



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

August 25, 2015

DEPARTMENT MEMORANDUM

No. 2015 - 0316

FOR: ALL UNDERSECRETARIES, ASSISTANT SECRETARIES, DIRECTORS OF BUREAUS, CENTER FOR HEALTH AND DEVELOPMENT (REGION VII AND NCR), SERVICES CHIEFS OF MEDICAL CENTERS, SPECIALTY HOSPITALS AND OTHER CONCERNED

SUBJECT: Guidelines in the Implementation of Human Papillomavirus (HPV) Vaccination

I. RATIONALE

Cervical cancer remains a public health concern that continues to threaten the welfare and well-being of women and the population as a whole. It is the second most common cancer among women worldwide and is the leading cause of cancer-related deaths among women in the majority of developing countries. It affects relatively the young women and results in many lost years of life. Cervical cancer deaths have significant economic costs and impact heavily on the families' resources. The biggest impacts of cervical cancer are on poverty, education and gender equity – the first three (3) Millennium Development Goals (MDGs) the Philippines and the other 189 countries aim to achieve by 2015.

According to the International Agency for Research on Cancer (IACR), cervical cancer is the fourth most common cancer in women, and the seventh most common cancer overall, with an estimated 528,000 new cases in 2012. There were an estimated 266,000 deaths from cervical cancer worldwide in 2012, accounting for 7.5% of all female cancer deaths. Almost nine out of ten (87%) cervical cancer deaths occur in the less developed regions.

Cancer prevention is an action taken to lower the chance of getting cancer. There are different ways to prevent women from developing cervical cancer. These include (i) undergoing routine screening through Visual Inspection using Acetic Acid (VIA) or Pap Smear Test; (ii) adoption of healthy lifestyle practices; (iii) undergo cryotherapy to treat a pre-malignant condition or to keep cancer from starting and (iv) HPV vaccination. While adopting a healthy lifestyle practices would help, vaccination against HPV remains the primary prevention against cervical cancer. However, HPV vaccination is not a substitute for the routine cervical cancer screening using the Pap Test or VIA in the low-resource health settings.

Human Papillomavirus (HPV) is the most common viral infection of the reproductive tract and it's a cause of a range of conditions in both females and males, including precancerous lesions that may progress to become cancerous. Although the majority of HPV infections do not cause symptoms or disease and resolve spontaneously, persistent infection

with high-risk HPV genotypes may result in disease. In women, persistent infection with specific types of HPV (most frequently types 16 & 18) may lead to precancerous lesions which, if untreated, may progress to cervical cancer. HPV is responsible for the vast majority of cases of cervical cancer. Most sexually active women and men are infected with HPV at some point in their lives, with maximum risk exposure in young adults between 15 and 24 years of age. Genital infection with HPV is one of the most common sexually transmitted infections today. The incidence of genital warts in particular is highest amongst adolescents and young adult ages 16-24 years old.

HPV vaccines should be introduced as part of a coordinated and comprehensive strategy to prevent cervical cancer and other diseases caused by HPV. HPV vaccination is a primary prevention tool and does not eliminate the need for screening later in life, since the vaccines do not protect against all high risk HPV types. If countries considered phased introduction, priority should be given to strategies that include populations which are likely to have less access to screening for cervical cancer later in life. For the prevention of cervical cancer, WHO recommended target age group for HPV vaccination are girls aged 9-13 years, prior to becoming sexually active. This is because HPV vaccines are most efficacious in those who have not been previously exposed to the virus.¹

II. SCOPE AND COVERAGE

This guideline covers the implementing procedure on Human Papillomavirus (HPV) vaccination among female children aged 9-10 years old at the health facilities in the priority provinces (Annex A).

III. GENERAL GUIDELINES

A. VACCINE INFORMATION

1. Types of Vaccine

There are two types of vaccine to prevent HPV-related disease: (1) a quadrivalent and (2) bivalent vaccine, both of which are directed against oncogenic genotypes. Neither of these vaccines contains live biological products or viral DNA, and both are therefore non-infectious; they do not contain any antibiotics or preservative agents.

1.1 Quadrivalent HPV vaccine

This is a suspension for intramuscular injection containing purified proteins for 4 HPV types (6, 11, 16 & 18). It is available in 1-dose vials or pre-filled syringes. This vaccine is indicated for use in females and males from the age of 9 years for the prevention of premalignant genital lesions (cervical, vulvar and vaginal), premalignant anal lesions, cervical cancers and anal cancers causally related to oncogenic types, and anogenital warts (condyloma acuminata) causally related to HPV types. The quadrivalent vaccine uses alum (225 µg amorphous aluminum hydroxyphosphate sulfate) as adjuvant.

