

This is an Accepted Manuscript of an article published in [Australian and New Zealand journal of public health] on 7 March 2011, available online at <http://onlinelibrary.wiley.com/doi/10.1111/j.1753-6405.2011.00652.x/full> (paywalled).

Self-archived in the [Sydney eScholarship Repository](#) by the Centre for Values, Ethics and the Law in Medicine (VELiM), University of Sydney, Australia

Please cite as:

Rae M, Kerridge I. Vaccines – but not as we know them: An ethical evaluation of HPV vaccination policy in Australia. Aust NZ J Pub Health. 2011;35(2):176-9. DOI 10.1111/j.1753-6405.2011.00652.x.

Vaccines – but not as we know them: an ethical evaluation of HPV vaccination policy in Australia

Rae M, Kerridge I. (2011)

Correspondence to:

Dr Merlyn Rae, Family Planning New South Wales, PO Box 148, Fairfield, New South Wales 1860; e-mail: merelynr@fpnsw.org.au

Abstract

Objective: To show how systematic ethical evaluation of public health policy may reveal issues of moral significance for critical examination.

Method: Using Australia's human papillomavirus (HPV) vaccination program as an exemplar and adopting an approach outlined elsewhere, we determine whether conditions of effectiveness, proportionality, necessity and least infringement, and public justification, are met such that any breach of autonomy or justice principles associated with this intervention can be defended.

Conclusions: While the HPV vaccine itself may be efficacious, some aspects of the program lack sufficient moral justification and raise concerns around procedural and social justice and gender equity.

Implications: Public health interventions deploying new technologies against new targets – such as vaccines against cancer and chronic illness – require approaches crafted to their specific risk-benefit profiles that have carefully considered the ethical issues involved. Systematic ethical reflection is a useful tool for this.

While growing interest in the ethics of public health, particularly around health promotion, is exploring its moral assumptions, the moral values relevant to specific public health interventions are rarely made explicit. An ethical perspective centred on the important moral principles of beneficence, respect for autonomy, and justice, posits the moral authority of much public health policy in the principle of beneficence. Public health interventions seek to benefit the community, exemplified in utilitarian approaches (seeking the greatest good for the greatest number). This nonetheless creates moral tensions, particularly with principles of respect for autonomy and justice.^{1–6}

Using the approach to resolving these tensions of Childress et al.² to critique Australia's HPV vaccination program, we conclude that parts of the program are difficult to morally justify. More importantly, we demonstrate how issues of moral significance, otherwise overlooked, are exposed.

Objective

Our objective in this paper is to demonstrate how a process of structured moral reflection can bring important issues to light, allowing their proper inclusion in policy deliberations.

Approach

As background, we briefly discuss some important criticisms of utilitarianism in public health before outlining Australia's recently introduced HPV vaccination program. We then evaluate key aspects of the program using the approach of Childress et al.² They proposed that where “there is conflict between the general moral considerations that are generally taken to instantiate the goals of public health – producing benefits, preventing harms, and maximising utility – and those that express other moral commitments” [p173], certain justificatory conditions (effectiveness, proportionality, necessity and least infringement, and public justification) should be met to merit the public health values prevailing.

Utilitarianism in public health

Public health authorities have historically taken an outcome-oriented approach to maximise utility (the ratio of benefits over harms). This approach may be uncontroversial. Mass immunisation programs have such an impressive record – smallpox eradicated, the impact of polio, measles, diphtheria and other infections dramatically reduced⁷ – that the broad-brush approaches that efficiently delivered the population coverage needed for disease control could be justified given the clear public benefit and the necessity for urgent action and absence of realistic alternatives.

However, strategies of highly selective framing and simplistic or emotional messages, while once acceptable as they sought an important social good, are difficult to transpose to situations where the trade-offs are not so clearly agreed. As the conditions targeted by public health become more complex, interventions entail risk-benefit calculations that are inevitably more uncertain, making any disregard for the principles of respect for autonomy or justice harder to defend.^{8,9} This disregard is seen as utilitarian approaches legitimise only one value (the pre-selected utility on offer), and may overlook benefits such as non-discrimination or social justice that, while harder to measure, are important to society. These considerations are especially relevant where interventions target issues that lack imperatives of urgency or necessity, and where any evidence-base supporting health promotion undertakings is weak.¹⁰ Also, people's decisions to participate may be only self-regarding, making interventions that require individuals' active cooperation, but which use only perfunctory consent procedures, difficult to justify.

The human papillomavirus

Genital infections caused by HPV are the most common sexually transmitted infections (STIs) in the world. The vast majority of infections are self-limiting. It is only persistent infection with high-risk strains of HPV that is linked to anogenital and other cancers and is a necessary causal factor for cervical cancer.

