

Ministry of Health

Department of Public Health, Division of Child Health  
Guidelines for HPV Supervisors

# Human Papillomavirus (HPV) Vaccination to Prevent Cervical Cancer

Republic of Botswana



2014



# Table of Contents

<b>Foreword</b> .....	3
<b>Acknowledgements</b> .....	4
<b>List of Abbreviations</b> .....	5
<b>Human Papillomavirus and Cervical Cancer</b> .....	6
1.1 What is the cervix?.....	6
1.2 What is cervical cancer?.....	7
1.3 The magnitude of the cervical cancer problem.....	7
1.4 Signs and symptoms of cervical cancer.....	8
1.5 What is Human Papillomavirus (HPV)?.....	8
1.6 What other diseases does HPV cause?.....	9
1.7 Risk factors for contracting HPV.....	9
1.8 Types of HPV.....	9
1.9 The development of cervical cancer.....	9
1.10 HIV and cervical cancer.....	10
<b>Cervical Cancer Prevention and the HPV Vaccine</b> .....	11
2.1 The prevention of cervical cancer.....	11
2.2 The HPV vaccine.....	11
2.4 Target group for vaccination.....	12
2.5 Dosage and immunization schedule.....	13
2.6 Instructions for Use.....	14
2.7 Vaccine safety.....	14
2.8 Possible side effects following HPV vaccination.....	14
2.9 Contraindications and special precautions.....	15
2.10 Concomitant vaccinations.....	15
<b>Lessons Learned from HPV Vaccination Programmes in Other Countries</b> .....	16
3.1 Global experience with HPV vaccines.....	16
3.2 Elements of successful HPV vaccine delivery programs.....	16
3.3 Using the lessons learned from other countries.....	17
<b>Advocacy, Communication and Social Mobilisation</b> .....	19
4.1 Advocacy.....	19
4.2 Community sensitization and mobilization.....	20
4.3 Managing rumours, misconceptions and misinformation.....	21
4.3.1 Rumours.....	21
4.3.2 Causes of rumours about immunization.....	22
4.3.3 How to respond to rumours and misconceptions.....	22
<b>Logistics and Management of the HPV Vaccine</b> .....	24
5.1 HPV immunization logistics.....	24
5.1.1 Estimating the size of the target population.....	24
5.1.2 Estimating vaccine dose amounts.....	24
5.1.3 Other logistic requirements.....	25
5.2 HPV vaccine handling and management.....	25
5.3 Preparations for vaccine delivery.....	28
5.4 Packing vaccines for an immunization session.....	28
5.5 Vaccine wastage.....	29
5.6 Strategies to reduce vaccine wastage.....	29

5.7 Issuing /recording of vaccines and other logistics .....	29
<b>Micro-Planning and Coordination of HPV Activities .....</b>	<b>30</b>
6.1 District level micro-planning .....	30
6.2 Micro-planning at health facilities .....	30
<b>Administration of the HPV Vaccine.....</b>	<b>32</b>
7.1 Planning an immunization session.....	32
7.2 The immunization sessions.....	32
7.3 Setting up an immunization session at the school .....	32
7.4 Example HPV vaccination session flow .....	33
7.5 Supplies required for the HPV vaccination session.....	33
7.6 Roles and responsibilities at immunization session .....	34
7.7 Step-by-step instructions to administer Gardasil®.....	35
7.8 Messages for girls regarding HPV vaccination .....	37
<b>Injection Safety during the Immunization Session .....</b>	<b>39</b>
8.1 Disposal of sharps and other vaccination material waste.....	39
8.2 Procedures to ensure a safe vaccine injection .....	39
<b>Adverse Events Following Immunization.....</b>	<b>41</b>
9.1 Classification of AEFI .....	41
9.2 Minor vaccine reactions or AEFI.....	42
9.3 Programme errors.....	42
9.4 Rare and most serious AEFI .....	43
9.5 AEFI reporting procedures .....	45
9.6 AEFI reporting roles and responsibilities.....	46
<b>Monitoring .....</b>	<b>48</b>
10.1 Monitoring coverage, drop-out, and vaccine wastage .....	48
10.2 Forms for monitoring activities .....	48
10.2.1 HPV Vaccine Register.....	48
10.2.2 HPV Vaccination Card.....	49
10.2.3 Daily Tally Sheet.....	49
10.2.4 AEFI Form.....	50
10.2.5 Resource Management and Vaccine Wastage Form.....	50
<b>Supportive Supervision .....</b>	<b>51</b>

# Foreword

Botswana has a high incidence of cervical cancer, and cervical cancer is the most common cancer in women in Botswana. Thus, cervical cancer is a primary concern of the Ministry of Health (MOH).

The principal causatory agent of cervical cancer is well-known, human papillomavirus (HPV). HPV is a sexually transmitted virus, and there are over 200 types of HPV. Fortunately, there are vaccines that can prevent HPV and HPV-related diseases. Though HPV vaccines have not been widely available in Botswana before now, HPV vaccines have been available around the world for many years, and the World Health Organization (WHO) recommends introduction of the HPV vaccine in all countries where material and financial resources permit it.

After much analysis, MOH has decided to introduce Gardasil®, the HPV vaccine made by Merck. Gardasil® is the only HPV vaccine that protects against the four types of HPV that cause 70% of cervical cancers and 90% of genital warts. The efficacy of Gardasil® has been demonstrated worldwide to reduce diseases caused by HPV, and the use of Gardasil® is expected to reduce the burden of cervical cancer in Botswana.

Because HPV is spread primarily through sexual contact, it is recommended that the vaccine be administered before exposure to the virus - that is before girls becomes sexually active. WHO guidelines indicate that the primary target cohort be girls aged 9-13 years old. After reviewing HPV vaccine rollout programs in many other countries, including Uganda, Tanzania, Zambia, and Rwanda and given the high rates of school enrolment in Botswana, MOH has decided to vaccinate all girls aged 9 to 13 years through school-based delivery for those in standards 5, 6, and 7 and health centre delivery to girls 9 to 13 years not attending school or absent from school on vaccination day.

This field guide is provided as a tool for HPV vaccination supervisors but can also be used by other personnel such as health workers or teachers, who play a critical role in the HPV vaccination sessions. As MOH plans to expand the HPV vaccination program nationally once we gain experience with HPV vaccination, I strongly recommend that you familiarize yourself with this guide so that you can provide the best possible services to protect girls in from this deadly disease.

Ms. Shanaaz El-Halabi  
Deputy Permanent Secretary, Preventative Health Services

# Acknowledgements

The Ministry of Health would like to thank the staff from the Child Health Division (CHD), Expanded Programme on Immunization (EPI), National Cervical Cancer Prevention Program (NCCPP), Sexual and Reproductive Health (SRH), Health Education and Promotion Division (HPED), Ministry of Education (MOE), Merck Sharp & Dohme (MSD), United Nations Children's Fund (UNICEF), World Health Organization (WHO), and District Health Management Teams from Kweneng East, Kweneng West, and Selebi-Phikwe districts.

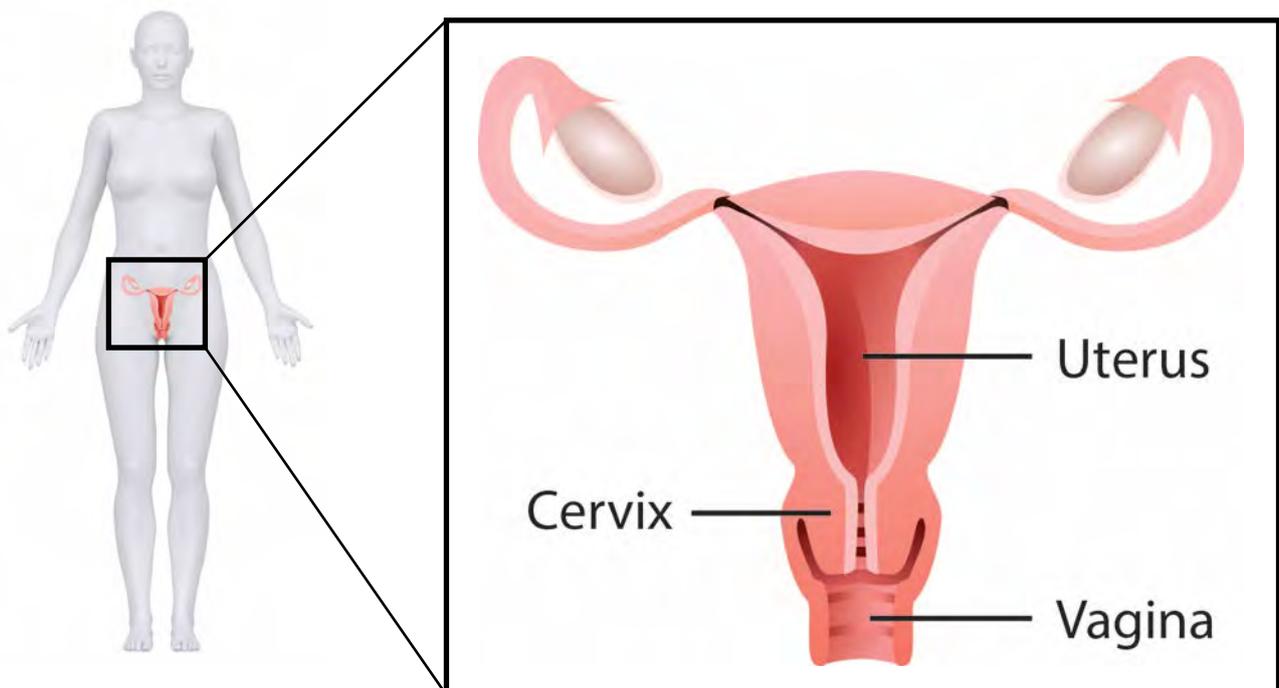
# List of Abbreviations

<b>ADs</b>	<b>Auto-Disabling Syringes (AD Syringes)</b>
AEFI	Adverse Events Following Immunization
BCG	Bacille Calmette-Guérin vaccine
CHW	Community Healthcare Worker
CMS	Central Medical Stores
DHMT	District Health Management Team
DMO	District Medical Officer
DPT-HepB+Hib	A combined vaccine (pentavalent) containing diphtheria, pertussis, tetanus, hepatitis B and haemophilus influenzae b
EPI	Expanded Programme on Immunization
FEFO	First-Expiry First-Out
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus
IEC	Information, Education and Communication
LEEP	Loop electrosurgical excision procedure
MOH	Ministry of Health
NCCPP	National Cervical Cancer Prevention Program
NGO	Non-Governmental Organisation
OPV	Oral Poliovirus Vaccine
STI	Sexually Transmitted Infections
TT	Tetanus Toxoid
UNICEF	United Nations Children's Fund
VIA	Visual Inspection with Acetic Acid
VVM	Vaccine Vial Monitor
WHO	World Health Organization

# Human Papillomavirus and Cervical Cancer

## 1.1 What is the cervix?

The female reproductive system refers to the parts of the body which allow a woman to get pregnant, give birth and nourish babies. The female reproductive system has three main parts: the uterus, the cervix and the vagina.



