Ministry of Health
Department of Public Health, Division of Child Health
Guidelines for HPV Vaccinators

Human Papillomavirus (HPV) Vaccination to Prevent Cervical Cancer

Republic of Botswana

2014
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OPENING REMARKS

Cervical cancer is the leading cause of cancer deaths of women in Botswana. Accordingly, cervical cancer represents a primary concern of the Ministry of Health (MOH).

The principal causatory agent of cervical cancer is well-known, the Human papillomavirus (HPV), a sexually transmitted virus with over 140 different types. Fortunately, a vaccine against certain types of HPV virus exists.

WHO recommends introduction of the HPV vaccine in all regions where material resources and finances permit it. With the agreement of public and private partners, the government of Botswana has decided to introduce Gardasil®, an HPV vaccine made by the American pharmaceutical firm Merck. The efficacy of Gardasil® has been demonstrated worldwide to reduce the incidence of cervical cancer, and the use of Gardasil® is expected to lighten the burden of cervical cancer among women in Botswana. MOH has decided to introduce the vaccine in a phased approach. Phase 1 was a Demonstration Project in Molepolole in 2013, and lessons learned from the project have informed planning for a national rollout of the vaccine. Phase 2 will expand HPV vaccinations to all eligible girls in Kweneng East, Kweneng West, and Selebi-Phikwe districts. Phase 3 will rollout vaccinations to the entire country.

To have a sustainable and lasting impact, the vaccination must reach girls before they become sexually active and MOH has therefore decided to vaccinate girls in standards 5, 6 and 7 and those aged 9 to 13 years in the entire district.

This guide is a tool for vaccinators. It can also be used by other personnel, such as teachers, who play a critical role in the organization of vaccination against HPV. MOH will expand the HPV vaccination program as Botswana gains experience with the HPV vaccine, and therefore MOH hopes and recommends that you familiarize yourself with this material so that you can educate the public about HPV and HPV vaccine and provide the best possible services to protect girls in Botswana from this deadly disease.

Dr. H.B. Jibril
Acting Director-Department of Public Health
Ministry of Health
1.1 What are cervical cancer and HPV?

The cervix is the lower part of the uterus or womb. Cervical cancer is a serious disease that can cause death. However, if recognized and treated early, cervical cancer can be easily prevented.

Almost all cases of cervical cancer (99%) are caused by a sexually transmitted virus called Human papillomavirus (HPV). HPV is a very common virus that 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 and are unaware of the infection. In most cases, HPV infection will clear on its own. However, persistent infection can lead to cervical cancer.

1.2 Cervical cancer in Botswana

- Cervical cancer in the most common cancer in women in Botswana.
- Cervical cancer in the most common cause of cancer death among women in Botswana.
- Cervical cancer Screen & Treat services are currently available in certain areas of Botswana, and scale up of these services throughout Botswana has commenced since 2013.
1.3 Symptoms of cervical cancer

**Abnormal vaginal bleeding**
- A woman bleeding after having sex
- An elderly woman having vaginal bleeding after cessation of her periods
- Vaginal bleeding in between periods

**Abnormal vaginal discharge**
- Every woman releases some mucus from the vagina. However, an unpleasant 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**

1.4 What other diseases does HPV cause?

In addition to cervical cancer, HPV can cause genital warts in both women and men. HPV can also sometimes cause other cancers, including cancers of the anus, vagina, penis, vulva, and throat. However, these cancers are much less common than cervical cancer.

![Photo: Genital warts on the vagina, penis, and anus, respectively. HPV causes 90% of genital warts.](image)
The HPV Vaccine: What You Need To Know

2.1 Prevention of cervical cancer using HPV vaccines

- Effective vaccines that prevent HPV infection exist.
- The vaccine should be administered before exposure to the virus, that is before a person becomes sexually active.
- Gardasil® has already been used with great success all over the world, including Africa.
- The vaccine is made of protein particles. It does not contain live virus, and therefore it cannot cause HPV infection.

2.2 Storage and packaging of HPV vaccine

- Each vial of Gardasil® contains one 0.5 ml liquid dose of the vaccine.
- Gardasil® does not need to be reconstituted.
- The recommended storage temperature is +2°C to +8°C, just like the tetanus vaccine.

The HPV vaccine must not be frozen, and therefore should not be put directly against frozen icepacks.
2.3 What diseases does Gardasil® prevent?

