NATIONAL EPI POLICY & STRATEGIC GUIDELINES PAKISTAN 2015

Ministry of National Health Services, Regulations and Coordination, Government of Pakistan

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World Health Organization

Expanded Program on Immunization

Contents

Message by Minister of State

Ministry of National Health Services, Regulations and Coordination

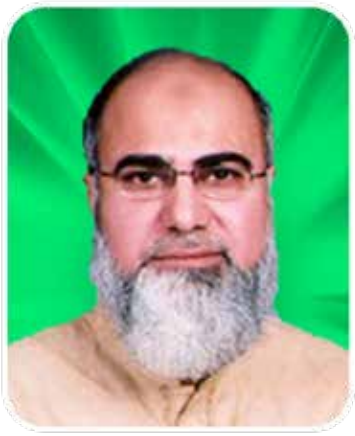
Mrs. Saira Afzal Tarar

The Ministry of National Health Services, Regulations and Coordination is committed to helping the people of Pakistan in improving their health. Our vision is the provision of a stronger health system through provision of an efficient, equitable, accessible & affordable health service deliveries with the objective to support people and communities with healthy nation.

The Government completely recognize the crucial role that immunization plays in reducing child morbidity and mortality and it is our prime responsibility to ensure that every child is protected from vaccine preventable diseases. To fulfil this mission, Federal EPI with partners has developed the immunization policydocument to guide the program in order to achieve its intended objectives and contribute to the achievement of Sustainable Development Goals (SDGs).

Given the positive political environment, it is high time to initiate a progressive change and build a society where vaccination services are utilized optimally and vaccination processes are undertaken in compliance with all international norms. I am sure this National Policy document will serve as a road map to plan and implement all operational and communication activities for EPI.

The technical assistance provided by partner organizations in developing the National EPI Policy is highly appreciated.



Message by Secretary

Ministry of National Health Services, Regulations and Coordination

Mr. Muhammad Ayub Sheikh

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 enhancing immunization coverage of vaccine Preventable Disease. It is manifested from the introduction of the National EPI Policy that there is a major opportunity to use evidence based vaccination practices in the country and to allow the 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 re-orient all immunization services in the country based on the policies, strategies, norms and guidelines incorporated in the immunization policy.

I really appreciate the technical assistance of development partners specially UNICEF and WHO in development of the National EPI Policy.

Message by Director General

Ministry of National Health Services, Regulations and Coordination

Dr. Assad Hafeez

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 initiated to develop this policy document so as to integrate all current and evidence based vaccination practices. The aim is to standardize practices and opportunities for vaccination services.

The National Policy for EPI is the result of a long process of intensive consultations, teamwork, detailed studies and information gathering. This National policy for immunization seeks to guide health workers on vaccination priorities and acceptable practices for the overall benefit of the National and Provincial EPI department of the country.

The Ministry of National Health Services, Regulations and Coordination would like to acknowledge the technical assistance of WHO and UNICEF alongwith all partners in preparing this National EPI Policy.

Message by
National Programme Manager, EPI
Syed Saqlain Ahmad Gilani

Today I feel pride in introducing the National EPI Policy of the Federal Expanded Programme on Immunization (EPI), ministry of National Health Services, Regulation and Coordination, Government of Pakistan. This policy document is based on wealth of technical experience of Government officials and development/ technical partners.

Firstly, I would like to take this opportunity to express my thanks to Minister of State, Ms. Saira Afzal Tarar sahiba and top officials of the Ministry of National Health Services, Regulations and Coordination for putting trust and confidence and for participating in the review process of this policy document, giving comments and recommending the necessary changes to ensure its finalization.

The EPI policy document provides strategic guidance for the implementation of the immunization programme. It builds on the direction and planning of the Comprehensive Multi-Year Plan (cMYP), experience gained during last many years of implementing routine and supplemental immunization activities and international technical immunization guidelines.

I kindly request all officials of the Federal and Provincial Expanded Programme on Immunization (EPI), and partners working in immunization to take the EPI policy as a guiding document and strategy guide in implementing Immunization services in the country.

I would also like to acknowledge and thank our development partners specially UNICEF and WHO for their technical assistance in moving forward the finalization process.

Foreword

Expanded Programme on Immunization (EPI) was launched in 1978. Initially the programme aimed at protecting children by immunization against Childhood Tuberculosis, Poliomyelitis, Diphtheria, Pertussis, Tetanus and Measles. Later, a number of new vaccines e.g. Hepatitis B, Haemophilus Influenza type b (Hib) and Pneumococcal vaccine (PCV10) were introduced in 2002, 2009 and 2012, and IPV in 2015 respectively. It also aims at protecting mothers and newborn against Tetanus. The national immunization programme contributed in significant decrease in childhood morbidity and mortality due to Vaccine Preventable Diseases (VPDs).

The first National EPI policy was formulated in 2004 by the National EPI Advisory Group (NEAG) and later adopted by the defunct Ministry of Health in 2005. Since then, new vaccines and technologies have been introduced in the programme and strategies for immunization and Vaccine Preventable Disease (VPD) surveillance were evolved with new dimensions. The programme also adopted its goals and strategies in accordance with priorities set at the global and regional level. In 2008, the then Ministry of Health (MoH) reformed the NEAG as the National Immunization Technical Advisory Group (NITAG) in accordance with the WHO guideline. It was rightly felt necessary by the NITAG and other stakeholders to revisit the EPI policy in the light of new developments in the programme. Accordingly a sub-committee of the NITAG constituted in 2009,which initially reviewed and revised the existing policy This revised document also laid policy direction and guideline for involvement of LHWs in immunization service delivery, and in the area of private sector's role in immunization.

After the massive Measles outbreak of 2013, the newly formed Ministry of National Health Service, Regulations and Coordination (MoNHSR&C) decided to develop the EPI on pure scientific grounds. In this context, the EPI reformulated its orientation towards evidence-base in infectious disease and immunization. This policy addresses the new vision of the programme, which is more focused on research, guidance, information system management and accountability.

The new Immunization Policy envisages **Pakistan's Vision 2025** by addressing its Pillar 1 i.e.,

- Reduce infant mortality rate from 74 to less than 40 (per 1000 births) and reduce maternal mortality rate from 276 to less than 140 (per 1000 births)

and continue contributing in deceasing IMR through immunization targets and activities as spelled in cMYPs in order to achieve SGD 3 for the country. Further, this Policy is a step forward in implementing National Plan for Vaccinations.

Policy's Goal

The goal of the EPI Policy is to achieve the targets spelled out in the cMYP, the DOV's, and the regional goals to which the country has agreed through its specific objectives and guiding principles

Policy Objectives

- To affirm the commitment of the Government of Pakistan (GOP) to provide safe, effective and cost-effective vaccination against Vaccine Preventable Diseases (VPDs).
- To set national standards and guidelines for immunization aligned with the global goals and evidence base, and encourage the programme for generation of local evidence for vaccination against VPDs.

Guiding Principles

- All children aged 0-23 months, Women of Reproductive Age (WRA) and other specific target population residing in Pakistan irrespective of gender, race, religion and ethnicity shall be eligible to receive vaccination offered by the National EPI programme according to the recommended schedule.
- All vaccines used in the country shall be safe, effective, cost-effective, WHO pre-qualified and approved by the National Regulatory Authority (NRA).
- All injection equipment used in the country shall be safe, cost-effective and WHO pre-qualified.
- All vaccines and injection equipment provided by the National EPI programme shall be free of cost.
- The EPI and service providers shall ensure maintaining vaccine efficacy, injection safety, medical ethics and professionalism and by adhering to the international standards and national guideline for proper handling, storage and delivery.
- Scope of EPI shall include all immunization programmes/initiatives including disease specific control/elimination/eradication programme.

