

2022
NATIONAL IMMUNIZATION POLICY
PAKISTAN





Contents

Message By The Special Assistant To The Prime Minister	4
Message By The Secretary	5
Message By The Director General (Health)	6
Message By The Director General FDI	7
FOREWORD	8
SECTION 1	8
1. Conceptual framework	8
1.1 Vision and Goal	8
1.2 National Immunization's objectives and targets	8
1.3 Policy Directions for Introduction of new vaccines	12
1.4 Fully Immunized Child	12
1.5 Zero Dose Child	12
SECTION 2	13
2. Immunization Pathways	13
2.1 Immunization reporting, surveillance and research	13
2.1.1 Routine EPI Reporting	13
2.1.2 VPD Surveillance	13
2.1.3 Immunization Data Quality Assessment	13
2.1.4 Research and Development	13
SECTION 3	14
3. Governance and Coordination	14
3.1 Role and functions of National Interagency Coordination Committee (NICC)	14
3.2 Role and functions of National Immunization Technical Advisory Group (NITAG)	15
3.3 Role and functions of public/private sectors at national provincial and district levels	15
SECTION 4	16
4. Service delivery	16
4.1 Immunization services in rural areas	16
4.2 Immunization in peri-urban and urban settings	17
4.3 Immunization Services for High Risk or Vulnerable Groups	17
4.4 Immunization campaigns and specific SIAs	17
4.5 Immunization in Schools	18

Contents

- 4.6 Communication, demand generation, advocacy, equity and universality*18
- 4.7 Policy on Gender and Immunization* 18
- 4.8 Policy on User Fees for Immunization*19
- 4.9 Policy on use of syringes and needle size*19
- 4.10 Policy on Distribution of Vaccinators/Skilled Immunization Staff in UC*19
- 4.11 Policy on vaccination of children of higher age* 19
- 4.12 Policy on EPI Waste Management* 20
- 4.12.1 The EPI waste management policy* 20
- SECTION 5 20
- 5. Human resources 20
- SECTION 6 21
- 6.Vaccine policy, and vaccines' security 21
- 6.1 Vaccine policy* 21
- 6.2 Vaccine security* 21
- SECTION 7 22
- 7. Management Information System, eHealth and Artificial Intelligence 22
- Annexure I 24
- a. National Vaccination schedule* 24
- Annexure II 25
- Evidence on use of mHealth in Immunization Programs* 25



MESSAGE BY THE SPECIAL ASSISTANT TO THE PRIME MINISTER

Ministry of National Health Services, Regulations and Coordination

Dr. Faisal Sultan

The Ministry of National Health Services, Regulations and Coordination is committed to helping the people of Pakistan to improve their health. Our vision is to strengthen Pakistan's health system and support our communities by providing efficient, equitable, accessible, and affordable health service. The Government of Pakistan recognizes the critical role immunization plays in reducing child and mother morbidity and mortality. Our responsibility is to ensure that every child is protected against vaccine-preventable diseases. To fulfill this mission, the Federal Directorate of Immunization with partner organizations has developed an immunization policy document, which will guide the program and contribute to achieving Sustainable Development Goals (SDGs) and the Immunization Agenda (IA2030). It is more important than ever to initiate progressive change and build a society where vaccination services are utilized optimally, and vaccination processes are implemented in compliance with international norms. I am optimistic this National Policy document will serve as an effective road for the planning and implementing all operational and communication activities. The technical assistance provided by partner organizations in developing the National Immunization Policy is highly appreciated.



MESSAGE BY THE SECRETARY

Ministry of National Health Services, Regulations and Coordination

Aamir Ashraf Khawaja

It is a proud moment when we present this important policy document that gives a basis for vaccination processes based on evidence and international standards. We see high level of commitment at the federal and provincial levels, and also among national and international partners to enhance immunization coverage of vaccine preventable diseases. It is manifested from the National Immunization Policy that there is a major opportunity to use evidence-based vaccination practices in the country and to allow vaccine preventable disease eradication and elimination targets to be achieved. It is designed to provide a technically sound basis for vaccination procedures according to proven international standards and norms. Therefore, it is very crucial to reorient all immunization services in the country based on the policies, strategies, norms and guidelines incorporated in the immunization policy. I would like to acknowledge the technical assistance provided by partners in the development of National Immunization Policy 2022.



MESSAGE BY THE DIRECTOR GENERAL

Ministry of National Health Services, Regulations and Coordination

Dr. Rana Muhammad Safdar

The vision of EPI is to improve the health of our children by eradicating and controlling vaccine preventable diseases. Vaccination is one of the most successful and cost-effective public health interventions in history as exemplified by the eradication of smallpox, significant lowering the prevalence of poliomyelitis and the dramatic reduction in morbidity and mortality from vaccine preventable diseases. Recognizing these achievements, Ministry of National Health Services, Regulations and Coordination has revised this policy document to integrate all current and evidence-based vaccination practices. The aim is to standardize practices and opportunities for vaccination services. The National Immunization Policy is the result of a long process of intensive consultations, teamwork, detailed studies, and information gathering. This policy seeks to guide health workers on vaccination priorities and acceptable practices for the overall benefit and welfare of EPI as a program. The Ministry of National Health Services, Regulations and Coordination would like to acknowledge the technical assistance of WHO and UNICEF along with all expanded and local partners in updating this National Immunization Policy.



MESSAGE BY THE DIRECTOR GENERAL, FDI

Ministry of National Health Services, Regulations and
Coordination

Dr. Muhammad Akram Shah

Today I feel pride in introducing the National Immunization Policy 2022 of the Expanded Program on Immunization. This policy document is based on the wealth of technical experience of government officials and development/ technical partners. Firstly, I would like to take this opportunity to express my gratitude to the Special Assistant to the Prime Minister on Health, Dr. Faisal Sultan and top leadership of the Ministry of National Health Services, Regulations and Coordination for putting trust and confidence in EPI team. I would also like to appreciate and acknowledge all development and technical partners for participating in the review process of this policy document, giving comments and recommending the necessary changes to ensure its finalization. This policy document provides strategic guidance for the implementation of the immunization program in Pakistan. It builds on the direction and planning of the comprehensive Multi-Year Plan (cMYP) 2020 - 2024, experience gained during recent years of implementing routine and supplementary immunization activities and international immunization guidelines. I kindly request all officials of the Federal and Provincial Directorates of Immunization and partners working in immunization to take the National Immunization Policy 2022 as a strategic and guiding document in relation to the implementation of immunization services in the country. I would also like to acknowledge and thank country teams of WHO and UNICEF for their technical assistance in terms of formulation of this document.

FOREWORD

Pakistan's Immunization program is in place since 1978. During this time, it has gone through a lot of improvement in vaccine management, vaccine delivery, introducing new vaccines in the program and vaccine coverage. The immunization policies are heavily influenced by the robust evidence and guidance by the National Immunization Technical Advisory Group (NITAG) and National Inter-agency Coordination Committee (NICC). Immunization policy has integrated service delivery for reaching the zero dose among its main objectives.

The EPI primarily covers the mothers, infants and children for immunization. The EPI program shall be including vaccines for prevention of vaccine preventable diseases among the adolescents and older age groups as the evidence of vaccines' effectiveness is acquired and advised by the NITAG. The immunization schedule shall thus be periodically updated as and when required depending upon the local disease burden and requirements. Private sector service providers will be required to provide data of vaccination for their clients to be incorporated into the immunization information system.

It has been realized that the National Immunization Policy needs to be aligned with socio-economic changes and health indicators at the international, national and sub-national levels, should take latest innovations into account and give directions to better engage parents and caregivers of the children. Further, coherence with the specific SDG3 targets, National Health Vision 2016-25 and Immunization Agenda 2030 (IA2030) is also required to align the vision of the program with the national and global health expected outcomes.

This immunization policy shall have its periodic updating considering the quality of evidence-based recommendations by the Strategic Group of Experts on Immunization (SAGE), Regional Immunization Technical Advisory Group (RITAG) and NITAG.

SECTION 1

1. Conceptual framework

1.1 Vision and Goal

The Expanded Program on Immunization envisions **“to achieve the universal immunization coverage leaving no one behind to die from a vaccine preventable disease”** (mortality from vaccine preventable disease should be less than 1 % of the total child mortality). The EPI vision incorporates international commitments and national directions and principles thereby contributing to SDG3 and the National Health Vision's (2016-2025) specific goals through program's objectives as given in its new comprehensive Multi-Year Plan (cMYP) 2020-24.

The **goal** of the EPI is **to reduce the infant, child and mother mortality and morbidity linked with vaccine preventable diseases, as per EPI's schedule, and to limit other infectious diseases** (epidemics and pandemics) through emergency vaccination drives.

1.2 National Immunization's objectives and targets

- (a) To reach more than **90% coverage with third dose of Pentavalent vaccine** among children under 1 year of age at national level and at least 80% coverage in every district through routine immunization by **2025 and sustain it.**

- (a) To **introduce the new available vaccines** based on evidence and epidemiological data complying to vaccine regulatory system of the country.
- (b) To strengthen the **VPDs surveillance** in order to provide complete and timely information backed with strong **monitoring system** for continuous improvement.
- (c) To **integrate EPI with primary health care** within a more comprehensive service delivery program.
- (d) To institute **robust vaccine supply chain system** ensuring availability of potent vaccines.
- (e) To enable the communities in enhancing their understanding and **ownership of the value of vaccination and demand vaccination as their right** and responsibility.
- (f) To enhance facility-based vaccination with **timely and effective AEFI management**
- (g) To improve **immunization waste management system**
- (h) To achieve **sustainability in financing and resource mobilization** for various immunization interventions in a timely and efficient manner.
- (I) To develop a strong **EPI/PEI Synergy Framework and Mechanism**.

Policy Statements

The overall aim of the policy is to contribute towards SDG3 goal through reduction in vaccine preventable diseases (VPDs) for all Pakistanis including infants, children, adolescents and mothers as routine, outbreak response and in campaigns, and for all eligible population during pandemics and emergencies.

Policy Guiding Principles

The EPI policy development and implementation has the following principles as its guiding light:

1. **Governance & Coordination:** Post 18th amendment era needs greater level of coordination and cooperation between the federal and provincial/ area health bodies. Immunization program will create better opportunities and aid the coordination within the public sector stakeholders, donors and partners. It would also engage the private sector through MOU in order to achieve the SDG3 targets. Result-based monitoring is one such tool that addresses effective implementation of the concept of good governance.
2. **Responsiveness:** The national immunization program needs to be more responsive by ensuring dignity, confidentiality, autonomy, prompt attention, participatory approach, and choice of provider on the service delivery side. At present, vaccine hesitancy and elements of non-trust in the publicly provided vaccines, which would be addressed through the improved Interpersonal Communication (IPC) skills for vaccinators in order to remove the barriers.
3. **Transparency and accountability at all levels:** To address this aspect, measures for internal transparency and accountability need to be strengthened where the measures for external accountability do exist usually.

4. **Vaccine forecasting and procurement:** All EPI vaccines are procured at federal level on behalf of provinces as pool procurement system and further distributed to the provincial levels according to share of the provinces. Procurement of vaccines is carried out on annual basis. The annual requirement is estimated through a forecasting process in consultation with provinces based on the target population for each vaccine, available balances, estimated coverage target, number of doses administered per target and wastage multiplying factor. The vaccines are procured following the Public Procurement Regulatory Authority (PPRA) 2004 rules. The vaccines like BCG, OPV and Td are procured through Government of Pakistan funds and the vaccines like Measles Rubella (MR), Pentavalent, Pneumococcal Conjugate Vaccine (PCV), Inactivated Polio Vaccine (IPV), Typhoid Conjugate Vaccine (TCV) and Rotavirus vaccines are procured as country co-financing share with Gavi as per Gavi vaccine policy until the country would graduate from Gavi support.

According to the current country decision, allowed open vial wastage of EPI routine vaccines is as below:

S/N	Name of Vaccine	Wastage (%)	Wastage Multiplying Factor (WMF)
1	BCG	50	2
2	OPV	20	1.25
3	Pentavalent	5	1.05
4	PCV (4 doses vial)	10	1.11
5	Rotavirus	5	1.05
6	IPV	20	1.25
7	MR	20	1.25
8	TCV	10	1.11
9	Td	20	1.25

EPI vaccines administered at service delivery levels as per following MDVP:

S/N	Name of Vaccine	Preservative	Placement of VVM	Multi Dose Vial Policy (MDVP)
1	IPV (10 doses vial)	Yes	Label	Vaccine can be used in subsequent session or up to 28 days at fixed sites, campaigns, and outreach sessions
2	PCV (4 doses vial)	Yes	Label	Vaccine can be used in subsequent session or up to 28 days at fixed sites, campaigns, and outreach sessions
3	Td (20 doses vial)	Yes	Label	Vaccine can be used in subsequent session or up to 28 days at fixed sites, campaigns, and outreach sessions
4	BCG (20 doses vial)	No	Top	Must be discarded no later than six hours after opening or at the end of the session, whichever comes first
5	MR (10 doses vial)	No	Top	Must be discarded no later than six hours after opening or at the end of the session, whichever comes first
6	OPV (20 doses vial)	Yes	Label	Vaccine can be used in subsequent session or up to 28 days at fixed sites, campaigns, and outreach sessions
7	TCV (5 doses vial)	No	Top	Must be discarded no later than six hours after opening or at the end of the session, whichever comes first

5. **Integration and cross-sectoral synergies with integrated service delivery concept with other PHC services:** There is enough evidence in support of integrating immunization program into maternal, newborn and child health services (MNCH), and LHW program at district level⁽¹⁾. Immunization coverage showed improvement after integration into the PHC initiatives. Emphasis will be on achieving equity at all levels and reaching out to the marginalized and most vulnerable population sub-groups. Strategies to reach zero dose and due defaulter will be developed and adopted by integrating into other programs, such as MNCH, LHW, and Nutrition program. Strong immunization systems are an integral part of a well-functioning health system.
6. **Equity and best practices:** As stated in the National Health Vision 2016 – 2025, adapt best practices for vaccine preventable diseases surveillance and addressing equity for the access and availability of vaccines in preventing those VPDs especially for the marginalized and hard-to-reach communities.
7. **Immunization services delivery and quality:** The availability of vaccination will be enhanced and maintained through the required regulatory mechanisms to ensure the quality of vaccines and sufficient and qualified human resource at all levels addressing the supply side of vaccination

8. **Immunization safety and monitoring:** Immunization services should not only be of highest possible quality but also safest possible. This shall be maintained through consistent implementation and monitoring and evaluation of the prescribed safety standards for immunization services (as per prescribed safety standards under this policy)
9. **Public Health and clinical evidence base:** Decision making for any changes and adoption for immunization schedules, introducing new vaccines and immunization strategies will be guided by high-quality evidence in respective areas.
10. **Sustainability:** EPI Pakistan considers sustainability a core component to ensure adequate resources to cover the cost of vaccines. As a country, Pakistan encourages and sensitizes the provinces and federating areas mobilize resources to share the cost by their own resources. In relation to Gavi supported vaccines, as per GAVI vaccine policy, the country will phase out from the support to self-financing in phases phase I & II, accelerated phase and transition phase based on GNI of the country. With Gavi supported vaccines, the country would have to follow GAVI vaccine policy in terms of the country co-financing share in the coming years. Point in time the country is at preparatory transition phase which would lead to the accelerated phase and then ultimate graduation from GAVI support which would result in additional financial resources to sustain the vaccine availability which are procured as country co-financing share. Additionally, community and private sector engagement, and strengthening of primary health care will further ensure sustainability.
11. **Use of technology and innovations:** eHealth is an emerging technology in the field of health. Improving immunization coverage and increasing demand has been tested and proven effective in various settings especially the low-income countries. These strategies and interventions will be given priority and be integrated into the routine immunization program. Innovations will be adopted by the program aiming to enhance demand for vaccines, better data integration and accuracy.
12. **Effective communication:** Communicating and pursuing immunization with parents and caregivers of the children needs a scientific approach. As a policy, the program will use effective and proven communication strategies to outreach the zero dose and dropouts.

1.3 Policy Directions for Introduction of new vaccines

After thorough epidemiological, cost-effective assessments, level of available evidence with stakeholders' consultation, the EPI program will introduce new vaccines into routine immunization as per recommendations of NITAG and subsequent approval of NICC.

1.4 Fully Immunized Child

A fully immunized child (FIC) is defined as a child who has received at least: BCG dose at birth, three doses of polio and two doses of IPV, three doses of Penta, three doses of PCV, two doses of Rota, and one dose of measles and rubella vaccines before 12 months of age.

1.5 Zero Dose Child

EPI Pakistan will follow the international definition set by WHO/UNICEF (2020)², a child will be considered a zero-dose child who has not received Pentavalent 1 vaccine.

¹ This FIC definition is the suggested one for Pakistan under new EPI policy. It is to highlight those provinces/areas do modify their FIC definitions as per their requirements and targets.

² Progress and Challenges with Achieving Universal Immunization Coverage
https://www.who.int/immunization/monitoring_surveillance/who-immuniz.pdf

SECTION 2

2. Immunization Pathways

2.1 Immunization reporting, surveillance and research

2.1.1 Routine EPI reporting.

2.1.1.1 All public health facilities and selected private health facilities with a gradual uptake with the EPI counterparts shall maintain a uniform prescribed vaccination register, both as paper and electronic record for the target population in the catchment area of the health facility, and if feasible, will link immunization registration to birth registration processes.

2.1.1.2 All public health facilities and selected private health facilities shall record vaccination given on an immunization card and updating the electronic cards (if available) maintain the minimum standards required by the country's immunization system.

2.1.1.3 All public health facilities and selected private service providers shall report on number and percentage of the target population vaccinated as per approved schedule to the district/provincial/area immunization program on monthly basis, which would then be reported to the federal immunization program on same frequency.

2.1.2 VPD Surveillance

2.1.2.1 All notifiable VPDs will be reported from all public and private health facilities on weekly basis using standard formats.

2.1.2.2 All districts will have trained and designated surveillance focal person(s) with liaison with field epidemiologists for active and passive surveillance of the VPDs, and to identify any potential outbreak for timely response and report to the surveillance cell of the respective EPI and controlling health authorities.

2.1.2.3 In the above context, Federal and Provincial Directorates of Immunization and all the public health facilities having EPI vaccination centers shall implement the required surveillance, vaccination and case management responses to vaccine preventable disease outbreaks according to the national guidelines in close collaboration with the supporting programs and resources.

2.1.2.4 All efforts shall be made through the appropriate forums, and with the health departments to establish or upgrade existing lab facilities and sentinel sites to assist in case-based surveillance and sustain district capacity for case-based surveillance.

2.1.3 Immunization Data Quality Assessment

2.1.3.1 Federal and Provincial Directorates of Immunization shall make sure that the data quality assessment is done and reported to the line ministry/department on periodic basis.

2.1.4 Research and Development

2.1.4.1 All EPI programs shall have a research and evaluation cell established comprising of highly qualified researchers, data analysts, epidemiologist and other relevant experts who would be conducting evidence-based research on EPI in general and synthesis for EPI targeted diseases (including pandemics and epidemics) for choice of most effective vaccines and recommendations of vaccines based on data of local strains and disease epidemiology

2.1.4.2 It would be desirable to conduct study on disease burden of new VPDs on periodic basis in order to suggest evidence-based informed decision-making for the NITAG.

2.1.4.3 For every new vaccine or new technology introduced in the program, a post introduction evaluation will be conducted through an independent third party.

2.1.4.4 The EPI shall conduct periodic immunization coverage survey through a third party on regular basis documenting impact of the immunization program ensuring quality of data and reporting.

2.1.4.5 The program shall conduct periodic consultation with Pakistan Bureau of Statistics in order to calculate province/district wise target population. Moreover, the EPI Program shall have consultation with provinces/ federating areas to assess population's barriers and enablers (both on the demand and supply sides) to immunization accessibility and availability especially considering equity and marginalized population sub-groups.

2.1.4.6 All research, whether on a small scale or at a large scale, shall abide by ethical code of conduct, and shall get prior approval from the appropriate Institutional Review Board (IRB) under the M/o NHSR&C at the federal level and by the respective provincial IRBs.

SECTION 3

3. Governance and Coordination

The overall governance and coordination will be with the NICC, Ministry of National Health Service, Regulations and Coordination along with the provincial/ area health departments.

3.1 Role and functions of National Interagency Coordination Committee (NICC)

Membership: All governmental and non-governmental organizations (partners and donors) providing technical and financial support to immunization program.

3.1.1 Assist country in becoming self-sufficient in its immunization programs

3.1.2 Coordinate support at national level from government and partner agencies to strengthen routine immunization and supplementary immunization activities including polio eradication, measles and neonatal tetanus elimination- activities in the country

3.1.3 Establish a forum for exchange of information and dialogue on immunization program in the country and facilitate dialogue by making data information sources readily available

3.1.4 Support M/o NHSR&C, Government of Pakistan in adopting appropriate policies, advice and tools.

3.1.5 Mobilize resources with the government, EPI partners and the NGOs to eradicate polio, eliminate/control Measles, Rubella and MNTE, and eliminate/control other vaccine-preventable diseases.

3.1.6 Assist the international and national community in identifying and developing support for new disease control programs when appropriate intervention tools, such as new vaccines, become available.

3.1.7 Assist the government in resource mobilization and encourage government in appropriate resource allocation for routine and supplementary immunization activities.

3.1.8 Advise the government in specific areas related to EPI and supplemental immunization activities for polio eradication, measles and neonatal tetanus elimination where partner agencies have specialized expertise. The committee will also advise the government in case of emergency vaccination as the need arises.

3.1.9 Review progress towards polio eradication, measles and neonatal elimination, and improving Routine Immunization with suggested plans for future

3.2 Role and functions of National Immunization Technical Advisory Group (NITAG)

3.2.1 The purpose of the NITAG is to guide policy makers in the M/o NHR&C and EPI Program of Pakistan to make evidence-based immunization related policy decisions. The NITAG shall do policy analysis and strategy formulation for control, elimination and eradication of VPDs diseases through immunization taking in consideration of latest scientific development in the relevant field.

3.2.2 The NITAG shall be formed by the executive order of the Federal Secretary (Health) on the basis of proposal from Federal Directorate of Immunization. Members should be nominated from the following field of expertise from local experts: pediatrics, infectious disease epidemiology, immunology, clinical research, virology, microbiology, health economics and social sciences. The NITAG shall have a total of maximum 15 members. The NITAG will convene meetings at least twice a year. If necessary, a meeting can be convened at any earlier date.

3.2.3 The NITAG will assist the M/o NHR&C, FDI, Drug Regulatory Authority of Pakistan (DRAP) and Inter-agency Coordination Committee (ICC) by providing evidence-based policy direction on various immunization related issues as required and desired. e.g., formulation of immunization policy and strategies for routine and supplementary immunization activities, introduction of new vaccine in routine EPI schedule, evaluation of new immunization technologies, vaccine quality and safety, immunization schedule, advocacy for immunization, vaccine handling and storage at public and private sector, licensing of new vaccine for public and private sector use, commissioning of new research, assessments/evaluations to guide policies.

3.2.4 The NITAG will also provide special policy and strategy direction to the M/o NHR&C in any emergency (e.g., earthquake, flood etc.) for any particular population in any particular area to control any imminent epidemic of VPDs.

3.3 Role and functions of public/private sectors at national, provincial and districts levels

3.3.1 Role and functions of the M/o NHR&C & Federal Directorate of Immunization (FDI)

3.3.1.1 Ensure ownership and accountability at the federal, provincial/ areas and district management levels.

3.3.1.2 Effective donor coordination and reporting, partnership building, proposal development after due consultation with provinces and federating areas.

3.3.1.3 Shall forecast and procure the required vaccine quantities, besides estimated "Buffer Stocks" of vaccines, syringes, supply chain equipment and allied equipment required for smooth functioning of the EPI program and to prevent and avert any outbreak of the vaccine preventable disease.

3.3.1.4 Shall train the adequate number of required staffs. The EPI will also train the staff of private sector where required.

3.3.1.5 Implement national immunization policy and procedures in letter and spirit.

3.3.1.6 Periodically conduct surveillance and monitoring activities.

3.3.1.7 Shall conduct regular research and evaluation studies and activities.

3.3.1.8 Enhance synergies between EPI and PEI and other vertical programs.

3.3.2 Role and functions of the Health Department (provincial and district levels)

3.3.2.1 Shall ensure timely availability of required quantities of vaccines, syringes and allied equipment required for smooth functioning of the EPI program, and to prevent and avert any outbreak of the vaccine preventable disease.

3.3.2.2 Shall recruit and train the adequate number of required staffs including staff from private health care providers where required.

3.3.2.3 Develop annual plans in line with cMYP and implement as per EPI policy.

3.3.2.4 Periodically conduct surveillance and monitoring activities.

3.3.2.5 Shall assemble and analyze EPI data, both from the public and private sectors and inform the federal level.

3.3.2.6 Conduct monthly review meetings on regular basis at district and provincial levels.

3.3.2.7 Enhance synergies between EPI and PEI and other vertical programs.

3.3.3 Role and functions of Private Sector

3.3.3.1 Where the private sector is involved as an implementing partner, it shall provide appropriate manpower, specialized CCE (ILR, SVC, etc.) dedicated cold chain equipment and space for providing immunization services to the people visiting the health facility or clinic for medical assistance/treatment.

3.3.3.2 Shall ensure monitoring and maintenance of cold chain for vaccines in accordance with the procedure laid down by the EPI Program.

3.3.3.3 Shall regularly maintain and share vaccination reports and record with the CEO/DHO Health on the standard reporting and recording tools.

3.3.3.4 Facilitate visits of external monitors (government/partners) to private health facilities to supervise cold-chain and vaccine management, stocks and safe injection practices, etc.

3.3.3.5 The cost of vaccines and injection supplies shall not be charged to the clients. Minimum service charges may be applied to cover overhead expenditures.

SECTION 4

4. Service delivery

4.1 Immunization services in rural areas

4.1.1 Immunization services shall be provided by the fixed, outreach and mobile strategies. Facility based fixed site vaccination will be enhanced from 30% to 70% with an exception to Balochistan where the current strategy for outreach services and mobile vaccination will continue along with fixed sites service delivery through EPI skilled staff.

4.1.2 Outreach services shall be provided on a daily basis as per plan in rural areas. Ideally, fixed health facilities shall be working 24/7.

4.1.3 In order to enhance integrated health services in hard to reach, and poor performing districts for improving the service utilization; considering UHC health benefit package, the already immunized target population would be linked through the EPI information system for other services such as birth registration, nutrition services and other mother and child services and programs.

4.1.4 Comprehensive microplanning on yearly basis shall be done in coordination with polio programs counterpart to reach each population pocket and children. Community engagement for microplanning will be considered for identifying the outreach sites.

4.2 Immunization in peri-urban and urban settings

4.2.1 EPI immunization services shall be available at fixed sites on all working days, with an aim to enhance the fixed site vaccination by 70%

4.2.2 The designated EPI staff shall provide services at the fixed sites. Outreach services will be provided as per micro-plans and outreach plans.

4.2.3 Private health facilities will be offered integration with the EPI information system and in turn they would get free vaccine bundle (diluent, AD syringes, safety boxes, etc.), which they would administer by charging minimum administration cost.

4.2.4 Every Union Council will have at least one fixed EPI center.

4.2.5 Available community volunteers to be engaged for building trust.

4.3 Immunization Services for High Risk or Vulnerable Groups

4.3.1 The Federal and Provincial Directorates of Immunization and polio program, CBOs, NGOs, Pakistan Pediatric Association and the Pakistan Medical Association will have an annual immunization micro-plan identifying strategies and actions to reach hard to reach and underserved populations, as well as a system to monitor and act on immunization zero dose, due defaulter and drop out.

4.3.2 It is the policy of the M/o NHR&C to support in implementation of travelers' vaccination check for Pakistanis travelling abroad for Polio (till it is implemented by the WHO), COVID-19 (as per requirement), travelers to African regions, and to all Haj Pilgrims.

4.3.3 It is the policy of the M/o NHR&C, depending on the availability of resources, to extend vaccination opportunity for COVID-19 and future pandemics of similar nature and other vaccinations against vaccine preventable diseases for identified high risk population groups.

4.4 Immunization campaigns and specific SIAs

4.4.1 Polio needs to be eradicated and whereas measles and rubella and maternal and neonatal tetanus should be eliminated. The immunity gap among target groups will demand SIAs at regular intervals. The EPI will implement mass campaigns with strict monitoring and safety of the vaccines.

4.4.2 Research will be made integral part of such campaigns and with new vaccine introductions to ensure that adequate post marketing research is implemented to assess safety and efficacy of vaccines, as well as to confirm campaign coverage rates, and document any adverse events or lessons-learnt for future reference.

4.4.3 The EPI will implement targeted campaigns pertinent to the context of outbreak response or in case of a disaster rendering populations internally displaced.

4.5 Immunization in Schools

4.5.1 All public and private sector schools shall be eligible for campaigns vaccination against VPDs. The schools will be bound to share vaccination data of the enrolled children.

4.5.2 The schools should check the vaccination status of the children at the time of admission and will report to the relevant health (EPI) and district authorities including booster doses wherever applicable.

4.5.3 The communication part of the EPI will ensure that all the schools have information and education materials for immunization including information on the immunization schedule, VPDs being prevented and controlled by the routine immunization and campaign.

4.6 Communication, demand generation, advocacy, equity and universality

4.6.1 The EPI through its partners and provincial/ area EPIs will update and implement communication strategy.

4.6.2 The communication strategy will not only be limited to the clients of the EPI program, but it will also engage mass media, social media, educational departments, inter-ministerial coordination mechanisms and local legislatures and parliamentarians.

4.6.3 All local strategies and community-based initiatives using different communication for development approaches will be developed in order to increase knowledge and demand for immunization services for the missed-out and unreached population subgroups.

4.6.4 The EPI will engage community, religious leaders, local influencers, philanthropists, mothers/caregivers and head of a family to persuade and convince them to extend their support for reaching the target population and completion of immunization adopting improved interpersonal communication skills.

4.6.5 Communication strategies will be periodically updated based on evidence gathered from social research.

4.6.6 The EPI will ensure that service providers in public and private sectors protect and promote client rights by:

4.6.6.1 Ensuring access to immunization regardless of religious belief, class, color, creed, geographic location, gender, income level, or ethnic background.

4.6.6.2 Ensuring all ethical principles are followed judiciously including verbal consent from mother/ caregiver of children for vaccination.

4.6.6.3 Ensuring all clients have been provided with information of the benefits and adverse events following immunization (if any) of the vaccines given their benefits in terms of protection and verbal reminders of the next visit along with information that they will be receiving through text messages from the EPI program for their next due vaccination for compliance and complete vaccination.

4.7 Policy on Gender and Immunization

4.7.1 The sex segregated data will be collected and reviewed for any disparities routinely through the EPI MIS and the coverage evaluation surveys.

4.7.2 Any barriers in accessing vaccines at gender level will be addressed with better communication strategies.

4.8 Policy on User Fees for Immunization

4.8.1 There will be no user fees for immunization services in Pakistan in public health facilities. In case the private sector is engaged for immunization services through provision of free of cost vaccines by the government, they will not charge the cost of the vaccines, however, they would charge minimum administration cost only.

4.9 Policy on use of syringes and needle size

4.9.1 The auto-disable syringes of international quality (WHO prequalified) and ISO certified companies will be procured/acquired having a needle size of 24G or 25G considering the smaller size of South Asian children as compared to the Caucasian children.

4.9.2 The vaccines should be injected in the area where local, neural, vascular or tissue injury is unlikely to occur. Longer needles are likely to cause less redness and swelling as compared to shorter needles. The length of the needle should be long enough to reach the muscle mass, to avoid seepage into the subcutaneous region. The vaccinators should have the knowledge of anatomy of the injection site.

4.9.3 Disposable single-use syringes and needles are not recommended for injections in immunization programs. Used auto-disable syringes will NOT be reused in any case and will be discarded as per the Environmental & Social Management Plan (ESMP) and Hospital Waste Management (HWM) Rules 2005.

4.10 Policy on Distribution of vaccinators/skilled immunization staff in Union Council

4.10.1 Vaccinator/skilled immunization staff is to be deployed in union councils according to population or catchment area (whichever is smaller).

4.10.2 At least two vaccinators/skilled immunization staff (one for fixed site and one for outreach) to be deployed in every union council irrespective of population, catchment area or target. However, vaccinator/skilled immunization staff can be increased per union council based on two criteria – population and/or geographical distance and terrain. One vaccinator/skilled immunization staff for every 10,000 (rural) to 20,000 (urban) population or 10 – 30 Sq Km area. A parent/care giver from any corner of such an area would have to travel maximum 2-3 Km distance to the central location. Smaller geographic unit (10 Sq Km) classified as G-3, can be used for difficult terrain like mountainous area, marsh land, desert, whereas medium geographic unit (20 Sq Km) classified as G-2 can be used for rural setting with small villages located at some distance and larger geographic unit (30 Sq Km) classified as G-1 can be used for urban setting, mohallas, flats, etc. Position of vaccinators to be determined in every UC following this guideline and accordingly distribution/recruitment of vaccinators to be done.

4.11 Policy on vaccination of children of higher age

4.11.1 Though undesirable but many children in Pakistan failed to complete their routine vaccination schedule within the recommended age. Children of higher age group remain unvaccinated or partially vaccinated for various reasons leading to potential outbreak. These children require completing their vaccination schedule as appropriate for their age. According to WHO guidelines for interrupted or delayed routine immunization (2021) and local country.

context, guidelines for vaccinating children aged above one year with different antigens is given below.

- For BCG, 1 dose should be given till the age of one year, however, BCG is not recommended for above one year.
- For bOPV, 3 doses with at least 4 weeks interval between each dose for children up to 5 years of age.
- For Pentavalent (DTP-HepB-Hib), 3 doses with at least 4 weeks interval in between each dose if the child is less than 1 year. If the child is between 1 – 2 years, then 1st dose followed by 2nd dose after 2 months, and 3rd dose of DTP after 6 – 12 months. If the child is between 2 – 6 years, then dose of DTP should be given as 1st dose of DTP, 2nd dose (after 2 months) and 3rd dose (after 6 – 12 months). If the child is between 6 – 7 years, then use DTaP, 3 doses with aforementioned interval. If the child is 7 years and above, then use Td, 3 doses with aforementioned interval.
- For PCV, if the child is less than 1 year then 3 doses with at least 4 weeks interval in between each dose, if the child is between 1 – 2 years then 2 doses at 4 weeks interval. For 2 – 5 years, only high-risk children should be given 2 doses at 4 weeks interval.
- For Rotavirus vaccine, if the child is less than 2 years then 2 doses with at least 4 weeks interval in between each dose. However, for children above 2 years, Rotavirus vaccine is not recommended.
- For IPV, 2 doses should be given to less than 1 year in routine, if the child is above 1 year, then 2 doses with 6 months interval between each dose.
- For MR vaccine, if the child is less than 1 year then 1 dose should be given. If the child is above 1 year, then 2 doses with at least 6 months interval between each dose.
- For TCV, if the child is less than 1 year then 1 dose should be given. If the child is above 1 year, then 1 dose should be given.

4.12 Policy on EPI Waste Management

4.12.1 The EPI waste management policy is guided by the Environmental Protection Act 1997. The HWM Rules 2005 have mandated the source segregation of EPI waste (vials, syringes, etc.) to handle by recovery, reuse and recycle. EPI has ensured to implement the HWM rules 2005 for safe collection, storage, transportation and treatment through innovative technologies (environment friendly incinerators, brick box and burial pits) at urban and remote areas. Daily waste generation and disposal data including reporting system has been maintained for future plan of action to safeguard public health and environment.

SECTION 5

5. Human resources

5.1.1 The EPI program shall hire new vaccinators as per requirement identified in 4.10.2 section of this National EPI policy.

5.1.2 All the staff involved in immunization will be given regular in-service training and other capacity building opportunities related to injection safety, vaccine handling and storage, surveillance, waste management, monitoring and evaluation.

5.1.3 Mechanisms for reward and accountability for high and low performing EPI staff will be in place.

5.1.4 EPI staff capabilities in interpersonal communication will be regularly enhanced to promote them as brand ambassador for the program.

5.1.5 In order to improve the program's efficiency, more emphasis will be given to skill-mix though improving the staff-mix will also be considered where there is shortage of vaccinators. Increasing the number of the vaccination staff, mixing their qualifications (where other paramedic and nursing staff could also be involved in vaccinating clients), balancing senior and junior staff members and mixing disciplines (all cadres can be involved for vaccinating clients, if required)

SECTION 6

6.Vaccine policy, and vaccines' security

6.1 Vaccine policy

6.1.1 Policy to changes in routine immunization schedule will be technically reviewed and recommended by the NITAG and endorsed by the NICC.

6.1.2 The changes will be based on recent research evidence of disease burden, vaccine efficacy, vaccine safety and program feasibility.

6.1.3 New vaccines inclusion into the vaccination schedule will be based on the following protocol:

6.1.3.1 Burden of the VPD in question (surveillance data, comprehensive studies, disease burden estimates by the WHO or Institute of Health Metrics and Evaluation).

6.1.3.2 Extensive review and systematic reviews/meta-analysis of latest international evidence including WHO's position papers on vaccine efficacy and safety.

6.1.3.3 Through assessment of system readiness and programmatic feasibility for inclusion of a new vaccine into the national schedule (cold chain capacity, surveillance capacity, monitoring capacity, human resource right mix, technology, safety requirements and country affordability).

6.2 Vaccine security

6.2.1 Any contraindications for vaccination will show compliance to the EPI's detailed guidelines and evidence from WHO position papers and updated advice from the UNICEF and other UN partners.

6.2.2 Federal and provincial/ area teams will be developed with competencies in:

6.2.2.1 Vaccine management within stores and at each level,

6.2.2.2 Keeping records of vaccines by batch numbers as a quality assurance measure,

6.2.2.3 Developing vaccine logistics forecasting and planning,

6.2.2.4 Understanding and operating vaccine management software used at all levels.

6.2.3 Costing and assessment of financing gaps, economic impacts, financial mechanisms for sustainability, cost estimations of possibilities to manufacture vaccines on local strains and local use for consideration of the higher authorities. The immunization program in Pakistan is shifting to the

recurrent side of its budgeting. Evidence suggests that the cost ranges may be higher than current estimates for LMICs (\$0.16-\$2.54 incremental cost per dose). Integration of the EPI program and putting it in recurrent side is estimated to avert 85% of deaths due to VPDs given sustainability in the required resources is ensured with strict accountability. A costed Plan of Action is desirable when the program shifts to the recurrent side of the budget. This will encompass:

6.2.3.1 The M/o NHR&C and the FDI, in collaboration with provinces/ areas and development partners, will mobilize sufficient resources to extend immunization services where needed

6.2.3.2 In lieu and compliance to the Economic Affairs Division's and Ministry of Finance's commitments, the EPI will develop case to gradually increase the government contribution for immunization services.

6.2.3.3 Any new vaccine's application for its introduction will be critically analyzed in terms of costs, financing gaps and efficacy.

6.2.3.4 Introducing a new vaccine will have the endorsement of the Ministry of Finance in order to ensure its financial sustainability when it comes to government's share of purchasing the vaccines.

6.2.3.5 In order to maintain transparency, accountability and trust and minimize elements of any corruption, vaccine procurement from the government's share will be done through the UNICEF or through open tendering process, as prescribed by the finance division and the controlling ministry.

6.2.3.6 All steps in the process of financial sustainability, acquiring and manufacturing of vaccines, and introducing new vaccines will be carefully considered to ensure that there is no conflict of interest in decision making.

6.2.4 Cold chain of the vaccines as per their prescribed requirement shall be fully ensured. In a Standard Cold Box/ Vaccine Carrier, cool packs shall be used for transportation and temporary storage of routine immunization vaccines.

6.2.5 Programmable and functional temperature monitoring devices shall be mandatory in all cold chain equipment used for storing vaccines.

6.2.6 Injection safety and safe waste management of the used syringes, vials, ampules and infected material will be implemented following ESMP and HWM Rules 2005.

6.2.7 Only the vaccines fulfilling WHO pre-qualification and registered with DRAP will be used.

SECTION 7

7. Management Information System, eHealth and Artificial Intelligence

7.1 EPI shall have advanced level standard management information system of its own, which would be capable of integrating with other health information systems and use eHealth technology when required.

7.2 The MIS will have its own dashboard where regular data of coverage, vaccine utilization and surveillance will be uploaded with real time analysis.

²Annexure II gives the evidence for use of eHealth (mHealth) in immunization programs

7.3 The MIS to be integrated with the National Immunization Management System of NADRA, Provincial/area vaccine management system and epidemic intelligence systems.

7.4 The eHealth would generate SMSs to the target population to address due defaulter and zero dose. The parents/caregivers will receive regular reminders for next vaccine dose and guidance about vaccines and immunization benefits.

7.4 The MIS will also receive data from the registered private health care providers.

7.5 The MIS platform will receive regular feedback from the parents/caregivers in order to improve the EPI service quality and timely respond to gaps in immunization program

Annexure I

a. National Vaccination schedule

b. Vaccination schedule for pregnant women for prevention of neonatal tetanus

Vaccine	When to give	Dose & Site	Expected duration of protection
Td 1	First contact during pregnancy	0.5ml intramuscular injection on upper arm	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 or subsequent pregnancy		10 years
Td 5	At least one year after Td 4 or subsequent pregnancy		Throughout productive years

- All women during their 1st pregnancy shall be targeted for 2 doses of Td vaccination through routine immunization
- The 2nd dose or any subsequent dose of Td vaccine (if due) preferably to be given to a pregnant mother at least 2 weeks before delivery
- After delivery, these women shall complete 5 doses of Td vaccination schedule with remaining doses at appropriate interval irrespective of pregnancy
- If a pregnant woman has received 5 doses of Td according to above schedule, there is no need of additional doses of Td during subsequent pregnancies
- Women entering reproductive age (>15 years) with documented evidence of three valid doses of DTP or Td containing vaccines (e.g. DTP, Tetravalent, Pentavalent vaccine) during childhood should resume the schedule outlined above from Td3 onwards.

Age	Antigen	Dose	Route of administration	Disease prevented
Birth	BCG	0.05 ml	Intra – dermal On right upper arm	Childhood Tuberculosis
	OPV-0	2 drops	Oral	Poliomyelitis
	Hepatitis-B	0.5 ml	Intramuscular injection on anterolateral site of left thigh	Hepatitis B
6 weeks	OPV-I	2 drops	Oral	Poliomyelitis
	Rota – I	1.5 ml	Oral	Diarrhea due to Rota Virus
	Pneumococcal (PCV) – I	0.5 ml	Intramuscular injection on anterolateral site of left mid-thigh	Pneumonia and Meningitis
	Pentavalent - I	0.5 ml	Intramuscular injection on anterolateral site of right mid-thigh	Diphtheria, Tetanus, Pertussis, Hemophilus Influenza Type B & Hepatitis B
10 weeks	OPV-II	2 drops	Oral	Poliomyelitis
	Rota – II	1.5 ml	Oral	Diarrhea due to Rota Virus
	Pneumococcal (PCV) – II	0.5 ml	Intramuscular injection on anterolateral site of left mid-thigh	Pneumonia and Meningitis
	Pentavalent - II	0.5 ml	Intramuscular injection on anterolateral site of right mid-thigh	Diphtheria, Tetanus, Pertussis, Hemophilus Influenza Type B & Hepatitis B
14 weeks	OPV – III	2 drops	Oral	Poliomyelitis
	Inactivated Polio Vaccine (IPV)– I	0.5 ml	Intramuscular injection on anterolateral site of left mid-thigh (at-least one inch away from the PCV injection)	Poliomyelitis
	Pneumococcal (PCV) – III	0.5 ml	Intramuscular injection on anterolateral site of left mid-thigh	Pneumonia and Meningitis
	Pentavalent - III	0.5 ml	Intramuscular injection on anterolateral site of right mid-thigh	Diphtheria, Tetanus, Pertussis, Hemophilus Influenza Type B & Hepatitis B
9 Months	TCV (Typhoid conjugated vaccine)	0.5 ml	Intramuscular injection on right mid-thigh	Typhoid
	MR (Measles & Rubella) – I	0.5 ml	Subcutaneous injection on left upper arm	Measles and Rubella
	Inactivated Polio Vaccine (IPV)– II	0.5 ml	Intramuscular injection on anterolateral site of left middle thigh (at-least one inch away from the PCV injection)	Poliomyelitis
15 Months	MR (Measles & Rubella) – II	0.5ml	Subcutaneous injection on left upper arm	Measles and Rubella
4-5 years	DPT Booster (For Punjab)	0.5 ml	Intramuscular injection on anterolateral site of right mid-thigh	Diphtheria, Pertussis and Tetanus

Annexure II

Evidence on use of mHealth in Immunization Programs

eHealth (mHealth) in Improving Immunization Coverage

Practice of medicine and public health support by using mobile technology is known as mHealth.(2) Routine Childhood Immunization reduces the child morbidity and mortality and is the cost effective public health intervention globally. Whereas, mHealth is consider as the one of the most effective way to robust immunization coverage especially in lower income countries (LMIC).(3)

Title	Year	Study Type	Sample Size	Evidence Level	Findings
Health applications impact in improving immunization coverage and maternal-child health in Africa	2017	Review Article	17	Level 5	mHealth applications shows robust increase in awareness, retention, coverage and effectiveness in childhood immunization, maternal-child quality care and outcomes.(4)
The Effect of mHealth on Vaccine Uptake, Coverage, and Acceptance Among Children, Adolescents and Adults: A Meta-analysis	2020	Meta-analysis	17	Level 1	Analysis shows a significant improvement in vaccine uptake, coverage, up-to date vaccination and completion of all doses of immunization.(5)
Using Mobile Phones to Improve Vaccination Uptake in 21 Low- and Middle-Income Countries: Systematic Review	2017	Systematic Review	21	Level 1	The potential for mhealth interventions shows the strong evidence in the improvement in vaccination uptake after interventions, including mobile phone apps, appointment reminders, and prerecorded messages.(6)
Use of mobile phones for improving vaccination	2016	Interventional Study (Pre-Post Test)	n=2,078 from Interve	Level 3	The electronic registration of child birth and the reminder for the date

Title	Year	Study Type	Sample Size	Evidence Level	Findings
coverage among children living in rural hard-to-reach areas and urban streets of Bangladesh			ntional area n=2,080 from Control area.		of vaccination to mothers on mobile phones showed enhance vaccination coverage to the rural harsh reach area and urban street dweller communities in Bangladesh.(7)

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