The First 5 years of HPV Vaccination in Australia - A National Evaluation

Aditi Dey  Stephanie Knox
The framework for evaluation was approved by the Australian Department of Health and Ageing on the 25th of January 2013 and the Final Evaluation in December 2014.
Acknowledgements

**Australian Government Department of Health**
- Michelle Bradley, Emma Hill and Joel Willis (Immunisation Programs Section)
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- Bronwen Harvey and Richard Hill

**Process evaluation**
- Medicare Local staff
- School-based vaccination coordinators and Regional immunisation coordinators
- Cervical screening program managers
But this was no ordinary evaluation
HPV vaccine programs - Diverse groups engaging for the first time
Pub Med search term – HPV vaccines Australia N = 362

Australia
Tabrizi
Frazer
Brotherton
Garland
Focus on routinely collected data at national level

Process Evaluation
- Describe program implementation processes
- Identify strengths, challenges and satisfaction of key groups

Coverage
- HPV vaccine coverage by region, age group and demographics

Adverse events following immunisation
- Vaccine safety events
- Ongoing monitoring procedures

Outcome evaluation
- By year and age group
- National and by jurisdiction
  - High-grade cervical abnormalities
  - Genital warts
Chapter authors

**Process evaluation**
Stephanie Knox and Aditi Dey (NCIRS)

**Coverage**
Julia Brotherton on behalf of the National HPV Vaccination Program Register, Victorian Cytology Service Inc. (VCS)

**Adverse events following immunisation**
Deepika Mahajan, Aditi Dey, Robert Menzies, Kristine Macartney (NCIRS)
Julia Brotherton (VCS) Bronwen Harvey, Jane Cook (TGA)

**Disease burden**

*High-grade cervical abnormalities:*
May Chiew, Aditi Dey, Peter McIntyre (NCIRS) Alison Budd (AIHW), Julia Brotherton, Dorota Gertig (VCS), Bette Liu (UNSW)

*Genital warts:*
Megan Smith, Karen Canfell, Bette Liu (Kirby and UNSW)
Aditi Dey, Robert Menzies, Peter McIntyre (NCIRS)
MEDIA RELEASE
Minister for Health and Ageing
Tony Abbott MHR

29 November 2006

The Commonwealth Government will fund the introduction of the HPV vaccine for young people and women aged 12 to 26 from 2007.

Gardasil® will be put on the National Immunisation Program for 12 year old girls to be delivered through schools. In addition, there will be a catch-up program for 13 to 18 year old girls in the first year of the program delivered through GPs.

The expected cost of the vaccine is $436 million over four years.

The initial submission from the vaccine’s maker to the Pharmaceutical Benefits Advisory Committee (PBAC) in early 2004 was unsuccessful due to concerns raised by the PBAC about Gardasil due to evidence not being conclusive.

Given the possibility of introducing an immunisation program, and after further discussions with the health sector, the Department and I had asked the PBAC to consider a revised submission. Today I am able to announce that the PBAC has been satisfied with the evidence and has recommended that the vaccine be funded for the program.

I would like to thank the PBAC for agreeing to the recommendation and also thank the health sector for the work they have done in supporting the vaccine program.
HPV vaccine use in Australia

- 4vHPV and 2vHPV registered
- NIP program start (4vHPV)
  - girls 12 - 18y school
  - women 18 – 26y GP
- 2006 April – June 2007
- Ongoing program 12-13 y girls, school based

- Dec 2008
  - School based catch-up ceased
- Dec 2009
  - 18-26 years Catch-up ceased
- Feb 2013
  - Boys program started
  - School based: 12–13 years
  - Catch-up: 14-15 years till end 2014
Process Evaluation: Scope

- Routine school-based vaccination program for 12–13 year old females


- Catch-up vaccination of routine adolescent cohort provided outside school-based vaccination programs (primarily general practice)

- Routine vaccination of 12–13 year old boys and 2-year catch-up for 14-15 year old boys
Implementation of the Australian HPV vaccination program for adult women: Qualitative key informant interviews

Julie Lesko\textsuperscript{a,b}, Cath Jackson\textsuperscript{c}, Lyndal Trevena\textsuperscript{d}, Kirsten McCaffrey\textsuperscript{e}, Julia Brotherton\textsuperscript{a,b}

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\textbf{ARTICLE INFO}

\textbf{ABSTRACT}

This study sought to evaluate the early implementation of Australia's national HPV vaccination program for adult women aged 18–26 years. We conducted qualitative in-depth interviews with 24 in-person interviews.
Process Evaluation: Methods