1.2 Bivalent HPV vaccine

This is a suspension for intramuscular injection containing purified viral proteins for 2 HPV types (16 & 18). It is available in 1-dose or 2-dose vials or pre-filled syringes. This vaccine is indicated for use in females from the age of 9 years for the prevention of premalignant genital (cervical, vulvar and vaginal) lesions

and cervical cancer causally related to certain oncogenic HPV types. The bivalent vaccine uses AS04 (500 µg aluminum hydroxide 50 µg 3-O-deacyl-4'-monophosphoryl lipid A) as adjuvant.

2. HPV vaccines can be given to the following :

- Lactating women.
- Patients with minor acute illnesses, such as diarrhea or mild upper respiratory tract infections, with or without fever.
- Women who have had an equivocal or abnormal Pap test, a positive HPV test, or genital warts. However, these patients should be advised that data do not indicate that the vaccine will have any therapeutic effect on existing Pap test abnormalities, HPV infection or genital warts.
- Patients who are immunocompromised, either from infection, disease or medication. However, the immune response to vaccination and vaccine efficacy might be less in immunocompromised people.

3. HPV vaccines should NOT be given to:

- Patients with moderate or severe acute illnesses. In these cases, patients should wait until the illness improves before getting vaccinated.
- Pregnant women. Although the vaccine has not been causally associated with adverse pregnancy outcomes or adverse events to the developing fetus, data on vaccination in pregnancy are limited. Any exposure to vaccine in pregnancy should be reported to the appropriate HPV vaccine pregnancy registry:

IV. SPECIFIC GUIDELINES

- A. All female aged 9-10 years old in the priority provinces shall be vaccinated with two (2) doses of HPV Quadrivalent vaccine, 0.5 ml, Intramuscular (IM), LEFT deltoid arm.
- **First dose:** at the time of visit with the health worker at age between 9 and 10 years old
 - **Second dose:** 6 months after the first dose

NOTE: Health workers must ensure that those who received the HPV 1st dose shall be given the 2nd dose of HPV vaccine after 6 months

- B. The DOH shall procure the single dose, quadrivalent HPV vaccines and distribute to the health facilities through DOH Regional health offices.
- C. HPV vaccines should not be given to anyone who has experienced a severe allergic reaction after a previous vaccine dose, or to a component of the vaccine. Individuals with hypersensitivity to any of the components of the vaccine should not receive further doses of HPV vaccine. Quadrivalent HPV vaccine is contraindicated for persons with a history of immediate hypersensitivity to yeast.
- D. HPV vaccines can be co-administered with other non-live and live vaccines using separate syringes and different injection sites. Examples are diphtheria, tetanus, acellular pertussis with or without inactivated poliomyelitis, Hepatitis A and Hepatitis B vaccines.
- E. Fear of injections resulting to fainting has been commonly observed in adolescents during vaccination. Fainting is an **immunization anxiety-related** reaction. It is not related to the content or quality of the vaccine, but to the

injection procedure. Fainting may also occur secondary to low blood sugar (hypoglycemia).

- Adolescents and adults should be seated or lying down during vaccination. Vaccinees should be carefully observed for approximately 15 minutes after administration of the vaccine.
- To reduce fainting, ensure that vaccinees have eaten before vaccination and be provided with comfortable room temperature and privacy during waiting/observation period.

The decision to administer or delay vaccination because of a current or recent febrile illness depends largely on the severity of the symptoms and their etiology. Low-grade fever itself and mild upper respiratory infection are not generally contraindications to vaccination.

As with all injectable vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine.

F. Immunization Safety and Adverse Events Following Immunization (AEFI)

1. Vaccines should be stored at temperatures between 2 to 8°C. DO NOT FREEZE.
2. Special precautions must be instituted to ensure that blood-borne diseases are not transferred to other persons. This shall include:
 - Always use the auto-disabled syringe (ADS) in all immunization sessions
 - Do not pre-fill syringes
 - Do not re-cap needles
 - Dispose used syringes and needles into the safety collector box
 - Proper disposal of safety collector boxes with used immunization wastes through the recommended appropriate final disposal for hazardous wastes
 - Use of aspirating needles is strictly prohibited
3. Adverse events following HPV vaccination are generally non-serious and of short duration. Vaccine adverse reactions from Human Papilloma Virus (HPV) vaccine can be found in Annex B of this document. Reporting of AEFI shall follow the existing DOH Guidelines in Surveillance and Response to Adverse Events Following Immunization.

