HPV types.

- Population prevalence of HPV antibody positivity in sera for types 6/11/16/18 over time by age group and sex.

**Rationale for surveillance**

As described under surveillance objective 2.1, genotype-specific HPV surveillance is required for monitoring changes in prevalence of vaccine targeted HPV types, non-vaccine types and to detect changes in prevalence consistent with type-replacement. As males are now receiving HPV vaccination under the National HPV Vaccination Program, reductions in HPV prevalence from direct protection, as well as from herd immunity due to the vaccination of females, can be anticipated. HPV age-specific prevalence is different in males\(^{34}\), with a flat prevalence curve throughout adulthood.\(^{35}\)

**History of surveillance**

There was no routine process for HPV genotyping of routinely collected diagnostic genital or other specimens from males in Australia.

Screening men for HPV infection is not currently recommended, because:

- Infection is too common.\(^{36,37}\)
- Progression from precursor lesions to cancer is not well characterised.\(^{38}\)
- Overall incidence of life-threatening HPV related malignancies in males is rare.\(^{38}\)
- No approved test is available.\(^{36,37}\)
- Finding HPV infection does not indicate increased risk of disease or cancer in men or their sexual partners.\(^{36,37}\)
- No treatment for infection is available.\(^{36,37}\)

**Current situation**

In June 2013, the Department of Health funded a HPV serosurvey, limited to males in the age group 15-39 years (N=300). Antibody assays will be conducted via Merck Laboratories, USA, as was done in the 2005 serosurvey (discussed under surveillance objective 2.1), using residual sera from specimens submitted to diagnostic laboratories in Queensland, New South Wales and Victoria. Males in this age group would not be expected to have been vaccinated and so antibody titers should reflect exposure to natural HPV infection, as was the case in the earlier serosurvey. This is one means of assessing whether there is any evidence that age-specific seroprevalence has changed in the male population more than 5 years post-introduction of the female program and before HPV vaccine was funded for males. Serosurveillance done by these means would be anticipated to have limited value for future monitoring, as the interpretation of post-vaccine antibodies is uncertain and vaccination status is unknown. It could be considered as part of an identified serosurvey, such as is being developed in association with the Red Cross Blood Service, which included information about vaccination status, especially if such a survey could be linked to the National HPV Vaccination Program Register. However, currently the capacity to test for the full range of HPV antibody levels is not available in Australia and the need to rely on overseas laboratories for testing has an additional negative impact on feasibility. Data from the HPV serosurvey is expected in mid-2014.
The ‘HPV infection in young men who have sex with men’ (HYPER) study, which commenced in 2010, aimed to investigate the baseline prevalence of HPV among young homosexual men prior to HPV vaccination. Recruitment for the study was conducted through Facebook, Twitter and other web based social networking sites, targeting individuals according to age, sexual preference and state of residence. Specimens sampled for HPV testing include:

- Anal – intra-anal and peri-anal swabs (collected by a clinician or research nurse).
- Penile – penile (glans penis, coronal sulcus, inner and outer foreskin and shaft of penis) swabs (self-collected).

Two hundred young males were recruited and followed up over a 12-month period, after which participants were offered the HPV vaccine. The HYPER study was completed in September 2013.

Currently there are no Australian data on HPV prevalence in heterosexual males. A study, commencing in 2014, will aim to determine the prevalence of genital HPV (via self-collected samples) among heterosexual males aged 17-19 years attending universities and sexual health services in Melbourne over a four-year period. This study is due to be completed in December 2017.

Due to inadequate sensitivity, urine samples are not recommended for HPV DNA sampling for surveillance purposes in males. A literature review of studies evaluating different anatomical sites for HPV DNA sampling, which could be used for monitoring HPV prevalence, included studies of multiple versus single-site sampling. Of the anatomical sites that yielded enough DNA, those collected from the prepuce, shaft, glans, corona, and scrotum were the most likely to have adequate DNA (70–98.5% were b-globin positive, which is a marker of the quality of the sample for PCR amplification). Combining samples from these sites may optimise results and should be considered when developing surveillance activities for males.
3. Non-cancer disease endpoints

3.1. Monitor the incidence of genital warts

**Recommended indicators**

- Monitor trends in genital wart incidence in clinic populations by:
  - Age and sex.
  - Vaccination status.
  - Indigenous status.
  - Sexual orientation.
  - Area of residence.

**Rationale for surveillance**

At least 90% of genital warts are caused by two low-risk HPV types, HPV-6 and HPV-11\(^1,2\) both of which are included in the quadrivalent vaccine currently used in the National HPV Vaccination Program. Because of the short lead-time (the average incubation period is 2.8 months and can range between 3 weeks to over 8 months\(^40\)) between HPV infection with types 6 and 11 and genital warts, decreases in incidence occur relatively rapidly following vaccination programs. This is in marked contrast to cervical and other HPV related cancer rates, which may take decades to fall. As they are frequently visible, genital warts usually result in the seeking of health care for treatment. Warts also require no routine diagnostic test for diagnosis other than visual inspection. Therefore, genital warts are a useful and early marker of the impact of the vaccination program on HPV infection rates at a population level.

