

## Submission to Pharmac

### Consultation on *Proposal to amend listings in the National Immunisation Schedule*, 6 November 2013

From the Gay Men's Sexual Health Research Group, University of Auckland  
19<sup>th</sup> November 2013

#### Summary

- Gay and bisexual men and HIV positive individuals are not currently offered the anti-HPV quadrivalent Gardasil® vaccine funded by the New Zealand Government. Pharmac has proposed not to extend comprehensive access to these groups from July 2014. We note this is at variance with aspects of the PTAC recommendations dated 2 August 2013.
- Gay and bisexual men and HIV positive individuals are at profound risk of HPV infection and related sequelae, including HPV-related anogenital warts, pre-cancerous lesions and anal cancer. The relative risk for anal cancer is up to 20 times higher than for the general population.
- Gay and bisexual men from a wide spectrum of age groups are likely to benefit from HPV vaccination. This is due to the rapid early acquisition of HPV, high ongoing prevalence and incidence, but absence of infection with the full range of vaccine-preventable HPV types.
- HPV infection is a risk factor for HIV acquisition. As the majority of domestically-acquired HIV infections occur between gay and bisexual men, control of HPV is likely to improve HIV control in New Zealand. Of particular relevance to gay and bisexual men is that Gardasil is both an anti-cancer vaccine and an anti-STI vaccine.
- Recent cost-effectiveness studies show that vaccinating gay and bisexual men is cost-effective.
- Consequently it is neither effective nor efficient public health policy to continue to withhold funded HPV vaccines from these groups. The HPV vaccination need among these groups is at least equal to and is probably greater than among young women, who are already granted free access.
- It also contravenes the intent of the Human Rights Act 1993, which protects gay and bisexual men and people living with HIV from discrimination in the provision of goods and services.
- There are multiple options to deliver HPV vaccines and to monitor their uptake among these groups.
- Questions regarding implementation ought to be informed by consultation with affected groups and their stakeholders, just as this is widely accepted practice in relation to the health of other disadvantaged minorities in New Zealand.
- Critically, perceived obstacles to standard implementation approaches should not be used to delay broadening free access to HPV vaccination for these groups. Instead, delivery can begin immediately, and processes surrounding optimal implementation can be developed over time.

### ***Recommendations***

- We submit that Pharmac review the proposal of 6 November 2013 and **extend access to HPV vaccination to the gay and bisexual male population.**
- We submit that Pharmac review the proposal of 6 November 2013 and **extend access to HPV vaccination to all HIV positive individuals.**
- We submit that Pharmac review the proposal of 6 November 2013 and **engage experts in gay and bisexual male communities and HIV positive people to inform decision making, particularly surrounding implementation.** However, it is submitted that improving the implementation of HPV vaccination to these populations will be an incremental process and that this should not delay broadening access to these groups from July 2014.

## Introduction

1. We recognise that HPV is the most common sexually transmitted infection worldwide and is causally related to the development of cervical, vulval, vaginal, penile, anal and oropharyngeal cancers. <sup>1</sup> Around forty HPV strains are known to infect mucosal sites such as the anogenital tract. These are classified into high risk (HR) types that are oncogenic, and low risk (LR) types that are associated with anogenital warts.
2. HR HPV types are associated with nearly 100% of cervical cancers, 85% of anal cancers, 50% of penile cancers, and 35% of cancers of the tongue and oropharynx, with HPV 16 and HPV 18 the most strongly associated. <sup>2</sup>
3. In New Zealand, the Government-funded quadrivalent Gardasil vaccine protects against HR HPV types 16 and 18, and LR HPV types 6 and 11. It is currently provided free for girls aged 12-20.
4. On 6 November 2013 Pharmac proposed changes to access for freely-available Gardasil. <sup>3</sup> From July 2014 this would apply to:
  - (i) women aged under 18 years old;
  - (ii) male patients aged under 25 years old with confirmed HIV infection; and
  - (iii) for use in transplant patients.
5. This proposal is at variance with the recommendations of the Pharmaceutical and Therapeutic Advisory Committee (PTAC) to Pharmac on 2 August 2013: <sup>4</sup>
  - 10.2 The Committee **recommended** that the HPV vaccine be available to all males aged 11-19 years of age be listed in the Pharmaceutical Schedule with a **low** priority.
  - 10.3 The Committee **recommended** that the HPV vaccine for males aged between 9 and 26 years who self-identify as having sex with other males be listed in the Pharmaceutical Schedule with a **high** priority.
  - 10.4 The Committee **recommended** that access in the Pharmaceutical Schedule to HPV vaccine for females be amended so they may receive the vaccine from 11 years rather than 12 years with a **high** priority.
6. Notably the Pharmac proposal of 6 November omitted gay and bisexual men from free Gardasil access. It also limited access for HIV positive individuals to males, and also to those aged under 25. No access was granted to boys.
7. We strongly call on Pharmac to review this proposal and grant HPV vaccine access to gay and bisexual males, and also to HIV positive individuals.
8. The basis for this is primarily equity - the very high need for HPV vaccination among these groups that will not be ameliorated by the vaccination of young women. It is also practically plausible, as there are multiple options for vaccine delivery to these minority groups, and for vaccine uptake monitoring.
9. When doing so we also submit that Pharmac consider carefully the terminology used in the PTAC recommendations. For example, in 10.3 the phrase "for males aged between 9 and 26 years who self-identify as having sex with other males" disqualifies young gay or bisexual males prior to sexual debut: the group who would receive the greatest benefit from vaccination. <sup>4</sup>

