

Australian Government Department of Health and Aged Care



Human Papillomavirus (HPV) Surveillance and Monitoring Plan 2023

Prepared in consultation with the HPV Surveillance Working Group of the Communicable Diseases Network Australia (CDNA)

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Title: Human Papillomavirus (HPV) Surveillance and Monitoring Plan 2023

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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 aims of the program are to prevent HPV infection and HPV-related diseases. Persistent infection with an oncogenic HPV type can cause cervical cancer, anal cancer, other anogenital cancers and a subset of head and neck cancers. HPV vaccination, under the National Immunisation Program (NIP) was introduced in 2007. 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 females delivered in schools commenced in 2007 (Patel et al. 2018).

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. In January 2018, further changes were made to the program, in which a 2-dose course of the nonavalent HPV vaccine (Gardasil®9) replaced the quadrivalent program. The nonavalent HPV vaccine protects against the four HPV types targeted by the quadrivalent vaccine (types 6, 11, 16, 18) as well as HPV 31, 33, 45, 52 and 58. On 6 February 2023, the 2-dose HPV vaccine schedule was replaced with a single dose schedule using the same Gardasil®9 vaccine. Currently a single dose of the Gardasil®9 is funded under the NIP for adolescents aged 12 to 13 years. Adolescents who missed the HPV vaccination at 12 to 13 years of age can catch up for free until age 25 years. Current recommendations for HPV vaccination can be found in the HPV section of the <u>Australian Immunisation Handbook</u>.

There are approximately 200 known different types of HPV of which approximately 40 infect mucosal sites, such as the anogenital tract and oropharynx, The International Agency for Research on Cancer classifies 12 HPV types as definitely carcinogenic (types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59) and 1 further type (type 68) as probably carcinogenic and an addition 1 type (type 66) as possibly carcinogenic (IARC Working Group 2012). As the HPV vaccine does not protect against all oncogenic HPV types, vaccinated and unvaccinated women and people with a cervix need to continue to participate in routine cervical screening (DoHAC 2021). Australia's secondary prevention program for cervical cancer, the National Cervical Screening Program (NCSP) which was established in 1991, is aimed at reducing morbidity and mortality from cervical cancer. The NCSP achieves this through organised population-based screening to detect and, where necessary, treat precancerous cervical abnormalities in asymptomatic women and people with a cervix. The NCSP is supported by the NCSP Clinical Guidelines which provide recommendations for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding (Cancer Council Australia 2022).

From 1991 to 2017, the NCSP provided organised cervical screening through regular Pap testing (Papanicolaou cervical cytology) every 2 years, targeting people aged 20 to 69 years. In December 2017, the five-yearly Cervical Screening Test (CST) replaced the two-yearly Pap test in the NCSP, and the target age group was amended to people aged 25-74 years. In contrast to the Pap test, which was only able to detect cell changes in the cervix, the CST detects oncogenic HPV through molecular detection of DNA at levels predictive of the presence of precancerous cervical lesions (DoHAC 2021). HPV based screening is more sensitive and more objective than cytology-based screening and is expected to protect up to 30% more people (Lew JB et al. 2017). The CST incorporates partial genotyping, differentiating infection with HPV types 16 and 18 which are the most oncogenic HPV types and the most common causes of cervical cancer. If HPV is detected, reflex liquid-based cytology is performed on the sample to detect cervical cell changes. For those with HPV types other than 16 or 18, the cytology test supports risk allocation (intermediate or higher risk) to the participants and determines the next steps to be undertaken at the conclusion of the screening episode (Cancer Council Australia 2022). All those with HPV 16 or 18 infection detected are deemed to be at higher risk and referred for further assessment regardless of their cytology findings. More information on the Cervical Screening Pathway can be found at Appendix A. Another change is the collection of cervical screening data by the National Cancer Screening Register (NCSR) which provides a single electronic record for each Australian taking part in the NCSP replacing the previous eight jurisdictional screening registers from 2017/18. Driving ongoing improvements in data guality and completeness is a key NCSP priority to achieve more effective and meaningful program monitoring, reporting and evaluation (AIHW 2022). The NCSP is currently exploring opportunities to link NCSR data with broader population datasets including national data collections through the Australian Bureau of Statistics and vaccination records in the Australian Immunisation Register. This will provide further context to NCSR data and enable better monitoring of the program and ability to better identify and understand

where it requires improvements and adaptations to better meet the needs of priority populations and groups, as well as evaluate the impact of key interventions more comprehensively, such as vaccination.

From 1 July 2022, anyone eligible for a CST under the NCSP has the choice of HPV testing through selfcollection of a vaginal sample. Self-collection aims to increase participation in the NCSP by removing barriers to traditional screening faced by many people, including physical, cultural and psychosocial barriers. This is of particular importance for Aboriginal and Torres Strait Islander people, culturally and linguistically diverse people, people with disability, people who have experienced sexual violence and trauma, and gender and sexually diverse people. Self-collection of a vaginal sample as a screening choice is also a key strategy in supporting Australia's commitment to achieving equitable cervical cancer elimination by 2035 (DoHAC 2023).

Australia has aligned its goal of achieving elimination of cervical cancer as a public health problem with the World Health Organization's (WHO) 2030 goals of 90% vaccination of females, 70% of women screened by age 35 and again by age 45 with a high precision assay, and 90% of people requiring treatment receive it (WHO 2020). By 2035, Australia will achieve the following targets beyond the WHO goals:

- 1. extending the 90% HPV vaccination target to include males as well as females
- 2. extending the 70% screening target to 5-yearly participation for eligible 25- to 74-year-olds, rather than twice in a lifetime; and
- 3. lifting the target for treatment of cervical precancer and cancer to 95% receive optimal care, as a commitment to achieving elimination as equitably as possible, leaving no-one behind (DoHAC 2023).

Purpose and overview of this document

The HPV Surveillance Plan (the Plan) outlines key HPV surveillance objectives and indicators focused on monitoring circulating HPV types and HPV related diseases in the context of HPV vaccination under the NIP. The Plan presents an overarching summary of HPV surveillance in Australia and incorporates selected indicators and data sources from existing national programs. The Plan is intended to be a complementary resource to existing and issue specific reporting outlined in other documents and reports (see Additional Resources).

This document updates the 2013 HPV Surveillance Plan to include surveillance findings as at the end 2023 and reflect changes to HPV prevention programs, including:

- the replacement of the three-dose schedule of the quadrivalent vaccine by the single dose schedule of the nonavalent vaccine through the National Immunisation Program from early 2023
- changes to the National Cervical Screening Program, including the Cervical Screening Test, and introduction of the choice of self-collection of a vaginal sample for all eligible participants
- Australia's commitment to eliminate cervical cancer as a public health issue by 2035
- inclusion of gender-neutral programs and language; and
- incorporating the greater understanding of association of HPV with a range of oropharyngeal and anogenital cancers.

Table 1 outlines the surveillance objectives from the 2013 Plan and the current status of these as at the end of 2022. In addition, the table notes the surveillance objectives from the 2013 Plan that are included in this current iteration of the Plan. The surveillance objectives and indicators outlined in this document aim to complement and where appropriate, align with existing national strategies and monitoring approaches related to HPV, including the:

- National Bloodborne Viruses and Sexually Transmissible Infections Strategies and associated monitoring plan
- Cervical Cancer Elimination Progress Report
- National Strategy for the Elimination of Cervical Cancer in Australia
- National Immunisation Strategy for Australia
- National Preventative Health Strategy 2021-2030
- The Australian Cancer Plan
- National Aboriginal and Torres Strait Islander Health Plan
- The National Agreement on Closing the Gap
- Australian Cancer Plan

The Plan is divided into four sub-sections, which groups together the surveillance objectives. Under each objective, the rationale for surveillance, data considerations and how the objective will be measured (i.e. indicators) are described. Each objective includes at least 1 indicator which references relevant data sources for reporting available at the time of writing.

In addition to population-level data, indicators that focus on priority populations, including Aboriginal and Torres Strait Islander people and where data are available culturally and linguistically diverse populations, will be presented throughout the Plan. Along with routine national data collections, the Plan aims to utilise data from sentinel and research-based data collections, including the Genital Warts Surveillance Network (GWSN) and the National HPV Monitoring Program (IMPACT). Each data source will include a footnote indicating whether it is a national routine data collection or is through sentinel and research-based data collections.

A consolidated table of objectives and related indicators detailing the data custodian and data availability is at <u>Appendix B</u>.

It is important to note that the programs mentioned in the Plan were operational at the time of writing. Inclusion of programs in the Plan does not denote funding from the Australian Government Department of Health and Aged Care.

Specific populations

The Plan recognises the need to continue to enhance our understanding of HPV-related disease burden on specific populations, including Aboriginal and Torres Strait Islander people, people from culturally and linguistically diverse backgrounds, people who identify as LGBTIQA+¹, people with disability, people living in rural and remote areas and people at a higher medical risk from HPV infection (including those living with HIV and immunocompromised people such as transplant recipients and those on immunosuppressive medications for autoimmune diseases). These priority groups are consistent with the National Strategy for the Elimination of Cervical Cancer and are a priority for HPV surveillance overall as they may be at higher risk of HPV-related cancer and poorer health outcomes as a result.

