Guidelines for Health Managers
and Service Providers

Human Papillomavirus (HPV) Vaccination to Prevent Cervical Cancer

Republic of Zambia

Ministry of Community Development,
Mother and Child Health

The Ministry of Community Development, Mother and Child Health (MCDMCH) would particularly like to acknowledge the contributions of the following individuals toward the finalization of this guide:

Dr. Penelope Kalesha, MCDMCH
Elicah Kamiji, MCDMCH
Dorothy Sikazwe, MCDMCH
Charles M Zulu, MoH
Lillian Mphuka, MoH
Faith M. Nchito, MESVTEE
Kennedy Siputuma, MESVTEE
Prisca Chanda Sikazwe, MESVTEE
Dr. Ngawa Ngoma, UNICEF
Christine M. Lemba, UNICEF
Deepa R. Pokharel, UNICEF
Givas Kalangu, UNICEF
Dr. Sarai Malumo, UNFPA
Victor Sakala, MSD
Dr. Jules Millogo, Merck
Alain Barry, Merck
Joan Littlefield, PATH
Dr. Emmanuel Mugisha, PATH
Dr. Scott LaMontagne, PATH
Dr. Ari De Lorenzi, PATH
O'Brien Mashinkila, PATH
Kristy Kade, PATH
Elizabeth Chiyende, PATH
Abraham Mwanamwenge, WHO
Dr. Helen Mutambo, WHO
Nora Mweemba, WHO
Mary Kaoma, ZISSP
Martha Mwendafulumba, WVZ
Dr. Sharon Kapambwe, CIDRZ
Dr. Allen Bateman, CIDRZ
Jenala Chipungu, CIDRZ
Lisa Grossman, CIDRZ

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Foreword

Zambia has the second-highest incidence of cervical cancer in the world, and cervical cancer is the most common cancer in women in Zambia. Cervical cancer represents a primary concern of the Ministry of Health and the Ministry of Community Development, Mother and Child Health.

The principal causatory agent of cervical cancer is well known: it is human papillomavirus (HPV), a sexually transmitted virus with many different types. Fortunately, there are vaccines that can prevent against diseases caused by this virus. The WHO recommends introduction of the HPV vaccine in all countries where material resources and finances permit it.

With the agreement of public and private partners, the government of Zambia has decided to introduce Gardasil, a vaccine made by Merck. 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 among women in Zambia. The target aged group recommended by the WHO is between 9 and 13. Because HPV is spread primarily through intercourse, it is recommended that the vaccine be administered before exposure to the virus (that is, before the person becomes sexually active).

Given the high rates of school enrolment in Zambia, it has been decided to target girls in grade 4. For out-of-school girls, the targeted age is ten years old.

The present guide is a simple tool for vaccinators on the ground. It can also be used by other personnel such as teachers, who play a critical role in the organization of vaccination against HPV. The Zambian government plans to expand the HPV vaccination program as Zambia gains experience with the HPV vaccine. I strongly recommend that you familiarize yourself with this guide, so that you can provide the best possible services to protect girls in Zambia from this deadly disease.

Prof Elwyn Chomba
Permanent Secretary
Ministry of Community Development,
Mother and Child Health (MCDMCH)

Acknowledgements

The Ministry of Community Development, Mother and Child Health (MCDMCH) would like to thank the staff from the following groups for their collaboration in the development of this field guide: Zambia National Expanded Programme on Immunisation (EPI), Ministry of Education, Science, Vocational Training and Early Education (MESVTEE), Ministry of Health (MoH), Centre for Infectious Disease Research in Zambia (CIDRZ), Merck, Merck Sharp & Dohme (MSD), Zambian Integrated Services Strengthening Program (ZISSP), United Nations Children's Fund (UNICEF), World Health Organization (WHO), World Vision Zambia (WVZ), United Nations Population Fund (UNPFA), and Program for Appropriate Technologies in Health (PATH). Special thanks to PATH and Merck for their technical support during the planning for scale-up of human papillomavirus (HPV) vaccination in Zambia. Additional thanks to Merck for the generous donation of the HPV vaccine.

List of Abbreviations

AD syringes	Auto-Disable syringes
AEFI	Adverse Events Following Immunisation
BCG	Bacille Calmette-Guérin vaccine
CHW	Community Health Worker
CIDRZ	Centre for Infectious Disease Research in Zambia
DHT	District Health Team
DMO	District Medical Officer
DPT-HepB+Hib	A combined vaccine (pentavalent) containing diphtheria, pertussis, tetanus, hepatitis B and haemophilus influenzae b
DVS	District Vaccine Store
EPI	Zambia National Expanded Programme on Immunisation
FEFO	First-Expiry First-Out
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus
IEC	Information, Education, and Communication
MCDMCH	Ministry of Community Development, Mother and Child Health
MCH	Mother and Child Health
MESVTEE	Ministry of Education, Science, Vocational Training and Early Education
MoH	Ministry of Health
NGO	Non-Governmental Organisation
NHC	Neighbourhood Health Committees
OPV	Oral Poliovirus Vaccine
PATH	Program for Appropriate Technology in Health
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

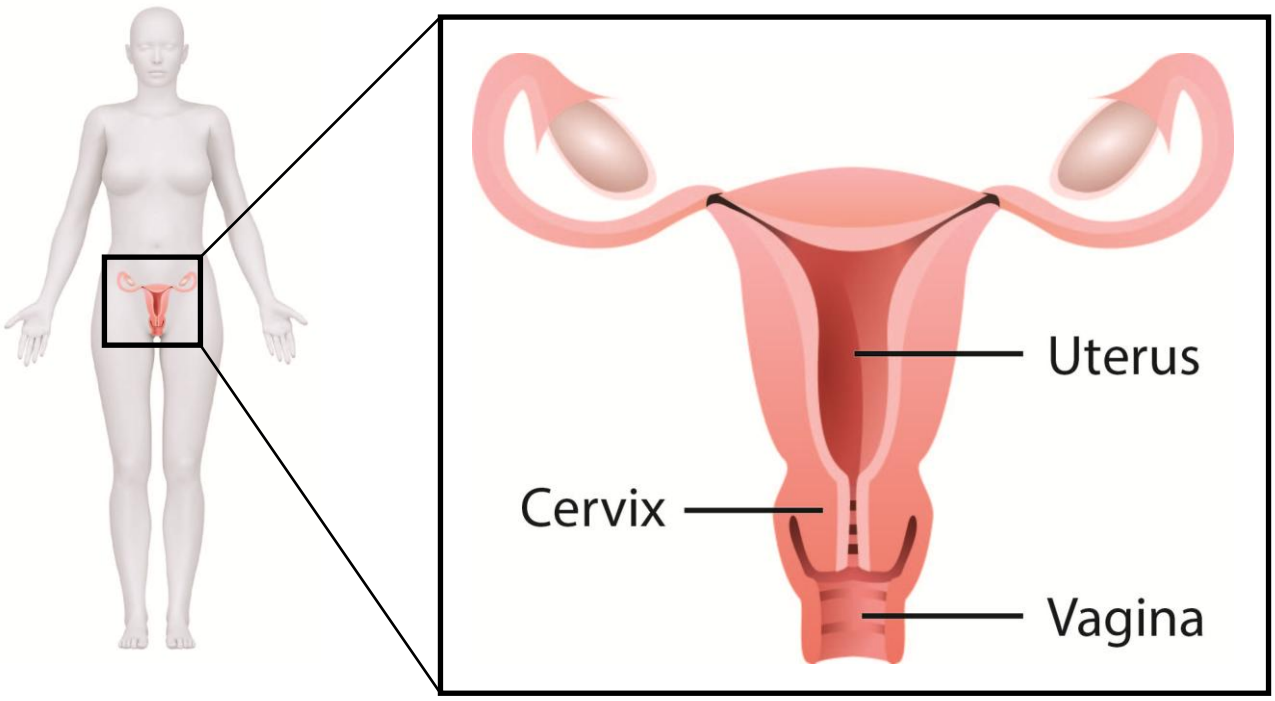
Chapter 1

Human Papillomavirus and Cervical Cancer: An Introduction

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:

1. The uterus
2. The cervix
3. 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. The cervix 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.

