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MINISTRY OF HEALTH-ETHIOPIA

የዜጎች ጤና ለሃገር ብልጽግና!
HEALTHIER CITIZENS FOR PROSPEROUS NATION!

National Implementation Guideline for Expanded Program on Immunization

June 2021

Addis Ababa, Ethiopia

National Implementation Guideline

for Expanded Program
on Immunization

(Revised edition)

June 2021
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Preface

The Federal Democratic Republic of Ethiopia Government Health policy states the mission of the Ministry of Health as “to reduce morbidity, mortality and disability and improve the health status of the Ethiopian people through providing and regulating a comprehensive package of promotive, preventive, curative, rehabilitative and palliative health services via a decentralized and democratized health system”. The Ministry of Health recognizes the crucial role immunization contributes in reducing child morbidity, mortality and disability and reaffirms its commitment to ensure that reaching every child with immunization services.

A life-course approach to immunization has been widely utilized by vaccination beyond childhood to adolescence and adulthood for combating Vaccine-Preventable Diseases (VPD). Hence, the Expanded Program on Immunization (EPI) is one of the best and cost effective preventive public health interventions. The EPI program builds on the direction and planning of the Government’s Health Sector Transformation Plan (HSTP), the Comprehensive Multi-Year Plan (cMYP), the Reach-Every-Child/Community (REC) immunization strategy, experience gained during the past years of implementing routine and supplemental immunization activities, new vaccine introduction and global technical immunization guidelines. This revised implementation guideline emanated from the need to incorporate the details of the implementation of newly introduced vaccines over the past few years as well as other new vaccines which are soon to be included in the routine immunization program.

Currently, Ethiopia is providing (12) antigens as part of the routine immunization program by targeting major deadly diseases during the childhood. Two new vaccines, Human Papillomavirus Vaccine (HPV) and 2nd dose of measles vaccine (MCV2) were introduced into the routine immunization program in December 2018 and February 2019 respectively in addition to the already existing (10) antigens. Moreover, the need to improve access to uninterrupted supplies and to maintain the delivery of potent vaccine through well managed cold chain system has been included in this version.

This updated guideline aims to provide strategic guidance to health administrators and programme managers at different levels, health service providers in health facilities as well as the different partners and actors contributing for implementation of the immunization program across Ethiopia. The Ministry of Health appreciates the role of partner organizations and individuals for their technical contribution in the revision of immunization implementation guideline. The Ministry would also like to express its appreciation for the unreserved efforts of the EPI team, other Directorates of the Ministry of Health and the EPI partner organizations for their inputs and constructive comments.



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Acronyms

AIDS	Acquired Immuno-Deficiency Syndrome
ANC	Ante Natal Care
BCG	Bacille-Calmette-Guerin (Tuberculosis vaccine)
cMYP	Comprehensive Multi-Year Plan
cVDPVs	Circulating Vaccine-Derived Polio Viruses
DPT	Diphtheria, Pertussis, Tetanus vaccine
EPHI	Ethiopian Public Health Institute
EPI	Expanded Program on Immunization
EUL	Emergency Use Listing
FDA	Food and Drug Authority
GER	Gross Enrollment Rate (School)
MOH	Ministry of Health
HDA	Health Development Army
HEW/HEWs	Health Extension Workers
HIV	Human Immunodeficiency Virus
HSDP	Health Sector Development Program
HSTP	Health Sector Transformation Plan
ICC	Inter-agency Coordinating Committee
IEC	Information, Education and Communication
IPV	Inactivated Polio Virus
MCH	Maternal and Child Health
MLM	Mid-Level Management (training)
NIDs	National Immunization Days
NNTE	Neonatal Tetanus Elimination
OPV	Oral Polio Vaccines
PAB	Protected At Birth
PCV	Pneumococcal Conjugate Vaccine
PEI	Polio Eradication Initiatives
PHCU	Primary Health Care Unit
REC	Reaching Every Community/Child
RED	Reaching Every District
RI	Routine Immunization
SIAs	Supplemental Immunization Activities
Td	Tetanus and diphtheria
TT2+	Tetanus Toxoid2+
VAD	Vitamin A Deficiency
VAPP	Vaccine Associated Paralytic Poliomyelitis
WCBA	Women in child-bearing age
WHO	World Health Organization

1. Introduction

1.1. Background

The Federal Democratic Republic of Ethiopia is the second populous country in Africa with ten administrative regions and two city administrations covering about 1.1 million square kilometers. The total population of the country is projected to be about (112,078,730) with more than (83%) of the population living

in rural areas. The regions are further divided into (115) Zones having (1,054) Woredas (Districts) and about (17,574) Kebeles. A Kebele is the smallest administrative unit which contains approximately an average of (1,000) households. The regions have population figures ranging from (39,074,864) for Oromia to (263,657) for Harari in 2019 (projection from Census 2007G.C.). The potential geographic health services coverage in the country is estimated to be more than (99%).



Figure 1: Map of Ethiopia

1.2. Health Care Delivery system

There are (395) hospitals, (3,704) health centers, and (18,202) health posts that constitute the national health services in the country (FMOH, HRIS/2018). All hospitals and health centers as well as health posts with vaccine refrigerators are expected to provide immunization services through static approach supported by additional outreach sites and mobile service in some parts of the country.

In Ethiopia, there are wide regional variations in population size, landscape, infrastructure, socio-economy and cultural backgrounds. The developing regional states such as Afar, Somali, Gambella, and Benishangul-Gumuz with low immunization performance have a shortage of qualified staff with weak infrastructure. Some of these areas have nomadic population that makes their access to immunization services challenging. Other regions like Oromia, Amhara and SNNP are highly populated and are in a

better position in terms of human resources and health infrastructure. Yet, within these regions, there are pockets of inaccessible areas with high number of unvaccinated children

and repeated VPD outbreaks such as measles indicating low immunization coverage that needs to be addressed.

Ethiopian Health Tier System

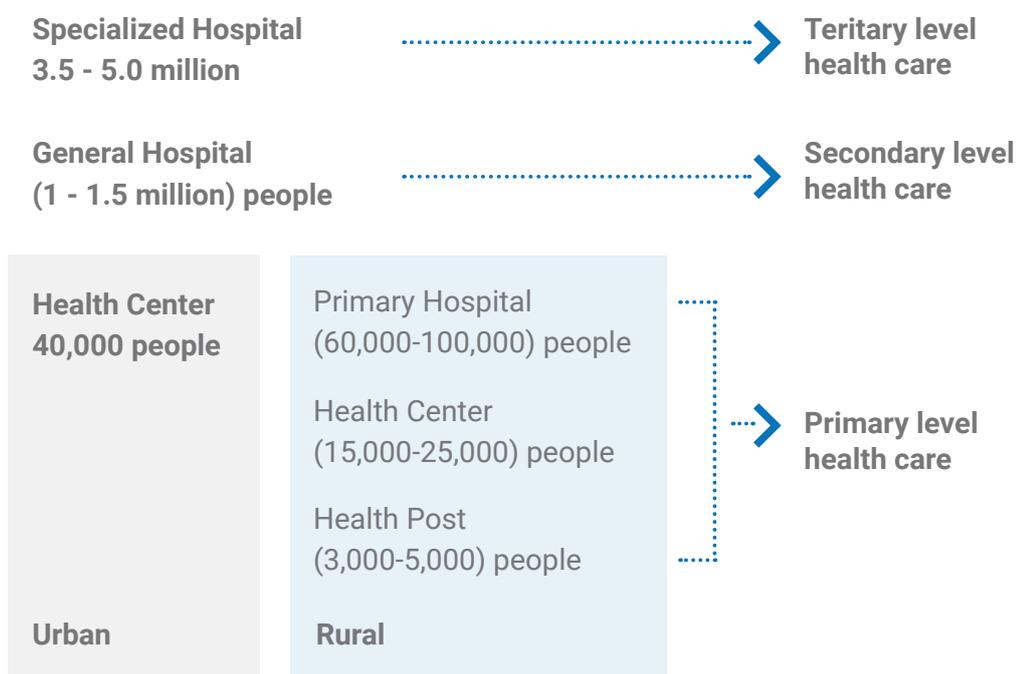


Figure 2: Ethiopian Health Care Tier System

1.3. Historical perspective/ development of the EPI program in Ethiopia

The Ethiopian National Expanded Program on Immunization (EPI) was launched in 1980 with the aim of reducing mortality, morbidity and disability of children and mothers from vaccine-preventable diseases. The target group when the program started were children under two years of age until it changed to infants

and mothers in 1986 which was to be in line with the global immunization target. Since 2019, infants, children in the Second Year of Life for MCV2, girls of 9-14 years old for HPV and women of reproductive age group are the primary targets for the immunization services in Ethiopia which is part of the implementation of immunization as a life-course approach. There is an established immunization program support system in the country starting from the Federal level down to the health post.