These priority groups will be represented in reports against the Plan where data are available, with a view to improve representativeness in the long-term in HPV surveillance data.

Type specific HPV infection prevalence data are currently not able to be routinely collected for heterosexual men, for inclusion in ongoing surveillance. This is because suitable specimens are not routinely collected for other clinical purposes. At present dedicated intermittent clinical studies are suggested for monitoring HPV prevalence in this group, noting that monitoring of HPV prevalence amongst females will provide indicative monitoring of likely prevalence amongst their male sexual partners.

Considerations for Aboriginal and Torres Strait Islander people have been incorporated into the Plan to ensure relevant data collection (including the output of point of care testing for remote communities), analysis and reporting are carried out, and that these data are reviewed, reported, and interpreted with an appropriate cultural lens and following principles of Indigenous data governance.

Data gaps

Data sources presented in the Plan reflect data readily available through established surveillance projects and data collection through national programs, such as the NIP. Limitations with the current data sources include issues related to data completeness and representativeness of all priority populations. It is acknowledged that there may be HPV surveillance activities underway, with outputs not yet available for routine reporting purposes. One such example is the considerable work being undertaken in relation to linked data sources through the Person Level Integrated Data Asset (PLIDA) (formerly known as Multi-Agency Data Integration Project (MADIP)), including linkage with the Australian Immunisation Register (AIR). It is expected that research projects related to AIR-PLIDA will enable improved reporting for priority populations and completeness of existing national data sets. While data are not readily available at the

¹ LGBTIQA+ refers to lesbian, gay, bisexual, transgender, intersex, queer, asexual and other sexually or gender diverse. Other variations of this acronym exist. Acronym choice can vary depending on the groups or issues being discussed and the available evidence.

time of writing, it is anticipated that indicators will be included in future iterations of the Plan to capture these data as they become available.

Additional gaps in current surveillance include:

- no routine screening coverage data available for HPV infection at anatomical sites other than the cervix (through the NCSP);
- HPV type status is not routinely tested or in cancer specimens or reported to the eight State and Territory cancer registries for HPV-related cancers;
- HPV vaccination status is not currently recorded or linked into cancer data held in the jurisdictional cancer registries or the Australian Cancer Database (ACD);
- no current data linkage between AIR and the NSCR; however, it is expected that this will occur in the future as indicated in the *National Cancer Screening Act* 2016 (Australian Government 2016);
- no current data linkage between the ACD and PLIDA; however, this has been noted as a strategic priority in the National Strategy for the Elimination of Cervical Cancer (DoHAC 2023);
- specific HPV individual genotype data are not available for cervical cancer specimens or other anatomical sites (as noted above). Not all screening HPV tests which may precede a diagnosis of cervical cancer test for or record an individual's HPV genotype.

Further information on data gaps are provided at Appendix C.

Reporting

All measures will be disaggregated, where appropriate, by the following parameters: age, sex, state and territory, remoteness area of residence, socioeconomic status, Indigenous status, gender (male female, non-binary and people who are intersex), sexual orientation/identity (including people who identify as lesbian, gay, bisexual, transgender, queer or asexual), culturally and linguistically diverse status, disability status, people who are immunocompromised and vaccination status.

Governance and implementation

The Plan was developed through the HPV Surveillance Working Group a sub-group of the Communicable Diseases Network Australia (CDNA). The Working Group is comprised of experts in disease surveillance, vaccine research, immunisation programs, virology, and cancer screening, working across government and non-government organisations. The membership of the Working Group is provided at Appendix D.

The 2023 Plan was endorsed by CDNA on 26 January 2024 and noted by CDNAs parent committee the Australian Health Protection Principal Committee (AHPPC) on 5 April 2024.

The Plan will be reviewed to ensure currency and alignment with relevant national policy and strategies, which will be led by the Australian Government Department of Health and Aged Care in consultation with the HPV Surveillance Working Group.

Additional Resources

The below resources provide further information and methodologies

- National Strategy for the Elimination of Cervical Cancer in Australia
- <u>Human papillomavirus (HPV) immunisation data</u>
- National Cervical Screening Program monitoring report 2022
- <u>Cervical Cancer Elimination Progress Report</u>
- Australian Immunisation Register
- Immunisation coverage data and reports NCIRS
- <u>National HPV Monitoring Program (IMPACT)</u>
- Genital Warts Surveillance Network Report
- Juvenile onset Recurrent Respiratory Papillomatosis (JoRRP) APSU
- <u>Cancer data in Australia AIHW</u>
- National Cervical Screening Program Quality Framework
- Standards for Statistics on Cultural and Language Diversity ABS

HPV surveillance objectives and indicators

Table 1 outlines the surveillance objectives from the 2013 HPV Surveillance Plan and the current status as at the end of 2022. In addition, the table notes the surveillance objectives from the 2013 Plan that will be included in this current 2023 Plan.

Section	Surveillance Objective	Current status (as at end of 2022)	Revised HPV Surveillance Plan 2023 (objective)
Program monitoring	Monitor vaccine safety	An overall high level of safety has been reported for HPV vaccines since their inclusion in the NIP schedule. From 2007 to 2020, rates of adverse events following HPV vaccine administration in Australia were consistent with international data (NCIRS 2021; TGA 2010, Dey et al. 2022). Over 500 million HPV vaccine doses have been given globally.	Objective excluded. This is regularly reported through other mechanisms. Monitoring of vaccine adverse events continues through the Therapeutic Goods Administration <u>Safety</u> <u>monitoring: Medicines</u> Active surveillance is routinely undertaken and publicly reported through <u>AusVaxSafety</u> .
Program monitoring	Assess age-specific HPV vaccination coverage achieved in the ongoing 12–13- year-old program and the catch-up programs	Single dose HPV vaccination coverage among males at 15 years of age in Australia in 2021 and 2022 was 84.4% and 83.1%, respectively. Coverage in females at 15 years of age is even higher in 2021 and 2022 was 86.2% and 85.3%, respectively (NCIRS 2023).	Revised objective included. - (revised) Monitor HPV vaccination coverage See <u>section 1.1</u> .
Program monitoring	Monitor the uptake of cervical screening in the eligible population	Prior to the introduction of the renewed NCSP in 2017, 56% of eligible people aged 20–69 years participated in the program. From 2018–2022, 77% of the eligible people population aged 25–74 years had a HPV or LBC test for any reason (AIHW 2023).	Objective included . See <u>section 1.2</u> .

Table 1 2013 HPV Surveillance Plan

Section	Surveillance Objective	Current status (as at end of 2022)	Revised HPV Surveillance Plan 2023 (objective)		
Program monitoring	Monitor knowledge, attitudes and beliefs about HPV, HPV vaccination and cervical screening	Knowledge, attitudes and beliefs about HPV, HPV vaccination and cervical cytology screening have not been routinely monitored in Australia.	Objective excluded . The monitoring of knowledge, attitudes and beliefs has been excluded in this version of the Plan as it is outside the usual scope of a disease surveillance plan. Mechanisms for understanding barriers and strategies to improve vaccination uptake and cervical screening are outlined in the respective Strategy and Program Frameworks (DoHAC 2017, DoHAC 2018)		
Infection monitoring	Monitor the prevalence of HPV genotypes in the general female population Monitor the prevalence of HPV genotypes in the general male population	Females Among young females, the population prevalence of HPV, particularly 4vHPV types, has declined since the introduction of HPV vaccination in Australia. Prevalence of cervical HPV types targeted by the quadrivalent vaccine declined by 93% for females aged 18–24 years and 90% for females aged 25–35 years from 2007 to 2015 (Machalek et al. 2018). Of primary screening tests performed in 2022 in participants aged 25–74 years, 1.9% were positive for oncogenic HPV types 16 or 18 and 8.4% were positive for oncogenic HPV types other than 16 or 18 (AIHW 2023). Low and stable positivity of oncogenic HPV types 16 and 18 reflects the impact of the vaccine on prevalence. In contrast, screening HPV test positivity for oncogenic HPV types other than 16 or 18 varied considerably, depending on whether participants were of an age at which HPV vaccination was offered or not offered (AIHW 2023). <i>Males</i> HPV prevalence studies among males undertaken on a smaller scale than females, have reported reductions among in heterosexual men and men who have sex with men (MSM). As a result of herd protection, reductions in 4vHPV types have been reported in heterosexual males since the introduction of the female-only vaccination program in 2007 (Chow et al. 2017). Prevalence in this group has remained low, following the introduction of male vaccination in 2012 (Machalek et al. 2017). Among	Revised objective included. - (revised) Monitor the prevalence of HPV genotypes See <u>section 2.1</u> .		
nterim Australian Centre for Disease Control					