### *HPV-related cancers among gay and bisexual men*

10. Gay and bisexual men, or behaviourally “men who have sex with men (MSM)” are consistently shown to experience disproportionately higher rates of anal cancer. This can be up to twenty-fold higher than in the general population, similar to rates of cervical cancer in women prior to the introduction of screening programmes.<sup>5</sup>
11. This disparity is even greater for HIV infected MSM. A recent international meta-analysis of HPV-related anal cancer reported rates among HIV infected MSM of 22 per 100,000 person-years pre-1996, when HIV antiretroviral therapies were introduced, increasing to 78 per 100,000 person-years post-1996, suggesting rates are increasing<sup>5</sup> (Appendix 1).
12. Data on the natural history of HPV disease including progression from infection to pre-cancer and cancer are limited but emerging. A prospective cohort study of gay men aged 35 and over in Sydney recently found a baseline prevalence of anal high grade squamous intraepithelial lesions (HSIL) of 34.8% and 44.6% among HIV negative and HIV positive MSM. Among participants without HSIL at baseline, the incidence was 20 and 30 per 100 person-years among HIV negative and positive MSM respectively<sup>6</sup> (Appendix 2).

### *High prevalence and incidence of HPV infection among gay and bisexual men*

13. Disparities in the prevalence of anal cancer among MSM are driven by a high prevalence and incidence of HPV infection. The Machalek et al. (Lancet Oncology, 2012) meta-review found 63.9% of HIV negative and 92.6% of HIV positive MSM respectively had any HPV type, 37.2% and 73.5% had any high risk HPV type, and 12.5% and 35.4% respectively had HPV type 16.<sup>5</sup>
14. Among younger MSM with fewer than five lifetime partners the prevalence of any HPV type in the anal canal was 42% in one study.<sup>7</sup>
15. Despite this, HPV infection is not universal among MSM, nor does it involve the full spectrum of vaccine-preventable HPV types.
16. The UK’s Health Protection Agency’s anonymous prevalence study reported that any HR HPV was found in less than 5% of MSM aged under 25, and in fewer than 10% of MSM aged 25-44.<sup>8</sup> This is supported by a study of young MSM aged 16-20 in Melbourne which found 69% remained uninfected with HR HPV types.<sup>9</sup> A further reported that no participants in a study of younger MSM were infected with the full range of HPV types (6, 11, 16, 18) protected by the Gardasil vaccine.<sup>10</sup>

### *High and universal need for HPV vaccination among gay and bisexual men*

17. The rapid early acquisition of HPV, high ongoing prevalence, but absence of infection with the full range of vaccine-preventable HPV types highlight two important issues for vaccine access policy among MSM: (i) the very high need for HPV vaccination for all MSM due to high ongoing acquisition of any HPV infection, and (ii) the very high residual potential benefit from vaccination since few will have been exposed to all types.
18. That is, vaccinating gay and bisexual men prior to initiation of sexual activity will confer the highest protection for that cohort, but sexually active MSM will also benefit from vaccination access.