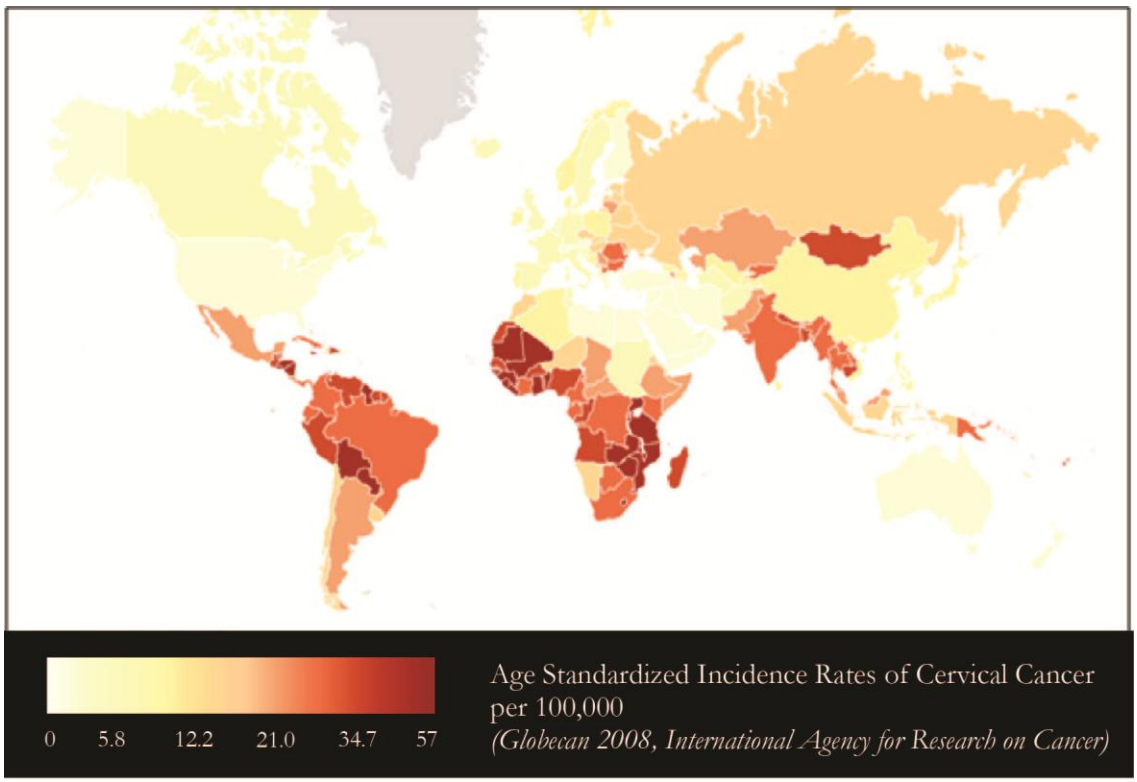
1.2 What is Cervical Cancer?

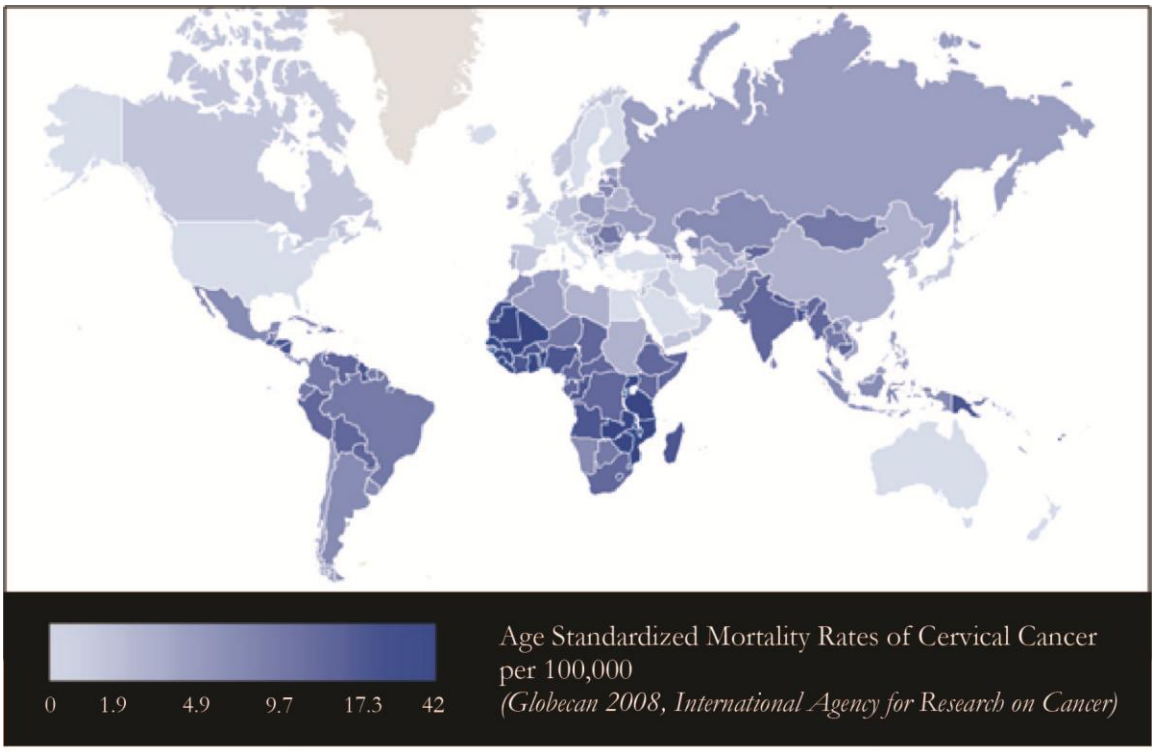
Cancer is a disease in which a group of cells in the body displays uncontrolled growth and sometimes spreads to other locations in the body. When this uncontrolled growth of cells occurs on the cervix, the disease is called cervical cancer. Cervical cancer is a serious disease and can cause death. However, 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, or 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, cervical cancer is the most common cancer in women.

Zambia has the 2nd highest rate of cervical cancer in the world, with 52.8 cases per 100,000 women per year. Cervical cancer is the most common of all cancers in Zambia regardless of gender. Unfortunately, over 80% of 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)?

A virus called human papillomavirus (HPV) causes almost all cervical cancers (99%). HPV is a sexually transmitted infection (STI). 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.

1.6 What Other Diseases Does HPV Cause?

HPV does not just cause cervical cancer. HPV can cause genital warts in both men and women. HPV causes other cancers, including most cancers of the anus and vagina, and some cancers of the penis, vulva,

and oropharynx. 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 all affect men.

Genital warts on the vagina, penis, and anus, respectively. HPV causes 90% of genital warts.

1.7 Risk Factors for Contracting HPV

Risk factors for contracting HPV include:

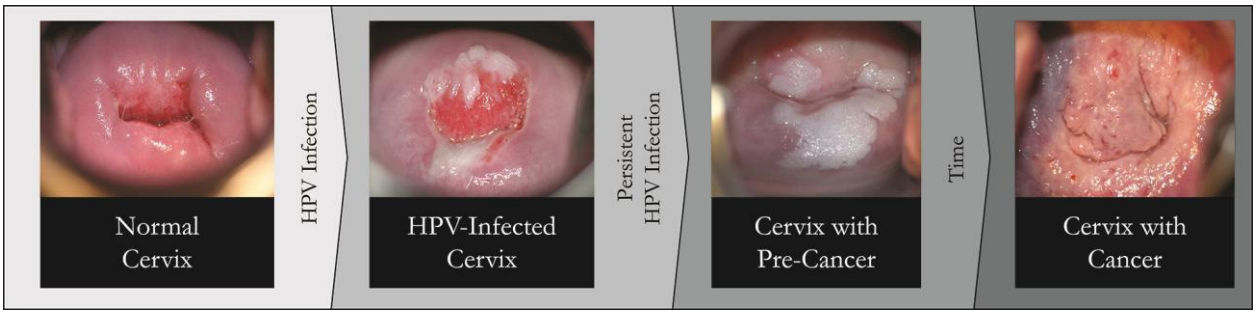
- Early age at first sexual intercourse
- Having multiple sexual partners
- Having a sexual partner with multiple sexual partners
- Presence of other genital infections
- Weakened immune systems as in people with HIV/AIDS

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 can cause genital warts. Types 6 and 11 are the two most common types associated with genital warts. High-risk types are cancer-causing. Types 16 and 18 are the two most common high-risk types. In fact, 16 and 18 alone 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 infections. Cervical cancer begins when 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, develop persistent HPV infection, and develop cervical cancer. 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.

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 Zambia
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

Exercises

1. What is the cause of 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?

Chapter

2

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. Prevention using the HPV vaccine
   - Recommended for girls ages 9-13 years prior to sexual debut

2. Prevention through lifestyle and behavioural changes
   - Delay the age of starting sexual intercourse
   - Limit number of sexual partners
   - Do not smoke
   - Eat more fruits and vegetables
   - Condoms may protect against HPV infection if used consistently and correctly

3. Prevention using 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 Zambia, a type of screening called visual inspection with acetic acid (VIA) is used.

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 of cervical cancers.

2.2 The HPV Vaccine

The Gardasil HPV vaccine 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 most commonly associated with cervical cancer, and types 6 and 11 cause the vast majority of genital warts. Gardasil prevents against cancers of the cervix, vagina, and vulva, and genital warts.

2.3 Gardasil Packaging and Storage

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

Figure: The Gardasil HPV vaccine

Gardasil HPV vaccine should be stored at +2°C to +8°C. It is sensitive to freezing, so it should never be frozen. It 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 to 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
The WHO recommends administering the HPV vaccine to girls 9-13 years of age, because the vaccine is more effective in girls who have not been exposed to the HPV virus.

The Zambia HPV Vaccination Program
Experience has shown that most of the girls in grade 4 in Zambia will be between 9 and 15 years of age. Therefore, the HPV vaccination will target girls who are in grade 4, as well as out-of-school girls aged 10 years.

Girls attending school
Schools will be the primary locations for HPV vaccine delivery. The target group is all girls in grade 4, because the majority are expected to be ages 9-13. Grade 4 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 ten years old. These girls will be vaccinated at the nearest existing outreach or health facility.

2.5 Dosage and Immunisation Schedule

The immunisation schedule consists of three doses. The recommended vaccination schedule is 0 (first dose or 1st contact), 2 months after the first dose (defined as on day 60 after first dose), and 6 months after the first dose (defined as on day 180 after first dose).

Table 1: Summary of Gardasil Immunisation Schedule

HPV vaccine dose	Time of administration
1st dose	First contact with girl
2nd dose	2 months after 1st dose
3rd dose	4 months after 2nd dose

! 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 the nearest health outreach or facility to receive the vaccine doses they missed. Girls who receive dose 1, but are absent at dose 2, should be given the missed dose at the earliest opportunity. The same applies for dose 3.

