

## SPECIAL ARTICLE

## IS ROUTINE HUMAN PAPILLOMAVIRUS VACCINATION AN OPTION FOR GHANA?

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## SUMMARY

Cervical cancer remains an important public health problem in developing countries where over 80% of the global burden occurs annually but screening has been ineffective. In a polygamous country like Ghana with a high incidence of cervical cancer but no national screening program, the Human Papilloma Virus (HPV) vaccine presents a unique opportunity to reduce the burden of HPV infection and cervical cancer in Ghanaian women. The evidence so far indicates that the vaccines are safe and efficacious. Although routine HPV vaccination of girls raises several religious, political, socioeconomic and ethical challenges, the emphasis of this paper will be on addressing the ethical challenges using the principles of autonomy, beneficence, non-maleficence and justice as a framework. Parental autonomy can be preserved with judicious exemptions for those who decline the vaccine on religious and philosophical grounds. This promotes public health without trampling parental authority. Routine HPV vaccination confers several benefits to individuals and society by preventing HPV infection. Instead of causing harm; it reduces harm by preventing the development of about 70% of cervical cancers and removing the negative physical and psychological impact of a cervical cancer diagnosis. It also has the potential to reduce the disparities in cervical cancer rates and its cost effectiveness will ensure considerable cost savings in terms of the money spent on diagnosis and treatment. Consequently, the HPV vaccine is an important public health landmark and achievement in women's health that must be heralded, especially in developing countries where the bulk of the disease and death occur.

**Keywords:** Human papilloma virus, vaccination, pre-adolescent girls, Ghana

## INTRODUCTION

Of all cancers, cervical cancer is the one that glaringly reflects global health inequity. Over 80% of the yearly 500,000 new cervical cancer cases and 280,000 cervical cancer deaths worldwide occur in developing coun-

tries. The highest burden and mortality associated with cervical cancer worldwide is in Sub-Saharan Africa where a woman has a 21% chance of surviving while a woman in the United States has a 70% chance of surviving.<sup>1</sup> Despite this, there are few, if any, primary and secondary prevention programs to combat cervical cancer in Sub-Saharan Africa.

In Ghana, cervical cancer constitutes about 57.8% of all gynaecological cancers.<sup>2</sup> It is the second most common cancer in women with an estimated incidence of 19.4 per 100,000. It is also the second most common cancer in women aged 15 to 44 years in Ghana. Every year, 1958 women are diagnosed with cervical cancer and 1572 die from it in Ghana.<sup>3</sup>

While the WHO estimates the Human Papillomavirus (HPV) prevalence in the West African sub-region, including Ghana, at 16.5% of women, a study estimating HPV prevalence among a sample of women attending a gynaecology outpatient clinic in Accra, Ghana found a crude HPV prevalence of 10.7%.<sup>4</sup>

Although cervical cancer screening has been effective in reducing morbidity and mortality over the past 50 years in many high income countries, this has not been the case in low income countries because of the absence of effective cervical cancer screening programs.<sup>5</sup> Despite the effectiveness of the Pap smear in reducing the burden of cervical cancer, it has significant limitations, the high false negative rate being the most critical. The limitations associated with the Pap smear become even more critical in a low income country such as Ghana where there is a dearth of qualified personnel needed for sample collection, slide preparation and slide interpretation. In addition to the Pap smear, Visual inspection with acetic acid (VIA) has been available in Ghana from 2001. This involves a single visit with visual inspection with acetic acid of the cervix and cryotherapy for lesions that are pre-cancerous.

Although there is evidence that a single visit VIA of the cervix is practical and sustainable and should therefore form part of a national program to prevent and control cervical cancer, “the lack of health infrastructure and political will has prevented scale-up to a national programme in Ghana”<sup>6</sup> Cervical cancer screening therefore may have a limited impact in such a population. On the other hand, primary prevention can be a more effective way of reducing the burden of cervical cancer by minimizing exposure to the HPV infection and utilizing routine HPV immunization.