- Cancers of the cervix, vagina, and vulva
- Genital warts
- Infections from certain types of HPV that cause cervical cancer and genital warts

2.4 Who is eligible for HPV vaccination in Botswana?

All girls in standards 5, 6 and 7 are eligible for vaccination and vaccine will be administered at schools. All girls aged 9 to 13 years who are not attending school are also eligible and vaccine will be administered at health clinics and health posts.

In 2014, three districts of Kweneng East, Kweneng West, and Selebi-Phikwe will implement the programme. In 2015, HPV vaccination will be rollout across the whole country.

2.5 HPV vaccination schedule in Botswana

The HPV vaccine is given in three doses. For maximum protection, each girl must receive all three doses. Girls will receive the three doses of the Gardasil® vaccine according to the calendar below. If a girl misses a dose, she should go to the identified clinic to make up for the missed dose as soon as possible. Subsequent doses will be adjusted to meet guidelines listed below.

<table>
<thead>
<tr>
<th>Dose #</th>
<th>Dosage</th>
<th>When to administer the vaccine</th>
<th>Route of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st dose</td>
<td>0.5 ml</td>
<td>At first contact with the girl</td>
<td>Intramuscular, in the deltid region of the left arm</td>
</tr>
<tr>
<td>2nd dose</td>
<td>0.5 ml</td>
<td>2 months after the first dose</td>
<td>Intramuscular, in the deltid region of the left arm</td>
</tr>
<tr>
<td>3rd dose</td>
<td>0.5 ml</td>
<td>4 months after the second dose</td>
<td>Intramuscular, in the deltid region of the left arm</td>
</tr>
</tbody>
</table>

2.6 Contraindications to Gardasil®

- Gardasil® should not be administered to girls with known hypersensitivity (allergic reaction) to vaccine components.
• Gardasil® should not be administered to girls who develop symptoms of hypersensitivity after having received an earlier dose of the vaccine.

2.7 Precautions for use

• Cases of syncope (fainting) have been reported after administration of the vaccine. Therefore, it is recommended that girls be observed for 15 minutes after receiving the vaccine.
• A pregnant girl should wait until after the pregnancy to receive the Gardasil® vaccination.
• Administer Gardasil® with caution to girls who have blood clotting disorders (wait for several minutes to make sure the injection site clots).

2.8 Simultaneous vaccination with other EPI vaccines

Gardasil® can be administered simultaneously with other EPI vaccines without danger. It is recommended to administer the vaccines on different parts of the body (for example, one injection in the left arm and the other in the right arm).
Administering HPV vaccine

3.1 Preparation checklist for administering HPV vaccines

- **HPV vaccine doses:** The Gardasil® HPV vaccine has one dose per vial, so the number of vials to bring to the vaccination site corresponds to the number of girls to be vaccinated. It is recommended that the vaccinator bring an extra 5% of vials as a precaution (for example, in case a few bottles break).

- **Syringes:** The number of syringes needed corresponds to the number of girls to be vaccinated. Bring an extra 5% to 10% of syringes in case some syringes do not work.

- **Sharps boxes:** Equal to the number of syringes divided by 100.

- **Other materials:** Drugs for handling serious adverse events following immunization (see page 18), cotton, clean water, and soap to wash hands or hand sanitizer.

- **Waste containers:** Bins or bags to collect empty vials and used cotton swabs.

- **Monitoring tools:** The HPV Vaccine Register, School Health Cards, HPV Vaccination Cards, the Daily Tally Sheet, and the AEFI Reporting Form.

- **Social mobilization tools:** HPV leaflet.
### 3.2 Step-by-step instructions for administering HPV vaccine