Worldwide cervical cancer affects about 500,000 women a year and causes about 270,000 deaths. Australia's rates are among the world's lowest, due largely to its cervical screening program, though certain under-screened groups retain incidence many times the national average.^{11–13}

Importantly, half of HPV-related cancers are non-cervical and one quarter occurs in men. In men who have sex with men, the risk of HPV-related anal cancer is equal to that of cervical cancer in unscreened women, and the correlation between oropharyngeal cancers (whose rising incidence mirrors that of oral sex) and high-risk HPV is even higher than that of cervical cancer.^{14,15}

The HPV vaccine

A prophylactic vaccine, Gardasil®, offers protection against acquisition of four HPV strains: 16 and 18, responsible for about 70% of cervical cancers, and 6 and 11, which cause 90% of genital warts. It induces strong antibody responses in girls and boys up to 15 years old. Clinical trials of 15–26 year old females have demonstrated efficacy of 90–100% in per-protocol populations against vaccine-type virus acquisition, persistent infection and cervical cancer precursor lesions, with an average of three years follow up.¹⁶ Much lower efficacy was seen in intention-to-treat analyses.¹⁷ Importantly, the projected lowering of cervical cancer risk associated with HPV vaccination translates to only a small benefit in absolute terms for screened women, reducing an individual's lifetime risk from 0.86% to 0.30–0.47%.¹⁸

Australia's HPV vaccination program

Australia was among the first countries to license Gardasil in mid-2006 following intense media coverage of the miracle of the 'cancer vaccine' and the key role played in its development by an Australian researcher, Dr Ian Frazer, and an Australian company, CSL. It is noteworthy, however, that in November 2006, the Pharmaceutical Benefits Advisory Committee (PBAC), an independent statutory body that evaluates new pharmaceutical products for public subsidy, initially rejected CSL's application for inclusion of Gardasil into Australia's immunisation program, citing inadequate data (particularly on duration of immunity and the long-term impact on cancer) and lack of cost-effectiveness.¹⁹ A public outcry ensued and the government requested that the PBAC urgently review its decision. That same month the PBAC received a revised submission from CSL, after which it reversed its initial decision.¹⁹

The government then announced a national program of vaccination of schoolgirls aged 12–13, the first country in the world to do so, along with a two year catch-up period for females aged 13–26. As part of this program, girls in the first year of high school in NSW were given a sealed Human Papillomavirus (HPV) Vaccination Parent Information Kit to take home. At the time that the program began this was available only in English. It contained a brief leaflet entitled 'Protecting your daughter against cervical cancer' and a question and answer page (Parents are referred elsewhere for further information). It also contained a consent form for a parent or guardian to sign and return within one week.

Semiotics of HPV vaccination information

The information provided in this kit and indeed the entire HPV vaccination campaign stressed the risk of cervical cancer, the urgent need for and the benefit of HPV vaccination. Certain facts implying high risk – "anyone who has ever had sexual contact could have HPV", "people do not know they have the infection"²⁰ and there being "no cure for HPV infection"²¹ – were given prominence over the fact that the vast majority of HPV infections resolve naturally and do not lead to cancer. All girls were regarded as at equal risk. The small reduction in absolute risk for screened women afforded by the vaccine was not mentioned; alternative strategies including delayed vaccination or compliance with current screening recommendations were either not referred to at all or not discussed in terms of their relative risk reduction.

No mention was made of the high efficacy against genital warts. Condoms were referred to in a rather disparaging way (they only "offer limited protection as they do not cover all the genital skin"²¹) and there was no reference to other prevention measures nor to sexual health more broadly.

Ethical evaluation using Childress's justificatory conditions

Any program promoting a new vaccine requires as a minimum an appropriate level of data regarding the efficacy and safety of the product. As outlined earlier, the HPV vaccine promised high efficacy against acquisition of vaccine-type virus. Vaccine-related adverse events – pain, erythema, swelling

and pruritis at the injection site, and fever, headache, arthralgia, fatigue, and myalgia – were minor; rare or long-term harms may yet emerge.¹⁶

However, while the short-term utility of the vaccine may be established our interest here is whether the overall program initiated in late 2006 meets Childress's justificatory conditions. This distinction is important as different aspects of any public health intervention may draw upon information of variable amount and quality, and may entrench, challenge or override different moral values.