Mixed methods approach

- Assessment of the peer-reviewed and grey literature including resources used to implement the program
- Online survey
- In-depth telephone interviews
Process Evaluation areas

Areas of focus

- Awareness and knowledge about the program
- Implementation processes
- Access to information/resources
- Communication
- Vaccine supply
- Indigenous identification
- Stakeholder collaboration
- Strengths
- Challenges
Stakeholders

- National interviews (n=29)
- Cervical screening program managers on-line (n = 7)
  - HPV vaccine incorporation into NIP
    - viewed as successful by most stakeholders
  - Challenges:
    - Short lead time
    - Rollout and availability of information resources
    - Vaccinating both males and females:
      - seen as more equitable
      - Alleviated potential issues of program delivery.
Well-accepted vaccination program

- Acceptance of female program grew over time as it became established on the NIP

  “*I think the program has progressed really well*”

- Lessons learnt from the female program helped with the male program

  “*the girls had to break through the barrier and then the boys have just been a walk in the park*”

- Including males has increased the success of the program

  “*…I think it makes it a more acceptable program now that it includes both males and females*”
Fury over sex shots

Aussie vaccine banned

By KAREN BROOKS

HOUSTON: A US state's plan to provide schoolgirls with an Australian-designed vaccine to prevent a sexually transmitted disease has run into opposition.

Texas yesterday kept Gardasil off its shots for school at Governor Rick Perry.

Gardasil was developed by Australian of the Year in 2006 Professor Ian Frazer.

It provides protection against strains of the human papilloma virus responsible for 70% of cervical cancers.

Religious objection to cancer vaccine

By CLARE MASTERS Health Reporter

SOME parents are refusing to let their daughters receive the cervical cancer vaccine Gardasil due to concerns the teenage girls are too young to be sexually active, as well as religious beliefs promoting abstinence from sex before marriage.

All NSW schools offer the free vaccination which guards against four strains of a sexually transmitted virus that can cause cervical cancer.

"Some parents feel it gives the children a sense they are going to be sexually active," Australian Family Association spokeswoman Gabrielle Walsh said.

"A lot of people are opposed to the prescriptive approach; it's not like this is a disease everyone is going to get... it's a culture leading them in that direction and it is probably not relevant for those girls who abstain while not married."

But a federal health department spokeswoman said recent overseas research had shown 14.3 per cent of young women who have had only one partner still carry the human papillomavirus.

Delaying sexual activity and having only one lifetime sexual partner should reduce the risk of acquiring HPV but will not eliminate the risk entirely," she said.

"HPV is very common and it is easily transmitted by any sexual activity. Vaccination with HPV vaccine is most effective when it is given to females before they are likely to be exposed to HPV, that is, before they start having sexual contact."

“At this age it is difficult to know what their future life course will be. While young people may intend to only have one partner, circumstances may change.”

Vaccination hotlines have also fielded calls from parents worried about minor adverse reactions arising from the jab, with students fainting after their injection.

A NSW Health spokeswoman said no major adverse reactions had been reported and incidents of fainting had been dealt with by the on-site clinic nurse.

The spokeswoman said officials were pleased with the 84 per cent vaccine uptake.

Editorial: Page 14
Print and electronic news media on the National HPV Vaccination Program 2007 to 2009 (435 reports sampled)

<table>
<thead>
<tr>
<th></th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
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</thead>
<tbody>
<tr>
<td>Negative</td>
<td>38 (16.4%)</td>
<td>20 (21%)</td>
<td>10 (9%)</td>
</tr>
<tr>
<td>Positive</td>
<td>194 (83.6%)</td>
<td>77 (79%)</td>
<td>96 (91%)</td>
</tr>
<tr>
<td>Total</td>
<td>232</td>
<td>97</td>
<td>106</td>
</tr>
</tbody>
</table>

Positive themes
- Australia as world leader in HPV vaccination
- Gardasil® a safe vaccine
- Advocating vaccination for boys

Negative themes
- Fear of early sexual debut/promiscuity (minor issue in Australia),
- Early fears of adverse events (changed to reassurance later in program)
Vaccination coverage

Coverage by dose number

Coverage by indigenous status and SES
National HPV vaccination coverage for females aged 12–26 years in mid 2007, by dose number*

*As notified to the National HPV Vaccination Program Register, Australia (Data as held at September 2011)

Lower coverage in Indigenous girls in NT and Qld for dose 3 but not dose 2

Lower coverage for dose 3 but not dose 2 in lowest SES
Adverse event evaluation

- Adverse event reports: TGA database
- HPV vaccine dose data: From National HPV Vaccination Program Register (NHVPR)
AEFI

Reports of adverse events following HPV vaccine 12-13 year olds, 14-17 year olds, and 18-26 year olds TGA database, April 2007 to 30 June 2013, by year of vaccination.
Cancer jab puts girls in hospital
Richard Kerbaj and Cath Hart
May 23, 2007

FOUR secondary-school girls were rushed to hospital this month after having a reaction to the vaccination that immunises against cervical cancer.