**History of surveillance**

There was no system of routine genital wart surveillance in Australia prior to vaccination. Genital warts are not a notifiable condition. Burden of disease prior to vaccination was estimated using national survey data, hospitalisation data (day stay for surgery), sexual health clinic data and from general practice through the Bettering the Evaluation and Care of Health (BEACH) program.\(^41,42\)

**Current situation**

Sentinel surveillance provides the most efficient means of surveillance for genital warts. Sexual health clinics, which serve a population of young sexually active people of whom approximately 1 in 10 were diagnosed with genital warts prior to vaccination, are an appropriate site for genital warts surveillance. In 2008, the Genital Warts Surveillance Network (GWSN) Project, maintained by the Kirby Institute, was established with the aim of enhancing data collection by participating sexual health services to undertake routine surveillance of genital warts. The GWSN Project involves the collection, analysis and reporting of routinely collected clinical data from eight large sexual health services across Australia. In May 2013, the Department of Health funded an expansion of the GWSN to include more than 20 additional sexual health services, including regional and remote services that see proportionately more Aboriginal and Torres Strait Islander patients. A study using hospital discharge data for genital wart related diagnoses recorded in the National Hospital Morbidity Database held by Australian Institute of Health and Welfare is also being undertaken and will provide data on males and females.

Since the introduction of the vaccination program in 2007, the number of vaccine age eligible young women diagnosed with genital warts has decreased dramatically. A similar pattern, though with less absolute reduction, was observed in age-matched heterosexual men but not homosexual men.\(^43,45\) A decline in genital wart treatments in private hospitals has also been observed\(^46\) and results from a population based survey suggest a similar decline in the general population of young women.\(^47\)
3.2. Monitor the incidence of recurrent respiratory papillomatosis

**Recommended indicators**

- Notification of incident cases of juvenile onset recurrent respiratory papillomatosis over time.
- Trends in HPV type over time, in cases of incident juvenile onset recurrent respiratory papillomatosis.
- Trends in hospitalisations coded using ICD code D14.1 Benign neoplasm of larynx by age and sex over time.

**Rationale for surveillance**

Recurrent respiratory papillomatosis (RRP) is a disease causing recurrent growths in the airways. It usually requires repeated surgical treatments, and is associated with high morbidity and occasionally death. There are two types of RRP, one which presents in young children, and an adult onset type. Two low-risk HPV genotypes, HPV 6 and HPV 11, cause the vast majority of RRP. In contradistinction to genital warts, where HPV 6 predominates, in RRP there is a reversal with genotype 11 more common. Although rare (incidence 1-4 per 100,000), epidemiologic data suggests that children delivered vaginally to young mothers with active genital warts are at greatest risk of the condition. As both HPV 6 and HPV 11 are included in the quadrivalent vaccine currently in use in the National HPV Vaccination Program, the rate of HPV 6 and 11 infection and genital warts in women of childbearing age should decrease over time. This should reduce the potential for vertical transmission of HPV 6 and 11 and thus RRP should become a vaccine preventable disease. The impact upon juvenile-onset RRP (JORRP) incidence should occur relatively rapidly (years), if indeed the disease predominantly occurs in first-born children of younger mothers. Australia is likely to be the first country to be able to demonstrate a decline in RRP incidence.

**History of surveillance**

Obtaining national population estimates of the incidence and prevalence of JORRP is complicated by the lack of a unique ICD (hospitalisation) code for the condition. A pilot study was undertaken to determine the positive predictive value for JORRP of several candidate disease and procedure codes. By retrieving medical records from separations occurring between 1998 and 2008 containing these codes, a review of hospitalisations for JORRP in a NSW tertiary paediatric hospital was undertaken. The study found that ICD code D14.1 Benign neoplasm of the larynx had a high positive predictive value for JORRP. By extrapolating this value, and the median number of admissions per case of RRP, to national hospitalisations data, estimates of prevalence of JORRP in Australia were made and found to be consistent with international estimates. A further study, extending the review to the two other major tertiary paediatric hospitals in NSW, is underway. An online survey of paediatric ENT surgeons was also undertaken to obtain an indication of case numbers and treatment practices.

**Current situation**

In October 2011, the Australian Paediatric Surveillance Unit (APSU), funded by the Department of Health, commenced surveillance of JORRP in Australia. HPV typing of biopsy samples is being offered, with funding provided by an investigator-initiated grant from Merck. Additional information on reported cases of JORRP, identified through routine reporting, is collected directly by the APSU from notifying paediatricians and ENT specialists. The aim of the surveillance is to estimate the incidence of JORRP in children less than 15 years of age and describe symptoms, clinical presentation, treatment, child and maternal HPV vaccination status/history, HPV genotypes and RRP distribution.

Data collected through this surveillance are reported annually to the Department of Health. In 2012, there were four confirmed clinical cases of JORRP reported to the APSU. Results of surveillance will be published in the regular APSU reports and in the peer-reviewed literature.
3.3. Monitor the prevalence of screen-detected cervical abnormalities

Recommended indicators

- The proportion of cytology test results in each result category in a 12-month period.

- The proportion of histology test results in each result category in a 12-month period.

- The number of women with a high-grade abnormality detected by histology per 1,000 women screened in a 12-month period for women aged <20 and 20-69 years.

The indicators above are to be monitored over time and analysed for trends by: age group, jurisdiction, socioeconomic status, remoteness of residence, Indigenous status and vaccination status in vaccine eligible age cohorts.

Note: The above bullet points are existing indicators from the National Cervical Screening Program.

Rationale for surveillance

One of the major impacts of HPV vaccination will be a reduction in cervical abnormalities (both high- and low-grade) caused by HPV types contained within the vaccine. International data indicate that approximately 55% of high-grade cervical abnormalities are associated with HPV 16 or 18. In Australia, 70-80% of cervical cancers and 50% of high-grade precancerous lesions are associated with HPV 16 or 18. Of low-grade cervical abnormalities, 25% are associated with HPV 16 or 18. A further proportion of cervical abnormalities are associated with HPV types against which HPV vaccines may provide some degree of cross protection. The extent of the impact on cervical abnormalities should increase as the cohort of vaccinated women ages and increased numbers of them become the target population for the screening program. Thus, monitoring the absolute numbers of abnormalities detected both cytologically and histologically is an important outcome indicator of the program’s effectiveness. This is important for both high-grade and low-grade abnormalities.