<table>
<thead>
<tr>
<th>Step</th>
<th>Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Welcome the girl in a friendly manner, and ask her if she has any questions about HPV vaccination. Answer all questions truthfully.</td>
</tr>
<tr>
<td>2</td>
<td>Ensure that the girl is eligible for the HPV vaccine. All girls currently enrolled in standards 5, 6 and 7 or who are aged 9 to 13 years if not attending school in Kweneng East, Kweneng West, and Selebi-Phikwe districts’ schools. Eligible girls should be listed in the register provided.</td>
</tr>
<tr>
<td>3</td>
<td>Check for contraindications to the 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.</td>
</tr>
<tr>
<td>4</td>
<td>Wash and dry or sanitize your hands.</td>
</tr>
<tr>
<td>5</td>
<td>Hold the HPV vaccine vial between your thumb and middle finger. Check the vaccine vial for the condition of the vial and expiry date. Inspect for particles and discoloration before administering the vaccine. If either is present, do not use the vaccine. Pick another vial.</td>
</tr>
<tr>
<td>6</td>
<td>Shake the vaccine vial until it is a white, cloudy liquid. This step is necessary to mix the vaccine.</td>
</tr>
<tr>
<td>7</td>
<td>Open the package for the 0.5 ml auto-disable (AD) syringe.</td>
</tr>
<tr>
<td>8</td>
<td>Draw all the contents of the HPV vaccine from the vial into the 0.5ml syringe. Pull the syringe until full of vaccine and push out any air.</td>
</tr>
<tr>
<td>9</td>
<td>The vaccine should be given in the left arm. Encourage the girl to relax her arm. The injection is less painful when the arm is relaxed.</td>
</tr>
<tr>
<td>10</td>
<td>Clean the injection site using a swab and clean water.</td>
</tr>
<tr>
<td>Step</td>
<td>Instructions</td>
</tr>
<tr>
<td>------</td>
<td>--------------</td>
</tr>
<tr>
<td>11</td>
<td>Inject the entire contents of the syringe in the <strong>deltoid muscle of the upper left arm</strong> (figure below), unless the girl is left-handed, in which case inject into the deltoid muscle of the upper 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.</td>
</tr>
<tr>
<td>12</td>
<td>Place cotton on the injection site, and ask the girl to press it hard on the site of injection to prevent bleeding. <strong>Do not massage the site of injection.</strong></td>
</tr>
<tr>
<td>13</td>
<td><strong>Do not recap the used syringe and needle.</strong> Put used syringes and needles in the sharps box.</td>
</tr>
<tr>
<td>14</td>
<td>Thank and congratulate the girl. Tell her the dates for her next dose of HPV vaccine. 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.</td>
</tr>
<tr>
<td>15</td>
<td>Complete vaccination information on the register, the School Health Card and the HPV Vaccination Card.</td>
</tr>
<tr>
<td>16</td>
<td>Wash hands before administering vaccine to every client or whenever necessary.</td>
</tr>
</tbody>
</table>

- **A separate syringe should be used for each injection**
- **HPV vaccine should be administered intramuscularly, into the deltoid muscle of the**
3.3 Flow of HPV vaccination in schools

Entrance

Waiting Area

Registration and Screening

Staffed By: Teachers and Health Workers

Immunization, Recording and Tallying of Girls

Staffed By: Health Workers

Giving Health Messages on the HPV Immunization Schedule

Staffed By: Health Workers, Teachers

15 Minute Observation

Exit
### 3.4 Messages about HPV Vaccination

1. Tell the girl that she is receiving the HPV vaccine that prevents cervical cancer.
2. Give her information on the number of doses (3) for her to be protected. Emphasize the importance of receiving all three doses according to the vaccination calendar.
3. Ask the girl to keep her 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 girl the dates of the next dose.
7. Thank the girl for coming for the vaccination. When she finishes the third dose, congratulate her.

### 3.5 Injection safety during vaccination

Unsafe injections can transmit blood-borne diseases such as HIV/AIDS and hepatitis B. According to WHO, a safe injection:

1. Does not harm the patient
2. Does not harm the health worker
3. Does not produce hazardous waste that could put the community in danger

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

- Organize the vaccination supplies and equipment on a table (vaccine carrier, syringes, clean cold water, cotton balls, etc).
- Wash or sanitize your hands before beginning a vaccination session.
- Use a cotton ball soaked with clean cold water to wash the girl’s arm.
- Use a new syringe and needle for each girl.
- Carefully inspect the packaging of each syringe. Throw away all syringes with damaged packaging.
- Do not touch the needle during the injection procedure.
- Insert the syringe into the vaccine vial only when the girl is ready to be vaccinated.
- Do not load multiple syringes in advance (in anticipation that many girls will come to the vaccination session).
- **Never recap needles after use.**
- 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).
• Immediately dispose of all syringes and needles in the sharps box.
• Avoid completely filling the sharps box. Fill it only until it is ¾ full.
• Do not put cotton balls or used vials in the sharps box.
• Bring the sharps box to the designated health center for incineration or control burning according to EPI national instructions.
Ensuring Vaccine Coverage

4.1 Tools given for monitoring HPV vaccination

It is important that all administered doses are correctly recorded to measure the progress of the vaccination project. The following tools have been given to you to collect data.