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

An HPV vaccination card will be produced for each vaccinated girl, and each vaccination will be recorded on this card and in a vaccine register. The register will be kept at the health facility and used at all immunisation sessions, including outreach. The vaccination cards shall be retained at school until the immunisation schedule is completed. The 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 vaccination card will be given to her.

For girls who will receive their HPV doses at a health facility or outreach, their cards will be kept by their parents/guardian, who will ensure that they complete the vaccination schedule.

!
Health workers should communicate:
- The benefits of HPV vaccination
- The HPV immunisation schedule
- Importance of completing all three doses of the schedule

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

2.6 Instructions for Use

Single Dose Vial Use

- The vials are 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 product if particulates are present or if it appears discoloured.
- Withdraw the 0.5mL 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 must 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 (Undesirable 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, the AEFI guidelines should be followed (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, administration of the HPV vaccine 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.

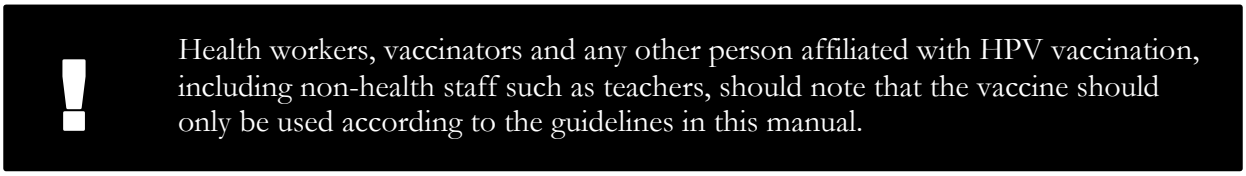
- HPV vaccine is a preventative vaccine. It is not intended to prevent progression of HPV-related lesions already present at the time of vaccination.
- Girls who are HIV-positive can still receive the Gardasil vaccine.

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 that the ones listed.



Chapter

3

Lessons Learned from HPV Vaccination Programmes in Other Countries

3.1 Global Experience with HPV Vaccines

To date, more than 50 countries have introduced the HPV vaccine into their national immunisation programs, including Rwanda in Africa which achieved more than 90% coverage in the first year. Lesotho and Uganda have also started national scale-up of HPV vaccinations from pilots conducted over the past few years. There have been an additional 22 small-scale pilots of HPV vaccination to gain experience using the vaccine and learn how to incorporate delivery into the existing immunisation system. In Africa, these pilots have been conducted in Cameroon, Kenya, Mali, Nigeria, and Tanzania.

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 young 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 on which Zambia is basing their HPV vaccine delivery strategy and program structure.

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 grade in school rather than age is easier to implement, as it 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, 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, as is done for infant immunisation.
- On average, HPV vaccine delivery requires additional work by the health workers and schools for a few days for each dose, resulting in about 10-14 total days of work over the course of one year.
- 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 government 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 HPV vaccine.
- Teachers and health workers play complementary roles in raising awareness in communities.

3.3 Using the Lessons Learned from Other Countries in Zambia

The lessons learned from the HPV vaccination programs in other countries will impact the Zambia HPV vaccine demonstration project in the following ways:

- Zambia has decided to use a grade-based strategy to deliver the HPV vaccine. This is because of the difficulties encountered using the age-based strategy in Uganda, a country which has many similarities with Zambia.
- The HPV vaccination schedule will align with the school schedule, with vaccinations beginning in March.
- Educational materials on the HPV vaccine will be widely distributed to raise community awareness.
- Health workers, teachers, and educators should work hard 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.
- The Zambian government and prominent personalities (e.g., the First Lady) will visibly endorse the HPV vaccine to increase community acceptance.

Chapter

4

Advocacy, Communication and Social Mobilisation

Effective sensitisation and social mobilisation are critical to a successful immunisation programme. In preparation for the HPV vaccination program, sensitisation and social mobilization will be undertaken and the target and general populations will be informed of the importance and benefits of HPV vaccination. Advocacy is essential to enlist the support and participation of leaders at all levels. When we equip people with the correct information, they can prevent or dispel rumours and misinformation. Use of clear, simple, and accurate messages is important so the messages are not misinterpreted or misunderstood.

Involvement of 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. Any rumour or misconception should be clarified with facts.

Key Objective
All stakeholders should appreciate the benefit of vaccinating all eligible girls against HPV and protecting them against cervical cancer in the future.

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 resources and policies to address the HPV vaccination program. This is not only needed during the demonstration phase, but also with the future nationwide roll-out of HPV vaccination.

Advocacy Targets

- Advocacy must be directed toward people with decision-making power and to those who influence decision makers, such as the media.
- Advocacy should be directed to key stakeholders for support and resource mobilization.

4.2 Community Sensitization and Mobilization

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

Table 2: Key Audiences for Sensitisation

Audience	Messages	Delivered by	Activities	Materials
District Health Teams (DHT)	- Facts about cervical cancer - Burden of disease - Importance of prevention - Facts about the preventive vaccine and immunisation schedule - Their roles and responsibilities	- MCDMCH	- Orientation workshops - Distributing materials	- HPV field guide - IEC Materials
Health Workers (public and private)	- Facts about cervical cancer - Burden of disease - Importance of prevention - Facts about the preventive vaccine and immunisation schedule - Their roles and responsibilities	- District Health Team - Health unit in-charges	- Orientation workshops - Distributing materials	- HPV Vaccinators Guide - IEC Materials
Neighbourhood health committees, community health workers and community leaders	- Burden of disease - Importance and benefits of prevention - Availability of preventive vaccine - Facts about the vaccine - Key messages to help dispel misinformation - Their roles and responsibilities	- District Health Team - Health workers	- Orientation workshops - Meetings - Distributing materials - Air radio messages - Publish information in local media	- HPV leaflet - Radio messages
School administration, school management and teachers	- Facts about cervical cancer and prevention - Availability of preventive vaccine - Facts about the vaccine - Age-appropriate approaches to	- District Health Team - School management - Health workers	- Orientation workshops - Meetings - Distributing materials - Air radio messages - Publish	- HPV leaflet - Radio messages - Articles in local media

	addressing cervical cancer with children - Their roles and responsibilities - Dates of vaccination		information in local media	
Parents	- Facts about cervical cancer and prevention - Availability of preventive vaccine - Facts about the vaccine - Dates and venues of vaccination - Age-appropriate ways to discuss cervical cancer with children - Their roles and responsibilities	- District Health Team - Health workers - Head teachers - NHCs - Mobilisers	- Distributing materials - Air radio messages - Radio and TV discussion - Publish information in local media	- HPV leaflet - Radio messages - Articles in local media
Children	- Basic facts about cervical cancer - Basic facts about the preventive HPV vaccine - Benefits of being vaccinated - Their role in HPV vaccination	- Health workers - Teachers - Parents - Mobilisers	- Sensitization meetings - Distributing materials - Air radio messages - Community drama	- HPV leaflet - Radio messages

4.3 Managing Rumours, Misconception, and Misinformation

Rumours and misinformation about immunisation are among the most serious threats to the success of the HPV vaccination programme. Once rumours and misinformation start, they can be very hard to stop. Experience in many countries has shown that rumours can be devastating to vaccination programmes. 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.

4.3.1 Common sources of rumours

Who starts rumours? Rumours are started by people who lack knowledge on the subject or who may have vested interests in the failure of the services being provided. These may include:

- **Some traditional healers**: these 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 immunisation and other modern health services.

- **Some religious sects/cultural groups**: Some religious sects in Zambia do not believe in or approve of immunisation and other modern medical practices. Consequently, they may advise their followers to refuse vaccinations.
- **Anti-vaccine/lobby groups**: These are groups which have organised to discourage people from utilising immunisation services. Such groups are common in Zambia and the world over and have published articles or distributed controversial, distorted, or malicious information on vaccination from the internet and other sources. These groups have worked to discredit immunisation through the internet, FM radio stations and other outlets.
- **Some misguided elements in the community**: These involve people 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. When some health workers fail to be good examples in taking their children for immunisation or providing the correct information, rumours may also start.

4.3.2 Causes of rumours about immunisation

Rumours often spread as a result of a number of factors that include the following:

- **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, this creates an opportunity for rumours to flourish. For example, the refusal by some health workers to have their children immunised and failure to answer some questions about immunisation create doubt in the community on the credibility of the vaccination program.
- **Coincidental events.** Occurrence of some events that coincide with routine and supplemental immunisation activities is another factor that fuels rumours.

4.3.3 How to respond to rumours and misconceptions

In Zambia the first to respond to rumours is the District Medical Office. In the case of a serious rumour, appropriate members of the government will respond to the rumour. Health workers at all levels of service delivery should develop a proactive plan that has a mechanism to prevent and counteract rumours in a community. This means having a comprehensive programme on education about immunisation so that you minimise chances of rumours starting and spreading.

Steps of the Comprehensive Response to Rumours:

Step 1	During preparation for the vaccination program, meet with key community partners to inform them about the HPV vaccination.
Step 2	Act swiftly to identify the source of the rumours and understand their contents (extent of the rumour, type of messages circulating about immunisation).

Step 3	Identify the people and organisations responsible for fabricating and spreading the rumours and design strategies to educate them.
Step 4	Collect data and facts about immunisation in preparation to respond to rumours by giving correct information.
Step 5	Determine the reasons behind the creation of these 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 opinion leaders in the affected area (community leaders, religious leaders, elders, clan leaders, etc.), sensitise them about immunisation and seek their support in mobilising for immunisation promotion.

