



## INFORMATION FOR RESEARCHERS REQUESTING DATA FROM THE NHVPR

### What is the NHVPR?

The National Human Papillomavirus Vaccination Program Register (NHVPR) is the Australian register which records HPV vaccine doses delivered as part of the National HPV Vaccination Program. The Program commenced in 2007 offering HPV vaccine to girls in the first year of high school (at age 12-13 years). A catch up program for females up to the age of 26 ran from 2007-2009. In 2013, the Program was expanded to include vaccinations for males in the first year of high school (at age 12-13 years). A catch up program for males aged 14-15 years ran in 2013 and 2014.

### Who can access NHVPR data?

The NHVPR is owned by the Australian Government Department of Health (DOH) and operated by VCS Ltd. **All requests for data from the NHVPR must be approved by the DOH.**

### NHVPR purposes

The purposes of the NHVPR, as defined by the National Health Amendment (National HPV Vaccination Program Register) Act 2007, are to ensure the successful implementation of the National Human Papillomavirus (HPV) Vaccination Program, and in doing so facilitate:

- i. establishment and maintenance of an electronic database of records for monitoring vaccination of participants in the HPV Program;
- ii. monitoring of the effectiveness of HPV vaccine in preventing certain cervical cancers by allowing for future cross referencing of data against Pap Smear and other cervical cytology or cervical cancer registers maintained by States and Territories;
- iii. establishment of mechanisms to advise eligible persons, or the parents or guardians of children, if doses of HPV vaccine have been missed or if booster doses are required in the future;
- iv. maintenance of a record of the HPV vaccination status of eligible persons for the purposes of certifying the completion of the course of vaccination; and,
- v. promotion of the health and wellbeing of persons by providing information on new developments associated with the Program to vaccination providers, eligible persons and parents or guardians of children.

Thus the legislation does not state that a primary function of the register is to provide data for research purposes. However analysis and dissemination of registry data would be required to fulfil the functions of items (ii) monitoring of effectiveness and (v) promotion of health and wellbeing by producing information. The accompanying explanatory memorandum flags that 'De-identified statistical information may also be published to raise awareness in the general population'.

### Information stored by the NHVPR

The NHVPR records notifications of HPV vaccines received by eligible persons in Australia, primarily as part of the National HPV Vaccination Program (doses paid for privately outside of the program may also be reported to the Register). A complete vaccination course consists of three doses of HPV vaccine and the Register matches individual vaccination dose notifications received to individuals on the register to assess vaccination completion.





The target population for the National HPV Vaccination Program 2007-2009 was all females aged 12-26 years in this period i.e. DOB July 1980 to 1997 (the general practice/community based program for women aged up to 26 commenced July 2007.) The ongoing target population is females in the first year of high school (usually aged 12-13 years) and, from 2013, males in the first year of high school and 2013/2014 two 'catch up cohorts' of boys in their second and third year of high school. For doses delivered in school based programs, notification of doses to the Register should be close to complete (data transfer from State/Territory administered school-based programs should be complete but some consumers may 'opt-off' and not consent to transfer of their data to the NHVPR). For doses delivered in general practice and other community based settings, notification of doses may not be complete. Vaccine providers are required to seek patient consent to notify the register of their doses. GPs received an incentive notification payment of \$6 per dose for doses administered on or before 31st December 2009 and notified before June 2010. Vaccine recipients may opt off the Register at any time.

Register information is held in a database and includes the following collected information:

- name; (mandatory field)
- date of birth (mandatory field)
- Sex (mandatory field from 2013)
- address (mandatory field)
- Medicare number (voluntary field)
- parent/guardian's name (voluntary field)
- parent/guardian's address (voluntary field)
- school details (voluntary field)
- practitioner and clinic details (mandatory field)
- date of vaccination (mandatory field)
- type of vaccine (mandatory field)
- dose number (mandatory field)
- batch number (voluntary field)
- Indigenous status (voluntary field)

The NHVPR also stores calculated fields which include (but are not limited to):

- Implied dose number (the dose number implied by the vaccination date, with reference to other doses notified to the NHVPR)
- Age at current date
- Age at each implied dose
- Total doses for each consumer
- Consumer completion status (whether vaccination course complete)
- Date of course completion
- Whether the consumer was vaccinated as part of the schools/community program (defined as receiving any doses from a non-GP provider. Note that consumers vaccinated at non-GP providers but not in school settings (e.g. community clinics) are also designated as part of the schools/community program.)

Please note that the NHVPR contains no other personal information such as marital status, country of birth, ethnicity, or socio-economic status of eligible persons vaccinated. It does not contain results of HPV DNA testing, Pap test results or information about adverse events following immunisation. Doses of both the quadrivalent vaccine Gardasil and bivalent vaccine Cervarix are recorded on the NHVPR.