Section	Surveillance Objective	Current status (as at end of 2022)	Revised HPV Surveillance Plan 2023 (objective)
		young MSM, reductions in 4vHPV type prevalence in the anus, penis and oral cavity have been reported post-vaccination as compared with the period prior to 2012, declining by 76%, 52% and 90% respectively (Chow et al, 2021).	
Non- cancerous disease endpoints	Monitor the prevalence of genital warts	Diagnoses of genital warts have declined in all age groups and have declined significantly among the cohorts eligible for HPV vaccination. Through sentinel surveillance conducted at sexual health clinics, among Australian-born, non-Indigenous females aged 21 years and younger, diagnoses of genital warts decreased from 13.0% in 2006 to 0.7% in 2021, and among Australian-born, non-Indigenous heterosexual men, diagnoses decreased from 9.8% in 2006 to <0.1% in 2021. Among Australian-born, non-Indigenous gay and bisexual men aged 21 years and younger, diagnoses decreased since the introduction of the male vaccination in 2013, from 6.3% to 1.5% in 2021 for gay men and 6.9% to 2.0% for bisexual men over the same time-period. The proportion of Aboriginal and Torres Strait Islander females and males aged 21 years and younger presenting with genital warts at their first visit to sexual health clinics has declined from 5.0% to 0.0% and 5.4% to <0.1%, respectively, between 2006 and 2021 (Kirby Institute 2022).	Objective included. See <u>section 3.1.</u>
Non- cancerous disease endpoints	Monitor the incidence of recurrent respiratory papillomatosis (RRP)	The incidence of juvenile-onset recurrent respiratory papillomatosis (JoRRP) has decreased since the introduction of HPV vaccination onto the NIP schedule in 2007. In 2022, there was one case of this condition identified through national surveillance (Teutsch et al. 2023). Routine surveillance for JoRRP is conducted through the APSU. There is currently no surveillance of adult-onset RRP.	Objective included . See <u>section 3.2</u> .
Non- cancerous disease endpoints	Monitor the prevalence of screen-detected cervical abnormalities	Detection of high-grade abnormalities provides an opportunity for treatment before cancer can develop. The NCSP aims to detect and treat high-grade in order to reduce the incidence of cervical cancer.	Objective included . See <u>section 3.3</u> .

Section	Surveillance Objective	Current status (as at end of 2022)	Revised HPV Surveillance Plan 2023 (objective)
		Prior to the introduction of the renewed NCSP in 2017, detection of high- grade abnormalities in participants aged 25–29 years declined from 20.3 per 1,000 participants screened in 2013 to 15.9 in 2016. There were also modest declines for participants aged 30–34 years from 14.1 in 2014, to 13.5 in 2015 and to 12.6 in 2016.	
		In 2022, 14.2 participants with a high-grade abnormality were detected per 1,000 participants screened in the target age group (25–74 years). The high-grade abnormality detection rate was highest for participants aged 30–34 years (22.4 per 1,000) (AIHW 2023).	
		On 1 December 2017, Australia moved to a new NCSP which uses primary HPV nucleic acid testing (NAT) followed by reflex liquid-based cytology, this has resulted in higher rates of detection due to the increased sensitivity of HPV-based screening (Hawkes 2018, AIHW 2022).	
Non- cancerous disease endpoints	Monitor the distribution of HPV genotypes detected in high-grade cervical lesions	The National Cancer Screening Register (NCSR) records HPV result for screening HPV tests and histopathology results for those who go on to biopsy. This means that screening HPV result can be reported for those diagnosed with high grade lesions, although most assays do not report to the individual genotype level. There will be a high but imperfect correlation between the screening HPV test type and the HPV causing the lesion/s, currently there is no routine or ongoing analysis of these data nor ongoing surveillance using HPV typing of high-grade lesions (Callegari E et al. 2014, Cornall et al. 2020).	Objective included . See <u>section 3.4</u> .

Section	Surveillance Objective	Current status (as at end of 2022)	Revised HPV Surveillance Plan 2023 (objective)
Cancer endpoints	Monitor cervical cancer incidence and mortality	With the introduction of organised population-based cervical screening through the NCSP in 1991, the incidence of cervical cancer decreased from 20.2 new cases per 100,000 people aged 25–74 years in 1990 to 9.9 new cases per 100,000 people in 2002. Incidence has since remained steady at 10–11 cases per 100,000 from 2002 to 2019 (AIHW 2023).	Objective included . See <u>section 4.1</u> .
		Cervical cancer mortality in Australia has followed a similar trend. Cervical cancer mortality decreased from 5.6 deaths per 100,000 people aged 25–74 years in 1990 to 2.4 deaths per 100,000 people in 2002 and has since remained steady between 2.0 and 2.5 deaths per 100,000 from 2002 to 2021 (AIHW 2023).	
		Aboriginal and Torres Strait Islander women are disproportionately represented in these data. Over the 5 years 2014–2018, the age-standardised incidence and mortality rates were 2.0 and 3.8 times the rate of non-Indigenous Australians, respectively (AIHW 2022).	
		There is a lack of timeliness in the Australian Cancer Database (ACD) with data currently lagged by 5-years, with modelled estimates provided in the remaining years.	
Cancer endpoints	Monitor anogenital and oropharyngeal cancer incidence and mortality	In contrast with trends in cervical cancer rates, anal cancer incidence increased in Australia between 1982 and 2005 for both males and females (from 0.6 to 1.5 per 100,000 per year and from 1.0 to 1.7 per 100,000 per year, respectively). However, age-standardised incidence rates have plateaued between 2015 and 2019, which rates still low in 2019 at 1.4 for males and 2.1 for females (AIHW 2022).	Objective included . See <u>section 4.2</u> .
		Certain population groups are known to have higher than average anal cancer risk, namely persons living with HIV, men who have sex with men, females diagnosed with HPV-related gynaecological precancerous lesions or cancer, solid organ transplant recipients (SOTRs) and patients with autoimmune diseases (Clifford GM et al. 2021)	
		Cancers of the penis, anus, vagina and vulva are rare in Australia and have varying proportions attributable to HPV (50%, 85%, 70% and 40%, respectively), with their progression from HPV infection to cancer being less	

Section	Surveillance Objective	Current status (as at end of 2022)	Revised HPV Surveillance Plan 2023 (objective)
		well understood than that for cervical cancer (Grulich et al. 2010; AIHW 2021).	
Cancer endpoints	Monitor the distribution of HPV genotypes detected in cervical cancers	Prior to Australia's HPV vaccination program, cervical cancers in Australia, compared to international data, had slightly higher proportions of HPV 16/18 and slightly lower rates of HPV31/33/45/52/58 detected. This was likely due to Australia's cervical screening program increasing the proportion of adenocarcinomas detected, in which HPV 16/18 are more predominant, due to prevention of squamous cancers (Brotherton et al. 2017).	Objective included . See <u>section 4.3</u> .
Cancer endpoints	Monitor the distribution of HPV genotypes detected in anogenital and oropharyngeal cancers	The distribution of HPV genotypes detected in anogenital, and oropharyngeal cancers has not been routinely analysed in Australia. A retrospective Australian study testing 112 anal cancer specimens obtained between 1999 and 2009 reported that 90% were caused by 4vHPV types, with HPV 16 being most commonly detected (75%). 9vHPV types were detected in 96% of the samples, implying that nearly all HPV-associated anal cancer cases may be potentially preventable with 9vHPV vaccine (Patel et al. 2018).	Objective included . See <u>section 4.4</u> .

Abbreviations

ABS	Australian Bureau of Statistics
ACD	Australian Cancer Database
AIHW	Australian Institute of Health and Welfare
AIR	Australian Immunisation Register
APSU	Australian Paediatric Surveillance Unit
CDNA	Communicable Diseases Network Australia
CIN	Cervical intraepithelial neoplasia
CST	Cervical Screening Test
DoHAC	Department of Health and Aged Care
GWSN	Genital Warts Surveillance Network
HPV	Human papillomavirus
HSIL	High grade squamous intraepithelial lesions
JoRRP	Juvenile onset recurrent respiratory papillomatosis
LBC	Liquid-based cytology
MBS	Medicare Benefits Scheme
NCSP	National Cervical Screening Program
NCSR	National Cervical Screening Register
NIP	National Immunisation Program
NHMD	National Hospital Morbidity Database
NMD	National Morbidity Database
9vHPV	nonavalent human papillomavirus
4vHPV	quadrivalent human papillomavirus

Surveillance objectives

1. Program monitoring

- 1.1 Monitor HPV vaccination coverage
- 1.2 Monitor coverage of cervical screening

2. Infection monitoring

2.1 Monitor the prevalence of HPV genotypes

3. Non-cancer disease endpoints

4. Cancer endpoints

- 4.1 Monitor cervical cancer incidence and mortality
- 4.2 Monitor anogenital² and oropharyngeal³ 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 anogenital² and oropharyngeal³ cancers

³ Includes base of the tongue and HPV related head and neck cancers.

² Includes anal, penile, vulval and vaginal cancers.

Interim Australian Centre for Disease Control

1. Program monitoring

1.1. Monitor HPV vaccination coverage

Indicators

- Single dose HPV vaccination coverage assessed at 15 years of age
- Single dose HPV vaccination coverage for Aboriginal and Torres Strait Islander people assessed at 15 years of age

Rationale for surveillance

From February 2023, HPV vaccination under the NIP changed from a two-dose nonavalent HPV (9vHPV) vaccine to a single-dose schedule. Catch up vaccination under the NIP was extended from 19 years to 25 years (<26) using a single dose. The 9vHPV vaccine provides protection against the four HPV types (6, 11, 16 and 18) in the 4vHPV vaccine⁴ and an additional five oncogenic HPV types (31, 33, 45, 52 and 58), which are the next most frequently detected in cervical cancers globally, after HPV types 16 and 18.