Broad Policy Statements

a) The Routine Immunization (RI) will be strengthen on priority to comply with the Polio, Measles, Rubella and Neonatal Tetanus eradication/ elimination targets, and other antigens

b) The Measles SIA shall be conducted periodically based on epidemiological evidence till its elimination

c) Introduction of new vaccines will strictly be

based on immunization profile of the country's population and on the risk analysis

d) The International Health Regulations regarding the VPDs will be obliged

e) Local evidence base will be generated and WHO-SAGE guidelines will be followed

f) Targets spelled in country's reports and cMYPs will be followed for immunization coverage

g) Encourage innovation and new solutions to overcome obstacles in immunization programme

EPI Vaccines

The vaccine preparations available in Pakistan for the use of National Expanded Programme on Immunization (EPI) are:

Types of vaccines

a) **Bacterial vaccines;** Bacillus Calmette Guerin (BCG) vaccine that contains live attenuated Mycobacterium bovis (M.bovis), Pertussis vaccine that contains killed Pertussis bacteria, and Hib vaccine that contains PRP-CRM conjugate from Haemophilus influenza bacteria and Pneumococcal vaccine.

b) **Toxoid (detoxified bacterial toxins) vaccines;** include diphtheria and tetanus;

c) **Viral vaccines;** include measles vaccine, oral polio vaccine and Hep B vaccine. Measles vaccine and OPV contain live attenuated viruses, IPV contains inactivated/killed virus, all the three types, and Hepatitis B vaccine is produced from the surface antigen of the virus.

Physical forms of the vaccines

Some vaccines are available in a fluid form ready for use: OPV/ IPV, Pentavalent (DPT, Hep B, Hib), PCV10 and TT.

Others are available in a freeze-dried (lyophilized) form: BCG and Measles which require reconstitution before administration.

Table 1. Routine Immunization Schedule for Children

Age	Antigen	Dose	Site of Administration
At Birth	BCG	0.05ml	Intradermal on right upper arm
	OPV0	2 drops	Oral
	Hepatitis-B	0.5 ml	Intramuscular injection on antero-lateral side of left thigh
6 weeks	*Pentavalent–I	0.5 ml	Intramuscular injection on antero-lateral side of right thigh
	Pneumococcal - I	0.5 ml	Intramuscular injection on antero-lateral side of left thigh
	OPV-I	2 drops	Oral
10 weeks	Pentavalent–II	0.5 ml	Intramuscular injection on antero-lateral side of right thigh
	Pneumococcal - II	0.5 ml	Intramuscular injection on antero-lateral side of left thigh
	OPV-II	2 drops	Oral
14 weeks	Pentavalent–III	0.5 ml	Intramuscular injection on antero-lateral side of right thigh
	Pneumococcal- III	0.5 ml	Intramuscular injection on antero-lateral side of left thigh
	OPV-III	2 drops	Oral
	IPV	0.5 ml	Intramuscular injection on antero-lateral side of right thigh at least one inch apart from the site of Penta injection
9 months	Measles-I	0.5 ml	Subcutaneous injection on left upper arm
15 months	^Measles-II	0.5 ml	

**Pentavalent::DPT+HepB+Hib ^ If the child is seen b/w 12-15 months of age, 2nd dose of measles can be given if one month passed since the Measles 1st dose is given.*

All eligible children shall receive 1 dose of HepB vaccine at birth (within first 24 hours), 1dose of BCG vaccine as soon as possible after birth, 1 dose of OPV at birth and 3 doses at 6, 10 and 14 weeks of age, 1 dose of IPV at 14 weeks of age with Penta3, 3 doses of Pentavalent (DPT-HepB-Hib) vaccine at 6, 10 and 14 weeks of age, 3 doses of Pneumococcal vaccine along with Pentavalent vaccine and 2 doses of Measles vaccine (upon completion of 09 months and 15 months) according to the recommended schedule, up to the age of 15 months.

Table2. Immunization schedule for pregnant women for prevention of neonatal tetanus

Vaccine	When to give	Dose & site	Expected duration of protection
TT 1	first contact during first pregnancy	0.5 ml intramuscular injection on upper arm	None
TT 2	at least 4 weeks after TT 1		1-3 years
TT 3	at least 6 months after TT 2		5 years
TT 4	at least 1 year after TT 3 or subsequent pregnancy		10 years
TT 5	at least 1 year after TT 4 or subsequent pregnancy		Throughout reproductive years

- All women during their 1st pregnancy shall be targeted for 2 doses of TT vaccination through routine immunization.
- The 2nd dose or any subsequent dose of TT 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 TT vaccination schedule with remaining doses at appropriate interval irrespective of pregnancy.
- If a pregnant woman has received 5 doses of TT according to above schedule there is no need of additional doses of TT during subsequent pregnancies.
- Women entering reproductive age (>15 years) with documented evidence of three valid doses of DTP or TT containing vaccines (e.g. DTP, Tetravalent, Pentavalent vaccine) during childhood should resume the schedule outlined above from TT3 onwards.

Interval between multiple doses of the same antigen

- For childhood vaccines that require administration of more than one dose, an interval of at least 4 weeks shall be ensured between two doses of any same vaccine.
- Any dose given before the recommended age or interval shall be considered INVALID and should be repeated as recommended.
- Any dose missed on scheduled date should be given on the next occasion along with other due vaccines.
- As many antigens as possible shall be given at a single visit but at the recommended sites of administration.
- The recommended schedule should always be followed irrespective of any additional doses received during Supplemental Immunization Activities (SIAs).

Immunization in Special Cases

With the exception of the situations listed below, no other conditions shall be considered as contraindications for immunization.

- A severe adverse event following a dose of Pentavalent (DPT+HepB+Hib) vaccine (anaphylaxis, collapse or shock, encephalitis/ encephalopathy, or non-febrile convulsions) shall be considered as absolute contraindication to repeat immunization with the same vaccine. The Pertussis component shall be omitted and diphtheria and tetanus immunization to be completed with DT vaccine. In case of non-availability of DT, TT shall be given.
- **Immunocompromised status:** Live vaccines should not be given to individuals
  - with known immunodeficiency diseases (except HIV)
  - who are immune-compromised due to malignant disease or cytotoxic drugs or radiotherapy
- **Immunization in HIV positive children** should proceed as immunization in other children with exception of BCG and Measles vaccines for which specific guidelines are given below,
  - BCG vaccination should not be given to infants
    - i. Who are known to be HIV infected with or without signs or reported symptoms of HIV infection and
    - ii. Infants whose HIV infection status is unknown but who have signs or reported symptoms suggestive of HIV infection and are born to HIV infected mothers
- Measles vaccination should be given to all asymptomatic HIV infected children and even to symptomatic HIV infected children who are not severely immunosuppressed. However, measles vaccine is contraindicated for children with severe HIV infection.
- **Hospitalized children:** severely ill hospitalized children if eligible for any vaccine should be considered for vaccination in consultation with the concerned physician.
- High grade fever >39oC and seizures/fits are not

contraindications for vaccination; In such cases vaccination is advised to be delayed in such case until recovery.

Vaccinating children of higher age

Though undesirable but many children in Pakistan failed to complete their routine immunization schedule within the recommended age. Children of higher age group remain unvaccinated or partially vaccinated for various reasons leading to accumulation of susceptible which has potential of explosive outbreak. These children require completing their schedule as appropriate for their age. A guideline for vaccinating children aged above one year with different antigens is developed according to WHO recommendation (Annex G). This guideline to be followed by all vaccinators/immunization staff in vaccinating higher aged children.

- Oral Polio vaccine given to children with severe diarrhea shall be repeated after recovery.
- Two different vaccines should never be mixed in the same syringe.
- No diluent other than that supplied with the vaccine should be used in reconstituting the vaccine

Immunizations are considered safe and can be given in the following conditions

- Minor illnesses such as upper respiratory tract infections or diarrhea, with fever <38.5oC
- Allergy, asthma or other atopic manifestations, hay fever
- Pre maturity, small for dates babies
- Malnutrition
- Breastfed child
- Family history of convulsions
- Treatment with antibiotics, low-dose corticosteroids or locally acting (e.g. topical or inhaled) steroids
- Dermatitis, eczema or localized skin infection
- Chronic diseases of the heart, lung, kidney and liver
- Stable neurological conditions, such as cerebral palsy and Down's syndrome
- History of jaundice soon after birth.