### *Vaccination is highly preferable to treatment*

19. Vaccination against HR HPV is the best candidate for the control of anal and other HPV-related cancers in MSM.
20. There is little evidence for the effectiveness of current treatment options for HSIL to prevent anal cancer.<sup>11</sup> Some lesions regress spontaneously,<sup>6</sup> all treatments are invasive and painful and many are ablative, therefore screening programmes alone may not be an appropriate public health control mechanism.<sup>12</sup>
21. The ubiquity of HPV in MSM communities, its high infectiousness, and the partial but incomplete protection afforded by condoms,<sup>13</sup> also means prevention by behaviour change is highly unlikely to be effective on its own.
22. Encouragingly, the development of a quadrivalent HPV vaccine has transformed cancer control as it is highly efficacious at preventing cervical cancer in women.<sup>14</sup> Efficacy against anal HSIL has subsequently been demonstrated among males up to the age of 26, including among MSM.<sup>15</sup>
23. The introduction of the quadrivalent HPV vaccine in New Zealand to young women in 2008 has since seen dramatic reductions in diagnoses of genital warts in this group.<sup>16</sup> More modest reductions in genital warts have also been observed among young males, evidence of indirect protection for heterosexual males via their female sexual partners due to a degree of herd immunity.
24. In Australia, uptake of the vaccine among young women has been higher than in New Zealand (~80% vs ~53%), with comparatively greater reductions in genital warts,<sup>17</sup> and early evidence of a decline in HPV-associated cervical abnormalities.<sup>18</sup>

### *Persisting disparities for gay and bisexual men*

25. In contrast, a decline in genital warts has not been seen among young MSM in Australia,<sup>17</sup> who receive no benefit from the vaccination of young women.
26. This raises considerable health equity issues, with MSM at heightened risk of vaccine-preventable cancers and other sequelae such as anogenital warts.
27. Similarly, some heterosexual men will continue to be placed at risk through contact with unvaccinated women, particularly through patterns of migration. Overall, a quarter of all vaccine-preventable cancers occur among men<sup>2</sup> and this burden will not be averted even if current vaccination programmes among women achieve high coverage.

### *Cost-effectiveness studies*

28. A study by Kim (Lancet Infectious Diseases, 2010) (Appendix 3) identified that a targeted HPV vaccination programme for MSM in the US would likely be cost-effective for the prevention of anal cancer and genital warts.<sup>19</sup> This is an updated study of the Kim and Goldie (2009) paper cited in the PTAC and Pharmac decisions which modeled the cost-effectiveness of vaccinating boys.<sup>20</sup>
29. The Kim (2010) study noted that the estimates were robust “irrespective of age at vaccination and proportion of MSM who have been exposed to vaccine-type HPV infections by the time of

vaccination.” (Kim 2010: 849). The cost-effectiveness estimates were also conservative as they did not include prevention of HPV-related oropharyngeal and penile cancers (Kim 2010:849-850),<sup>19</sup> and used estimates of HPV prevalence that predated the Machalek et al. (2012) meta-review.<sup>5</sup>

30. The author states: “Despite uncertainty about previous exposure of HPV in the MSM population, health benefits are expected to be greatest when vaccination is done early, ideally before sexual debut, after which HPV infection can be acquired quickly. Several obstacles challenge early uptake in this high-risk subgroup, including age at which people self-identify as MSM, willingness to disclose sexual identity to others, acceptability of the vaccine, and social stigma of vaccination against a sexually-transmitted infection (especially if vaccination is targeted to a subgroup with a specific sexual orientation). Strongly influenced by social norms, these factors could obstruct access to a vaccine that might benefit a high-risk population that otherwise is offered no routine services for prevention of anal cancer. Whether or not HPV vaccination of all men and boys can or should be used as a means to achieve maximum benefits for MSM is a topic of debate; however, this analysis provides compelling evidence that HPV vaccination of MSM need not occur at the earliest ages to be good value for money. Indeed, targeting of HPV vaccination to MSM up to age 26 years, although not as beneficial as vaccinating early, had a cost effectiveness ratio that is less than the lower-bound threshold of cost-effectiveness in the USA (ie, \$50 000 per QALY), even when previous exposure to vaccine-targeted HPV types was high.” (Kim 2010:850).

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31. Furthermore, trials of both the bivalent<sup>21</sup> and quadrivalent<sup>22</sup> HPV vaccine have now shown that efficacy among previously exposed but not currently infected women (HPV non-naïve women) is comparable to that among HPV naïve women. A study by Turner et al. (PLoS, 2013) (Appendix 4) has recently re-modeled the cost-effectiveness when including vaccine protection among non-naïve women.<sup>23</sup> This had substantial effect on cost-effectiveness for various scenarios, particularly for catch-up programmes among older women and when coverage among younger age cohorts was low. This has implications for funding targeted vaccination programmes for non-naïve MSM who are sexually active.

