Economic Case Analysis: Human Papilloma Virus (HPV) Vaccination in the United States.

Introduction: Overview of HPV and HPV Vaccination in the United States

HPV consists of over 200 related viruses, and is the most prevalent sexually transmitted infection (STI) in the United States (U.S). Most commonly, low-risk HPVs can result in warts on or around the genitalia, anus, mouth, or throat. More than 90% of anal and cervical cancers, 70% of oropharyngeal cancers, 60% of penile cancers, and 70% of vaginal and vulvar cancers are believed to be caused by about 14 high-risk HPV strains (Centers for Disease Control and Prevention, 2021). According to data from 2015 to 2019, there are an estimated 42.5 million HPV-infected people in the U.S, and every year, there are roughly 47,199 new cases of HPV-attributable cancers (26,177 in women and 21,022 in men), except vaginal and cervical cancers whose rates have dramatically increased since 1999 (National Cancer Institute, 2021).

HPV vaccine offers protection against infections that could result in the aforementioned cancers later in life, yet in the U.S, uptake has been relatively low. The Centers for Disease Control and Prevention (CDC) recommends at least two doses before age 15, and 3 doses for those who start the series at age 15 through 26 (Centers for Disease Control and Prevention, 2021). However, based on the 2020 CDC National Immunization Survey-Teen Morbidity and Mortality report (2020), only around 54% of teens were up-to-date (UTD) on HPV vaccination. State-by State, this figure varies, with Mississippi (least) at 31% and Rhode Island (highest) at 79%. Compared to other high-income countries, the U.S trails behind. As of 2019, the US overall coverage among female adolescents only was at 57%, compared with 67% in Canada, 80% in Australia, and 90% in the United Kingdom-Scotland (Kaizer Family Foundation, 2021).

This paper aims to first identify and describe key demand and supply side market failures in HPV vaccination in the United States (See 2.0). In 3.0, government policy interventions on how to address the identified market failures will be proposed. In 4.0, I will further explore how realistic the proposed solutions will be, while also highlighting problems that might emerge while implementing them.

Market Failures with HPV Vaccination in the United States

Imperfect Information

When the HPV vaccine was introduced in 2006, the U.S Food and Drug Administration (FDA)'s approval was female-specific, and the CDC's Advisory Committee on Immunization Practices (ACIP) guidelines were for HPV vaccination for only girls aged 11-12 years against cervical cancer. It was not until 2011 that the ACIP expanded the guidelines to include vaccination for boys of the same age bracket. In June 2019, it was expanded further to cover people from age 15 through age 26 years if the person was not adequately vaccinated when younger. Even with the adjustments to the guidelines, over time, the HPV vaccination recommendations have maintained a gender and age discrepancy, thereby creating the sense that HPV disproportionately affects females compared to males, when in reality, it is not gender-selective. Feminizing the HPV vaccine has resulted in an undesirable distribution pattern in uptake between males and females. Consequently, there is reduced protection from HPV-related illnesses for males, and many missed vaccination opportunities for persons who were 13-26 years old at the time when earlier ACIP recommendations did not accommodate them (Daley et al., 2017).

Furthermore, many persons (parents, school teachers, and even healthcare workers) are insufficiently informed to understand and trust the vaccine safety. Concerns that it could cause infertility and stress-related responses have been raised, and this fear gets even worse when there is news (usually exaggerated) about cases of serious adverse effects after HPV vaccination (Wagner et al., 2020). The descriptions above are related to the demand side because they affect consumer uptake.