Immunization Service Delivery

- Immunization service delivery to be done through static EPI center, outreach vaccination service and mobile vaccination service
  - Static EPI center
    - Population residing in areas within 3 km radius around the health facility or 30 minutes travel distance is to receive immunization service from the static EPI center.
    - All UCs should have at least one functioning static EPI center.
    - All public sector health facilities must have a functional EPI center.
    - Immunization service delivery in static center should be done by skilled health facility staff e.g. Nurse, Medical Assistant, LHV, Medical Technician etc.
    - Static EPI Center shall provide immunization services on all working days.
  - Outreach vaccination service
    - Population living beyond the catchment area of a static EPI center where vaccination team can provide service from the nearest health facility in a day trip, are to be served through outreach strategy
    - Outreach vaccination activity to be done following a micro-plan
    - Every community in an outreach plan should be reached at least once a month
  - Mobile vaccination service
    - Mobile strategy to be adopted in far flung areas where it is not possible for a vaccination team to return to the health facility on the same day after providing service and has to stay overnight.
    - This strategy mostly to be used for remote and hard to reach areas
    - At least four contacts to be made every year with communities planned for mobile service
    - Immunization service provision through outreach and mobile strategy is expensive. Monitoring its implementation and assuring quality and safety through these strategies is also challenging. Hence, Provincial governments are suggested to adopt long term goal in increasing immunization service provision through static center and gradual reduction of reliance on outreach and mobile service. Attempt should be made to deliver at least two-third of the immunization service through static center in next five years period.
    - The goal of 80% immunization coverage in all districts and 90% at national level

to be achieved adopting Reaching every district" (RED) according to WHO protocol.

- Access and utilization of immunization services will be increased by addressing existing and emerging challenges through improving governance and management, building/strengthening capacity at every level and establishing accountability.
- To ensure equity in immunization access, special emphasis to be given for reaching the underserved/ vulnerable section of the population. It shall be undertaken through ed micro-plans and implementing strategies/ actions to reach all children, especially those in socially disadvantaged and marginalized communities and ensuring the inclusion of additional strategies and activities at each level of the immunization system that target the "High Risk Communities" through fixed, outreach, mobile or additional immunization session.

Furthermore gender segregated data to be collected by EPI.

- The accredited EPI service providers are

  (i) Vaccinators

  (ii) Nurses

  (iii) Dispensers

  (iv) Lady Health Visitors (LHVs)

  (v) Medical Technicians (MT), Female Medical Technicians (FMT)

  (vi) Mid-wives

  (vii) Lady Health Workers (LHWs) or any other health staff trained in immunization service delivery

  (viii) Medical doctors

- Vaccinators are responsible for outreach and mobile activities in their assigned areas.
- Every UC must have adequate number of vaccinators/skilled immunization staff proportionate to population and area. They should be based in their assigned union council.
- LHWs' role in routine EPI
  - Health Houses (HH) shall act as outreach vaccination sites
  - LHWs trained in EPI shall provide vaccination service. Otherwise, she shall assist the vaccinator in providing vaccination service by organizing the session and mobilizing the community.
  - LHSs or any other designated person will be responsible for supplying vaccine and related logistics to HH from the health facility. They are also responsible for monitoring and reporting on EPI services delivered by LHWs.
- All Union Council must have their micro plan for reaching all communities for routine EPI identifying
  - specific vaccination strategy for service delivery
  - time and place of service delivery
  - responsible person for service delivery
  - assigned supervisor
  - vaccine and logistics requirement
- Micro-plans are to be developed under the leadership of the UCMO and reviewed by District.
- A designated community focal person shall be engaged in immunization session planning, implementation and community mobilization.
- Accountabilities for planning, social mobilization, service delivery and monitoring shall be clearly specified in union council micro plans.

Distribution of vaccinators/skilled immunization staff in Union Council

Vaccinator/skilled immunization staff are to be deployed in Union Councils according to population or catchment area (whichever is smaller). One vaccinator/skilled immunization staff to be deployed for every 5,000 (rural) to 10,000 (urban) population or 13 – 28 SqKm area. A parent from any corner of such an area would have to travel maximum 2-3 Km distance to the central location. Smaller geographic unit (13 Sq Km) can be used for difficult terrain like mountainous area, marsh land, desert and larger geographic unit (28 Sq Km) can be used for normal terrain. Position of vaccinators to be determined in every UC following this guideline and accordingly distribution/recruitment of vaccinators to be done.

Minimizing Missed Opportunities

Missed opportunities shall be minimized through screening children and their mothers eligible for immunization in every health encounter and by tracking of defaulters on regular basis.

The programme must ensure the following:

- All vaccines, for which a child is eligible, shall be administered concurrently at the same visit.
- A false contra indication must never be the cause of refusing immunization to a child.
- Children and women attending any health facility to be screened routinely about their

immunization status and to be referred to the vaccination room for due vaccination (if any).

Missing Doses

(i) All children shall be targeted to complete their immunization schedule up to second dose of Measles by the age of fifteen months.

(ii) Children who have missed any scheduled dose shall be vaccinated to complete the schedule according to his/her current age. Guideline for vaccinating higher aged children in Annex G is to be followed for vaccinating such children.

Transportation

- Appropriate transportation to be made available for service provision, supervision and vaccine and logistics supply and distribution.
- Budgetary allocation shall be made for fuel and maintenance expenses for all transportation.
- Provision shall be made in local plans for replacement of vehicles that have completed 10 years of service.
- EPI vehicles should be used for EPI activities only.

Role of Autonomous Bodies, Private Sector and Civil Societies

- National EPI shall encourage partnership with autonomous bodies, professional organizations such as Pakistan Pediatric Association (PPA), Pakistan Medical Association (PMA), research/ academic institutions and civil societies to promote and strengthen routine and supplemental immunization services.
- The professional bodies, associations and civil societies / organizations with relevant expertise shall be encouraged to assist the programme by monitoring immunization activities.
- Partnership shall be encouraged with Non-Governmental Organizations (NGOs), Community Based Organizations (CBOs), private institutions, registered health service providers for immunization service delivery especially in areas with significant gaps in services through signing a Memorandum of Understanding (MoU), adhering to the guiding principles of this document.
- The cost of vaccines and injection supplies shall not be charged to the recipient. Small service charges may be applied in accordance with the MoU.
- MoUs shall be signed with the respective district health authority and shall be linked to the micro-plan of respective union council.

Supplementary Immunization Activities (SIAs)

Pakistan shall be guided by the recommended global policies based on national/provincial situation. National EPI shall decide to conduct Supplementary Immunization Activities (SIAs) after recommendation of NITAG/Polio Technical Advisory Group (TAG) in line with the global immunization policies.

Various activities undertaken at all levels during planning, implementation and monitoring of the Supplemental Activities for Polio Eradication, Measles and Neonatal Tetanus Elimination shall be used to strengthen routine EPI activities.

Outbreak response shall include investigation & supplementary immunization according to the WHO recommendation and national guidelines. The district health offices shall be responsible for conducting outbreak responses. Further supplemental activities shall be implemented in consultation with provincial/ national EPI cell.

For each of the SIAs there should be specific planning, implementation and monitoring guidelines.

It is advisable to add routine immunization antigens in every supplementary immunization activities as appropriate.

Vitamin A supplementation shall continue to be provided biannually to all children age 6-59 months through supplementary immunization activities and subsequently with routine EPI after phasing out of SIAs.

Other appropriate interventions such as de-worming, bed-nets etc may also be considered.

