

## RESEARCH

# Genital warts in young Australians five years into national human papillomavirus vaccination programme: national surveillance data



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## Abstract

**Objective** To measure the effect on genital warts of the national human papillomavirus vaccination programme in Australia, which started in mid-2007.

**Design** Trend analysis of national surveillance data.

**Setting** Data collated from eight sexual health services from 2004 to 2011; the two largest clinics also collected self reported human papillomavirus vaccination status from 2009.

**Participants** Between 2004 and 2011, 85 770 Australian born patients were seen for the first time; 7686 (9.0%) were found to have genital warts.

**Main outcome measure** Rate ratios comparing trends in proportion of new patients diagnosed as having genital warts in the pre-vaccination period (2004 to mid-2007) and vaccination period (mid-2007 to the end of 2011).

**Results** Large declines occurred in the proportions of under 21 year old (92.6%) and 21-30 year old (72.6%) women diagnosed as having genital warts in the vaccination period—from 11.5% in 2007 to 0.85% in 2011 ( $P<0.001$ ) and from 11.3% in 2007 to 3.1% in 2011 ( $P<0.001$ ), respectively. No significant decline in wart diagnoses was seen in women over 30 years of age. Significant declines occurred in proportions of under 21 year old (81.8%) and 21-30 year old (51.1%) heterosexual men diagnosed as having genital warts in the vaccination period—from 12.1% in 2007 to 2.2% in 2011 ( $P<0.001$ ) and from 18.2% in 2007 to 8.9% in 2011 ( $P<0.001$ ), respectively. No significant decline in genital wart diagnoses was seen in heterosexual men over 30 years of age. In 2011 no genital wart diagnoses were made among 235 women under 21 years of age who reported prior human papillomavirus vaccination.

**Conclusions** The significant declines in the proportion of young women found to have genital warts and the absence of genital warts in vaccinated women in 2011 suggests that the human papillomavirus

vaccine has a high efficacy outside of the trial setting. Large declines in diagnoses of genital warts in heterosexual men are probably due to herd immunity.

## Introduction

In 2007 Australia became one of the first countries to implement a nationally funded programme of quadrivalent human papillomavirus vaccination for girls and young women.<sup>1</sup> The ongoing programme offers free vaccination to girls aged 12-13 years in schools. In addition, from 2007 to 2009 two catch-up programmes were implemented—one for 13-18 year old schoolgirls and the other for 18-26 year old women in the community. The quadrivalent vaccine provides protection against human papillomavirus types 6 and 11, which cause genital warts, in addition to the cancer causing types 16 and 18.<sup>2,3</sup> In 2010 the vaccination coverage rates in the school based programme were reported to be 83% for the first dose, 80% for the second dose, and 73% for the third dose in 12-13 year olds,<sup>4</sup> with coverage rates decreasing with increasing age. The lowest rates of 52% for the first dose in 20-26 year olds were observed in the community catch-up programme.<sup>4,5</sup> Few men, or women who were over 26 years of age in 2007, have been vaccinated.<sup>6</sup>

We established a sentinel surveillance network to monitor the effect of the vaccine on cases of genital warts seen at sexual health services across Australia. Earlier data from the network showed that two years after the vaccine was introduced the proportion of genital wart diagnoses declined by 59% in vaccine eligible young women aged 12-26 years in 2007 and by 39% in heterosexual men of the same age.<sup>6</sup> No significant decline was observed in older women or men, non-resident young women, or men who have sex with men.<sup>6</sup> In the same two year period, data from the Victorian cervical cytology registry

showed a significant decrease in the incidence of high grade cervical abnormalities in girls aged under 18 years.<sup>7</sup>

In this study, we describe the ongoing population effect of the quadrivalent human papillomavirus vaccination programme on genital warts in Australian patients five years after the programme was established.