Although routine HPV vaccination of girls raises several religious, political, socioeconomic and ethical challenges, the emphasis of this paper will be on addressing the ethical challenges using the principles of autonomy, beneficence, non-maleficence and justice as a framework. As argued below, for those against routine HPV immunization claim it violates parental autonomy, involves risks which are not offset by the benefits of vaccination, causes more harm than good and is unjust. For those in favor, it enhances parental autonomy, is beneficial, reduces harm and is just.

In a polygamous country with a high incidence of cervical cancer but no national screening program, the HPV vaccine presents a unique opportunity to reduce the burden of HPV infection and consequently cervical cancer in Ghanaian women. This paper aims to show that the Centers for Disease Control and Prevention (CDC)’s Advisory Committee on Immunization Practices’ (ACIP) recommendation of routine vaccination of females aged 11–12 years<sup>7</sup> is a policy that can be justifiably adopted as a more effective way of reducing the public health burden of cervical cancer in Ghana provided the subtypes in the vaccines are effective in the Ghanaian population.

## THE CASE AGAINST ROUTINE HPV VACCINATION

### Autonomy

Autonomy goes hand in hand with self-determination.<sup>8</sup> By extension, parents should have a choice in determining what is done to their children. Parental autonomy is therefore a core issue of concern in routine HPV vaccination.<sup>9</sup> Unlike other mandatory childhood immunizations such as polio and measles, HPV is not a contagious disease. Since it is transmitted sexually, placing it on the same level as other contagious diseases is unjustifiable. Although there are exemptions to vaccine requirements for parents who do not want their children vaccinated based on religious and philosophical grounds, this imposes an unfair burden on parents who want to do so. In addition, the protection is incomplete - the vaccine gives protection against the high

risk HPV types responsible for 70% of cervical cancers.<sup>10</sup> As a result, women would still need other preventive measures against cervical cancer. Routine HPV vaccination for preteen girls is therefore an unnecessary measure that ends up trampling parental autonomy.

### Beneficence

Beneficence is the moral obligation to act for the benefit of others, including the prevention of harms.<sup>8</sup> This means maximizing potential benefits to individuals and society while minimizing potential harms. Although there are benefits to the HPV vaccine such as prevention of HPV infection, the risks of routine HPV vaccination are not offset by the benefits. There are still many unknowns for it to be considered as a credible extension to the abstinence-only campaign. The vaccine was not tested on enough preteen girls to make it a routine requirement. Of the 25,000 participants in the clinical trial, only 1184 were preteen girls.<sup>10</sup> Other unknowns include not knowing if and when boosters will be required; not knowing all the side effects and long term effects of the vaccine including its effects on fertility and pregnancy.

### Non-maleficence

Non-maleficence is the obligation of not inflicting harm on others.<sup>8</sup> By making HPV vaccination routine, several harms could be inflicted not only on young girls but on society as a whole.<sup>9</sup> Routine HPV vaccination will encourage premarital sex in adolescents and give them tacit permission to engage in risky sexual behaviours. In addition, because adolescents may not fully understand the utility of the HPV vaccine, they may over-generalize its protection to include other sexually transmitted infections (STIs) like HIV and therefore practice unsafe sex with devastating consequences. Young people who may want to abstain from sex may also be pressured by their peers to engage in premarital sex due to a false sense of protection.

Adolescents are developmentally vulnerable to risky behavior including experimenting with sex without full understanding of the consequences. To counteract this, they need to know emphatically that abstinence is the only foolproof method against STIs and unwanted pregnancies. Moreover, some people may not understand that the vaccine does not give full protection against cervical cancer and may therefore not participate in screening programs. There is also the danger that vaccination and screening may be seen as mutually exclusive rather than complementary.