Effectiveness

This program of universal vaccination slotted into the national immunisation schedule is likely to achieve high uptake, however it had an expressly-stated goal of reducing cervical cancer. It is difficult to provide robust evidence in advance for the likely effectiveness of any cancer prevention program.^{16,22} Results from limited follow-up of study populations using surrogate endpoints may not translate into long-term effectiveness of widespread administration in real-world populations; modelling is imprecise and not all relevant variables can be foreseen.¹⁷ Many questions remain unanswered, key among them the duration of protection (with possible need for booster vaccination), the implications of poorer screening program performance resulting from reduced disease prevalence, and the risk of reduced screening participation, or increased risk behaviour, from a perception of adequate protection by the vaccine alone.⁷

Proportionality

The notion of proportionality requires that the benefits should exceed harms. Such analysis depends on the appropriate selection, definition and evaluation of the harms and benefits of public health programs, and, critically, on an understanding of how they impact differently on different people.

Benefits to vaccine recipients of reduced incidence of screen-detected cervical abnormalities and of genital warts are expected to be realised early (though screening is still required given the role of non-vaccine-type high-risk strains in cervical cancer). No vaccine-related serious adverse events had been seen.¹⁶

Taking a broader perspective on the benefits and harms of the program, however, raises important questions. It is not known whether policy deliberations canvassed alternative program design offering additional benefits or considered any potential for the program's utilitarian approach to further disadvantage vulnerable subgroups or be discriminatory.

We note that the burden of vaccination falls on girls, while the benefit from reduced viral prevalence extends to males. Furthermore, vaccinating both sexes, while perhaps adding little to cervical cancer reduction, would directly benefit males, offering protection against genital warts and oropharyngeal and anogenital malignancies (a benefit particularly for men who have sex with men, who are at greatest risk but not readily identifiable for targeted vaccination prior to risk acquisition). Another benefit may be reducing male sub-fertility as the virus has been isolated in semen and linked with reduced sperm motility.²³

The decision not to vaccinate boys, if indeed any consideration was given to postponing the program until efficacy data in males was available, perpetuates discriminatory gender-role stereotypes. In reinforcing the idea that STIs are a 'women's issue' it permits boys to take less responsibility for their behaviour, even though their sexual behaviour (with males generally having a higher number of previous partners and partnering with younger females) contributes to the risk of HPV acquisition for females. Given that we already have evidence that a range of reproductive and sexual health concerns in young people are responsive to school-based programs, the failure to genuinely engage boys in this program is a missed opportunity to address gender inequity.²⁴

Regarding differential program impact on different subgroups, one concern is that high overall vaccine acceptance could mask low uptake in those women most at-risk of cervical cancer (and thus most likely to benefit from vaccination.) These include those likely to be under-screened and those

who live in areas with significant levels of high school absenteeism (who may potentially miss vaccination days); there appear to be no programmatic features addressing this.

Necessity and least infringement

These conditions require that any public health intervention is necessary and that it involve the least possible infringement of important values. Many HPV vaccines are being researched and may prove a valuable addition to existing cervical cancer control measures. Given the latter's established success, however, urgently introducing a program of mass administration of a prototype vaccine appears unjustified by any necessity.

Public justification

Childress proposes that in order to be morally defensible, public health interventions should be publicly justified. This attention to transparency and accountability would ideally involve considered community consultation around ethical and social issues. By way of comparison, public communications surrounding this program, focused exclusively on cervical cancer and an allegedly urgent need to tackle it, were characterised by an exaggerated perception of risk and themes of a noble cause and civic responsibility. Given the complexity of issues raised by a program vaccinating one sex against an STI-induced cancer (leaving aside the issue of a minor's capacity to consent), a more inclusive public discourse would seem to be required to satisfy this condition.

Conclusion

Assessing Australia's HPV vaccination program against Childress's framework of justificatory conditions challenges its moral reasoning. The conditions of necessity and public justification cannot be demonstrably met, and many questions remain around effectiveness. Regarding proportionality, the apparent lack of attention to gender equity and social justice issues are of concern. This process has demonstrated how systematic ethical reflection can bring forward a range of issues relevant to public health interventions for critical evaluation.

Implications

While vaccines against infectious disease have traditionally raised little controversy, new targets, given the rising burden of chronic disease, and new biomedical technologies bring moral hazards. Evaluations of benefits and harms for vaccines against STI-induced cancers, and for emerging vaccines against non-infectious chronic disease (such as degenerative diseases²⁵) and even non-disease entities (risk factors for cardiovascular disease, or nicotine, for example^{26,27}) are much less straightforward and community consensus cannot be assumed. Careful examination of the medical, socio-cultural, and moral issues that may arise with their dissemination is required, especially if the decision to have a particular vaccine is largely self-regarding. Systematic ethical reflection can provide a mechanism for this and invite confidence in public health authority.