History of surveillance

As mentioned under surveillance objective 1.3, opt-off cervical screening registers operate in each state and territory. The registers operate to collect screening histories of individual women, including screen-detected abnormalities, send reminders to women apparently overdue for routine screening and provide the laboratory and/or clinician with results of previous abnormal smears, so that a more detailed evaluation can be done of the present smear if necessary. They also support monitoring of laboratory quality and provide data for analysis and consideration in policy development for the National Cervical Screening Program (NSCP).

The Australian Institute of Health and Welfare (AIHW) publishes an annual report on the performance of the NSCP called *Cervical Screening in Australia*. State and territory cervical screening registers provide data for this report to the AIHW for national reporting. Prior to 2008, national indicators monitored cytologically predicted and histologically confirmed high-grade abnormalities but not the rates of low-grade cytology reports.

Current situation

Following the implementation of the updated guidelines for management of screen-detected abnormalities in 2006, and with the commencement of the National HPV Vaccination Program, key indicators for the NCSP were revised and an indicator reporting cytology tests by category of abnormality was added, in order to be able to monitor rates of low-grade cytology diagnoses nationally for the first time. The new indicators were used for the first time in the 2008-2009 *Cervical Screening in Australia* report.
Since the vaccination program, rates of high-grade abnormalities have declined in the youngest women in the screening program. This decline was initially noted in an analysis of incident histologically confirmed CIN2+ lesions up until the end of 2009, using data held on the Victorian Cervical Cytology Registry (VCCR) amongst women over 18 years of age.\textsuperscript{56} This decline has been confirmed in national data in women under 20 \textsuperscript{17,57} and in updated statistical reports from the VCCR.\textsuperscript{58} 2011 data indicate a decline in women aged 20-24 years with rates in this age group below those of the 25-29 year old age group for the first time. The high-grade rate in the 25-29 group also fell slightly for the first time, reversing the trend towards a higher rate each year. There appears to be an underlying trend towards higher rates of high-grade cervical abnormalities over time, probably relating to patterns of sexual behaviour and possibly the gradual decline in participation amongst women in their twenties.
3.4. Monitor the distribution of HPV genotypes detected in high-grade cervical dysplastic lesions

**Recommended indicators**

- Prevalence of HPV by type in women with histologically proven CIN3:
  - Comparisons over time and with sufficient power to detect significant changes.
  - Analysis by age, vaccination status and Indigenous status.
  - An estimate of the proportion of CIN3 lesions attributable to vaccine preventable and non-vaccine preventable HPV types.

**Rationale for surveillance**

As described under surveillance objective 2.1, genotype-specific HPV surveillance is required for monitoring changes in prevalence of vaccine targeted HPV types, non-vaccine types and to detect changes in prevalence consistent with type-replacement. Histopathologically confirmed cervical intraepithelial grade 3 (CIN3) lesions are definitively diagnosed lesions with true precancerous potential, unlike CIN2 lesions or cytologically predicted high grade smears.

**History of surveillance**

There is currently no routine or ongoing type-specific HPV typing of high-grade cervical lesions in Australia. Whilst HPV testing is recommended in Australia as a test of cure following treatment of high-grade lesions, these specimens are taken post-treatment, are not biopsy specimens and do not always determine the HPV type present. Data is available on HPV genotype prevalence in cervical intraepithelial lesions collected prior to implementation of the HPV vaccination program; these studies showed a preponderance for 16 and 18 in high-grade lesions\(^5\), with higher proportions of HPV 16 detected in lesions from younger women (>60%) consistent with international data.\(^5\)

**Current situation**

A study in Victoria is prospectively HPV typing all CIN3 biopsy lesions from vaccine age eligible women submitted to two Victorian laboratories (Royal Women's Hospital and Victorian Cytology Service) (funding from the Victorian Cancer Agency.) The study will define HPV type attribution in CIN3 lesions amongst women vaccinated during the catch up program and is using a technique called laser capture microdissection to determine the HPV type found within the CIN3 lesions itself where more than one HPV type is detected in the biopsy.
4. Cancer endpoints

4.1. Monitor cervical cancer incidence and mortality

**Recommended indicators**

- The number of new cases of cervical cancer per 100,000 estimated resident female population in a 12-month period.

- The number of deaths from cervical cancer per 100,000 estimated resident female population in a 12-month period.

**Rationale for surveillance**

Prevention of cervical cancer is the major aim of population based HPV vaccination programs. Although the impact of vaccination on the prevention of cervical cancer will not be realised for a decade or more, given the natural history of the disease, continued high quality surveillance of cervical cancer incidence and mortality is required.

**History of surveillance**

All Australian states and territories operate cancer registries, to which reporting by selected health care providers is mandatory under the various state and territory laws. Therefore, national and state and territory reporting of cervical cancer incidence and mortality is currently comprehensive.

**Current situation**

State and territory registers, as well as the Australian Institute of Health and Welfare (AIHW) and the Australian Association of Cancer Registries, regularly publish comprehensive cancer registry data including cervical cancer data.

Additionally, the annual AIHW *Cervical Screening in Australia* report presents national data on cervical cancer incidence and mortality. Incidence data is collected from state and territory cancer registries through the Australian Cancer Database held by the AIHW. Mortality data is provided by the Registrars of Births, Deaths and Marriages to the National Mortality Database held by the AIHW.
4.2. Monitor anogenital$^3$ and oropharyngeal$^4$ cancer incidence and mortality

**Recommended indicators**
- The number of new cases of HPV related cancers per 100,000 estimated resident population in a 12-month period.
- The number of deaths from HPV related cancers per 100,000 estimated resident population in a 12-month period.