### Justice

The cost effectiveness of routine HPV vaccination is questionable. Since health resource is not unlimited,

money spent on routine vaccination would be better spent addressing other health problems and making Pap smears available to those who cannot access it. Justice denotes fair and equitable treatment,<sup>8</sup> thus, the vaccine should be available to all who need it. Unfortunately, the HPV vaccine is more likely to create health disparities because there are still questions regarding how poor, underserved and hard-to-reach girls, who as women are the most vulnerable group to develop cervical cancer, will receive the 3 doses over a 6 month period.<sup>10</sup> Moreover, since HPV infection is an STI, it is unjust to require that adolescents who plan life-long abstinence should be vaccinated. It is also wrong to target only females with HPV vaccination, since females get the infection from males. For justice to be served, the vaccine should be given to boys as well.

## THE CASE FOR ROUTINE HPV VACCINATION

### Autonomy

In requiring that the HPV vaccine be given routinely, the potential public health benefits of protecting individuals against HPV infection and consequently reducing the public health burden of HPV infection and cervical cancer must far outweigh government's interference in parental autonomy. In as much as parental autonomy gives parents the right to make decisions on behalf of their children, the State also has an interest in protecting the health of children. In the past, mandates regarding certain vaccines being given routinely have succeeded in reducing infectious diseases and establishing herd immunity. Although some argue that it is unjustified for the State to have a mandate regarding routine vaccination of a sexually transmitted infection, there is a precedent of routine vaccination against the hepatitis B virus, which, like HPV, is a largely sexually transmitted infection.<sup>11</sup>

To maintain parental autonomy, there are exemptions for parents who do not want their children vaccinated based on religious and philosophical grounds. Furthermore, rather than trample parental autonomy, public health officials can enhance parental autonomy by making reliable information on HPV and HPV vaccination readily available to parents. Access to such information can motivate parents to be proactive in making health care decisions for their children. Parental autonomy can therefore be enhanced whether parents participate in routine vaccination or opt out because of various concerns.

### Beneficence

The benefits of routine HPV vaccination are obvious. These include decreased HPV infection, decreased cervical cancer, decreased genital warts and establishing

herd immunity against HPV. A worldwide test of the HPV vaccine with over 11,000 females between 9 – 26 years showed that it is 100% effective in preventing the four HPV strains responsible for 70% of cervical cancers and 90% of genital warts.<sup>12</sup> Routine HPV vaccination therefore has the potential to drastically reduce the public health burden of cervical cancer. Combined with cervical cancer screening, routine HPV vaccination presents an exceptional opportunity to eradicate cervical cancer.

In addition, even if a female is abstinent until marriage and stays faithful in marriage, she can still be at risk of getting HPV because her husband who may not have abstained and/or is unfaithful can still transmit HPV to her. Furthermore, females who abstain are not exempt from sexual violence and therefore HPV exposure. Considering that HPV infection occurs in about 43–44% of women after 3 years of sexual activity and many adolescents are sexually active, it makes good public health sense to vaccinate preteen girls to protect them from HPV infection.<sup>13</sup> With regards to if and when boosters will be required, although future research is needed to know precisely the long-term efficacy of the vaccine, a recent modelling study indicates that the vaccine may remain efficacious for at least 12 years.<sup>14</sup> It is therefore likely that the vaccine will protect young women throughout the years when they are most susceptible to HPV infection.

### Non-maleficence

Although non-maleficence is the obligation of not inflicting harm on others, it “does not preclude balancing potential harms against potential benefits”.<sup>15</sup> The premise that HPV vaccination of preteen girls implies a tacit consent to engage in sexual activity is akin to saying that letting children wear bicycle helmets when riding their bicycles is a tacit consent for them to crash their heads. Encouraging prevention is not the same as giving permission to take health risks. As rightly put by Monk and Wiley: “HPV vaccination is not synonymous with support and approval of promiscuity rather a cry to rally together to eradicate cervical cancer worldwide”.<sup>16</sup> It is vital that this remarkable public health breakthrough is not equated with endorsing adolescent sexual irresponsibility. Rather, it must be seen as an essential step in promoting the next generation's health.