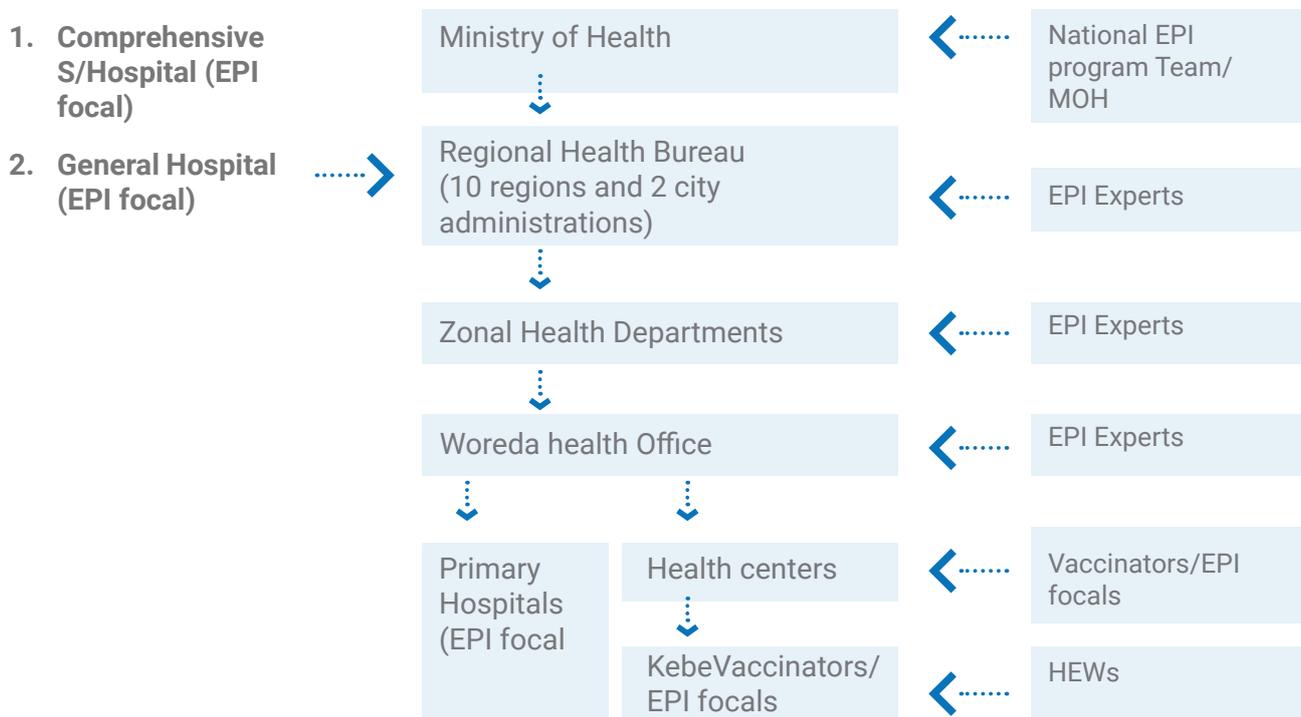


Figure 3: Organogram of Ethiopian health administrative and EPI unit

The immunization system comprises of five key operational components namely service delivery, communication, cold chain and logistics, vaccine supply and quality, and VPD surveillance and response. It also consists of three supportive components which are management, financing and capacity strengthening.

At the launch of EPI in Ethiopia in 1980, six antigens (BCG, DPT, OPV, and Measles) have been given in both public health facilities and few private health facilities. The country later introduced Hep-B and Hib (as Pentavalent vaccine), PCV, Rotavirus, IPV, HPV and measles second dose (MCV2) vaccines into the routine immunization program in 2007, 2011, 2013, 2015, 2018 and 2019 respectively. The total number of antigens in the national schedule reached twelve (including TT for women of reproductive age). In 2020, the country switched

from TT to Td. In the near future, the country is planning to introduce Meningitis A, Yellow Fever, Hepatitis B birth dose, Typhoid, and school Td vaccines to replace the TT vaccine for women of reproductive age (and/or pregnant women as per the national immunization target), older children and adolescents.

Immunization service provision has shown gradual increments from (66%) in 2005 reaching (97%) administrative coverage of Penta3 in 2019 (MOH). The current administrative coverage as reported in the Joint Reporting Framework (JRF) 2019 reached (97%) for Penta3 and (91%) for measles first dose (MCV1). Based on the Ethiopian Demographic and Health Survey (EDHS), EPI coverage estimated that Penta3 coverage increased from (29%) in 2005 to (53%) in 2016 and (61%) in Mini EDHS 2019 (Figure 4).

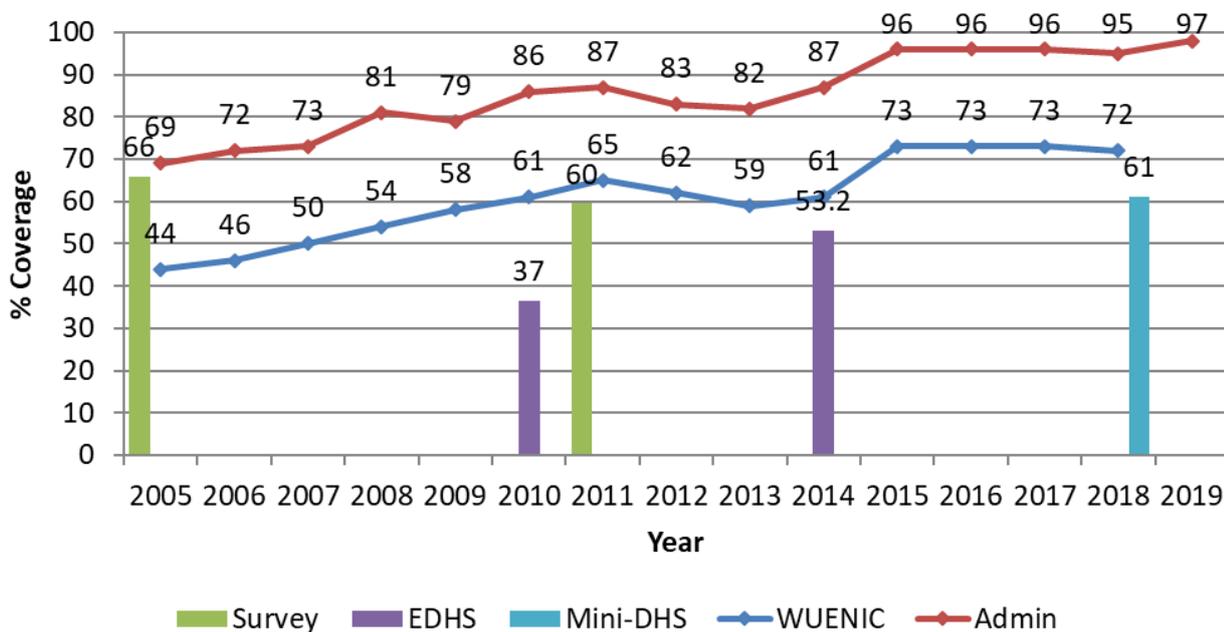


Figure 4: Trends of Penta3 coverage by different data sources 2005 – 2019, Ethiopia

Supplemental Immunization Activities (SIAs) are being conducted for different prioritized diseases such as polio, measles, and tetanus to augment the RI efforts and close population immunity gaps by providing additional doses through mass vaccination. Progress to achieving optimal SIA quality is monitored by readiness assessment tool (RAT). The main objective of RATs is to ensure a high-quality campaign through timely and excellent preparations. To achieve equity, transforming the “Reaching Every District (RED)” concept to “Reaching Every Community/Child (REC)” approach was used. Such mechanisms require management efficiency, evidence-based interventions, and community-based planning. By applying these approaches, Ethiopia has achieved MNTN elimination status in 2017, certified for wild polio eradication in 2020 and switched from TT in Td in 2020.

1.4. The Ethiopian Health Extension Program

Cognizant of the inherent problems in access and utilization of the community health programs, the government of Ethiopia decided to employ Health Extension Workers (HEWs) as salaried government staff since 2004. The deployment of a new cadre of salaried government employees was the advancement from the previous volunteer Community Health Worker program in Ethiopia. The overall goal of Health Extension Program (HEP) is to create a healthy society with focus on maternal and child health. It targets households and communities based on the principle of primary health care to improve the families’ health status with their full participation. Rapid expansion of HEP services is a core component of the broader health system and it is one of the strategies adopted

with a view to achieving universal coverage of primary health care to the rural and urban population in a limited resource setting. Thus, HEP ultimately aims to overcome geographic barriers, reach the underserved, and foster equity. It also aims to reduce mortality and morbidity through high impact interventions such as the immunization program.

About (39,947) HEWs have been trained and deployed to render the services. The HEWs are recruited from the local communities and trained for one year. They are providing a package of eighteen health interventions for rural and fifteen health intervention for urban areas in which immunization service has been one of the crucial interventions. In pastoralist and developing regional states, the government has been providing special support such as capacity building activities for the HEWs. Two HEWs are assigned in each health post to undertake health promotion and preventive interventions as well as to provide selected high impact and simple curative services. Moreover, about (4,124) Urban Health Extension professionals are trained nurses who are deployed and mobilizing parents/caregivers to vaccinate their children at health facilities, tracing defaulters and other duties as necessary.

HEP optimization program

Changes in literacy rate, socioeconomic status, demographic and epidemiologic trends, and rapidly increasing urbanization require more comprehensive health care services covering a wide range and quality of curative, promotive and preventive services. To respond to this rapidly changing global and country level situations, the Ministry of Health Ethiopia is currently revisiting the HEP. Addressing equity and quality in health services are the main focuses of the new Ethiopian Health

Sector Transformation Plan. The strategic themes of HSTP focus on excellences: health service delivery, quality improvement and assurance; leadership and governance; and health system capacity. Most basic services will be shifted, and responsibility will be shared with the community level structures. Therefore, improving the competence of HEWs and the Health Development Army (WDA) is crucial. Renovating, expanding, equipping, and supplying health posts with the necessary equipment and supplies, shifting essential services to the community level, and institutionalizing of the HDA platform will also be essential.

1.5. The Health Sector Development Program

The Government of Ethiopia has instituted health reforms under the Health Sector Development Program (HSDP) promoting decentralization and standardization of levels of health care. Ethiopia has also implemented HSTP (2016- 2020) focusing on maternal and child health particularly on immunization activities as a priority program and increasing the number of total antigens to (12) with a focus on quality and equity in health. The HSTP (2016-2020) was designed to sustain the gains, further scale up and achieve the universal health coverage (UHC). In order to drive HSTP, four transformation agendas were designed: the Woreda transformation, ensuring health service quality and equity, information revolution and creating caring, respectful and compassionate health care professionals. These agendas are believed to complement each other and have synergistic effect contributing to the successful achievement of the Health Sector Transformation Plan. The comprehensive multi-year plan (cMYP) for immunization 2016-2020 served as the source document for EPI and was aligned and synchronized with HSTP.