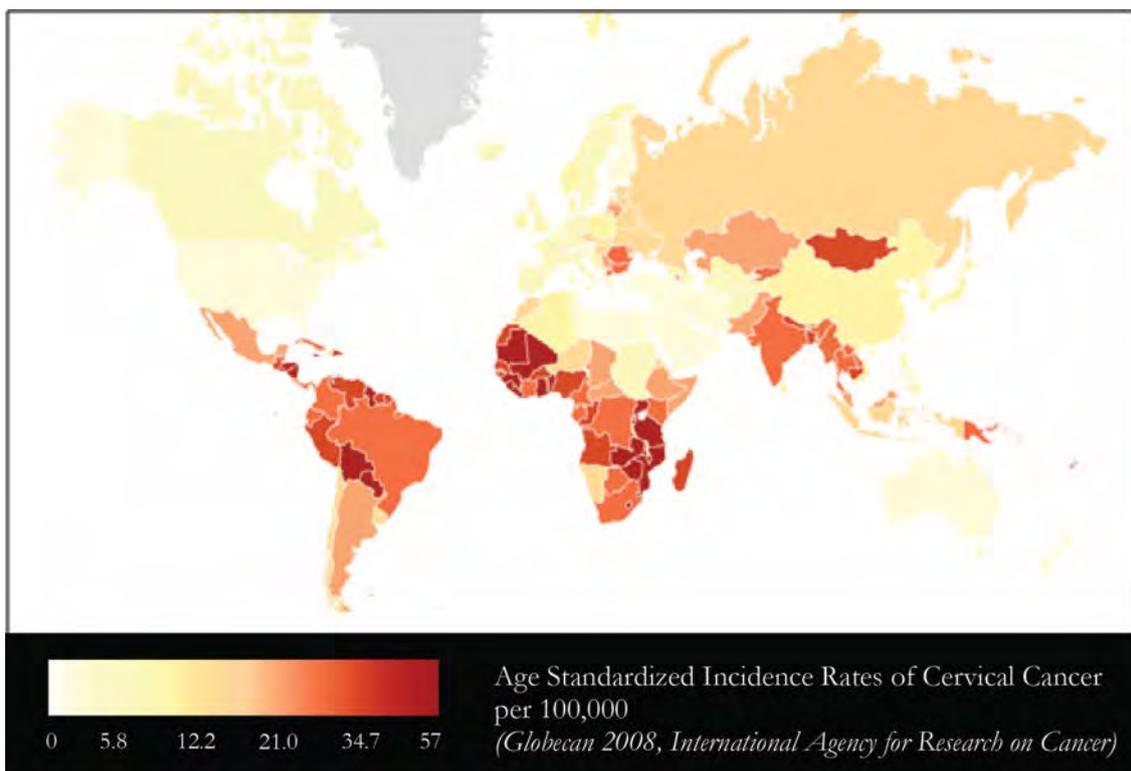
The uterus is also called the womb. During pregnancy, the uterus expands to hold the baby. The cervix is the lower part of the uterus and is located at the upper end of the vagina. The vagina, also called the “birth canal,” connects the uterus and cervix to the outside of the body.

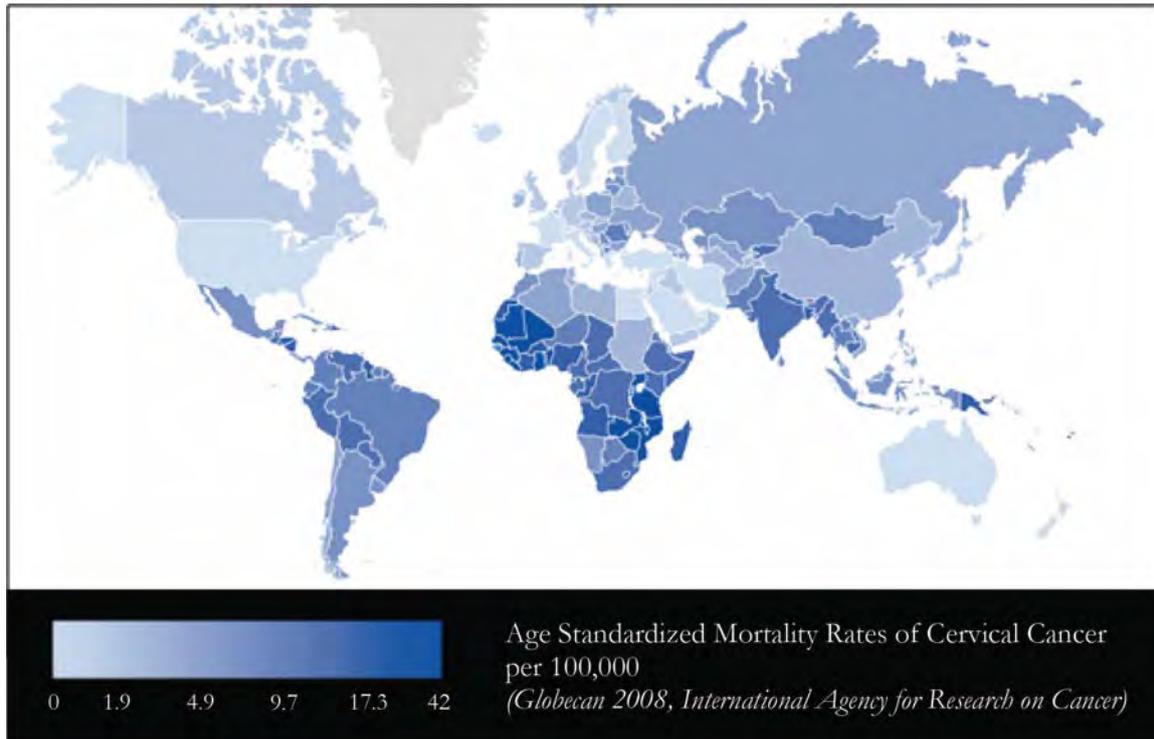
## 1.2 What is cervical cancer?

Cancer is a disease in which a group of cells in the body displays uncontrolled growth and sometimes spreads to other locations in the body. When this uncontrolled growth of cells occurs on the cervix, the disease is called cervical cancer. Cervical cancer is a serious disease and can cause death. However, if recognized and treated early, cervical cancer can be easily prevented. Almost all cases of cervical cancer are caused by a virus called Human papillomavirus (HPV) (see Section 1.5).

## 1.3 The magnitude of the cervical cancer problem

Cervical cancer is common and can affect any woman. Cervical cancer is the third most common cancer in women worldwide. Each year, approximately 500,000 new cases of cervical cancer occur worldwide. In 2008, cervical cancer killed 275,000 women. More than 85% of all cervical cancers and 88% of cervical cancer deaths occur among women who live in developing nations. In sub-Saharan Africa and in Botswana, cervical cancer is the most common cancer in women and is the leading cause of cancer related death in women. Cervical cancer is the most common of all cancers in women in Botswana, and tragically most cases present at an advanced stage which is difficult to treat.





## 1.4 Signs and symptoms of cervical cancer

Most of the time, cervical cancer doesn't have any symptoms. Symptoms of cervical cancer only tend to appear after the cancer reaches an advanced stage. Symptoms may include:

### Abnormal vaginal bleeding

- A woman bleeding after having sex with her husband
- An older woman having vaginal bleeding after menopause
- Vaginal bleeding in between periods

### Abnormal vaginal discharge

- Every woman releases some mucus from the vagina. However, a foul-smelling discharge from the vagina, which may be pale, watery, pink, brown, or bloody, can be a sign of cervical cancer.

Pain in the back, leg, or pelvis

## 1.5 What is Human Papillomavirus (HPV)?

HPV is the name of a group of more than 200 sexually transmitted viruses spread through skin-to-skin contact during sexual activity. More than 40 of these viruses infect the genital area, including the skin of the penis, vulva or anus and the lining of the vagina, cervix or rectum. HPV causes almost all cervical cancers (99%). HPV is a very common and can infect both men and women.

Four out of every five people will get HPV at least once in their lifetime. Almost all people with HPV do not have any signs or symptoms of infection and are unaware of the infection.

### 1.6 What other diseases does HPV cause?

In addition to cervical cancer, HPV can cause genital warts in both men and women. HPV also causes other cancers, including most cancers of the anus and vagina and some cancers of the penis, vulva, and oropharynx. However, these cancers are much less common than cervical cancer. HPV-associated cancers do not just affect women; cancers of the penis, oropharynx, and anus can affect men.



### 1.7 Risk factors for contracting HPV

Risk factors for contracting HPV include:

- Early age at first sexual intercourse
- Multiple sexual partners
- Having a sexual partner who has multiple sexual partners
- Presence of other genital infections
- Weakened immune systems as in people with HIV/AIDS

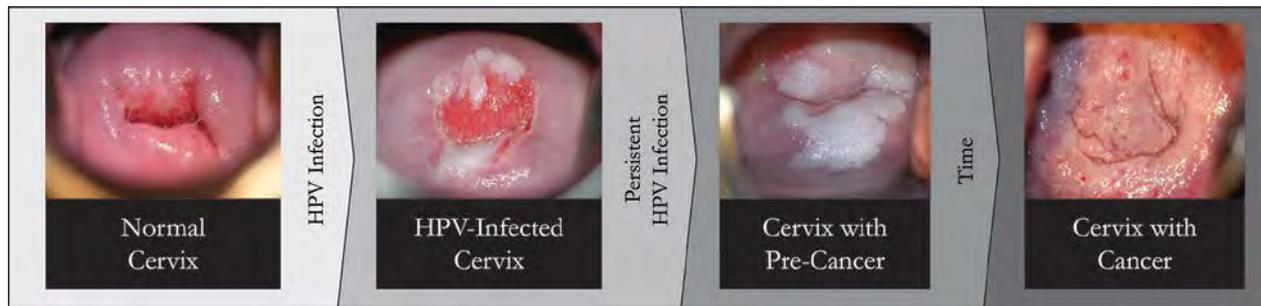
### 1.8 Types of HPV

More than 200 types of HPV exist. However, only around 50 types of HPV can infect the cervix. HPV types can be classified as either low-risk or high-risk. Low-risk types do not cause cancer but may cause mild Pap test abnormalities or genital warts (condylomata acuminata). HPV types 6 and 11 are the most common types associated with genital warts. High-risk, or oncogenic, types may cause abnormal Pap tests and can lead to cancer. HPV types 16 and 18 are the most common high-risk HPV types and cause over 70% of cervical cancers.

### 1.9 The development of cervical cancer

Most HPV infections go away on their own within 1–2 years and do not cause cancer. However, about 5–10% of women infected with high-risk HPV types develop

persistent HPV infection. Persistent HPV infection causes changes to the cervix, which may cause cervical pre-cancer. Cervical pre-cancer is not cervical cancer, but may become cervical cancer over time. Cervical cancer takes about twenty years to develop in a woman with a persistent HPV infection.



### 1.10 HIV and cervical cancer

HIV-infected women are more likely to get HPV infection, develop persistent HPV infection and develop cervical cancer. Further, HIV-infected women can get cervical cancer at a much younger age.

Because HPV and HIV are both sexually transmitted and have similar names, they are sometimes confused. It is important to differentiate between HPV and HIV when educating patients and the public about HPV.

#### Key Messages

1. The cervix is the lower part of the womb.
2. Cervical cancer is a serious disease of the cervix that can be treated if detected early.
3. Cervical cancer is the most common cancer in women in Botswana.
4. HPV causes cervical cancer.
5. HPV is sexually transmitted and can cause genital warts in addition to cervical cancer.
6. HIV infected women are more likely to get cervical cancer.

#### Test Your Knowledge

1. What causes cervical cancer?
2. What are the signs and symptoms of cervical cancer?
3. How does cervical cancer develop?
4. Who is most at risk of getting infected with HPV? Why?
5. How does HPV spread?

# Cervical Cancer Prevention and the HPV Vaccine

## 2.1 The prevention of cervical cancer

Cervical cancer is a highly preventable disease. There are three main ways to prevent cervical cancer:

1. HPV vaccination
  - Recommended for girls ages 9-13 years prior to sexual debut
  - HPV vaccination does not replace the need for screening, because the vaccine does not protect against all the cancer-causing HPV types. However, the vaccine protects against the majority (70%) of cervical cancers.
2. Lifestyle and behavioural changes
  - Delay the age of starting sexual intercourse
  - Limit the number of sexual partners
  - Do not smoke
  - Eat more fruits and vegetables
  - Though not 100% effective, condoms may help protect against HPV infection if used consistently and correctly
3. Cervical cancer screening
  - Cervical cancer screening detects cervical pre-cancer in women. If cervical pre-cancer is found, it is treated and cured before it progresses to cancer.
  - In Botswana, a type of screening called visual inspection with acetic acid (VIA) is used.

## 2.2 The HPV vaccine

Gardasil®, the HPV vaccine being introduced by MOH, is a recombinant vaccine made of virus-like particles (VLPs). These VLPs do not contain live virus (i.e., they are not live-attenuated vaccines). Gardasil® is a quadrivalent vaccine that contains

VLPs of HPV types 6, 11, 16, and 18. Types 16 and 18 are associated with 70% of cervical cancers, and types 6 and 11 are associated with 90% of genital warts.