Monitoring vaccination coverage aims to:

- Monitor progress against the National Cervical Cancer Elimination Strategy Vaccination Targets
- Identify groups or areas with lower vaccine uptake

Data considerations

The Australian Immunisation Register (AIR) is a national register that can record vaccinations for people of all ages given by a registered vaccination provider.

The HPV Register was established in 2008 to capture HPV vaccinations administered as part of the National Immunisation Program. In 2018, data held in the HPV Register were transferred to AIR. All HPV vaccinations given through school-based programs, as well as any HPV vaccinations given by other immunisation providers, are now reported directly to AIR.

Immunisation coverage is reported in individuals aged 15 years to allow for catch-up. Reporting coverage amongst 15-year-olds is consistent with World Health Organization reporting. The current WHO HPV Vaccine Coverage Monitoring Manual counts doses received before 15 years (WHO 2020b).

AIR data for HPV vaccination captures an in/out school flag and provider type. This will be considered in the monitoring if appropriate based on data availability and usability.

HPV vaccination status should be collected and reported against indicators below where available.

There is no current data linkage between AIR and the NSCR. However, there is work underway to establish this linkage.

Reporting against indicators

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	AIR⁵	Number of people who have received a single dose of HPV vaccine by age 15 years (estimated per birth cohort).	Services Australia	Annually
Denominator	AIR⁵	Total number of people aged 15 years per calendar year (birth cohort), registered in AIR ⁶ .	Services Australia	Annually

Single-dose vaccination coverage assessed at 15 years of age

Single dose HPV vaccination coverage for Aboriginal and Torres Strait Islander people assessed at 15 years of age

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	AIR⁵	Number of Aboriginal and Torres Strait Islander people who have received a single dose of HPV vaccine by age 15 years (estimated per birth cohort).	Services Australia	Annually
Denominator	AIR⁵	Total number Aboriginal and Torres Strait Islander people aged 15 years per calendar year (birth cohort), registered in AIR ⁶ .	Services Australia	Annually

⁵ Routine national data collection.

⁶ Individuals are automatically registered for AIR when enrolled in Medicare. Interim Australian Centre for Disease Control

Indicators

- Number of eligible people aged 25–74 years screened in a 5-year period as a percentage of eligible people in the population*
- Number of eligible Aboriginal and Torres Strait Islander people aged 25–74 years screened in a 5-year period as a percentage of eligible people in the Aboriginal and Torres Strait Islander population

*This is an existing indicator from the NCSP.

Rationale for surveillance

If detected, precancerous cervical abnormalities can be treated before progression to cancer. Higher coverage in cervical screening, through early detection and treatment of precancerous lesions, reduces the incidence of and mortality from cervical cancer. Monitoring the uptake of cervical screening aims to:

- Monitor progress against screening coverage targets
- Identify groups or areas with lower screening coverage

Data considerations

Under the renewed NCSP⁷, people aged 25 to 74 years are recommended to have a 5-yearly Cervical Screening Test. Data from the NCSP is held on the National Cancer Screening Register (NCSR). Following the replacement of state-based registers in 2017, the NCSR represents a single national database of cervical screening records under the NCSP.

The measure of coverage is to be calculated to include everyone who had an HPV or liquid based cytology (LBC) for any reason, including primary or repeat screening, investigation of signs or symptoms, test of cure, as part of a colposcopy, or for any other reason as specified in the clinical guidelines for cervical screening. The first 2 years of the renewed NCSP was a transition period in which people who had had a Pap test under the previous NCSP become due for their first screening HPV test, after which time they then moved to a 5-yearly screening interval.

The Australian Institute of Health and Welfare (AIHW) publishes an annual report on the performance of the NCSP, the <u>National Cervical Screening Program monitoring report</u> (formerly *Cervical Screening in Australia*). Performance indicators have been developed to support monitoring and reporting of the NCSP, including the indicator used to report against this objective.

HPV vaccination status should be collected and reported against these indicators where available. There is no current data linkage between AIR and the NSCR; however, there is work underway to establish this linkage.

Terminology regarding sex is reflective of the data available within the relevant data source.

Hysterectomy fractions

Hysterectomy fractions represent the proportion of females with an intact uterus (and cervix) at a particular age and are used to adjust the population for participation calculations. This is because females who have had a hysterectomy with their cervix removed do not require cervical screening. Since a substantial proportion (20%–30%) of eligible middle-aged and older people in Australia do not have an intact cervix, the population is adjusted to remove these, so that participation in cervical screening can be more accurately estimated. Hysterectomy fractions are calculated by the AIHW based on data from the National Hospital Morbidity Database (AIHW 2022).

⁷ This document uses the terms 'participants' when referring to data collected under the NCSP. For NSCP data, 'participant' refers to any person with a cervix. This may include women, transgender men, intersex people, and non-binary people.

Reporting against indicators

Number of eligible people aged 25–74 years screened in a 5-year period as a percentage of eligible people in the population

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	NCSR ⁸	Number of eligible people aged 25–74 years who had at least one primary screening or follow- up HPV test (or LBC for any other reason) in a 5-year period.	DoHAC	Annually
Denominator	ABS ⁸ , AIHW National Hysterectomy Fractions ⁸	Estimated resident population of eligible people aged 25–74 years averaged over the 5 years of the reporting period, adjusted for the estimated proportion of eligible people who have had a hysterectomy.	ABS; AIHW	Annually

Number of eligible Aboriginal and Torres Strait Islander people aged 25–74 years screened in a 5-year period as a percentage of eligible people in the Aboriginal and Torres Strait Islander population

Indicator components	Source	Description	Custodian/ stakeholder	Availability of data for reporting
Numerator	NCSR ⁸	Number of eligible Aboriginal and Torres Strait Islander people aged 25–74 years who had at least one primary screening or follow-up HPV test (or LBC for any other reason) in a 5-year period.	DoHAC	Annually
Denominator	ABS ⁸ , AIHW National Hysterectomy Fractions ⁸	Estimated resident population of eligible Aboriginal and Torres Strait Islander people aged 25–74 years averaged over the 5-years of the reporting period, adjusted for the estimated proportion of eligible people who have had a hysterectomy.	ABS; AIHW	Annually

2. Infection monitoring

2.1. Monitor the prevalence of HPV genotypes

Indicators

- Prevalence of HPV infection among people participating in the National Cervical Screening Program
- Prevalence of HPV infection among Aboriginal and Torres Strait Islander people participating in the National Cervical Screening Program
- Prevalence of HPV infection among young people (16–24 years) not yet eligible for cervical screening
- Prevalence of HPV infection among men who have sex with men

Rationale for surveillance

There are more than 200 different HPV genotypes. The 4vHPV vaccine used in the NIP from 2007–2018 provides protection against four HPV types (6, 11, 16 and 18), and the 9vHPV vaccine used in NIP since 2018 provides protection against an additional five oncogenic HPV types (31, 33, 45, 52 and 58). Monitoring the prevalence of HPV genotypes aims to:

- 1. monitor changes in the prevalence of vaccine-targeted HPV types to assess the effectiveness of the vaccination program in preventing infection with these HPV types
- 2. monitor changes in the prevalence of non-vaccine types to assess the effectiveness of the program in providing cross protection against non-vaccine types as well as monitoring cancer causing HPV types that are not vaccine preventable
- 3. monitor potential type replacement, where a previously uncommon non-vaccine genotype becomes more common, replacing the common HPV genotype targeted by the vaccine.

Data considerations

Under the NCSP⁹, eligible people aged 25 to 74 years are recommended to have an oncogenic HPV NAT test 5-yearly. Data on rates of vaccine targeted HPV types 16/18 and other oncogenic types (not 16/18) detected are reported to the NCSR, enabling passive monitoring of HPV genotypes among people attending screening. Following the replacement of state-based registers in 2017, the NCSR represents a single national database of cervical screening records under the NCSP. The NCSR is currently unable to report grouped or individual vaccine targeted HPV genotypes due to the use of grouped genotypes screening assays and a lack of systematic data collection fields where individuals genotyping data are available, this will need to be addressed to facilitate future reporting.

There is currently no equivalent, routine surveillance for other HPV sites such as oropharyngeal and anogenital regions, including for men who have sex with men, which can currently only be obtained using research studies of sentinel surveillance approaches.

Monitoring of HPV infection prevalence at the cervix amongst people too young for routine cervical screening (age <25 years), of particular importance for early monitoring of 9vHPV vaccine impacts, can be performed through sentinel surveillance as part of the National HPV Monitoring Program (IMPACT), or other dedicated research studies.

Numerator and denominators should not include 12-month/24-month follow up (test of cure) repeat HPV testing.

HPV vaccination status should be collected and reported against these indicators where available.

All data should be reported by Aboriginal and Torres Strait Islander status where available.

HPV genotype prevalence should be reported by HPV16/18 and other oncogenic type groupings as per the NCSP and by individual genotype where available.