## Information published by the NHVPR

National coverage data is available on the NHVPR website at:  
<http://www.hpvregister.org.au/research/coverage-data>





Details of published research can be found at:

<http://www.hpvregister.org.au/research/relevant-research-publications>

A number of standard statistical reports containing aggregated data are released on a quarterly basis to state and territory health authorities using on-line facilities and to the Australian Government Department of Health. These are available to authorised users only at this stage.

## Information that can be provided by the Register on request and with DOH approval

A Data Request form can be submitted by researchers to the NHVPR after the request has been discussed with a Registry Health Information Manager. Where the research proposal is particularly complex, the Health Information Manager may seek the input of the VCS Registries Research Review team (data managers, medical director/epidemiologists) to enable appropriate feedback to the researcher prior to submitting the request to DOH.

Data provided by the NHVPR is to be used only for the explicit purpose for which it was requested and is not to be published in a format that could potentially identify an individual.

Data requests fall into two types:

1. Summary or aggregate data
2. line/itemised data

### 1. Summary or aggregate data request

Upon request, aggregate or group summary data can be provided once approved by DOH (see section A of request form). No individual data are provided as the data are summarised. If the request for aggregate numbers is at a level small enough that an individual could possibly be identified (such as with age groups within a remote location) then a summary of the data may only be provided, or censoring of some cells may occur (for example cells with fewer than 10 people).

Examples of aggregate data requests would include:

- total number of HPV doses by State and year of administration
- vaccination coverage rate by age, State and dose number, using ABS estimated residential populations as the denominator
- Number of consumers completing vaccination course within 6 months and one year.
- Number of consumers vaccinated in general practice by age.

### 2. Line/ itemised data request

Individual line data may be provided by the NHVPR subject to the researchers providing documentation of ethical approval for such release from a properly constituted Human Research Ethics Committee, and following review and approval by the DOH. The Register refers to statements on individually identifiable, re-identifiable and non-identifiable data made in the NHMRC *National Statement on Ethical Conduct in Human Research (2007) (updated may 2015)* as specified below:

**“Individually identifiable data**, where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual’s name, image, and date of birth or address;

**Re-identifiable data**, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets





**Non-identifiable data**, which have never been labeled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown."

The NHVPR will review whether the data sought will be individually identifiable, potentially re-identifiable or non-identifiable. Where third parties hold individual consent from the consumer to release information held on the NHVPR to them, individually identifiable data can be lawfully released from the NHVPR. Consent forms must be provided to the Register in order for the data to be released.

As a Commonwealth owned data collection, release of personal information from the NHVPR for use in research or statistical purposes *without individual consent* is governed by the Australian Privacy Principles in Schedule 1 of the Privacy Act 1988. Specifically APP6 (Use or disclosure of personal information) provides guidance upon specific circumstances when such release is lawful. Guidelines under Section 95 of the Privacy Act 1988 provide explicit guidance for researchers as to the requirements for seeking and obtaining approval from a Human Research Ethics Committee for release of identified or re-identifiable information. The researchers must clearly show how the public interest in the research outweighs the public interest in adhering to the relevant information privacy principle(s).

Decisions regarding release of line data from the NHVPR will be made by the owners of the NHVPR, the DOH. They will require the full research proposal, and copies of any ethics submissions and approvals which clearly identify the potential ethical and privacy concerns to inform their decision. These documents should be provided to the NHVPR at the time of submission of the data request form. The NHVPR will forward the request to DOH.

## Human Research Ethics Committee (HREC) approval

It is strongly recommended that HREC approval is obtained for all line data requests. The NHVPR and DOH reserve the right to request that HREC approval is obtained, including for requests for aggregated data. Whilst a HREC will determine the ethical acceptability of such proposals, the authority to release data lies with the DOH.

## Limitations to data that can be provided by the NHVPR

Data about HPV vaccination coverage in the National HPV Vaccination program can be provided but when interpreting these estimates it is important that researchers be aware that measurement error may affect both the denominator and the numerator.

The denominator for coverage estimates is Australian persons eligible for vaccination under the Program: the best available estimates of this population are from ABS ERPs. For small areas and Indigenous populations these estimates are less robust.

The numerator comprises HPV vaccination doses *notified* to the NHVPR. For doses administered in school based programs, central notification processes should mean that doses notified closely equate to doses administered (i.e. with the exception of doses delivered to consumers who did not consent for their data to be transferred to the NHVPR.) Consent forms and policies differ slightly across States and Territories. Doses delivered in other settings may be incompletely notified as notification is not compulsory and requires consent





from the vaccinated person. The extent of notification may also differ by State/Territory. The Northern Territory and Queensland have state based vaccination registers and centrally notify HPV vaccine doses administered from all providers, and are therefore likely to have the most complete data. South Australia also collected HPV vaccination dose information from providers during the first year of the catch-up program and notified it centrally.