There are justifications for targeting preteen girls.<sup>11</sup> Firstly, because the vaccine is preventive, and not therapeutic, it has to be given before exposure. As such, by targeting this group, we ensure that most young women are protected, whether they initiate sex early or late. By routinely vaccinating girls at the recommended age and before engaging in sexual activity, we have a greater

chance of preventing cervical cancer and its impact on poor and vulnerable women. Secondly, as seen with the initiation of the HBV vaccinations, age-based vaccinations have been more successful than risk-based vaccinations. Thirdly, younger adolescents have a better immunogenic response than older adolescents. Fourthly, parents and guardians, if they choose, may well use HPV vaccination as an opportunity for them to discuss their views on sex with their children.

Similarly, it is unlikely that a mandate for routine HPV vaccination will give a false sense of protection from STIs and lead to sexual dis-inhibition with decreases in safer sex practices. There is no empirical evidence in support of this and fear of an STI is not a primary reason for adolescents not to engage in sex.<sup>10</sup> In any case, it is unlikely that HPV vaccination will undermine years of good communication of parental values regarding sex and sexuality. Moreover, routine HPV vaccination should not lead to an inappropriate decrease in cervical cancer screening. Even with routine HPV vaccination, cervical cancer screening will still be necessary because some women are already infected and the vaccine does not protect against all cervical cancers. However, with the availability of the HPV vaccine, thousands of new cases of cervical cancer can be prevented every year.

### Justice

The economic and social burden of HPV infections and their sequelae is huge, especially in Ghana where it is the second most frequent cancer in women aged 15 to 44 years (women in the prime of life raising their families). Studies show that compared to current cervical cancer prevention protocols, "a prophylactic vaccine targeting high-risk HPV subtypes decreased cervical cancer risk by 46 to 66 per cent and significantly increased quality-adjusted life expectancy".<sup>17</sup> In essence, the vaccine is cost-effective. In addition, non-monetary cost savings such as the emotional pain and reactions associated with an abnormal Pap smear as well as coping with the invasive treatment of cancerous and pre-cancerous lesions are very significant.

Justice requires that the vaccine should be accessible to all. In this vein, there are measures in place to ensure that the vaccine gets to all those who need it. In Ghana, all routine vaccines are given free. As such, unlike screening for cervical cancer which is accessible to only those who can afford it, routine HPV vaccination will decrease health disparities, thereby ensuring that justice is done. In addition, even though some people may choose a lifetime abstinence lifestyle, there is no guarantee that they may not become victims of sexual assault. It would therefore be unjust to exclude such people.

Even though routine vaccination is free, the cost of introducing the HPV vaccine may depend on source of funding and assurance of sustainable funding. This is where endorsement by GAVI is crucial. This is particularly important since the HPV vaccine is still too costly for those who need it. The support garnered by GAVI with the wide availability of the hepatitis B vaccine in developing countries testifies to the fact that vaccine prices inevitably decline with the rising demand<sup>18</sup>. Similarly, such an initiative by GAVI can significantly reduce the cost of the HPV vaccine.

Although vaccinating both girls and boys is the best way to achieve herd immunity, there is currently no efficacy data available on boys.<sup>11</sup> However, it is safe to assume that when efficacy is demonstrated with consequent licensing of the vaccine for use in boys, they will also be vaccinated. Therefore the argument that not giving boys the vaccine now is unjust becomes untenable.

### JUSTIFICATION OF ROUTINE HPV VACCINATION FOR GHANA

How a society defines a particular situation determines the nature of its response. When syphilis was demystified, addressed with adequate resources and defined as a public health rather than a moral problem in the US, great strides were made in controlling it.<sup>19</sup> In the same way, defining HPV infection as a public health rather than a moral problem resulting from promiscuity is vital for the measures we as a society put in place to address it. "Cancer is a public health challenge that needs to be conquered; it is not an appropriate venue for political or ideological debate".<sup>10</sup>

Is routine HPV vaccination an option for Ghana? Yes it is, with far more going in favour of this option than against it.