1.6. Rationale for Implementation Guideline revision

- Requirements for updated accurate data and information
- Revised guideline will be an input for strengthening the EPI program
- Introduction of the new vaccines (IPV, MCV2, HPV) since 2015
- Considering other new vaccines on the pipeline soon to be included in EPI program
- Engagement of private health facilities
- The need to take into consideration of the COVID-19 circumstances
- To maintain the timeline of guideline revision
- To sustain the progress of global, regional, and national VPD control, elimination and eradication goals
- Mitigate re-emerging VPD transmission

Legal and Regulatory Framework

The constitution of Ethiopia recognizes the right to health and Ethiopia has ratified international and regional human rights instruments which guarantee the right to health as a fundamental human right. Child's right to health and health services article 24 (1) assures the right of children to the highest attainable standard of health and access to facilities for the treatment of illness and rehabilitation of health.

2. Vision

"To see healthy, productive and prosperous Ethiopians"

3. Mission

"To promote health and wellbeing of Ethiopians through providing and regulating a comprehensive package of promotive, preventive, curative and rehabilitative health services of the highest possible quality in an equitable manner."

4. Objective of this guideline

To provide updated guidance and direction on implementation of immunization for health managers, service providers in government and private health facilities, administrators at different levels as well as different partners and actors in Ethiopia to enable the delivery of quality and equitable immunization services to every target population against vaccine-preventable diseases.

5. Major vaccine-preventable diseases initiatives

Vaccine-preventable diseases contribute substantially to reduce under five morbidity and mortality. By implementing the package of newborn and child survival interventions including immunization, proportions of lives saved by addressing leading causes of mortality such as diarrhea (9%), pneumonia (28%), meningitis (5%) and measles (1%) will significantly improve (National Child Health Report 2019). Due to expansion of access to immunization services and introduction of new vaccines, complementary with other interventions, many more deaths due to vaccine-preventable disease are averted than

ever before. Despite the gains of accelerated VPD control, elimination and eradication, there remains risks of cVDPV, measles outbreaks and population immunity gaps have continued due to high number of unvaccinated children.

5.1. Polio Eradication

Ethiopia adopted the goal of polio eradication in 1996 and AFP surveillance system was established in 1997 as part of the global polio eradication initiatives (GPEI). Since then, strengthening OPV vaccination, introduction of IPV and several OPV campaigns have been conducted at national and sub-national levels.

To eradicate polio from the world, four strategies are globally adopted:

1. Reaching and maintaining at least (90%) coverage with three doses of OPV in children aged <1 year through routine EPI services
2. Conducting Supplemental Immunization Activities (SIAs) to interrupt transmission of polio virus. In such campaigns, repeated doses of OPV will usually be given to children 0-59 months old and based on epidemiological data, children up to 15 years old receive the vaccine irrespective of their immunization status
3. Surveillance for Acute Flaccid Paralysis (AFP) cases, including collection and examination of stool specimens for isolation of poliovirus
4. Mop-up immunization campaigns in which surveillance data will be utilized to identify where the last cases of polio occurred to focus on the activities to be undertaken. Areas where wild poliovirus were identified, and neighboring areas will be targeted for the mop up. All these strategies implemented for several years enabled Africa to be declared as a region free of wild poliovirus in 2020. Ethiopia was granted wild polio free status in 2017.

Moreover, Ethiopia introduced IPV into the routine immunization program in 2015. Although IPV consists of inactivated poliovirus strains from all three poliovirus types, it does not replace OPV doses and it will continue to be provided side by side. Based on epidemiological evidence and global directions, the use of trivalent OPV (t-OPV) was switched to bivalent OPV (b-OPV) in 2016.

5.2. Accelerated Measles Elimination Strategies with Targets

Despite availability of a safe and cost-effective vaccine, measles is still one of the leading causes of death among children across the globe. Accelerated immunization activities have had a major impact on reducing measles deaths. During 2000–2016, measles vaccination prevented an estimated (20.4) million deaths globally. During this period, global measles deaths have decreased by (84%) and annual reported measles incidence decreased by (87%), from (145) to (19) cases per million. In September 2011, the Sixteenth Regional Committee, by its Resolution AFR/RC61/R1, adopted a goal of measles elimination from the African Region by the year 2020.

Ethiopia has developed a Measles Elimination strategy which aligns with the target set by Regional Offices with an aim to achieve Measles Elimination by 2020. In Ethiopia, though marked achievements in reduction of measles disease burden was achieved, the incidence of measles has remained high and above the targets set for measles reduction by 2012 (<5 cases/1,000,000 population) and measles elimination by 2020 (<1 cases /1,000,000 population). As a continued effort, Ethiopia has introduced measles second dose vaccination for children at the second year of life (age of 15 months) to decrease the disease burden and accelerate measles

elimination. All eligible children will receive two doses of measles vaccine through the routine immunization program. To prevent measles epidemics, vaccination coverage with two doses of measles vaccine needs to be maintained at high level, above (95%) in all districts. The introduction of measles second dose vaccination in Ethiopia will significantly contribute to the reduction of measles morbidity and mortality and to accelerate achieving the measles elimination goals.

Ethiopia adopted the measles accelerated control initiative since 2011 and envisions achieving measles elimination by 2025.

The following strategies and targets set for the accelerated measles elimination efforts are recommended:

1. Strengthen routine measles immunization coverage among infants to reach (98%) coverage measles containing vaccine (MCV1) at nine months of age at national and (93%) and above in every district by 2025
2. Provide measles second dose (MCV2) at the age of 15-23 months and achieve (87%) MCV2 coverage nationally and (88%) and above in every district
3. Provide an opportunity for measles vaccination through supplemental immunization activities by achieving at least (95%) coverage
4. Establish and maintain effective measles case-based surveillance. Achieve the surveillance performance targets of at least two-suspected cases reported with serum sample per (100,000) population per year and achieve an annualized non-measles febrile rash rate of (2/100,000) population with (80%) of Woredas reported at least one suspected measles case with adequate serum sample for measles IgM test and confirmation.

5. Provide standard case management to measles cases according to the standards set in the IMNCI protocols

The routine immunization schedule recommends two doses of measles vaccine; the first one given for all infants at the age of nine months and a second dose given at (15) months of age in the routine EPI program or at a later age in the form of SIAs. As MCV1 will no longer be restricted to children under the age of one year, the minimum interval between MCV1 and MCV2 will be one month if child received MCV1 at or after age 15 months.

The advantage of MCV2 introduction is that there will be 2nd year of life immunization of measles to those children who would be missed or remained unprotected in the routine immunization during the first year of life. In addition, having an established platform for immunization in the 2nd year of life will also increase the potential uptake of other vaccines and other health services which are being given or will be introduced in the future (Vitamin A, nutrition, growth monitoring, deworming, etc.).

The following are strategies to increase the chance of providing additional doses of measles,

- Screening of vaccination history of children at the time of school entry and providing measles vaccine for those lacking evidence of MCV1 and/or MCV2 dose of measles vaccine. And in collaboration with Ministry of Education, it is planned for the screening on the vaccination history of children at school entry.
- Linking measles MCV2 dose delivery to other child health programs such as Vitamin A supplementation, deworming, growth monitoring, Comprehensive Integrated Nutrition Services (CINS) etc.

- Avoiding missed opportunities through training of health workers how to open measles vaccine vial even if one child presents who is eligible for measles or BCG vaccination at an appropriate time, ensuring that all children coming to health facilities and outreach sites receive the vaccination.
- Integration with other programs such as safety net, food for work program, especially in drought affected communities to ensure equity in uptake of measles vaccine.
- Conducting catch-up vaccination for those children who didn't take their vaccination for any reason

5.2.1. Target age group for measles containing Vaccine (MCV)

In the Ethiopia context, MCV1 will be administered at the age of (9) months or soon after the child comes to Health Facility under the age of (12) months. MCV2 will be

administered at the age of (15) months if the child was given MCV1 at (9) months. If the child receives MCV1 at or after (15) months of age, MCV2 will be given with minimum interval of (4) weeks between MCV1 and MCV2 until the age of (23) months.

The general principles are:

- All children should receive 2 doses of measles containing vaccine (MCV)
- The first dose should be administered at first contact at or after (9) months of age
- The second dose should be administered at or after (15) months of age, or one month after the first dose if given at or after (15) months of age, whichever comes first

The vaccine dose (MCV1, MCV2) refers to the number of doses received, and not to the age that the dose is administered.

Table 1: target age group for MCV1 & MCV2 doses Schedules

Age at contact	MCV 1	MCV 2	Remark
Child (9-11) months	MCV1	NA	Advise the mother to return when the child is (15) months old for the MCV2
Child (12-14) months old who have received MCV1	NA	Wait until (15) months of age	Advise mother to return when child is (15) months old
Child (12-14) months old who have not received MCV1	MCV1 at contact	MCV2 between (15-23) months of age	Give MCV1 and record as MCV1 and advise mother to return when the child is (15) months old for MCV2
Child (15-23) months who have not received MCV1	MCV1 at first contact	And MCV2 after one month of MCV1 administration	Give MCV1 and record as MCV1 and advise mother to return in (1) month for MCV2
Child (15-23) months who had received MCV1 but not MCV2	NA	MCV2 at least after one month of MCV1 administration	Give MCV2 and record as MCV2

5.3. Sustaining Neonatal Tetanus Elimination

Elimination of Neonatal Tetanus (NNT) is an effort exerted to bring the level of NNT to less than one case for every (1,000) live births annually in each Woreda throughout the country. Promotion of deliveries by skilled birth attendants and immunizing women of childbearing age, elementary school girl and pregnant women against tetanus are critical interventions in preventing NNT. All women giving birth and their newborn babies should be protected against tetanus and all pregnant women (PW) attending visiting a health facility for any reason should be screened for their tetanus toxoid (Td) immunization status and be immunized if they are eligible for a dose.

A child is protected at birth against NNT if the child is born within the period of protection conferred by the maternal immunization status, which can be verified by monitoring of PAB through cards, register, or collection of history of Td vaccination. Only valid doses (at least two) or those given with the minimum required time intervals between doses, are to be counted. A birth is considered protected if it occurred within the duration of protection offered by the last valid dose of tetanus toxoid (Td) given to the mother. Certifying graduating mothers who completed all (5) doses supported by card must be documented and excluded from the target population for Td.