If you hear of a rumour, you must refer the matter to your supervisors **as quickly as possible**. You will need to work under their direction; 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.

Exercises

1. List the partners/stakeholders that will be influential in mobilisation for HPV vaccination.
2. What will be 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?

Important to Note

- 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.
- The HPV vaccine is safe and effective.

Chapter

5

Logistics and Management of the HPV Vaccine

5.1 HPV Immunisation Logistics Requirements

5.1.1 Estimating size of the target population

The number of girls in grade 4 plus the number of 10 year old out-of-school girls will be determined through existing records at the Zambian Ministry of Education (MESVTEE).

5.1.2 Estimating vaccine amount

The amount of vaccine for the HPV vaccination should be estimated according to the size of the target population. Each district will receive 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.

Estimation of vaccine doses required on the district level

Target population for HPV immunisations x 1.05% = Vaccine doses required in district

Estimation of vaccine doses required on the post level

Estimated daily target population at post x 1.05% = Vaccine doses required at a post/day

! After each round of HPV vaccination, the unused HPV vaccine should be transported to the DVS for proper storage.

5.1.3 Estimating other logistics requirements

Auto-disable syringes (AD syringes)

The number of AD syringes required at district, sub-county and post level is calculated as follows:
Target population for HPV immunisation x 1.05 = Number of auto-disable syringes and needles

! The number of the vaccine doses should equal the number of the AD syringes.

Safety boxes

The number of safety boxes required at district, sub-county and post level is calculated as follows:
Number of safety boxes = AD syringes and needles x 1.05/100

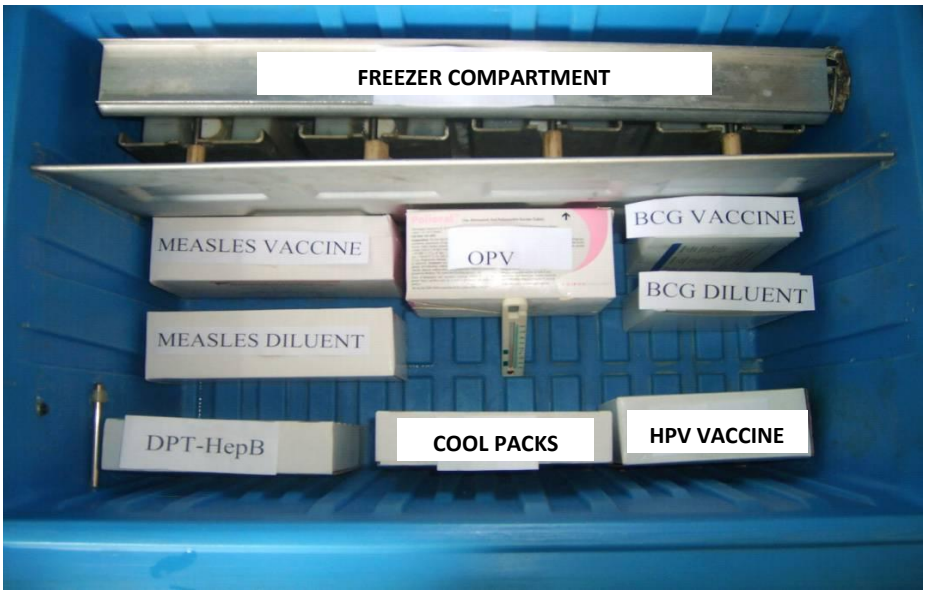
Table 3: Estimating Vaccines, AD Syringes, and Safety Boxes Needed for Vaccination Session

	Vaccines/Supplies	Formula	Example
	Total Population in District "X"	Census data	200,000
A	Target of girls age 10 years for HPV vaccine	Data from MESVTEE	3,200
B	Number of vials per girl	1	1
WF	Wastage factor	1.05	1.05
C	Number of HPV doses	A x B x WF	3,360
D	Number of doses per vial	1	1
E	Number of HPV vaccine vials	C/D	3,360
F	AD syringes (wastage factor =1.05)	A x WF	3,360
G	Number of safety boxes (1.05 wastage factor)	(F x 1.05)/100	36

5.2 HPV Vaccine Handling and Management

Storing Vaccines in Top-Opening Refrigrators

Like DPT-HepB+Hib vaccines, the Gardasil HPV vaccine should be stored away from the freezer compartment, as shown below. However, the vaccine can be stored next to the cool packs.



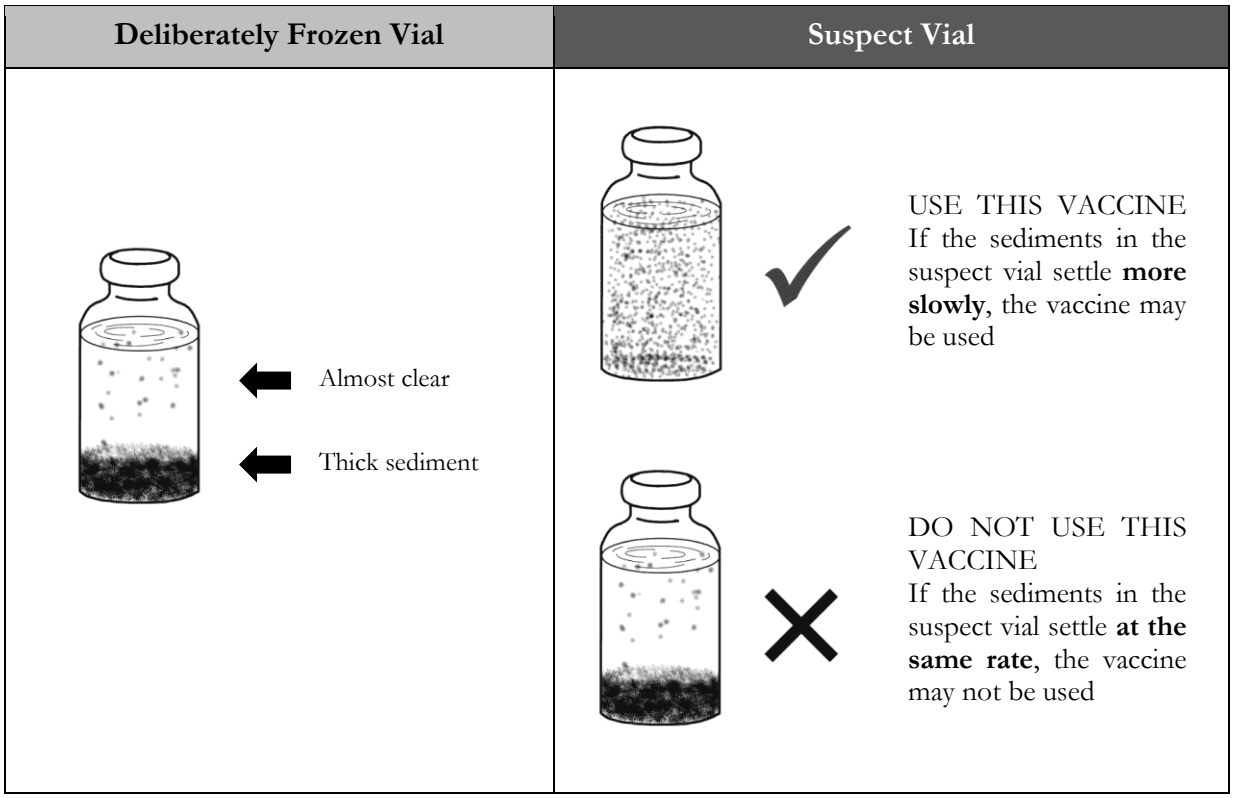
Storing HPV vaccine in a top opening regrigerator

HPV vaccine should be protected from freezing. Therefore, do not place vaccines on frozen ice packs; always use cool packs in the vaccine carrier. If you suspect that the vaccine has been frozen, carry out the shake test described below.

The Shake Test
The shake test is a method of testing suspected freezing of HPV, DPT-HepB, TT and Hepatitis B vaccine vials (vaccines which are not supposed to be frozen).

Illustration of the Shake Test

Compare the Deliberately Frozen Vial to the Suspect Vial



The shake test is applied as follows:

Step 1 Prepare a frozen control sample. Take a vial of vaccine of the same type, batch number and manufacturer as the vaccine you want to test. Freeze the vial until the contents are solid (at least 10 hours at -10°C) and then let it thaw. This vial is the control sample. Mark the vial clearly "CONTROL" so that it is easily identifiable and will not be used by mistake.

Step 2 Choose a test sample. Take a vial of vaccine from the batch that you suspect has been frozen. This is the test sample.

Step 3 Shake the control and test samples. Hold the control sample and the test sample together in one hand and shake 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.

! If the test procedure indicates that the test sample has been damaged by freezing, you should notify your supervisor immediately.

