

Legal & Ethical Implications of Gender-Neutral Human Papillomavirus Vaccination

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Human papillomavirus (HPV), a common sexually transmitted infection, is associated with malignant and benign diseases in females and males¹. Common HPV-associated diseases include cervical, vaginal, vulvar, oropharyngeal, penile, and anal cancers as well as genital warts¹. Although HPV affects everyone, there is a high female disease burden as HPV causes almost all cases of cervical cancer². Initially, vaccines were developed for females for the prevention of cervical cancer. Two vaccines, Gardasil and Gardasil 9, were approved for use in males by the Food and Drug Administration in 2009 and 2014, respectively, and several countries have begun vaccinating males^{3,4,5}.

The World Health Organization (WHO) has made two important calls that have legal and ethical ramifications. In May 2018, the WHO set a goal to eliminate cervical cancer by 2030, by having 90% of 15 year old females vaccinated against HPV, 70% of women screened for cervical cancer once by 35 and twice by 45, and 90% of women who receive a cervical cancer diagnosis treated⁶. Accordingly, HPV vaccine demand is expected to increase, and vaccine manufacturers cannot meet the growing demand⁷. In 2019, the WHO called to temporarily halt gender-neutral HPV vaccination (GNV) as well as older age group (>15) and multi-cohort HPV vaccination due to a vaccination shortage; limiting vaccination to females ages 9-14⁸. This call was made to ensure that females globally, who have the highest burden of HPV-associated diseases, have access to a vaccine and subsequently reduce vaccine demand⁸.

Whether to implement or withhold GNV is controversial amongst professionals. From an ethical perspective, some argue that HPV vaccination should be female-only. Among the factors to be considered are the limited economic resources and the lower HPV disease burden in males compared to females according to Diane Harper, an HPV expert interviewed on this topic⁹. By contrast, several arguments hold true for GNV. First, vaccinating only females against HPV suggests that HPV is a female problem¹⁰. GNV would allow for males to share the responsibility for prevention of both cervical cancer and sexually transmitted infections¹¹. Second, although males would benefit from herd immunity (disease protection for unvaccinated individuals as a large enough proportion of the population become immune) and indirect protection from female-only vaccination¹², other groups including unvaccinated females and men who have sex with men remain unprotected from female-only vaccination¹³. Third, although effective cervical cancer screening exists, screening for HPV-associated cancers that affect both sexes is non-existent¹⁴. Finally, HPV-associated diseases affect both males and females suggesting that health equity should be considered during vaccination distribution¹⁵.

Legally speaking, there has been a discussion as to whether an HPV vaccination mandate should be implemented, such as requiring HPV vaccination for school entry. The U.S. Education Amendments Act of 1972 prohibits sex discrimination in any education program or activity receiving federal financial

assistance¹⁶. Therefore, when the HPV vaccine was initially approved, it could be considered discriminatory as the vaccine was only available for females¹⁷. However, the vaccine is now available for both sexes and could help to correct the belief that HPV vaccination is a female problem¹⁰.

Canada began GNV in 2017, however this vaccination strategy evolved across the country overtime¹⁸. The first province to begin vaccinating males in addition to females was Prince Edward Island in 2013¹⁸. All other provinces and territories followed suit: Alberta in 2014, Nova Scotia in 2015, Manitoba, Quebec and Ontario in 2016 and British Columbia, New Brunswick, Newfoundland, Nunavut, the Northwest Territories, Saskatchewan, and Yukon in 2017¹⁸. As of 2020, following the WHO call to halt GNV, Canada has continued vaccinating males and females against HPV⁵. The debate between the GNV and girls-only vaccination sides will continue as long as the potential for vaccine shortage remains.

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