Adopted strategic recommendations to sustain MNT Elimination are,

1. Screening to routinely immunize women during pregnancy and immunization of women of reproductive age (15-49 years) at fixed sites or through outreach or mobile

service delivery strategy with Td vaccine with a special focus on the remote and underserved areas

2. Routinely immunize all children age (0-11) months with 3 does of DPT/pentavalent vaccine
3. Immunize school children (girls) in the 1st cycle of primary schools with (3) doses of tetanus diphtheria toxoid (Td)
4. Promoting skilled birth attendants at all level of health facilities to ensure skilled delivery practices
5. Improve neonatal tetanus surveillance in all woredas
6. Effective program communication on Td immunization and RMNCH
7. Immunize women of childbearing through localized SIAs in identified high risk areas for MNT where structural improvements of routine immunization or skilled delivery services is lacking/suboptimal (new cohort) and where Td immunity from past Td SIAs may have declined (old cohort) , and in areas where school enrolment is low

6. EPI implementation strategies

The achievement of immunization program goals depends on strong immunization programs that are closely coordinated and work in synergy with other primary health care delivery programs. Effective integration of between immunization and other health programs can contribute to improving immunization coverage by reducing missed opportunities for vaccination and zero-dosed children. The strategies outlined below are applicable in all EPI plus (Vitamin A supplementation, ECD & GMT, Deworming, etc.) programs.

6.1. Strategies for increasing immunization access and coverage

- Increasing access to immunization services by integrating with RMNCH services
- Strengthen existing static EPI sites and establish immunization service in the newly constructed health facilities
- Strengthen regular outreach services in hard to reach areas including periodic intensified immunization services (PIRI), RED/REC, child health days and SIAs
- Exert more efforts to reach underserved and un-reached children through innovative approaches
- Encourage and support the private health institutions to provide immunization services based on the national immunization implementation guideline
- Use SIAs as opportunities to strengthen routine immunization
- Provide adequate cold chain equipment, injection materials, vaccines, and other necessary supplies on timely and regular basis
- Enhance public awareness and community engagement interventions in collaboration with the HEWs, Health Development Army and community volunteers
- RED/REC will be one of the key strategies for increasing coverage and equity
- Strengthen monitoring and use of data for action including process and coverage indicators
- Reduce missed opportunities for vaccination, promoting the routine checking of the immunization status of children and women whenever they visit the health services and immunize accordingly (service integration)

- Using African Vaccination Week to mobilize communities for vaccination and reduce missed opportunities

6.2. Strategies to reduce Dropout/Defaulter Tracing

- Sustain regularity of immunization sessions fixed, outreach, mobile and PIRI implementations
- Engage the community particularly women for immunization services including planning, implementation, and evaluation in the framework of REC/RED
- Strengthen information provision to parents/caregivers on key immunization messages through interpersonal communications, community dialogues, home visits, electronic/social media, and distribution of IEC materials
- Enhance interpersonal communications skills among health care providers
- Promote proper use of the electronic Community-Based Health Information System (e.g. eCHIS) and practicing proper registry system at facility level
- Establish or strengthen defaulter-tracing mechanisms using the existing HDA, other relevant community structures and applying other communication strategies
- Track zero-dosed and under-immunized children from all Maternal and Child Health service delivery units (FP, ANC, delivery unit, IMNCI, ICCMNCI, OPD, etc.)
- Avoid vaccine stock out through an effective vaccine management system
- Address rumors, misinformation, and disinformation around immunization and AEFIs in the community and different media by applying appropriate risk communication interventions and AEFI management

6.3. Increasing the quality of immunization services

- Ensure the provision of adequate and safe vaccines at all service delivery points
- Minimize waiting hours through appropriate mechanisms
- Provide adequate cold chain and injection materials and ensure reliable vaccine stock management
- Strengthen the cold chain maintenance system at all level
- Apply cold chain monitoring system at all levels using functioning refrigerator, fridge tags, temperature monitoring charts and other new technologies appropriately
- Introduce and use quality assurance methods on immunization activities at each health service level through proven approaches such as RED/QI
- Collaborate with the national regulatory body, the Food and Drug Authority (FDA) to ensure the quality of vaccines
- Capacity building of health workers on immunization in practice (IIP), RED/REC, vaccine management, PIRI, IRT for HEWs, Mid-level Management (MLM) for mid-level managers and conduct periodic supportive supervision visits
- Reinforce the skills of health care workers on immunization service delivery
- Use the multi-dose open vial policy for PCV 13, Td, IPV and oral polio vaccine

7. Advocacy, Communication and Social Mobilization

- Ensure high level EPI advocacy both at national and regional levels to ensure political commitments and financial sustainability towards achieving high immunization coverage and diseases reduction goals

- Improve public awareness through intensive, regular, and widely implemented social mobilization, demand promotion and health education interventions in order to ensure participation of the public in EPI activities
- Develop IEC materials in different local languages to promote the public understanding on benefits of vaccines, immunization services and schedules
- Promote public demand for vaccination through multi-channel interventions such as IEC (electronic/print media), social and behavioral change communication, public meetings, health education in health institutions, dissemination of information through schools and other events
- Increase communication skills of health workers, in public and private sectors, through training, availing IEC materials and job aids, review meetings, dissemination of achievements and progress
- Increase the involvement and support from community, political and religious leaders through sensitization workshops, review meetings, direct contacts from health workers at all levels
- Utilize community platforms and structures like Women Health Groups, religious leaders, clan leaders, Kebele leaders, Town administrators, Youth Associations, and “Edirs” as much as possible

8. Strategies to achieve and sustain high immunization coverage

- Ensure political commitments and inter-sectoral collaboration towards achieving high and sustained immunization coverage to achieve VPD related morbidity and mortality reduction goals
- Enhance financial sustainability through government budget allocation and resource mobilization for immunization at national and sub-national levels

- Ensure bottom-up equity focused micro planning is prepared and planned sessions are implemented fully
- Ensure last mile vaccines and supplies delivery is continuing as planned
- Regular monitoring of the program at all levels by using both process and outcome indicators
- Implement REC/RED approach to strengthen routine immunization services and management to increase and sustain equitable immunization coverage

9. Strengthen surveillance of target diseases and adverse events following immunization (AEFI)

9.1. Vaccine-Preventable Diseases Surveillance

Currently, diseases targeted for eradication and elimination are included in the national list of priority diseases for surveillance such as poliomyelitis, measles and NNT. These target diseases should be immediately reported to the Ethiopian Public Health Institute (EPHI) and investigated accordingly as per the National Surveillance Guidelines. Community-based surveillance for active case searching is already instituted. MOH EPI program will continuously utilize the National and Subnational VPD Surveillance data for data triangulation to guide strengthening RI and conducting campaigns as needed.

Types of surveillance

Active Surveillance

Active surveillance involves visiting health facilities, talking to health-care providers and reviewing medical records to identify suspected cases of disease under surveillance.

Designated active surveillance staff regularly visit health facilities in person to search for suspected cases among persons who might have attended the facility. It involves physical review of medical records and registers, interviews with health workers and visits to relevant outpatient clinics and inpatient health facility wards.

Passive Surveillance

Passive but regular notification and reporting of disease data by all institutions that see patients (or test specimens) and are part of a reporting network is called passive surveillance. It is a common method which is utilized to detect vaccine-preventable diseases.

Sentinel Surveillance

A sentinel surveillance system is used when high-quality data are needed about a particular disease that cannot be obtained through a passive system. Selected reporting units, with a high probability of seeing cases of the disease in question, good laboratory facilities and experienced well-qualified staff, identify and notify on certain diseases.

9.2. Adverse Events Following Immunization (AEFI)

Adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

Classification of AEFI

1. Mild, Moderate and Severe AEFI

- Defined as an incident or reaction that is not serious
- Most vaccine-induced reactions are mild and transient, most frequently soreness at the injection site and mild fever

2. Serious AEFI

- Defined as an event causing a potential risk to the health/life of a recipient leading to death, hospitalization, or prolongation of existing hospitalization (e.g. seizures), significant disability or incapacity, congenital anomalies/birth defect or life-threatening conditions

Adverse Events Following Immunization (AEFI) should be documented, reported, investigated, and monitored at different levels in the routine, campaigns, and reactive implementations. Appropriate management and communication should be followed the detection of immunization adverse events with parents, health workers and with the community. AEFI should be reported regularly at all levels; however, severe cases of AEFI should be reported immediately and investigated. The AEFI report will be compiled by EFDA and shared with the national EPI program and EPHI.

A national Task Force for AEFI follow up, led by EFDA is already established by members from various institutions such as EFDA, MOH, EPHI, medical teaching institutions, WHO, and other organizations.

10. Targeted strategies to address immunization inequalities (urban slums, rural, pastoralist, hard to reach, conflict affected areas and IDP)

Data from DHIS2 analysis has shown that most unimmunized and under-immunized children and children who dropped from subsequent vaccinations are more likely from poor households, uneducated caregivers and migrants. The buildup of unvaccinated children or those who are missed from consecutive vaccination are mainly in urban slum, remote rural, pastoralist, hard to reach, conflict affected, urban outskirts and IDP areas in which it creates

risk for the occurrence of vaccine-preventable disease outbreaks. The key to reaching every child with vaccination is the availability of an equity-based complete micro-plan capturing all catchment areas along with target children and required resources including vaccines and mobility and proper implementation and monitoring of the plan.