Both incidence and mortality to be monitored over time and by sex, age, Indigenous status, country of birth/ethnicity, socioeconomic status, remoteness of residence and HPV vaccination status.

**Rationale for surveillance**
The introduction of HPV vaccination for both sexes in 2013 will increase the overall impact of vaccination in the population on the incidence of HPV related cancers. Whilst detectable reductions in cervical, vaginal, vulval and anal cancers/HPV related head and neck cancers in females should follow the female only program, the herd immunity benefits to men and related prevention of anal cancers, penile cancer and HPV related oropharyngeal cancers may be more difficult to measure, particularly given increasing rates of anal and oropharyngeal cancers over time in Australian men$^{60,61}$. Vaccination of males will over time impact on HPV infection rates among men who have sex with men, who have high incidence rates of anal and HPV related oropharyngeal cancers. Although the impact of vaccination on the prevention of these cancers will not be realised for a decade or more, given the natural history of HPV related cancers, continued high quality surveillance of the incidence and mortality from all HPV related cancers is required.

**History of surveillance**
All Australian states and territories operate cancer registries, to which reporting by selected health care providers is mandatory under the various state and territory laws. Therefore, national and state/territory reporting of cancer incidence and mortality$^{17}$ is currently comprehensive.

**Current situation**
State and territory registers, as well as the Australian Institute of Health and Welfare (AIHW) and the Australian Association of Cancer Registries regularly publish comprehensive cancer registry data including HPV related cancer data. HPV related head and neck cancers are not currently grouped together however using HPV related cancer site ICD codes: this enhancement would improve ability to routinely monitor trends in these cancers separately from trends in incidence in non-HPV related head and neck cancers.

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$^3$ Includes anal, penile, vaginal and vulval cancers.
$^4$ Includes base of the tongue and HPV related head and neck cancers.
4.3. Monitor the distribution of HPV genotypes detected in cervical cancers

**Recommended indicators**
- Prevalence of HPV by type in cervical cancer specimens:
  - Comparisons over time.
  - Analysis by age, histological type, Indigenous status and vaccination status.
  - The proportion of cervical cancers attributable to vaccine preventable and non-vaccine preventable HPV types.
  - Number of cancer specimens typed for HPV as a proportion of all cancers diagnosed (aim for complete capture).

**Rationale for surveillance**
As described under surveillance objective 2.1, genotype-specific HPV surveillance is required for monitoring changes in prevalence of vaccine targeted HPV types, non-vaccine types and to detect changes in prevalence consistent with type replacement.

**History of surveillance**
Cervical cancers in Australia are not routinely tested for HPV genotypes. A meta-analysis of Australian studies showed a preponderance of types 16 and 18, consistent with world data.62

**Current situation**
As the number of cervical cancers in Australia is small, all cancers should be tested for HPV genotypes. It would be logical to record this data on the existing state based cancer registries. Data on vaccination status from the HPV register should be linked to each cancer record including the HPV genotype information. Indigenous status of women diagnosed with cervical cancer should be obtained from cancer registries, the National HPV Vaccination Program Register or other sources to detect any differences in HPV types found in cervical cancer by Indigenous status.

The logistics of ensuring HPV testing of all cervical cancer specimens will involve all pathology laboratories that currently perform cervical histology. Reporting laboratories will need to be requested to forward a paraffin block, containing the cancer, to an accredited World Health Organization regional reference laboratory for HPV detection and typing. Initial scoping and communication should occur with the state and territory cancer registries in order to piggyback on existing processes for the reporting of cervical cancer to the registries. Consideration would have to be given to logistics, ethics approval, patient consent and funding. Implementation via the Quality Use of Pathology Program could be explored in the first instance.
4.4. Monitor the distribution of HPV genotypes detected in anogenital\textsuperscript{5} and oropharyngeal\textsuperscript{6} cancers

**Recommended indicators**

- Prevalence of HPV by type in HPV related cancer specimens:
  - Comparisons over time.
  - Analysis by age, histological type, Indigenous status and vaccination status.
  - Number of cancer specimens typed for HPV as a proportion of all cancers diagnosed (aim for complete capture).
  - The proportion of each cancer attributable to vaccine preventable and non-vaccine preventable HPV types.

**Rationale for surveillance**

As described under surveillance objective 2.1, genotype-specific HPV surveillance is required for monitoring changes in prevalence of vaccine targeted HPV types, non-vaccine types and to detect changes in prevalence consistent with type replacement.

**History of surveillance**

HPV related cancers in Australia are not routinely tested for HPV genotypes. However, some oropharyngeal cancers may undergo diagnostic HPV detection given the prognostic significance for these cancers. Research studies have described HPV genotypes present in Australian case series of oropharyngeal\textsuperscript{63}, vulval and anal cancers.\textsuperscript{64-67}

**Current situation**

In the absence of routine diagnostic testing of these cancers for HPV, periodic research studies may be the most feasible method initially of obtaining baseline data and monitoring changes in type distribution over time. In the longer term, consideration should be given to all such cancers being routinely referred for HPV typing at diagnosis, with results routinely recorded on the cancer registries.

\textsuperscript{5} Includes anal, penile, vaginal and vulval cancers.

\textsuperscript{6} Includes base of the tongue and HPV related head and neck cancers.
References


20 Watson, M., Shaw, D., Molchanoff, L. & McInnes, C. Challenges, lessons learned and results following the implementation of a human papillomavirus school vaccination program in South Australia. *Australian and New Zealand Journal of Public Health* 33, 365-370 (2009).


Hillman, R. J. et al. Human papillomavirus (HPV) genotypes in an Australian sample of anal cancers (manuscript under review).