Terminology regarding sex is reflective of the data available within the relevant data source.

⁹ This document uses the terms 'participants' when referring to data collected under the NCSP. For NSCP data, 'participant' refers to any person with a cervix. This may include women, transgender men, intersex people, and non-binary people.

Reporting against indicators

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	NCSR ¹⁰	Number of primary screening HPV tests that detected oncogenic HPV in people aged 25–74 years.	DoHAC	Quarterly
Denominator	NCSR ¹⁰	Number of people aged 25–74 years who had a screening HPV test (primary screening).	DoHAC	Quarterly

Prevalence of HPV infection among people participating in the National Cervical Screening Program

Prevalence of HPV infection among Aboriginal and Torres Strait Islander people participating in the National Cervical Screening Program

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	NCSR ¹⁰	Number of primary screening HPV tests among Aboriginal and Torres Strait Islander people aged 25–74 years that detected oncogenic HPV.	DoHAC	Quarterly
Denominator	NCSR ¹⁰	Number of Aboriginal and Torres Strait Islander people aged 25–74 years who had a screening HPV test (primary screening).	DoHAC	Quarterly

Prevalence of HPV infection among young people (16-24 years) not yet eligible for cervical screening

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	IMPACT ¹¹	Number of people aged 16–24 years participating in the National HPV monitoring program who have an anogenital ¹² HPV type detected.	IMPACT study group	Ad hoc
Denominator	IMPACT ¹¹	Number of people aged 16–24 years participating in the National HPV monitoring program.	IMPACT study group	Ad hoc

Prevalence of HPV infection among men who have sex with men

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	IMPACT ¹¹	Number of men who have sex with men aged 16–24 years participating in National HPV monitoring program who have an anogenital ¹² HPV type detected.	IMPACT study group	Ad hoc
Denominator	IMPACT ¹¹	Number of men who have sex with men aged 16–24 years participating in the National HPV monitoring program.	IMPACT study group	Ad hoc

 ¹¹ Sentinel/funding-based research data collection. The <u>National HPV Monitoring Program (IMPACT</u>) provides sentinel data on circulating HPV genotypes in Australia.
 ¹² For the purposes of this indicator data collection for anogenital includes HPV types 6, 11, 16 and 18.

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3. Non-cancer disease endpoints

3.1. Monitor the incidence of genital warts

Indicator

Genital wart incidence in sexual health clinic populations

Rationale for surveillance

At least 90% of genital warts are caused by two HPV types, HPV-6 and HPV-11, which are included in both the previously used 4vHPV vaccine, and the currently used 9vHPV vaccine in the NIP. As they are frequently visible, genital warts usually result in seeking of health care for treatment so are an early marker of the impact of the vaccination program on HPV infection rates at a population level.

Data considerations

Data on genital warts are not routinely collected, with the exception of hospitalisation data which only represent severe cases requiring hospital treatment. Dedicated research studies, including data collected through the Genital Warts Surveillance Network (GWSN) are required. Only a subset of clinics in the GWSN collect data on HPV vaccination status.

Data should be reported by age, sex, HPV vaccination status, Aboriginal and Torres Strait Islander status, sexual orientation and remoteness area of residence where available.

Reporting against indicator

Indicator components	Source	Description	Custodian/ stakeholder	Availability of data for reporting
Numerator	GWSN ¹³	Number of new patients diagnosed with genital warts at first visit to a participating sexual health clinic (by age and sex; vaccination status; Aboriginal and Torres Strait Islander status; sexual orientation; and remoteness area of residence).	Kirby Institute	Quarterly

Genital wart incidence in sexual health clinic populations

¹³ Sentinel/funding-based research data collection. The Genital Warts Surveillance Network (GWSN) Project, maintained by the Kirby Institute, is a sentinel surveillance system that monitors trends in the diagnosis of genital warts in Australia. The network comprises 55 sexual health clinics based in all states and territories. Routinely collected information at sexual health clinics includes data on demographics, sexual behaviour, wart diagnosis and (in a subset of clinics) HPV vaccination status. These data are extracted directly from patient management information systems at each clinic and are collated at the Kirby Institute (Callander et al. 2016).

Indicator components	Source	Description	Custodian/ stakeholder	Availability of data for reporting
Denominator	GWSN ¹³	Number of new patients seen at a participating sexual health clinic (by age and sex; vaccination status; Aboriginal and Torres Strait Islander status; sexual orientation; and remoteness area of residence).	Kirby Institute	Quarterly

3.2. Monitor the incidence of recurrent respiratory papillomatosis

Indicators

- Incidence of juvenile onset recurrent respiratory papillomatosis
- Incidence of juvenile onset recurrent respiratory papillomatosis in Aboriginal and Torres Strait Islander children
- HPV type in cases of juvenile onset recurrent respiratory papillomatosis
- HPV types in cases of juvenile onset recurrent respiratory papillomatosis in Aboriginal and Torres Strait Islander children
- Hospitalisations for benign neoplasm of larynx (coded using ICD code D14.1) by sex over time
- Hospitalisations for benign neoplasm of larynx (coded using ICD code D14.1) by Aboriginal and Torres Strait Islander status and sex over time

Rationale for surveillance

Recurrent respiratory papillomatosis (RRP) is a disease in which benign tumours grow in the air passages leading from the nose and mouth into the respiratory tract. RRP may occur in adults (adult-onset RRP) as well as infants and small children (juvenile-onset RRP) (NIDCD 2017).

The most common modes of transmission for HPV genotypes 6 and 11 are vertical transmission at birth, vertical transmission in utero and horizontal transmission via the child's environment. The age distribution of RRP is trimodal, with a first peak in children younger than 5 years, a second peak in adults between 20 and 40 years and a final peak in those around 64 years (Lépine C et al. 2020).

The mode of transmission for adults is not as well known. Some cases may acquire infection during infancy that remain latent until being triggered for unknown reasons in adulthood. Some circumstantial evidence suggests that RRP can develop after HPV is transmitted through oral sexual contact (NORD 2023).

RRP usually requires repeated surgical treatment and is associated with high morbidity and occasionally death. RRP is caused by HPV infection, with over 85% thought to be related to HPV-6 or 11 genotypes. HPV-11 appears to be associated with more aggressive clinical disease, especially in children (Novakovic et al. 2018).

Data considerations

The Australian Paediatric Surveillance Unit (APSU), funded by the Department of Health and Aged Care, is a national mechanism for monitoring rare paediatric diseases. APSU commenced surveillance of JoRRP in October 2011. Surveillance involves the reporting of cases via a monthly report card that is emailed to approximately 1500 paediatricians and other child health specialists. Through this mechanism, clinicians are asked to report any infant or child under the age of 15 years diagnosed with JoRRP. A follow-up questionnaire requesting further details is then forwarded to clinicians who report a case of JoRRP together with details on accessing HPV typing (APSU 2018). Data collected through this surveillance are reported annually to the Department of Health and Aged Care and are published in the regular APSU reports and in the peer-reviewed literature.

Noting that APSU surveillance of JoRRP was only established following the vaccination program, a complimentary mechanism for monitoring JoRRP prevalence through routinely collected hospitalisation data in Australia has been developed. This method involves the use of International Classification of Disease code D14.1 (benign neoplasm of the larynx), which was identified as a very sensitive and specific ICD-10 code for JoRRP (PPV 98.1%) and applying this to national hospital separations data. While there is currently no routine collection of this data, (Novakovic *et al.* 2016) conducted a 10 year-audit (2000–2013) of the prevalence of JoRRP using this method, which can be used as a baseline to compare post-vaccination prevalence.

APSU data on JoRRP should be reported by Aboriginal and Torres Strait Islander status where available. The current APSU JoRRP Case Report Form collects data on child and mother HPV vaccination status, this should be reported alongside indicators. Data should be reported by HPV genotype where available. The Plan notes the current gap in surveillance for adult-onset recurrent respiratory papillomatosis and the need to undertake research to validate the use of ICD codes for this disease to facilitate routine surveillance.

Reporting against indicators

Number of incident cases of juvenile onset recurrent respiratory papillomatosis in children aged 0– 14 years

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Single measure	APSU ¹⁴	Number of new cases of JoRRP notified in children aged 0–14 years.	APSU	Annual

Number of incident cases of juvenile onset recurrent respiratory papillomatosis in Aboriginal and Torres Strait Islander children aged 0–14 years

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Single measure	APSU ¹⁴	Number of new cases of JoRRP notified in Aboriginal and Torres Strait Islander children aged 0–14 years.	APSU	Annual

Number of incident cases of juvenile onset recurrent respiratory papillomatosis in children aged 0– 14 years by HPV type

Indicator components	Source		Description	Custodian/stakeholder	Availability of data for reporting
Single measure	APSU ¹⁴	Numb notifie childre by HP	er of new cases of d JoRRP cases in en aged 0–14 years, V type.	APSU	Annual

Number of incident cases of juvenile onset recurrent respiratory papillomatosis in Aboriginal and Torres Strait Islander children aged 0–14 years by HPV type

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Single measure	APSU ¹⁴	Number of new cases of notified JoRRP cases in Aboriginal and	APSU	Annual

¹⁴ Sentinel/funding-based research data collection.