G. Recording and Reporting

- Recording and reporting forms shall be completed and submitted from the service delivery point to the next higher administrative level found in Annex C of this document

V. IMPLEMENTING MECHANISM

A. Department of Health (DOH). The National DOH and the collaborating bureaus, or units are tasked to do the following:

- a. **Disease Prevention and Control Bureau (DCPB)** shall develop the guidelines, policies, and standards for immunization in collaboration with key partners and other stakeholders and report to the Secretary of Health as needed. DPDB shall also provide the necessary vaccines and other immunization logistics (e.g. safety collector boxes, immunization cards).
- b. **Epidemiology Bureau** shall collect reporting forms and AEFI reports and submit to DPCB and to Secretary of Health as needed.
- c. **Health Promotion and Communication Service** shall develop advocacy and communication plans and IEC materials for replication by the regional health offices.
- d. **Bureau of Local Health Development** shall ensure the preparedness and acceptance of the various local government units of the vaccination activity.
- e. **Logistics Management Division** shall be responsible for the delivery of vaccines and other logistics in coordination with national cold chain manager.
- f. **Regional Health Offices** shall ensure orientation of health workers and be responsible for monitoring the vaccination activity at local or subnational levels.
- g. **Hospitals** shall provide vaccinations in coordination with either regional/local health offices for the vaccine allocation. They shall submit reports and referral for severe AEFIs to government hospitals as per Administrative Order on AEFI surveillance and response.

B. Local Government Unit (Provincial/City/Municipality)

- a. Municipality/City shall provide support in the actual vaccination activities through deployment of vaccination teams.
- b. Municipality/City shall ensure timely submission of accomplishment reports to the Provincial Health Office.
- c. Provincial Health Office shall ensure timely submission of accomplishment reports to their respective Regional Health Offices.
- d. Province/City/Municipal Epidemiology & Surveillance Units (ESU) shall investigate and report detected AEFI to the next higher level.
- e. Conduct advocacy/promotion activities emphasizing the prevention of HPV infection and vaccination

C. Private Sector/Professional Organization

- a. Provides a technical assistance in the conduct of lectures, awareness campaigns on HPV vaccination

By Authority of the Secretary of Health:



VICENTE Y. BELIZARIO, JR., MD, MTM&H
Undersecretary of Health
Office for Technical Services

ANNEX A**Priority Provinces for HPV Vaccination, Phase 1**

Region	Province	Region	Province
CAR	Apayao	VIII	Leyte
	Ifugao		Eastern Samar
I	Pangasinan		Northern Samar
IVA	Quezon	IX	Zamboanga del Sur
V	Camarines Sur	XI	Davao Oriental
	Masbate	XII	North Cotabato
VI	Iloilo	ARMM	Sarangani
	Negros Occidental		Lanao Sur
VII	Cebu		Maguindanao
	Negros Oriental	Sulu	

ANNEX B

Vaccine Adverse Reactions from HPV Vaccine

Vaccine	Adverse Reaction	Frequency Rate	Frequency Category	Treatment/Management
HPV Bivalent	Fever	3%	Common	Analgesics
	Headache	30%	Very common	
	Injection site pain	78%	Very common	Symptomatic treatment with analgesic
	Redness	30%	Very common	
	Swelling	26%	Very common	
	Rash	1%	Uncommon	
	Arthralgia	10%	Very common	Analgesics
	Myalgia	28%	Very common	
	Fatigue	33%	Very common	
Gastrointestinal disorders	13%	Very common		
HPV Quadrivalent	Fever	13%	Very common	
	Headache	26%	Very common	
	Injection site pain	5.7%	Common	
	Redness	5.7%	Common	
	Swelling	5.7%	Common	
	Urticaria	3%	Common	
	Arthralgia	1%	Common	
	Myalgia	2%	Common	
	Gastrointestinal disorders	17%	Very common	
	Anaphylaxis	1.7 - 2.6 per 10 ⁶	Very rare	

Reference: Adverse Events Following Immunization (AEFI) Manual of Procedures version 2014, National Epidemiology Center, Department of Health, Philippines