Vaccination in emergency settings

- Measles and OPV/ IPV shall be the first immunization response along with Vitamin A Supplementation in any humanitarian disaster.
- Routine immunization shall continue in any emergency situation.
- Supplementary immunization activities may also be considered if recommended by the NITAG.

New vaccines and immunization technology

Improvements in scientific knowledge and development of new technologies have accelerated vaccine development and resulted in the testing of new vaccines against common infectious diseases. Vaccination against infectious diseases already saves millions of lives around the world each year. Even more deaths can be prevented through development of new vaccines and improvement in existing vaccines. A number of new vaccines are already on offer from GAVI to be introduced in the routine immunization schedule of GAVI eligible countries

e.g. Rotavirus vaccine, Measles-Rubella vaccine, Meningitis A vaccine, HPV vaccine, Yellow fever vaccine etc. Vaccine delivery system and vaccine administration technology is also evolving with new scientific knowledge e.g. needle-free injection.

Introduction of new vaccines and immunization technology in EPI have immense potential in improving programme performance and reducing mortality and morbidity. However, such decision to be made through careful evaluation and recommendation of the NITAG. Following factors are to be considered by the NITAG in making a recommendation for introduction of any new vaccine or immunization technology,

1. Disease burden in the country
2. Epidemiology of the disease
3. Economic impact
4. Impact on public health
5. Public perception
6. Availability and ease of distribution of a vaccine
7. Effectiveness of the vaccine and its safety
8. Method of administration of the vaccine (invasiveness)
9. Financial aspects (cost-effectiveness, cost-benefit)
10. Priority of a vaccine related to other vaccine preventable diseases
11. WHO recommendations

Supervision, Surveillance, Monitoring & Evaluation

Supervision & monitoring

- The local health facility in-charge shall be responsible for supervising immunization activities in his/her catchment area and to monitor immunization indicators, accuracy of data and timely reporting.
- Immunization activities shall be supervised by the District Health Management Team (DHMT) to ensure that every eligible mother and child residing in his/her district/agency is fully immunized.
- At least 30% of district vaccination session should be monitored by district supervisory staff every month.
- A well-defined supervision and monitoring plan should be available at all levels (Federal, provincial, district/agency, sub-district and union council) specifying the frequency of supervisory visits for each supervisory tier especially at the district and sub-district level (EDO/DHO/Focal Person EPI/DDHO/DSV/TSV/ASV).
- Supervision should be structured, using standard supervisory guidelines, tools and checklists.
- Immunization indicators are to be monitored regularly at national, province and district levels.
- Data quality to be monitored at various level using standard tools and mechanisms e.g. DQA, DQS etc.
- Regular review meetings shall be convened on quarterly basis by province and federal EPI cells and on monthly basis by the district.
- Inter-provincial and inter district monitoring activities shall be carried out regularly.

Surveillance

- The EPI programme shall establish a functioning Vaccine Preventable Disease Surveillance system, either as a part of the integrated national disease surveillance system or in isolation **with EPI Information System**, which includes active and passive; sentinel and community based AFP, case-based and Measles and NT surveillance system with appropriate laboratory component.
- The programme also shall make a functioning Adverse Event Following Immunization (AEFI) surveillance system to ensure pharmaco-vigilance for the National Regulatory Authority.
- Each district must have a District epidemiologist or a designated 'District Surveillance Coordinator'.
- The District Health Manager shall be responsible for submission of weekly Vaccine Preventable Disease Surveillance and AEFI surveillance reports. AFP cases to be notified immediately.
- National Expert Review Committees for final classification of AFP cases, Measles cases and AEFIs are to be formulated along with their provincial equivalents.

Evaluation

- Third party evaluation of various features of the EPI programme including service provision, coverage, surveillance, communication, monitoring mechanisms, inventories etc. shall be carried out every three to five years to monitor the progress of the programme
- Programme related studies such as sero-conversion and disease reduction, shall be carried out every five years or as recommended by NITAG to examine the impact of the immunization programme.

Social Mobilization and Communication

- Regular advocacy, communication and social mobilization activities should be an integral

component of all immunization plans to create awareness of the benefits of vaccination and demand for immunization services.

- Activities should include advocacy and partnerships with relevant stakeholders and community elders and opinion makers such as community and religious leaders, teachers, legislators, professional bodies and media.
- Appropriate communication material should be developed for specific target groups.
- Use of print, electronic media and digital technology shall be encouraged to create public demand for vaccination services and to mitigate negative propaganda.
- Advocacy, communication and social mobilization activities for routine immunization should be an ongoing process.
- Adequate resources shall be allocated for advocacy, communication and social mobilization activities for routine and supplementary immunization activities.

Vaccine Management

To maintain programme performance at optimal levels, the programme shall implement Standard Operating Procedures for all levels of Vaccine Management following the principles of effective vaccine management. Implementation of the EVM improvement plan to be monitored regularly. The EVM assessment shall be planned at appropriate intervals for the oversight purpose.

Reconstitution of Vaccines

- A freeze dried vaccine shall always be reconstituted using separate syringe and the diluent supplied with it for the purpose.
- The whole amount of diluent supplied with the vaccine should be used for reconstitution or as stated by the manufacturer.
- Diluent to be kept at 02 – 08o C at least for 12-24 hours prior to reconstitution.
- Date and time of reconstitution should be recorded on the vial label of lyophilized vaccines.
- Reconstituted vaccine must be discarded no later than **six hours** after reconstitution or at the end of immunization session, whichever comes first.

Vaccine Wastage Reduction

Regarding opening of vials of BCG, measles and other antigens the following strategies are recommended:

- At the district and tehsil/taluka head quarter hospitals, civil hospitals and tertiary level hospitals where daily average client turnout is high, BCG and measles vaccine vials should be opened daily as required. No specific days needed to be assigned for BCG or measles vaccination.
- All EPI centers in places other than those mentioned above like Rural Health Centers (RHC), Basic Health Units (BHUs) and dispensaries etc. District health authority may assign specific days of a week for opening of BCG and measles vials depending on daily client turnout in the specific facilities.
- All functioning EPI center should offer immunization service with all other antigens (OPV/ IPV, Penta, PCV10, Measles and TT) on each working day. All antigens are to be offered during outreach and mobile vaccination service. Attempt to be made to administer at least 50% of the doses in vials of BCG, Measles and TT vaccines to the eligible recipients.
- Opening BCG vaccine vial for vaccinating newborns in obstetric units of health facilities depends on average number of deliveries take place daily. A vial to be opened if at least 10 newborns are available.

Use of Multi-dose vials

Vaccine vials opened in subsequent immunization sessions:

A partially used multi dose vaccine vial with preservative can be used in the next immunization session only *if all of the following conditions are met*:[1]

a) The vaccine is prequalified by WHO

b) The vaccine is approved for use up to 28 days after opening the vial, as determined by WHO

c) The expiry date has not passed; **and**

d) The vaccine has not been contaminated; **and**

e) The vials have been stored at WHO or manufacturer recommended temperature **and**

f) The VVM on the vial, if attached, has not reached the discard point.

To avoid any adverse event multi dose vaccine vial without preservative such as PCV-10 must be discarded no later than six hours after opening or at the end of the session, whichever comes first

A partially used TT vial in an outreach session should not be reused later because of risk of contamination. However, at static EPI centers, a partially used TT vial can be used on the next day if the safety conditions are met as mentioned earlier. Same practice is applicable for multi-dose vial of Hepatitis B vaccine for birth dose.

For OPV, multi-dose vial policy shall be applicable for all partially used vials both at static and outreach vaccination centers provided safety conditions are met and the vial is properly capped.

[1] - WHO Policy Statement: Multi-dose Vial Policy (MDVP), Revision 2014

Vaccine vials without labels or unreadable labels shall not be used.

Use of Vaccine Vial Monitor (VVM) in Immunization Services

- VVM shall be used to monitor the potency of the vaccine at every level and to identify the weak link in the cold chain if any.
- All vaccines shall be procured with VVMs., where available.
- Staff responsible for cold chain and those who use the vaccine must know the interpretation and importance of VVM.