#### *Additional public health benefits of vaccinating gay and bisexual men*

32. HPV infection has been identified as a risk factor for HIV acquisition.<sup>24</sup> As MSM account for approximately 75% of newly diagnosed HIV infections that were acquired in New Zealand,<sup>25</sup> prevention of HPV infection will contribute to enhanced HIV control in New Zealand. This is relevant, since a relatively high proportion of MSM are HIV infected (although our rates are currently low by international standards)<sup>26</sup> and the number of MSM living with HIV is increasing,<sup>27</sup> with high associated treatment costs.

33. Research in New Zealand has also shown MSM to report an elevated prevalence of lifetime anogenital warts (11.7%), being 40% among those diagnosed with HIV.<sup>28</sup> The rate of self-reported first-diagnosis anogenital warts among MSM was 2% in the previous 12 months in a community-based study, a proxy for incidence.<sup>29</sup>

34. MSM furthermore have high sexual health needs across age cohorts that are not limited to younger gay and bisexual males. In a study of MSM from community-based venues and Internet dating sites in New Zealand in 2011, 7.5% of 16-24 year olds, 8.5% of 25-39 year olds, and 8.6% of respondents aged 40 and over reported an STI diagnosis in the previous 12 months, suggesting ongoing acquisition risks.<sup>30</sup>

35. Vaccination of gay and bisexual men in New Zealand will consequently have both a direct and indirect impact on the costs associated with the diagnosis, morbidity and treatment of sexually transmitted disease in addition to being a cancer control mechanism.

*The urgent priority of improving gay and bisexual men's health status*

36. Gay and bisexual men and HIV positive individuals in New Zealand are small, stigmatised minority groups who experience profound disadvantage across several facets of health and wellbeing. This translates into greater need for targeted and appropriate health services.
37. Few data on HPV-related issues affecting these groups are available in this country. However they are likely to be similar to those identified in the international meta-review by Machalek et al. (2012).<sup>5</sup>
38. Doing nothing in response to this evident need is unethical when there is a proven effective vaccine available, and when it is already funded in New Zealand for other groups. Historical precedents such as failing to immediately screen for Hepatitis C virus in the blood supply when a test became available in the early 1990s provide a context for the current decision.
39. The dual efficacy of Gardasil as both an anti-cancer vaccine and an anti-STI vaccine is particularly relevant to gay and bisexual men, who experience disproportionate rates of anogenital warts and HIV infection.
40. There is no official register of such individuals in New Zealand. Where their health need is equal to or exceeds that of already targeted groups, then vaccine delivery as well as programmes monitoring uptake will have to be conducted differently to that for the general population.
41. Most HIV positive individuals who have been diagnosed are under active clinical follow up. Clinicians providing outpatient care will be able to offer HPV vaccination to this group and be involved in monitoring uptake, for example by periodic audit.
42. Gay and bisexual men are both dispersed through the population and geographically concentrated,<sup>31</sup> as is typically true for ethnic minorities. However sexuality is an invisible trait, and sexual orientation is seldom a variable captured in routine healthcare databases, such as NHI, creating obstacles to delivery.
43. The absence of robust population estimates on sexual orientation minorities in New Zealand - despite repeated calls to improve this situation<sup>28, 31, 32</sup> – means there are scarce data available to enumerate the potential vaccine eligible population, and to calculate vaccine uptake rates for gay and bisexual men by age and geographic area for example.
44. Furthermore, the safety of individuals disclosing their sexual orientation in the context of health service provision needs to be considered, especially for younger gay or bisexual men.
45. In general these issues speak to the fact that the New Zealand health system has not yet responded well to the particular health needs of sexual orientation minorities. Many needs and barriers have recently been acknowledged and summarised in a report commissioned by the Auckland District Health Board on "Rainbow Health", providing momentum for action.<sup>33</sup>

46. Several New Zealand researchers have conducted work in these areas and have expertise to offer, including our own group, and could be consulted about decisions affecting the health of such communities.

*Vaccine delivery and monitoring for gay and bisexual men and HIV positive individuals*

47. As a guiding principle, assumptions surrounding vaccine delivery and monitoring for gay and bisexual men and HIV positive individuals, namely the potential opportunities and barriers, should not be made without direct involvement of those affected communities. The rationale for this is exactly the same as it is for the involvement of Maori and Pacifica peoples in relation to the health of their communities.