### 2.3 Gardasil® packaging and storage

Gardasil® is contained in single-dose vials and does not require reconstitution.



Figure: Gardasil® HPV vaccine

Gardasil® should be stored at +2°C - +8°C. It is sensitive to freezing; it should **never** be frozen. Gardasil® should be stored under the same conditions as TT and DPT-HepB+Hib vaccines.



**If you suspect that the vaccine has been exposed to freezing, conduct the shake test described in Chapter 5.**

### 2.4 Target group for vaccination

#### **Vaccine licensure and target group for HPV vaccination**

According to the manufacturer's label, "Gardasil® is indicated in girls and women aged 9-26 years for the prevention of cervical, vulvar and vaginal cancer, precancerous or dysplastic lesions, genital warts, and persistent infection caused by Human Papillomavirus (HPV) Types 6, 11, 16, and 18 (which are included in the vaccine)."

#### **World Health Organization (WHO) recommendations**

WHO recommends administering the HPV vaccine to girls age 9-13 years, because the vaccine is more effective in girls who have not been exposed to the HPV virus, that is prior to sexual debut.

#### **Botswana HPV Vaccination Program**

The HPV vaccination will target girls who are in primary school standards 5, 6 and 7 and out-of-school girls aged 9 to 13 years.

### **Girls attending school**

Schools will be the primary sites for HPV vaccine delivery. The target group is girls who are in standards 5, 6, and 7, because MOH expects that the majority of girls in these standards are expected to be aged 9 to 13 years. Girls who are below 9 years of age should not receive the vaccine.

### **Girls out of school**

For girls who are out of school, the target age is from 9 to 13 years. These girls will be vaccinated at designated health clinics and health posts.

## **2.5 Dosage and immunization schedule**

The immunization schedule consists of three doses. The recommended vaccination schedule is 0, 2 and 6. The first dose is at first contact). The second dose is 2 months after the first dose (defined as on day 60 after first dose), and the third dose is 6 months after the first dose (defined as on day 180 after first dose) or 4 months after the second dose (defined as on day 120 after second dose).

**Table 1: Summary of Gardasil® Immunization Schedule**

<b>HPV vaccine dose</b>	<b>Time of administration</b>
1 <sup>st</sup> dose	First contact with girl
2 <sup>nd</sup> dose	2 months after dose 1
3 <sup>rd</sup> dose	4 months after dose 2

**! A girl must receive all three doses of the HPV vaccine to be fully protected.**

Girls who are absent on the day of vaccination at a school will be given a referral slip to go to a designated health clinic or health post to receive the vaccine dose(s) they missed. Girls who miss a dose should be given the missed dose at the earliest opportunity, but it is never too late to go for a missed dose.

Health workers, teachers, parents, guardians, and others involved in the vaccinations must inform the girls when and where they should receive their subsequent or missed doses.

An HPV Vaccination Card will be provided for each vaccinated girl, and each vaccination will be recorded on this card and in a HPV Vaccine Register. The register will be kept at the health facility and used at all immunization sessions. HPV Vaccination Cards will be kept at school until the immunization schedule is completed. Teachers will use the cards to remind the girls of the next dose and to track defaulters. Once a girl has received all three doses, the card will be given to her.

Parents/guardian will keep HPV Vaccination Cards for girls who receive HPV doses at a health facility, and parents/guardian will ensure that girls complete the vaccination schedule.

Health workers should communicate:

- The benefits of HPV vaccination
- The HPV immunization schedule
- The importance of completing all three doses of the schedule

These messages should be communicated during routine immunization visits, antenatal care, school health programs, and home visits by health workers and Community Health Workers (CHWs).

## 2.6 Instructions for Use

Gardasil® comes in a single dose vial.

- Each vial is for use in one girl only.
- No dilution or reconstitution is necessary.
- Thorough agitation immediately before administration is required. After thorough agitation the vaccine is a white, cloudy liquid.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Discard the Gardasil® vial if particulates are present or if it appears discoloured.
- Withdraw the 0.5 ml dose of vaccine from the single-dose vial using a sterile needle and syringe free of preservatives, antiseptics and detergents.
- Once the single-dose vial has been penetrated, the withdrawn vaccine should be used promptly, and the vial should be discarded.

## 2.7 Vaccine safety

The HPV vaccine has a good safety profile. The most common normal reactions are pain, swelling, itching, redness, and soreness at the site of injection (the arm). These reactions are mild, and they disappear within a few days after vaccination.

## 2.8 Possible side effects following HPV vaccination

Gardasil® demonstrated a favourable safety profile when compared with a placebo (aluminium or non-aluminium containing).

The following injection site reactions were observed among recipients of Gardasil® at a frequency of at least 1.0% and also at a greater frequency than that observed among placebo recipients:

- Pain
- Swelling
- Erythema
- Bruising
- Pruritus

Overall, 94.4% of subjects who received Gardasil® judged their injection-site adverse experience to be mild or moderate in intensity. Bronchospasm was reported very rarely as a serious adverse event. More serious adverse side effects are rare, but if they occur, follow AEFI guidelines (see Chapter 9).

## 2.9 Contraindications and special precautions

- Hypersensitivity to active substances or to any of the components of the vaccine.
- Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of Gardasil® should not receive further doses of Gardasil®.
- Caution should be exercised when vaccinating any girl who has a bleeding disorder or who is taking anticoagulant therapy. Bleeding may occur after an intramuscular injection in these individuals.
- As with other vaccines, HPV vaccination should be postponed if a girl is suffering from acute severe febrile illness. However, a minor infection such as a cold is not a contraindication for vaccination.
- As with any injectable vaccine, the appropriate medical treatment for rare anaphylactic reaction should be readily available.
- HPV vaccine is a preventative vaccine. It is not intended to prevent progression of HPV-related lesions already present at the time of vaccination.
- Girls who are HIV-positive can still receive the Gardasil® vaccine.

## 2.10 Concomitant vaccinations

Results from clinical studies indicate that Gardasil® may be administered concomitantly (at a separate injection site and in separate limbs) with:

- Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed (Tdap)
- Hepatitis B vaccine (recombinant)
- Meningococcal (Groups A, C, Y and W-135) polysaccharide diphtheria toxoid conjugate vaccine
- Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)

Gardasil® has not been studied in clinical trials with vaccines other than those listed.



Health workers, vaccinators and any other person affiliated with HPV vaccination, including non-health staff such as teachers, should note that the vaccine should only be used according to the guidelines in this manual.

## Lessons Learned from HPV Vaccination Programmes in Other Countries

### 3.1 Global experience with HPV vaccines

To date, more than 60 countries have introduced the HPV vaccine into their national immunization programs, including Rwanda in Africa which achieved more than 90% coverage in the first year. Lesotho and Uganda have also initiated national scale-up of HPV vaccination from pilots conducted over the past few years. There have been more than 25 other small-scale pilots of HPV vaccination to gain experience using the vaccine and learn how to incorporate delivery into the existing immunization system.

A variety of delivery strategies have been implemented, including school-based vaccinations, delivery through health centres, and combining HPV vaccination with other existing community-based programs. The target group for vaccination is usually adolescent girls aged 9 to 13 years. All pilot programs included training for health workers and community sensitisation activities. Pilots have been run by both government and non-government agencies. Many elicited political support and leadership from government.

### 3.2 Elements of successful HPV vaccine delivery programs

Summaries of the experiences from HPV vaccination pilots in Africa, as well as rigorous evaluations of these and other pilots conducted globally, have resulted in some common lessons learned. Botswana is basing its HPV vaccine delivery strategy and program structure on these lessons learned.

#### **Delivery strategy and implementation**

- Where school enrolment is high, primary delivery of the HPV vaccine at schools helps secure high coverage.

- Opportunities to vaccinate girls not regularly attending school or who were absent on the day of school-based vaccinations are critical for equity and ensuring girls are not missed.
- Selecting girls for vaccination based on their standard in school rather than age is easier to implement, results in minimal disruptions in the school and is easy for health workers to remember who to vaccinate.
- School-based vaccinations require careful micro-planning and coordination between health centres and schools to ensure vaccine delivery does not disrupt school activities and exams or does not occur during breaks and holidays.
- HPV vaccine delivered over a few days for each dose is less disruptive and easier to implement than provision of vaccinations on a daily basis.
- On average, HPV vaccine delivery requires additional work by the health workers and schools for only a few days for each dose.
- Training of health workers, teachers, mobilizers, and persons assisting with community sensitization before the vaccination program start is critical for successful implementation.
- Health workers, teachers, and communities need to clearly understand who is eligible for the HPV vaccination program.

### **Community sensitization and acceptance**

- Visible endorsement by national and district leaders is critical to community acceptance and parental trust.
- Making comprehensive educational materials with simple language/graphics widely available to the community helps raise community awareness.
- Describing the HPV vaccine as a “cervical cancer vaccine” facilitates understanding by the public, focuses interest on preventing disease and provides a building block for messages.
- Refusal to accept HPV vaccination often is due to misunderstanding or misinformation.
- Communities become reassured as they gain direct experience with the HPV vaccine.
- Teachers and health workers play complementary roles in raising awareness in communities.

## **3.3 Using the lessons learned from other countries**

The lessons learned from HPV vaccination programs in other countries will impact the vaccine rollout in Botswana in the following ways:

- Botswana has decided to use a standard-based strategy to deliver the HPV vaccine.
- The HPV vaccination schedule will align with the school schedule.
- Educational materials on the HPV vaccine will be distributed to raise community awareness.
- It’s important that health workers, teachers and educators work hard to provide clear information to the community because refusal to vaccinate is often due to misunderstanding or misinformation.
- Health workers, teachers, and educators should emphasize the eligibility criteria for HPV vaccination to the community

- The HPV vaccine will be described as a cervical cancer vaccine.
- Botswana government and prominent personalities will visibly endorse the HPV vaccine to increase community acceptance.

# Advocacy, Communication and Social Mobilisation

Effective sensitisation and social mobilisation are critical to a successful immunization programme. All stakeholders, target groups and general populations must be informed of the importance and educated on the benefits of HPV vaccination. Once equipped with correct information, these groups can prevent or dispel rumours and misinformation.

The involvement, support and participation of leaders at all levels including political, civic, traditional, cultural, religious leaders, youth and women's groups, school or teacher's associations, and NGOs is critical in providing accurate information to the population and mobilizing girls for HPV vaccination. Clear, simple, and accurate messages are important so that programme messages are not misinterpreted or misunderstood. Any rumour or misconception should be clarified with facts.

## 4.1 Advocacy

Advocacy includes understanding public perceptions and opinions, addressing misconceptions and working with community leaders, media and decision makers to build social, political and popular support for resource allocation and policy development to direct the HPV vaccination program.

### Advocacy targets

- People with decision-making power and people who influence decision makers, such as the media
- Key stakeholders for support and resource mobilization

## 4.2 Community sensitization and mobilization

Community sensitization and mobilization are necessary at all levels to successfully implement the HPV vaccination program.