Vaccine Storage

The following standard for storage for EPI vaccines shall be followed

GUIDELINES ON VACCINE STORAGE
• Vaccines shall be stored at standard temperatures in official EPI store only.
• Vaccines should not be stored for more than a period of six months at federal level, three months at the provincial level, one month at the district and two weeks at the facility level.
• Vaccines stored for more than the recommended period that have not expired and meet other criteria for viability should be used first.
• In national and sub-national stores, OPV should be kept in -15oC to -25oC if stored for more than a month. All other vaccines including BCG and Measles are recommended to store in +2oC to +8oC at national and sub-national stores irrespective of duration of storage.
• All vaccines including OPV should be stored at a temperature between +2oC to +8oC at district levels and below.
• Diluents can be stored at room temperature, but should be refrigerated with the vaccine in between +2 to +8 °C at least 12-24 hours before use
• Temperature monitoring of cold chain equipment storing vaccines to be recorded and updated regularly.
• Standard stock ledger with name of the vaccine, quantity in doses, vial size, manufacturer, expiry date, VVM status, batch/lot number, date of receive and supply to be maintained at all level and updated regularly.

BUFFER STOCK	
Federal EPI store	6 month national requirement
Provincial EPI store	3 months provincial requirement
District EPI store	1 month district requirement
Static EPI centers	2 weeks requirement of the UC

Monitoring of stock: Stock position for both vaccines and injection devices to be monitored regularly at every level through a vaccine and logistics management information system to immediately address any shortfall or risk of stock out.

Bundle supply of vaccines: At service delivery level vaccine, diluents, syringes and safety boxes shall always be supplied as a "bundle" to ensure safe injection practices.

Quality of Vaccine & Injection Supply

WHO Pre-Qualification

The WHO Department of Essential Medicines and Health Products (EMP), Prequalification Team (PQT) is responsible for prequalifying vaccines, immunization related equipment and devices – to ensure that these meet global standards of quality, safety and efficacy. The reassessment at regular intervals ensures the continuing quality of vaccines and devices.

Only WHO prequalified vaccines and immunization devices listed on the regularly updated WHO website shall be acceptable for EPI.

(link: http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/)

Only the finished product (vaccine) including presentation and manufacturing site duly tested by an accredited laboratory will be considered as WHO pre-qualified vaccine, as long as it is part of the WHO Pre-qualification list.

However, an exception to this policy can be practiced only in emergency humanitarian situation upon advice of appropriate technical authority and recommendation of NITAG.

Quality Issues

Any quality issues observed for vaccines and/or devices are to be reported to WHO – as the organization managing the WHO Pre-qualification programme – for further assessment. All documentation, data and pictures are to be submitted as a report to WHO.

Estimation for vaccines & injection devices

Estimation for vaccines shall be based on:

- Annual estimated target children and WRA based on latest national census data.
- Actual consumption of vaccines in the previous supply cycle.
- Acceptable wastage factors for each vaccine as given in the table below:

Table 3: Acceptable wastage factors for each vaccine

Name of vaccine	Acceptable wastage rate	Wastage factor
BCG	50%	2
Hepatitis B (birth dose)	10%	1.11
OPV	20%	1.25
IPV	20%	2
Pentavalent (DPT+He B+Hib)	5%	1.05
PCV10	10%	1.11
Measles	20%	1.25
Tetanus Toxoid (TT)	20%	1.25

A WHO pre-qualified source for bulk or active pharmaceutical ingredients (API) for vaccines cannot be considered as a WHO pre-qualified vaccine, as it does not represent the finished product.

For Polio, Measles and TT SIAs the wastage rate shall not exceed 10% (equivalent wastage factor 1.11)

Estimation for immunization injection equipment shall be undertaken according to the vaccine requirement.

Current stocks of vaccines and injection devices are to be taken into account for determining any new supply requisition at all levels.

Supply of Vaccine & Injection Equipment (Ref. Annexure-H)

Vaccine Arrival Report

Vaccine consignments must be accompanied by a Vaccine Arrival Report (VAR). The VAR is to be filled in immediately upon receipt of a vaccine consignment to ensure the safety and quality of the vaccines. Any supply or quality issues are to be reflected in the VAR and addressed with the concerned authorities with due diligence within no later than 72 hours from receipt of the consignment.

Distribution Principle – First-Expiry-First-Out

At any time of the distribution of vaccines and injection equipment the First-Expiry-First-Out (FEFO) principle shall be followed. This applies to all levels of storage and distribution points.

Flow of vaccine and injection equipment supply and responsibilities:

- Federal EPI Cell shall be responsible for ensuring regular supply of vaccines and injection devices to the provincial EPI offices till June 2015. Afterwards, provinces will be responsible for procuring their share of vaccines and devices by themselves or through a mutually agreed mechanism.
- Provincial EPI office shall have the responsibility to ensure regular supply of vaccines and injection devices to the districts either directly or through divisional stores
- Local health facility in-charge shall ensure collection of vaccines from the district store for all EPI activities in the union council.

Vaccine Procurement

Procurement of vaccines and devices through EPI Programme must ensure the safety, quality and efficacy of the vaccine as well as the best value for public funds and greater benefit to the health of the population.

The planning for procurement of vaccines and injection devices shall be planned well in advance taking into account the procedures for procurement, the estimated suppliers lead times and administrative processes for approvals and release of funds.

Government should ensure allocation and timely release of adequate resources for procuring vaccine/ injection devices and fulfilling country's GAVI co-financing obligation for Pentavalent and PCV10 vaccines and any other new vaccines introduced in future under similar arrangements to ensure timely availability of vaccines for the programme.

Injection safety

Every injection given to administer a vaccine must be safe for the administrator, recipient and the community. Safety should be ensured by administering vaccine using appropriate equipment and according to the recommended procedures for injection, ensuring sterilization and safe disposal.

Type of Syringe

- Recommended equipment to be used to administer injectable vaccines is auto-disable (AD) syringes with fixed needles only.
- Country shall procure only WHO pre-qualified auto-disable syringes for EPI vaccine injections.

[2] A WHO pre-qualified source for bulk or active pharmaceutical ingredients (API) for vaccines cannot be considered as a WHO pre-qualified vaccine, as it does not represent the finished product.

Disposal of used syringes, needles and sharps

For collection and disposal of used syringes, needles and other injection materials Safety boxes shall be used in all immunization activities.

Injection waste management

Disposal of injection waste at immunization site:

Sharp wastes such as, used syringes and its parts and needles are to be disposed in the safety box immediately after use. Other wastes such as, empty vial/ampoule, blister pack, cotton etc are to be collected in a separate bag/container in the immunization sites. Safety boxes and other waste bags are to be returned to the nearest health facility for storage at a secured place for future re-use (if partially filled) or final disposal.

Final disposal of injection waste:

Auto combustion type of incinerators which achieve temperatures in excess of 800oC are preferred to destroy all contaminated sharp wastes, including syringes and needles used for immunization. This equipment ensures the most complete destruction of sharp wastes and also reducing environmental pollution. However, in situations of limited resources and low level of immunization activities waste disposal may proceed as follows:

- The facilities that are remote and cannot undertake transport of immunization waste to a facility with incinerator the immunization waste (filled safety boxes and other waste bags) shall be stored in a secured place in the health facility. All filled safety boxes shall be burnt in a pit prepared for the purpose. The pit to be prepared in a secluded area out of reach of children and domestic animals within the premises of the health facility. After burning, the left overs shall be covered with a thin layer of earth.
- The facilities without incinerators that are located close to a facility with incinerator, the waste should ideally be transported to the facility with incinerator for incineration.
- Incineration of the injection waste is recommended where standard incinerator is available.
- Pit burning or incineration whatever method is adopted, that always to be done under direct supervision of a responsible officer.
- The EDO (H) shall be responsible for providing instructions for disposal of injection waste according to local arrangements in accordance with the National Injection Safety Policy.
- Federal EPI Cell shall facilitate the designated Ministry of Health (MoH), in collaboration with other concerned agencies in developing plans for injection safety.