# Appendix A – Membership of the working party

<table>
<thead>
<tr>
<th>Chair:</th>
<th>Dr Rosemary Lester</th>
<th>Department of Human Services, Victoria</th>
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<tbody>
<tr>
<td>Secretariat:</td>
<td>Ms Amy Bright</td>
<td>Health Emergency Management Branch, Australian Capital Territory</td>
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<td>Ms Natasha Wood</td>
<td>Health Emergency Management Branch, Australian Capital Territory</td>
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<tr>
<td>Members:</td>
<td>Dr Julia Brotherton</td>
<td>Victorian Cytology Service, Victoria</td>
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<td></td>
<td>Dr Kerryn Coleman</td>
<td>Medical Advisor, Office of Health Protection, Department of Health, Australian Capital Territory</td>
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<tr>
<td></td>
<td>Prof Suzanne Garland</td>
<td>WHO HPV Reference Laboratory, Western Pacific Region, Victoria</td>
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<td></td>
<td>Prof John Kaldor</td>
<td>Royal Women’s Hospital Melbourne and the Kirby Institute for infection and immunity in society, Sydney, New South Wales</td>
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<td></td>
<td>Prof Peter McIntyre</td>
<td>National Centre for Immunisation Research and Surveillance, Sydney, New South Wales</td>
</tr>
<tr>
<td></td>
<td>Ms Rhonda Owen</td>
<td>Health Emergency Management Branch, Department of Health, Canberra, Australian Capital Territory</td>
</tr>
<tr>
<td></td>
<td>A/Prof Marion Saville</td>
<td>Director, Victorian Cytology Service, Melbourne, Victoria</td>
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<tr>
<td></td>
<td>Ms Lesley Scott</td>
<td>Department of Health, Darwin, Northern Territory</td>
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<td></td>
<td>Dr Christine Selvey</td>
<td>New South Wales Health, New South Wales</td>
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<td>Dr Rosalind Webby</td>
<td>Department of Health, Darwin, Northern Territory</td>
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<td></td>
<td>A/Prof Sepehr Tabrizi</td>
<td>Royal Women’s Hospital, Victoria</td>
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</table>
Appendix B – Changes since 2009 Surveillance Plan

Since the 2009 Surveillance Plan, there have been a number of changes to HPV surveillance activities. A summary of what has changed since 2009 is detailed in the table below.

The revised Surveillance Plan also includes two new surveillance objectives reflecting the expansion of the program to males and beyond cervical cancer prevention. These objectives include:

- Monitor the prevalence of HPV genotypes in the general male population.
- Monitor anal, penile, vulval, vaginal and oropharyngeal/base of tongue/HPV related head and neck cancer incidence and mortality.

### Surveillance objectives | What has changed since 2009?
---|---
Assess age-specific HPV vaccination coverage achieved in the ongoing 12-13 year old program and the catch up program | The catch up program in females ceased at the end of 2009. Coverage rates for the third dose of the vaccine in the school catch up program in 14-15 year olds and 16-17 year olds were 72% and 70% respectively. In the general practice/community based catch up program in 18-19 year olds and 20-26 year olds the coverage rates were 62% and 32% respectively. 
In February 2013, the National HPV Vaccination Program Register started collecting data for males.
HPV vaccine safety | Analyses of adverse events following immunisation since the commencement of the vaccination program have been published annually.
There have been a number of enhancements to the existing surveillance system.
Monitor the prevalence of specific HPV genotypes in: the general female population; high-grade cervical dysplasia lesions; and cervical cancers | Significantly lower vaccine-type HPV prevalence have been observed among vaccinated women in the post-vaccine sample (5%) compared with both unvaccinated women from the same period (15.8%) and women from the pre-vaccine period (28.7%).

This objective has now been divided into three separate objectives.
Continue to monitor the uptake of cervical screening in the eligible population and the prevalence of screen-detected cervical abnormalities | In October 2011, a process called the Renewal of the National Cervical Screening Program commenced to ensure that all Australian women, HPV vaccinated and unvaccinated, have access to a cervical screening program that is safe, acceptable, effective, efficient and based on current evidence.
Participation in the National Cervical Screening Program (NSCP) has remained relatively stable overall, declining slightly from 58.9% in 2008-2009 to 57.2% in 2010-2011. Ongoing declines in participation among young women have been noted, following an increase in participation during the HPV vaccination catch up program.
Preliminary data until the end of 2009 on the Victorian Cervical Cytology Registry indicated a decrease in the incidence of high-grade cervical abnormalities in women under 18 years following the implementation of the National HPV Vaccination Program.
<table>
<thead>
<tr>
<th>Surveillance objectives</th>
<th>What has changed since 2009?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continue to monitor cervical cancer incidence and mortality</td>
<td>There were 631 new cases diagnosed in 2009, and 152 women died from cervical cancer in 2010. This is equivalent to 9 new cases and 2 deaths per 100,000 women, respectively. Incidence and mortality have both halved since the NCSP was introduced in 1991, remaining at their historic lows of 9 new cases and 2 deaths per 100,000 women since 2002.</td>
</tr>
<tr>
<td>Monitor the incidence of genital warts</td>
<td>Since 2008, the Genital Warts Surveillance Network (Kirby Institute) has monitored trends in diagnosed cases of genital warts. In May 2013, the Department of Health funded an expansion of the network to include more than 20 additional sentinel sites. Data also shows declines in private hospital treatments for genital warts.</td>
</tr>
<tr>
<td>Monitor the incidence of recurrent respiratory papillomatosis</td>
<td>Since 2011, the Department of Health has funded the Australian Paediatric Surveillance Unit (APSU) to collect data on juvenile onset recurrent respiratory papillomatosis (JORRP). In 2012, there were 4 confirmed clinical cases of JORRP reported to the APSU.</td>
</tr>
<tr>
<td>Monitor knowledge, attitudes and beliefs about HPV, HPV vaccination and cervical cytology screening</td>
<td>A number of research activities have been completed that have reviewed the current perceptions and attitudes towards HPV, HPV vaccination and awareness of current HPV policy.</td>
</tr>
</tbody>
</table>
Appendix C – Timeline of HPV surveillance objectives