**Table 2: Key Audiences for Sensitisation**

<b>Audience</b>	<b>Messages</b>	<b>Delivered by</b>	<b>Activities</b>	<b>Materials</b>
District Health Management Teams (DHMTs)	<ul style="list-style-type: none"> <li>- Facts about cervical cancer</li> <li>- Burden of disease</li> <li>- Importance of prevention</li> <li>- Facts about the HPV vaccine and the immunization schedule</li> <li>- Their roles and responsibilities</li> </ul>	<ul style="list-style-type: none"> <li>- MOH</li> </ul>	<ul style="list-style-type: none"> <li>- Orientation workshops</li> <li>- Materials distribution</li> </ul>	<ul style="list-style-type: none"> <li>- HPV Vaccine disc</li> </ul>
Health Workers (public and private)	<ul style="list-style-type: none"> <li>- Facts about cervical cancer</li> <li>- Burden of disease</li> <li>- Importance of prevention</li> <li>- Facts about the HPV vaccine and the immunization schedule</li> <li>- Their roles and responsibilities</li> </ul>	<ul style="list-style-type: none"> <li>- DHMT</li> <li>- Health unit supervisors</li> </ul>	<ul style="list-style-type: none"> <li>- Orientation workshops</li> <li>- Materials distribution</li> </ul>	<ul style="list-style-type: none"> <li>- HPV Vaccine disc</li> </ul>
Community health workers and community leaders	<ul style="list-style-type: none"> <li>- Burden of disease</li> <li>- Importance and benefits of prevention</li> <li>- Availability of HPV vaccine</li> <li>- Facts about the vaccine</li> <li>- Key messages to help dispel misinformation</li> <li>- Their roles and responsibilities</li> </ul>	<ul style="list-style-type: none"> <li>- DHMT</li> <li>- Health workers</li> </ul>	<ul style="list-style-type: none"> <li>- Orientation workshops</li> <li>- Meetings</li> <li>- Materials distribution</li> <li>- Radio and local media information messages</li> </ul>	<ul style="list-style-type: none"> <li>- HPV materials</li> <li>- Media messages</li> </ul>
School administration and teachers	<ul style="list-style-type: none"> <li>- Facts about cervical cancer and prevention</li> <li>- Availability of HPV vaccine</li> <li>- Facts about the vaccine</li> <li>- Age-appropriate information about cervical cancer</li> <li>- Vaccination dates</li> <li>- Their roles and responsibilities</li> </ul>	<ul style="list-style-type: none"> <li>- DHMT</li> <li>- School management</li> <li>- Health workers</li> </ul>	<ul style="list-style-type: none"> <li>- Orientation workshops</li> <li>- Meetings</li> <li>- Materials distribution</li> </ul>	<ul style="list-style-type: none"> <li>- HPV materials</li> <li>- Media messages</li> </ul>

Parents	<ul style="list-style-type: none"> <li>- Facts about cervical cancer and prevention</li> <li>- Availability of HPV vaccine</li> <li>- Facts about the vaccine</li> <li>- Dates and venues of vaccination</li> <li>- Age-appropriate ways to discuss cervical cancer with children</li> <li>- Their roles and responsibilities</li> </ul>	<ul style="list-style-type: none"> <li>- DHMTs</li> <li>- Health workers</li> <li>- Teachers</li> <li>- Mobilizers</li> </ul>	<ul style="list-style-type: none"> <li>- Distributing materials</li> </ul>	<ul style="list-style-type: none"> <li>- HPV materials</li> <li>- Media messages</li> </ul>
Children	<ul style="list-style-type: none"> <li>- Basic facts about cervical cancer</li> <li>- Basic facts about the HPV vaccine</li> <li>- Benefits of being vaccinated</li> <li>- Their role in HPV vaccination</li> </ul>	<ul style="list-style-type: none"> <li>- Health workers</li> <li>- Teachers</li> <li>- Parents</li> <li>- Mobilizers</li> </ul>	<ul style="list-style-type: none"> <li>- Sensitization meetings</li> <li>- Materials distribution</li> <li>- Community drama</li> </ul>	<ul style="list-style-type: none"> <li>- HPV materials</li> <li>- Media messages</li> </ul>

### 4.3 Managing rumours, misconceptions and misinformation

Rumours refer to information that is spread in the community on a certain subject but is not necessarily true. Misconceptions refer to wrong thinking or incorrect perceptions of a certain situation or subject. Misinformation refers to giving false information either accidentally or deliberately. Rumours, misconceptions and misinformation about HPV vaccination are among the most serious threats to the success of the programme. Once rumours, misconceptions and misinformation start, they can be very hard to stop, and experience in many countries has shown that they can be devastating to vaccination programmes.

#### 4.3.1 Rumours

Rumours are started by people who lack knowledge on a subject or who may have vested interests in the failure of service provision. These people may include:

- **Some traditional healers** that do not believe in modern medicine but believe in the traditional power of preventing disease. They may want to promote their activities by creating negative attitudes about vaccination and other health services.
- **Some religious sects/cultural groups** in Botswana do not believe in or approve of vaccination and other medical practices. Consequently, they may advise their followers to refuse vaccination.
- **Anti-vaccine/lobby groups** that have organised to discourage people from utilising vaccination services. Such groups have published articles or

distributed controversial, distorted or malicious information about vaccination. These groups have worked to discredit vaccination through the internet, FM radio stations and other outlets.

- **Some misguided community members** who seek to politicise vaccination or to sabotage government programmes as a deliberate move to make government lose popularity among the population.
- **Sometimes health workers may not be well-equipped with information to dispel rumours or misconceptions circulating in their communities.** At other times, some health workers may not be vigilant enough to cope with the rate at which a rumour is spreading or may fail to be good examples in taking their children for vaccination or providing the correct information.

#### 4.3.2 Causes of rumours about immunization

Rumours typically spread because of a number of factors that include:

- **Mistrust of health workers by the community.** It is well known that health workers are a source of information about health issues. Once the community develops doubt about the credibility of health workers, opportunities for rumours flourish. For example, the refusal by some health workers to have their children vaccinated and failure to (correctly) answer questions about vaccination create doubt in the community on the credibility of the vaccination programme.
- **Coincidental events.** Occurrence of some events that coincide with routine and supplemental vaccination activities can fuel rumours.

#### 4.3.3 How to respond to rumours and misconceptions

In Botswana, DHMT staff and trained health workers should be the first to respond to rumours, and rumours should be reported to MOH. MOH will strategize about scaled responses to rumours. Still, health workers at all levels of service delivery should develop a proactive plan and education programme about HPV immunization that can be used to prevent and counteract rumours within their community.

#### Steps of a comprehensive response to rumours

- Step 1 Meet with key community partners to inform them about the HPV vaccination during preparation for the vaccination program.
- Step 2 Quickly identify the source of the rumours and understand their contents (extent of the rumour, type of messages circulating about vaccination).
- Step 3 Identify people and organisations responsible for fabricating and spreading the rumour(s). Design strategies to educate them.

**Step 4** Collect correct data and facts about HPV vaccination in preparation for rumour response.

**Step 5** Determine the reasons behind the rumours (is it lack of information, religious/cultural opposition, beliefs, or mere propaganda?).

**Step 6** Turn the rumour around by going to the source and asking the people what solution they can offer to diffuse the rumour.

**Step 7** Target key and credible leaders in the affected area (community leaders, religious leaders, elders, clan leaders, etc.), sensitise them about vaccination and seek their support in mobilising for vaccination promotion.

Tell your supervisors **about any and all rumours you hear as quickly as possible**. Work under their direction in the short term. Your supervisor should report rumours to MOH, and MOH will determine what, if any, action may even need to be taken at the national level. The consequences of rumours can be serious and, if unchecked, they can travel quickly beyond your local area.

### **Test Your Knowledge**

1. List the partners/stakeholders that will be influential in mobilisation for HPV vaccination in your community.
2. What are their roles and responsibilities?
3. What are the key messages to communicate on HPV vaccination?
4. Which channels of communication will be most appropriate for HPV vaccination social mobilisation activities?

### **Key Messages**

- The HPV vaccine is safe and effective.
- The HPV vaccine does not cause infertility.
- Being vaccinated against HPV does not protect one against getting pregnant, HIV/AIDS, or any other sexually transmitted infections.

# Logistics and Management of the HPV Vaccine

## 5.1 HPV immunization logistics

### 5.1.1 Estimating the size of the target population

The number of girls in standards 5, 6 and 7 and the number of out-of-school girls aged 9 to 13 years will be estimated through existing records at the Botswana Central Statistics Office and Ministry of Education.

### 5.1.2 Estimating vaccine dose amounts

Vaccine doses for the HPV vaccination sessions should be estimated according to the size of the target population. Calculate an additional 5% of vaccine supply to account for girls coming from other catchment areas to receive the vaccine and rare cases of vaccine wastage. A buffer stock of 10% should also be factored into supply calculations in case of underestimation of the target population.

#### Vaccine doses required at district level

Target population for vaccination x 1.05 (wastage) x 1.10 (buffer) = required doses for the district

#### Vaccine doses required at healthcare centre level

Estimated daily target population x 1.05 (wastage) = required doses per centre per day



After each HPV vaccination session, unused HPV vaccine vials should be returned to the appointed site for proper storage.

### 5.1.3 Other logistic requirements

#### Auto-disabling syringes (AD syringes) and needles required:

Target population for vaccination session x 1.15 = required AD syringes and needles

#### Sharps boxes required:

AD syringes and needles x 1.05/100 = required sharps boxes

**Table 3: Vaccines, AD syringes, and sharps boxes needed for vaccination session**

	<b>Vaccines/Supplies</b>	<b>Formula</b>	<b>Example</b>
	Total Population in District “X”	Census data	200,000
<b>A</b>	Target cohort of girls	Data from MOE	3,200
<b>B</b>	Number of vials per girl	1	1
<b>WF</b>	Wastage factor	1.05	1.05
<b>C</b>	Number of HPV doses	A x B x WF	3,360
<b>D</b>	Number of doses per vial	1	1
<b>E</b>	Number of HPV vaccine vials	C/D	3,360
<b>F</b>	AD syringes (wastage factor =1.15)	A x WF	3,864
<b>G</b>	Number of sharps boxes	(F x 1.05)/100	41

## 5.2 HPV vaccine handling and management

### Storing vaccines in top-opening refrigerators

Like DPT-HepB+Hib vaccines, Gardasil® must be protected from freezing. Store vaccine vials away from the freezer compartment (as shown below), and do not place vaccines on frozen ice packs. Always use cool packs or thawed ice packs in the vaccine carrier. If you suspect that the vaccine has been frozen, carry out the shake test.

FREEZER COMPARTMENT

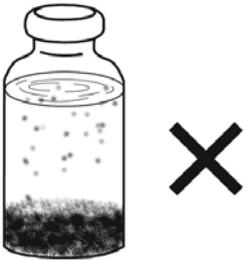
COOL PACKS

HPV VACCINE

## The Shake Test

Use the Shake Test to analyze vaccine vials suspected freezing (the vaccines should **never** be frozen).

Compare a deliberately frozen vial to the suspect vial

Deliberately Frozen Vial	Suspect Vial
<p data-bbox="416 779 632 931">← Almost clear ← Thick sediment</p>	<div data-bbox="778 555 1034 815"></div> <p data-bbox="1086 629 1385 763">USE THE VACCINE if sediments in the suspect vial settle <b>more slowly</b>.</p> <div data-bbox="778 898 1023 1158"></div> <p data-bbox="1086 949 1374 1117">DO NOT USE THE VACCINE if the sediments in the suspect vial settle <b>at the same rate</b>.</p>

To apply the Shake Test:

- Step 1** Prepare a frozen control sample. Take a vial of the vaccine from the same batch number as the vaccine you want to test. Freeze the vial until the contents are solid (at least 10 hours at  $-10^{\circ}\text{C}$ ), and then let it thaw. This vial is the control sample. Clearly mark the vial “CONTROL” so that it is easily identifiable and will not be used by mistake.
- Step 2** Identify a vial of vaccine from the batch that you suspect has been frozen as the test sample.
- Step 3** Hold the control sample and the test sample together in one hand and shake them gently for 10–15 seconds.
- Step 4** Leave both vials to settle. Place the two vials in a position with adequate light.

## Step 5

Compare the vials. View both vials against the light to compare the sedimentation rate (Figure 3). If the test sample shows a much slower sedimentation rate than the control sample (milky appearance), the test sample has most probably not been frozen and can be used. If the sedimentation rate is similar to the control sample and the test sample contains flakes, the vial has probably been damaged by freezing and should not be used. Dispose of according to national standards and record damage vials on the Resource Management and Vaccine Wastage Form.

! If the Shake Test indicates that the test sample has been damaged by freezing, notify your supervisor immediately.