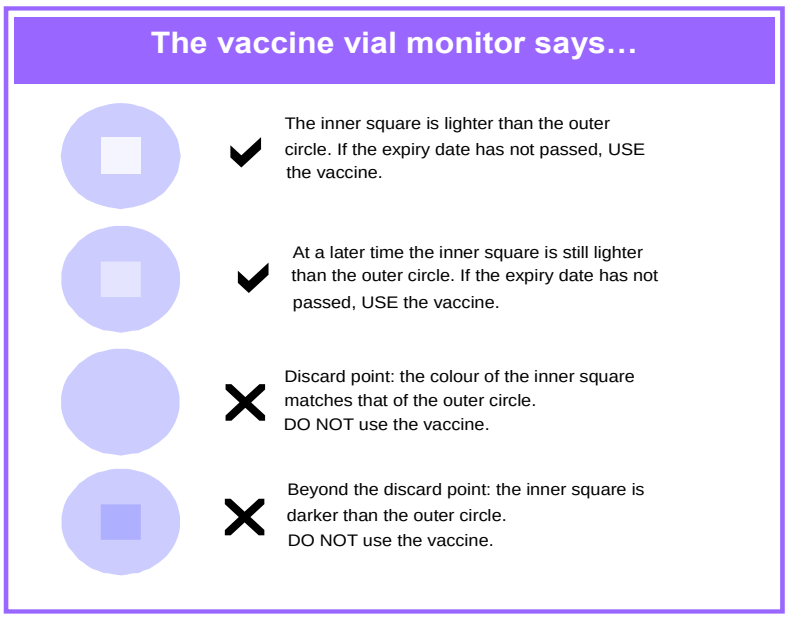
! Some vials have large labels, which cover the vial contents. This makes it difficult to see the sedimentation process. In such cases, turn the sample and reference vials upside down and observe sedimentation taking place in the neck of the vial.

Vaccine Vial Monitor (VVM)

HPV vaccines, like all other routine immunization vaccines, have a Vaccine Vial Monitor (VVM) attached, to determine whether the vaccine has been damaged by heat. Health workers must check the status of the VVM at all times:

- 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 each individual vial. If the inner square is lighter than the outer circle, the vaccine should be used. If the inner square is the same colour as, or darker than, the outer circle, the vaccine should be discarded.



! For this demonstration project, the vaccine will not have the VVM.

5.3 Preparations for Vaccine Delivery

When preparing to deliver vaccines to a district vaccine store (DVS), a health centre, or for an outreach immunisation session, the health worker should:

- Make sure there are adequate stocks of vaccines and injection materials.
- Make sure the cold box or vaccine carrier is clean and not cracked.
- Make sure there are cool packs.
- Estimate the number of vaccines to deliver depending on the supply needed for the estimated session size for schools.
- First Expiry–First Out (FEFO) method should always be followed.

To ensure that cold chain safety procedures are followed during transportation of vaccines:

- Ensure that cold box/vaccine carrier has an intact rubber seal.
- Make sure that the cold box/vaccine carrier is securely closed.
- Ensure availability of reliable transport to deliver the vaccines.
- The supply requisition and appropriate monitoring form should accompany the amount of vaccine to be delivered or issued to the unit.

5.4 How to Pack Vaccines in a Vaccine Carrier for an Immunisation Session

Check for the following as you pack the vaccines:

- Labels attached
- Check for vaccine expiry
- Check the condition of the vial; it should not be cracked
- Check for the colour of the vaccine. The vaccine should be translucent white and cloudy when shaken, without any black particulate matter.
- Vaccines that were previously taken out of the fridge for an immunisation should be picked first for the next session

How to pack the vaccines

1. Place two to three cool packs around the inside walls of the vaccine 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
- 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 are used to estimate vaccine and injection materials needed. Using accurate data prevents stock outs or over-stocking.
- Vaccine use and wastage are monitored. Please use Form 1a (see chapter 12) to monitor wastage of vaccine vials.
- A checklist is used to carefully distribute vaccines and supplies to the health facilities.
- Cold chain maintenance is carried out to avoid fridge break down or freezing of vaccines.

5.7 Recording/Issuing of Vaccines and Other Logistics

All items received for HPV immunisation should be recorded in the same manner as routine supplies using the Vaccine and Injection Materials Stock Register. Amounts, batch numbers, and expiry dates should be indicated at all levels.

Key messages

1. Record vaccines and injection materials received as soon as they are put in the refrigerator/store.
2. At the time of issuing for the static or outreach sessions, record the amount issued without waiting for the teams to come back.
3. Balance the vaccine control book every time you receive or issue vaccines and injection materials and on returning from the outreach or static session.

Chapter

6

Micro-Planning and Coordination of HPV Activities in the District

6.1 District Level Micro-Planning

Before the implementation months for HPV vaccination, it is important to hold coordination and micro-planning meetings. The national immunisation program will organize an orientation meeting for the District Medical 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 requirement 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 in-charge should present the list of school and the number of girls in Grade 4 in their catchment area. Girls out of school should have been registered by the CHW or neighbourhood health committees (NHCs), and the registered girls submitted to the health facility in-charge of that catchment area. It is at this meeting that community leaders should be assigned with the responsibility of announcing the vaccination dates in all public gatherings including markets and places of worship.

6.2 Micro-Planning at Health Facilities

In collaboration with school heads in their catchment area, the health facility in-charge will identify all schools. Within each school they will identify the number of girls in grade 4 and develop a schedule as to when they will visit each targeted school for the purpose of:

- Sensitization of teachers and girls
- Displaying posters and share flyers
- Scheduling the dates for immunisation in schools

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.

Chapter

7

Administration of the HPV Vaccine

7.1 Planning for the Immunisation 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 contacts with the school to plan for the vaccination day. The school authority should schedule the day of vaccination in relation to school programs. The school authorities should identify a convenient location within the school where the vaccination can be carried out.

7.2 The Immunisation Sessions

Immunisation sessions (static or outreach) should be conducted in a clean environment, preferably in a building or in a shady spot.

7.3 Setting up the Immunisation Session Post at the School

The immunisation session post needs to be well-organised to create a conducive environment for efficient vaccination delivery. The following areas are essential:

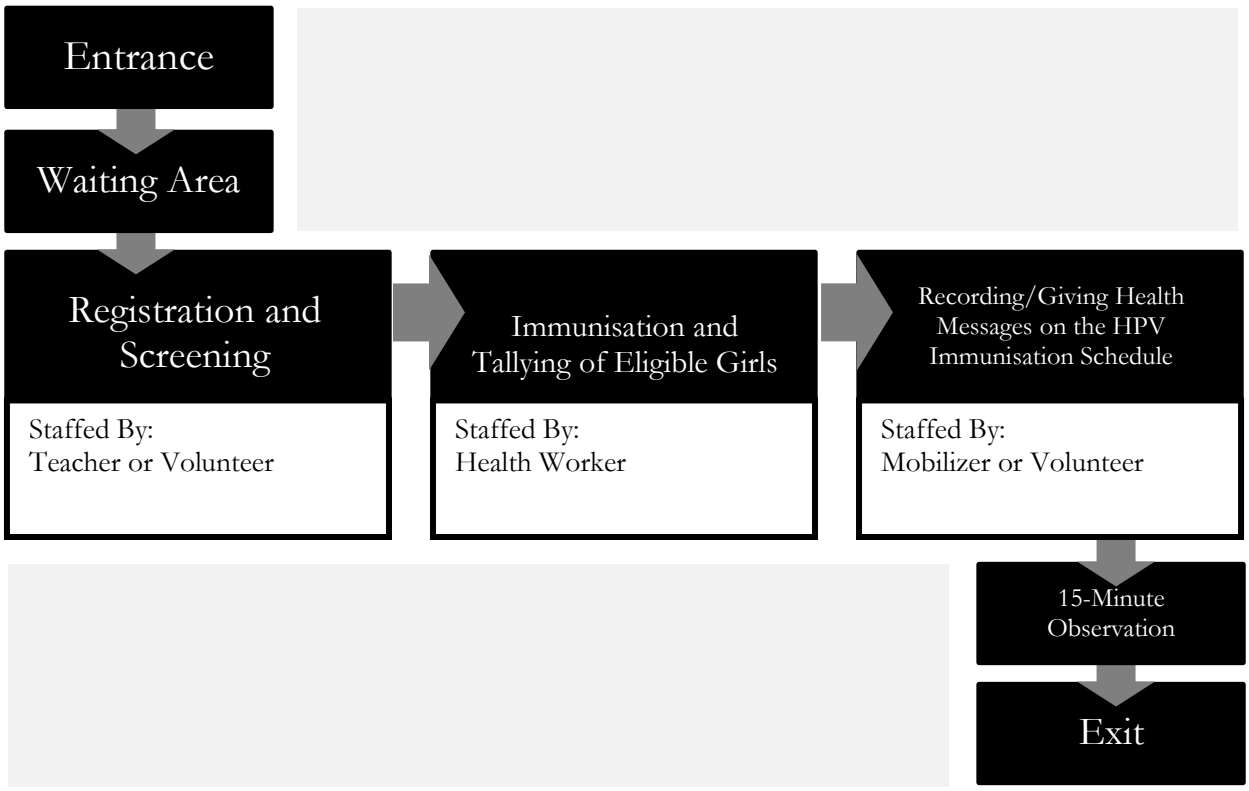
- Waiting area
- Registration/screening
- Immunisation table
- Check point/recording area (tallying area)

Design the immunisation post for efficient flow. Avoid "bottle necks," excess crowding, long waiting times, or confusion. Ways to avoid overcrowding and inefficient flow of clients include:

- Opening the post as early as possible

- Ensuring adequate space at the post site chosen
- Effective crowd control by the mobiliser
- Immunisation on a "first come, first serve" basis
- Designated entry and exit points and a one-way flow of girls through the post to prevent backtracking through the crowd following immunisation

7.4 Example HPV Vaccination Flow



7.5 Supplies Required for the HPV Vaccination Session

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

- Chairs and tables
- Plastic sheeting (optional)
- Water and soap for washing hands
- Cotton swabs and cool boiled water for cleaning the site of injection
- A vaccine carrier with cool packs, HPV vaccines, thermometer, and a sponge.
- Shallow large tray (1), kidney dish (1), gallipots (2)
- 0.5 ml AD syringes for administering HPV vaccine
- Safety boxes
- Containers for used/empty vaccine vials and swabs
- Emergency tray
- Monitoring tools – HPV vaccination register, HPV immunisation cards, and HPV tally sheets

- Guide for vaccinators
- Calendar for the return date
- AEFI form and pen
- Posters and leaflets about HPV

> **!** You may need more than one vaccine carrier depending on the day's target population.