References

- 1 Bayer R, Fairchild A. The genesis of public health ethics. *Bioethics*. 2004;18(6):473–92.
- 2 Childress JF, Faden R, Gaare RD, Gostin LO, Kahn J, Bonnie RJ, et al. Public health ethics: mapping the terrain. *J Law Med Ethics*. 2002;30(2):170–8.
- 3 Kass N. An ethics framework for public health. *Am J Public Health*. 2001;91(11):1776–82.
- 4 Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 5th ed. New York (NY) : Oxford University Press; 2001.
- 5 Daniels N. Justice, health and healthcare. *Am J Bioeth*. 2001;1(2):2–16.

- 6 Gostin L, Powers M. What does social justice require for the public's health? Public health ethics and policy imperatives. *Health Aff (Millwood)*. 2006;25(4):1053–60.
- 7 Kahn JA. Vaccination as a prevention strategy for human papillomavirus-related diseases. *J Adolesc Health*. 2005;37(6 Suppl 1):1–6.
- 8 Bayer R. Stigma and the ethics of public health: Not can we but should we. *Soc Sci Med*. 2008;67:463–72.
- 9 Guttman N, Salmon CT. Guilt, fear, stigma and knowledge gaps: ethical issues in public health communication interventions. *Bioethics*. 2004;18(6):531–2.
- 10 Rychetnik L, Wise M. Advocating evidence-based health promotion: reflections and a way forward. *Health Promot Int*. 2004;19(2):247–57.
- 11 Sankaranarayanan R, Ferlay J. Worldwide burden of gynaecological cancer: the size of the problem. *Best Pract Res Clin Obstet Gynaecol*. 2006;20(2):207–25.
- 12 O'Brien ED, Bailie RS, Jelfs PI. Cervical cancer mortality in Australia: contrasting risk by Aboriginality, age and rurality. *Int J Epidemiol*. 2000;29:813–16.
- 13 Supramaniam R, O'Connell D, Tracey EA, Sitas F. Cancer incidence in NSW migrants 1991–2001. Sydney (AUST) . The Cancer Council NSW; 2006.
- 14 Burki T. Should males be vaccinated against HPV? *Lancet Oncol*. 2009;10:845.
- 15 Garland S. The Natural History of HPV: Your Questions Answered. In: Annual Hormone and Women's Health Update and Education Day; 2007; Sydney , Australia . Royal Hospital for Women, 2007.
- 16 Garland SM, Hernandez-Avila M, Wheeler CM, Perez G, Harper DM, Leodolter S, et al. Quadrivalent vaccine against human papillomavirus to prevent anogenital lesions. *N Engl J Med*. 2007;356(19):1928–43.
- 17 Kahn JA, Burk RD. Papillomavirus vaccines in perspective (editorial). *Lancet*. 2007;369:2135–7.
- 18 Goldie SJ, Kohli M, Grima D, Weinstein MC, Wright TC, Bosch FX, et al. Projected clinical benefits and cost-effectiveness of a human papillomavirus 16/18 vaccine. *J Natl Cancer Inst*. 2004;96(8):604–15.
- 19 Roughead EE, Gilbert AL, Vitry AI. The Australian funding debate on quadrivalent HPV vaccine: A case study for the national pharmaceutical policy. *Health Policy*. 2008;8:250–7.
- 20 The National HPV Vaccination Program. Protecting Your Daughter from Cervical Cancer. Canberra (AUST) : Commonwealth Department of Health and Ageing; 2007 March.
- 21 NSW Health. Questions & Answers (Q&A) about HPV Vaccination Program 2007 A Prevention Strategy for Cervical Cancer [leaflet]. Sydney (AUST) : State Government of New South Wales; 2007.
- 22 Schiffman M, Castle PE, Jeronimo J, Rodriguez AC, Wacholder S. Human papillomavirus and cervical cancer. *Lancet*. 2007;370:890–907.
- 23 Foresta C, Ferlin A, Garolla A. What about male-specific HPV related diseases? [letter]. *BMJ*. 2009;339:b4514.
- 24 Williams H, Davidson S. Improving adolescent sexual and reproductive health. A view from Australia: learning from world's best practice. *Sex Health*. 2004;1:95–105.
- 25 Barabas AZ, Weir DM, Cole CD, Bahlis NJ, Graeff RM, et al. Preventing and treating chronic disorders using the modified vaccination technique. *Front Biosci*. 2009;14:3892–8.

- 26 Ryan US, Rittershaus CW. Vaccines for the prevention of cardiovascular disease. *Vascul Pharmacol.* 2006;45(5):253–7.
- 27 Hasman A, Holm S. Nicotine conjugate vaccine: is there a right to a smoking future? *J Med Ethics.* 2004;30(4):344–5.