According to the Institute of Medicine (IOM), "Public health is what we, as a society, do collectively to assure the conditions for people to be healthy".<sup>20</sup> Ensuring that preteen girls get the HPV vaccine is in keeping with this definition of public health. Routine vaccinations ensure high herd immunity, thereby protecting all members of the community including those who cannot receive the vaccine.

Although the primary reason for HPV vaccination of pre-adolescent girls is to protect them from long-term risks, rather than to prevent immediate harm to others, it is justified to make HPV vaccination routine in Ghana. The available data<sup>21</sup> makes this imperative - 4 in 10 Ghanaian females 15-19 years have had sex. By 20

years, 83% of women have had sex. Of this group, 4 in 10 women 12 – 24 years have had more than one sexual partner.

Sexual coercion is common with 1 in 4 sexually experienced young women having ever been forced against their will to have sexual intercourse. Twelve per cent of women were forced into their first sexual experience.

Since HPV infection is an STI, making it voluntary may be ineffective because parents who choose to let their daughters have the vaccine may be seen as having promiscuous daughters. This would result in the stigmatization of HPV vaccination. If it is routine, however, there will be no stigma attached to getting the vaccine and the majority of girls would be immunized. However, it is important that before routine vaccination against HPV is embarked upon in Ghana, information, education and communication on the need to reduce cervical cancer through HPV vaccination should be done. In addition, though routine, informed consent should still be sought and there should be guidelines in place for those who may choose to opt out.

Although Ghana has a strong case for routine HPV vaccination, it simply cannot afford it. Neither is it feasible for the National Health Insurance Scheme (NHIS) in Ghana to cover the cost of routine HPV vaccination with its current funding. What is feasible, however, is to make it a part of the Expanded Program of Immunisation (EPI) and source for funding from The Global Alliance for Vaccines and Immunization (GAVI).

Since The GAVI Alliance has decided to include the HPV vaccine among its next priorities,<sup>22</sup> Ghana could source for funding from The GAVI Alliance. In addition, special pricing from the pharmaceutical companies for poor countries<sup>23</sup> and contribution from donor partners can provide substantial support in obtaining the vaccine.

There is the need for some preparatory activities before the introduction of routine HPV vaccination. This should include information, education and communication on HPV and cervical cancer, advocacy, training and pharmacovigilance. Potential barriers should be identified so that the necessary steps can be taken in addressing them. This has been useful in other countries. For example, in a South African study investigating the key barriers and challenges to the introduction of HPV vaccination, the findings, not only identified these barriers and challenges. One particular finding of note was that marketing the HPV vaccine as preventing cervical cancer rather than an STI was unlikely to be

opposed. The findings were also important in informing policy development of programs to support HPV vaccination in South Africa and other African countries.<sup>24</sup>

## CONCLUSION

Cervical cancer remains an important public health problem in developing countries where over 80% of the global burden occurs annually but screening has been largely ineffective. Evidence so far indicates that the vaccines are both safe and efficacious. The ACIP recommends routine vaccination of females aged 11-12 years. This can be started at 9 years with a catch-up vaccination of females aged 13-26 years. This is a policy which can be justifiably adopted in Ghana.

Parental autonomy can be preserved with judicious exemptions for those who decline the vaccine on religious and philosophical grounds. This promotes public health without trampling parental authority. Routine HPV vaccination confers several benefits to individuals and society by preventing HPV infection. Instead of causing harm; it reduces harm by preventing the development of about 70% of cervical cancers and removing the negative physical and psychological impact of a cervical cancer diagnosis. It also has the potential to reduce the disparities in cervical cancer rates and its cost effectiveness will ensure considerable cost savings in terms of the money spent on diagnosis and treatment.

Consequently, the HPV vaccine is an important public health landmark and achievement in women's health that must be heralded, especially in developing countries where the bulk of the disease and death occur. With the availability of the HPV vaccines, we have the potential to prevent thousands of new cases of cervical cancer every year and HPV vaccination with cervical cancer screening makes cervical cancer the most preventable form of cancer.

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