In the 2 years following the introduction of the vaccine, the surveillance objectives that can be monitored are:

- Vaccine safety (1.1);
- Vaccine coverage (1.2);
- Knowledge, attitudes and beliefs about HPV, HPV vaccination and cervical cytology screening (1.4);
- The prevalence of HPV genotypes in the population (2.1 & 2.2);
- Incidence of genital warts (3.1);
- Incidence of recurrent respiratory papillomatosis; and
- The uptake of cervical screening in the eligible population (females only) (1.3).

In the 2–7 years following the introduction of the vaccine, the surveillance objectives that can be monitored are:

- The prevalence of screen detected cervical abnormalities (3.3); and
- Distribution of HPV genotypes detected in high grade cervical dysplasia lesions (females only) (3.4).

In the 7–17 years following the introduction of the vaccine, the surveillance objectives that can be monitored are:

- Distribution of HPV genotypes detected in HPV related cancers; and
- HPV related cancer incidence and mortality.

Notes:

- All surveillance objectives are ongoing. Surveillance objectives appear on the timeline at the time they would be first required post-vaccination.
- **HPV related cancers include:** cervical, anal, penile, vulval, vaginal, oropharyngeal/base of tongue/HPV related head and neck cancer.
## Appendix D – Recommended indicators and data availability

<table>
<thead>
<tr>
<th>Objective</th>
<th>Recommended indicator</th>
<th>Data availability and source</th>
<th>Frequency of reporting</th>
<th>Data gaps and limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor HPV vaccine safety</td>
<td>HPV vaccine related adverse events are routinely analysed and published in a timely manner, including rates derived from denominator data collected by the National HPV Vaccination Program Register (NHVPR) and analysis by sex.</td>
<td>All adverse events are reported to the Therapeutic Goods Administration (TGA) through its passive surveillance system. These data are collated by the National Centre for Immunisation Research and Surveillance (NCIRS) and reported in annual reports published in <em>Communicable Diseases Intelligence (CDI)</em> - 'Adverse events following immunisation'‡‡. Adverse events related to the HPV vaccine have been reported in this publication since 2007.</td>
<td>Annual.</td>
<td>N/A.</td>
</tr>
</tbody>
</table>

| Asses age-specific HPV vaccination coverage achieved in the ongoing 12-13 year old program and the catch up program | HPV vaccination coverage by dose number and sex for:  - The ongoing school based cohort (12-13 years).  - Those turning 15 years of age in the year of report (World Health Organization recommended indicator).  - The cohorts vaccinated in the female catch up program 2007-2009 (12-26 years).  - The cohorts vaccinated in the male program 2013-2015 (14-15 years). | NHVPR receiving data for males from 2013. Coverage data is reported regularly in CDI and on the Immunise Australia website. | Regular reporting.  Male data not yet reported.  Last reported in 2012 (2011 data).§§ | Timeliness of national data is significantly impacted by the timeliness of the jurisdictions in data reporting to the register. Indigenous coverage not well reported as not all states and territories provide an Indigenous indicator. VCS is working with states and territories but the identifier is not very reliable at this time. Only the Northern Territory and Queensland Indigenous data has been analysed to date due to concerns with data completeness in other jurisdictions for catch up program data. |