7.6 Roles and Responsibilities of Staff at the Immunisation Session Post

A health worker, teacher (or volunteer), and mobiliser (or volunteer) should be available at the immunisation post to organize the post, vaccinate, and keep proper records.

Roles of the Vaccinator

- Ensures adequate vaccine is packed in the vaccine carrier with at least three cool packs
- Ensures adequate availability of auto-disable (AD) syringes and needles
- Ensures order in the vaccination post
- Ensures that the 15 minute observation of each girl is completed
- Assists the team in crowd control
- Assists the team with any other tasks assigned
- Prepares the AD syringes for vaccine administration
- Vaccinates the children
- Ensures that the vaccination area remains safe and clean
- Ensures correct storage of vaccine
- Ensures safety in immunisation procedures
- Gives health advice to the parents and girls about HPV vaccine and possible side effects
- Monitors any reactions and responds to parent's/caretaker's/children's questions
- Manages and reports AEFI
- Makes sure the tally sheets are completed
- Ensures the return of all the equipment/logistics, tally sheets, unused vaccines to storage centre
- Ensures proper disposal of all used syringes and needles using the MoH recommended procedure

Roles of the Teacher

- Thanks parent/caretaker/girl for coming
- Writes the age of the girl on the HPV immunisation card
- Keeps the vaccination card for each girl until all three doses are given
- Tallies HPV vaccinations
- Informs the parent/caretaker/girl of the next vaccination date

Roles of the Volunteer

- Ensures order/crowd control at the vaccination post
- Ensures that the 15 minute observations is completed
- Assists the team with any other tasked assigned

Roles and Responsibilities of the Health Centre In-Charge

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 reactions of community on HPV immunisation and EPI in general
- Build alliances with opinion leaders and community leaders
- Detect rumours from the community and address them immediately
- Promote and co-ordinates all HPV vaccination activities at the health centre level
- Monitor and supervise all activities at immunisation posts during HPV immunisations and advise operational staff accordingly
- Supervise the distribution and replenishment of vaccine, cool packs, and tally sheets at the distribution centre, both at the beginning and throughout the vaccination program
- During HPV vaccination implementation, carry extra vaccines and supplies for distribution to immunisation posts with shortages
- Receive tally sheets, returned vaccines and other supplies from the posts
- Collect tally sheets for onward submission to the District Medical Officer within two days of completion of the vaccination
- Ensure proper collection and disposal of the waste generated at the vaccination post

7.7 Step-by-Step Instructions for Administering the Gardasil HPV Vaccine

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. All girls currently enrolled in grade 4 are eligible. If the girl is not attending school, only vaccinate her if she is 10 years old.
Step 3	Determine which dose is needed (first, second, or third) by looking at the vaccination card or the register.
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 your hands before the immunisation session.
Step 6	Hold the HPV vaccine vial between your thumb and middle finger. Check the vaccine vial for 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.
Step 7	Shake the vaccine vial until it is a white, cloudy liquid. This step is necessary to mix the vaccine.

Step 8 Open the package for the 0.5 ml auto-disable syringe (AD syringe).

Step 9 Draw all the contents of the HPV vaccine from the vial into the 0.5ml AD syringe. Pull the AD until you feel a click.

Step 10 The vaccine should be given in the left arm, as the injection can cause discomfort such as soreness and swelling, which can increase if the arm is in constant movement. If the girl is left-handed, give the injection in the right arm.

Step 11 Encourage the girl to relax her arm. The injection is less painful if the arm is relaxed.

Step 12 Clean the injection site using a swab and clean water.

Step 13 Inject the entire contents of the syringe in the **deltoid muscle of the upper left arm** (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 14 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 15 **Do not recap the used syringe and needle.** Put used syringes and needles in the safety box.

Step 16 Thank the girl, and tell her the dates for her next dose of Gardasil. If it is the third dose, congratulate her. 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 hands before administering vaccine to every client, or whenever necessary.

An auto-disable syringe should be used for each injection

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

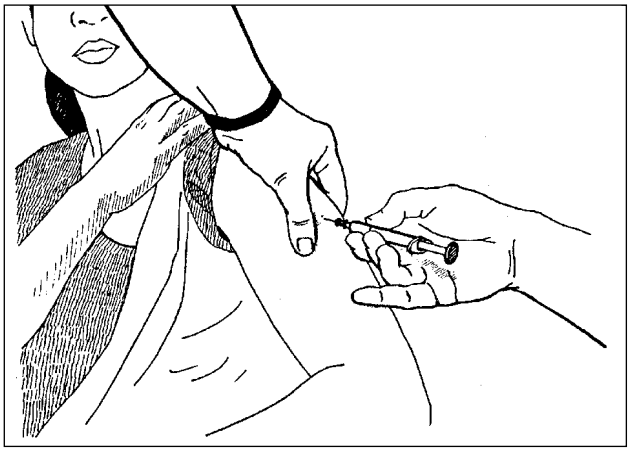


Illustration of a girl receiving the Gardasil vaccine against HPV

7.8 Short Messages for Girls and Parents Regarding HPV Vaccination

1. Tell the girl 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. Insist on the importance of completing all three doses according to the vaccination calendar.
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 might 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 dates of the next doses.
7. Thank the girl for coming for the vaccination. When she finishes the third dose, congratulate her.

Chapter

8

Injection Safety during the Immunisation Session

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

A safe injection in immunisation is one where a potent vaccine is administered using the right technique at the right site. To be safe, the vaccinator must administering the correct vaccine and dose using 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 Injection Material Waste

Sharps and other injection materials generated during the vaccination sessions must be taken to the incinerator at the district.

8.2 Procedures to Ensure a Safe Vaccination Injection

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

- Organize the vaccination materials on the table (vaccine carrier, AD syringes, cool boiled water, and cotton balls).
- Wash hands before beginning the vaccination session.
- Use a cotton ball soaked with cool boiled 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.
- Observe 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).
- **Do not ever recap needles after use.**
- All syringes and needles should be immediately thrown away in the safety box.
- Avoid completely filling the safety box. Fill it only until it is ¾ full.
- Do not put cotton balls or used vials in the safety box.
- Collect the filled safety boxes and deliver to the incinerator at the end of each session for proper disposal.
- Every vaccination location (static or outreach) should be left clean.

For more information on injection safety, refer to the "EPI Vaccination Manual."

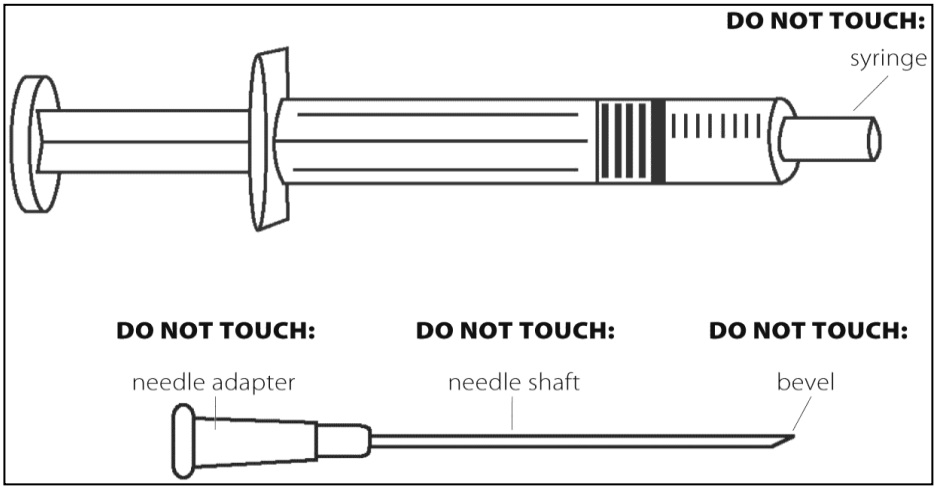


Figure: Parts of a needle and syringe that must never be touched

Key Messages for Injection Safety

Before injecting, ensure the following:

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

Chapter

9

Adverse Events Following Immunisation (AEFI)

The WHO defines AEFI as medical events that take place after immunization, cause concern, and are believed to be caused by immunization. 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 promptly and effectively is critical to maintaining public confidence in immunisation. A single serious event or cluster of events may result in rapid erosion of public confidence in vaccinations and a decline in immunisation rates. The majority of adverse events are not caused by the vaccine itself. A significant increase in reporting of adverse events 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 Adverse Events Following Immunisation

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

Table 4: Classification of Adverse Events Following Immunisation (AEFI)

AEFI Classification	Definition
a) Vaccine reaction	Event caused or precipitated by the vaccine when given correctly, 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 immunisation 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

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

9.3 Programme Errors

The following measures should be put in place to prevent occurrence of AEFIs due to programme errors:

- Comprehensive training of health workers with emphasis on proper administration techniques and communication.
- Identification of at least one qualified health worker per immunisation session (static or outreach).
- Proper distribution of HPV vaccine ensuring bundling with injection materials.
- Use of vaccine control book to ensure that quality vaccines are used.
- Exclusive use of auto-disable syringes and needles.
- Proper waste disposal of injection materials.
- Proper cold chain maintenance.
- Proper storage and handling to avoid freezing. This vaccine should never be frozen.
- Strengthened Pharmacovigilance Team to manage AEFIs effectively.