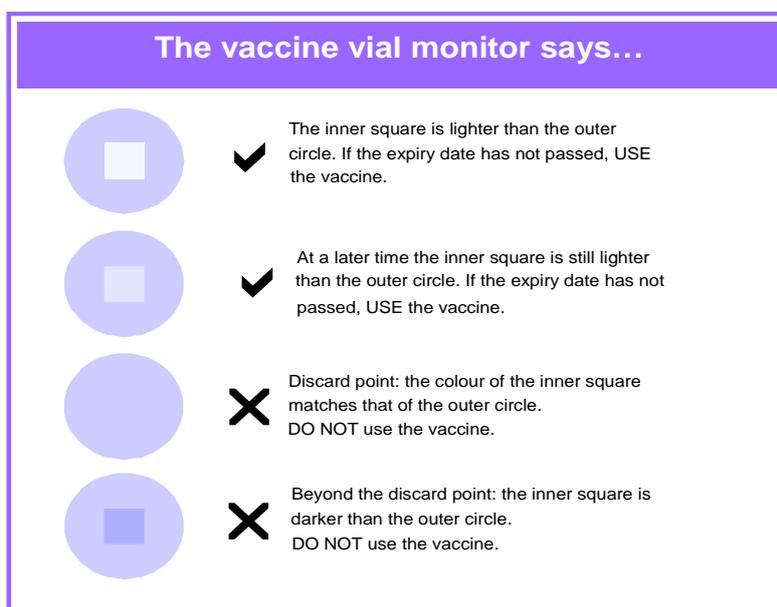
! Some vials have large labels, which cover the vial contents. This makes it difficult to see the sedimentation process. In such cases, turn the sample and reference vials upside down and observe sedimentation taking place in the neck of the vial.

### Vaccine Vial Monitor

HPV vaccines usually have a Vaccine Vial Monitor (VVM) to help determine whether the vaccine has been damaged by heat. Though Gardasil® is not heat sensitive, protocol indicates that health workers should check the status of the VVM:

- As vaccines are received for storage (at all levels)
- As vaccines are packed for the immunization session
- Before vaccine vials are opened at the immunization session

The VVM provides guidance on whether to use an individual vial. If the inner square is lighter than the outer circle, the vaccine can be used. If the inner square is the same colour as, or darker than, the outer circle, the vaccine should be discarded.



! Vaccine doses for the demonstration project will not have VVM. This is acceptable because Gardasil® is not heat sensitive, and cold chain is in place for the project.

### 5.3 Preparations for vaccine delivery

#### Vaccine delivery to a DHMT

- Ensure adequate amounts of vaccine doses and injection materials.
- Ensure that cold boxes/vaccine carriers are clean and not cracked.
- Ensure sufficient cool packs or **thawed** ice packs.
- Estimate the number of vaccine doses to be delivered to each vaccination session.
- Always follow First Expiry–First Out (FEFO) methods.

#### Cold chain procedures during vaccine transport

- Ensure that cold box/vaccine carrier has an intact rubber seal.
- Ensure that cold box/vaccine carrier is securely closed.
- Ensure availability of reliable transport to deliver the vaccine.
- Ensure that appropriate form(s) accompany the vaccine to be delivered or issued to the unit.

### 5.4 Packing vaccines for an immunization session

As you pack the vaccines, confirm that:

- Labels are attached
- The vaccine expiry has not passed
- The vial is in good condition (it should not be cracked)
- The colour of the vaccine (it should be translucent white and cloudy when shaken, without any black particulate matter)
- Vaccines previously taken out of the fridge for an immunization session should be used first in the next session

To pack the vaccines:

1. Place 2-3 cool or **thawed** ice packs around the inside walls of the carrier.
2. Place a thermometer in the vaccine carrier.
3. Place vaccines in the vaccine carrier.
4. Place a sponge on top of the vaccines in the vaccine carrier.
5. Close the lid of the vaccine carrier.
6. Do not overfill the vaccine carrier.

## 5.5 Vaccine wastage

Vaccine wastage is the loss of vaccine by use, decay, erosion, or leakage. The causes of vaccine wastage may be system or programme related. Causes of vaccine wastage include:

- Breakage of vials
- Freezing of vaccine
- VVM colour change to discard point
- Loss of labels
- Expiry
- Break down in the cold chain system

## 5.6 Strategies to reduce vaccine wastage

To reduce vaccine wastage, make sure that:

- Accurate data is used to estimate vaccine and injection materials needed at a vaccination session. Accurate data use prevents stock outs or over-stocking.
- Vaccine use and wastage are monitored. The Resource Management and Vaccine Wastage Form must be completed after every vaccination session (see Chapter 10) to monitor wastage.
- Use a checklist to carefully distribute vaccines and supplies to health facilities.
- Monitor and maintain cold chain upkeep to avoid refrigerator break down or vaccine freezing.

## 5.7 Issuing /recording of vaccines and other logistics

All items received for HPV immunization activities should be documented in the same manner as routine supplies using the Resource Management and Vaccine Wastage Summary. Amounts, batch numbers, and expiry dates should be indicated at all levels.

### **Key Messages**

1. Document vaccine doses and injection materials upon receipt and as soon as they are put in the refrigerator/store.
2. Record the doses and supplies issued to health workers as they prepare for individual vaccination sessions.
3. Balance the Resource Management and Vaccine Wastage Summary every time you receive, issue or return vaccines and injection materials (to and from vaccination sessions).

## **Micro-Planning and Coordination of HPV Activities**

### **6.1 District level micro-planning**

It is important to hold coordination and micro-planning meetings before the implementation of the HPV vaccination programme. The national immunization program will organize an orientation meeting for the DHMT Officers, MCH coordinators, and EPI cold chain technicians. The District Medical Officers and EPI coordinators will then organize planning and preparations for district level training.

The meeting is expected to review the performance by the health facility and the logistical requirements in preparation for the next rounds of vaccination/cohort. The inception meeting shall include health facility in-charges and other key stakeholders like the District Education Officer, Health Development Partners, and NGOs operating in the district.

At the micro-planning meeting, each health facility should present the list of schools and a list of girls in standards 5, 6 and 7 in their catchment area. Out-of-school girls aged 9 to 13 years should be registered with the CHW or neighbourhood health committees (NHCs), and the registered girls submitted to the health facility in-charge of that catchment area. During this meeting, community leaders should be identified and assigned with the responsibility of announcing the vaccination dates in all public gatherings including markets and places of worship.

Information regarding HPV and the HPV vaccine should be shared so that everyone has accurate information and messaging.

### **6.2 Micro-planning at health facilities**

In collaboration with school heads, the identified health facility will list schools (public and private) in their catchment area. Within each school, they will identify the girls in standards 5, 6 and 7 and develop a schedule as to when they will visit each school to:

- Sensitize parents, teachers and girls

- Display posters and share flyers
- Plan the immunization dates so that the immunization schedule aligns with the school calendar (immunization dates do not fall on holidays or school breaks)

The district MCH coordinator and the District Health Information Officer shall compile the data at the end of the vaccination month indicating the girls vaccinated by age.

# Administration of the HPV Vaccine

## 7.1 Planning an immunization session

During micro-planning and training for HPV vaccination, the health workers must:

- List all schools in their catchment area.
- Make a schedule of when they are visiting each school and who will visit each school.
- Establish contact with the school to plan for the vaccination day. School administration should schedule the day of vaccination in relation to school programs and should identify a convenient location within the school where the vaccination can be carried out.
- Make a schedule to provide vaccine at health clinics and health posts for girls not attending school aged 9 to 13 years or for those who miss vaccination day at the school during the month designated for HPV vaccine delivery (April, June, and October).

## 7.2 The immunization sessions

Immunization sessions should be conducted in a clean environment, preferably in a building or in a shady spot.

## 7.3 Setting up an immunization session at the school

The immunization session staging area needs to be well-organised to create an environment conducive to efficient vaccination delivery. Plan to include the following essential areas:

- Waiting area
- Registration/screening
- Immunization station(s)
- Check point/recording (tallying)

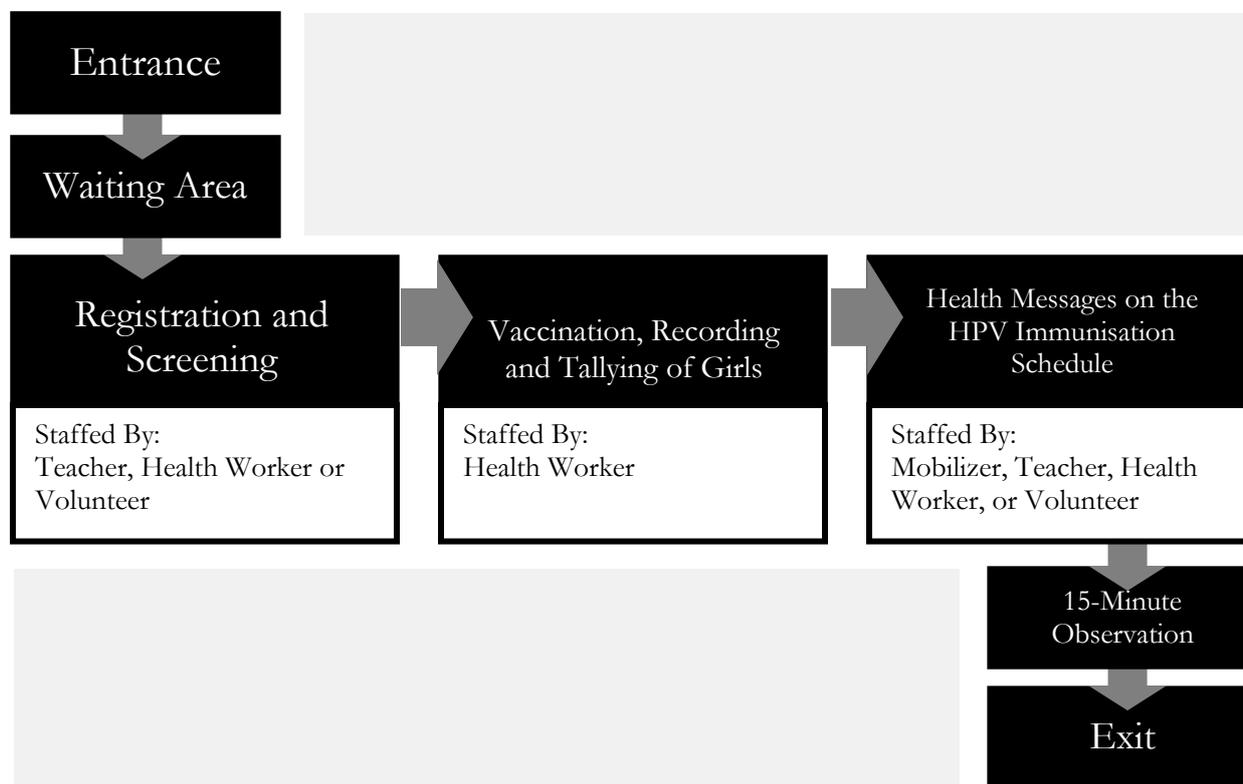
- An area where girls can sit for 15 minutes post vaccination

Design the immunization post for efficient flow. Avoid bottle necks, excess crowding, long waiting times, or confusion. Suggestions to avoid overcrowding and inefficient flow include:

- Open the post as early as possible.
- Ensure adequate space at the session site.
- Effective crowd control by a teacher, mobilizer or other staff/volunteer.
- Immunization on a “first come, first serve” basis.
- Designated entry and exit points and a one-way flow of girls through the session area to prevent backtracking through the crowd after immunization.

Immunization sessions at health clinics and health posts should operate as per structures used for delivering infant vaccinations.

#### 7.4 Example HPV vaccination session flow



#### 7.5 Supplies required for the HPV vaccination session

Health workers should prepare and complete a checklist before packing the vaccines for the session. Below is standard checklist in preparation of administering EPI vaccines.

- HPV Vaccine doses plus buffer
- 0.5 ml auto disposable syringes

- Chairs and tables (should be provided by the school)
- Plastic sheeting (optional)
- Hand soap or hand sanitizer
- Cotton and sterile or boiled water for cleaning the injection site
- A vaccine carrier with cool packs, HPV vaccines, thermometer, and a sponge.
- Shallow large tray (1), kidney dish (1), gallipots (2), and forceps
- Sharps boxes
- 50ml bottles of sterile water
- Cotton rolls
- Gloves
- Plasters
- Paper towels
- Red and black garbage bags for used vaccine vials, swabs and other waste
- Emergency tray (see Section 9.4)
- Monitoring tools (HPV vaccination register, HPV Vaccination Cards, Daily Tally Sheets, and AEFI Form)
- Guidelines for HPV Supervisors booklet
- Date for the next vaccination dose
- Pens and EPI stamps
- HPV brochures



You may need more than one vaccine carrier depending on the size of the day's target population.