Cold Chain & Logistics Management (Ref. Annexure-H)

Cold Chain Assessment

Federal, provincial district level cold chain assessment shall be undertaken **annually** by respective offices for ensuring timely maintenance and replacement of equipment.

Each vaccine store shall do self-assessment using standard self-assessment tools (e.g. EVM tool) at least on a half-yearly basis and make action plans to address gaps identified.

Cold Chain Inventory

The inventory of Cold chain equipment at federal, provincial, district and sub-district level should be developed using the Cold Chain Equipment Manager tool (CCEM-II), integrated with vLMIS and should be updated regularly.

Cold Chain Replacement and Maintenance

Decisions for any cold chain equipment replacement shall be made on the basis of the cold chain inventory and results of periodic assessments.

Standard cold chain equipment should be identified for different levels and functions i.e storage at the sub district, district, divisional and provincial levels and service point (BHU, RHC, THQ) keeping in view the climatic condition of Pakistan, availability of the power source and requirement of the cold chain space according to the target population at each level.

Facilities functioning as fixed EPI centers should ideally have at least:

- One functioning Ice Lined Refrigerator (ILR) with adequate capacity.
- One cold box.
- Three standard vaccine carriers with required number of ice/cool packs and foam pad.

Repair and Maintenance

- A costed-plan for the preventive and curative maintenance of the Cold Chain Equipment should be developed.
- The provincial EPI offices shall be responsible for major repair and maintenance of cold chain equipment and EPI vehicles. Regional engineering workshops can be established under the program for this purpose.
- The districts shall be responsible for minor repair

and maintenance of cold chain equipment and EPI vehicles.

- Adequate financial and human resource to be allocated/deployed for regular preventative maintenance of the cold chain equipment and vehicles.
- Replacement plan for old cold chain equipment should be in place.

Human Resource Management

Recruitment

- Adequate vaccinators/skilled immunization staff should be deployed at each union council according to population and geographical area.
- At least one qualified cold chain technician should be recruited for every district and refresher trainings to be given after every three years. Newly recruited vaccinators must have a minimum of 10 years of schooling, be more than 18 years of age, and go through necessary theoretical and practical training.
- The vaccinator must be a resident in his/her assigned union council.

Trainings

- Federal EPI Cell in collaboration with other federal institutes to arrange short courses/trainings on public health epidemiology, different operational aspects in immunization for capacity building of the mid-level managers, vaccinators and supervisors.
- All newly recruited vaccinators shall undergo intensive three month practical training before being authorized to administer EPI injections independently.
- LHWs shall be provided training in administration of the EPI vaccines.
- Refresher trainings to be provided to all immunization service providers at least **once every two years.**
- The EPI management staff should undergo MLM trainings before assuming immunization programme responsibilities at any level.
- All Mid-Level Managers shall be given standard MLM training on EPI at least **once every two years.**

Role of Lady Health Workers in EPI

- Lady Health Workers shall be responsible for ensuring immunization of all eligible children and pregnant women within their catchments areas.
- Health Houses should be used as outreach vaccination center for their respective catchment areas.
- Lady Health Workers trained to give injections shall be responsible for vaccination of children in their catchment areas.
- The Lady Health Workers who are not trained in EPI shall work as social mobilizer and facilitate vaccinators during the vaccination sessions.

Financial Resource Management

Financial allocation for EPI at all levels (Federal, provincial and district) should be in accordance with programme requirements.

Following steps are to be taken at district/provincial level for implementation:

- EPI Manager and DHO/EDO Health shall be responsible for development of annual immunization Plan of Action (PoA) for their respective province/district identifying resource requirement.
- The provincial and local governments (where applicable) must allocate adequate resources (human & financial) for implementation of immunization plans.
- EPI Manager and DHO/EDO Health shall ensure judicious utilization of available resources.
- Government and Partners' support shall be well coordinated to ensure efficient use of resources.
- Detailed accountability mechanism shall be in place at all levels (Federal, provincial & district) to monitor use of financial allocations earmarked for EPI activities.

Information Management

Recording & Reporting Mechanism

- Vaccinator shall issue/update vaccination cards, maintain daily and update permanent registers, monitoring charts, records of inventories and cold chain maintenance (temperature monitoring charts).
- Vaccinator shall be responsible for timely submission of monthly immunization reports, vaccine requisition, and vaccine arrival report.
- The local health facility in-charge shall ensure accurate and timely recording and reporting of immunization performance and diseases surveillance data. S/he is also responsible for timely submission of the weekly surveillance report and monitoring the indicators.
- Sub-district and District Health management, Provincial and Federal EPI Offices shall be responsible for timely collation, verification and transmission of all data/information to all stakeholders and feedback.
- All reporting will be done through any new forms, portals and systems implemented from time to time.

Annexure A

National Immunization Technical Advisory Group (NITAG) Pakistan

Purpose of NITAG

The purpose of the NITAG is to guide policy makers in the Federal Ministry of Health and Federal EPI of Pakistan to make evidence based immunization related policy decisions for routine immunization activities and for national emergencies.

The NITAG shall do policy analysis and strategy formulation for control, elimination and eradication of vaccine preventable diseases through immunization taking in consideration of latest scientific development in the relevant field. NITAG's policy guideline and recommendations shall be submitted to the Ministry of Health for final approval and implementation.

The guidelines of international bodies like World Health Organization Strategic Advisory Group of Experts (WHO-SAGE) should be assessed in context of the capacity of Pakistan's National Immunization program to absorb a particular vaccine. The country specific "situational analysis" for each vaccine should be done by this expert group. The inputs from translational research in the country to support such introduction should be improved. Capacity and infrastructure in this field should be created/ revamped. The interdisciplinary collaborations within the nation and at global level need to be initiated and established. The members of NTAG should have sufficient interaction with each other and other global advisory bodies

The NITAG shall also assist in bridging partnerships among different stakeholders of immunization from other government and or non-government organizations, associations, bodies and civil societies.

Formation of NITAG

The NITAG shall be formed by the executive order of the Federal Secretary (Health) on the basis of proposal from Federal EPI. The NITAG shall have a total of maximum 15 members of which not more than one-third shall be affiliated with the Ministry of Health. The two categories of members shall be as follow:

Core members: Independent experts, who function in their own capacity, enjoy satisfactory credibility and are not attached to a particular interest group. They shall participate in group decision making process. Core members should be nominated from the following field of expertise from local experts:

a. Pediatrics
b. Infectious disease epidemiology
c. Immunology
d. Clinical Research
e. Virology
f. Microbiology
g. Health Economics
h. Social sciences (anthropology, behavioral science, communications etc.)

Liaison members: They shall represent different government offices, departments and partner organizations. They shall not take part in the final decision making process, but shall bring knowledge to the group to assist the core members in their decision making. They shall be nominated against the following ex-officio positions

a. National Programme Manager – EPI, Secretary of the NITAG
b. Chief Health, Planning Commission
c. Chief, Public Health Division, National Institute of Health
d. Coordinator, National Emergency Operation Centre (EOC)
e. National Team Leader – PEI, World Health Organization
f. Chief – Health & Nutrition, UNICEF
g. Medical Officer – EPI, World Health Organization
h. Executive Director – Pakistan Medical Research Council
i. President – Pakistan Pediatrics Association

Chairperson of the NITAG

A senior and widely respected core member who has no affiliation with any government offices or any other interest groups shall be nominated as chairperson.

Nomination Process of Members

The Ministry of Health through the National EPI Steering Committee of the Federal EPI shall identify and nominate potential core members from different areas of expertise after taking their consent.

Potential core members who gives consent to become members of the NITAG shall have to sign a (i) declaration of conflict of interest and (ii) confidentiality agreement for placing their name in the proposal for nomination.