## Methods

### Surveillance network

Details of the surveillance network methods have been reported elsewhere.<sup>6</sup> In summary, we recruited eight sexual health services dispersed across Australia that were able to provide retrospective data to 2004. Routine data on patients' demographics and behaviour (age, sex, country of birth, and gender of their sexual partners) and clinical diagnosis of genital warts were collated from all sites. In addition, the two largest clinics (Melbourne Sexual Health Centre and Sydney Sexual Health Centre) collected data on self reported human papillomavirus vaccination status of new patients from 2009. This was a dichotomous question (yes/no) and did not record date of vaccination or number of doses of vaccine received.

### Data presentation

Australian born patients who attended any of the services for the first time between January 2004 and December 2011 were included in the analysis. Men who reported having sex only with men or with both men and women in the previous 12 months were referred to as men who have sex with men, men who reported having sex with both men and women were referred to as bisexual, men who reported having sex only with men were referred to as homosexual, and men who reported having sex only with women were referred to as heterosexual.

We divided the study period into the pre-vaccination period (from January 2004 to June 2007) and the vaccination period (from July 2007 to December 2011) on the basis of the vaccination programme starting in mid-2007. We calculated the proportion of patients diagnosed as having genital warts by dividing the total number of new diagnoses of warts by the total number of new patients seen. We stratified findings by age group at the time of presentation at the clinic: under 21 year olds—all women in this age group were eligible for the free vaccine at any time in the vaccination period; 21-30 year olds—only a proportion of women in this age group were eligible for the free vaccine; and over 30 year olds—none of the women in this age group were eligible for the free vaccine at any time. We used the same age groups for heterosexual men, although none of these men were eligible for the free vaccine. For comparison, we calculated the proportion of Australian born patients who visited the eight services for the first time between 2004 and 2011 and tested positive for chlamydia.

### Statistical analysis

We compared the proportion of patients diagnosed as having genital warts in the pre-vaccination and vaccination periods by using rate ratios and determined summary rate ratios along with 95% confidence intervals over the eight year study period. Statistical significance was set at 0.05. We used Stata version 12.1 to do all analyses and fit all models.

## Results

Between 2004 and 2011, 85 770 Australian born patients were seen for the first time at the eight sexual health services. Of

these, 7686 (9.0%) patients (2394 women and 5292 men) were diagnosed as having genital warts (table 1). Overall, the proportion of women diagnosed as having genital warts increased during the pre-vaccination period, from 8.9% in 2004 to 9.6% in 2007, and then decreased in the vaccination period to 2.7% in 2011. In men, the proportion remained relatively stable in the pre-vaccination period, from 12.8% in 2004 to 11.7% in 2007, and then decreased in the vaccination period to 7.4% in 2011.

### Women under 21 years

We found no significant trend in the proportion of under 21 year old women diagnosed as having genital warts in the pre-vaccination period—8.8% in 2004 and 11.5% in 2007 ( $P=0.23$ ). In the vaccination period, the proportion declined dramatically by 92.6%, to 0.85% in 2011 with only 13 cases diagnosed ( $P<0.001$ ) (fig 1). The summary rate ratio comparing the vaccination period with the pre-vaccination period in these women was 0.64 ( $P<0.001$ ) (table 2).

Data from the two largest clinics showed that the proportion of under 21 year old women who reported being vaccinated had stabilised (71.7% (246/343) reported being vaccinated in 2009 and 71.2% (235/330) in 2011). Notably, in 2011, among 235 women under 21 years of age who reported prior vaccination, none was found to have genital warts (upper end of 95% confidence interval 1.5%). Furthermore, among 161 unvaccinated women aged under 21 in 2009-11, only 7.3% (4/55) were found to have genital warts in 2011 (fig 2), compared with 10.5% in 2006 when all women were unvaccinated ( $P=0.14$ ).

### Women aged 21-30 years

We saw no significant decline in the proportion of 21-30 year old women diagnosed as having genital warts in the pre-vaccination period—12.5% in 2004 and 11.3% in 2007 ( $P=0.89$ ). In the vaccination period, the proportion declined by 72.6%, to 3.1% in 2011 ( $P<0.001$ ) (fig 1). The summary rate ratio comparing the vaccination period with the pre-vaccination period in this age group was 0.81 ( $P<0.001$ ) (table 2).