## 7.6 Roles and responsibilities at immunization sessions

A health worker, teacher (or volunteer), and mobilizer (or volunteer) should be available at the immunization session to organize the vaccination area, vaccinate, accurately record vaccination activities, properly collect and dispose of activity waste, and provide correct information about HPV and the HPV vaccine.

### The vaccinator

- Ensures adequate vaccine doses are packed in the vaccine carrier with at least three cool packs or **thawed** ice packs
- Ensures correct storage of vaccine
- Ensures minimal to no wastage of vaccine
- Ensures adequate availability of AD syringes and needles
- Ensures safety in immunization procedures
- Ensures order at the vaccination session and assists in crowd control
- Assists the team with any other tasks assigned
- Prepares the AD syringes for vaccine administration
- Vaccinates the girls
- Ensures that the vaccination area remains safe and clean and that activity waste is properly collected

- Gives health advice to the parents and girls about HPV vaccine and possible side effects
- Monitors any reactions and responds to guardian's/children's questions
- Manages and reports AEFI and any rumours regarding the vaccine
- Completes all paperwork
- Ensures that each girl is observed for 15 minutes after vaccination
- Ensures the return of all the supplies, equipment, paperwork, unused vaccines to appointed health site
- Ensures proper disposal of all used syringes and needles using the MOH recommended procedure

### **The Teacher**

- Thanks guardian/girl for coming
- Keeps and organizes the vaccination cards for each girl until all three doses are given
- Informs the parent/caretaker/girl of the next vaccination date
- Ensures that each girl is observed for 15 minutes after vaccination
- Ensures order at the vaccination session and assists in crowd control

### **The Mobilizer or Volunteer**

- Ensures order at the vaccination session and assists in crowd control
- Ensures that each girl is observed for 15 minutes after vaccination
- Assists the team with any other tasks assigned

### **The Supervisor and Programme Officers**

During the month of HPV vaccinations, supervisors at all levels should be actively visiting schools. The supervisors should:

- Disseminate prime messages on HPV vaccination.
- Enlist community buy in on HPV vaccination and EPI in general.
- Build alliances with opinion and community leaders.
- Detect rumours from the community and address them immediately.
- Promote and coordinate HPV vaccination sessions.
- Monitor and supervise all activities at immunization sessions and advise Programme Officers accordingly.
- Supervise the distribution and replenishment of vaccine doses, cool packs, and forms at vaccination sessions, both at the beginning and throughout the vaccination program.
- During HPV vaccination sessions, carry extra vaccines and supplies for distribution to vaccination sessions with shortages.
- Receive and review forms, vaccines and other supplies returned from the vaccination sessions.
- Collect and forward forms to the district health management team within two days of completion of the vaccination.
- Report any known AEFI to MOH within 24 hours.
- Ensure proper collection and disposal of the waste generated at the vaccination session.

## **7.7 Step-by-step instructions to administer Gardasil®**

- Step 1 Welcome the girl in a friendly manner, and ask her if she has any questions about HPV vaccination. Answer all questions truthfully.
- Step 2 Ensure that the girl is eligible for the HPV vaccine. Eligible girls must be enrolled in standards 5, 6 and 7, or, if the girl is not attending school, aged 9 10 13 years.
- Step 3 Determine which dose is needed (first, second, or third) by looking at the vaccination card or the register, and confirm that the correct amount of time has passed between doses.
- Step 4 Check for contraindications to vaccination by asking the girl about any current acute severe febrile illness or hypersensitivity to vaccine components. Caution should be exercised when vaccinating any girl who has a bleeding disorder or who is taking anticoagulant therapy. Bleeding may occur after an intramuscular injection in these individuals.
- Step 5 Wash and dry or sanitize your hands.
- Step 6 Hold the HPV vaccine vial between your thumb and middle finger. Verify that the vial is in proper condition and not past its expiry date. Inspect for particles and discoloration; if either is present, do not use the vaccine. Pick another vial.
- Step 7 Mix the vaccine by shaking the vaccine vial until it is a white, cloudy liquid.
- Step 8 Open the package for the 0.5 ml auto-disable (AD) syringe.
- Step 9 Draw all the contents of the HPV vaccine from the vial into the 0.5 ml AD syringe. Pull the AD until you feel a click.
- Step 10 The vaccine should be given in the left arm. Encourage the girl to relax her arm. The injection is less painful if the arm is relaxed.
- Step 11 Clean the injection site with a swab and clean water.
- Step 12 Inject the entire contents of the syringe in the **deltoid muscle of the upper left arm** (see figure below), unless the girl is left-handed, in which case inject into the right arm. Injections should be given at a perpendicular angle (90 degrees). If there is reduced muscle mass, the needle can be inserted slightly obliquely, using an angle greater than 65 degrees.

- Step 13 Place a cotton ball on the injection site and ask the girl to press it hard on the site of injection to prevent bleeding. **Do not massage the site of injection.**
- Step 14 **Do not recap the used syringe and needle.** Put used syringes and needles in the sharps box. Dispose of other vaccination waste properly.
- Step 15 Complete appropriate paperwork (the HPV Vaccine Register, the Student Health Card, the HPV Vaccination Card, and the Daily Tally Sheet).
- Step 16 Thank and congratulate the girl. Tell her the date for her next dose of Gardasil®. Stress the importance of getting all three doses as indicated. Ask the girl to rest nearby for 15 minutes to observe if she is dizzy or feels faint.
- Step 17 Wash or sanitize hands before administering vaccine to each client or as necessary.

**! A new AD syringe should be used for each injection.**

**! Gardasil® should be administered intramuscularly, into the deltoid muscle of the upper arm.**

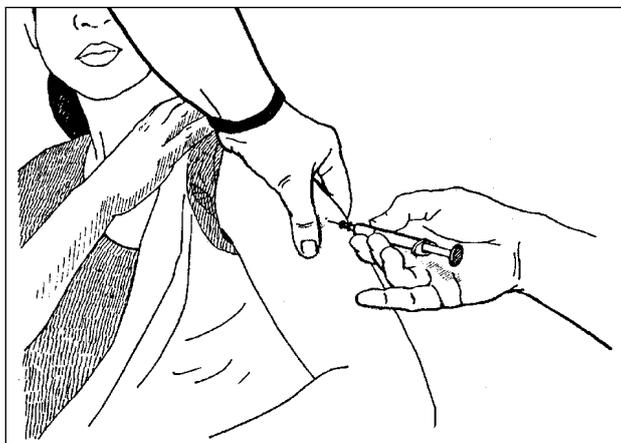


Illustration of a girl receiving Gardasil®

## 7.8 Messages for girls regarding HPV vaccination

1. Tell the girl she is receiving the HPV vaccine that helps prevent cervical cancer.
2. Give her information on the number of doses (three) for her to be protected. Insist on the importance of completing all three doses according to the vaccination schedule.
3. Keep the arm relaxed to diminish the risk of swelling at the point of injection.
4. Remind the girl that nothing needs to be applied to the site of injection after vaccination. Swelling and pain can be present at the point of injection, but it is temporary.
5. **Observe the girl for at least 15 minutes after vaccination.**
6. Give the date of the next dose.
7. Thank the girl for coming for the vaccination. When she finishes the third dose, congratulate her.

# Injection Safety during the Immunization Session

Unsafe injection practices put clients, health workers/service providers and the community at risk of injection abscesses and blood-borne diseases.

A safe vaccine injection is when a vaccine is administered using the right technique at the right site with the right needle and syringe.

According to the WHO, a safe injection:

- Does not harm the recipient
- Does not expose the provider to any avoidable risk
- Does not result in any waste that is injurious to the community

## 8.1 Disposal of sharps and other vaccination material waste

Sharps and other injection materials generated during the vaccination sessions must be collected and taken to appointed district sites for proper disposal (usually incineration).

## 8.2 Procedures to ensure a safe vaccine injection

To ensure the safe injections of Gardasil®, please adhere to the following guidelines during each vaccination:

- Organize the vaccination supplies and equipment on the table/tray (vaccine carrier, AD syringes, sterile or cool boiled water, cotton balls, etc).
- Wash or sterilize hands.
- Wash the injection site (the left arm) with a cotton ball soaked with sterile or cool boiled water.
- Use a new syringe and needle for each girl.
- Carefully inspect the packaging of each syringe. Throw away all syringes with damaged packaging.

- Use the non-touch technique (see figure below); do not touch any part of the needle that has to come into contact with the vaccine or the client. Discard a needle that has touched any non-sterile surface.
- Draw the vaccine into the syringe only when the girl is ready for vaccination.
- Do not load multiple syringes in advance in anticipation that many girls will come to the vaccination session.
- Avoid giving injections in places where there are wounds or signs of infections on the skin.
- Give the intramuscular injection according to recommendations (deltoid region of the arm).
- **Never recap needles after use.**
- All syringes and needles should be immediately disposed of in the sharps box. Avoid completely filling the safety box. Fill it only until it is  $\frac{3}{4}$  full.
- Dispose of cotton balls or used vials in the red medical waste bags.
- Leave every vaccination session location clean.
- Collect and deliver filled sharps boxes and other medical waste to the appointed health facility at the end of each session for proper disposal.

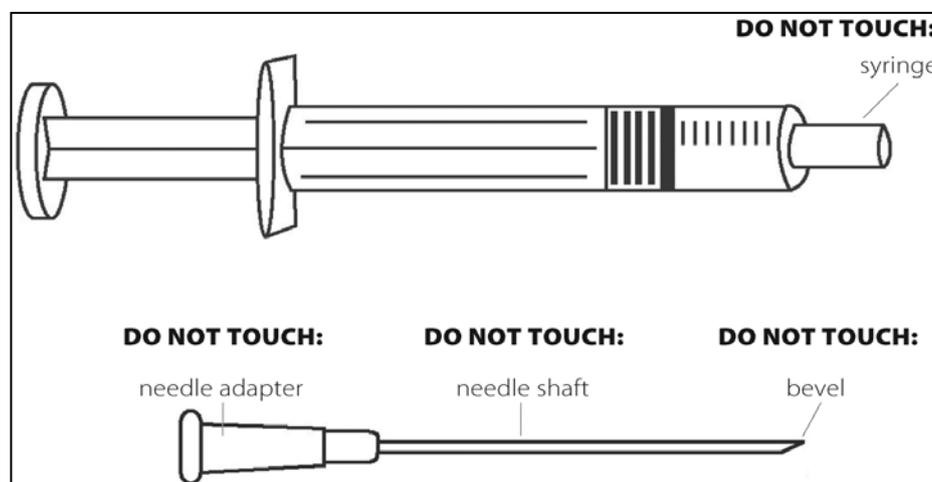


Figure: Parts of a needle and syringe that must never be touched

### Key Messages

Before injecting, ensure:

1. Right client
2. Right vaccine storage
3. Right dose
4. Right injection site
5. Right syringe and needle
6. Right vaccine is administered by a skilled health worker
7. Right procedure of administering the vaccine
8. Right disposal of sharps and waste generated

# Adverse Events Following Immunization

Adverse Events Following Immunisation (AEFI) are events or reactions observed following immunisation. Some of these may be due to the vaccine or error in the administration of the vaccine. Others may have causes that are not vaccine-related.

Handling Adverse Events Following Immunization (AEFI) promptly and effectively is critical to maintaining public confidence in HPV immunization. A single serious event or cluster of events may result in rapid erosion of public confidence in HPV vaccination and a decline in immunization rates. The majority of AEFI are not caused by the vaccine itself. A significant increase in reporting of AEFI is sometimes seen after a new vaccine is introduced because of the higher level of awareness and the public's lack of familiarity with a new product.

## 9.1 Classification of AEFI

AEFI can be classified into five categories (Table 4). There are a variety of strategies health workers can employ to minimize AEFI, prevent them completely or manage them should an AEFI occur.

