# Improving Global Human Papilloma Virus (HPV) Vaccination Rates

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## Presenter & Author(s) Disclosures

**Dr. Oroma Nwanodi**

(1) The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months: Merck, nonspecific ownership interest, less than $5,000 common stock outside a mutual fund.

(2) My presentation will include discussion of "off-label" use of the following: Human papilloma virus vaccines, condensed schedule dosing, which is approved in Canada and Mexico, but is not approved by the US FDA.

**Dr. Patrick Palmieri**

(1) The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months: NONE outside investments in mutual funds with holdings in health care enterprises.

(2) My presentation will include discussion of "off-label" use of the following: Human papilloma virus vaccines, condensed schedule dosing, which is approved in Canada and Mexico, but is not approved by the US FDA.



## Learning Objectives

- Describe the benefits of herd immunity to the *Human Papilloma Virus (HPV)*
- Identify the three barriers to increasing HPV vaccination rates in *Low- and Middle-Income Countries (LMICs)*
- Evaluate the available global resources for improving HPV vaccination rates
- Formulate an HPV vaccination program from available organizational resources

## Overview

- **Disease epidemiology attributable to HPV**
  - Annually 610,000 (4.8%) of estimated 12.7 million global cancers
- Success of school-based HPV vaccination programs
  - Australia (79%), Brazil (85%), Britain (80.1%) versus clinic-based programs in Belgium (29%) and the U.S. (32%).
- **Global benefits of high HPV vaccination rates**
- Examples of school-based HPV vaccination programs in LMICs
- World Health Organization (WHO) vaccination program requirements
  - Year of life saved (YLS) or incremental cost-effectiveness ratio (ICER) per quality-adjusted-life-year (QALY) for less than a nation's gross domestic product (GDP)
- **Optimal use of existing HPV vaccination provisions in LMIC**



## Epidemiology

- **Incidence of HPV attributable cancer ranges from 1.2% in Australia and New Zealand to 15.5% in India** (Forman et al., 2012)
- Age-standardized incidence of cervical cancer range from 5.7 per 100,000 women in north-America to 87.3 per 100,000 in Haiti, see table 1, figures 1 and 2 (Tsu, 2009; Uusküla et al., 2013)
- HPV is responsible for more than 99% of 530,000 annual global cases of cervical cancer
  - About 70-75% are due to infection with HPV types 16 and 18 which are covered by the heat-labile bivalent (HPV2) and quadrivalent (HPV4) vaccinations (Forman et al., 2012; Schobert et al., 2012; Westra et al., 2013)
- **There is cross protection from both HPV2 and HPV4 vaccines to some of the remaining HPV types etiologic of cervical cancer** (Banura, Mirembe, Katahoire, Namujju, & Mbidde, 2012)



## HPV Attributable Disease

| Country | GAVI Category | WHO Region | Morbidity (Annual new cases of HPV induced cervical cancer)[8,9] | Morbidity Rate (Cases per 100,000 female population)[10] | Mortality (Annual deaths from HPV induced cervical cancer) | Mortality Rate (Deaths per1,000,000) |
|---|---|---|---|---|---|---|
| Viet Nam | Intermediate | WPRO | 6,224 | 16 | 3,334 | 83 |
| Uganda | Poorest | AFRO | 2,429 | 20 | 1,932 | 155 |
| Haiti | Fragile | AMRO | 2,774 | 65 | 1,484 | 376 |
| Bolivia | Least Poor | AMRO | 1,831 | 42 | 987 | 226 |
| Cuba | Intermediate | AMRO | 1,346 | 24 | 567 | 101 |
| Guyana | Least Poor | AMRO | 160 | 41 | 71 | 182 |
| Nicaragua | Intermediate | AMRO | 809 | 30 | 354 | 132 |
| Honduras | Least Poor | AMRO | 664 | 20 | 361 | 108 |

Table 1. *Cervical cancer disease burden in GAVI-eligible countries. Morbidity and mortality. Adapted from GAVI Alliance. (2008, October 27). GAVI vaccine investment strategy. Human papillomavirus analysis. San Mateo, CA: Applied Strategies.*



## World Wide Cervical Cancer Summary

Worldwide Cervical Cancer Incidence
Incidence/100,000, age-standardized to WHO*

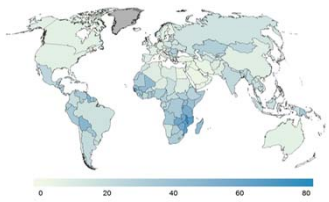



***Figure 1.*** Cervical cancer disease burden geographic distribution – incidence. Reproduced with permission from Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No.11. Lyon, France: International Agency for Research on Cancer, 2013. Available from: http://globocan.iarc.fr, accessed on July 7, 2014.