Liaison members shall be automatically nominated against their ex-officio position. In accordance with the National EPI Steering Committee's decision the Federal EPI shall draft the proposal for nomination for members and shall send to the Ministry of Health. Federal Secretary (Health) shall formally appoint the NITAG members each for a specific duration and form the group by issuing an executive order from MOH.

Rotation of Members

Core members, including the chairman, shall be appointed for a maximum of 5 (five) year duration.

Renewal of appointment of a particular member can be made by the Ministry of Health, if deemed necessary, for a maximum of two consecutive terms.

Individuals appointed as core member who hold a government or any other organizational position shall continue their full tenure even if they cease to hold their official capacity before completion of the term.

Liaison members shall continue their appointments in the group till they continue to hold their official position. After removal of such members from their official position, their successors shall automatically become member of the NITAG.

Separation of Members

The Federal EPI, upon decision of the NITAG may consider sending proposal to MOH for separation of a member from the group if any of the following conditions are satisfied,

a. Fails to attend three consecutive meetings of the NITAG

b. Change in affiliation resulting in conflict of interest

c. Breach of confidentiality

d. Any permanent mental or physical disability which hinders in the performance of his/her duty

e. Resignation

A decision to separate a member of the NITAG is to be done by an executive order of the same appointing authority.

Terms of Reference (TOR) of NITAG

1. The NITAG will assist the MOH, Federal EPI, National Regulatory Authority (NRA) and Inter-agency Coordination Committee (ICC) by providing evidence-based policy direction on various immunization related issues as required and desired. e.g.,
    a. Formulation of immunization policy and strategies for routine and supplementary immunization activities
    b. Introduction of new vaccine in routine EPI schedule
    c. Evaluation of new immunization technologies
    d. Vaccine quality and safety
    e. Immunization schedule
    f. Advocacy for immunization
    g. Vaccine handling and storage at public and private sector
    h. Licensing of new vaccine for public and private sector use
    i. Commissioning of new research, assessments/evaluations to guide policies
2. The NITAG will also provide special policy and strategy direction to the Ministry of Health in any emergency situation (e.g. earthquake, flood etc.) for any particular population in any particular area to control any imminent epidemic of vaccine preventable diseases.

Mode of function of NITAG

Meeting of NITAG

The NITAG will perform its responsibilities by convening meetings at regular intervals. The recommendations of the group will be documented in the meeting minutes and communicated with the Ministry of Health.

The NITAG will convene meetings at least twice a year. If necessary, a meeting can be convened at any earlier date.

In consultation with the chairperson, the secretary of the NITAG (NPM-EPI) will issue notification of a meeting to all members specifying date, time, venue and agenda of the meeting with necessary working papers.

Quorum of the meeting requires at least half of the core members to be present to conduct an official working meeting.

Any member can participate in the meeting through audio/video conference system if facilities available.

Liaison members, in case of their unavailability will be allowed to participate in a meeting by a representative of their office. However, representation of the core members by any other person will not be accepted.

The secretary, in consultation with the chairperson, will decide in advance about participation of non-members in the group meeting, and accordingly invitations will be sent to the intended guests.

Decision making process

Core members will participate in the decision making process. Liaison members and non-member experts will provide the appropriate information, data and evidence to assist the core members in their decision making.

Decisions will be taken on consensus of majority of the core group members present in the meeting. However, members (including liaison members) who hold different opinion will have the right to record their reservations in the meeting minutes.

The NITAG can form any number of sub-groups with a specified duration for accomplishing any specific task. This sub-group may consist of NITAG members as well as any non-member experts as the discretion of the group. The sub-group(s) will be automatically abolished after expiration of its duration unless

extended by the decision of a working meeting of the NITAG.

The following factors to be considered by the group for preparing its decision/recommendation,

12. Disease burden in the country
13. Epidemiology of the disease
14. Economic impact of the disease
15. Impact on public health of the disease
16. Public perception of the disease
17. Availability and ease of distribution of a vaccine against the disease
18. Effectiveness of the vaccine and its safety
19. Method of administration of the vaccine (invasiveness)
20. Financial aspects (cost-effectiveness, cost-benefit)
21. Priority of a vaccine related to other vaccine preventable diseases
22. WHO recommendations

Access to information by the NITAG

For ease of making decisions/recommendations in the country context, the NITAG will have access to the relevant information within the Ministry of Health. This could include the following information,

1. EPI coverage of different antigens
2. Coverage of different SIAs
3. Vaccine Preventable Disease surveillance data
4. AEFI surveillance data
5. Cost incurred for different antigens used by EPI
6. Cost involvement of operation of different routine and supplementary immunization activities
7. Standard indicators used to monitor performance of the EPI program

Federal EPI will ensure that the NITAG has access to all necessary information.

Additionally, NITAG members as individuals or as a group can acquire any other relevant national or international data, information, document, research papers on vaccines and immunization from any authentic source to be shared with the group in the decision making process.

Recording of meeting proceedings, communication and implementation

The Secretary of the NITAG (National Programme Manager, EPI) will be responsible for recording proceedings of the meeting. S/he will share the draft proceedings with all members and will finalize the document taking into consideration feedback from the members as meeting minutes within two weeks after the date of the meeting. The minutes will be signed by both the chairperson and the secretary and will be communicated to all members and to the MOH for further action. The MOH will bring necessary changes in the EPI policy and strategy based on the recommendations of the group as deemed necessary and will issue executive orders accordingly. Federal EPI will be responsible for communicating the approved recommendations by the MOH to the National EPI Steering Committee and provinces and ensure its implementation. The secretary of NITAG will update the group on status of previous meeting decisions/recommendations in the next meeting. Public disclosure and dissemination of the NITAG meeting proceedings and communications will be restricted but not the recommendations unless the committee or MOH decides otherwise case to case basis.

Support and resources

Federal EPI will provide secretarial, financial and logistical support to the group for its regular activities. Budget for the regular meetings and other support will be reflected in the annual EPI budget.

Annexure B

Inter-Agency Coordination Committee (ICC)

Membership

All governmental and non-governmental organizations (Partners and Donors) providing technical and financial support to immunization programme.

Terms of Reference

- Coordinate support at national level from government and partner agencies to strengthen routine immunization and supplementary immunization activities including polio eradication, measles elimination and neonatal tetanus elimination activities in the country
- Mobilize the national governments and NGOs to eradicate polio and eliminate/control other vaccine-preventable diseases.
- Assist country in becoming self-sufficient in its immunization programmes
- Establish a forum for exchange of information and dialogue on immunization programme in the country and facilitate that dialogue by making data information sources readily available
- Support Government of Pakistan in adopting appropriate policies, advice and tools.
- Assist the international and national community in identifying and developing support for new disease control programmes when appropriate intervention tools, such as new vaccines, become available.
- Assist the government in resource mobilization and encourage government in appropriate resource allocation for routine and supplementary immunization activities.
- Advice the government in specific areas related to EPI and supplemental immunization activities for polio eradication, measles elimination and neonatal tetanus elimination where partner agencies have specialized expertise.
- Review progress towards polio eradication, measles elimination and neonatal elimination and improving EPI, and plans for further activities.

Annexure C

National Steering Committee for EPI

Composition

- National Programme Manager, EPI.
- Directors, Surveillance and M&E, Federal EPI
- Health Education Advisor – Ministry of Health
- In-charge/Virologist - Regional Reference Laboratory, NIH.
- WHO National Team Leader for Polo Eradication Initiative
- WHO Medical Officer - EPI
- Chief Health & Nutrition –UNICEF
- Health Specialist (Immunization) – UNICEF
- Programme Communication Specialist – UNICEF
- Health Advisor – EPI, JICA Pakistan
- Representatives from Rotary International
- Representative from WB, USAID, DFID, CIDA.