**Table 4: Classification of AEFI**

<b>AEFI Classification</b>	<b>Definition</b>
a) Vaccine reaction	Event caused or precipitated by the vaccine when given correctly and caused by inherent properties of the vaccine
b) Programme error	Event caused by an error in vaccine preparation, handling or administration
c) Coincidental	Event that happens after immunization but is not necessarily caused by the vaccine; a chance association
d) Injection reaction	Event occurring due to anxiety of or pain from the injection

	itself rather than the vaccine
e) Unknown	Cause of the event cannot be determined

## 9.2 Minor vaccine reactions or AEFI

Table 5 provides a list of common minor reactions and the proposed treatment if these are observed after delivering the HPV vaccine.

**Table 5: Minor Reactions to Vaccinations and their Treatment**

Reaction	Treatment
Soreness, redness, edema, and induration	Rarely require treatment, but if necessary give Paracetamol 10mg/kg every 6 hours to girl to relieve pain.
Fever	Rarely lasts more than 48 hours. If so, first rule out any infection, for example malaria, by doing a blood slide and treat accordingly. Meanwhile, give Paracetamol 10mg/kg every 6 hours.
Headache	Give Paracetamol 10mg/kg every 6 hours.
Myalgia	Give Paracetamol 10mg/kg every 6 hours.
Nausea, vomiting, diarrhoea, and abdominal pain	Reassure the client, investigate for any infection and give ORS.
Itching/pruritus, rash and urticaria	Give chlorphenamine 2mg every 8 hours.
Arthralgia	Give Paracetamol 1g 10mg/kg every 6 hours.

## 9.3 Programme errors

The following measures should be in place to prevent AEFIs due to programme error:

- Comprehensive training of health workers with emphasis on proper administration techniques and communication.
- Identification of at least one qualified health worker per immunization session.
- Proper distribution of HPV vaccine doses and correct bundling with injection materials.
- Ensure that quality vaccines are used.
- Exclusive use of AD syringes and needles.
- Proper disposal of vaccination waste materials.
- Proper cold chain maintenance.

- Proper vaccine storage and handling. **NEVER freeze this vaccine.**
- Proper and effective management of any AEFIs.

An abscess at the site of injection is a programme error that, while minor, can still require clinical intervention. If an abscess develops at the injection site, incise and drain the abscess, give an antibiotic, give a pain killer, and dress the wound daily.

#### 9.4 Rare and most serious AEFI

Rarely, a serious AEFI, such as an anaphylactic reaction, may occur after immunization. In post-licensing global surveillance of persons who have received HPV vaccines (which now number in the millions), there have not been any reports of anaphylactic reactions to the vaccines to date. A few serious AEFI have been reported, such as Guillain-Barré Syndrome, but these have been investigated by global experts and determined to not have occurred more than expected compared to populations who have not received HPV vaccines.

Still, health workers should be prepared to respond to an unexpected or serious event. Recommendations stipulate that health workers bring an emergency tray with the following drugs to each vaccination activity. DHMTs should ensure that emergency trays are available at vaccination sessions.

**Table 6: List of Emergency Drugs for the Emergency Tray**

Drugs	Supplies
Adrenaline (injectable)	Drinking water
Paracetamol	Needles and syringes
Chlorpheniramine	Intravenous cannulas
Hydrocortisone (HC IV)	Normal saline
Diazepam	5% Dextrose

Though extremely rare, an anaphylactic reaction may occur following vaccination. Anaphylactic reaction is less frequent among children and the symptoms tend to appear suddenly – generally **a few minutes to 30 minutes** after vaccination though they occasionally appear after a few hours. Some symptoms and signs to look out for include pruritus, urticaria, pins and needles, a feeling of hotness, reddening and angioedema on the face, eyelids or limbs; high level of respiratory congestion with anxiety and sometimes nausea, vomiting and abdominal pain; difficulty in breathing; or hypotension, collapse and tachycardia (often fatal and referred to as anaphylactic shock). Treatment should be administered immediately by a trained professional on the slightest suspicion of above. It is strongly recommended that written protocols be placed somewhere visible and known by all health workers involved.

## Treatment protocol for anaphylactic shock

- Step 1 Place the patient in a prone or left lateral decubitus position with the head to one side. If possible, the patient should be placed in the Trendelenburg position where the body is laid on the back (supine position) with the feet higher than the head



- Step 2 Keep airway free (attentive to possible vomiting). Administer oxygen through a mask if possible.
- Step 3 Administer intramuscular adrenaline (1/1,000): 0.01ml/kg/dose, with a maximum dose: 0.5 ml. This should be administered via 0.9% saline solution (if possible).
- Step 4 Corticoids may be necessary. Options include:  
Hydrocortisone, ACTOCORTIN® i.v. or i.m. 5 mg/kg/dose. Max. dose: 250 mg/kg/dose.  
Methylprednisolone, URBASON® i.v. or i.m. 2 mg/kg/dose. Max dose: 60mg/dose.  
Dexchlorpheniramine, POLARAMINE® i.v. or i.m. 0.04 mg/kg/dose. Max. dose: 6 mg/day.
- Step 5 In the case of bronchospasm: Salbutamol, VENTOLIN® in aerosol 0.03 cc/kg/dose + 3cc physiological serum. Administer with oxygen at 6–8 ml/minute.
- Step 6 In the case of vascular shock or collapse: ADRENALIN I.V.: one vial diluted in 10 ml of 0.9% saline solution (1 ml/minute) until a response is obtained.

### **Reactions that must be reported as an AEFI**

Local reactions are mild, non-serious reactions during or after HPV vaccination. Severe local reactions including swelling further than 5 cm from injection site or pain, redness, and swelling that lasts more than 3 days after the vaccination event. All injection site abscesses should be reported.

Systemic reactions are serious reactions during or after HPV vaccination. The following systemic reactions should be reported:

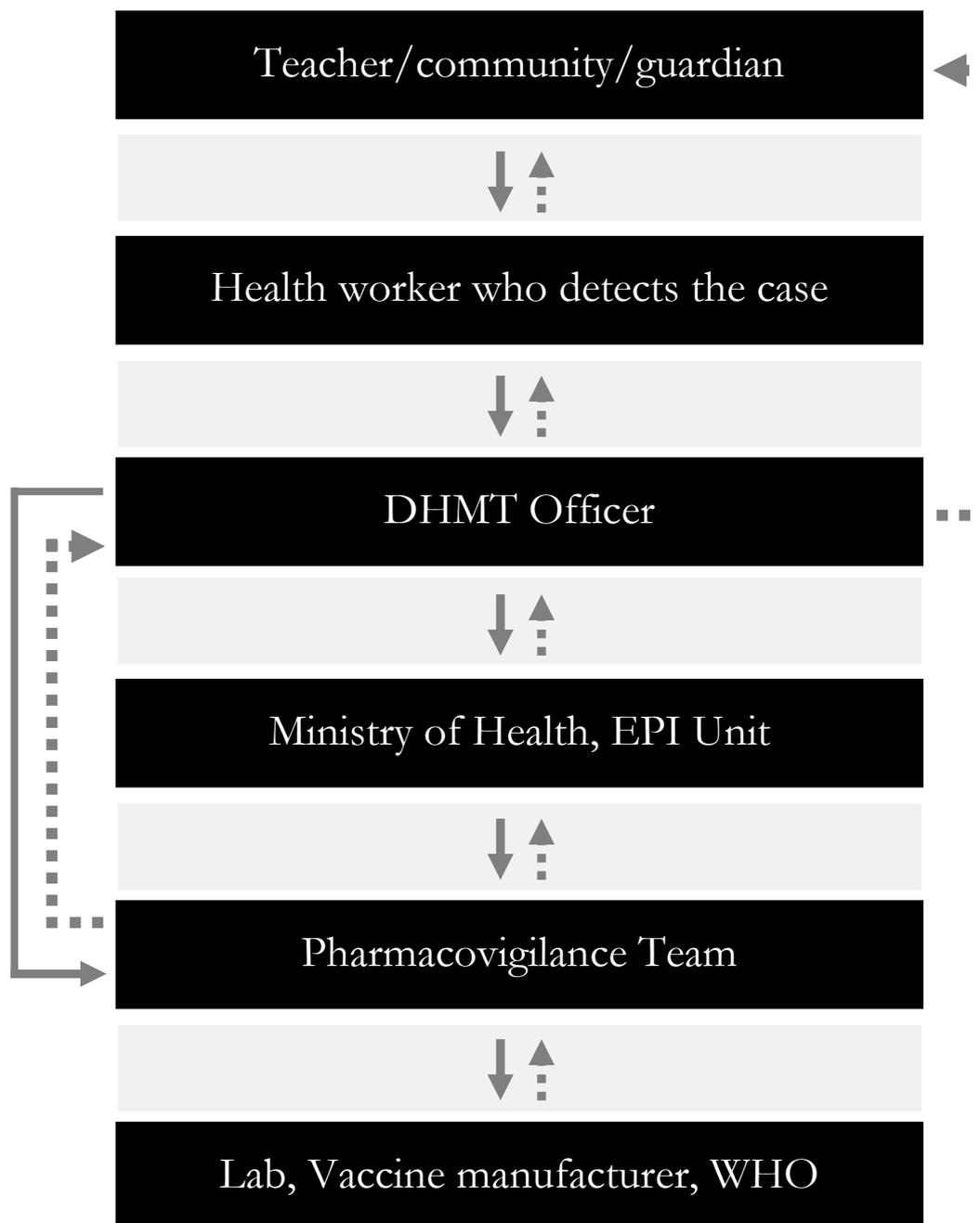
- All cases of anaphylaxis suspected to be related to HPV immunization
- Collapse or shock-like state within 48 hours of HPV immunization
- Seizures within 3 days of HPV immunization
- All deaths thought to be related to HPV immunization
- Any severe or unusual events due to HPV immunization or thought by staff or parents to be due to HPV vaccine (including clusters)

## **9.5 AEFI reporting procedures**

AEFIs are more likely to be observed during immunization activities. Therefore, health workers should monitor for any and all AEFI during immunization sessions and immediately afterwards. Reporting channels for an AEFI are indicated below. The flow chart provides an inclusive system detailing the chain of events from the moment a single AEFI or cluster of AEFIs becomes apparent to the final implementation of a plan of action at national and possibly international level. Only certain AEFIs require all relevant personnel to be consulted.

The DHMT should notify MOH and initiate an investigation into the cause of the AEFI. An AEFI form should be completed and sent with any specimen sent to the laboratory. Reporting to MOH should be done by telephone, radio call or fax.

## AEFI Reporting Flow Chart



### 9.6 AEFI reporting roles and responsibilities

#### **Teacher/Community/Caretaker/Mother**

- Be informed about potential AEFIs
- Reports to the health worker if the vaccinated girl complains of any symptoms
- Reports to the health worker for unusual behaviour or absence from school

#### **Health Worker**

- Familiarizes self with AEFI types in the list
- Initiates immediate and first aid treatment of an AEFI

- Talks immediately, openly and sympathetically to the girl, teacher or caretaker without admitting liability or becoming defensive
- Obtains background information from the reporting person
- Completes an AEFI Form
- Informs MOH within 24 hours of an AEFI through telephone or text message

### **DHMT Officer**

- Interviews parents, discusses concerns and deals with concerns or anger
- Interviews vaccinator in a non-threatening and supportive way
- Initiates rapid response
- Informs the MOH by fax/telephone of an AEFI and if there is any technical assistance required
- Compiles a detailed report and submits it to the MOH

### **Medical Officer**

- Treats any “difficult or severe” AEFI
- Works closely with the DHMT Officer
- Facilitates further case investigation as needed (e.g. vaccine testing, post-mortems, etc.)
- Assists with secondary response if necessary
- Assists with managing political aspects and media
- Provides technical assistance to the DHMT during the process of compiling a detailed report
- Facilitates submission of the report to MOH

### **Ministry of Health**

- Receives reports from all district AEFI focal persons
- Quickly reviews all reported events and analyses data
- Determines what to investigate further
- Classifies the reported AEFI
- Keeps record of all reported AEFIs during immunization sessions
- Provides feedback to the community, mobilizes the community to continue with HPV immunization and counteracts rumours and allays community anxiety through appointed MOH spokesperson

#### **Test Your Knowledge**

1. What is an AEFI?
2. What are the categories of AEFI related to HPV vaccination?
3. A ten year old girl is in line at an outreach to receive the HPV vaccine and collapses. All the other girls at the session run away. How would you respond in this scenario?
4. At the same session, you receive information that five girls have fainted after receiving the HPV vaccine. How would you investigate and respond?