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
		Torres Strait Islander children aged 0–14 years by HPV type.		

Hospitalisations for benign neoplasm of larynx (coded using ICD code D14.1) by sex over time

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	NHMD ¹⁵	Hospitalisations for benign neoplasm of larynx (coded using ICD code D14.1) in children aged 0–14 years, by sex.	AIHW	Annual
Denominator	ABS ¹⁵	Estimated resident population of children aged 0–14 years, by sex.	ABS	Quarterly

Hospitalisations for benign neoplasm of larynx (coded using ICD code D14.1) among Aboriginal and Torres Strait Islander children by sex over time

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	NHMD ¹⁵	Hospitalisations for benign neoplasm of larynx (coded using ICD code D14.1) among Aboriginal and Torres Strait Islander children aged 0–14 years, by sex.	AIHW	Annual
Denominator	ABS ¹⁵	Estimated resident Aboriginal and Torres Strait Islander population of children aged 0–14 years, by sex.	ABS	Quarterly

¹⁵ Routine national data collection.

3.3. Monitor the prevalence of screen-detected cervical abnormalities

Indicators

- Number of participants aged 25–74 years with a high-grade abnormality detected on histology in a calendar year per 1,000 participants screened*
- Number of Aboriginal and Torres Strait Islander participants aged 25–74 years with a high-grade abnormality detected on histology in a calendar year per 1,000 Aboriginal and Torres Strait Islander participants screened

*This is an existing indicator from the NCSP.

Rationale for surveillance

Detection of high-grade abnormalities provides an opportunity for treatment before cancer can develop.

Data considerations

As mentioned under surveillance objective 1.2, the NCSR is a national electronic infrastructure for the collection, storage, analysis and reporting of screening data for the NCSP**Error! Bookmark not defined.**. The NCSR operates to maintain a national database of cervical screening records; inviting eligible individuals to commence cervical screening when they turn 25 years; reminding participants when are they are due and overdue for cervical screening; and providing a participant's cervical screening history to laboratories to inform screening recommendations.

The Australian Institute of Health and Welfare (AIHW) publishes an annual report on the performance of the NCSP, the <u>National Cervical Screening Program monitoring report</u> (formerly *Cervical Screening in Australia*). Performance indicators have been developed to support monitoring and reporting of the NCSP, including the indicator used to report against this objective.

Where possible, rates by age group, HPV genotype (group or individual) and HPV vaccination status and HPV type should be provided.

Terminology regarding sex is reflective of the data available within the relevant data source.

Reporting against indicators

Number of participants ¹⁶ aged 25–74 years with a high-grade abnormality detected on	histology i	n a
calendar year per 1,000 participants screened.		

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	NCSR ¹⁷	Number of participants ¹⁶ aged 25–74 years with a high-grade abnormality detected on histology in a calendar year.	DoHAC	Annually
Denominator	NCSR ¹⁷	Number of participants ¹⁶ aged 25–74 years screened in a calendar year.	DoHAC	Annually

Number of Aboriginal and Torres Strait Islander participants16 aged 25–74 years with a high-grade abnormality detected on histology in a calendar year per 1,000 Aboriginal and Torres Strait Islander participants screened.

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	NCSR ¹⁷	Number of Aboriginal and Torres Strait Islander participants ¹⁶ aged 25–74 years with a high-grade abnormality detected on histology in a calendar year.	DoHAC	Annually
Denominator	NCSR ¹⁷	Number of Aboriginal and Torres Strait Islander participants ¹⁶ aged 25–74 years screened in a calendar year.	DoHAC	Annually

¹⁶ This document uses the terms 'participants' when referring to data collected under the NCSP. For NSCP data, 'participant' refers to any person with a cervix. This may include transgender men, intersex people, and non-binary people.

¹⁷ Routine national data collection.

3.4. Monitor the distribution of HPV genotypes detected in highgrade cervical lesions

Indicators

- Prevalence of HPV by type in participants where a high-grade abnormality is detected on histology
- Prevalence of HPV by type in Aboriginal and Torres Strait Islander participants where a high-grade abnormality is detected on histology

Rationale for surveillance

Genotype specific 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 CIN3 lesions are definitively diagnosed lesions with true cancerous potential unlike CIN2 lesions or cytologically predicted high-grade smears.

Data considerations

The Plan notes the complexities in attributing and reporting on causative HPV genotypes in high-grade lesions. This indicator is a proxy for definitive genotyping data of high-grade lesions themselves and a validation study should be undertaken to assess the likely extent of correlation between the two methods. Additionally, only some laboratories currently utilise assays that can report to the level of single HPV genotype and these data are not always reported to the NCSR and are not easily extractable for analysis at present.

These indicators should be reported by age group.

HPV vaccination status should be collected and reported against these indicators where available.

Reporting against indicators

Prevalence of HPV by type in participants with histologically proven high grade squamous intraepithelial lesions (HSIL) or adenocarcinoma in situ (AIS)

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	NCSR ¹⁸	Number of histologically confirmed CIN III/HSIL/AIS, by HPV type detected in the primary screening test.	DoHAC	Quarterly
Denominator	NCSR ¹⁸	Number of histologically confirmed CIN III/HSIL/AIS.	DoHAC	Quarterly

¹⁸ Routine national data collection.

Prevalence of HPV by type in Aboriginal and Torres Strait Islander participants with histologically proven high-grade squamous intraepithelial lesions (HSIL) or adenocarcinoma in situ (AIS)

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	NCSR ¹⁹	Number of histologically confirmed CIN III/HSIL/AIS, by Aboriginal and Torres Strait Islander status and HPV type detected in the primary screening test.	DoHAC	Quarterly
Denominator	NCSR ¹⁹	Number of histologically confirmed CIN III/HSIL/AIS, by Aboriginal and Torres Strait Islander status.	DoHAC	Quarterly

¹⁹ Routine national data collection

4. Cancer endpoints

4.1. Monitor cervical cancer incidence and mortality

Indicators

- Number of new cases of cervical cancer by type of cancer and vaccination status in females aged 25– 74 years per 100,000 estimated resident population in a calendar year
- Number of new cases of cervical cancer by type of cancer and vaccination status in Aboriginal and Torres Strait Islander females aged 25–74 years per 100,000 estimated resident Indigenous population in a calendar year
- Number of deaths from cervical cancer by type of cancer and vaccination status in females aged 25–74 years per 100,000 estimated resident population in a calendar year*
- Number of deaths from cervical cancer by type of cancer and vaccination status in Aboriginal and Torres Strait Islander females aged 25–74 years per 100,000 estimated resident Indigenous population in a calendar year

*This is an existing indicator from the NCSP.

Rationale for surveillance

To monitor the impact of the HPV vaccination program on the incidence of cervical cancer. Given the natural history of HPV related cancers, the impact of vaccination on the prevention of cervical cancer will be evident from around 10 to 15 years after introduction of the vaccination program.

Data considerations

Cancer is a notifiable disease in all Australian jurisdictions which requires notification of all new cases of cancer to the jurisdiction's central cancer registry. These registries supply data annually to the Australian Institute of Health and Welfare (AIHW) who produces the Australian Cancer Database (ACD).

The National Mortality Database holds records for deaths in Australia. The cause of death data are sourced from the Registrars of Births, Deaths and Marriages in each state and territory, the National Coronial Information System and complied and coded by the Australian Bureau of Statistics (ABS).

The Plan notes the delay in data within the ACD with a current average delay of 5-years. The National Strategy for the Elimination of Cervical Cancer highlights a strategic priority to increase timeliness of cervical cancer data with an aim to have data from the preceding year available by November 1 of each calendar year. The Strategy also outlines the expansion of data collection for priority populations mentioned in the <u>Data gaps</u> section of this Plan. These priority populations should be reported in this indicator when data are made available.

HPV vaccination status should be collected and reported against these indicators where available. Cervical cancer type should also be reported here due to certain cervical cancers (notably some rarer types of adenocarcinoma) not being associated with HPV and therefore not preventable through HPV vaccination.

Rates by age group, summed over several calendar years where necessary to accommodate low numbers, should also be reported given that vaccine impact will occur in the youngest cohorts first.

Where available, these rates should be age adjusted against the world population to facilitate international comparisons and progress against WHO elimination targets.

Terminology regarding sex is reflective of the data available within the relevant data source.

Reporting against indicators

Number of new cases of cervical cancer by type of cancer and vaccination status in females aged
25-74 years per 100,000 estimated resident female population aged 25-74 years in a calendar year

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	ACD ²⁰	Number of new cases of cervical cancer by type of cancer and vaccination status in females aged 25–74 years in a calendar year.	AIHW	Annually
Denominator	ABS ²⁰	Estimated resident female population aged 25–74 years.	ABS	Annually

Number of new cases of cervical cancer by type of cancer and vaccination status in Aboriginal and Torres Strait Islander females aged 25–74 years per 100,000 estimated resident Aboriginal and Torres Strait Islander female population aged 25–74 years in a calendar year

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	ACD ²⁰	Number of new cases of cervical cancer by type of cancer and vaccination status in Aboriginal and Torres Strait Islander females aged 25–74 years in a calendar year.	AIHW	Annually
Denominator	ABS ²⁰	Estimated resident Aboriginal and Torres Strait Islander female population aged 25–74 years.	ABS	Annually

Number of deaths from cervical cancer by type of cancer and vaccination status in females aged 25–74 years per 100,000 estimated resident female population aged 25–74 years in a calendar year

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	NMD ²⁰	The number of deaths from cervical cancer by type of cancer and vaccination status in females aged 25–74 years in a calendar year.	AIHW	Annually
Denominator	ABS ²⁰	Estimated resident population for females aged 25–74 years.	ABS	Annually

²⁰ Routine national data collection.