Barriers to Entry

Gardasil 9 is currently the only HPV vaccine available in the U.S (Centers for Disease Control and Prevention, 2021). It is also highly promoted and recommended by the CDC. Previously, Cervarix vaccine was available, but due to the low market demand, its manufacturer (GlaxoSmithKline) made a voluntary decision to pull out of the U.S. market. News concerning their exit highlighted that there was a death case

of a 14-year old girl who died after taking the Cervarix vaccine in Britain. The issue was later proven to be unrelated to the vaccine. The U.S Food and Drug Administration had a very extended period of review and delayed decision on Cervarix's continued use, even after acknowledging that the delay was not related to Britain's event or any safety concern (Kaizer Family Foundation, 2021). The U.S HPV vaccine market has become monopolized by Gardasil 9 (manufactured by Merck Sharp & Dohme Corp). In a free market, a single supplier assuming such a dominant position in the industry is discouraged because it stifles competition, slows product evolution, restricts consumer choice, and reduces consumer surplus and economic welfare. This is a supply-side issue - Monopolization could lead to too low supplies for the large US population, and a high cost of supply of the vaccines to the US government.

Uncertainties
HPV vaccination is estimated to prevent up to 90% of HPV-related cancers. However, no studies have been done to investigate this. Moreover, there is no test to find out a person's "HPV status." As with all vaccines, the HPV vaccine will no longer be efficacious after a person has already been exposed to the virus – the high probability of exposure is the key reason that routine vaccination is not recommended by the CDC for non-vaccinated adults over the age of 26 (except a shared clinical decision with their doctor after a comprehensive risk assessment is done).

However, studies have shown that 15-24-year-olds represent only 25% of the sexually active population but account for nearly half (9.1 million) of the 18.9 million new cases of STIs each year. 66% of teens & young people aged 15-24 have had sexual intercourse (vaginal or anal sex) at least one time. (Wagner et al., 2020). Therefore, with no HPV tests available to confirm negative status before HPV vaccination is administered to the eligible age groups, resources may be wasted for those already exposed among them.

Studies show that the HPV vaccine is long-lasting (with over 10 years of follow-up data indicating its continued efficacy); however, there is no evidence about waning protection, and it is still uncertain if recipients will require a booster in the future (Elam-Evans LD et al., 2020). This lack of clarity on the guideline recommendations and other uncertainties highlighted above may have likely influenced the low uptake of the vaccines – a big demand-side problem.

Government Policy Interventions
When a market failure occurs, primarily, the government uses taxes, subsidies, price floors, and ceilings to internalize additional costs to move markets closer to efficient points. Other interventions, such as education and awareness, introducing, streamlining, or enforcing laws and regulations, and easing trade restrictions, can help to shift demand and supply to an optimal level.

In the case of HPV vaccination in the U.S, the vaccines are administered for free for both the insured and uninsured through different channels, so price-related government interventions like taxes, price ceilings and floors, and subsidies may not be applicable. Rather, introducing new laws, reviewing and enforcing existing laws, and facilitating the wide dissemination/publicizing of relevant information (education) will be more applicable.

For the market failures highlighted in 2.0 above, I am proposing the following policy interventions for consideration by the government in order to improve social outcomes:

#1: Policy Intervention – Imperfect Information:
Feminizing the HPV vaccination resulted in a gap in the uptake among boys and girls. To correct this, the government needs to design gender-neutral HPV vaccination policies and guidelines and facilitate the wide dissemination and implementation of the gender-neutral policies across different channels and tiers in the United States. Regarding the issue of insufficient information about vaccine safety and side effects, the U.S Food and Drug Administration already has a robust and long-standing vaccine safety system. With this system, comprehensive pre-licensure vaccine safety testing and continuous safety monitoring upon vaccine deployment are ensured. However, not many of these safety procedures have been widely publicized in the past. To reduce vaccine hesitancy and distrust and resulting low uptake, the efforts on safety testing and

safety monitoring should be communicated widely and consistently to the public. That way, the public will be better informed, more trusting, and also more willing to take the vaccines.