## Monitoring

During the planning and implementation of HPV vaccination, monitoring of daily progress and supervision at all levels is very important to ensure the quality of service provided, coverage and the impact of vaccination. Health workers, supervisors and DHMT Officers need to monitor the following:

- Coverage, dropout rates and vaccine wastage
- Cold chain maintenance and vaccine storage temperatures (HPV vaccine is sensitive to freezing and low temperatures)
- Adverse Events Following Immunization (AEFI)

### 10.1 Monitoring coverage, drop-out, and vaccine wastage

Monitoring tools (forms) are provided to collect data on HPV vaccination activities. Data collected with these tools will be used to calculate coverage, drop-out and wastage after each vaccination session.

### 10.2 Forms for monitoring activities

Data collection forms to be used in vaccination activities include:

- HPV Vaccine Register
- School Health Cards
- HPV Vaccination Cards
- Daily Tally Sheet
- Resource Management and Vaccine Wastage Form
- AEFI Forms

#### 10.2.1 HPV Vaccine Register

The health worker will register each girl receiving the HPV vaccine. The register will be kept at the health facility. The register needs to be brought to each vaccination session; one register per immunization post. Bring the original register to

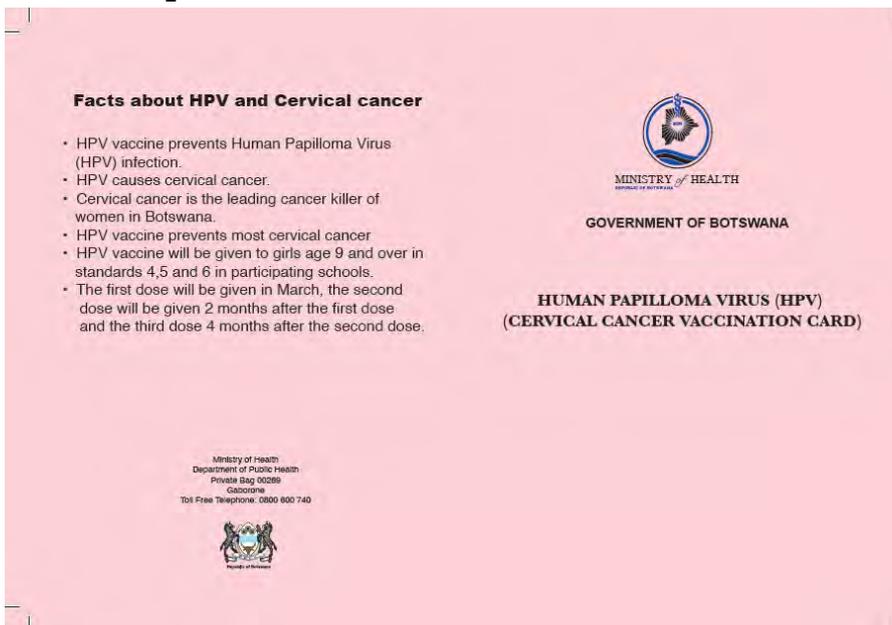
subsequent vaccination sessions to verify the girls that need their second and third doses.

The HPV Register lists all girls that are in standards 5, 6 and 7 in participating schools and girls not attending school who are aged 9 to 13 years.

### 10.2.2 HPV Vaccination Card

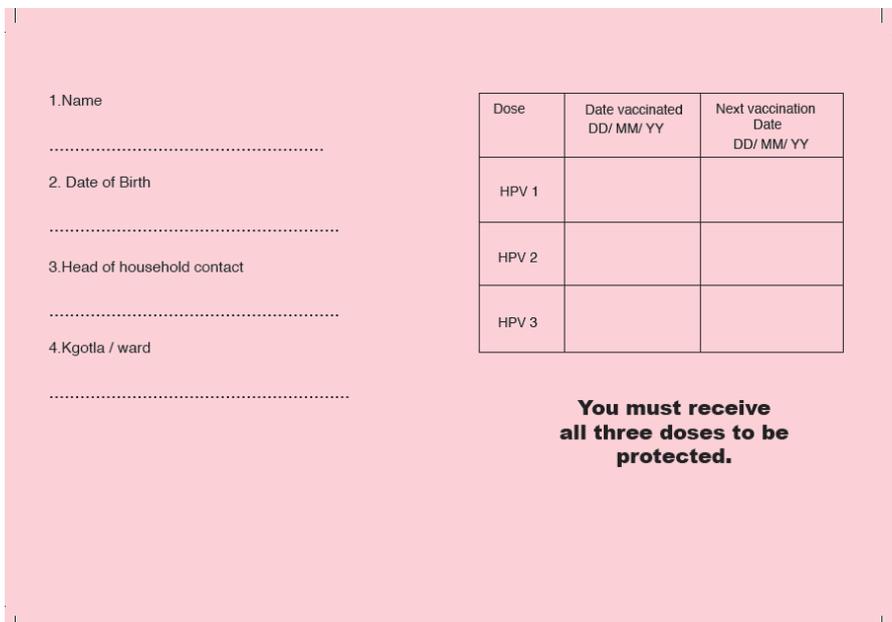
There will be an HPV Vaccination Card for each girl who receives the HPV vaccine. The card will be filled by the health worker at the immunization session and kept at the school until completion of the three-dose vaccination series.

#### Draft sample of HPV Vaccination Card



Back page

Front Page



Inner page 1

Inner page 2

### 10.2.3 Daily Tally Sheet

This form is filled out at the vaccination post by the health worker who administers the vaccine.

- Each girl who receives the vaccine is represented by striking one zero on the tally sheet at the time of vaccination. Do not merely mark the vaccine doses used, as this would include any wasted doses and result in an inaccurate tally.
- At the end of the day, the number of girls vaccinated are added up and recorded in the total column according to their age.
- Tally sheets provide primary data that will be used to calculate final coverage. The tally sheets must be completed for each day of the vaccination and stored until completion of the 3 doses.

#### **10.2.4 AEFI Form**

This form should be filed for all AEFI (see Chapter 9).

#### **10.2.5 Resource Management and Vaccine Wastage Form**

Complete this form at the end of every vaccination session.



All report forms should be filled in duplicate. One copy will remain at that level and the other will be submitted to the next level.

#### **Test Your Knowledge**

1. What key activities must be monitored during HPV vaccination sessions?
2. Who are the main supervisors and what are their roles/responsibilities?
3. What are your roles/responsibilities?

Discuss your answers with your trainer/supervisor.

## Supportive Supervision

During the HPV vaccination activities, supportive supervision at all vaccination sessions (school, health facility, or outreach) shall be carried out to:

- Assess the quality of services being offered at the centres.
- Reinforce the knowledge and skills of the service providers.
- Provide additional information to the communities, especially the eligible girls and their guardians, about the HPV vaccine.
- Provide extra logistics as needed.
- Respond to rumours or misconceptions about the vaccine.

Hard to reach areas/populations should receive more supervisory visits.



Supervision of HPV vaccination should be supportive and not fault-finding.

As the introduction of HPV vaccinations is integrated into routine immunization activities, supervision of HPV vaccination will be integrated into normal EPI activities for new vaccine introduction. Therefore, the supervisors who usually oversee normal EPI activities at the district level will be the same supervisors to oversee HPV vaccination. These supervisors should be part of the training in preparation for HPV vaccination. All supervisors for HPV vaccination will determine the:

- Proportion of target population immunised at the district level
- Quality of services provided, with an emphasis on injection safety
- Major lessons learnt and suggested adjustments to strategy implementation

A checklist will be used to ensure that all areas of concern are addressed.



**MINISTRY OF HEALTH**  
**HPV VACCINE DEMONSTRATION PROJECT**  
**Daily Tally Sheet to Record Doses Given on a Single Vaccination Day**

Date of vaccination ...../...../.....	District: Molepolole School: _____					Tally Sheet N°: _____ of _____										
<b>Age (years)</b>	<b>No. Girls vaccinated ( HPV1)</b> (please put a hash mark through one circle for each girl immunized)					<b>No. Girls vaccinated ( HPV2)</b> (please put a hash mark through one circle for each girl immunized)					<b>No. Girls vaccinated ( HPV3)</b> (please put a hash mark through one circle for each girl immunized)					<b>Total sum rows</b>
<b>9</b>	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	<b>9yrHPV1=</b>					<b>9yrHPV2=</b>					<b>9yrHPV3=</b>					=
<b>10</b>	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	<b>10yrHPV1=</b>					<b>10yrHPV2=</b>					<b>10yrHPV3=</b>					=
<b>11</b>	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	<b>11yrHPV1=</b>					<b>11yrHPV2=</b>					<b>11yrHPV3=</b>					=
<b>12</b>	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	<b>12yrHPV1=</b>					<b>12yrHPV2=</b>					<b>12yrHPV3=</b>					=
<b>13</b>	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	<b>13yrHPV1=</b>					<b>13yrHPV2=</b>					<b>13yrHPV3=</b>					=
<b>14</b>	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	<b>14yrHPV1=</b>					<b>14yrHPV2=</b>					<b>14yrHPV3=</b>					=
<b>15 - 20</b>	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	
	<b>15-20yrsHPV1=</b>					<b>15-20yrsHPV2=</b>					<b>15-20yrsHPV3=</b>					=
																=
	<b>Total girls vaccinated (HPV1)=</b>					<b>Total girls vaccinated (HPV2) =</b>					<b>Total girls vaccinated (HPV3)=</b>					=

Number of vaccine vials received: \_\_\_\_\_  
 Number of health workers: \_\_\_\_\_  
 Name: \_\_\_\_\_

Number of vials used: \_\_\_\_\_  
 Number of teachers: \_\_\_\_\_  
 Signature: \_\_\_\_\_

Number of vials discarded/wasted: \_\_\_\_\_  
 Date: \_\_\_\_\_



REPUBLIC OF BOTSWANA

**MINISTRY OF HEALTH**  
**HPV DEMONSTRATION PROJECT**  
**Adverse Events Following Immunization (AEFI) Form**

**Patient Information:**

District: Kweneng East

School: \_\_\_\_\_

Health Clinic/Hospital: \_\_\_\_\_

Name: \_\_\_\_\_

Birthdate:    /    /

Sex:    F = female

Guardian Name: \_\_\_\_\_

Physical Address : \_\_\_\_\_

Kgotla/Ward: \_\_\_\_\_ City or Village: \_\_\_\_\_

Guardian Phone: \_\_\_\_\_ Guardian Cell Phone: \_\_\_\_\_

**Adverse event information :**

Date of vaccination: \_\_\_\_\_.

Type of vaccination: Gardasil                      Lot #: \_\_\_\_\_                      Expiry date: \_\_\_\_\_

Type of injection: Intramuscular                      Injection site: \_\_\_\_\_

Date AEFI onset of symptoms: \_\_\_\_\_

Where did AEFI occur: \_\_\_\_\_

Interval from immunization to onset of symptoms: \_\_\_\_\_

Date AEFI reported to health care worker: \_\_\_\_\_

History of reaction to previous dose:    Y    N

Describe: \_\_\_\_\_

Known allergy to vaccine or vaccine component:    Y    N

Describe: \_\_\_\_\_

**Description of AEFI/symptoms:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Development/progress of AEFI (circle one) :**

Resolved

Healed without reoccurrence

Healed with reoccurrence

**Description of treatment/outcome:**

---

---

---

---

**The adverse event** (tick applicable description):

- Is isolated
- There are several similar/identical incidents among vaccinated girls within the vaccination period
- The same symptoms are observed concurrently within the household of vaccinated girls and among household members that were not vaccinated

**Supply chain and vaccine management** (tick applicable description)::

- Non-adherence to cold chain guidelines
- Aseptic technique

**Additional information and observations:**

---

---

---

---

**Interviewer :**

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Health Facility: \_\_\_\_\_

Cell: \_\_\_\_\_

Address: \_\_\_\_\_