Number of deaths from cervical cancer by type of cancer and vaccination status in Aboriginal and Torres Strait Islander females aged 25–74 years per 100,000 estimated resident Aboriginal and Torres Strait Islander female population aged 25–74 years in a calendar year

Indicator components	Source	Description	Custodian/stakeholder	Availability of data for reporting
Numerator	NMD ²¹	The number of deaths from cervical cancer by type of cancer and vaccination status in Aboriginal and Torres Strait Islander females aged 25–74 years in a calendar year.	AIHW	Annually
Denominator	ABS ²¹	Estimated resident Aboriginal and Torres Strait Islander female population aged 25–74 years.	ABS	Annually

²¹ Routine national data collection.

4.2. Monitor anogenital²² and oropharyngeal²³ cancer incidence and mortality

Indicators

- The number of new cases of anogenital and oropharyngeal cancer, by age, type, vaccination status and sex per 100,000 estimated resident population in a calendar year
- The number of new cases of anogenital and oropharyngeal cancer in Aboriginal and Torres Strait Islanders, by age, type, vaccination status and sex per 100,000 estimated resident Aboriginal and Torres Strait Islander population in a calendar year
- The number of deaths caused by anogenital and oropharyngeal cancer, by age, type, vaccination status and sex per 100,000 estimated resident population in a calendar year
- The number of deaths caused by anogenital and oropharyngeal cancer in Aboriginal and Torres Strait Islanders, by age, type, vaccination status and sex per 100,000 estimated resident Aboriginal and Torres Strait Islander population in a calendar year

*Data to be reported for all cancers indicated in the indicator and separately for each cancer.

Rationale for surveillance

To monitor the impact of the HPV vaccination program on the incidence of HPV related anogenital and oropharyngeal cancers including vaginal, vulval, anal, base of the tongue, head and neck cancers. Given the natural history of these HPV related cancers (which have an older median age of onset than cervical cancers), the impact of vaccination on the prevention of HPV related anogenital and oropharyngeal cancers may become evident until at least 20 years after introduction of the vaccination program (Wei et al. 2023).

Data considerations

Anogenital and oropharyngeal cancers can be caused by a number of risk factors, including HPV infection. While cancer data are routinely collected and reported, the data does not indicate the cause of the cancer. As an interim solution for reporting against this surveillance objective, data from the Australian Cancer Database (ACD) will be used as a proxy. ICD codes that are more specific to HPV-related cancers (e.g. of the head and neck) are available and data should be presented by these recommended ICD code groupings (Hocking et al. 2011, Senkomago et al. 2019).

HPV vaccination status should be collected and reported against these indicators where available.

Several research projects and pilot studies are being funded in anal cancer screening. Where suitable data and research become available, it should be considered for suitability in reporting against indicators that could be developed to monitor HPV prevalence and disease amongst groups at highest risk of anal cancer.

Terminology regarding sex is reflective of the data available within the relevant data source.

²² Includes anal, penile, vaginal and vulval cancers.

²³ Includes base of the tongue and HPV related head and neck cancers.

Reporting against indicators

Number of new cases of anogenital and oropharyngeal cancer by age, type, vaccination status and sex per 100,000 estimated resident population in a calendar year.

Indicator components	Source	Description	Custodian/ stakeholder	Availability of data for reporting
Numerator	ACD ²⁴	Number of new cases of anogenital and oropharyngeal cancer* in a calendar year by age, type, vaccination status and sex.	AIHW	Annually
Denominator	ABS ²⁴	Estimated resident population, by age and sex.	ABS	Annually

* Presented separately by ICD code groupings for vaginal, vulval, penile, anal and oropharyngeal cancers

Number of new cases of anogenital and oropharyngeal cancer in Aboriginal and Torres Strait Islanders, by age, type, vaccination status and sex per 100,000 estimated resident Aboriginal and Torres Strait Islander population in a calendar year

Indicator components	Source	Description	Custodian/ stakeholder	Availability of data for reporting
Numerator	ACD ²⁴	Number of new cases of anogenital and oropharyngeal cancer* in Aboriginal and Torres Strait Islander people in a calendar year, by age, type, vaccination status and sex.	AIHW	Annually
Denominator	ABS ²⁴	Estimated resident Aboriginal and Torres Strait Islander population, by age and sex.	ABS	Annually

* Presented separately by ICD code groupings for vaginal, vulval, penile, anal and oropharyngeal cancer

²⁴ Routine national data collection.

The number of deaths caused by anogenital and oropharyngeal cancer, by age, type, vaccination and sex per 100,000 estimated resident population in a calendar year

Indicator components	Source	Description	Custodian/ stakeholder	Availability of data for reporting
Numerator	NMD ²⁵	Number of deaths caused by anogenital and oropharyngeal cancer* in a calendar year, by age, type, vaccination status and sex.	AIHW	Annually
Denominator	ABS ²⁵	Estimated resident population, by age and sex.	ABS	Annually

* Presented separately by ICD code groupings for vaginal, vulval, penile, anal and oropharyngeal cancers

The number of deaths caused by anogenital and oropharyngeal cancer in Aboriginal and Torres Strait Islanders, by age, type, vaccination status and sex per 100,000 estimated resident Aboriginal and Torres Strait Islander population in a calendar year

Indicator components	Source	Description	Custodian/ stakeholder	Availability of data for reporting
Numerator	NMD ²⁵	Number of deaths caused by anogenital and oropharyngeal cancer* in Aboriginal and Torres Strait Islander people in a calendar year, by age, type, vaccination status and sex.	AIHW	Annually
Denominator	ABS ²⁵	Estimated resident Aboriginal and Torres Strait Islander population, by age and sex.	ABS	Annually

* Presented separately by ICD code groupings for vaginal, vulval, penile, anal and oropharyngeal cancers

²⁵ Routine national data collection.

4.3. Monitor the distribution of HPV genotypes detected in cervical cancers

Indicators

- Prevalence of HPV, by type, age, sex and vaccination status, in cervical cancer specimens.
- Prevalence of HPV, by type, age, sex and vaccination status, in cervical cancer specimens from Aboriginal and Torres Strait Islander females

Rationale for surveillance

To monitor the:

- prevalence of vaccine and non-vaccine HPV types in cervical cancer over time at the population level.
- proportion of cervical cancer that is potentially vaccine preventable over time.

Data considerations

Routine data are not yet available to support the reporting of this indicator and this space should be noted for development in the future. In the interim, sentinel surveillance or research studies are important to monitor vaccine impact on cancers. Once available, data should be reported per histological cervical cancer type.

4.4. Monitor the distribution of HPV genotypes detected in anogenital²⁶ and oropharyngeal²⁷ cancers

Indicators

- Prevalence of HPV, by type, age, sex and vaccination status, in anogenital cancer specimens
- Prevalence of HPV, by type, age, sex and vaccination status, in anogenital cancer specimens from Aboriginal and Torres Strait Islander people
- Prevalence of HPV, by type, age, sex and vaccination status, in oropharyngeal cancer specimens
- Prevalence of HPV, by type, age, sex and vaccination status, in oropharyngeal cancer specimens from Aboriginal and Torres Strait Islander people

Rationale for surveillance

To monitor the:

- prevalence of vaccine and non-vaccine HPV types in anogenital and oropharyngeal cancer over time at the population level.
- proportion of anogenital and oropharyngeal cancers that are potentially vaccine preventable over time.

Data considerations

Cancers of the anogenital and oropharyngeal regions have varying proportions attributable to HPV, with their progression from HPV infection to cancer being less well understood than for cervical cancer.

Data are not yet available to support the reporting of this performance indicator, and this space should be noted for development in the future. In the interim, sentinel surveillance or research studies are important to provide baseline data and monitor vaccine impact on cancers. Once available, data should be reported per cancer type (e.g. vaginal, vulval, anal, penile, oropharyngeal)

²⁶ Includes anal, penile, vaginal and vulval cancers.

²⁷ Includes base of the tongue and HPV related head and neck cancers.

Appendix A – Cervical Screening Pathway



CERVICAL SCREENING PATHWAY (CLINICIAN COLLECTED OR SELF-COLLECTED)

Suggested citation: Cancer Council Australia Cenvical Cancer Screening Working Party. Clinical pathway: Cenvical screening pathway: National Cenvical Screening Program: Guidelines for the management of screen detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding. CCX 2016. Accessible from http://wiki.cancer.org.au/australia/Guidelines.Cenvical_cancer/Screening. Updated Dec 2020.