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, treatment should be as follows: incision and drainage, give an antibiotic, give a pain killer, and dress the wound daily.

9.4 Rare and Most Serious Reactions

Rarely, a serious adverse reaction, such as an anaphylactic reaction, may occur after an immunisation. To date, in the 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. A few serious events 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.

However, to be prepared if an unexpected or serious event occurs, it is recommended that each vaccination session has an emergency tray with the following drugs. The District Medical Office should ensure these emergency trays are available at the health posts.

Table 6: List of Proposed 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

In the unlikely event that a serious reaction should occur, below are notes on the signs and symptoms and treatment of persons who may experience an anaphylactic reaction following immunisation. Anaphylactic reaction is less frequent among children and the symptoms tend to appear suddenly: **a few minutes to 30 minutes** after the vaccine is administered, although 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 angioendema 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 any trained professional on the slightest suspicion of above. It is strongly recommended that written protocols be placed somewhere visible and known by all the professionals involved.

Treatment Protocol for Anaphylactic Shock

Step 1 Place the patient in the 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.

Local and Systemic Reactions that are Required to be Reported in the AEFI Process
Local reactions are mild, non-serious reactions during or after HPV vaccination. Severe local reactions including swelling further than 5cm 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:

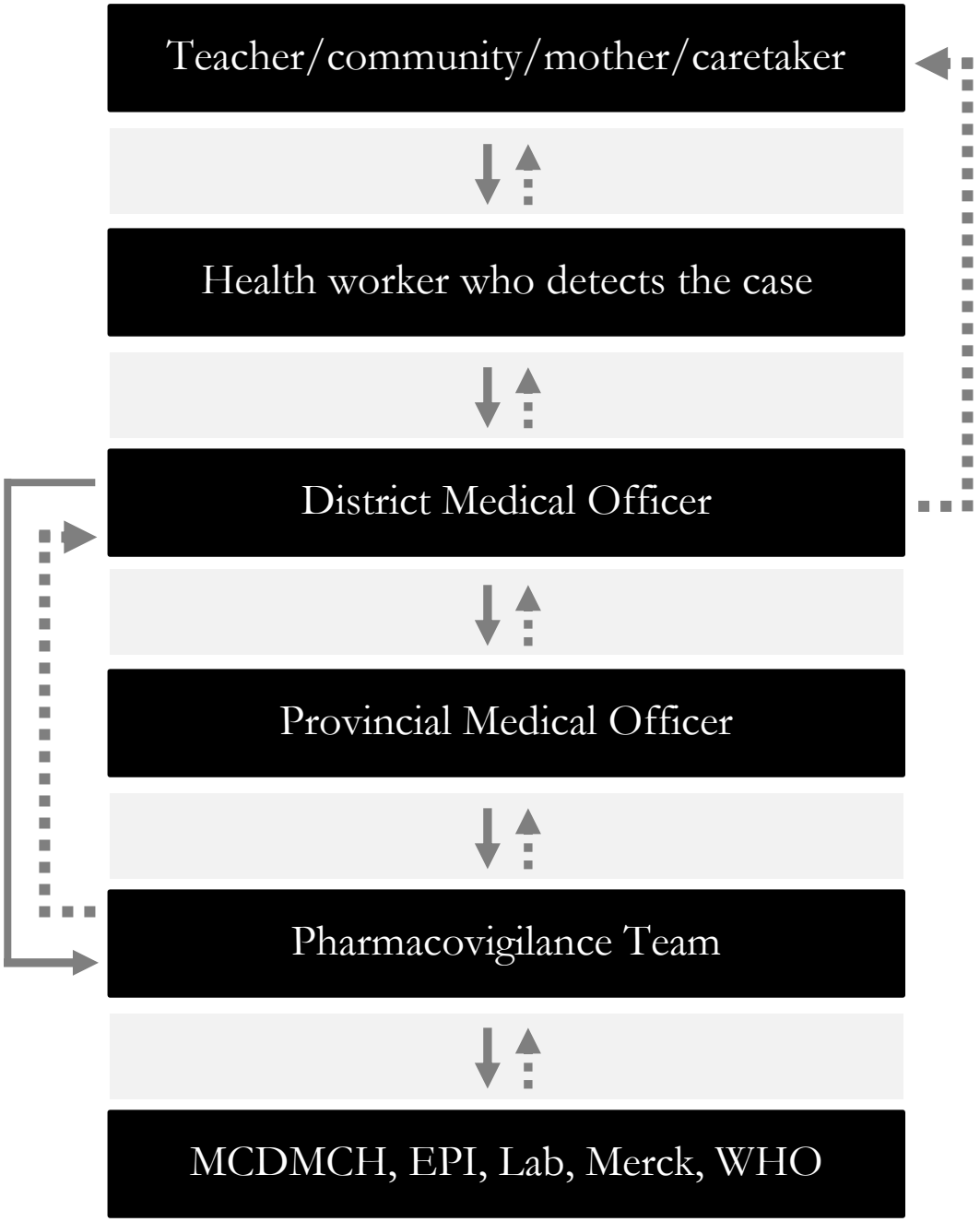
- All cases of anaphylaxis suspected to be related to immunisation with HPV vaccine
- Collapse or shock-like state within 48 hours of immunisation with HPV vaccine
- Seizures within 3 days of immunisation with HPV vaccine
- All deaths thought to be related to immunisation with HPV vaccine
- Any severe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

9.5 Reporting Procedures for AEFI

Because of the increased likelihood that AEFIs may be observed during immunisation activities, there must be a rapid surveillance system which is capable of monitoring adverse events operating during immunisation activities and immediately afterwards. The established reporting channels for an AEFI are indicated below. The flow chart provides an inclusive system encompassing 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 District Medical Office should notify EPI and initiate an investigation into the cause of the AEFI. The AEFI form should be filled in and sent with any specimen being sent to the laboratory. The reporting should be done by telephone, radio call or fax.

AEFI Reporting Flow Chart



9.6 AEFI Reporting Channel Roles and Responsibilities at Each Level

Role of the Teacher/Community/Caretaker/Mother

- Be informed about the expected AEFI
- 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

Role of a Health Worker

- Familiarises himself or herself with an AEFI that fits in the list
- Initiates immediate and first aid treatment of the case

- Talks immediately, openly and sympathetically to the girl, teacher or caretaker without admitting liability or becoming defensive
- Obtains background information from the parents/guardian/caretakers/community/teacher
- Fills in the AEFI investigation form A
- Informs the DMO within 24 hours through telephone or text message

Role of District Medical 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 EPI Manager by fax/telephone if there is any technical assistance required
- Compiles a detailed report and submits it to the Provincial Medical Officer EPI

Role of Provincial Medical Officer

- Handles any "difficult or severe" AEFI
- Works closely with the EPI manager and the District Medical Officer
- Reports to the Pharmacovigilance Team
- 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 DMO during the process of compiling a detailed report
- Facilitates submission of the report to the National AEFI task force spokesperson

Role of Director Mother and Child Health

- Provides feedback to the community through the media
- Mobilizes the communities to continue with immunisation
- Counteracts all rumours and allays community anxiety.

Role of National AEFI Task Force

- Receives reports from all regional AEFI focal persons/districts through AEFI focal person
- Reviews all reported events and analyses data quickly
- Determines what to investigate further
- Classifies the reported AEFI
- Keeps record of all reported AEFIs during the immunisation activities. Provides feedback through the spokesperson (Director Mother and Child Health)

Exercises

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 respond the scenario?
4. From the same post, you receive information that five girls have fainted after receiving the HPV vaccine. How would you investigate and respond?

Chapter

10

Monitoring

During the planning and subsequent 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 service providers, supervisors/in-charges and health district managers need to monitor the following:

- Coverage, dropout rates and vaccine wastage
- Storage temperatures (HPV vaccine is sensitive to freezing and low temperatures)
- Adverse Events Following Immunisation (AEFI)

10.1 Monitoring Coverage, Drop-Out, and Vaccine Wastage

Tally sheets and monitoring tools are provided to collect data on HPV vaccination (see chapter 12).

Data collected with those tools will be used to calculate district coverage, wastage and drop-out after each round. Coverage surveys will be carried out to verify the reported coverage.

10.2 Data Collection Forms for Monitoring Activities

Several data collection tools will be available:

- HPV vaccination card
- HPV register
- HPV forms
    - Form 1a: Tally sheet for HPV vaccination
    - Form 1b: Health facility report form
    - Form 1c: District report form

10.2.1 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 immunisation post and kept at the school until completion of the three-dose vaccination series. Cards for girls attending community school or out-of-school girls will be kept at the health centre.

Draft sample of HPV vaccination card

<table>
<tr>
<td>
Ministry of Community Development, Mother and Child Health

HPV (Cervical Cancer)
Vaccination Card

</td>
<td>
Serial No.
_____
Name
_____
Date of Birth
_____
Household head name
_____
Name of school
_____
Class in school
_____
Village/ residential area
_____
_____
_____
District
_____
</td>
<td>
<table>
<tr><th>Dose</th><th>Date vaccinated</th><th>Next vaccination date</th></tr>
<tr><td>HPV1</td><td></td><td></td></tr>
<tr><td>HPV2</td><td></td><td></td></tr>
<tr><td>HPV3</td><td></td><td></td></tr>
</table>

You must receive all three doses to be protected
</td>
<td>
FACTS ABOUT
HPV and CERVICAL CANCER

• HPV vaccine prevents human papillomavirus (HPV) infection
• The HPV virus causes cervical cancer
• Cervical cancer is the biggest cancer killer of women in Zambia
• HPV vaccine prevents most cervical cancer
• HPV1 is given to grade 4 girls or 10 years (out of school)
• HPV2 is given 2 months after HPV1
• HPV3 is given 4 months after HPV2
</td>
</tr>
<tr>
<td>Front Page</td>
<td>Inner page 1</td>
<td>Inner page 2</td>
<td>Back page</td>
</tr>
</table>

10.2.2 HPV vaccination 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 immunisation post. At the time of the second dose, bring the original register to the vaccination session to verify the girls that need their second dose. Any new girls beginning the three doses at this time will be added to the bottom of the register for that vaccination post, but clearly mark the date of vaccination for dose one.