### Women over 30 years

We saw no significant trend in the proportion of women aged over 30 years diagnosed as having genital warts either in the pre-vaccination period (from 3.8% in 2004 to 5.6% in 2007;  $P=0.07$ ) or in the vaccination period (4.4% in 2011;  $P=0.99$ ) (fig 1). The summary rate ratio comparing the vaccination period with the pre-vaccination period in this age group was 1.03 ( $P=0.48$ ) (table 2).

### Heterosexual men under 21 years

We found a significant increasing trend in the proportion of under 21 year old men diagnosed as having genital warts in the pre-vaccination period, with a 68.0% increase from 7.2% in 2004 to 12.1% in 2007 ( $P<0.01$ ). In the vaccination period, the proportion declined dramatically by 81.8%, to 2.2% in 2011 ( $P<0.001$ ) (fig 3). The summary rate ratio comparing the vaccination period with the pre-vaccination period in these men was 0.72 ( $P<0.001$ ) (table 2).

### Heterosexual men aged 21-30 years

We saw no significant decline in the proportion of 21-30 year old men diagnosed as having genital warts in the pre-vaccination period—16.9% in 2004 and 18.2% in 2007 ( $P=0.32$ ). In the

vaccination period, the proportion declined by 51.1%, to 8.9% in 2011 ( $P<0.001$ ) (fig 3). The summary rate ratio comparing the vaccination period with the pre-vaccination period in this age group was 0.88 ( $P<0.001$ ) (table 2).

## Heterosexual men over 30 years

We saw no significant trend in the proportion of men aged over 30 years diagnosed as having genital warts in either the pre-vaccination period (from 14.5% in 2004 to 11.1% in 2007;  $P=0.17$ ) or in the vaccination period (9.4% in 2011;  $P=0.45$ ) (fig 3). The summary rate ratio comparing the vaccination period with the pre-vaccination period in this age group was 0.97 ( $P=0.19$ ) (table 2).

## Men who have sex with men

We saw no significant trend in the proportion of men who have sex with men diagnosed as having genital warts in the pre-vaccination period—9.0% in 2004 and 8.5% in 2007 ( $P=0.11$ ). In the vaccination period, the proportion declined by 24.7%, to 6.4% in 2011 ( $P=0.04$ ). The summary rate ratio comparing the vaccination period with the pre-vaccination period in men who have sex with men was 0.93 ( $P=0.01$ ) (table 2). In homosexual men, we saw a similar trend in both periods (summary rate ratio 0.92;  $P<0.01$ ); in bisexual men, we saw no particular trend in either the pre-vaccination or vaccination period (summary rate ratio 1.01;  $P=0.80$ ) (fig 4).

## Chlamydia

We found no significant trend in the proportion of under 21 year old women ( $P=0.06$ ), under 21 year old heterosexual men ( $P=0.43$ ), and men who have sex with men ( $P=0.89$ ) who tested positive for chlamydia in the pre-vaccination period. However, in the vaccination period a significant increase occurred in the proportion that tested positive for chlamydia in all three groups: under 21 year old women—37.8% increase to 17.5% in 2011 ( $P<0.001$ ); under 21 year old heterosexual men—46.4% increase to 20.5% in 2011 ( $P=0.05$ ); men who have sex with men—30.5% increase to 7.7% in 2011 ( $P=0.03$ ) (fig 5). The summary rate ratios comparing the vaccination period with the pre-vaccination period were 1.19 for under 21 year old women ( $P<0.001$ ), 1.58 for under 21 year old heterosexual men ( $P<0.001$ ), and 1.15 for men who have sex with men ( $P<0.08$ ).

## Discussion

This study shows that the proportion of young women diagnosed as having genital warts has continued to decline since the quadrivalent human papillomavirus vaccination programme started in Australia in 2007. Less than 1% of women aged under 21 years presenting at sexual health services were found to have genital warts in 2011, compared with 10.5% in 2006 before the vaccination programme started. By 2011, no genital warts were diagnosed in women aged under 21 who reported being vaccinated. A significant decline also occurred in genital wart diagnoses in 21-30 year old women, a trend not observed in older women. A similar pattern of declining diagnoses, but of a lesser magnitude, was seen in young heterosexual men.