The four students from Melbourne’s Sacred Heart Girls College were among 20 who reported sick following the Gardasil injection.

But health authorities and the vaccine’s co-creator, Australian of the Year Ian Frazer, yesterday defended the immunisation program, saying symptoms such as dizziness and fainting after followed injections, particularly with young girls.

PUBLIC HEALTH

Mass psychogenic response to human papillomavirus vaccination
Jim P Buttery, Simon Madin, Nigel W Crawford, Sonja Elia, Sophie La Vincente, Sarah Hanieh, Lindsay Smith and Bruce Bolam
CNS demyelination and quadrivalent HPV vaccination.

Sutton I, Lahoria R, Tan I, Clouston P, Barnett M.
Department of Neurology, St Vincent's Hospital, Darlinghurst, New South Wales, Australia.

Vaccination is generally considered safe in patients with multiple sclerosis (MS). We report five patients who presented with multifocal or atypical demyelinating syndromes within 21 days of immunization with the quadrivalent human papilloma virus (HPV) vaccine, Gardasil.

- TGA expert panel convened in advance of publication
- Highlighted the issue of rare events occurring during a large scale rollout with rapid, high coverage
- Danish/Swedish population cohort study – JAMA January 2015
### Adverse events following HPV vaccination in females, TGA Adverse Drug Reaction System database, 1 April 2007 to 31 December 2012

<table>
<thead>
<tr>
<th>AEFI records*</th>
<th>Only HPV vaccine received</th>
<th>≤13 years</th>
<th>14–17 years</th>
<th>≥18 years</th>
<th>Reporting rate per 100,000 doses†</th>
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<tbody>
<tr>
<td></td>
<td>Total (Serious)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>381 (19)</td>
<td>304</td>
<td>161</td>
<td>132</td>
<td>82</td>
</tr>
<tr>
<td>Nausea</td>
<td>293 (23)</td>
<td>232</td>
<td>106</td>
<td>111</td>
<td>71</td>
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<tr>
<td>Dizziness</td>
<td>273 (17)</td>
<td>204</td>
<td>126</td>
<td>93</td>
<td>51</td>
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<tr>
<td>Fever</td>
<td>231 (12)</td>
<td>175</td>
<td>100</td>
<td>75</td>
<td>54</td>
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<tr>
<td>Syncope</td>
<td>201 (10)</td>
<td>134</td>
<td>89</td>
<td>59</td>
<td>49</td>
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<tr>
<td>Injection site reaction</td>
<td>191 (3)</td>
<td>160</td>
<td>68</td>
<td>52</td>
<td>70</td>
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<tr>
<td>Pruritus</td>
<td>163 (7)</td>
<td>140</td>
<td>58</td>
<td>50</td>
<td>50</td>
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<tr>
<td>Urticaria</td>
<td>155 (5)</td>
<td>128</td>
<td>54</td>
<td>62</td>
<td>38</td>
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<tr>
<td>Myalgia</td>
<td>140 (12)</td>
<td>113</td>
<td>46</td>
<td>42</td>
<td>52</td>
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<td>Reduced sensation</td>
<td>138 (10)</td>
<td>118</td>
<td>45</td>
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<td>48</td>
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<td>57</td>
<td>58</td>
<td>29</td>
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<tr>
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<td>48</td>
<td>39</td>
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<td>Neurological/ psychological</td>
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<td>85</td>
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<td>89</td>
<td>26</td>
<td>28</td>
<td>44</td>
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<tr>
<td>Abdominal pain</td>
<td>96 (14)</td>
<td>83</td>
<td>42</td>
<td>38</td>
<td>16</td>
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<tr>
<td>Convulsion</td>
<td>70 (12)</td>
<td>56</td>
<td>28</td>
<td>20</td>
<td>21</td>
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<tr>
<td>Vision impaired</td>
<td>56 (6)</td>
<td>47</td>
<td>18</td>
<td>22</td>
<td>15</td>
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<tr>
<td>Lymphadenopathy/itis</td>
<td>47 (1)</td>
<td>43</td>
<td>19</td>
<td>10</td>
<td>18</td>
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<td>Anaphylaxis</td>
<td>16 (4)</td>
<td>12</td>
<td>3</td>
<td>10</td>
<td>3</td>
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<tr>
<td>Pancreatitis</td>
<td>8 (7)</td>
<td>8</td>
<td>2</td>
<td>2</td>
<td>6</td>
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<tr>
<td>Thrombocytopenia</td>
<td>4 (4)</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>2</td>
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<tr>
<td>Encephalitis</td>
<td>2 (1)</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Guillain-Barré syndrome</td>
<td>2 (2)</td>
<td>2</td>
<td>0</td>
<td>2</td>
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</table>