NATIONAL CERVICAL SCREENING PROGRAM Ajor Austilia, Data and Tentoy Genermant Program



Appendix B – Summary of objectives and indicators

Objectives	Indicators	Data custodian/s	Data availability
1.1. Monitor HPV vaccination coverage	 Single dose HPV vaccination coverage assessed at 15 years of age Single dose HPV vaccination coverage for Aboriginal and Torres Strait Islander people assessed at 15 years of age 	Services Australia	Annually
1.2. Monitor coverage of cervical screening	 Number of eligible people aged 25–74 years screened in a 5-year period as a percentage of eligible people in the population Number of eligible Aboriginal and Torres Strait Islander people aged 25–74 years screened in a 5-year period as a percentage of eligible people in the Aboriginal and Torres Strait Islander population 	DoHAC/ABS/AIHW	Annually
2.1. Monitor the prevalence of HPV genotypes	 Prevalence of HPV infection among people participating in the National Cervical Screening Program Prevalence of HPV infection among Aboriginal and Torres Strait Islander people participating in the National Cervical Screening Program Prevalence of HPV infection among young people (16–24 years) not yet eligible for cervical screening Prevalence of HPV infection among men who have sex with men 	DoHAC/IMPACT study group	Quarterly/Ad hoc
3.1. Monitor the incidence of genital warts	Genital wart incidence in sexual health clinic populations	Kirby Institute	Quarterly
3.2. Monitor the incidence of recurrent respiratory papillomatosis	 Incidence of juvenile onset recurrent respiratory papillomatosis Incidence of juvenile onset recurrent respiratory papillomatosis in Aboriginal and Torres Strait Islander children HPV type in cases of juvenile onset recurrent respiratory papillomatosis HPV types in cases of juvenile onset recurrent respiratory papillomatosis in Aboriginal and Torres Strait Islander children Hospitalisations for benign neoplasm of larynx (coded using ICD code D14.1) by age and sex over time 	APSU/ABS/AIHW	Annually/Quarterly

Objectives	Indicators	Data custodian/s	Data availability
	 Hospitalisations for benign neoplasm of larynx (coded using ICD code D14.1) by Aboriginal and Torres Strait Islander status, age and sex over time 		
3.3. Monitor the prevalence of screen-detected cervical abnormalities	 Number of participants aged 25–74 years with a high-grade abnormality detected on histology in a calendar year per 1,000 participants screened Number of Aboriginal and Torres Strait Islander participants aged 25–74 with a high-grade abnormality detected on histology in a calendar year per 1,000 Aboriginal and Torres Strait Islander participants screened 	DoHAC	Annually
3.4. Monitor the distribution of HPV genotypes detected in high- grade cervical lesions	 Prevalence of HPV by type in participants where a high-grade abnormality is detected on histology Prevalence of HPV by type in Aboriginal and Torres Strait Islander participants where a high-grade abnormality is detected on histology 	DoHAC	Quarterly
4.1. Monitor cervical cancer incidence and mortality	 Number of new cases of cervical cancer by type of cancer and vaccination status in females aged 25–74 years per 100,000 estimated resident population in a calendar year. Number of new cases of cervical cancer by type of cancer and vaccination status in Aboriginal and Torres Strait Islander females aged 25–74 years per 100,000 estimated resident Indigenous population in a calendar year Number of deaths from cervical cancer by type of cancer and vaccination status in females aged 25–74 years per 100,000 estimated resident Indigenous population in a calendar year Number of deaths from cervical cancer by type of cancer and vaccination status in females aged 25–74 years per 100,000 estimated resident population in a calendar year* Number of deaths from cervical cancer by type of cancer and vaccination status in Aboriginal and Torres Strait Islander females aged 25–74 years per 100,000 estimated resident Indigenous population in a calendar year 	AIHW/ABS	Annually

Objectives	Indicators	Data custodian/s	Data availability
4.2. Monitor anogenital and oropharyngeal cancer incidence and mortality	 The number of new cases of anogenital and oropharyngeal cancer, by age, type, vaccination status and sex per 100,000 estimated resident population in a calendar year The number of new cases of anogenital and oropharyngeal cancer in Aboriginal and Torres Strait Islanders, by age, type, vaccination status and sex per 100,000 estimated resident Aboriginal and Torres Strait Islander population in a calendar year The number of deaths caused by anogenital and oropharyngeal cancer in cancer, by age, type, vaccination status and sex per 100,000 estimated resident population in a calendar year The number of deaths caused by anogenital and oropharyngeal cancer, by age, type, vaccination status and sex per 100,000 estimated resident population in a calendar year The number of deaths caused by anogenital and oropharyngeal cancer in Aboriginal and Torres Strait Islanders, by age, type, vaccination status and sex per 100,000 estimated resident population in a calendar year 	AIHW/ABS	Annually
4.3. Monitor the distribution of HPV genotypes detected in cervical cancers	 Prevalence of HPV, by type, age, sex and vaccination status, in cervical cancer specimens. Prevalence of HPV, by type, age, sex and vaccination status, in cervical cancer specimens from Aboriginal and Torres Strait Islander females 	No data available	N/A
4.4. Monitor the distribution of HPV genotypes detected in anogenital and oropharyngeal cancers	 Prevalence of HPV, by type, age, sex and vaccination status, in anogenital cancer specimens Prevalence of HPV, by type, age, sex and vaccination status, in anogenital cancer specimens from Aboriginal and Torres Strait Islander people Prevalence of HPV, by type, age, sex and vaccination status, in oropharyngeal cancer specimens Prevalence of HPV, by type, age, sex and vaccination status, in oropharyngeal cancer specimens from Aboriginal and Torres Strait Islander status, in oropharyngeal cancer specimens from Aboriginal and Torres Strait Islander people 	No data available	N/A

Appendix C – Data gaps

Identified Data Gaps	Notes
No routine screening coverage data available for HPV infection at anatomical sites other than the cervix, such as oropharyngeal and anogenital regions.	Continuous surveillance may not be necessary; periodic sentinel surveillance may suffice. Several research projects and pilot studies are being funded in anal cancer screening.
HPV type status is not routinely tested for in cancer specimens or reported for HPV related cancers.	Need to develop routine typing and reporting to cancer registries for incorporation into the Australian Cancer Database (ACD). This is highlighted in the National Strategy for the Elimination of Cervical Cancer in Australia under strategic priority 7.10.2.
ACD delay of 5 years for data availability.	The National Strategy for the Elimination of Cervical Cancer highlights a strategic priority to increase timeliness of cervical cancer data with an aim to have data from the preceding year available by November 1 of each calendar year. Requires further exploration for other HPV related cancers.
HPV vaccination status is not routinely available in some national data sets, such as the ACD (for HPV related cancers) and the National Cervical Cancer Screening Register (NCSR).	Data linkage between Australian Immunisation Register (AIR) and the NCSR is currently underway.
Limited data on priority populations and opportunities for disaggregation of national data collections related to HPV vaccination, infection and related disease.	Work being undertaken in relation to linked data sources through the Person Level Integrated Data Asset (PLIDA) including linkage with AIR. It is expected that research projects related to AIR-PLIDA will enable improved reporting for priority populations and completeness of existing national data sets. Data linkage between the ACD and PLIDA has been noted as a strategic priority in the National Strategy for the Elimination of Cervical Cancer
Data on adult-onset recurrent respiratory papillomatosis not routinely available.	Need to undertake research to validate the use of ICD codes to facilitate routine surveillance.
Definitive genotyping data of high-grade lesions. Only some laboratories currently utilise assays that can report to the level of single HPV genotype are not always reported to the NCSR and are not easily extractable for analysis at present.	Further investigation required.

Appendix D – Membership

Name	Organisation	
Government representatives		
Stephen Lambert	Queensland Health	
Vicky Sheppeard	New South Wales Health	
Rosalind Webby	Northern Territory Health	
Donna Mak	Western Australia Department of Health	
Jon Moore	Tasmanian Department of Health	
Alison Budd	Screening analysis and monitoring unit, AIHW	
Dejan Krstik	Cervical Screening Section, DoHAC	
Tom Watson (proxy Allison Cairns)	Immunisation Policy Section, DoHAC	
Kate Ward	First Nations Health Division, DoHAC	
Amy Bright (Chair)	Communicable Disease Epidemiology and Surveillance Section, DoHAC	
Louise Blunden (Secretariat)	Communicable Disease Epidemiology and Surveillance Section, DoHAC	
Non-government representatives		
Dorothy Machalek	Kirby Institute, UNSW	
Suzanne Garland	The Royal Woman's Hospital, NHMRC Centre for Research Excellence in Cervical Cancer Control	
Julia Brotherton	University of Melbourne, Professional Fellow NCIRS, NHMRC Centre for Research Excellence in Cervical Cancer Control	
David Hawkes	Australian Centre for Prevention of Cervical Cancer	
Marion Saville	Australian Centre for Prevention of Cervical Cancer, NHMRC Centre for Research Excellence in Cervical Cancer Control	
Skye McGregor	Kirby Institute, UNSW	

Name	Organisation
Kristine Macartney	National Centre for Immunisation Research and Surveillance
Michelle Giles	Australian Technical Advisory Group on Immunisation representative
Nick Silberstein	Australian Technical Advisory Group on Immunisation representative

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