It should also be noted that the NHVPR Coverage data currently does not include doses administered outside of the recommended minimum intervals (too close to previous dose) as valid doses. These doses (dose 2 or dose 3) are excluded from coverage calculations.

The NHVPR uses record-linkage methods to match doses received from different vaccination providers to the same individual (e.g. dose 1 received at school, dose 2 at surgery 1 and dose 3 at surgery 2). Imperfect record-linkage between vaccine doses from the same person could result in an overestimate of the number of people receiving any vaccine doses and an underestimate of the percentage of courses completed. For these reasons data provided by the NHVPR is intended to be used as a guide only and should be interpreted with caution.

## Process to request data from the NHVPR

The steps to request data are summarised below:

1. To determine the precise data needs, the request should first be discussed with a NHVPR Health Information Manager on 1800 478 734.
2. Initial discussions with the Health Information Manager will assist in clarifying what is required and the feasibility of the request. It is helpful for the request to be specific by stating which variables are required, the time frame, the location and the population. Providing a mock-up table of how the data is to be presented is very useful.
3. The researcher must then submit a 'Request Form for data from the NHVPR'. Ensure that any necessary attachments are also provided. Applications can be submitted by fax (03) 8417 6835 or by email to [datarequests@vcs.org.au](mailto:datarequests@vcs.org.au).
4. The application will be forwarded by the NHVPR to the DOH, owners of the NHVPR, for approval to release the data. The researcher will then be notified of the outcome and, if approved, given a timeline for the release of the data request.

### **Data format**

Data files will typically be in Microsoft Excel format, PDF or CSV and password protected as required.

## Conditions of use of data

1. Third parties who are provided with any data from the NHVPR are required to comply with all relevant legislation and guidelines including:

The 13 Australian Privacy Principles (Commonwealth Privacy Act). Particularly:

- the collection and use of information is necessary for research relevant to public health or public safety or the compilation or analysis of statistics relevant to public health or public safety (Privacy Act Section 16B)
- information does not identify any individual or from which the individual's identity cannot reasonably be ascertained
- health information is not disclosed to another party or published in a form where an individual can be identified (Privacy Act Section 16B)





- reasonable steps are taken to protect the health information from misuse, interference and loss, and to protect information from unauthorised access, modification or disclosure (APP 11.1)
  - take reasonable steps to destroy or de-identify health information if it is no longer needed (APP 11.2)
  - Information to be transferred out of Australia must abide by APP 8.
  - Guidelines Approved under Section 95A of the Privacy Act, including written proposals to a HREC to use health information.
2. Third parties are only to use data from the NHVPR for the purpose specified on the Request for Data Form.
  3. Third parties must not publish NHVPR data without first informing the NHVPR.
  4. Third parties must provide a copy of all released reports or published manuscripts to the NHVPR for our records.
  5. Third parties must comply with any other requirements specified by DOH as a condition of approving data release.
  6. The NHVPR must be acknowledged in all publications and reports where NHVPR data has been used and the acknowledgement include the statement that 'The NHVPR is fully funded by the Australian Government and operated by the Victorian Cytology Service Ltd.'
  7. Third parties must ensure that any data, whether identified or de-identified, are stored securely and only those named in the application form will have access to it.
  8. Data from the NHVPR is not to be published in a format that could potentially identify an individual consumer (for example cells with fewer than 10 people).
  9. Third parties must agree to provide an annual update or more frequently if requested, to the NHVPR regarding the status of the research/use of data and certify ongoing safe storage of the data.
  10. Third parties must agree to pay a cost recovery fee in order to obtain the data requested if applicable.
  11. Notify the NHVPR of any changes of staff who hold the NHVPR data.
  12. Not link NHVPR data to another dataset without appropriate approval.

*The NHVPR is fully funded by the Australian Government and operated by VCS Ltd.*

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## Useful references

National HPV Vaccination Program Register website

[www.hpvregister.org.au](http://www.hpvregister.org.au)

Australian Immunisation Handbook

<http://www.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home>

HPV Vaccination Program information on the Immunise Australia website

<http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/immunise-hpv>

NH&MRC Guidelines Approved under Section 95A of the Privacy Act 1988

<http://www.nhmrc.gov.au/guidelines-publications/pr2>

NH&MRC Guidelines under Section 95 of the Privacy Act 1988

<http://www.nhmrc.gov.au/guidelines-publications/pr1>



*National Statement On Ethical Conduct In Human Research (NHMRC, 2007 – updated May 2015)*  
<http://www.nhmrc.gov.au/guidelines-publications/e72>

*Privacy Act 1988*  
<http://www.comlaw.gov.au/Series/C2004A03712>