†Reporting rates per 100,000 doses are calculated from 1 April 2007 to 31 December 2011.
## Most frequently reported adverse events
### Males and Females - 1 February 2013 to 30 June 2013

<table>
<thead>
<tr>
<th></th>
<th>Males</th>
<th></th>
<th></th>
<th>Females</th>
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<td></td>
<td>AEFI records</td>
<td>Only HPV vaccine received</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>≤13 years</td>
<td>14–17 years</td>
<td>≥18 years</td>
<td></td>
<td>≤13 years</td>
</tr>
<tr>
<td>Syncope</td>
<td>173 (6)</td>
<td>77</td>
<td>121</td>
<td>40</td>
<td>1</td>
<td>123 (1)</td>
</tr>
<tr>
<td>Presyncope</td>
<td>28 (0)</td>
<td>17</td>
<td>16</td>
<td>11</td>
<td>1</td>
<td>39 (0)</td>
</tr>
<tr>
<td>Nausea</td>
<td>28 (1)</td>
<td>19</td>
<td>20</td>
<td>7</td>
<td>–</td>
<td>23 (0)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>26 (1)</td>
<td>12</td>
<td>21</td>
<td>5</td>
<td>–</td>
<td>24 (1)</td>
</tr>
<tr>
<td>Headache</td>
<td>23 (5)</td>
<td>13</td>
<td>12</td>
<td>11</td>
<td>–</td>
<td>15 (2)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>16 (1)</td>
<td>8</td>
<td>11</td>
<td>5</td>
<td>–</td>
<td>17 (0)</td>
</tr>
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<td>Pyrexia</td>
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<td>13</td>
<td>7</td>
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<td>11</td>
<td>8</td>
<td>7</td>
<td>–</td>
<td>9 (0)</td>
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<td>Malaise</td>
<td>15 (1)</td>
<td>6</td>
<td>10</td>
<td>5</td>
<td>–</td>
<td>7 (0)</td>
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<tr>
<td>Injection site reaction</td>
<td>11 (2)</td>
<td>6</td>
<td>7</td>
<td>4</td>
<td>–</td>
<td>8 (0)</td>
</tr>
<tr>
<td>Rash</td>
<td>16 (0)</td>
<td>11</td>
<td>8</td>
<td>8</td>
<td>–</td>
<td>12 (0)</td>
</tr>
<tr>
<td>Pallor</td>
<td>5 (0)</td>
<td>5</td>
<td>5</td>
<td>–</td>
<td>–</td>
<td>6 (0)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>4 (0)</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>–</td>
<td>6 (0)</td>
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<td>4</td>
<td>1</td>
<td>–</td>
<td>4 (0)</td>
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<td>Lethargy</td>
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<td>3</td>
<td>1</td>
<td>4</td>
<td>–</td>
<td>4 (0)</td>
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<td>Paraesthesia</td>
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<td>4</td>
<td>3</td>
<td>3</td>
<td>–</td>
<td>3 (0)</td>
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<td>Anxiety</td>
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<td>3</td>
<td>3</td>
<td>1</td>
<td>–</td>
<td>4 (0)</td>
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<tr>
<td>Hypersensitivity</td>
<td>6 (1)</td>
<td>3</td>
<td>4</td>
<td>1</td>
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<td>2 (0)</td>
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<td>Injection site pain</td>
<td>6 (0)</td>
<td>6</td>
<td>3</td>
<td>3</td>
<td>–</td>
<td>2 (0)</td>
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<td>Rash pruritic</td>
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<td>1</td>
<td>4</td>
<td>–</td>
<td>–</td>
<td>4 (0)</td>
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<td>Cold sweat</td>
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<td>2</td>
<td>4</td>
<td>–</td>
<td>–</td>
<td>3 (0)</td>
</tr>
<tr>
<td>Vision blurred</td>
<td>3 (2)</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>–</td>
<td>4 (2)</td>
</tr>
</tbody>
</table>
Hypersensitivity reactions to human papillomavirus vaccine in Australian schoolgirls: retrospective cohort study

Syncope and seizures following human papillomavirus vaccination: a retrospective case series

Nigel W Crawford, Hazel J Clothier, Sonja Elia, Teresa Lazzaro, Jenny Royle and Jim P Buttery
Conclusions – HPV adverse events