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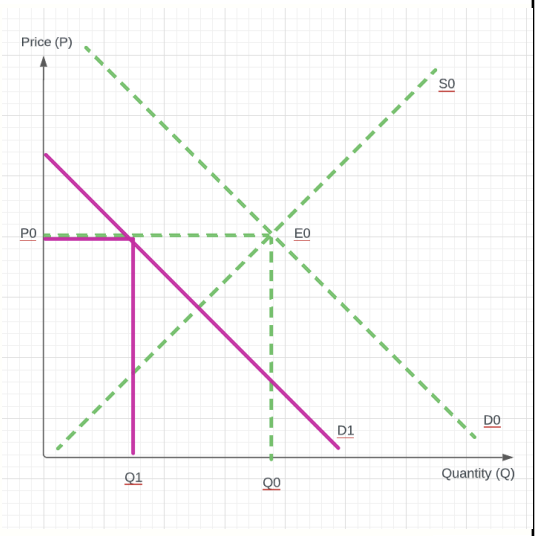

Fig 1: Underutilization of the HPV vaccine before government intervention.

At Q1 and D1, the HPV vaccine is under-utilized due to the market failure of imperfect information (below equilibrum point).

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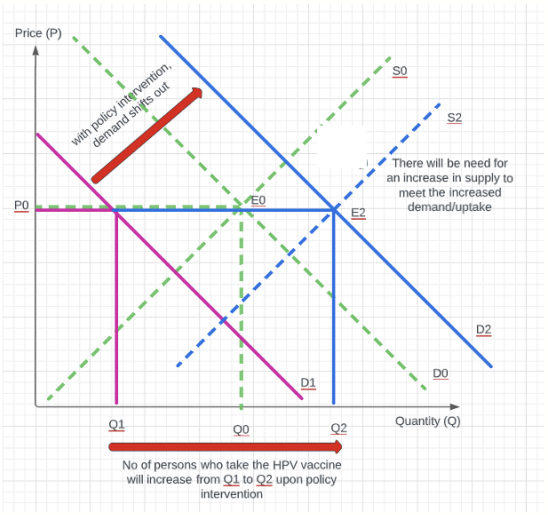

Fig 2: Increased Uptake of the HPV Vaccine after Government intervention

Government intervention includes non-price interventions like the introduction and wide dissemination of gender-neutral HPV policies and guidelines, and education of the masses on vaccine quality assurance testing and monitoring. Demand will shift out from D1 to D2; and the number of persons who receive the vaccine will increase from Q1 to Q2. There will be a need to increase the supply of the HPV vaccine (S2) to meet the increased demand for the vaccine.

#2: Policy Intervention – Uncertainties:
If the government invests in research for a test that can show an individual's HPV status, it will be a more permanent (but future) fix to the uncertainties in that regard. It will take a lot of time to achieve.

CDC recommends that vaccination start from age 9, and catch-up vaccinations can continue through to age 26. Based on the aforementioned uncertainties, a more immediate government policy to come up with is a **new law** that mandates that HPV vaccination should be embedded in elementary school routine health/immunization programs, targeting 9-year-olds (ethical considerations have to be incorporated). In addition, HPV vaccination can be listed as part of the entry requirements for middle school and high school. That way, there will be significantly reduced missed opportunities for HPV vaccination. This will increase uptake by children/teens before they get to the sexually-active age range.

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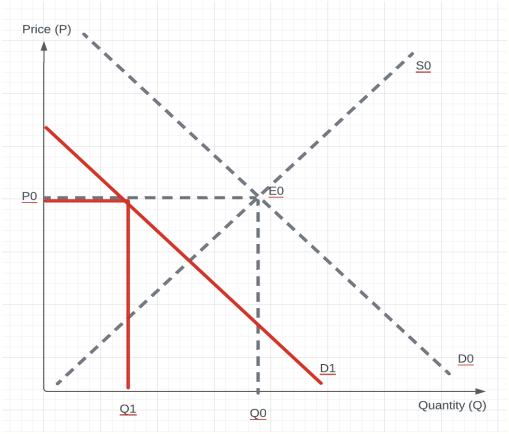

Fig 3: Low uptake of the HPV vaccine due to uncertainties.

With the uncertainties, demand is low. That is, uptake of the vaccine is not at optimal levels

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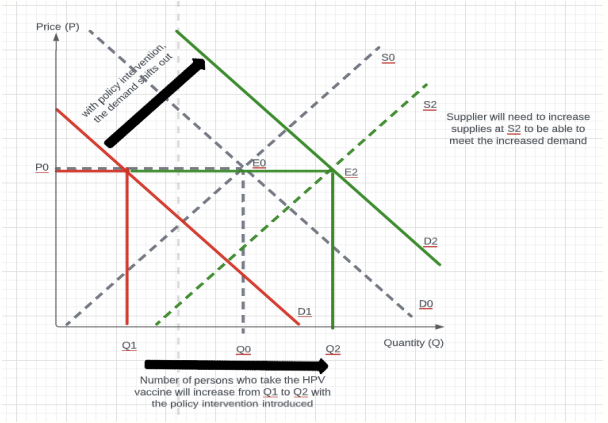

Fig 4: HPV vaccination uptake after the uncertainties have been addressed through government intervention

With government intervention, demand increases. There is a shift out in the demand curve from D1 to D2, and the uptake increased from Q1 to Q2. In order for suppliers to meet the increased demand for the HPV vaccine, they need to increase supplies (S2).

#3: Policy Intervention – Barriers to Entry:

With the implementation of the new law in #2 above, demand for the HPV vaccine will increase. The existing monopolized supply may not be able to match the increased demand. The U.S Federal Trade Commission has antitrust laws for health care markets that should help to prevent anticompetitive conduct. These antitrust laws have to be enforced for the HPV vaccine market to open room for competition by suppliers, including foreign ones. Additionally, processes for market entry (e.g., licensing) have to be streamlined and widely publicized. The CDC should not publicly declare its institutional preferences for a particular vaccine brand (as with the current situation with Gardasil 9), so as not to influence consumer choice decisions. Bottlenecks that do not allow market thriving (as with the case of Cervarix explained in #2.2 above) have to also be curbed by the Government to allow for fair competition.

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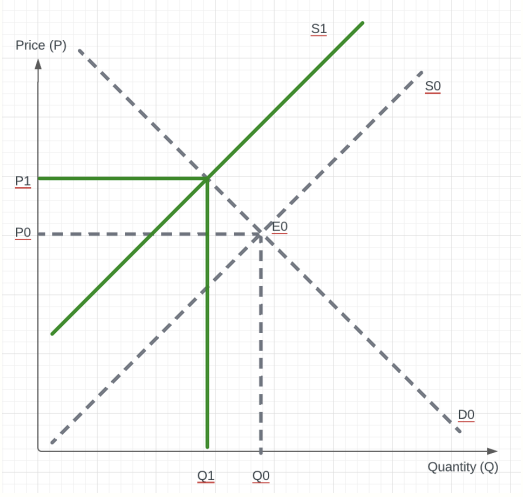

Fig 5: US HPV vaccine market monopolized by one supplier.

Here, Merck Sharp & Dohme Corp manufacturer, is supplying Gardasil 9 at a non-competitive (and possibly high) price to the government. The government purchases a lesser quantity at a high price.

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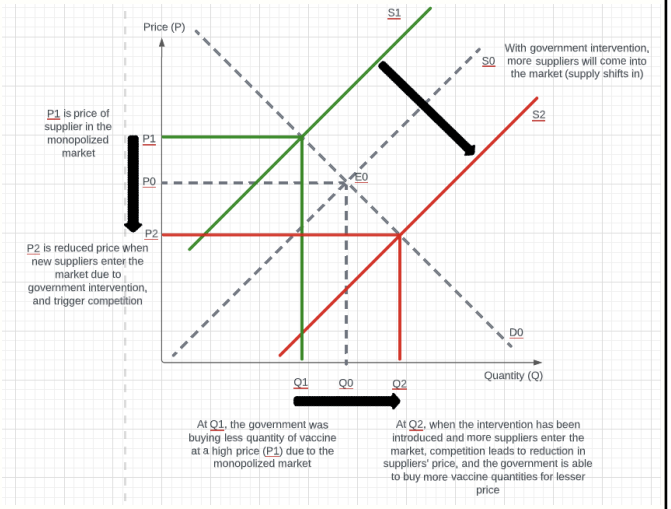

Fig 6: US HPV Vaccine market when barriers to entry have been addressed by government policy intervention

Here, with the introduction of policies/interventions to address the barriers to entry, new suppliers come into the market, and this triggers competition. To this effect, the price supplied to the government will be reduced, and the government will be able to purchase more vaccines at lower prices. Consumers will then also have surplus/a surplus of options to choose from.

4.0 Anticipated Problems with Implementation of the Proposed Solutions.

This section explains how realistic the proposed solutions will be, and what problems I anticipate in implementing them. Government intervention intended to correct market failure can lead to an inefficient allocation of resources (known as government failure) if challenges are not identified and addressed in a timely and systematic manner. There are some of the anticipated problems with the implementation of the proposed solutions. First, the feasibility of getting a new law or policy passed or modified/updated is relatively low. This is because the process is highly competitive, with every other group also strongly advocating for their requests to be prioritized by policymakers. It takes time as well as consistent and deliberate advocacy to achieve success in this regard.

Additionally, government policy makers do not necessarily 'know' enough about public health and HPV to enable them to make effective decisions about the best way to address related market failure. The solution to this is for public health experts and health economists to get involved in providing guidance and influencing those decisions. In addition, the public health community should put in efforts to facilitate policy implementation. The policy cannot be implemented effectively without collaboration with other relevant sectors, e.g., the education sector for the implementation of the school routine health/immunization programs, and the information sector for the wide dissemination of important messages to the public.

The increase in demand/uptake for the vaccines that is expected to occur with the introduction of the government interventions could result in shortage problems and access gaps, if the current monopolized market is not opened up for new suppliers to come in.

As highlighted in #2.1, it took about 5 years (2006 – 2011) for the HPV vaccine guidelines to be modified to include vaccination for males, and another 8 years (till 2019) to extend coverage from age 15 through 26. Obviously, it takes time to review any guidelines (amidst other competing demands on the government's

table), especially when it is not an emergency situation. A solution to this is for the public health community to reframe the HPV/HPV vaccination as a big issue of public health concern, and its adverse consequences on the US economy. That way, their proposed solutions in #3.0 above will attract a more prompt action by the government.

Finally, ome laws (such as the antitrust law) are already in existence but not well-enforced. If mechanisms for enforcing and monitoring them are not put in place, then the essence of having them will be defeated. This situation is also applicable to the new laws that have been proposed.

References

Centers for Disease Control and Prevention. (2021). *Cancers Caused by HPV Are Preventable.* https://www.cdc.gov/hpv/hcp/protecting-patients.html

Daley, E., Vamos C, Thompson, E., Zimet, G., Rosberger, Z., Merrell, L., & et al. (2017). The feminization of HPV: how science, politics, economics and gender norms shaped US HPV vaccine implementation. *Papillomavirus Res*, *3*, 142–148. https://doi.org/doi: 10.1016/j.pvr.2017.04.004

Elam-Evans LD, W. C. et al, Yankey, D., Singleton, J., Sterret, N., Maekowitz, L., Willams, C., & et al. (2020). National, regional, state, and selected local area vaccination coverage among adolescents aged 13–17 years - United States, 2019. *MMWR Morb Mortal Wkly Rep.* , *69*, 1109–1116. https://doi.org/doi: 10.15585/mmwr.mm6933a1

Kaizer Family Foundation. (2021). *The HPV Vaccine: Access and Use in the U.S.* https://www.kff.org/womens-health-policy/fact-sheet/the-hpv-vaccine-access-and-use-in-the-u-s/

National Cancer Institute. (2021). *HPV and Cancer*. https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-and-cancer

Wagner, C., Prentice, J., Saad-Roy, C., Yang, L., Grenfell, B., Levin, S., & Laxminarayan, R. (2020). *Economic and Behavioral Influencers of Vaccination and Antimicrobial Use*. https://www.frontiersin.org/articles/10.3389/fpubh.2020.614113/full