The following are key strategies to address immunization inequalities,

- Analysis of available immunization data and information (EDHS, EPI performance reviews, previous SIAs, VPD surveillance reports) at all levels for the existence of immunization inequities (using equity markers) between different socio-economic groupings within the country
- Identification of areas with poor immunization performance (by zone, woreda and PHCU) and low coverage including “high risk” or “hard-to-reach” communities; identify and examine underlying reasons for unvaccinated and under vaccinated
- Identify information on barriers that affect community members’ ability to access and utilize immunization services; also identify the challenges of HFs to address vaccination services to all segments of the community
- Update “Reaching Every District” to “Reaching Every Community” in order to address inequities within woredas micro plans and to reduce inequities by ensuring every community is accounted for and receive immunization services
- Allocation of resources to reduce immunization inequities at the level they can be overcome, within health at the level they can be overcome, and within Health Centers and communities
- Support Periodic Intensified Routine Immunization (PIRI) outreaches and mobile strategies to reach the unreached children

11. Life-course approach For Vaccination

As per Immunization agenda 2030, global immunization efforts will expand to focus on vaccination throughout the life course – including booster doses for older age groups and immunizing the elderly where vaccinating individuals beyond the current EPI targets with lifesaving vaccines. It will contribute to health as an individual as well as decrease the spread of diseases to infants. This will also protect the general population from VPD through herd immunity.

12. The COVID-19 Pandemic

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It was first identified in December 2019 in Wuhan, Hubei, China, and has resulted in an ongoing global pandemic. On 30th January 2020, WHO declared the COVID-19 outbreak as a public health emergency of international concern, WHO highest level of urgency and on 11th March 2020, WHO made the assessment that COVID-19 should be characterized as a pandemic.

As the pandemic started to overwhelm the world, COVID-19 disease prevention and control strategies included,

- Establish sensitive COVID-19 surveillance system that can detect, investigate, confirm, and manage each cases of COVID-19 disease
- Avoid crowding conditions and poorly ventilated indoor spaces

- Maintain (2) meters distance from others
- Wearing a face mask that protects oneself and others
- Maintain hand hygiene all the time by frequent hand washing or using sanitizers
- COVID-19 vaccination to the priority target population to decrease mortality with COVID-19

Following the SARS-CoV-2 (COVID-19) pandemic that presents an extraordinary challenge to global health; commercial vaccine manufacturers and other entities are developing COVID-19 vaccine using different technologies including RNA, DNA, protein, and viral vectored platforms.

Currently, many countries are scaling up their vaccination efforts and there are varieties of COVID-19 vaccines produced by different drug manufacturers. Among the COVID-19 vaccines, some of them are approved for emergency use (EUL) by WHO. AstraZeneca and SinoPharm vaccines are currently in use in Ethiopia at the time of developing this guideline (June 2021). Ethiopia will introduce other COVID-19 vaccines as available which are EUL approved.

Target Population and Vaccination Delivery Strategies

Administration of COVID-19 vaccine will require a phased approach due to the incremental availability of vaccine supply over time. Built on the WHO fair allocation mechanism for COVID-19 vaccines through the COVAX Facility, Oxford-AstraZeneca and SinoPharm vaccine of China are available in Ethiopia. The vaccines are administered as two doses scheduled within interval of 8-12 weeks apart from the first dose.

COVID-19 vaccine allocation is planned in two phases,

Phase 1: Initially covers **3%** of the national population. This initial allocation will be for **health workers, highest risk and other essential/frontline workers**. Incremental shipments to reach a further **17%** of the country's population will follow. This will likely be for **older people and individuals with underlying health conditions**.

Phase 2: Countries will receive more doses to vaccinate populations **beyond the initial 20%** who are included in the first phase. Consideration may be given to a country's risk in establishing the pace at which it would receive additional volume of vaccines.

Key Objectives for Prioritization of Groups

1. To avert COVID-19 morbidity and mortality by stopping the spread of COVID-19 infection
2. To minimize societal and economic disruption
3. To protect the integrity of the health care system by vaccinating more than (90%) frontline health workers
4. To reduce morbidity and mortality by vaccinating more than (90%) of individuals with comorbidities and aged population above (55) years.
5. To restore social and economic functionality by vaccinating more than (90%) of individuals working in essential societal services
6. To ultimately reach population immunity and reduce transmission on COVID-19 by vaccinating more than (90%) of healthier adults and younger population

The potential strategies for delivering the vaccine will depend on the vaccine properties,

vaccine availability and characteristics of the prioritized target population. The traditional delivery strategies such as at health facilities, community outreaches and settings where the target population will easily access the vaccines will be employed.

13. Immunization Leadership, Management and Coordination

Strengthening coordination and accountability through improved EPI management at all levels enable to successfully deliver a robust immunization program deliverable. The MCH directorate of MOH is the overall coordinating body for the EPI activities at the national level. It coordinates the EPI interagency coordinating committee (ICC) efforts in achieving common national goals and targets. At national level, Ethiopia has a strong immunization interagency coordinating committee (ICC) which is chaired by the State Minister of the MOH and consists of members from UN agencies, Partners, Directorates of MOH, Civil Society Organizations and other key immunization partners. As advisory body to MOH, ICC provides overall guidance for the program and supports in resource mobilization.

Technical Inter-agency Coordinating Committee (ICC) is immunization task force with three technical working groups under the EPI task force. The Technical Working Groups are named as the monitoring and evaluation, and logistics and communication technical working groups. FMOH and partner agencies are represented in all technical working groups. There is an independent National Immunization Technical Advisory Group (NITAG) which advises the ministry on immunization policies, strategies, and technical issues including NVI and AEFI.

To effectively oversee and coordinate immunization programs at subnational level, the immunization task forces composed with appropriate stakeholders and partners have been established at region and zonal levels. The technical working groups at all level contribute to the improved vaccination coverage and equity.

14. National Immunization Schedule

14.1. Vaccines administration and schedules

The principle of immunization is to achieve the protection of the target age groups—who are at risk of developing the vaccine-preventable diseases—having adequate antibody response with minimal adverse effects from the vaccines. The immunization schedule for all infants is to receive one dose of BCG, three doses of DPT-HepB-Hib, three doses of pneumococcal conjugate vaccine, two doses of rotavirus vaccine, four doses of OPV, one dose of IPV, one dose of measles before the age of one year and one dose in their second year, and two dose of HPV with at least six month interval for (9-14) years old girls; although HPV is currently administered to girls aged (14) years due to the global HPV vaccine supply shortage. The minimum interval between each dose of the multi-dose vaccines should be four weeks; however, there is no maximum interval between the doses as long as it is given before the age of one year except for measles and HPV. If a subsequent dose of Pentavalent, PCV, OPV,

measles or rotavirus is missed, immunization on the next occasion should be continued as if the usual interval had elapsed; no extra dose is needed. (Table 2)

- If a child is previously vaccinated with BCG (verified verbally or by card), absence of BCG scar should not be a condition to provide additional dose of BCG vaccine to a child
- Additional “booster” doses are not recommended except for diseases targeted for elimination and eradication, where an additional dose would be provided through periodic SIAs
- Birth dose OPV means vaccine given within fourteen days of delivery
- Birth dose of BCG vaccine means dose given at birth. BCG can be given for children less than one year old, if not received at birth. BCG should not be given to children above one year of age
- Immunization of preterm infants should begin at the same chronological age recommended for term infants.
- All the EPI antigens are safe and effective when administered simultaneously, i.e. during the same immunization sessions, but injectable antigens must be administered on different sites
- The child should be considered as fully immunized if he/she received all vaccines including MCV1 before 1st birth date. However, the certification of completion of RI should be issued to the caretaker or child when she/he received MCV2 during the 2nd year of life

Table 2. National EPI Schedule and route of administration for antigens

No	Vaccines	Target diseases to be prevented	Age	Route/Site of administration
1	Hep B Vaccine Birth dose	Hepatitis B Virus Infection	At birth or within 24 hours of birth. If child is born out of HFs or at home, track baby and vaccinate until the age of 14 days.	IM, left anterolateral thigh
2	BCG	Severe forms of tuberculosis	At Birth or as soon as possible after birth	Intradermal (ID) right deltoid
3	PCV	Meningitis and pneumonia associated with Streptococcus pneumoniae bacteria	Weeks 6, 10 and 14	Intramuscular (IM), Right anterolateral thigh
4	OPV	Poliomyelitis	Birth (OPV0), weeks 6, 10 and 14	Oral drops
5	IPV	Poliomyelitis	Week 14	IM, right anterolateral thigh 2.5 cm apart from the injection site of PCV
6	DPT-Hib-Hep B	Diphtheria, Pertussis, Meningitis and pneumonia associated with <i>Hemophilus influenzae bacteria</i> and Liver disease due to Hepatitis B virus	Weeks 6, 10 and 14	IM, left anterolateral thigh
7	Measles containing vaccine	MCV	9 and 15 months	Subcutaneous (SC), left deltoid
8	Rota virus vaccine	Rota virus associated gastro-enteritis	Weeks 6 and 10	Oral only
9	HPV Vaccine	Human papilloma virus associated with cervical cancer and anogenital wart	14 years old girls and after 6 months of 1 st dose	IM, left deltoid muscle of upper arm
10	Td	Maternal & Neonatal Tetanus & Diphtheria	Td1 at first contact, Td2 4 weeks later, Td3 6 months after Td2, Td4 1 year after Td3, Td5 1 Year after Td4	IM, right deltoid Muscle

14.2. Tetanus (Td) immunization schedule for women of childbearing age (15–49 years)

Five doses of Td immunization for women of childbearing age is the recommended schedule to have adequate protection against neonatal tetanus. Table 3 shows the schedule and expected duration of protection for women of childbearing age.

For practical purpose, a child is said to be protected at birth (PAB) or a child is said to

be protected against neonatal tetanus if the mother received two doses of Td at least 4 weeks apart during the last pregnancy (assuming the last pregnancy was less than 3 years) or if she received at least three doses in the past.

Only well documented immunizations should be counted. If in doubt, give an extra dose. As the risk for adverse reaction is negligible, there is no contraindication to the administration of Td.

Table 3: schedule and expected duration of protection for women of childbearing age, in the routine immunization

Dose	Schedule	Expected Duration of Protection
Td-1	At first contact of childbearing age or as early as possible in pregnancy	None
Td-2	At least 4 weeks after Td-1	1-3 years
Td-3	At least 6 months after Td-2	5 years
Td-4	At least one year after Td-3	10 years
Td-5	At least one year after Td-4	All childbearing years

Schedule of school-based Td in primary school

Tetanus/diphtheria(Td)vaccine implementation in school immunization programs in all regions with School Enrolment Rate more than (70%) is recommended to provide at least two doses. Additional days can be used to reach out of school children following the school vaccination days or to reach out of school children in parallel with school vaccination days.

14.3. HPV vaccination for girls

The national EPI guideline targeting for HPV vaccination is girls of (9-14) years old. The immunization schedule consists of two doses. The recommended vaccination schedule is first dose at 1st contact and the second dose at (6) months after the first dose (defined as after 180 days from the first dose). Girls who are absent on the day of vaccination at a school or out of schoolgirls will be given a referral slip to go to the nearest health facility or outreach services

provided by the health facility to receive the vaccine doses. Girls who received the first dose but missed for the second dose should be given the missed dose at the earliest opportunity. 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 given 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 during immunization sessions, including outreach. The vaccination cards shall be retained at school until the immunization schedule is completed. The teachers will use the cards to remind the girls for the next dose and to track defaulters. Once a girl has received the two 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 after the 1st dose, or HFs where they were vaccinated and the provider will need to ensure that eligible girls completed the vaccination schedule.

15. Conditions and contraindications to immunization

It is recommended that health workers should use every opportunity to vaccinate eligible children and avoid unnecessary contraindications. Based on numerous studies on this issue, the WHO confirms that there are only a few absolute or true contraindications to the vaccines.

Contraindications to Vaccinations

- Persons with a history of anaphylactic reactions (e.g., difficulty in breathing, swelling of the mouth and throat, hypotension or shock) following egg ingestion should not receive yellow fever and influenza vaccines).
- Children with HIV infection/AIDS should not be immunized with yellow fever and BCG vaccine.
- Children who are HIV-infected when vaccinated with BCG at birth are at increased risk of developing disseminated BCG disease. However, if HIV-infected individuals including children who are receiving ART, are clinically well and are immunologically stable (CD4% >25% for children aged under 5 years) they should be vaccinated with BCG. (BCG vaccines: WHO position paper – February 2018)
- A severe adverse event following a dose of vaccine (anaphylactic reaction) is a true contraindication to a subsequent dose of the same vaccine. A second or third dose of vaccine (e.g. Penta injection) should not be given to a child who has suffered severe anaphylactic reaction to the previous dose.

In a child with acute febrile illness with fever of 38.5°C or above is a relative contraindication in which case the child should be managed for the illness and get the vaccine upon improvement.

The risk of delaying an immunization because of a mild illness is that the child may not return, and the opportunity is lost. Missed immunization opportunities because of false contraindications are the major cause of delay in completing the schedule or of no immunization at all. Children with serious illness should be vaccinated as soon as their general condition improves and at least before discharge from hospital.

Premature babies should be vaccinated on discharge. It is particularly important to immunize children suffering from malnutrition. Low-grade fever, mild respiratory infection and other minor illnesses should not be considered as contraindications to immunization.

Conditions that are NOT contraindicated to immunization

- Minor illnesses such as upper respiratory infections or diarrhea with fever <38.5oC
- Allergy, asthma, hay fever or snuffles
- Prematurity or low-birth-weight infants
- Malnutrition
- Child being breastfed
- Family history of convulsions
- Treatment with antibiotics, low-dose corticosteroids, or locally acting steroids (e.g. topical or inhaled)
- Dermatoses, eczema, or localized skin infections
- Chronic diseases of the heart, lung, kidney, and liver
- Stable neurological conditions such as cerebral palsy and Down's syndrome
- History of jaundice after birth

16. Modalities of Immunization Service Delivery

The common delivery strategies are static, outreach and mobile strategies.

Fixed (static) strategy is the regular daily delivery of vaccinations in a health facility or in the compound of health facility on specified days of the week and hours of the day that are consistent and regularly communicated

to the community. It regularly provides routine immunization services to communities that are located near the health facility.

Outreach strategy is the delivery of services to people who cannot go to health facilities or who can do so only with difficulty. This usually covers settlements that are more than (5 km) away, but less than (10 km) from the health facility. Trips to the outreach sites are usually completed within a day and are made by health facility staff on foot or using motorized vehicles, bicycles, or pack animals.

Mobile strategy takes more than one day to several days by health workers to deliver services to people living in remote areas which are not covered by health facilities. Mobile teams may spend several days travelling to reach the community and can cover several settlements in one trip.

Immunization services should be regularly available on daily basis in all health facilities, government, NGOs or private facilities with functional vaccine refrigerator and trained health care workers. Mobile services are appropriate for pastoralist and hard to reach areas. It is important to establish and maintain regular outreach sites in hard to reach areas. The mobile strategy is scheduled at least quarterly to complete the (4) doses of scheduled vaccines before (1) year of age. Immunization status of all children and women in childbearing age should be screened or assessed at every contact with health service and appropriate antigens should be given.

17. Vaccine Supply, cold chain and quality control

The Ministry of Health mobilizes resources needed for vaccines, supplies, CCE procurement and ensure availability of potent vaccines at all levels. The Ethiopian Food and Drug Authority (FDA) will oversee the licensing of WHO prequalified vaccines and vaccine safety issues. The regulatory body also monitor any adverse effects following immunization and take the necessary actions in coordination with the ministry and other stakeholders.

The Ethiopian Pharmaceutical and Supply Agency (EPSA) manage and distribute vaccines and related supplies. MOH and EPSA quantify and estimate the needed vaccines, procure and distribute for health facilities by ensuring the quality of the vaccines and practice bundling where applicable. The MOH and stakeholders are responsible for monitoring and ensuring sustainable availability of vaccine and supplies in all health facilities.

All health facilities and stores handling the vaccines need to monitor and record the temperature of the vaccines in the cold chain at least twice daily including weekend and holidays for timely action. All institutions and health facilities handling EPI services should use standard refrigerators (WHO PQS prequalified) to store the vaccines. Continuous temperature monitoring devices such as the fridge tags, RTMDs and others must be utilized to monitor the integrity of cold chain during the storage and the transportation at all levels.

Freeze sensitive vaccines such as Hep B, DPT, and Td should not be frozen. If there is a suspect of freezing, shake test shall be conducted as per the standard protocol and decide whether

to use the vaccines or not. All vaccines should be stored and handled between (+2 to +8oC) at public or private facilities. OPV vaccine shall be stored between (-15 to -25oC) at national and subnational levels. BCG, and measles are light sensitive vaccines and required to store appropriately between and during the immunization sessions.

All institutions and health facilities that provide EPI services should have annual as well as quarterly forecast and annually and quarterly updated micro plan.

a. Use of opened vial of vaccines in subsequent immunization sessions

Multi-dose Open Vial Policy is applicable in the Ethiopian context. Opened vials of Td, OPV, IPV and PCV13 vaccines can be used in subsequent immunization sessions until the vaccines in the vials are fully used and the following conditions are met:

- The expiry date has not passed
- The vaccines are stored under appropriate cold chain conditions
- The vaccines vial monitor (VVM) has not been submerged in water
- The VVM, if attached, has not reached its discard point
- Aseptic technique followed
- The date on which the vaccine is opened is clearly labelled

All opened vials of vaccines that have been taken to outreach, mobile team or in a fixed facility should be stored in the refrigerator under appropriate temperature and used first on the following vaccination sessions.

Opened vials of measles, BCG, PCV13, yellow fever and meningococcal vaccines must be discarded (6) hours after reconstitution or at the end of each immunization session whichever comes first.

b. Safe injection and infection prevention in immunization

Since 2002, injectable vaccines are delivered with bundled auto disabled (AD) syringes and needles. Immunization sessions are safe when the correct vaccines are administered with AD syringes. Disposable syringes are not recommended for EPI.

- Vaccines that need reconstitution should be reconstituted with diluents from the same manufacturer.
- Single reconstitution syringe should be used for a single use and be used only for one vial of the vaccine.
- Use only auto disable (AD) syringe or RUP (reuse prevention) syringes with needle.
- All used syringes and needles should NOT be re-capped; must be collected in safety boxes and dispose following the appropriate procedures of waste disposal.

18. Capacity building for EPI

It is required to have trained providers and coordinators who are assigned and able to run the EPI program at the health facility as well as different administrative levels. Standardized national training manuals and job aids should be availed. Periodic needs-based trainings should also be implemented accordingly for all program level on IIP, MLM, IRT, VMA, CCE Technician.

Training in EPI

Conduct pre-service and in-service trainings for those assigned for the EPI Program; pre-service trainings for the relevant health workers in health training schools, universities, and colleges; and regular integrated refreshing training (IRT) for Health Extension Workers.

- Conduct Mid-Level Management (MLM) training to all mid-level managers.
- Train health care providers at the health facility level on Immunization in Practice (IIP).
- Provide training for cold chain users and cold chain technicians.
- Training on other relevant topics which are related to EPI program and services.

Supervision

Checklists based supportive supervision should be arranged for health facilities and vaccine storage facilities for regular monitoring and corrective actions. Health care workers and mid-level managers need to get hands on coaching by experienced officers from higher administrative level, colleagues, and partner organizations such as RHB, ZHD, WHO and partners at service delivery points. Troubleshooting and target disease surveillance will be integrated into the existing EPI program through regular supervision and mentoring activities.

Review meetings

EPI review meetings should be conducted regularly at different administrative levels with key actors and partners to review the performance progress, to identify challenges

and opportunities, to celebrate success, to document good practices and to develop and share action plans for subsequent implementation periods. Review meeting will be coordinated by respective MOH, RHB, ZHD, sub-cities, woreda health office and partner organizations.

19. Monitoring and evaluation of routine immunization

Immunization coverage should be monitored and analyzed in order to identify areas with low coverage or high dropouts and to take actions as appropriate. Availability of recording and reporting tools including tally sheets should be ensured in health facilities at Woreda and Regional levels for at least five years. Data should be analyzed at all levels and utilized for decision making. Proper recording, timely reporting and record keeping are prerequisites for monitoring and evaluation of the program.

Routine immunization recording and reporting system

Vaccination recording and reporting forms including vaccination cards, forms for AEFI, vaccine request form and vaccine stock ledger book require periodic update particularly when new vaccine introduction and/or switch of an antigen is made. The reporting process includes aggregate immunization coverage data from the vaccination site upwards. All facilities providing routine immunization should maintain an immunization record register as per the format recommended by Ministry of Health (DHIS2, CHIS) and should submit monthly report to the next level.

The main recording tools that each health facility uses are,

Immunization Register: Any child who received vaccination should be registered and all information including name, sex, age, type of vaccine received etc. should be completed.

Child Immunization Card: Maternal and child's health (health passport) immunization card is a document that reflects child's immunization status and it can be a separate document or part of a general child health record (family folder). Each child should have an immunization card. The immunization card should reflect the national immunization schedule with the child's immunization history and status which are correctly marked. The immunization card should be kept by the child's parents/guardian.

Tally sheets: Tally sheets are the forms on which health care workers make a mark every time a dose of vaccine is administered. Tally sheets are useful for survey and reporting purposes. A new tally sheet should be used for each vaccination session. Information obtained will be utilized for monitoring the vaccination performance and prepare a monthly report.

Vaccine and cold chain monitoring:

Administration of potent vaccines relies on the thermoregulation of the vaccines by keeping the cold chain system is well functioning. All vaccines are heat sensitive and most are freeze sensitive. Utilizing the new technologies or tools for the cold chain monitoring such as fridge tag, thermometers and others are crucial. Health facilities and storage sites should measure the temperature of the cold rooms, refrigerators, and other storages twice per day and keep track of the record and report accordingly to the higher

level. Immediate responses need to be taken for the timely identification of any abnormal temperature ranges.

Vaccination Adverse Events reporting form:

An adverse event following immunization (AEFI) is any untoward medical occurrence, which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease. Common events are to be expected (usually within one month of immunization) and health professionals should advise parents on the likely consequences of vaccination and how to deal with them during each visit. AEFI events that must be reported by using standard reporting format include,

- All cases of anaphylactic shock after vaccination,
- All injection site abscesses,
- All severe or unusual medical events thought to be related to immunization, and
- All deaths thought to be related to immunization.

WHO's guiding principles for immunization activities during the COVID-19 pandemic

“Do-no-harm and limit transmission of COVID-19 while providing immunization activities”

“Immunization services should be maintained for the prevention of VPDs even in the COVID-19 situation”

Measures that should be taken to minimize the COVID-19 virus transmission during immunization sessions are to,

- Conduct vaccination sessions in well-ventilated areas and disinfect the areas often,
- Ensure hand washing units (water and soap) are available for mothers at the entrance to EPI room,
- Post information about COVID-19 prevention at vaccination waiting area which illustrates
 - correct hand washing techniques
 - physical distancing at all time (two meters apart) and
 - what to do during sneezing or coughing,
- Use outdoor spaces for immunization service if vaccination room is not wide enough or with poor ventilation, and
- Separate immunization services and waiting areas from the curative services.

Guidance for immunization providers

- Perform hand hygiene frequently.
- Wash your hands before performing any clean or aseptic procedure.
- Sanitize your hands every time after you vaccinate a child.
- Wash your hands frequently with water and soap during vaccination service provision.
- Avoid touching your eyes, nose, and mouth.
- Practice respiratory hygiene by coughing or sneezing into a bent elbow or tissue and then immediately disposing of the tissue into safety box.
- If you are experiencing symptoms, such as cough or fever, you should self-isolate, contact your medical provider, and not be working.

20. Surveys

National EPI coverage surveys should be conducted every two to three years to see the broader status of vaccination for the tracer vaccines as well as validating the reporting of administrative data. When survey results do not validate the administrative rates, efforts need to be made to improve administrative coverage reporting. Post introduction evaluation should be completed after six to twelve months for every new vaccine introduced. In the future, the role and contribution of PHF in RI will be evaluated in terms of contribution in coverage, quality and negative impacts ensured to enhance their competencies and improvement.

21. Immunization Guideline specific to Private Health Facilities performing the service

21.1. Introduction

The challenge of national Immunization program is to achieve the goal of high vaccination coverage, quality of services towards standardization and reducing equity gaps, often in resource-constrained settings.

To optimize effective vaccination services, engagement of private sector, is a means to improve the program and increase access and quality coverage for immunization services, but only if the roles are clearly defined and the services are collaborative with the existing public health system and standards.

Strong immunization systems that are an integral part of a well-functioning health system) is critical to ensure coordination between the public nonprofit organization and

private sectors. Accessing vaccination services and ensuring the quality of vaccination services in both the public and private sectors need to be coordinated to achieve the desired objectives of morbidity and mortality reduction of VPDs.

In countries where there is both public and private immunization service delivery, there is often variation in coverage, quality and accessibility of providers unless equally coordinated and treated by similar guidelines, rules and regulations

The role of the private sector contribution to coverage, service quality, disease and adverse events following immunization (AEFI) surveillance, and its engagement with national immunization program varies within and between regions and remains poorly understood in Ethiopia. This applies not only to the direct contribution of the private sector to the delivery of vaccines and the provision of health care, but also to the interaction between sectors, its impact on equity of services, level of monitoring, and degree of regulations on private providers need to be assessed and standardized. In this case, section 2 of the EPI policy is intended to be used as a guideline for the public private partnership in immunization program in addition to the general guideline incorporated with the public sector in section one.

21.2. Private Health facilities engagement and guiding principles

The Public Private Partnership in Health (PPPH) is an element in the Health Sector Transformation Strategic Plan (HSTP) and comprehensive multi-year plan (cMYP). The private sector is comprising all health care providers who are outside of the public health sector, whether their aim is “private not for

profit” or “private for profit”. There is a need to further provision of guidance and financing of health services outside of the public health sector to engage them to contribute to the national immunization service delivery.

The national EPI guideline can serve as tool to govern both the public and private sectors/ health facilities providing immunization services. However, some distinct issues need to be separately addressed for the private sector as stated below.

21.3. Strategies of immunization service

Based on the national EPI guideline, private health facilities can voluntarily provide immunization services. All vaccines are provided according to the national immunization schedule and delivery by fixed strategy at the health facilities. PHFs should be using appropriate cold chain equipment, recording, and reporting tools and skilled health personnel trained on EPI.

21.4. National EPI Program Schedule

The national schedule for EPI targeted diseases remains the same for both public and Private sector. The private providers therefore should follow the national policy guideline strictly. (see the section 16)

21.5. Cold chain equipment

Using non-standard cold chain equipment (refrigerators, freezers, and passive containers, etc.) will affect quality/potency of the vaccines. Therefore, private health facilities should also be equipped with WHO-prequalified cold chain equipment (refrigerators, vaccine carriers/ cold boxes, etc.) with standby generator as a prerequisite to provide immunization services.

21.6. Vaccine management and wastage monitoring

Vaccines are very expensive and precious supplies which requires strong management and monitoring. Therefore, private health facilities should train their staff on vaccine management, standard tools for requesting, recording, and reporting on vaccine consumptions, and vaccine wastage monitoring.

21.7. Supervision and Capacity Building

Enhancing professional knowledge and skills through regular mentoring or supervision, training and competency exams ensures accurate knowledge and skill transfer directly impacts the success of immunization program and particularly the quality of the vaccination program.

Vaccines are administered to healthy eligible individuals (infants/children/girls/women) and need to be provided with maximum precautions without any danger or harm. Single mistake/ error may affect the lives of people and the whole immunization program. Therefore, private health facilities should assign skilled staff on injection techniques, such as for BCG vaccine, interpersonal communications (IPC) skills, cold chain and vaccine management, recording and reporting of immunization data, monitoring performance and management of AEFI to be able to provide quality vaccination services. The Immunization staff can be trained in coordination with respective government health sector and EPI partners through the supportive supervision and/or by organizing in-service training sessions. Skilled staff turnover and assigning trained staff at different service unit in rotation will compromise the quality of immunization services. Thus, managers of the

private health facilities should give due attention to prevent and minimize those challenges.

21.8. Immunization Communication activities

Health workers serve as an important source of information for parents and communities on immunization services. A health worker's perception of and communication about effectiveness and safety of the vaccines are important in encouraging parents/caregivers/communities to seek vaccination for children and women. If a provider, private or public, is unable to communicate effectively on the need/benefits of vaccination, it will likely have a negative impact on vaccine uptake and will contribute to a loss of public confidence and possible vaccine hesitancy. It has been noted that there is insufficient knowledge among private providers including administration of multiple vaccines in one visit and hesitancy is the highest around the new vaccines.

Vaccinators should pass the following key messages to parents/caregivers during each visit,

- Advice on what is given (vaccine) including type of vaccine and what disease/s it prevents
- Alert on possible side effects and how to respond
- Arrange for when to return (to complete the follow-up doses and provide information on place and date for the next visit to reduce DOR)
- Request to keep the health card/vaccination card in a secure place

21.9. Safe injection

Private health facilities should follow standard injection safety rules such as use of safety boxes, standard waste disposal system, and

AEFI monitoring mechanism, just like in the public health sectors, to provide immunization services.

21.10. Service Charge

The vaccines under the routine immunization program, AD syringes and reconstitution syringes are supplied free of charge by the government to the private health facilities. Private health facilities are expected to charge the minimum amount of service fee based on an agreed estimated cost.

21.11. Recording, reporting, and monitoring of immunization services

It is important to utilize immunization data for planning and monitoring of immunization services specifically for forecasting and procuring the vaccines and supplies in the right amount. Capturing of vaccination data from all health facilities (public and private) is crucial. Therefore, private health facilities should submit their vaccination data to respective government health institutions on a regular basis by applying the standard templates and timeframes developed by the government.

21.12. Documentation and Reporting immunization data

Immunization data should be collected by using the standard reporting formats then consolidated into a summary report with data from the health facilities every month. At each level, data should be analyzed and utilized to improve the immunization services. Responsible person for reporting should ensure that the prepared reports are complete, timely and accurate as well as they are in consistent with the facilities EPI register, tally sheet and public HFs data.