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‡‡ Adverse events following immunisation annual reports (Health website)  
§§ National HPV Register (Health's Immunise website)
<table>
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<tr>
<th><strong>Objective</strong></th>
<th><strong>Recommended indicator</strong></th>
<th><strong>Data availability and source</strong></th>
<th><strong>Frequency of reporting</strong></th>
<th><strong>Data gaps and limitations</strong></th>
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<tr>
<td>Assess age-specific HPV vaccination coverage achieved in the ongoing 12-13 year old program and the catch up program</td>
<td>Indigenous status</td>
<td>NHVPR – Indigenous status recorded (optional field). All jurisdictions collecting Indigenous status on school consent forms from 2010. As not all states and territories provide an Indigenous indicator this may be difficult. Victorian Cytology Service (VCS) are working with them but the identifier is not very reliable at this time.</td>
<td>Ad hoc. Publication in press, Medical Journal of Australia (as at 3 September 2013).</td>
<td>As above.</td>
</tr>
<tr>
<td>Assess age-specific HPV vaccination coverage achieved in the ongoing 12-13 year old program and the catch up program</td>
<td>Area level socioeconomic status</td>
<td>NHVPR – addresses recorded for vaccinees and the immunisation provider. Victorian data on participation in HPV vaccination analysed by socioeconomic status (1 July 2006 to 30 June 2008). National level analysis of coverage by socioeconomic status and remoteness classification submitted for publication in 2013. Coverage data by small area for Australia pending release on social health atlas website.</td>
<td>Ad hoc.</td>
<td>As above.</td>
</tr>
<tr>
<td>Monitor the uptake of cervical screening in the eligible population</td>
<td><em>The percentage of women screened in a 2-year, 3-year and 5-year period for women aged 20 years and over and for the target age group 20-69 years.</em></td>
<td>The Australian Institute of Health and Welfare (AIHW) monitors and reports on the performance of the NCSP through screening data. Participation data are analysed by socio-demographic variables</td>
<td>Annual reporting. The most recent participation data are for the 2010–2011 reporting</td>
<td>Currently, there is no ability for data to be reported by HPV vaccination status because state and territory legislation governing the operation of the cervical screening registers</td>
</tr>
<tr>
<td>Objective</td>
<td>Recommended indicator</td>
<td>Data availability and source</td>
<td>Frequency of reporting</td>
<td>Data gaps and limitations</td>
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<tr>
<td><em>existing National Cervical Cancer Screening Program (NCSP) indicators</em></td>
<td><em>Stratified by age, location of residence and socioeconomic status of residence.</em> Participation stratified by HPV vaccination status for women who were vaccine program eligible (date of birth July 1980 or after). Participation stratified by Indigenous status.</td>
<td>such as age, state and territory, geographic area and socioeconomic status***.</td>
<td>Ad hoc.</td>
<td>do not allow for data linkage. States and territories are working to amend jurisdictional legislation to allow data linkage with the NHVPR in the future. Of the performance indicators used to monitor the NCSP, only incidence and mortality can be disaggregated by Indigenous status. The collection of reliable information by the state and territory cancer registries on the Aboriginal and Torres Strait Islander status of individuals diagnosed with cancer is problematic, since primary cancer diagnosis information is sourced from pathology forms that do not have the capacity to record this information. Some data available through a number of different studies. Ad hoc.</td>
</tr>
<tr>
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<tr>
<td>Monitor the prevalence of HPV genotypes in the general female population</td>
<td>Prevalence of HPV by type in women with: • Comparisons over time and with sufficient power to detect significant changes. • Analysis by age cohort, vaccination status, Indigenous status and geographical area. • An estimate of the proportion of HPV infection attributable to vaccine preventable and non-vaccine preventable HPV types.</td>
<td>Some data available from the WHINURS study – Indigenous (655) and non-Indigenous (1497) – prevalence of HPV genotypes. Data available from post-vaccination program study – Vaccine Impact in the Population (VIP) – 338 women aged 18-24 years – prevalence of HPV genotypes.</td>
<td>Ad hoc.</td>
<td>There is no systematic surveillance of HPV genotypes – surveillance occurs through smaller studies, e.g. WHINURS study.</td>
</tr>
<tr>
<td>Monitor the prevalence of HPV genotypes in the general female population</td>
<td>Population prevalence of HPV antibody positivity in sera for types 6,11,16,18 over time by age group and sex.</td>
<td>Some baseline data collected through an NCIRS ad hoc serosurvey using sera collected in 2005††† – HPV types 6, 11, 16 and 18 for men, women and children in Australia.</td>
<td>Ad hoc.</td>
<td>As above.</td>
</tr>
<tr>
<td>Monitor the prevalence of HPV genotypes in the general male population</td>
<td>Prevalence of genital HPV by type in men: • Comparisons over time and with sufficient power to detect significant changes. • Analysis by age cohort, vaccination status, Indigenous status, sexual orientation and geographical area. • An estimate of the proportion of HPV infection attributable to HYPER study to be completed in 2013 – prevalence of HPV in homosexual men prior to the HPV vaccination program. Similar study to HYPER looking at the heterosexual male population is due to commence in 2014. Baseline serosurvey data of men aged 15-39 years will be available mid-2014.</td>
<td>HYPER††† study to be completed in 2013 – prevalence of HPV in homosexual men prior to the HPV vaccination program. Similar study to HYPER looking at the heterosexual male population is due to commence in 2014. Baseline serosurvey data of men aged 15-39 years will be available mid-2014.</td>
<td>Ad hoc.</td>
<td>Difficult to monitor in the short term.</td>
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††† HPV serosurvey (NCIRS website)
‡‡‡ HPV infection in young men who have sex with men (HYPER website)
<table>
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<tr>
<td>Monitor the prevalence of HPV genotypes in the general male population</td>
<td>Population prevalence of HPV antibody positivity in sera for types 6/11/16/18 over time by age group and sex.</td>
<td>Some baseline data collected through an ad hoc serosurvey using sera collected in 2005. HPV types 6, 11, 16 and 18 for men, women and children in Australia. A serosurvey, undertaken by NCIRS, using sera collected in 2012 for HPV types 6, 11, 16 and 18 for men aged 15-39 years in Australia.</td>
<td>Ad hoc.</td>
<td>As above.</td>
</tr>
<tr>
<td>Monitor the incidence of genital warts</td>
<td>Monitor trends in genital wart incidence in clinic populations by: • Age and sex. • Vaccination status. • Indigenous status. • Sexual orientation. • Area of residence.</td>
<td>Estimates potentially available through hospitalisations data (day stay for surgery), sexual health clinics, general practices through the Bettering the Evaluation and Care of Health (BEACH) program. Data collected through the Kirby Institute for the Genital Warts Surveillance Network (GWSN) Project includes HPV vaccination status, past or current diagnosis of genital or anal warts.</td>
<td>Data available collected through the GWSN Project. Genital warts surveillance data was last reported in the HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2011§§§. Data was first published on the GWSN in 2010****.</td>
<td>-</td>
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<tr>
<td>Monitor the incidence of recurrent respiratory papillomatosis</td>
<td>Trends in notification of incident cases of juvenile onset recurrent respiratory papillomatosis over time. Trends in HPV type over time, in cases of incident juvenile onset recurrent respiratory papillomatosis.</td>
<td>The Australian Paediatric Surveillance Unit (APSU) is currently collecting juvenile onset recurrent respiratory papillomatosis (RRP) data, including HPV maternal HPV vaccination status, HPV genotypes and RRP distribution. The APSU began collecting data in October 2011. The 2012 APSU Annual Report will be published in CDI in 2013.</td>
<td>Baseline data on prevalence have been estimated using hospitalisation data.</td>
<td>-</td>
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§§§ HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2011 ( Kirby Institute website)
**** HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2010 ( Kirby Institute website)
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| Monitor the prevalence of screen-detected cervical abnormalities          | *Cytology  
The proportion of cytology test results in each result category in a 12-month period.  
*Histology  
The proportion of histology test results in each result category in a 12-month period.  
*High grade abnormality detection rate  
The number of women with a high-grade abnormality detected by histology per 1,000 women screened in a 12-month period for women aged <20 and 20-69 years. | The AIHW monitors and reports on the performance of the NCSP through screening indicators compiled from aggregated data provided by state and territory cervical cytology registries. | Annual reporting.     | New performance indicators were developed following a review of original indicators. These new performance indicators were officially endorsed in September 2009. Data on the new indicators were first published by the AIHW in October 2011.  
The latest AIHW publication ‘Cervical screening in Australia 2010-11’ was published in June 2013.  
The most recent cytology data are for the year 2011.  
The most recent histology data are for the year 2011.  | Currently, there is no ability for data to be reported by HPV vaccination status because state and territory legislation governing the operation of the cervical screening registers do not allow for data linkage. States and territories are working to amend jurisdictional legislation to allow data linkage with the NHVPR in the future.  
Of the performance indicators used to monitor the NCSP, only incidence and mortality can be disaggregated by Indigenous status.  
The collection of reliable information by the state and territory cancer registries on the Aboriginal and Torres Strait Islander status of individuals diagnosed with cancer is problematic, since primary cancer diagnosis information is sourced from pathology forms that do not have the capacity to record this information. |
| Monitor the distribution of HPV                                            | Prevalence of HPV by type in women with histologically proven CIN3:  
Study that is HPV typing 500 CIN3 lesions from vaccine age eligible Victorian women | Ad hoc.                                                                  |                         | There is no systematic surveillance of HPV genotypes in CIN3 –                          |