**Number of eligible girls attending school**
The health workers should know the number of eligible girls in standards 5, 6 and 7 in each school. MOH will calculate the number of HPV vaccine doses needed at each vaccination session. On the day of vaccination, MOH will provide administering nurses with a complete list (register) of eligible girls. This register will include each girl’s name, date of birth, address, name of guardian, guardian contact information, school and class. This will permit good organization of the vaccination session, ensure that all the girls are vaccinated, and ensure only the girls who are supposed to be vaccinated are vaccinated.

**School Health Card**
Each girl will have a School Health Card. Vaccine doses will be recorded on this card. The card will stay at school.

**Number of eligible girls in the community not attending school**
The health workers should estimate the number of eligible girls aged 9 to 13 years who are not attending school in the catchment area of each health clinic. MOH will calculate the number of HPV vaccine doses needed at each health clinic or health post to ensure access for girls not attending school. A list (register) of eligible girls should be added to the vaccine register for the clinic. This register will include each girl’s name, date of birth, address, name of guardian, guardian contact information, school and class. This will permit good organization of the vaccination session, ensure that all the girls are vaccinated, and ensure only the girls who are supposed to be vaccinated are vaccinated.
**HPV Vaccination Card**
Each girl will have an HPV Vaccination Card. Vaccine doses will be recorded on this card. The card will stay at school or health clinic until after the third dose and will be given to the girl after she has received all three vaccine doses.

**HPV Vaccine Register**
MOH will provide an HPV Vaccine Register for each school or health clinic. Vaccine doses will be recorded on this register. The register should be kept at the health clinic and brought to the schools only during vaccination sessions.

**The Daily Tally Sheet**
For each girl who receives the vaccine, the dose is recorded on the Tally Sheet under her age. At the end of the vaccination session, the total administered doses in each age are calculated, and the numbers of doses wasted due to contamination or breakage are listed at the bottom of the Tally Sheet.

**The Adverse Events Following Immunization (AEFI) Form**
An AEFI Form should be completed for any and each AEFI observed following immunization.

**The Resource Management and Vaccine Wastage Form**
At the end of the day or when you return to the health center, the Team Leader should report all administered doses by age and all doses wasted on the Resource Management and Vaccine Wastage Form.
**Adverse Events Following Immunization (AEFI)**

**5.1 What are AEFI?**

WHO defines AEFI as a medical event that takes place after immunization, causes concern and is believed to be caused by immunization. Though rare, like all vaccinations, those who receive Gardasil® can present with AEFI.

**5.2 Important notes on AEFI**

- The vast majority of AEFI have no real biological relationship with the vaccine itself. Events linked to vaccinations by coincidence can be falsely attributed to vaccination.
- Among the AEFI linked to vaccination, the most common are linked to programmatic errors.
- Most AEFI are minor.
- In rare cases, serious manifestations can result and may be fatal.
- Whatever the severity of AEFI, it is important to treat them seriously. This applies to both medical treatment and communication, because AEFI can be the source of rumours about the vaccine project which can compromise vaccination as a whole.

**5.3 Your role as a health worker at the onset of an AEFI**

1. Initiate care and immediate relief.
2. Speak directly and openly without being defensive to parents or teachers and without admitting guilt (remember, the AEFI may have nothing to do with vaccination or the vaccine).
3. Inform the Team Leader, a Matron or a MOH Program Officer immediately (as soon as possible) by telephone.
4. Obtain the basic information of the girl (medical history, family history, and personal history).

**5.4 List of emergency drugs to have in case of an AEFI**

Certain AEFI are minor (headaches, muscle aches, or nausea) or local reactions (redness, swelling and/or pain at the injection site) and can be resolved by using Tylenol or other over-the-counter medications. In extremely rare cases, severe AEFI which necessitates immediate hospitalization can occur and can result in severe handicaps or even death of the patient. To prepare for severe AEFI, prepare an emergency medical kit containing the drugs and supplies listed below:

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Supplies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenaline (injectable) (HC IV)</td>
<td>Drinking water</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>Needle and syringes</td>
</tr>
<tr>
<td>Chloropheniramine (Piriton)</td>
<td>Intravenous cannulars</td>
</tr>
<tr>
<td>Hydrocortisone (HC IV)</td>
<td>Normal saline</td>
</tr>
<tr>
<td>Diazepam (HC IV)</td>
<td>5% Dextrose</td>
</tr>
</tbody>
</table>