## Strengths and limitations of study

The major strength of this study is the inclusion of data from a range of services dispersed across the country, alleviating the concern about possible biases when data are reported from one service or one geographical location. The main limitation of the study is that sexual health services typically target populations

that are at higher risk of sexually transmissible infections. In Australia, patients with symptoms are triaged into sexual health services, so these data represent a higher risk section of the population. Thus, a higher proportion of patients seen at sexual health services are expected to have genital warts than in the general population. That being said, the main purpose of this sentinel network was to evaluate trends, and, as shown in our analysis, a sharp decline in diagnoses has occurred in young women and men since the vaccination programme was rolled out in 2007. By contrast, our analyses showed that a significant increase occurred in the proportion of under 21 year old women, under 21 year old heterosexual men, and men who have sex with men who tested positive for chlamydia in the vaccination period (2007-11), suggesting that the decline in genital warts could not be attributable to the clinics seeing patients at lower risk.

## Possible explanations for findings

The greatest decline in the proportion of women diagnosed as having genital warts was seen in the youngest age group (under 21 years), and all these women were eligible for the free quadrivalent human papillomavirus vaccine. A higher proportion of these women would have received the vaccine in school before becoming sexually active.<sup>4</sup> The more modest decline in women aged 21-30 years reflects lower vaccine coverage.<sup>8</sup> The proportion of women aged over 30 years with genital warts was low in the pre-vaccination period, as the peak age for developing genital warts is the late teens and early 20s.<sup>9</sup> No significant drop occurred in the proportion of diagnoses in these older women in the vaccination period, probably because they were ineligible for the free vaccine.

Our data show that genital warts may have disappeared in young women who reported being vaccinated. We were surprised by this finding, as some of these women probably had only one or two doses of vaccine,<sup>8</sup> and false positive diagnoses are always possible. A randomised controlled trial of the quadrivalent human papillomavirus vaccine showed that the vaccine's efficacy as regards clinical disease associated with human papillomavirus 6 and 11 was 100%.<sup>10</sup> Historically, about 90% of cases of genital warts have been assumed to be attributable to human papillomavirus 6 and 11. However, a recent study that analysed lesion tissues reported that 97% of genital warts were attributable to human papillomavirus 6 or 11.<sup>11</sup> Authors of this study point out that most studies use surface swabs to detect human papillomavirus DNA, with the potential that the detection may reflect carriage but not necessarily permissive viral growth. As no genital warts were detected in 2011 in young women vaccinated with quadrivalent human papillomavirus vaccine, it is possible that all cases of genital warts in Australia are attributable to human papillomavirus 6 and 11 (plus possibly human papillomavirus 16 and 18) or that the vaccine is providing cross protection against the other human papillomavirus types that cause warts. It will be interesting to see if this unexpected finding continues into the future and is replicated in other studies.

The decline in genital warts in the two younger age groups of heterosexual men can most likely be attributed to herd immunity, which is the indirect protection that unvaccinated people enjoy as a result of reduced exposure to infection.<sup>12</sup> The decline was greater in men aged under 21 years compared with 21-30 year old men. The decline observed in genital warts in younger women in our study is in line with a published model of transmission of human papillomavirus 16 in Australia, which predicted a 60-100% decline in human papillomavirus 16 in



vaccinated women with vaccination coverage of 80% of 12 year old girls.<sup>13</sup>

A modest but significant decline occurred in the proportion of men who have sex with men who were diagnosed as having genital warts in the vaccination period. This decline was not evident in bisexual men, so it is unlikely to be due to herd immunity resulting from the vaccination of women. The decline was limited to homosexual men who reported no female partners in the previous 12 months. This decline in the proportion of men who have sex with men diagnosed as having genital warts could be because the number of these men seen at the clinics increased between 2007 and 2011 (table 1⇓). This confirms that asymptomatic men who have sex with men have been successfully triaged into sexual health services in Australia in recent years.<sup>14</sup> This explanation is supported by data from the Sydney Sexual Health Centre, which reported that the positivity rates for sexually transmitted infections that are mostly symptomatic have decreased in men who have sex with men.<sup>15</sup> It is also important to appreciate that men were classified into men who have sex with men, heterosexual, homosexual, or bisexual on the basis of the self reported sex of their partners in the previous 12 months. Some misclassification could be present due to the 12 months definition used.