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†††† Cervical screening in Australia 2008–2009 (AIHW website)  
‡‡‡‡ Cervical screening in Australia 2010–2011 (AIHW website)
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<td>genotypes detected in high-grade cervical dysplasia lesions</td>
<td>• Comparisons over time and with sufficient power to detect significant changes.</td>
<td>using laser capture microdissection technique.</td>
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<td>surveillance occurs through smaller studies.</td>
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<td>• Analysis by age, vaccination status and Indigenous status.</td>
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<td></td>
<td>An estimate of the proportion of CIN3 lesions attributable to vaccine preventable and</td>
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<td>non-vaccine preventable HPV types.</td>
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<tr>
<td>Monitor cervical cancer incidence and mortality</td>
<td>*Incidence – The number of new cases of cervical cancer per 100,000 estimated resident female population in a 12-month period.</td>
<td>Uses cervical cancer incidence data collected in the Australian Cancer Database.</td>
<td>Annual reporting.</td>
<td>The collection of reliable information by the state and territory cancer registries on the Aboriginal and Torres Strait Islander status of individuals diagnosed with cancer is problematic, since primary cancer diagnosis information is sourced from pathology forms that do not have the capacity to record this information.</td>
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<td>*Mortality – The number of deaths from cervical cancer per 100,000 estimated resident female population in a 12-month period.</td>
<td>Uses mortality data provided by the Registrars of Births, Deaths and Marriages to the national Mortality Database held by the AIHW.</td>
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<tr>
<td>Monitor anogenital and oropharyngeal cancer incidence and mortality</td>
<td>Incidence – The number of new cases of cervical cancer per 100,000 estimated resident population in a 12-month period.</td>
<td>The major source of cancer incidence data is the Australian Cancer Database, compiled at the AIHW from cancer data provided by the state and territories, which contains records of all primary, malignant cancers diagnosed in Australia between 1982 and 2000§§§§.</td>
<td>Regular reporting.</td>
<td>HPV related head and neck cancers are not readily monitored through routine publications. It would be helpful to group site-specific ICD codes together for proven HPV related head and neck cancer sites in routine reports.</td>
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<tr>
<td>Monitor the distribution of HPV genotypes detected in cervical cancers.</td>
<td>Prevalence of HPV by type in cervical cancer specimens:</td>
<td>Births, Deaths and Marriages to the National Mortality Database held by the AIHW. Mortality data is available (via the AIHW) up to 2010.</td>
<td>Ad hoc.</td>
<td>N/A</td>
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<tr>
<td></td>
<td>- Comparisons over time</td>
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<td>- Number of cancer specimens typed for HPV as a proportion of all cancers diagnosed (aim for complete capture).</td>
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<td>- Analysis by age, histological type, Indigenous status and vaccination status.</td>
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<td></td>
<td>- The proportion of cervical cancers attributable to vaccine preventable and non-vaccine preventable HPV types.</td>
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<tr>
<td></td>
<td>Prevalence of HPV by type in HPV related cancers specimens:</td>
<td>Historical pre-vaccination data available from research studies</td>
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<td></td>
<td>- Comparisons over time</td>
<td>Cancer typing study funded by CSL to commence 2013 through Victorian Cytology Service and Regional WHO Lab Melbourne</td>
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<tr>
<td></td>
<td>- Number of cancer specimens typed for HPV as a proportion of all cancers of that type diagnosed (aim for complete capture).</td>
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<td>- Analysis by age, histological type, Indigenous status and vaccination status.</td>
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<td></td>
<td>- The proportion of each cancer attributable to vaccine preventable and non-vaccine preventable HPV types.</td>
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<tr>
<td>Monitor the distribution of HPV genotypes detected in anogenital and oropharyngeal cancers</td>
<td>Prevalence of HPV by type in HPV related cancers specimens:</td>
<td>Nil.</td>
<td>N/A</td>
<td>N/A</td>
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