48. Crucially, uncertainty surrounding vaccine delivery and monitoring must not be used to justify continued exclusion to government-funded HPV vaccination, given the unambiguously high HPV-related needs among gay and bisexual men and HIV positive individuals, including anal cancer and anogenital warts.

49. That is, need that is at present higher than the population currently offered free vaccination, being young women. And need which will not in the case of gay and bisexual men be ameliorated by greater efforts to raise vaccine coverage among young women.

50. To do so would in effect be using existing disadvantage to justify further discrimination.

51. It may also contravene the intent of the Human Rights Act 1993. Both gay and bisexual men and people living with HIV are protected from discrimination in the provision of goods and services under the Human Rights Act 1993 (sexual orientation and disability provisions, respectively). Discrimination is unlikely to be ethical given the high HPV vaccination needs of these groups and the current practice of providing free vaccination to young women. The high need would almost certainly outweigh arguments promoting the purported barriers to implementation, as, for a start, these barriers are not of these groups' making. Furthermore, imperfect access and incomplete uptake among young women have not been used to justify the withholding or cessation of HPV vaccination programmes for this group.

52. There are multiple options to promote, deliver and evaluate HPV vaccination for gay and bisexual men.

53. Vaccine awareness can be promoted through gay community organisations and their members. Targeted promotional campaigns for gay and bisexual men have been conducted by the New Zealand AIDS Foundation for 29 years with considerable success. Gay venues and events can be encouraged to raise awareness and encourage vaccine uptake. Social media can be harnessed to circulate information among networks of gay and bisexual men. Gay community media can be used by opinion leaders to influence community attitudes.

54. Vaccine delivery can begin immediately as many gay and bisexual men will have already disclosed their sexual orientation to their general practitioner. Sexual health clinics routinely identify gay and bisexual men when they collect client information on sex of partner/s. Large-scale vaccination programmes can be trialed at community events, such as the regional Pride festivals, in partnership with health providers.

55. Vaccine uptake monitoring can utilise systems that already exist or that are about to be implemented. These include the 3-yearly GAPSS and GOSS behavioural surveys that recruit large

and diverse samples of gay and bisexual men (Ministry of Health funded, conducted since 2002, next round in 2014),<sup>34,35</sup> sentinel sites such as the national network of sexual health clinics, and the proposed national probability sexual and reproductive health survey of the Ministry of Health, which already has a question on HPV vaccine uptake for young women (first round in 2014, to be repeated every 5 years).

56. In other words, gay and bisexual men have common physical, virtual and media communities that have been and can be exploited to respond to public health challenges, such as HPV vaccination delivery. It is important to appreciate that most gay men are linked into some form of network, because that is the only way members of a small, permanent and invisible minority are able to meet potential life partners and participate in gay community cultural exchanges.
57. Current health system imperfections, limited official understanding of gay communities, and a focus towards primary care should not delay the funding and introduction of HPV vaccination for gay and bisexual men and HIV positive individuals. If health service delivery to all minority groups had to wait until such systems were perfected then very little progress on minority health would ever occur.
58. Long-term transformative responses to the health system to improve the health of gay and bisexual men (as well as other sexual orientation and transgender minorities) would of course support immediate actions. For example, if some gay and bisexual males feel uncomfortable disclosing their sexuality to health providers, and if this is impacting on their care, then cultural safety training surrounding sexual orientation to improve staff and service competency are one obvious response. These are established practices within an Ottawa Charter-style framework for improving the health status of populations. They are also widely accepted (and adopted) practices for addressing the health of ethnic minorities in New Zealand, and these should provide initial models for a “best-practice” strategic response.

### ***Recommendations***

- We submit that Pharmac review the proposal of 6 November 2013 and extend access to HPV vaccination to the gay and bisexual male population.
- We submit that Pharmac review the proposal of 6 November 2013 and extend access to HPV vaccination to all HIV positive individuals.
- We submit that Pharmac review the proposal of 6 November 2013 and engage experts in gay and bisexual male communities and HIV positive people to inform decision making, particularly surrounding implementation. However, it is submitted that improving the implementation of HPV vaccination to these populations will be an incremental process and that this should not delay broadening access to these groups from July 2014.

Thank you for considering this submission.

Yours sincerely,

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