## Comparison with other studies

Findings from our study show a larger decline in young women and men than was seen in a recent study from Sweden, which reported an approximately 25% decline in incidence of genital warts in 17-18 year old women and no decline in men from 2006 to 2010.<sup>16</sup> However, the quadrivalent human papillomavirus vaccine was not available free of cost in Sweden during this period; rather, it was commercially available at subsidised rates for girls aged 13-17 years only, leading to low coverage rates (25% among 13-20 year olds for the first dose) compared with the high coverage rates observed in Australia.<sup>16</sup> Similar findings were reported in female patients under 21 years of age presenting to family planning clinics in California, with a 35% decline between 2007 and 2010 (vaccine coverage rate in United States: 49% among 13-17 year olds for first dose); a 19% decline in male patients under 21 years of age was also reported.<sup>17</sup> However, a study from Auckland sexual health service reported relatively larger declines: 63% decline in female patients under 20 years of age (vaccine coverage rates in Auckland: 52% among female patients under 20 years) and a 40% decline in male patients under 20 years of age between 2007 and 2010.<sup>18</sup>

## Likely future trends

In 2013, the Australian government started a publically funded programme in which 12-13 year old boys are eligible to receive free quadrivalent human papillomavirus vaccination through school based programmes. A catch-up programme provides free vaccination to 14-15 year old boys for a two year period.<sup>19 20</sup> In addition to preventing genital warts and anal, penile, and oropharyngeal cancer in men, the vaccination programme is expected to increase herd immunity and provide further indirect protection to unvaccinated women.<sup>21</sup> The male quadrivalent human papillomavirus vaccination programme in addition to enhanced coverage rates in the female programme may lead to the control (defined as a reduction of disease incidence or prevalence to a locally acceptable level<sup>22</sup>), if not elimination, of the target human papillomavirus types in young people in Australia. Future monitoring using data from this network may confirm these expected benefits.

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Contributors: BD, CKF, and AEG designed and were principal investigators of the study, with assistance from RJG and DGR. HA coordinated the surveillance network, collated data for this study, did the analysis with HW, and wrote the first draft. BD, RJG, THRR and CKF advised on analysis and interpretation. All authors contributed to the final report. BD and HA are the guarantors.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare: CKF owns shares in CSL Biotherapies; CKF, AEG, DGR, RJG, and BD have received honorariums from CSL Biotherapies; BD and RJG have received honorariums from Sanofi Pasteur MSD; BD, CKF, DGR, AEG, and RJG receive research funding from CSL Biotherapies; BD, CKF, and AEG have received honorariums from Merck; AEG sits on the Australian advisory board for the Gardasil vaccine; TRHR is a site investigator for a Merck human papillomavirus vaccine study.

Ethical approval: Ethical approval for the study was provided by the St Vincent's Hospital's ethics committee (EC00140) and the University of New South Wales ethics committee (EC00142). Further approval was provided by local research ethics committees of all sites.

Data sharing: Study protocol and data dictionary are available from the first author at [hali@kirby.unsw.edu.au](mailto:hali@kirby.unsw.edu.au).