10.2.3 Form 1a: Tally sheet for HPV vaccination

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.
- These tally sheets are the source of the primary data that will later be used to calculate final coverage at district levels. The tally sheets must be completed for each day of the vaccination and stored until completion of the 3 doses.

10.2.4 Form 1b: Health facility report form

This form is filled by the health facility in-charge to summarise the number of girls vaccinated by age. It is derived from form 1a (the tally sheets).

10.2.5 Form 1c: District report form

This form is filled by the district EPI focal person to summarise the number of girls vaccinated by age for the entire district. It is derived from form 1b (the health facility report form).

Information derived from this form includes:

- District immunisation summary by health facility.
- Total number of girls immunised (for all the days of vaccination) according to their age.

A sample of these forms can found in chapter 12.

Exercises

1. What key activities will be monitored during the period of HPV vaccination?
2. Who will be the main supervisors and what will be their roles/responsibilities?
3. Design a support supervision checklist for use during HPV vaccination period.

Discuss your answers with your trainer/supervisor.

Chapter

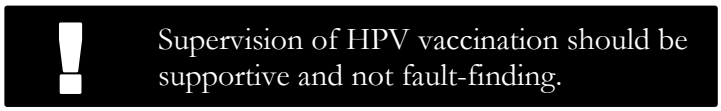
11

Supportive Supervision

During the HPV vaccination periods, supportive supervision to all vaccination centres (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.



As the introduction of HPV vaccinations is integrated into the routine immunisation activities, supervision for 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.

Chapter

12

Forms

HPV vaccine monitoring forms
The following forms will be provided for all three rounds of HPV vaccination:
Form 1a: Tally sheet for HPV vaccination
Form 1b: Health facility report form
Form 1c: District report form

Form 1a can be used to record all the 3 doses of HPV vaccination. The same form started for HPV dose 1 should be stored and used for the subsequent doses until all doses are completed; the same applies for health facility and district report forms. The forms should be filled in duplicates.

HPV Register
Information about all girls who receive the HPV vaccine should be recorded on the HPV register.

Case Investigation Form for Adverse Events Following Immunisation (AEFI)
This form should be filed for all AEFI (see chapter 9).

Vaccine and Injection Materials Stock Register
All received and issued HPV vaccines and injection materials should be recorded on the stock register.

HPV VACCINATION REGISTER

District:_____

Name of school, outreach, or facility:_____

							Date (dd/mm/yy) for		
Serial No.	Child's Name	Date of Birth	Household Head Name	Village/ Residential Area	Class in School	Age at Dose 1	HPV1	HPV2	HPV3

Vaccine and Injection Materials Stock Register

VACCINE: **MONTH……** **YEAR……..**

RECEIVED						ISSUED							
DATE	NAME OF UNIT	STOCK AT HAND	DOSES RECEIVED	BATCH NUMBER	EXPIRY DATE	DOSES ISSUED	BATCH NUMBER	EXPIRY DATE	DOSES USED	DOSES WASTED	DOSES RETURNED	TOTAL BALANCE	REMARKS

FORM 1a: HPV TALLY SHEET

Use a separate tally sheet each day of vaccination. Tally sheet to record the number (No.) of HPV doses given on a single vaccination and ages of the girls.

Date of vaccination (DD/MM/YYYY):	**District: _____** **Health facility: _____** **Vaccination post/outreach/school name: _____**		
Age (years)	No. of HPV1 doses given	No. of HPV2 doses given	No. of HPV3 doses given
9	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 00000 00000 00000 00000 00000 00000
	Subtotal 9yrHPV1=	***9yrHPV2=***	***9yrHPV3=***
10	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 00000 00000 00000 00000 00000 00000
	10yrHPV1=	***10yrHPV2=***	***10yrHPV3=***
11	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 00000 00000 00000 00000 00000 00000
	11yrHPV1=	***11yrHPV2=***	***11yrHPV3=***
12	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 00000 00000 00000 00000 00000 00000
	12yrHPV1=	***12yrHPV2=***	***12yrHPV3=***
13	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 00000 00000 00000 00000 00000 00000
	13yrHPV1=	***13yrHPV2=***	***13yrHPV3=***
14	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 00000 00000 00000 00000 00000 00000
	14yrHPV1=	***14yrHPV2=***	***14yrHPV3=***
≥15	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 00000 00000 00000 00000 00000 00000
	15yrHPV1=	***15yrHPV2=***	***15yrHPV3=***
Unknown	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 00000 00000 00000 00000 00000 00000
	UknHPV1=	***UknHPV2=***	***UknHPV3=***
OPTIONAL CHECK ROW(sum up columns)	=	=	=

Wastage: i) Number of vials contaminated..... ii) Number of vials broken..... iii) Other.....

Number of vials taken from health centre..... Number of vials returned to health centre.....

Name of vaccinator..... Signature of vaccinator.....

FORM 1b: HEALTH FACILITY REPORT FORM

In-school girls

Date of vaccination report (DD/MM/YYYY):	**District: _____** **Health facility name: _____** **HPV dose being reported: _____**								
	8 years or below	9 years	10 years	11 years	12 years	13 years	14 years	15 and above	Unknown
HPV 1									
HPV 2									
HPV3									
	Notes/comments:								

Wastage: i) Number of vials contaminated: _____ ii) Number of vials broken: _____ iii) Other: _____

Total number of eligible girls in school: _____ Number of girls vaccinated in school: _____ Coverage: _____ (%)

Out-of-school girls

Date of vaccination report (DD/MM/YYYY):	**District: _____** **Health facility name: _____** **HPV dose being reported: _____**								
	8 years or below	9 years	10 years	11 years	12 years	13 years	14 years	15 and above	Unknown
HPV 1									
HPV 2									
HPV3									
	Notes/comments:								

Wastage: i) Number of vials contaminated: _____ ii) Number of vials broken: _____ iii) Other: _____

Total number of eligible girls in school: _____ Number of girls vaccinated in school: _____ Coverage: _____ (%)

Name and signature of the person compiling report: _____

Name and signature of the health facility in charge: _____

FORM 1c: DISTRICT REPORT FORM

In-school girls

Date of vaccination report (DD/MM/YYYY):	**District: _____** **Health facility name: _____** **HPV dose being reported: _____**								
	8 years or below	9 years	10 years	11 years	12 years	13 years	14 years	15 and above	Unknown
HPV 1									
HPV 2									
HPV3									
	Notes/comments:								

Wastage: i) Number of vials contaminated: _____ ii) Number of vials broken: _____ iii) Other: _____

Total number of eligible girls in school: _____ Number of girls vaccinated in school: _____ Coverage: _____ (%)

Out-of-school girls

Date of vaccination report (DD/MM/YYYY):	**District: _____** **Health facility name: _____** **HPV dose being reported: _____**								
	8 years or below	9 years	10 years	11 years	12 years	13 years	14 years	15 and above	Unknown
HPV 1									
HPV 2									
HPV3									
	Notes/comments:								

Wastage: i) Number of vials contaminated: _____ ii) Number of vials broken: _____ iii) Other: _____

Total number of eligible girls in school: _____ Number of girls vaccinated in school: _____ Coverage: _____ (%)

Name and signature of the person compiling report: _____

Name and signature of the health facility in charge: _____

CASE INVESTIGATION FORM FOR AEFI

Identification / Address

Case number:		
Patient's first name:	Family name:	
Address:		
Date of birth:	Age (if no DOB):	Sex: [ ] Male [ ] Female

Immunization History and Procedures

Date of vaccination:	Vaccination post (if applicable):		
Health facility:	Name of vaccinator:		
Vaccines given that day to the patient:	Manufacturer:	Batch number:	Expiry date:
1.			
2.			
3.			
Were the vaccines handled correctly at all times? YES NO If no, please explain:			
Was the vaccination technique adequately sterile? YES NO If no, please explain:			
How many other people received vaccine from the same batch?			

Medical History (tick which applies)

Local Reactions		Systemic reaction	
Injection site abscess		Anaphylaxis	
Severe local reaction (swelling extending >5cm from the injection site, or redness and swelling for more than 3 days)		Hospitalization thought to be related to vaccination	
		Shock or collapse within 48 hours of vaccination	
		Fever of >40.5 within 48 hours of vaccination	
		Seizures within 3 days	
		All deaths thought to be related to vaccination	
		Other (please describe)	
Details of symptoms:			
Date and time of onset of symptoms:			
Laboratory findings:			
Any history of reactions to previous vaccines, drug allergies, etc.?			
Treatment given and outcome:			
Information given to parents/caretakers:			

Cluster Details

Is this AEFI part of a cluster? YES NO
If yes, how many people who received vaccine from the same batch, post, or vaccinator fell ill? How many people fell ill at other immunization posts?
AEFI investigated by (name):
Health facility or district:
Designation: Date: