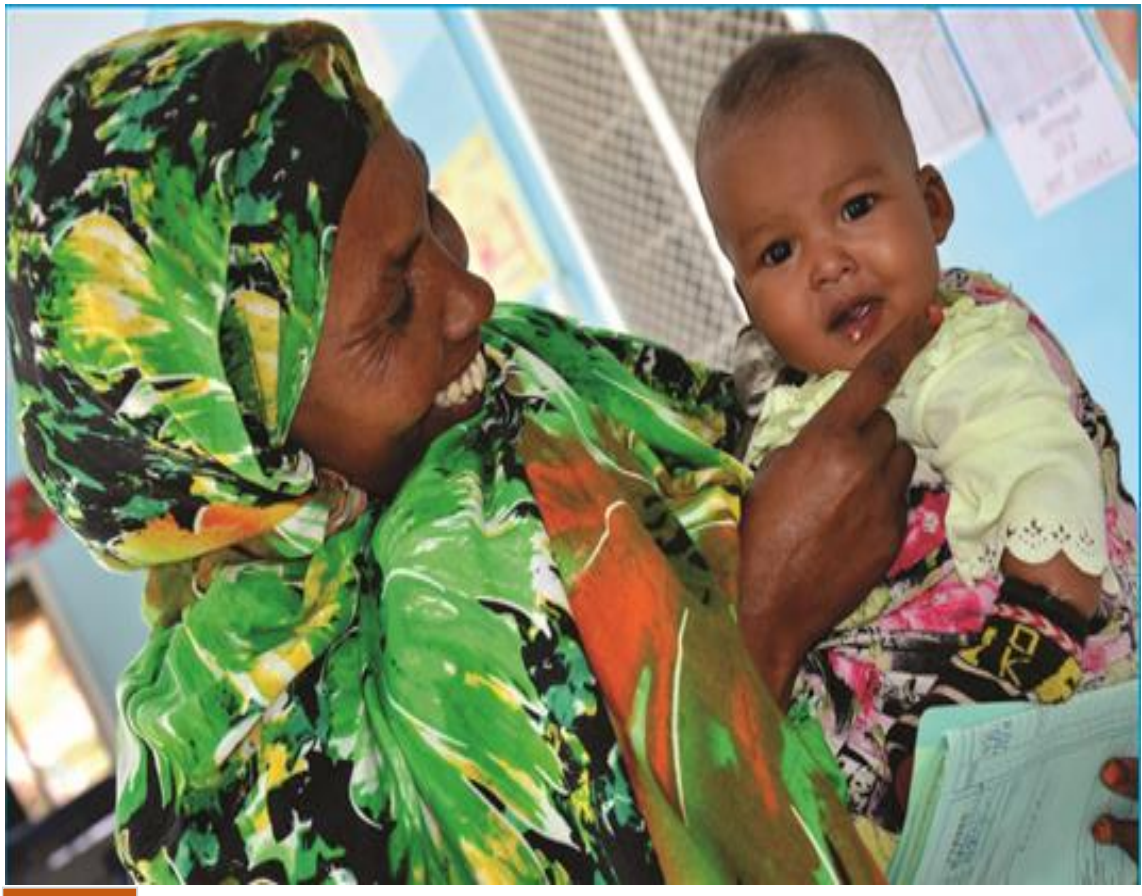
Somali Federal Republic
Ministry of Health & Human Services

SOMALIA IMMUNIZATION POLICY



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Acronyms

AD	Auto-disable syringes
AEFI	Adverse Events Following Immunizations
AFP	Acute Flaccid Paralysis
BCG	Bacillus Calmette–Guérin
CBOs	Community Based Organizations
cMYP	comprehensive Multi-Year-Plan
CCT	Country Cold Chain Team
CHD	Child Health Days
CHW	Community Health Worker
CSOs	Civil Society Organizations
DPT	Diphtheria Pertussis Tetanus
DPT-HepB-Hib	Diphtheria, Pertussis, Tetanus, Hepatitis B & Haemophilus Influenza type b vaccine
EPHS	Essential Package of Health Services
EPI	Expanded Program on Immunization
EVM	Effective Vaccine Management
FHW	Female Health Workers
GAVI	Global Alliance for Vaccines and Immunization
GVAP	Global Vaccine Action Plan
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
HiAP	Health-in All-Policies
HMIS	Health Management Information System
ICC	Inter-agency Coordination Committee
IEC	Information Education and Communication
ILRs	Ice lined Refrigerators
IPV	Inactivated Polio Vaccine (Check the statement in the policy)
JRF	Joint Reporting Format (UNICEF/WHO)
MCH	Maternal and Child Health
MCH/OPDs	Maternal and Child Health/ Out Patient Department
MDG	Millennium Development Goal
MNT	Maternal and Neonatal Tetanus
MOH	Ministry of Health
NGOs	Non-Governmental Organizations
NID	National Immunization Days
NITAG	National Immunization Technical Advisory Group
NRA	National Regulatory Authority
OPV	Oral Polio Vaccine
PHC	Primary Health Care
REC	Reaching Every Child
RED	Reaching Every District
RMNCH	Reproductive, Maternal, Neonatal and Child health
SDGs	Sustainable Development Goals
SIA	Supplemental Immunization Activity
SMA	Somali Medical association
SWOC	Strengths, weaknesses, opportunities and challenges
Td	Tetanus and diphtheria
UHC	Universal Health Coverage
UNDP	United Nations Development Program
UNICEF	United Nations Children's Fund
VPD	Vaccine Preventable Diseases
VVM	Vaccine Vial Monitor
WCBA	Women of Child bearing Age
WHO	World Health Organization

Forward

Pursuant to the over-arching reforms in the health sector, the Federal Ministry of Health (FMOH) has laid out its strategic directions and road map towards the achievement for Universal Health Coverage by 2030 in terms of policy formulation, good governance, strategies and plans, and implementation put in place an effective monitoring and evaluation of health programs. The maternal, neonatal, and child health is placed at the top of the national health agenda and the Somali government is a key partner with all Global Health Initiatives (GHI) and has endorsed the strategy of Global Alliance for Vaccines and Immunization (Gavi), the Global Vaccine Action plan (GVAP), and most recently the Global Financing Facility (GFF) for the Reproductive, Maternal, Newborn, Child and Adolescent Health (RMNCAH).

The Government of Somalia recognizes the importance of immunization as the most cost-effective life-saving public health intervention in the Essential Package of Health services (EPHS) and, as such, has always been at the forefront to reach its people with equitable immunization services. The FMOH strongly believes that investing in immunization services throughout the country is investing the future of the nation. However, it underscores that EPI program will only achieve its objectives through a well-functioning health system. Thus, the FMOH policy is dedicated to immediately deploy two-pronged strategy, the first of which is addressing the vaccination activities and the second is about strengthening the national health system.

The country ratified the Universal Declaration of the Convention of Children's Right and is guided by the principles and values enshrined in the convention. Somalia has until now, followed an outdated national immunization policy that had been in place for more than 30 years. With the evolving immunization and vaccines technology and with the introduction of DPT-Hep B+Hib Pentavalent vaccine, and a future plan of subsequent introduction of other new and under-used vaccines, there was a pressing need to develop an updated policy that provides viable strategic directions for improving and scaling up national efforts towards the universal health coverage goal (UHC2030).

The new policy highlights the partnership goal of the SDGs. It reiterates the leadership's commitment to the principles of aid-effectiveness, and, it underlines the importance of ownership by the government. In a nutshell, the Somali government believes that ownership without delivering should not be the case whatsoever, but it should be measured only against concrete EPI outcomes. The policy urges that the minimum acceptable vaccination coverage throughout the country should be at least 90% of infants receiving all vaccines in the EPI schedule before age of 1 year and 80% of pregnant women receive minimum 2 doses of TT at least one month before delivery.

On behalf of the Federal Ministry o Health of Somalia, I take this opportunity to reaffirm the full support of the government to further strengthen the delivery capacity of the health sector in scaling up the immunization services across the country. The FMOH has already taken concrete steps in supporting the health sector decentralization process with the focus on stewardship, governance, human resources development and financing. Every effort will be made to strengthen the State's planning process, implementation, capacity development, supervision and logistic support with regards to vaccination activities.

I take this opportunity to express my sincere thanks to our partners who have been with us all the time to finally embark on a new platform for the benefit of our women and children. My special thanks goes to those who were involved in developing this policy that will consolidate all our efforts and will undoubtedly help all partners to streamline their activities so as to ensure the attainment of this policy's overarching goal which calls "leaving no one behind".

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Acknowledgement

This National Immunization Policy is the result of a long process of intensive consultations, teamwork, detailed studies and information gathering.

The Ministry of Health and Human Service spearheaded the drafting of the National policy guidelines to its conclusion through the Expanded Program on Immunization (EPI) unit, and sincerely appreciates the financial and technical support provided by the World Health Organization, United Nations Children's Fund- UNICEF

The Ministry of Health and Human Service also thanks the Global Alliance for Vaccines and Immunization (GAVI) and all the members of the Technical Working Group that were tasked to steer the process of developing these policy guidelines.

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1. Background and Introduction

The Health Sector of Somalia has been in transition moving from emergency through rehabilitation to a fully-fledged development of the health system. Given the political developments during the last decade, the national and international efforts had collectively made significant progress in scaling up their commitments through enhanced collaboration and ensuring programmatic responses. Following this, the health sector was among the first sectors which have made major strides in developing robust polices and medium-term strategic plans.

The service delivery framework, commonly known as the essential package of health services (EPHS) has been a major milestone, not only in delivering basic services but it has turned out to be a far-reaching tool for unifying partners to stand behind one strategy, for better resource allocation and use, for improving quality and equity, and for monitoring program performance.

The health sector profile of the country is shaped by a combination of certain strengths, weaknesses, opportunities and challenges. The key strengths include: the health system thinking at policy-making level; the continuous expansion in service delivery; the existing health sector strategies and plans; the shifting of available resources from emergency to system development; the defined essential health packages; and the donor's alignment around the national health policy; and the increasing role of the Diaspora. Among the weaknesses documented include: fragmentation of health system functions; chronic under-funding of the health sector, poor health infrastructure in many districts; shortage of qualified health workers in remote districts; weak institutional capacities (MOH) in many States, scarcity of data; and unregulated private sector.

The challenges include: meager resources for the public health sector; poor health service infrastructure mainly in the 4 recently established federal member states; unpredictable external aid to the health sector; loss of human capital; poor access to health care by the rural and nomadic populations; inaccessibility to insecure areas; unhealthy lifestyle and harmful practices; and major determinants of health such as unplanned urbanization and deteriorating environmental factors.

However, many opportunities are out there that requires to be thoroughly examined. Among others, the on-going political developments and increased stability in most of the regions in south and south west of the country, the growing pre-service training institutions, the improved communication and increasing penetration of mobile phones in the country, the return of Diaspora health professionals, and the increasing role of civil society organizations in health sector are all encouraging signs for embarking on a far-reaching health sector reform.

The country has fallen short in achieving the MDGs health-related goals. Infant and under five mortality rates remain abysmally high, and the maternal mortality is among the one worst in the world. A critical shortage of health workforce coupled with continuous challenges of recruiting new professionals at all levels remain a daunting challenge for the health sector.

Emergency-oriented and humanitarian activities still play a major role in the health sector, and the burden of 2.6 million of internally displaced persons remains an overwhelming task for the health sector and its partners especially in the South. Successive outbreaks of vaccine preventable diseases such as measles have claimed significant number of children under five years of age and still remain a major public health threat in this country. Without strong and effective routine EPI program, the national efforts towards polio eradication will also be in jeopardy. Moreover, an uncontrollable and open border poses a serious threat to the polio endgame plan.

The EPI is a priority program which has relatively been successful especially in most parts of the country; nonetheless, the overall immunization coverage in Somalia has been unacceptably low. As compared to other public health programs, the EPI program is by far well-funded and has relatively adequate resources, both material and manpower but in reality it has not been able to translate this opportunity into acceptable gains.

Only one reason might be accepted without further argument for not performing well but largely there are unknown factors that are responsible for the poor EPI program performance throughout the country. Needless to say that security remains the main culprit in many districts of the federal member states of Galmudug, Hirshabelle, South-west and Jubbland and therefore lack of access to these areas is considered as the key factor behind the missing children.

In light of the current situation, a pathfinder EPI policy with new strategic directions, and well-articulated action points that enjoys the full support of all stakeholders is being launched. The policy is based on lessons from past experiences; the overall context of the country, on profound SWOT analysis, and on the development of innovative approaches intended to effectively address the immunization program gaps and challenges. This policy highlights the guiding principles and values of the development process, it outlines the health care delivery model- the EPHS through which EPI is being delivered, and more importantly, it outlines the core strategic directions for translating the policy objectives into activities and outcomes.

2. The Scope:

The EPI policy operates within the framework of the national health policy, and is delineated by the overall objectives of the Somali health system. The national EPI Policy is a handy instrument that provides the overall strategic directions and key policy recommendations to the national health authorities and its partners on EPI program objectives and priorities. It covers the sub-national level including the States, Regions, and Districts.

This policy document conveys a clear message on the commitment to a priority health program that is led and owned by the government. It represents a key component of the essential package of health services aimed at delivering the objectives outlined in the roadmap towards achieving universal health coverage by 2030. The document furnishes policy statements on the overall government decisions vis-à-vis immunization requirements, it underlines eligibility with clear technical guidelines on various antigens, immunization schedule, cold chain and vaccine management systems, injection safety, and on reporting and monitoring procedures.

3. Context

Somalia occupies approximately 637,657 square kilometers of area in Africa, on the Eastern coast borders the Indian Ocean and the Gulf of Aden. Djibouti on the northwest, Ethiopia on the east and Kenya on the South. The population of the country is estimated of 15.6 million in 2019 with an overall population density of nearly 24 people per square kilometer[1]. Somalia has the second longest coastline in Africa, estimated of 3300 km.

The defining feature of the country is vast expanses of semi-arid or arid, low-lying scrubland, most of which is suitable only for nomadic pastoralism. Because of climate change, severe drought affecting both agriculture and livestock remain some of the major challenges the country has been facing. Epidemics and outbreaks of communicable diseases are quite common. The internally displaced populations are scattered all over but are concentrated in the South.

The number and density of doctors, nurses and midwives in Somalia remain below four per 10,000, which is far below the minimum threshold of 23[2]. Challenges in recruitment exist as limited posts are provided by the civil service commissions to employ trained health professionals due to paucity of resources. There are little or no financial incentives to attract and deploy health workers to rural and remote areas. Health workforce salaries are very low and often released after long delays. Salary top-ups are provided by donors through various externally funded projects to specific staff, leading to discrepancies and demotivation among others. The Per capita public expenditure on health is about US$ 10–12 per person per year[3], which increases the risk of financial burden especially on poor populations with high out-of-pocket expenditure.

3.1. Immunization System

The EPI program was launched in 1978 with the support of bilateral and multilateral organizations. UNICEF and WHO were the lead UN agencies providing technical and material support to the Ministry of Health. The program expanded through the PHC networks in the country with the purpose of reaching the rural and the nomadic population which represent that significant of the underserved population in the country.

The performance of the routine immunization was not very successful; however, the policy of mass campaigns uplifted the coverage throughout the country. Whatever the program has achieved, the civil unrest and conflict that started in 1988 and 1991 have devastated the nation's health infrastructure. The EPI was one of first public health preventive program that was re-launched again soon after stability returned to some parts of the country.
Currently there are more than 500 health centers that are providing immunization services. The outpatient department of these centres are networks of close-to-client outlets of primary health care unit. The ministry of health of Federal Republic of Somalia is fully responsible to provides leadership in policy formulation and in program strategies and plans

[1] PESS, UNFPA https://somalia.unfpa.org/sites/default/files/pub-pdf/PESSBriefingNote_Nov13.pdf
[2] Somali high level health sector review, 2015
[3] WHO estimates in Somali health sector reviews, 2015

implementation. The Global Vaccine Alliance (GAVI) along with UNICEF and other partners are the chief financiers and partners of EPI program in Somalia. Their support to EPI includes: procurement and distribution of vaccines and injection equipment of assured quality, maintenance of cold chain, production and dissemination of monitoring and management tools, production and dissemination of Information Education and Communication (IEC) materials, provision of financial support to the MOH through implementing partners for the execution of the EPI program including outreach immunization services.

WHO provides technical assistance to the MOH and all other partners; and as such is the second major financier of immunization activities in the country. It provides technical guidelines and training programs to health workers and management structures. WHO supports an extensive network of the Global Polio Eradication Initiative (GPEI) through an elaborate micro planning and a network of dedicated polio health workers and volunteers conduct periodic supplementary polio immunization campaigns; and the surveillance of vaccine preventable diseases (VPD). There are a number of international and national NGOs supporting immunization activities in the country which are accountable to the ministry of health. These NGOs run most of MCHs, and are involved in immunization service delivery, disease surveillance, social mobilization, training of health workers, supporting logistics and provision of technical and financial support.

3.2. Higher Level Frameworks and Immunization Program:

3.2.1. Government Policy and High Level Commitment:

An action-oriented facts reflects the existing high-level commitment to the social sector in general and to immunization in particular:
The Federal Government of Somalia has officially launched 2030 development agenda of SDGs in an event participated by more than 200 people representing national stakeholders and development partners[4]. This was a sensitizing event where the government reiterated its commitment to the social sector including health. The MOH capitalized the presence of all key stakeholders led by the highest government authorities and communicated loud enough and long enough with health agenda and priority goals including vaccine preventable diseases. The EPI program will be an integral part of the global financing facility for RMNCAH. The latter is a country-driven partnership that aims to accelerate efforts to end preventable maternal, newborn, child and adolescent deaths and improve the health and quality of life of women, adolescents and children.

The government health policy emphasizes the importance of the EPI program that is well placed in the national health policy (NHP), it reflects the objectives of the Comprehensive Multiyear Plans; it is connected to the global vaccine action plan (GVAP); the sustainable development goals (SDGs); and to the Roadmap towards the achievement of universal health coverage initiative (UHC) 2023. Immunization is documented as a priority program in the NHP, and remains one of the core programs in the delivery of the essential package of health services. The NHP urges the Somali leadership and development partners to join

[4] Somalia Launching SDGs, http://sdgs.nayd.org/2016/04/somalia-launches-2030-sustainable,

hands in effectively pursuing the policy of sustainability. It recommends the holistic approach for building the country's health system and raises the role of EPI high enough in moving towards the SDGs and ultimately the UHC goal.

3.2.2. Advocacy for Immunization Program:

The high-level advocacy for immunization is based on legally-binding resolutions of the World Health Organization[5]. The resolution urges Member States to strengthen the governance and leadership of national immunization programs, and improve monitoring and surveillance systems to ensure up-to-date data guides policy and programmatic decisions to optimize performance and impact. It also calls on countries to expand immunization services beyond infancy, mobilize domestic financing, and strengthen international cooperation to achieve GVAP goals.

The immunization policy of Somalia strongly advocates for what the country has endorsed in the GVAP, it observes its guiding principles, and pursues the GVAP six strategic objectives which calls: (i) All countries commit to immunization as a priority; (ii) Individuals and communities understand the value of vaccines and demand immunization as both their right and responsibility; (iii) The benefits of immunization are equitably extended to all people; (iv) Strong immunization systems are an integral part of a well-functioning health system; (v) Immunization programs have sustainable access to predictable funding, quality supply and innovative technologies; and (vi) Country, regional and global research and development innovations maximize the benefits of immunization.

3.3. Service Delivery Model: Essential Package of Health Services

UHC means that all individuals and communities receive the health services they need without suffering financial hardship. It includes the full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and palliative care[6]. Fully immunization child is among the WHO defined 16 essential health services. In 2018, Somalia joined the UHC Partnership (UHC-P), which supports the development of a roadmap towards health systems in emergencies and the launch of a humanitarian-development nexus to support health system strengthening in 2019[7]. The UHC-Partnership supports the planned revision of the essential package of health services to ensure a comprehensive package that includes referral hospitals, health centers, Primary health units and community level health services to strengthen PHC. Immunization is well-placed in UHC framework with focus on those with the greatest need.

The essential package of health services (EPHS 2009) is designed for the four levels of health service provision and divided into 10 programs, of which six core programs are provided at all levels and four additional programs are provided only at the referral level. Full implementation of EPHS in all regions was not possible due to shortage of funds and trained

[5] 70th WHA, endorsed GVAP, 2012
[6] WHO UHC factsheet
[7] UHC 2030 partnership, 2018

staff, scarcity of medical supplies and indeed security concerns in certain districts[8]. Nevertheless, rolling out of EPHS in a relatively short time has helped turn around deteriorated facilities, improve standards of staff performance, implement essential drug lists and ensure better treatment.

The EPHS is the vehicle for the EPI delivery at all levels. The primary health unit (PHU) which is at the grass-root level has so many roles to play in immunization activities. The policy strongly advocates the use of the protocols provided in the Standard Operating Procedures (SOPs) or Minimum Service Delivery standards (MSDS) for EPI under EPHS framework. In short, this level which is run by a CHW will help the expansion of immunization through routine immunization activities including outreach services, the polio campaigns, in addition to the micro planning for activities related to advocacy, mobilization, organization and coordination. They are considered as input indicators at PHU level that will be measured against the work of the community health workers.

The health center level (HC) is the main delivery arm for immunization services. The policy recommends all levels of the health care system should be able to deliver the EPI services that achieve at least 90% coverage of all vaccines in the EPI schedule before age 1 year and at least 80% of pregnant women receive minimum 2 doses of Td before delivery. The policy supports the provisions in the SOPs to be closely observed to ensure that EPI requirements are explicitly defined at all levels of the health care system of the country.

The required minimum standard for human capital such as the number of workforce, skills and competencies, the equipment, the reporting mechanisms, and the system of program coordination are unambiguously provided in SOPs. Similarly, the requirements for EPI program delivery for the remaining levels of the health care system including the referral health centers and the hospitals should be defined and applied on the ground. Thus, the policy anticipates that the existing gap between immunization services and the EPHS delivery levels will be bridged once the minimum acceptable standards for the vaccination program are fulfilled.

The national policy foresees the possibility of engaging selected private sector facilities in EPI service delivery where vaccination activities are regularly carried out in line with the national EPI policy guidelines and recommendations are strictly followed. The policy fully supports all workable strategies and approaches but indeed of acceptable quality for expanding the immunization services to reach the missing children. Every service delivery model, through public and/or private will remain central to national efforts in improving EPI coverage in Somalia. The policy underlines equity as a value-based principle with focus on the vulnerable segments of the populations throughout the country to ensure the benefits of immunization are equitably extended to all people.

The public-private mix in health care is another delivery model that could be explored further. The advantage is linked to the fact that the ministry of health is reaching out to private providers -be the for-profit or not-for-profit in order to tap into their resources and

[8] Somali high-level health sector review, 2015

experiences. The policy supports all efforts for seeking innovative approaches for the purpose of expanding the immunization services.

The national EPI policy calls for health partners to continuously review the program performance, not only in terms of outcomes such as the coverage but rather focus on higher level commitments, policy and strategic planning, program governance, partnerships, role of all stakeholders and service delivery models. The EPI program reviews should use relevant performance assessment frameworks and instruments that have multiple purpose and not looking immunization services in isolation. Previous reviews were sketchy and have not produced any meaningful results as far as program performance is concerned. Proper templates for collecting data and information should be designed, field-tested and deployed.

Immunization equity assessment was conducted in 2017 to identify gaps in vaccination services and bottlenecks. The study was designed to focus on equity and SWOT analysis, using disaggregated data from Surveys, HIS, surveillance and other sources by geographic, demographic and socioeconomic factors. The study found disparities between the regions (Northeastern, Northwestern and Southcentral), disparities between the urban and the rural areas and disparities between the wealthiest quintile and the poorest quintile[9]. Based on data from 2020 SDHS, the immunization coverage was extremely very low and showed 11% of children aged 12-23 months are fully vaccinated, meaning that they received the basic vaccinations (one BCG vaccine, three doses of pentavalent and polio vaccines, and one dose of measles vaccine) at any time before the survey was conducted[10].

4. Immunization Vision, Goal and Objectives

4.1. Vision

A healthy start early in life for all the Somali children, guaranteed through administration of safe, potent and effective vaccines against the vaccine Preventable childhood diseases, led by the UHC principles of leaving no one behind. Every Somali Citizen; mainly the children and women, enjoy the highest standard of health and quality of life and free from all vaccine preventable diseases.

4.2. Goal and Objectives

4.2.1. Overall Objective

- Decrease mortality and morbidity levels from vaccine preventable diseases through the provision of vaccines of assured quality to all eligible target populations.

[9] UNICEF, immunization equity assessment report
[10] SDHS 2020 Somalia

4.2.2. Specific Objectives

- Increase and sustain high quality immunization coverage rates
- Reach the missing children through increased access to immunization services.
- Ensure Immunization program as integral part of primary health care and through Essential Package of Health Services framework
- Ensure proper reporting and effective data management
- Ensure proper surveillance and outbreak response of vaccine preventable diseases

5. Strategic Directions

The EPI policy envisages eight policy directions that will help attain the aforementioned goals and objectives of the program:

(1) Ensure and maintain political and community level commitment and ownership
(2) Reach every child and women of childbearing age through the realization of EPI initiative
(3) Increase and develop skilled human resources for EPI program
(4) Introduce new vaccines and additional doses of existing vaccines
(5) Scale up vaccine safety efforts
(6) Explore sustainable EPI financing mechanisms
(7) Enhance EPI partnership and coordination efforts
(8) Strengthen advocacy and communication for EPI

Ownership and commitment by the government and its citizen/community will remain as the key message of the policy. Every effort will be made to ensure that no one of EPI target population should be left out. The human capital for the program is at the forefront and should be underscored. The policy advocates for introduction of new and underused vaccines and additional doses of existing vaccines provided that the necessary conditions are satisfactorily met. A detailed action plan on vaccine and injection safety should be formulated and made available for all delivery outlets. Both domestic and external financing opportunities should be explored. Community engagement and participation is considered paramount and the Partnership approach with all partners – including sectoral and multi-sectoral is critical to ensure broader support. The existing health coordination mechanism must be beefed up at all levels. Communication through all feasible and appropriate channels should be reinforced with focus on those who need most.

The policy strongly recommends that a detailed action plan is developed for each policy direction, highlighting the key interventions, outlining specific benchmarks, targets and indicators for each and every strategic direction. This will be an integral part of the EPI comprehensive multiyear plan and should be reviewed periodically. An inclusive process is highly recommended when action plans for each strategic direction is being formulated. The policy also recommends the following guidelines for the implementation of the policy directions:

- Revisiting the EPHS framework;
- Orientation of all stakeholders in the new EPI policy;
- Using Minimum Service Delivery Standards in the field;
- Ensuring the integration of EPI activities into relevant RMNACH initiative;
- Exploring workable strategies to involve the private sector in service delivery.
- Exploring strategic options to reach the hard to reach, rural and nomadic population.

6. The EPI Policy: Technical Component

The scope of the national EPI Policy is to provide policy and strategic framework for Federal, State, Region, District and Facility level immunization practices.

6.1. EPI target diseases, vaccines and target population

Immunization is free and is delivered through the national EPI Program against the following childhood diseases:

- Tuberculosis
- Poliomyelitis
- Diphtheria
- Pertussis
- Tetanus
- Hepatitis B
- Meningitis diseases caused by Haemophilus influenza type B and Measles.

6.2. Policy on vaccine quality

1. All vaccines used in Somalia by EPI program are safe, procured exclusively through UNICEF from manufactures pre-qualified and accredited by WHO, under the guidance of the MOH.
2. The national EPI Program provides the following vaccines:
    a) BCG: It contains live attenuated Mycobacterium bovis (M. bovis) and comes in powder form. It must be reconstituted with a diluent before use. It is essential that

only the diluent supplied with the same batch number of the vaccine be used. BCG vaccine should be kept at +2°C – +8°C after reconstitution. Any remaining reconstituted vaccine must be discarded after six hours or at the end of the immunization session, whichever comes first or according to the manufactures' instructions.

b) Oral Polio Vaccine (bOPV): It is prepared from attenuated live polio virus and is presented as a liquid vaccine that is provided in glass/plastic vials with droppers in a separate plastic bag. In consultation with global partners, the country will make an informed decision phasing-out of OPV. According to international guidelines, Somalia has switched from tOPV to bOPV and has successfully introduced one dose IPV as additional protection against polio disease.
c) IPV, inactivated polio virus vaccine, is provided in liquid form in glass vials. The vaccine should be kept in +2°C – +8°C at all time.
d) Pentavalent DTP-HepB-Hib vaccine: It contains diphtheria toxoid, tetanus toxoid, pertussis, Hepatitis B and Haemophilus influenza type b vaccine; and is provided as liquid form in vials of ten doses and the vaccine should be kept at +2°C – +8°C
e) Measles vaccines provided as a powder, with a diluent in a separate vial. Before it can be used, it must be reconstituted. It is essential that only the diluent supplied with the vaccine be used. After reconstitution, measles vaccine should be kept at +2°C – +8°C. Any remaining reconstituted vaccine must be discarded after six hours or at the end of the immunization session, whichever comes first or according to the manufactures' instructions.
f) Tetanus and Diphtheria (Td) is provided as a liquid in vials and also in prefilled auto-disable injection devices.

3. New vaccines shall be introduced by the Government of Somalia depending on burden of disease as well as technical, managerial and financial feasibility.

4. Other vaccines, though not part of routine immunization schedule, against *Yellow Fever*, *Meningitis*, *Influenza* or any other disease might be provided to travelers or special groups as the need arise. However, the country with support of EPI partners is advocating introducing PCV13 (Pneumococcal Conjugate Vaccine 13) into routine Immunization schedule.

5. Additional doses of existing vaccines if meeting all the standard set by WHO like MCV2 and IPV2 etc.

6. National Immunization Technical Advisory Group or Immunization Coordination Committee (ICC) or any high level sector coordination, if Immunization Coordination committee is merged into the national level sector coordination, will advise the national EPI program on issues related with vaccines to be used in the country.

6.3. EPI Target Population

The following table illustrates who is eligible for the routine vaccination services. Eligibility reflects a fundamental principle of rights to health. The Somali government is committed to ensure that all eligible population should equitably benefit from the immunization services. The policy strongly advises periodic equity analysis to inspect gaps in accessibility.

No	Policy statement	Remarks
1	Immunization shall be delivered to all eligible children and all eligible women without any discrimination with respect to gender, race, wealth, religion or any other demographic attributes.	Value and equity-based statement
2	Target populations for the routine EPI program are the following: - Children less than one year of age. All children should complete the primary immunization series by their first birthday and give MCV2 at 15 months - Children under two years of age: Children who have not completed the primary series by their first birth day will be eligible to finalize the series. Children above 1 year previously unvaccinated should receive OPV, IPV, PENTAVALENT & MCV	Eligible population
3	Women of Child Bearing Age - All women of child-bearing age (15 to 49 years of age): - All pregnant women will be given special emphasis to ensure protection of all neonates against Neonatal Tetanus.	To control MNT

4	Target population for supplemental immunization activities - Children under five years of age, or any age as may be determined by the government in consultation with partners based on epidemiology of disease. - All women of child bearing age	As dictated by epidemiological picture

6.4. Immunization Schedule and Vaccine administration

6.4.1. Vaccination Schedule

According to the recommended schedule, all children will receive one dose of BCG vaccine, 3 doses of DPT-HepB-Hib (Penta), 4 doses of OPV, one dose of IPV and one dose of measles vaccine at 9 months and second dose of measles and IPV 2 in the second year of life. The routine program schedule is illustrated in table 1.

Table 1: Routine Immunization Schedule for infants, 0-15 months

Age	Vaccines	
At Birth[11] (up to 2 week)	BCG	OPV0
6 weeks (42 days)	DPT-HepB+Hib1	OPV1
10 weeks	DPT-HepB+Hib2	OPV2
14 weeks	DPT-HepB+Hib3	OPV3
14 weeks	IPV1	
9 months	Measles (MCV1)	
9 months	IPV2	
15 months	Measles (MCV2)	

Immunization for the 2nd year of life

The policy highlights that the 2nd year of life is an opportunity to further integrate immunizations with other health interventions such as Vitamin A supplementation, nutrition, growth monitoring, and deworming. Booster doses of routine immunization such as DTP4; Second Measles Containing Vaccine dose (MCV2), IPV2 is recommended; and some new vaccines are strongly recommended beyond infancy.

[11]Give OPV-0 within 2 weeks of birth. If given later, it delays the first dose of OPV1 to be given at 6 weeks of age along with DTP-HepB+Hib1.BCG should be given at birth or as early in life as possible normally up to the 1st birthday

Table 2: Immunization Schedule for Pregnant women and WCBA (15-49 YEARS)

Dose	Time for administration	Duration of protection
Td1	at first contact OR as early as possible during pregnancy	None
Td2	at least 4 weeks after Td1	1-3 years
Td3	at least 6 months after Td2	5 years
Td4	at least 1 year after Td3	10 years
Td5	at least 1 year after Td4	For all childbearing age years and possibly longer

The current policy emphasizes that due to the high prevalence of MNT in Somalia, pregnant women for whom reliable information on previous tetanus vaccinations is not available should receive at least 2 doses of Td with an interval of at least 4 weeks between the doses. To ensure protection for a minimum of 5 years, a third dose should be given at least 6 months later. A fourth and fifth dose should be given at intervals of at least 1 year, or during subsequent pregnancies, in order to ensure long-term protection. The policy calls for special attention should be given to the nomadic population through mobile and outreach services.

6.5. Interval between multiple doses of the same antigen

Up-to-date technical information should be regularly provided to the concerned staff in EPI program. The use of locally translated guidelines, clearly indicating the recommended technical advices should be developed. The policy recommends that NITAG technical guidelines should be strongly followed.

Vaccines	Recommended Action
For vaccines that require administration of more than one dose (DTP-HepB-Hib, OPV, TT, measles)	An interval of at least 4 weeks will be ensured between two doses of these vaccines, for development of an adequate antibody response
✓ A dose of one of these vaccines must not be given at an interval of less than 4 weeks and if given must not be counted as part of the primary series. ✓ Longer-than-recommended intervals between doses do not reduce final antibody concentrations.	

Supplementary immunization [NIDS/SNIDS/mop-ups]	OPV doses and /or measles doses will be given irrespective of the child's history of vaccination and will not be counted as part of the child's primary immunization series.
✓ At all EPI centers (Health center, Referral Health Center and hospitals), BCG and measles vials should be opened daily as required. No specific day's need be assigned for BCG or measles vaccination to avoid missed opportunities. All eligible children are vaccinated whenever they are presented to health facility.	

6.6. Simultaneous administration of vaccines

1. To reduce the number of contacts required to complete the immunization series, as many antigens as possible are given at a single visit, at the recommended sites. This policy recommendation is vital especially in areas where the population is not easily accessible such as the nomadic people.

2. All the EPI antigens are safe and effective when administered simultaneously, i.e. during the same immunization session but at different sites. For example, an 11-month old child who has never previously been immunized should receive BCG, measles, and the first dose of DTP-HepB-Hib and polio vaccines.

6.7. Routes of Administration

Policy guidelines:

The national EPI policy is aligned with the global standards and protocols for routes of administration. The following are instructions to be strictly observed:

1. Vaccine administration differs according to the vaccine antigenicity and composition:
    a. BCG is administered intra-dermally on left upper arm
    b. DPT-HepB-Hib is given intramuscularly on antero-lateral side of Right mid-thigh
    c. OPV is administered orally
    d. IPV is given intramuscularly on antero-lateral side of left mid-thigh
    e. Td is injected intramuscularly on Left Upper Arm
    f. Measles vaccine is administered subcutaneously on Right Upper Arm
2. The preferred site for intramuscular injection in infants and young children is the antero-lateral aspects of the mid-thigh since it provides the largest muscular mass.
3. In adult women, the deltoid is recommended for routine intramuscular injection of Td.

4. The buttock should not be used routinely as an immunization site for infants, children, or adults because of the risk of injury to the sciatic nerve.

Table 3: Summary of Route of Administration and Injection Site:

Vaccine	Route of administration	Injection site
BCG	Intradermal	Left upper Arm
DPT-HepB+Hib	Intramuscular	Outer mid-thigh of the right leg
IPV	Intramuscular	Outer mid-thigh of the left leg
OPV	Oral	By Mouth
Measles	Subcutaneous	Right upper arm
Td	Intramuscular	Outer, upper left arm

The policy stresses that clear instructions including illustrative graphics for the vaccination injection sites should be made available at all health centers. Orientation of new staff on standard operating procedures should always be prioritized. The policy reiterates that the standard of care and the overall requirements for immunization including administration of doses and injection safety should be continuously inspected.

6.8. Reconstitution of vaccines:

6.9. A dried vaccine will always be reconstituted using the diluent supplied with it for the purpose. It is essential that only the diluent supplied with the vaccine be used

6.10. Missing doses

The policy objective reiterates that all children will be targeted to complete their immunization schedule before the age of one year. But, in cases where a child has not received any vaccine or doses are missed, and the child reaches ages of more than one year, those children are eligible to receive vaccination up to 23 months:

- All antigens that a child is eligible must be given as soon as possible with appropriate intervals between doses and recorded in the registers and on the vaccination card.

- Screening is preferably done on the basis of written records available at the facility in the registers or the vaccination card with the client. But, due to the low card retention rate in Somalia, verbal screening could/may also be done to determine vaccination status. If immunization history is not clear or unknown, the decision is to be made by the facility health worker and it's recommended that it should be based on risk benefit analysis

- Defaulter tracing protocol, using the following key policy action points are strongly recommended:

- Update information on immunization at facility level, using defaulter tracing template
- Identification of children who have not returned for their scheduled immunization
- Continuing training of health workers on immunization practice
- Scaling up community awareness of the importance of immunization
- Strengthen community-based information systems
- Explore innovative approaches for tackling defaulters

6.11. Contraindications to Immunization

Policy guidelines and recommendations
In general, the EPI program recommends that health workers should use every opportunity to immunize an eligible child. Vaccines should be given to all eligible children attending outpatient clinics.
Children who are hospitalized should be immunized as soon as their general condition improves and at least before discharge from hospital.
Generally speaking, live vaccines should not be given to individuals with immune deficiency diseases or to individuals who are immune-suppressed due to malignant disease, therapy with immunosuppressive agents, or irradiation. However, both measles and oral poliomyelitis vaccines should be given to persons with HIV/AIDS. Children with symptomatic HIV infection should not be immunized with BCG and yellow fever vaccines. Children who are known to be HIV-infected, even if asymptomatic, should not be immunized with BCG vaccine.
A severe adverse event following a dose of vaccine (anaphylaxis, collapse or shock, encephalitis/encephalopathy, or non-febrile convulsions) is a true contraindication to immunization. Such events can be easily recognized by the mother and the health worker. A second or third DTP-HepB-Hib injection should not be given to a child who has suffered such a severe adverse reaction to the previous dose. Vaccines containing the whole cell pertussis component should not be given to children with an evolving neurological disease (e.g. uncontrolled epilepsy or progressive encephalopathy).
Persons with a history of anaphylactic reactions (generalized urticaria, difficulty in breathing, swelling of the mouth and throat, hypotension, or shock) following egg ingestion should not receive vaccines prepared on hen's egg tissues (e.g. yellow fever vaccine and influenza vaccine).

All adverse events following immunization must be reported and investigated.

6.12. Conditions which are NOT Contraindications to immunization

a) Minor illnesses such as upper respiratory infections or diarrhea, with fever <38.5 C
b) Allergy, asthma or other atopic manifestations, hay fever
c) Prematurity, (small for dates) babies
d) Malnutrition
e) Breastfed child or non-breastfed child.
f) Family history of convulsions
g) Treatment with antibiotics, low-dose corticosteroids or locally acting (e.g. topical or inhaled) steroids
h) Dermatoses, eczema or localized skin infection
i) Chronic diseases of the heart, lung, kidney and liver
j) Stable neurological conditions, such as cerebral palsy and Down's syndrome
k) History of jaundice soon after birth.

7. Immunization Service Delivery Strategy

7.1. Service delivery outlets and strategies:

Under the Government public health law, immunization services should be delivered through all public health facilities. The new policy encourages exploring innovative approaches to expand the vaccination activities through all possible channels including the private health facilities.

a) Immunization services should be delivered primarily at all health facilities (Primary Health Unit, Health Centre, Referral health Centre and hospitals), as an integral component of Maternal and child health and nutrition services in EPHS and primary health care.

b) Immunization services should also be provided through outreach sessions and through mobile teams by adopting RED (reach every district) approach or any other mass campaign strategies.

c) Outreach services from the health facilities should be provided in all areas in the jurisdiction of the concerned facility.

d) EPI Mobile teams are recommended and may be deployed in hard to reach areas and nomadic population

e) At fixed EPI centers, immunization of all target groups with all antigens will be carried out by a trained health worker on Immunization in all working days of the week.

f) Outreach activities in the specified areas will provide immunization services to all target groups with all antigens by a trained health worker on Immunization at least once every month or as planned in the maintenance phase.

7.2. Health workers roles & responsibilities in immunization

According to the existing public health law, qualified health worker or trained vaccinators should be responsible to deliver and monitor the vaccination services in different facilities, sessions, and campaigns.

- At fixed center, immunization services should be provided by the trained health worker specifically designated for this duty by head of the facility.
- Health workers engaged in vaccination activities are responsible to ensure quality and safety.
- Health workers at facilities should be responsible for outreach and mobile activities to the communities within their catchment area.
- Community health workers and Female Health Workers should be responsible for social mobilization for routine immunization activities in their own catchment areas. Those trained as vaccinators could also administer vaccines under the supervision.
- The health facility team leader/head should be responsible to supervise and monitor vaccination activities including vaccine recording, reporting and stock monitoring in the health facility.

7.3. Supplemental Immunization Activities

The ministry of health through its EPI department shall decide to conduct SIAs against polio, measles, MNT, CHD, OCV or any other disease as deemed necessary. The policy also recommends that partners in EPI should be part of the decision-making process.

7.3.1. Vitamin A supplementation

Policy guidelines
▪ Vitamin A supplementation will be provided to all children between 6 months to 59 months, or as per the standard protocol, with the recommended doses along with OPV on National Immunization Days and during any other supplemental immunization activities (e.g. Measles follow up campaign).

- Vitamin A supplementation will also be provided to children at the time they receive the first measles dose (9months) and the second measles dose (15 month) as a part of the essential routine EPI service delivery package.
- WHO recommends that Vitamin A should be administered to children with acute measles, once measles is diagnosed, one dose of 50,000 IU to children less than 06 months, 100,000IU to children aged 6 to 11 months and 200,000 UI to children aged 12 months and above. A second dose should be administered the following day.
- Vitamin A supplement of one dose of 200,000 IU will be given to all women post-partum within 6 weeks of delivery.

7.4. Minimizing missed opportunities:

1. A missed opportunity for immunization occurs when a child or woman of childbearing age comes to a health facility or outreach site and does not receive any or all of the vaccine doses for which he or she is eligible.
2. To reduce missed opportunities, all health facilities seeing women and children should offer immunization services as frequently as possible, according to the immunization schedules.
3. The immunization status of all children and child bearing women in the target age group should be screened routinely and immunization should be provided at every opportunity. Health workers should be taught which are true and which are false contraindications, and supervisors should monitor compliance with recommendations. Steps for minimizing missed opportunity will include:

- All vaccines, for which a child and women of child bearing age are eligible, will be administered simultaneously.
- A false contra indication must never be the cause for refusing immunization to a child.
- Multi- dose vial policy will be fully implemented. Health workers shall not refuse vaccination to avoid opening a multi-dose vial for a small number of eligible children or even for one child.
- All health facilities shall screen patients and accompanying children / women for incomplete immunization or missed doses and will offer immunization services.
- Family practice approach might be applied to take family history and identify any unvaccinated / uncompleted child vaccination in the family.

7.5. Vaccination in emergency settings:

Somali is prone to both man-made and natural disasters thus; the policy of the Government during emergencies recommends that Measles and OPV/ IPV shall be the first immunization response along with Vitamin A Supplementation in any humanitarian disaster. Routine immunization should be maintained during emergency situation; however, safety of vaccinators and care givers should always come first. It is always important to adhere to local authorities' decisions regarding service delivery during emergency. Routine immunization should be considered in response, recovery and development plans. Supplementary immunization activities may also be considered if recommended by the ICC/ NITAG.

Periodic Intensification of Routine Immunization (PIRI) can also be applied in areas with high unimmunized children and to bridge the coverage gap between routine immunization and campaigns.

8. Recording, Reporting and Storing of Data

In general, the health sector policy is to strengthen information and health intelligence system of the country with the purpose of establishing reliable, relevant, timely and complete health information that operates at the health facility, district, regional, state and national level. Health information facilitates the decision-making process and it fosters the planning process of all health programs. Immunization entirely depends on proper information system in terms of planning, implementation and evaluation activities. It is widely believed that poor recording and reporting of immunization activities has been very damaging and has negatively impacted on developing evidence-based policies and strategic planning for EPI.

Policy recommendations

- Integration of all EPI routine information systems into the DHIS2/ HMIS
- Regular coordination between the various levels of service delivery
- Enhancing staff and institutional capacities in data management
- All necessary data recording, data storing, and data processing tools must be made available in all relevant facilities.

The facility level vaccination activities' recording and reporting is critical for the program and special attention is required. The health facility staff should be always encouraged to keep up the momentum of improving the recording and reporting activities. Checking and cross-checking of the vaccination records is recommended. Feedback from the higher levels on the regular reports they receive is absolutely vital and should be practiced at all levels. Regular orientation for staff on the importance of quality recording, reporting and archiving is strongly recommended. A backup system should always be made available.

Recommended action points at health facility Level and community Level
1. All health workers providing immunization services should keep records of all immunizations provided, in the daily registers, vaccination cards and tally sheets.
2. All immunizations given in static center or outreach site or during mobile round should be entered in the daily register.
3. Every child or WCBA immunized for the first time should be given a vaccination card with instructions for card retention. In case of card loss, a new card will be given to the child/woman with entry of previous vaccination based on the facility record. Health Workers should promote the card retention by the caregivers and family members.
4. On the last working day of the month there should be a meeting at the facility level which should be attended by the vaccinator and head nurse during which the immunization data should be validated and monthly report prepared.
5. Reporting of adverse events following immunizations (AEFI) should be incorporated in the routine monthly reporting systems. Reporting of adverse events following immunization should be the responsibility of every health worker especially the worker who administered the vaccine and his/ her supervisor.
6. All health facilities public and private with established EPI centers and all outreach sites should officially submit end activity report at the end of every month to the next higher office.
7. The monthly report should reach the next higher health office before the end of first week of the next month or as per the HMIS Standard Operating Procedure
8. All facilities shall retain a copy of all reports and are required to produce the copies of reports for data quality assessment needs.
9. All Health Facilities might use electronic recording system at health facility and community level based on the priorities of Ministry of health

The recommended policy action points with regards to recording and reporting procedures from the district to higher levels in the country is outlined in the following table:

Table 4: Reporting procedures by level

Level	Recommended actions for reporting
District Level	1. All reports will be compiled at the district level by the by HMIS Officer at District level if any with the support of District EPI officer to enhance the use of EPI data at district health planning, and monitoring.

	2. Reports will be submitted to the regional office regularly at the designated reporting timeframe.
Regional Level	1. All data reported from the different districts will be recorded and compiled by the regional HMIS Officer 2. The regional EPI coordinator will ensure the EPI service planning and management using the data compiled at regional levels
State Level	1. The state office will compile and review all regional reports by the designated reporting timeframe for feedback to regional health office on monthly basis and onward submission to the EPI department of the Federal Ministry of Health and in close collaboration with HMIS Section on issues related to data management
Federal Level	2. The federal MOH HMIS Section together with EPI Program section, will compile, analyze and interpret all reports by the designated timeframe and provide feedback to state health authorities drawing their attention for any corrective action which may be required. 3. The Federal MOH will provide data and information to wider stakeholders, regional and global level repositories. Feedback will be given to the relevant health partners on monthly basis.

The performance of the vaccination activities depends on the quality of reporting. The EPI national policy recommends the report compilation, the cross-checking, the validation, the submission, the analysis and the feedback should be meticulously undertaken. Periodic staff orientation on the importance of reporting is advised. The leadership and management at all levels should be closely monitoring the reporting quality. Different reporting levels are required to establish necessary forums for reviewing the process on regular basis. Strong collaboration between the different levels and all partners on recording and reporting is advised.

10. Social Mobilization (SM)

The EPI policy urges to scale up SM efforts at national, State, Regional and District level with the purpose of increasing demand for immunization and encourage care givers to utilize

existing services. The policy strongly advocates pursuing innovative approaches and interventions for improving SM program performance at all levels. The SM target is to mobilize various societal groups such as health committees, religious structures, professional associations, NGOs, the private sector, women's associations, youth groups, and school programs. The policy pinpoints to use of the social media more effectively and sensitize the media before it engages the SM program to appropriately disseminate the necessary information to people. As well, Mobile message platforms such as SMS can be explored as reminders to parents to complete immunization and for tracking missed children.

11. Monitoring and Evaluation

The policy reiterates that quality program monitoring and evaluation should always be maintained at all levels. Every effort should be made to continuously and consistently improve local capacities for effective monitoring.

Policy action areas:

1. The national EPI program shall have a five-year cMYP and annual work plans for the country against which all EPI achievements shall be monitored.

2. All regions/districts and facilities shall have their respective micro-plan to guide immunization activities.

3. The country will conduct regular data quality assessment to ensure quality, accuracy, timeliness and completeness of the immunization coverage reporting system.

4. The policy recommends the health system strengthening (HSS) activities for EPI should be regularly monitored.

5. The EPI policy recommends skill development initiatives such as in-service and on-the-job training sessions on program monitoring.

6. The policy recommends accountability framework should be developed and observed.

9.1. Indicators for monitoring and evaluation

The country will use the following indicators for monitoring and evaluation of its national EPI program.

Indicator type/level	Indicator description

National	**1.** Immunization coverage indicators at national level
Subnational	**2.** Immunization coverage at State, Regional, District and facility level
Drop-out	**3.** Annual drop-out rate
VitA	**4.** Vitamin A supplementation coverage
Supply	**5.** Vaccine supply and vaccine wastage
Safety	**6.** Injection Safety data
Financing	**7.** Financing and details of expenditure
AEFI	**8.** Number of AEFI cases reported and outcome
Outbreak	**9.** Number of Vaccine preventable diseases cases reported

9.2. Use of monitoring chart and minimizing dropout rate

- All facilities are required to have a catchment population and annual, quarterly and monthly target.
- All health facilities should use the immunization monitoring chart to track performance of immunization activities as against the facility's monthly, quarterly and annual targets
- The health workers should convey EPI standard essential messages to the parents/caregiver during the immunization session to minimize dropouts.
- Using the register and the tickler file, the Health workers should prepare a list of dropouts by village/section and engage12 CHWs, FHW and local elders to trace dropouts and advise on the resumption of their vaccination.
- A difference of more than 10% between Penta1 and Penta3 coverage should alert the facility and should be discussed during monthly review meetings.

9.3. Program implementation review meetings

The purpose of review exercises at all levels is to ensure that the national immunization policy and strategic plans are effectively pursued.

[12]Engaging CHWs and the community through its local and traditional leaders is an integral component of RED approach and is a requirement for local ownership and sustainability of immunization programs.

- A review meeting for routine EPI activities should be conducted once every month in the facility and district levels and will be attended by all EPI related staff including all supervisors.
- Recommendations of the review meeting should be shared with the regional EPI office and implemented at the district.
- A review meeting should be held at the regional level at least once every three months attended by concerned district supervisors.
- A review meeting should be held at State level at least every 6 months and attended by regional supervisors.
- A national planning and review meeting led by the Ministry of Health of Federal Government of Somalia, with the participation of all stakeholders, should be conducted on bi-annual basis.

9.4. Reporting of administrative coverage

1. Administrative coverage will be calculated using doses administered
2. The ministry of health in collaboration with WHO and UNICEF will compile annual administrative coverage and shall submit the JRF to WHO and UNICEF on time.
3. The figures submitted in the JRF shall be the official estimate of the country.

9.5. Coverage evaluation and external EPI review

The immunization policy underscores the importance of evaluation of the programs through all possible mechanisms. The periodic vaccination coverage survey is hereby recommended with the support of our health partners. In addition, the policy urges partners to give attention to equity analysis through periodic studies and as advised by the government.

1. Independent EPI coverage evaluation survey should be conducted in the country at least once in 5 years, before development of new cMYP.
2. External EPI review of various aspects of the program including service provision, coverage, surveillance, monitoring mechanisms, inventories etc. will be carried out as required.

9.6. Reporting requirements

Somalia recognizes its international obligation regarding reporting requirements with respect to:

1. Joint Reporting Form to WHO and UNICEF
2. Joint appraisal (JA) Report to GAVI, and Annual Reports to non-GAVI institutions who are collaborating with the Federal Ministry of Health.
3. Other reporting requirements as advised by WHO and UNICEF in the spirit of partnership
4. UHC progress report to WHO with focus on women and children is essential.

Some of the above-mentioned reports are legally-binding and must be fulfilled by the Somali health authorities. The policy underlines the importance of shared responsibility and program accountability in order to uphold the principles of partnership and collaboration.

10. Ensuring Safety Injections

The policy on safety promotes strict rules and protocols to be consistently observed:

Policy Action Level	What has to be done
Safe injection	1. Every injection given to administer a vaccine must be safe (for the vaccinator, recipient, community and environment). 2. Safety will be ensured by administering vaccine using appropriate equipment and according to the recommended procedures for injection, ensuring sterilization and safe disposal.
Type of syringe and equipment	1. Only AD syringes will be used in all immunization sessions to administer injectable vaccines. 2. Puncture resistant containers for collecting and disposing of used syringes, needles and other injection materials must be provided and used in all immunization activities.
Incineration equipment	1. In facilities with incinerators, all immunization wastes (safety box filled with used syringes) will be incinerated daily or when required. 2. In facilities without incinerators, all immunization wastes (safety box filled with used syringes) will be burnt and buried in pits within the compound of the health facility.

11. Cold Chain and Vaccine Management

11.1. Cold chain inventory: Policy recommendations and action points

1. Ensure that Cold chain equipment inventory at federal, state, region, district and facility level should be developed and updated annually.

2. Cold chain inventory will be used to plan for repair, maintenance and replacement of equipment.

3. Monitoring the quality of a country's vaccine supply/cold chain systems through conducting periodic assessment using the effective vaccine management (EVM) tools including human resources assessment.

4. Decisions for any cold chain equipment replacement should be made on the basis of the cold chain inventory and results of periodic assessments by MOH. The policy reiterates the importance of staff capacities in logistics and cold chain management.

11.2. Availability of cold chain equipment:

Policy guidelines

1. Facilities functioning as fixed centers should ideally have:

    - At least one Solar Direct Drive (SDD) vaccine refrigerator or ice-lined solar powered refrigerator with freezing compartment or a simple ILR with a separate freezer (for freezing of icepacks), Temperature chart, two cold boxes and four vaccine carriers.

    - At least one cold box where necessary; and at least two vaccine carriers for every outreach team

2. Cold chain and other required equipment for these centers will be provided by federal and state EPI offices.
3. Central/middle-level and peripheral EPI stores should have cold rooms / sufficient ILRs and freezers according to their needs.

11.3. Repairs and maintenance: Policy recommendations

1. The State EPI office should be equipped so that it may provide support for major repairs for the state cold rooms and equipment in its jurisdiction.

2. All regions and districts should be equipped to carry out minor repairs and maintenance of the cold chain equipment.

11.4. Vaccine management

Policy guidelines:

1. The systems of shipment, storage, handling, reconstitution and administration should ensure that the quality of vaccines is maintained in line with international standards.
2. Vaccines should ideally not be stored for more than a period of six months at federal level, three months at the state/regional level, one month at both the district and facility level.
3. All vaccine should be stored at a temperature in between +2 to +8 degrees except OPV that should be stored at –15 to -25 degrees, if stored for three or more months.
4. Vaccines, syringes and safety boxes will always be supplied as "bundle" of all three items to all levels from the federal to service delivery level.
5. All vaccines will be procured with the support of UNICEF from a WHO pre-qualified and accredited manufacturers.
6. The government of Somalia will establish National Regulatory Authority that will be the body responsible for ensuring quality of the incoming vaccines.
7. Vaccine management assessment, using standard WHO/UNICEF tools such as Effective Vaccine Management (EVM), will be carried out regularly.

11.5. Supply of vaccines, syringes and safety boxes

1. Vaccine supply should be on the basis of target population.
2. Federal MOH should be responsible for ensuring regular supply of vaccines to all levels.
3. Federal MOH should maintain reserve supply of vaccines for six months' country wide requirement.
4. Facilities should ensure receipt of every month's supply of vaccines for all EPI activities in their catchment area.
5. Buffer stock of three months must be maintained at the state/regional level, of one month at the district cold rooms and of two weeks at least at the facilities with fixed centers.

11.6. Use of multi-dose vials of vaccine in subsequent immunization sessions

1. Multi dose vials of OPV, DPT-HepB-Hib, IPV and Td from which one or more doses of vaccines have been removed during an immunization session maybe used in

subsequent immunization sessions for up to a maximum of 4 weeks, provided that all of the following conditions are met:

a. the expiry date has not passed;

b. the vaccines are stored under appropriate cold chain conditions;

c. the vaccine vial septum has not been submerged in water;

d. aseptic technique has been used to withdraw all doses;

e. The vaccine vial monitor (VVM), if attached, has not reached the discard point.

2. The policy underlines that vaccine vials without labels must not be used.

Given the quality with respect to efficacy and safety, the policy fully supports the global WHO guidelines on the use multi-dose vials as illustrated above.

11.7. Use of vaccine vial monitors in immunization services

1. VVMs should be used to monitor the potency of the vaccine at every level and to identify the weak link in the cold chain if any, and to calculate the wastage of the vaccine.

2. All vaccines will be procured with VVMs, where available.

3. Everyone responsible for cold chain and those who use the vaccine must know how to use and interpret the VVMs.

12. Surveillance and Outbreak Response

12.1. Surveillance of Vaccine Preventable Diseases

The EPI policy is to enhance and sustain national efforts for strengthening the epidemiological surveillance of vaccine preventable diseases in the country. The policy strongly recommends scaling up disease surveillance efforts and keeps the country free from Vaccine Preventable Diseases (VPD) through the watchful eye of integrated disease surveillance system and the delivery of quality immunization services. The policy encourages all partners to work on feasible options for tackling the challenges facing the surveillance program.

1. The surveillance system of VPD should collect aggregate data on all VPD diseases; and case-based data on selected diseases as will be determined by the government.

The following VPD diseases are currently under surveillance:

- Acute Flaccid Paralysis (AFP)
- Measles/Rubella

- Diphtheria
- Pertussis
- Hepatitis B
- Neonatal Tetanus

2. All the above diseases should be reported by all health facilities
3. The list of reportable VPD will be regularly updated by the government.
4. The designated health workers in the health facilities will be responsible for reporting of VPDs to the higher levels. Weekly reporting of AFP and measles and monthly reporting of other VPD is recommended.
5. Prompt and appropriate outbreak response should be an integral component of VPD surveillance.

13. Adverse Events Following Immunization

1. Although vaccines are extremely safe, as with all medicinal products vaccines are not totally free of adverse reactions. The occurrence of an adverse event after the administration of a vaccine, however, does not prove that the vaccine caused the symptoms.
2. All immunization programs should monitor adverse events following immunization. Casualty assessment committee should be established to investigate any AEFI report.
3. Each Adverse Event Following Immunization (AEFI) should be investigated and efforts should be made to determine its cause.
4. The detection of AEFI should be followed by appropriate measure and communication with parents, health workers, and if several persons are affected, with the community.
5. If the adverse event was determined to be due to program errors, operational problems must be solved, by appropriate logistical support, training and supervision.
6. All AEFI will be reported by the concerned health care provider to the next higher Office for response using standard reporting format.
7. District health office will share the reports with the regional offices for any further action on monthly basis. The district will also maintain a line listing of AEFI.
8. Reporting of AEFI will form an integral part of the routine reporting of the program.

14. Advocacy and Communication

The policy underlines the importance of advocacy in EPI program and urges the concerned institutions and organizations to scale up advocacy efforts. The policy strongly recommends consolidated efforts by all stakeholders including the community and civil society organizations (CSOs) to promote the benefits of immunization, the importance of equity and the overarching call of UHC. Religious leaders and structures should be encouraged to assist in all matters related to promoting the vaccination program against the target diseases. Communication is critical and should be thoroughly reviewed in order to identify and pinpoint the major obstacles the program has experienced. The current policy calls for immediate attention to the following action points:

Policy guidelines:

1. Currently existing advocacy and communication strategies for health should be reviewed and a uniform and comprehensive communications strategy developed to be used across the country.
2. Advocacy at all levels should target the key decision makers including political leaders, religious leaders, clan elders and all opinion leaders.
3. Social mobilization activities should continue to target the whole population in general and the parents in particular.
4. Program communication should use all forms of mass media and other sources of information and dissemination with focus on the following:
    - House hold/community and caretaker mobilization and education towards the benefits of Immunizations and information related to Vaccine Preventable Diseases.
    - The importance of completing immunization schedule of all antigens
    - The importance of community participation and acceptance
5. The ministry of health will conduct annual vaccination weeks in line with Global and Regional themes.

15. Collaboration with Local Institutions

Inter-sectoral collaboration (IC) is critical for all health programs including immunization. The EPI policy outlines that IC is the joint action taken by health and other government sectors, as well as representatives from private, voluntary and non-profit groups, to improve the health of populations. The policy, therefore, calls for pursuing all options to strengthen collaboration with line ministries, CSOs through health-in-all policies (HiAP) approach. Alliances, coalitions, cooperatives whatever form possible should be established at all levels. Every effort should be made to explore innovative approaches and options for reinforcing the existing collaboration. Seeking international experiences on intersectoral action will remain a

key aspect of the national effort towards strengthening partnerships on immunization. The Somali government is committed to the SDGs and particularly honors the partnerships goal, where a collective vision is absolutely necessary for pursuing the UHC 2030 goal in particular and SDGs in general.

15.1. Collaboration with other government Institutions

Policy guidelines:

1. The ministry of health will collaborate with the ministry of education to make screening of children for vaccination a mandatory procedure for school enrollment. A mechanism to vaccinate children for missed doses will be established.

2. The health sector will collaborate and seek the assistance of all other line ministries such as ministries of Finance, Information, Religion, Women and Family Affairs and other government agencies in the implementation of vaccination activities.

3. The health sector will collaborate and seek the assistance of all government organs in making reporting of reportable diseases a mandatory requirement as will be stipulated in further and successive directives.

4. National and State-level collaboration bodies working under the national high level intersectoral action (ISA) for promoting EPI program will be established. A clear TOR for the intersectoral group shall be developed and endorsed by all line ministries.

15.2. Collaboration and Partnership with Non- governmental Organizations and UN Agencies

Based on the strategic directions of the national health policy, the EPI policy reaffirms the government's aspirations for stronger partnership with the global vaccine alliance (Gavi), UNICEF, and WHO. Such partnerships will continue with greater spirit and with a collective vision for improving immunization outcomes in this country. The policy upholds the establishment of high-level interagency forum where joint decisions are collectively taken, where agencies transfer expertise to locals, where high level national EPI benchmarks and targets are deliberated, and where program sustainability and financing (external and domestic) are examined. Action points and policy recommendation are provided below:

1. The MOH will provide leadership in all collaborative programs related to policy development, joint planning, implementation, joint monitoring and joint evaluation

2. The MOH shall periodically undertake stakeholder analysis and develop database for partnership to use as observatory tool for EPI partnership program

3. The health sector will collaborate with UN health supporting agencies in all matters related to EPI activities. The policy acknowledges the existing collaboration as there is always a room for improvement vis-à-vis cooperation and partnership with all UN agencies and notably with UNICEF, WHO, UNFPA, WFP, UNDP, FAO and UN Habitat. On

SDGs, the health goal is a cross-cutting which brings many key players together and improving the lives of women and children, and is indeed a key component of the polices of all these agencies

4. Collaboration with professional associations, academic institutions, and non-governmental organizations through technical forums shall be strengthened. The academia is expected to play a major role in program planning and evaluation. It is a major partner and collaborator with MOH in research activities and in health surveys, including the vaccination program. Further areas of collaboration in expanding immunization activities will be explored with medical and public health schools.

16. EPI Capacity-building initiatives

The national immunization policy reiterates the high level commitment of the Federal Government of Somalia to strengthen skill development activities under the capacity building initiatives, through continuous transfer of knowledge and expertise. It calls upon to all partners, particularly the World Health Organization and UNICEF to assist in the following areas:

1) Leadership and management of immunization managers at national, Regional and States level.
2) Immunization practices
3) Microplanning
4) Cold chain training along with UNICEF.
5) Data quality improvement
6) Surveillance
7) Health system strengthening [planning, proposal writing etc.]
8) UHC 2030 and SDGS
9) Role of CSOs
10) Integrated and supportive supervision & monitoring
11) Communication strategy
12) Equity analysis

17. Program Coordination

Coordination in immunization program is a governance function and is a key ingredient for improving the performance of the vaccination program. Strong coordination among actors in EPI is vital and should always remain central to the overall health system strengthening efforts especially in countries in political transition. The presences of large number of actors often pose a serious challenge to the health authorities. Among others, poor coordination undermines the ownership and always impedes efforts to achieve successful and sustained aid and cooperation. Ownership, itself presents particular difficulties in situations of fragility and conflict which is further aggravated by the large number of health supporting agencies engaged in delivering various programs and projects.

Poor coordination affects the focus on results where national benchmarks and targets are poorly met given the fragmentation of efforts. Effective coordination fosters ownership which once developed represents a win-win situation for the government and its partners. Coordination ensures joint assessments, progress towards shared responsibility and mutual accountability. It promotes inclusive development partnerships where issues are collectively addressed, and decisions are made through a broader consultative process.

Given the importance of program coordination the policy advises that regular assessments should be undertaken to ensure that coordination at all levels is running smoothly. It is crucial to review the organizational structure at national and subnational levels; to review the tools and resources such as stakeholder's data-base, and communication channels; and to examine the implementation of proposed tasks for coordinating bodies.

The national policy EPI calls that necessary technical and material support should be provided to Federal and State level national teams to strengthen EPI coordination at all levels. The EPI teams at regional and district level should be strengthened through skill development interventions. The national EPI policy recognizes the following coordinating forums and urges for continuous improvement of the existing structures, TORs, composition, organization, methodology, and input and output performance indicators. The nationals should provide the necessary leadership for convening the following immunization coordination activities on regular basis.

- The Somali Health Sector and Nutrition Coordination meetings
- EPI working group (Monthly)
- EPI review meetings (Monthly at district level, Quarterly at Regional /State level).
- EPI Planning meetings (Quarterly and Annually)
- Cold chain review meeting jointly with UNICEF.
- Facilitating ICC meetings at national level and State level
- Joint appraisals
- GAVI review meetings.

18. Conclusion

The EPI policy document is a living document which is subject to continuous review, adjustments and updates. Fifteen health agencies were engaged in deliberating the development of an evidence-based policy, designed to tackle the major challenges facing the vaccination program. The policy development process identified eight (8) strategic directions for improving planning, implementation and monitoring phases of the EPI program. High level commitment to program sustainability through enhanced collaboration and dedicated leadership is one of the key policy messages. Linking the immunization to the higher national development frameworks such as the universal health coverage and SDGs is a priority decision for the government to ensure the immunization services remain central to attaining some of the SDGs health-related goals.

The policy recommends the functional integration of EPI into the overall health system framework, it calls for exploring innovative approaches in reaching the missing children and it supports the introduction of new vaccines and additional doses for existing vaccines like 2nd dose of MCV and IPV vaccines. It is important for all levels of health system to implement this policy. The guiding principles of the immunization program as expressed in the national policy are the realization of equitable services with the purpose of "leaving no one behind.

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