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**What is already known on this topic**

Clinical trials have shown that the quadrivalent human papillomavirus (HPV) vaccine offers up to 100% protection against lesions caused by HPV 6 and 11

Declines in the incidence of genital warts have been documented in several countries, depending on the level of coverage with quadrivalent HPV vaccine

About 90% of cases of genital warts are generally thought to be due to HPV 6 and 11

**What this study adds**

In women, with 83% first dose vaccine coverage, a 93% decline in diagnosis of genital warts was seen by the fifth year of the national quadrivalent HPV vaccination programme in Australia

Despite men not being vaccinated, an 82% decline in genital warts occurred in heterosexual men, attributable to herd immunity

No women who reported that they had been vaccinated were diagnosed as having genital warts in the final year of the study

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## Tables

**Table 1 | Numbers of Australian born men and women diagnosed as having genital warts by numbers seen for first time at sexual health services, 2004-11**

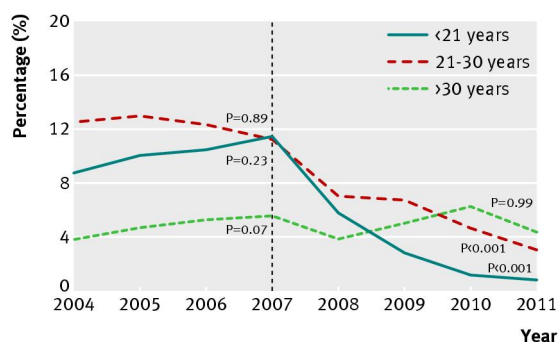
	2004	2005	2006	2007	2008	2009	2010	2011	Total
<b>Women</b>									
Total	377/4228	387/3971	404/4110	433/4504	247/4267	233/4544	189/4693	124/4583	2394/34 900
<21 years	86/981	92/908	100/956	127/1104	70/1192	36/1288	17/1451	13/1525	541/9405
21-30 years	240/1919	235/1809	238/1927	229/2028	128/1810	130/1924	92/1971	57/1840	1349/15 228
>30 years	51/1326	59/1250	66/1226	77/1368	49/1259	67/1330	80/1270	54/1217	503/10 246
<b>Men</b>									
Total	722/5620	716/5596	689/5667	720/6173	617/6246	669/7158	641/7437	518/6973	5292/50 870
Heterosexual, total	554/3715	548/3590	530/3427	547/3773	463/4013	519/4658	463/4934	375/4671	3999/32 781
<21 years	23/321	20/280	42/301	47/387	30/492	33/686	14/784	16/731	225/3982
21-30 years	275/1627	311/1664	291/1582	318/1744	285/1892	301/2151	254/2297	194/2190	2229/15 147
>30 years	256/1765	217/1646	197/1544	182/1641	148/1628	185/1821	195/1853	165/1749	1545/13 647
Men who have sex with men, total	126/1394	140/1463	109/1490	134/1568	114/1538	120/1807	146/1986	117/1826	1006/13 072
Homosexual	100/1102	114/1149	86/1189	115/1234	92/1214	101/1493	121/1589	93/1489	822/10 459
Bisexual	26/292	26/314	23/301	19/334	22/324	19/314	25/397	24/337	184/2613

Table 2| Average annual trends in diagnosis of warts at sexual health services with summary rate ratios, 2004-11

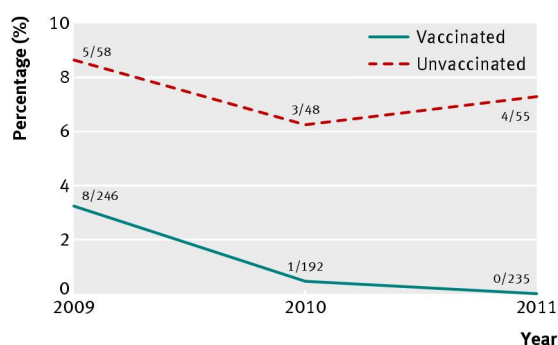
Group	Pre-vaccination period*		Vaccination period*		Pre-vaccination v vaccination period	
	Average annual trend (95% CI)	P value	Average annual trend (95% CI)	P value	Summary rate ratio (95% CI)	P value
Women:						
<21 years	1.10 (0.95 to 1.26)	0.232	0.50 (0.45 to 0.55)	<0.001	0.64 (0.59 to 0.69)	<0.001
21-30 years	1.00 (0.91 to 1.09)	0.891	0.74 (0.70 to 0.79)	<0.001	0.81 (0.77 to 0.85)	<0.001
>30 years	1.18 (0.99 to 1.42)	0.071	1.00 (0.93 to 1.08)	0.993	1.03 (0.96 to 1.10)	0.485
Heterosexual men:						
<21 years	1.44 (1.10 to 1.87)	0.007	0.61 (0.54 to 0.70)	<0.001	0.72 (0.65 to 0.81)	<0.001
21-30 years	1.04 (0.96 to 1.13)	0.316	0.84 (0.81 to 0.87)	<0.001	0.88 (0.85 to 0.91)	<0.001
>30 years	0.94 (0.85 to 1.03)	0.168	0.98 (0.94 to 1.03)	0.448	0.97 (0.93 to 1.01)	0.193
Men who have sex with men:						
Homosexual	0.90 (0.78 to 1.03)	0.127	0.92 (0.87 to 0.98)	0.011	0.92 (0.87 to 0.97)	0.003
Bisexual	0.93 (0.70 to 1.23)	0.593	1.03 (0.91 to 1.19)	0.590	1.01 (0.90 to 1.15)	0.797