- Important lessons learnt from girls program
  - Being prepared for big increase in AEFI following initiation – proactive
  - Conduct of large scale school-based vaccination

- These were put into place when boys program began
Outcome Evaluation

- Collaboration between AIHW, VCS, Kirby/UNSW and NCIRS
  Two major components:

- Trends in high-grade cervical abnormalities
  - Victorian data previously reported
  - Aggregated national data collected and collated for AIHW monitoring reports ‘Cervical screening in Australia
  - Rate (High grade abnormality (HGA) per 1,000 women screened during baseline period set to 1.0 and Rate Ratio by age calculated

- Trends in genital warts
  - Multiple previous publications from STI clinic populations
  - National hospitalisation data from AIHW
High grade abnormalities
Rate ratio of women detected with a HGA per 1000 women screened by age group, 2008 to 2011*^
High-grade abnormalities detected, per 1,000 females aged <20 years screened, by jurisdiction, 2004 to 2011

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<tr>
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<td>Rate (CI)*</td>
<td>Rate (CI)*</td>
<td>Rate ratio (CI)†</td>
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<td>NSW</td>
<td>16.2</td>
<td>10.8</td>
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<td></td>
<td>(15.3–17.2)</td>
<td>(9.7–11.9)</td>
<td>(0.59–0.75)</td>
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<td>VIC</td>
<td>10.8</td>
<td>9.7</td>
<td>0.90</td>
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<td>(9.9–11.7)</td>
<td>(8.5–11.1)</td>
<td>(0.77–1.06)</td>
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<td>QLD</td>
<td>13.6</td>
<td>8.8</td>
<td>0.65</td>
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<td></td>
<td>(12.7–14.6)</td>
<td>(7.8–9.9)</td>
<td>(0.56–0.74)</td>
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<td>WA</td>
<td>10.0</td>
<td>8.0</td>
<td>0.80</td>
</tr>
<tr>
<td></td>
<td>(9.0–11.2)</td>
<td>(6.7–9.5)</td>
<td>(0.65–0.98)</td>
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<td>SA</td>
<td>9.1</td>
<td>9.7</td>
<td>1.07</td>
</tr>
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<td></td>
<td>(7.8–10.6)</td>
<td>(7.7–12.1)</td>
<td>(0.81–1.40)</td>
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<td>NT</td>
<td>18.5</td>
<td>17.8</td>
<td>1.04</td>
</tr>
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<td>(12.8–26.1)</td>
<td>(13.9–22.5)</td>
<td>(0.67–1.60)</td>
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<td>TAS</td>
<td>18.1</td>
<td>16.8</td>
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</tr>
<tr>
<td></td>
<td>(15.4–21.2)</td>
<td>(12.8–21.5)</td>
<td>(0.68–1.25)</td>
</tr>
<tr>
<td>ACT</td>
<td>11.7</td>
<td>6.2</td>
<td>0.53</td>
</tr>
<tr>
<td></td>
<td>(8.9–15.0)</td>
<td>(3.4–10.4)</td>
<td>(0.27–0.96)</td>
</tr>
<tr>
<td>National</td>
<td>13.1</td>
<td>9.8</td>
<td>0.75</td>
</tr>
<tr>
<td></td>
<td>(12.7–13.6)</td>
<td>(9.3–10.4)</td>
<td>(0.70–0.80)</td>
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Impact of HPV program on High Grade Cervical Abnormalities – summary

Effectiveness of quadrivalent human papillomavirus vaccine for the prevention of cervical abnormalities: case-control study nested within a population based screening programme in Australia

Genital Warts - females

Age-specific hospitalisation rates* of genital warts in females per 100 000 population, Australia, 1999/2000 to 2010/2011

* Admission rates

Line indicates commencement of National HPV Vaccination Program
Genital Warts - males

Age-specific rates of admissions involving genital warts in males, per 100,000 population, July 1999 to June 2011

Line indicates commencement of National HPV Vaccination Program

* Admission rates
Equivalent impact in Indigenous and Non-Indigenous Women
Successes and Lessons from the first 5 years of the Australian HPV vaccine program

- High coverage achieved following a rapid roll out of vaccine enabled by school-based delivery – ongoing
- Strong collaboration in service delivery and research across multiple disciplines – especially important given the significant flow on impacts
- Learnings in vaccine safety monitoring, communication and optimum delivery in school setting are providing leadership regionally and internationally
  - eg Japan 2014
- Good evidence of impact against cervical disease and anogenital warts
  - Equivalent in Indigenous women + herd impact in males for anogenital warts