21.13. Capacity building or training of immunization focal persons for PHF

Enhancing professional knowledge and skills through trainings and competency exams ensure accurate knowledge transfer and it will directly contribute to the success of immunization program including the quality of the vaccination services, monitoring as well as AEFI and disease surveillance. All vaccinators, whether in public or private HFs, should undergo standard EPI training using standard national EPI training manuals and modules. Assigning the trained EPI staff enables the immunization delivery with safe and appropriate use of injections, proper vaccines storage and handling, screening for contraindications, proper recording and reporting, proper interpersonal communication, and safety surveillance.

21.14. EPI Coordination

The MOH/MCH Directorate is the overall coordinating body for the EPI activities at all administrative structural levels and coordinates ICC efforts towards common national goals and targets. MOH/MCH Directorate also provides technical and financial support to the regions and ensures updating EPI implementation guideline, standardization of training manuals, job aids, IEC materials and any related supplies. Monitoring, supervision and program reviews will be coordinated through the Directorate. Regional Health Bureaus (RHB) will also provide similar supports to the lower administration levels and health facilities.

Engaging private providers, PHF associations, and professional associations; supporting professional development; organizing immunization forums; and creating health-

information communication linkages can strengthen and support the collaborative relationship and build understanding between the two sectors.

21.15. Immunization Financing for PHF

Vaccines and injection materials in the national immunization program are provided to private HFs free of charge by the MOH. Private health facilities should cover their costs related to the immunization services (such as staff training, transportation, salary etc., except vaccines and injection materials).

21.16. Private health facilities linkage with respective government health sectors

Even though private health facilities are providing the immunization services voluntarily, they should provide the services based on the government national EPI policy and WHO standards. Roles and responsibilities of the government health sector and private health sectors are summarized below.

21.16.1. Roles and responsibilities of the government health sector (MOH/RHB/ZHO/Sub-city/Woreda HO/PHCU)

- All levels of the MOH be willing to coordinate and collaborate with the private sector through the Public-Private Partnership
- Develop and provide the national immunization policy guidelines and monitor the adherence by the public and the private HFs
- Provide vaccines, AD syringes and reconstitution syringes, etc. which are necessary to run routine immunization services with free of charge

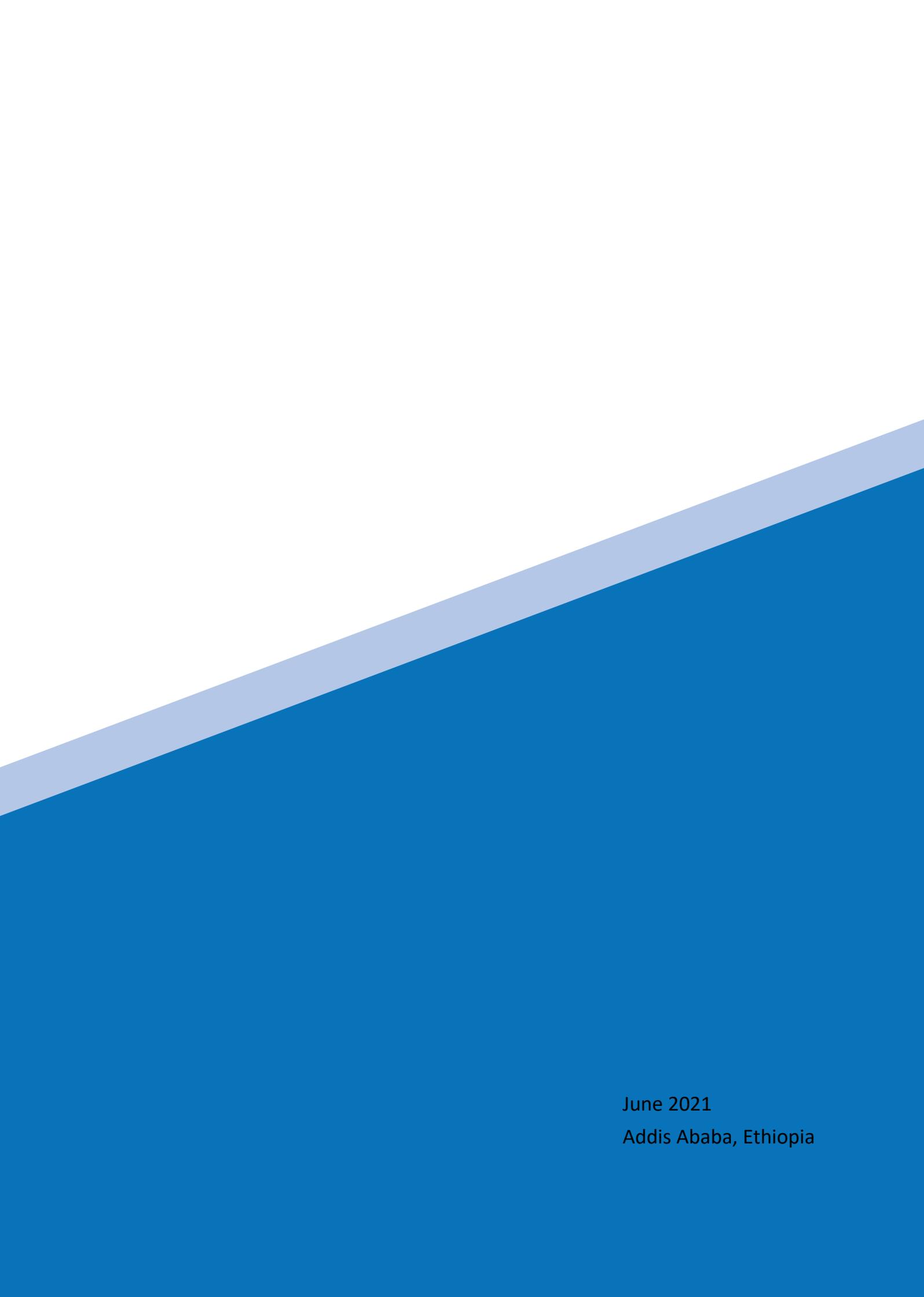
- Make sure the availability of the standard EPI monitoring tools such as EPI registers, tally sheets, vaccine ledger book, reporting formats, job aids, guidelines, temperature recording pad, feedback books, file folders, etc. with specifications for standard documentation
- Provide information on new vaccine introduction and other immunization related updates on regular basis
- Monitor and evaluate the EPI activities which are carried out accordance with the national standards
- Conduct supportive supervision and give feedback (written and/or oral)
- Provide technical support on capacity building activities for public and private health facilities staff who are working on immunization services based on the gaps identified during supportive supervision
- Provide opportunities of in-service capacity building for health workers who oversee EPI service delivery in private health facilities as needed
- Ensure private health facilities are providing EPI services in accordance with the national schedules, quality, practices, and compliant with vaccine management standards
- Discuss on the PHF service payment issues (free or charging) to reach the consensus
- Provide standard EPI equipment through public-private partnership or setting procurement norms
- Assess and supervise the current status and role of private sector EPI service delivery
- Submit a formal request and obtain the permission from respective RHB to provide immunization services
- Collaborate with the public sector at all levels in all issues related to EPI services through Public-Private Partnership health policy
- Maintain the minimum infrastructure and human resource requirements for the delivery of immunization services and provide these services as per the national EPI implementation guideline
- Ensure timely request and collection of required supplies/logistics to maintain minimum stocks availability and prevents intermittent supply stock out as per EPI implementation guideline
- Adhere to the national recording, information and data documentation and compilation of timely report on EPI data, as per the standard reporting requirement, to the relevant government health authority (RHB)
- Since immunization is free of charge in Ethiopia, agree to provide EPI services with minimum cost (service fee) that will not be a barrier for the caregivers to return multiple times to complete the immunization schedules
- Receive guidelines, technical assistance, training, and supportive supervision from the RHB and its structure or from a partner delegated by the RHB to execute the EPI services as per the standard
- Agree to assign dedicated, trained, and skilled individual working on immunization. The skill required will be on injection technique, vaccine management, interpersonal communication skills, recording, reporting immunization data, and monitoring performance of the immunization services

21.16.2. Roles and responsibilities of private health facilities delivering RI

- PHFs should ensure that the EPI services are run by trained HCW and should request the relevant section of the MOH to train their EPI staff when their trained staff leave the EPI unit or the facility for any reason
- Avail the EPI standard or WHO prequalified dedicated vaccine refrigerators and vaccine carriers for vaccine storage and transportation which are prerequisite to run the EPI program
- Monitor vaccine supply for proper utilization so that vaccine wastage is kept at the optimum as per the country's and WHO's standards

21.16.3. Prerequisite for immunization services provision by PHF

- PHF should request the relevant unit of MOH/RHB to assess if the requirements are fulfilled to deliver EPI services and secure permission. If PHF did not have the right set up and standards, the MOH will provide support to the PHF to fulfil the gaps for the next evaluation and permission.
- MOH and PHF providing immunization services should sign an MOU for accountability purpose
- The private sector granted to provide the EPI services should include private for profit hospitals, MCH and pediatric specialty clinics and private not for profit NGO clinics fulfilling all the standard prerequisites to deliver EPI services with an optimal quality which will contribute to the EPI coverage and equity
- The clinic should have a standard WHO prequalified refrigerator and vaccine carriers for vaccine storage and transportation which can be supplied by the MOH or facilitated by the MOH for private HFs to procure the standard cold chain equipment
- The PHF should commit in provision of the immunization services with free of charge or the minimum amount of service fee which is set by the relevant unit of the MOH to avoid vaccine drop-out/defaulters caused by service charge
- The PHF should commit to respect the national immunization policies on delivery of the EPI services (follow the national immunization guidelines)
- PHF should be monitored by the relevant MOH/RHB supervisors/evaluators on the requirements before commencing the delivery of EPI services
- PHF should have an appropriate waste disposal system such as safety boxes and incinerators for injection wastes disposal



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