\*Pre-vaccination period=1 January 2004 to 30 June 2007; vaccination period=1 July 2007 to 31 December 2011.

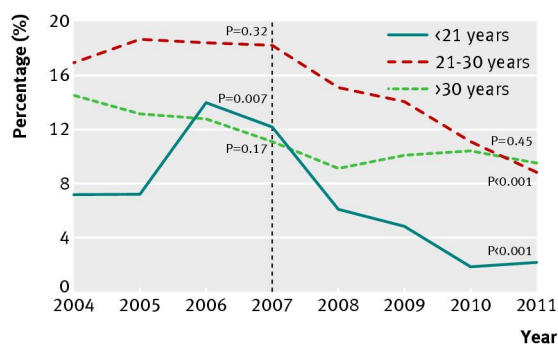
## Figures



**Fig 1** Proportion of Australian born women diagnosed as having genital warts at first visit, by age group, 2004-11

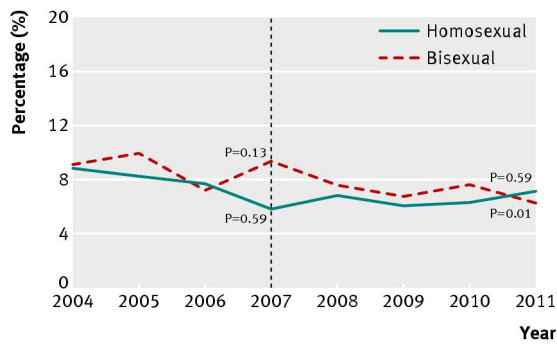


**Fig 2** Proportion of Australian born women aged under 21 years diagnosed as having genital warts at first visit to Sydney and Melbourne Sexual Health Centres, by vaccination status, 2009-11. Numbers are number diagnosed as having genital warts/number seen

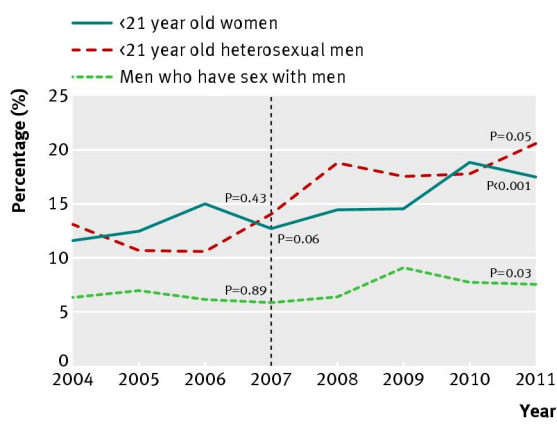


**Fig 3** Proportion of Australian born heterosexual men diagnosed as having genital warts at first visit, by age group, 2004-11





**Fig 4** Proportion of Australian born homosexual and bisexual men diagnosed as having genital warts at first visit, 2004-11



**Fig 5** Proportion of Australian born women aged under 21 years, heterosexual men aged under 21 years, and men who have sex with men who tested positive for chlamydia at first visit, 2004-11