Worldwide Cervical Cancer Mortality
Incidence/100,000, age-standardized to WHO*

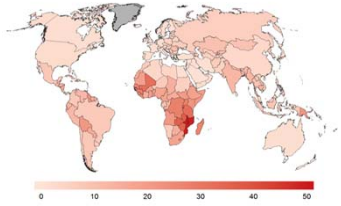



***Figure 2.*** Cervical cancer disease burden geographic distribution – mortality. Reproduced with permission from Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No.11. Lyon, France: International Agency for Research on Cancer, 2013. Available from: http://globocan.iarc.fr, accessed on July 7, 2014.

## HPV Attributable Disease Epidemiology

- HPV etiological in up to 95%, 87%, 65%, and 25% of female anal, oropharyngeal, vaginal, and vulvar cancers respectively (Banura et al, 2012)
  - Unlike three major infectious agents (H. pylori, Hep B & C), HPV is an STD (Forman et al., 2012)
  - A single sexual partner can lead to 50% HPV infection rate within 4-years of coitarche (Tsu, 2009)
  - Oropharyngeal cancers are more likely to occur in persons who have had more than six oral sex partners, 46% versus 20% (Joseph, & D'Souza, 2012)
- HPV is etiological in 36% of penile cancers (Mortensen, 2010)
- HPV related anal, oropharyngeal, penile, vaginal, and vulvar cancers account for annual incidence of 80,000 cancers (Foreman et al., 2012)
  - France spends $346.4 million annually to treat all HPV related cancers (Coughlan, & Frick, 2012).
- **HPV types 6 &11 cause 4.3 cases of recurrent respiratory papillomatosis (RRP) per 100,000 children, 1.8 cases per 100,000 adults** (Chirillă & Bolboacă, 2013; Mayeaux & Khan, 2013)
  - The female-to-male ratio of RRP ranges from 1:1 to 1:4 (Mayeaux & Khan, 2013)
  - HPV4 protects against RRP (Drolet, Laprise, Bolly, Franco, & Brisson, 2013)
  - Protection against RRP is significant as there is a one-year delay in diagnosis, treatment may require 20 procedures; tracheostomy necessary for 10-15% of children (Mayeaux & Khan, 2013)



## School-based HPV Programs: Global

- **European Medicines Agency and Health Canada approved HPV4 in 2006** (Guichon, Mitchell, Buffler, & Caplan, 2013; Tsu, 2009)
  - From 2008, school-based HPV vaccination in British achieved a three-dose 80.1% female vaccination rate (Hayashi et al., 2012)
- Despite 65% of Australian girls, 12-26 years-old, received HPV vaccination by 2009, from 2007-2011 the incidence of female EGW fell from 18.6% to 1.9%, and incidence of male fell from 22.9% to 2.9% (Schobert et al., 2012)
  - Subsequently, the Victoria, Australia school immunization program achieved a 79% three-dose vaccination rate for first year of high school students (Hayashi et al., 2012)
- Belgium, France, and Luxembourg, with non-school based vaccination programs, have lower three-dose HPV vaccination rates, at 29%, 23.7-33.3%, and 29% respectively (Hayashi et al., 2012)



## School-based HPV Programs: "Americas"

- **Brazil approved the HPV4 in 2006, without inclusion in a public immunization program**
  - A demonstration school-based HPV4 vaccination program, with scheduled vaccination days and rescue vaccination appointments as needed in Barretos, Brazil achieving a 85% female, three-dose vaccination rate (Fregnani et al., 2013)
- **The United States Centers for Disease Control recommended female HPV4 vaccination for 9 to 26-year-olds in 2006** (Perkins, Pierre-Joseph, Marquez, Iloka, & Clark, 2010), **and in 2011 for 11-26 year-old males** (Newman, Logie, Doukas, & Asakura, 2013)
  - Opposition to mandatory vaccination resulted in only Virginia and the District of Columbia successfully mandating HPV vaccination in the US (Perkins et al., 2010)
  - Only 32% of U.S. female 13-17-year-olds complete the three-dose vaccination course (Perkins, Brogly, Adams, & Freund, 2012)
- School-based HPV vaccination can achieve higher immunization rates than clinic based vaccination programs
- **Back-up vaccination days can improve the success of school-based vaccination programs**
  - Limited vaccination days in school year, as opposed to year round availability, give vaccination rates that parallel the absentee rate for any given vaccination day (Banura et al., 2012)



## Barriers Overview: HPV Vaccination

- **Acceptance and cost of HPV vaccine as well as programs**
- **Acceptability of HPV vaccination is varies within populations**
  - Beliefs regarding vaccination in general, attitudes towards sexuality and sexual transmitted infections (STIs), and attitudes towards cancer prevention
  - Governmental support of vaccination programs in general and HPV vaccination in particular
- **Acceptable vaccination cost may be linked to both personal and national income, referred to in terms of gross domestic product (GDP)**
  - Non-acceptability of vaccination precludes immunization irrespective of cost.
  - Conversely, acceptability of vaccination only leads to immunization if affordable vaccine is available
- **Globally there are resources available to provide HPV vaccination to LMICs and to resource poor communities within non-LMIC**
  - HOWEVER, the "introductory" approach to HPV vaccination in LMIC countries may predetermine, perhaps even predict, the successful attainment of adequate vaccination rates

## Barriers: Lack of Government Support

- Public health and local government laws enabling governmental vaccination programs support vaccination programs (Banura et al., 2012)
- Government support for vaccination programs promotes positive family attitudes towards any given vaccine (Tsu, 2009; Wong et al., 2013)
  - Parents in Hong Kong base vaccination acceptance on governmental recommendations (Wong et al., 2013)
  - In Uganda, government sponsorship of HPV vaccination increased parents' acceptance of the HPV vaccine for their daughters (Banura et al., 2012)
  - The Shiki City, Japan free, non-mandatory HPV2 vaccination program, achieved a 64.75% single-dose vaccination rate, and a 48.17% three-dose vaccination rate for 11-15-years-old girls (Hayashi et al., 2012)
    - The program success led the government to offer a free HPV2 vaccination program in November, 2010 with 50% national government and 50% regional government funding (Hayashi et al., 2012)



## Barriers: Culture and Religion

- **Religious objectors whose congregation believes in preaching against immunization rarely accept any dialogue with counterarguments to their beliefs**
  - Religious leaders are vested in maintaining a doctrine 'status quo' and discourage congregants from receiving immunization (Ruijs et al., 2013)
- **At least six studies from Europe and US refute sexual disinhibition or post HPV vaccination sexual risk compensation** (Zimet, et al., 2013)
  - Latino parents support HPV vaccination to preclude the stigmatization of having a STI in Latino populations (Perkins at al., 2012)
    - Mexican undergraduates (89%) believe protection from EGW by vaccination is important, only 25% thought HPV vaccination would increase promiscuity (Ramírez-Rios and Bonnez, 2013)
- Calgary Catholic school-based HPV vaccination ban in 2008, led to a 18.9% vaccination rate from free public clinics for the affected children (Guichon et al., 2013)
  - Calgary public schools children had a 70% school-based HPV vaccination rate
  - This discrepancy prompted a campaign from 2008 to 2012 by parents, HCWs, and school administrators who relentlessly and successfully sought re-instatement of school based vaccination for all schools (Guichon, et al., 2013)
- With clinic-based immunization programs, the need for clinic visits is a barrier to completion of HPV vaccination series (Perkins et al., 2012)
  - Clinic visits involve time, transportation, and possibly co-pays, which are costs



## Barriers: Safety, Efficacy, Gender

- Low safety belief for vaccination (58.9%), main reason for refusal (Pierce et al., 2013)
- **Aichmophobia (fear of needles) or trypanophobia (fear of injections), remain problematic** (Rambout et al., 2013)
  - Fear of adverse events, aichmophobia / trypanophobia is statistically significantly negatively correlated with HPV vaccination, $p<0.01$, $r=-0.09$ / $p<0.05$, $r=-0.11$ (Newman et al., 2013)
  - Injection site pain is a real concern of adolescents (Gowda et al., 2012), and may contribute to drop-off in receipt of the second and third doses of HPV vaccination
- The Kaiser Permanente Vaccine Study Center demonstrates safety and efficacy
  - Risk-interval controlled phase IV safety surveillance found day-of-vaccination syncope (odds ratio [OR] 1.8; 95% confidence interval [CI] 3.9-9.2) and skin infections occurring within two weeks of vaccination (OR 1.8; 95% CI, 1.3-2.4) (Baxter, & Klein, 2013)
- **Development of an oral or nasal version of HPV vaccine is important**
- **Concern the vaccine is actually a different medication to that advertised, such as an infertility promoting agent** (Banura et al., 2012; Tsu, 2009)
- **Low income mothers are statistically significantly more willing to vaccinate their daughters, than their sons, 71% versus 44%, $p<.001$** (Berenson, & Rahman, 2012)



## Barriers: Health Care Worker Support

- **Physicians' adherence with preventative health care increases their patients' preventative health care by 14%** (Frank et al., 2012)
- **Lack of health care worker (HCW) discussion about alcohol use and prior sexually transmitted infections is associated with failure to offer vaccination** (Perkins et al., 2012)
- Lack HCW discussion of HPV may be due to lack of knowledge
  - In some studies 38-55% of physicians have unsatisfactory knowledge of either cancer promotion by HPV or the HPV vaccine (Gowda et al., 2012; Wong et al., 2013)
- HCW recommendation or lack thereof is a major reason for vaccination or non-vaccination in health care settings, increased HPV vaccination rates rely on improved vaccine advocacy by HCW (Zimet et al., 2013)
- Incorporation of HPV vaccination rates into population health benchmarking guidelines as well as private health insurance guidelines (Zimet et al., 2013), may reduce the stigma associated with discussion of HPV vaccination

## Benefits: High HPV Vaccination Rates

- Smallpox vaccination programs eradicated smallpox (Mbulaiteye, & Buonaguro, 2013)
- **High HPV vaccination rates facilitate rapid reduction in incidence of anal, cervical, oropharyngeal, penile, vaginal, and vulvar cancers, EGW, and RRP**
- Reduction of the 275,000 cervical cancer deaths annually (Kawai et al., 2012)
  - 85% (233,750) of cervical cancer deaths are in LMIC (Levin et al., 2013)
  - 12% (33,000) of cervical cancer deaths are in LAC (Andrus et al., 2008)
- Saving the 7.8 million female years of life lost (Foreman et al., 2012), increasing the global socioeconomic contribution of women
  - The age-standardized incidence of cervical cancer is 47.5 per 100,000 in Uganda
  - Annually 2,400 Ugandan women die from cervical cancer (Banura et al., 2012)
  - Without intervention, such as HPV vaccination, by 2025, up to 4,300 Ugandan women annually, may die from cervical cancer (Banura et al., 2012)
  - While the 5 year survival for cervical cancer is 64% for black Americans, this rate is 20% for Ugandans (Banura et al., 2012)

**LMIC / LAC are the major beneficiaries of high HPV vaccination rates!!!**



## Herd Immunity: Benefits Everyone

- Herd immunity is the protection of unimmunized persons from infection by the larger group of immunized persons, preventing outbreaks
- Due to herd immunity, vaccination rates affect men and women (Lowy, & Schiller, 2012)
  - Prerequisite vaccination rate for maintenance of HPV herd immunity is undetermined
    - For the measles, mumps, and rubella vaccine, herd immunity requires a 95% vaccination rate (Cockman, Dawson, Mathur, & Hull, 2011)
- Herd immunity within 2 years of starting HPV vaccination in Australia explains the 28% reduction of EGW in unimmunized Australian men who had female partners (Lowy, & Schiller, 2012)
  - Immunized women had 60% reduction in EGW, but incidence of EGW in unimmunized men who have sex with men was unchanged (Lowy, & Schiller, 2012)
  - By 2011, immunized women no longer had incident EGW (Mbulaiteye, & Buonaguro, 2013)
  - Consistent with a per protocol 94.5% end-point efficacy of HPV4 vaccination for cervical cancer caused by HPV types 16 and 18 ($p<0.001$), and 100% efficacy for clinical disease from HPV types 6, 11, 16, and 18 using placebo controls (Yoshikawa et al, 2012)



## School-Based Success: *Examples in LMICs*

- **School-based HPV4 vaccination program, scheduled vaccination days and rescue vaccination appointments as needed, Barretos, Brazil in 2010, achieved 85% female, three-dose vaccination rate** (Fregnani et al., 2013)
- **Program for Appropriate Technology in Health (PATH), school-based outreach programs in Peru, Uganda, and Viet Nam, achieved 82.6%, 88.9%, and 87.8% vaccination rates respectively** (Levin, et al., 2013)
- **Gardasil Access Program (GAP) funding in Boliva:**
  - School-based non-government organizations (NGO) program achieved 96.1% three-dose vaccination rates in a 3,480 target population (Ladner et al., 2012)
  - Mixed school- and clinic-based NGO program achieved a 96.2% three-dose vaccination rate in a 30,900 target population (Ladner et al., 2012)



## WHO Vaccination Program: *Requirements*

- **WHO's goal is affordable, cost-effective vaccination programs befitting the public good** (Banura et al., 2012)
- Vaccines should prevent diseases affecting public health
- Vaccinations should be administered prior to exposure to the agent the vaccine is to protect against
  - HPV vaccination should occur before coitarche (Banura et al., 2012; Zimet et al., 2013)
- Vaccination programmes should be logistically possible
- Vaccination programs can be financed
- **Vaccination programs should be cost-effective**

## WHO Vaccination Program: *Speaking with Data*

- For WHO purposes, cost-effectiveness is achieved if program year of life saved (YLS) or incremental cost-effectiveness ratio (ICER) per quality-adjusted-life-year (QALY) is less than a nation's gross domestic product (GDP)
- The Peruvian cost would be $500-1,300 per year of life saved (YLS) at a $30.33-72.48 cost for one course vaccine per girl, which is less than the 2005 Peruvian per capita GDP of $2,852, in 2009 US$ (Goldie et al., 2012)
  - HPV vaccination with current screening in Peru has a discounted ICER of $4,576, (in 2006 US$) per QALY (Colantonio et al., 2009)
- At $500-1,300 per YLS, HPV vaccination is also less than the Haitian per capita GDP of $1,712, in 2008 US$ (Goldie et al., 2008)
- **In Brazil, an 85% vaccination rate of 12 year-old girls, with catch-up vaccination of women up to 26 year-old results in a 99% reduction of HPV 16 and 18 caused cervical cancer** (Kawai et al., 2012)
  - Yields an ICER of $450 per QALY, less than Brazil per capita GDP $10,710 (Kawai et al., 2012)
  - HPV vaccination with current screening in Brazil has ICER of $10,181 in 2006 US$ per QALY (Colantonio et al., 2009)



## Optimal Use in LMICs: Vaccine Supply

- Legislation requiring LAC nations to use the Pan American Health Organization (PAHO) Revolving Fund vaccines provides both cost savings and increased equity in vaccine provision (Andrus et al., 2009)
- Prior to the PAHO, the LAC experienced inadequate vaccine supply
  - Frequently out of stock (stock out), mismanaged supply, and impaired demand forecasting requiring expensive purchases to meet demand (Andrus et al., 2009)
- Heat labile vaccinations require cold storage and transportation infrastructure (cold chain) from point of national receipt of vaccine stock to point of administration, to preclude vaccine wastage (Tsu, 2009)
  - In most nations transportation infrastructure is a governmental provision.
- **Vaccination provision and cold chain costs include the cost of wastage from unused doses in multi-dose vials or an increased number of vials when single dose vials are used** (Goldie et al., 2008)



## Optimal Use in LMICs: Vaccine Schedule

- Provision of HPV vaccine at age 11-12 years with the meningococcal conjugate vaccine and tetanus, diphtheria, and pertussis vaccines are administered reduces vaccine program administration costs
- With condensed vaccination schedule, administration of HPV vaccine as early as school entry (4-6 years instead of 9 years old) when inactivated polio (IPV); diphtheria, tetanus and pertussis (DTaP); measles, mumps, and rubella (MMR); and varicella vaccinations are administered (Goldie et al., 2008)
- Preliminary studies support efficacy of two-dose HPV vaccination series instead of approved three-dose vaccination series (Dobson et al., 2013; Kreimer et al., 2011)
  - Two dose HPV4 schedules are currently in use in British Columbia and Quebec, Canada, more long-term data will be eventually be available on the efficacy of condensed schedule HPV4 administration (Dobson et al., 2013)
- **Condensed vaccination schedules can further reduce both material and administration costs, while possibly increasing completed vaccination course rates** (Dobson et al., 2013; Kreimer et al., 2011)
- **Longer term outcome data is awaited on-going trials of condensed schedule HPV administration**



## Global Resources: GAVI Program Overview

- There are 75 nations eligible for support from the Global Alliance for Vaccines and Immunizations (GAVI)
  - Works with the United Nations Children's Fund, (UNICEF) the WHO, the World Bank, and other organizations to assist in vaccination delivery in LMIC (Peny, Gleizes, & Covilard, 2005)
    - Collaboration with GAVI and UNICEF helps to assure smooth inception of vaccination programs, reducing initial frustrations such as patients presenting for vaccine which is unavailable although the vaccine was advertised available
- GAVI can defray initial funding for national vaccination programs including cold chain provision, subsequently transitioning to local funding (Banura et al., 2012; Peny, Gleizes, & Covilard, 2005)
  - By 2014, nearly 400 million HPV vaccination doses are needed to meet demands from eligible nations (Peny, Gleizes, & Covilard, 2005)

## Global Resources: GAVI Financials

- HPV4 vaccine is available to GAVI at $5 per dose (Levin et al., 2013)
  - Price is less than both the $34 per dose cost negotiated by Mexico, and the $120 per dose price in the US (Andrus et al., 2009)
- At $5 per dose, this is $25 per vaccinated person
  - HPV vaccination is equivalent to other vaccination series and is also less than per capita GDP for all LAC (Goldie et al., 2008)
- HPV vaccination is further subsidized by GAVI in the most economically disadvantaged nations (Lowy, & Schiller, 2012)
  - Of the LAC, Bolivia, Cuba, Guyana, Haiti, Honduras, and Nicaragua qualify for new vaccine program subsidy (Andrus et at., 2008; Goldie et al., 2008)
- **Tiered pricing for economic status of nations in which HPV vaccinations are sold, assists GAVI in the provision of subsidized HPV vaccination** (Lowy, & Schiller, 2012)



## Global Resources: PAHO Program Overview

- HPV vaccine is available for $10-15 per dose via the Pan American Health Organization (PAHO) Revolving Fund of the WHO established in 1977 for LMIC LAC (Andrus et al., 2009; Levin et al., 2013)
- PAHO Revolving Fund $40 million working capital allows LMIC LAC to prepay or reimburse PAHO within 60 days of receipt of vaccine (Andrus et al., 2009)
- PAHO nations like Nicaragua are also GAVI eligible (Andrus et al., 2009)
- **PAHO adopted a Regional Strategy and Plan of Action for Cervical Cancer Prevention and Control in 2008** (Tsu, 2009)



## Global Resources: PATH Program Overview

- Immunization is a global health focus area of the Program for Appropriate Technology in Health (PATH)
  - Working within WHO guidelines, investigated school based outreach, health center based outreach, and integrated outreach into Expanded Program on Immunization (EPI) for delivery of HPV vaccination in Peru, Uganda, and Vietnam (Levin, et al., 2013)
- **Examples of PATH Projects**
  - **School-based outreach, achieved 82.6%, 88.9%, and 87.8% vaccination rates respectively for Peru, Uganda, and Vietnam** (Levin, et al., 2013)
  - **School-based outreach can cost more than twice health-center based or integrated outreach** (Table 2 and Figure 3)
  - The lowest delivery cost per dose of HPV vaccine was $1.44 for Ugandan integrated outreach, contrasted with $3.88 for Peruvian school based outreach (Levin et al., 2013)
  - Due to geographical logistics school based outreach in Uganda was proportionately more expensive than in Peru or Vietnam
  - Integrated outreach costs are dependent upon existing program capacity especially for storage and transportation, and simultaneous introduction of other new vaccines (Levin, et al., 2013)



## Strategy: *Financial Considerations*

**Table 2. Incremental cost of delivering HPV vaccine in young adolescent girls in demonstration projects in Peru, Uganda, and Vietnam, in US$, 2008-2010 ***

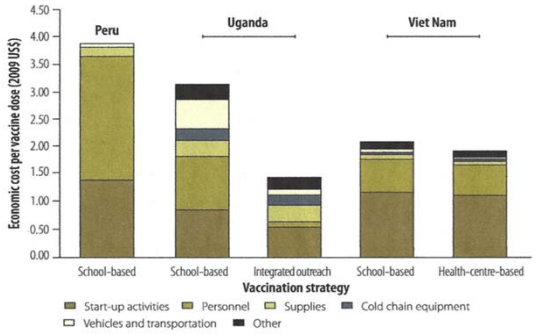
| Country and delivery strategy | Average delivery cost per dose (2009 USA $) | | No. of doses given each year | No. of fully immunized girls[a] | Annual delivery costs[b] (2009 USA $) | |
|---|---|---|---|---|---|---|
| | Economic[c] | Financial[d] | | | Economic[c] | Financial[d] |
| Peru | | | | | | |
| School based | 3.88 | 2.03 | 26,798 | 8,895 | 103,976 | 54,400 |
| Uganda | | | | | | |
| School based | 3.15 | 2.10 | 9,729 | 3.038 | 30,646 | 20,431 |
| Integrated | 1.44 | 1.11 | 8,624 | 2,388 | 12,419 | 9,573 |
| Viet Nam | | | | | | |
| School based | 2.08 | 1.62 | 5,324 | 1,766 | 11,074 | 8,625 |
| Health center | 1.92 | 1.55 | 3,550 | 1,181 | 6,816 | 5,503 |

a A fully immunized girl was one who received all three vaccine doses
b Annual delivery costs for the demonstration projects do not include the cost of the vaccine.
c The economic delivery cost was defined as the cost of all resources uses, including donated or discounted goods and services, regardless of who paid.
d The financial delivery cost was defined as the actual experience on goods and services.

* Reproduced with permission from Levin et al. (2013), Table 2.

## Strategy: *Examples Uganda & Vietnam*

**Figure 3. Profile of the economic cost of human papillomavirus vaccination strategies for young adolescent girls, Peru, Uganda and Viet Nam, 2008-2010 (in US$) ***




* Reproduced with permission from Levin et al. (2013), Figure 1.



## Program Development: *Global Resources*

- The Gardasil Access Program (GAP) supplies no cost HPV4 to the lowest income countries, which in the LAC includes Bolivia (Ladner et al., 2012)
- **Two Bolivian NGO have received GAP sponsorship** (Ladner et al., 2012)
- A school-based Bolivian NGO program achieved 96.1% three-dose vaccination rates in a 3,480 target population (Ladner et al., 2012)
- A mixed school- and clinic-based Bolivian NGO program achieved a 96.2% three-dose vaccination rate in a 30,900 target population (Ladner et al., 2012)
- **Combined regional and national funding can be a viable option** (Hayashi et al., 2012)



## Program Development: *Build it.....*

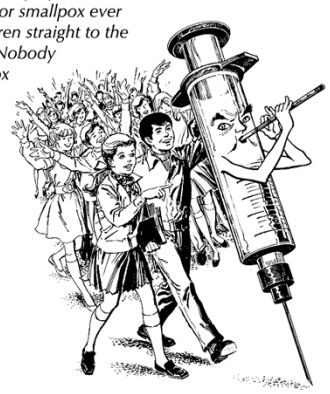
- Increased publicity on HPV vaccination prevention of anal, cervical, oro-pharyngeal, and penile cancer instead of EGW prevention (Berenson, & Rahman, 2012; Newman, et al, 2013)
  - Young adults from 22-26 years, for catch-up immunization, parents of 8-17 year old children, ethnic minorities, and members of public HMOs (Pourat, & Jones, 2012)
- Media campaigns with internet components which parents believe to be less biased than their health care providers (Gowda et al., 2012)
  - **Reinforce the 10 year efficacy data for HPV vaccination hopefully dispelling doubts of long term vaccine efficacy and safety** (Marlow, Wardle, & Waller, 2009)
  - **Expose sexual disinhibition as a myth** (Marlow, Wardle, & Waller, 2009)
    - Religious beliefs is greater driver for parental/familial rejection of vaccination
- **As HPV vaccination becomes the norm, there will be a pressure for normalcy that promotes vaccination acceptance** (Rambout et al., 2013)
- The Call to Action Campaign of Cervical Cancer Action (CCA), 2007
  - Continued collaboration between CCA and the International Union Against Cancer (IUAC) supported by over 700 other organizations (Tsu, 2009)
    - An example of the grassroots collaboration that can be brought forth in the fight to eradicate cancer of infectious etiology



## *.....and they will come.*

- HCW should be targeted for new media campaigns (Gowda et al., 2012; Wong et al., 2013)
  - Increased recommendation of both female and male HPV vaccination by HCW can facilitate HPV vaccine acceptance (Newman, et al., 2013; Rambout et al., 2013)
- **For HCW, increased education about the administration guidelines for the HPV vaccination, should include:**
  - Receiving the initial dose at 9 years old (Berenson, & Rahman, 2012)
  - Adjustable spacing of the vaccination dosing for flexibility for visit schedule
    - Second HPV dose such that it may be from 1-3 months from the first dose
    - Third dose still be given at six months
  - **Emphasizing that although the preferred course of three vaccines is given over 6 months, due to increased immunogenic response, efficacy is maintained if doses are further spaced out in adolescents** (Lowy, & Schiller, 2012)
    - **Peak and sustained antibody titers demonstrate that doses at zero and six months in 10-15 year olds are equivalent to three doses in six months in older persons.**
    - **In Canada and Mexico HPV vaccination may be dosed at zero, six, and 60 months** (Lowy, & Schiller, 2012)

*And the evil Mr. Vaccine played his flute of never getting polio or smallpox ever again, luring the children straight to the town of Notice How Nobody Gets Polio Or Smallpox Anymore.*



**Delaying Vaccines Is Not A Good Idea**



# *Continuing Medical Education* Activity

Begin 7-question CME activity . . . . .



## CME Activity: Questions 1 and 2

1. **Which of the following diseases are attributable to human papilloma virus (HPV)?**
   a. Recurrent respiratory papillomatosis (RPP) and external genital warts (EGW).
   b. Anal and oropharyngeal cancer.
   c. Cervical, vaginal, and vulvar cancer.
   d. Penile cancer.
   e. All of the above.

2. **Which of the epidemiological statements about the human papilloma virus (HPV) is incorrect?**
   a. Human papilloma virus (HPV) causes at least 99% of 530,000 annual global cases of cervical cancer.
   b. Human papilloma virus (HPV) causes 610,000 annual global cases of cancer.
   c. Human papilloma virus (HPV) causes less than 95% of external genital warts (EGW).
   d. The age-standardized incidence of cervical cancer is as high as 87.3 per 100,000 in Haiti.
   e. Women younger than 50 years old incur almost half of all human papilloma virus related cancers.



## CME Activity: Questions 3 and 4

3. **Which of the following factors affect human papilloma virus (HPV) vaccination acceptance?**
   a. Beliefs pertaining to vaccination in general and vaccine safety in particular.
   b. Attitudes towards cancer prevention, sexuality and sexually transmitted infections (STIs).
   c. Public policy pertaining to human papilloma virus (HPV) vaccination.
   d. Cost of vaccination.
   e. All of the above.

4. **Which of the following statements concerning the human papilloma virus (HPV) vaccine is incorrect?**
   a. The human papilloma virus (HPV) vaccines protect from 70% of infections from HPV types 16 and 18.
   b. Australia achieved herd immunity within 2 years of starting human papilloma virus (HPV) vaccination.
   c. In clinical trials human papilloma virus has achieved up to 94% end-point efficacy.
   d. Human papilloma virus cost per person can be the equivalent of $500-1,300 per year of life saved (YLS).
   e. The per person cost of human papilloma virus vaccination is greater than the gross domestic product of Brazil, Haiti, or Peru.

## CME Activity: Questions 5 and 6

5. **Which was not an outcome of herd immunity from human papilloma virus (HPV) vaccination in Australia?**
   a. There was a 28% reduction in external genital warts (EGW) in unimmunized male partners of immunized women.
   b. Initially, there was a 60% reduction in external genital warts (EGW) in immunized women.
   c. Eventually, immunized women no longer had incident external genital warts (EGW).
   d. Men who have sex with men (MSM) also experienced a reduction in human papilloma virus associated diseases.
   e. All of the above.

6. **The World health Organization (WHO) criteria for establishment of vaccination programs do not include which of the following?**
   a. The vaccine should prevent a disease important to public health.
   b. The vaccination program should be logistically possible.
   c. Financing mechanisms should be in-place to support the vaccination program.
   d. The vaccination program does not need to be cost effective.
   e. Vaccination should be administered before exposure to the agent the vaccine is protective against.



## CME Question: 7

7. **Funding support for human papilloma virus (HPV) vaccination programs include:**
   a. The Pan American health Organization (PAHO) Revolving Fund.
   b. The Global Alliance for Vaccines and Immunizations (GAVI).
   c. Reduced delivery costs by simultaneous administration of human papilloma virus (HPV) vaccination with pre-existing vaccination programs such as inactivated polio (IPV); diphtheria, tetanus and pertussis (DTaP); measles, mumps, and rubella (MMR); and varicella vaccination programs.
   d. The Program for Appropriate Technology in Health (PATH).
   e. All of the above.

Answers: 1-E; 2-C; 3-E; 4-E; 5-D; 6-D; 7-E.

End of CME activity



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## Abbreviated Biography: Dr. Palmieri

**Dr. Palmieri is a professor, health services researcher, accreditation surveyor, consultant, and former senior executive with 18+ years of domestic and international experience in leading health systems with multiple sites and varying degrees of vertical integration.** He achieved the first international accreditation of a healthcare organization in Peruvian history. In addition, he built the first health enterprise risk management program, developed the first formal insurance based wellness program, and established the healthcare partnership with Johns Hopkins International.

- **Academic:** More than 60 peer-reviewed publications, presentations, and book chapters; Founding professor at the first American degree granting institution in Peru; Taught the first formal health and wellness course in Peru; Former professor at Texas Tech University Health Sciences Center where he co-taught (with Dr. Alexia Green) the first graduate course in patient safety in the USA.
- **Senior leader:** Fellow, American College of Healthcare Executives; Built a vertically integrated delivery system; Developed quality, safety, and risk management programs; Established successful partnerships; Led large construction projects; Reorganized health services into service lines; Implemented clinical practice models.

**Employment History (Clinical & Management)**
- A. T. Still University; Accreditation Association for Ambulatory Health Care; University San Ignacio de Loyola; Walden University; Pacifico Salud, Healthcare Corporation of America, Vanderbilt University, Duke Health Technology Solutions, Johns Hopkins Hospital, National Surgical Hospitals, Tenet Healthcare Corporation, Avera Health, and Walmart Inc.

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