Terms of Reference

- Shall be sub-committee of National Interagency Coordination Committee (NICC)
- Shall operate under the guidance and the policies laid down by National Immunization Technical Advisory Group (NITAG).
- Oversee the progress and implementation of national EPI as per the national policy guidelines and national ICC recommendations.
- Ensure routine EPI duties and responsibilities laid upon officials at all levels are balanced and properly executed in harmony with other priority areas such as Polio Eradication, Measles elimination and Neonatal Tetanus elimination.
- Issue directives to facilitate implementation of RED strategy that prioritize activities & areas to cover maximum number of unvaccinated children.
- Exercise supportive leadership to obtain cooperation and involvement of other government and non-government organizations in EPI activities.
- Hold quarterly provincial meetings to monitor progress, seek evidence on performance and achievement, capitalize on successes and solve problems.

Annexure D

Memorandum of Understanding between Executive District Officer – Health

This Memorandum of Understanding (MoU) is made between the Executive District Officer (Health) of .....(name of the district, Government of ..... (name of province) hereinafter called the Government and ---------- (name of the organization / service provider), hereinafter called the 'Implementing Partner' (IP), on this ------- day of ---------- (month) ---------(year).

Introduction

Whereas it is essential to involve the private sector in the provision of immunization services to the masses, this MoU shall be implemented in the greater interest of the people in accordance with the following terms and conditions:

Obligations of the Implementing Partner (IP)

(i) shall provide appropriate manpower, dedicated cold chain equipment and space for providing immunization services, to the people visiting its health facility(ies) or clinic(s) for medical assistance/treatment;

(ii) shall ensure monitoring and maintenance of cold chainfor vaccines in accordance with the procedure laid down by the Programme;

(iii) shall regularly maintain and share vaccination reports and recordwith the EDO Health on the standard reporting / recording tools;

(iv) shall allow the staff of EDO-Health to undertake visits of IP's immunization facility(ies) to inspect cold-chain and vaccine management, stocks and safe injection practices, etc.

(v) The cost of vaccines and injection supplies shall not be charged to the recipient. Small service charges may be applied to cover overhead expenditures.

Obligations of the Government (Department of Health)

(i) shall provide all types of vaccines, syringes and safety boxes to the IP in accordance with its needs;

(ii) shall provide adequate recording and reporting tools, forms to the IP in accordance with its needs;

(iii) shall provide adequate training to the staff designated by the IP for providing immunization services;

(iv) shall provide feedback to IP on immunization coverage reports;

(v) shall conduct periodic review meetings with the IP to discuss issues and problems as well as measures to raise immunization coverage.

This MoU shall come into force with effect from ---------- (date, month and year) and shall remain applicable for one year unless rescinded earlier.

----------the Govt.)

---------- (IP)

Annexure E

Information Management Activity Level Recording (Registration)

- All immunizations given in static center or outreach site or during mobile activities shall be entered in the daily register and routine EPI tally sheet.
- At the end of every session or field activity, data shall be transferred from the daily to the permanent register.
- **Only one permanent register shall be made for one union council.** Permanent register shall have data of all routine immunization activities in an union council.
- Permanent registers shall have entries of only those children who are permanent residents of that union council.
- Any immunization given to a child resident of some other union council shall be recorded separately. The report shall be sent to the child's union council of residence through a stamp, printed post card to the concerned EDO for onward submission to the concerned center, or through other suitable mechanism.
- Lady Health Workers would be provided a daily register for recording immunization activity provided by themselves in their catchment areas.
- Lady Health workers shall provide immunization activities information to the UC in-charge vaccinators through LHS for recording of the information on the permanent register, and for non-permanent residents for further action, besides transferring it to her diary.
- To review EPI progress, there would be a meeting at the facility level, chaired by the health facility in-charge on the last working day of the month. The meeting shall be attended by the vaccinators, LHV, LHS, LHWs and other vaccination staff.
- Every child or pregnant women immunized for the first time shall be given a vaccination card with appropriate entries and instructions to retain the card.
- If the card is lost; a new card shall be issued to the child/woman with the same registration number after completing all entries from previous vaccination record (permanent register).

Union Council Level

- The in-charge of EPI centers in consultation with area vaccinators shall compile all UC immunization coverage reports and surveillance reports.
- VPD surveillance report to be sent in Form B weekly to the EDO (Health) office.
- AEFI surveillance report to be sent weekly along with VPD surveillance report to the EDO (Health) office
- All surveillance reports and immunization coverage reports shall be verified and signed by the health facility in-charges before submission to the concerned Tehsils/Talukas and districts.
- All monthly immunization performance reports for Static Centers, outreach and mobile activities shall be submitted to the district office by **2nd working day of the following month.**

District Level

- All district reports shall be compiled by the DSV.
- The surveillance reports shall be countersigned by the District Surveillance Coordinator and the EDO (Health) before forwarding to the provincial offices.
- VPD and AEFI surveillance reports to be sent weekly and can be sent electronically to the provincial offices.
- The monthly immunization reports shall be countersigned by the district EPI Coordinator and EDOs-Health and submitted to the provincial offices by **7th of the following month.**
- Feedback by district office to the facilities in charges shall be given every month in review meeting to be held at district level under the chairmanship of EDO (H) or his nominee.

Provincial Level

- The provincial office shall compile and submit all district reports by **10th day of the following month** to the Federal EPI Cell. VPD surveillance reports to be sent weekly.
- Feedback shall be given to the district offices directly one week before the next report is due.

Federal Level

- The Federal EPI Cell shall complete consolidate all reports by **15th day of the following month.**
- Feedback shall be given to the provincial offices directly one week before the next report is due.

Annexure F

Vaccine Preventable Disease (VPD) Surveillance

List of EPI Notifiable Diseases

- Childhood Tuberculosis, AFP, Diphtheria, Pertussis, Maternal and Neonatal tetanus, suspected Measles and other diseases against which EPI provide vaccines e.g. bacterial meningitis and pneumonia due to Hib and Pneumococcus are included in the list of notifiable diseases.
- All cases shall be reported by the health facilities, hospitals, private practitioners' clinics and private hospitals where first contact with the patient occurs.

Adverse Events Following Immunization (AEFI)

AEFIs shall be reported on weekly basis.

Serious AEFI (death, hospitalization, cluster of AEFI and any AEFI that causes serious community concern) shall be reported immediately and investigation is to be initiated within 48 hours of notification.

In the case of AEFI; the district health authorities shall ensure:

- Investigation process shall follow the national guidelines and collaborating with National Regulatory Authority (NRA) at all level.
- Corrective measures are taken immediately to reassure the community regarding the nature of the problem.
- The district shall maintain a line listing of AEFI.
- Adverse events reporting shall be the integral part of the routine disease reporting system of the programme.

Weekly Reporting of Disease

- Each health facility shall report all cases of EPI target diseases on weekly basis.

Flow of Surveillance Information

- The in-charge(s) of the health facility shall be responsible for reporting of Vaccine Preventable Diseases (VPDs) to the EDO-H.
- AFP and any other EPI diseases out breaks shall be reported immediately.
- The District EPI Coordinator/Epidemiologist / Surveillance Coordinator shall be responsible for consolidating the facility reports and ensuring that appropriate response has been initiated by concerned officials.

Flow of surveillance reports

All public health facilities at primary, secondary and tertiary level

By facility in-charge (MO/ MS etc.)

1. AFP case & outbreak report shall be sent immediately.
2. Weekly VPD surveillance zero report for a given week shall be sent out by Saturday using Form B.

Executive District Officer Health's Office

By District EPI Coordinator

/Epidemiologist

/Surveillance Coordinator:

1. AFP case & outbreak report shall be sent immediately.
2. Compiled weekly report of a given week shall reach the Provincial EPI Office by Tuesday of the following week either electronically or hard copy.

Provincial EPI Office

By Epidemiologist

/Surveillance focal person:

1. AFP case & outbreak report shall be sent immediately.
2. Compiled weekly report of a given week shall reach the Federal EPI Cell by Thursday of the following week.
3. Weekly analysis of data and appropriate feedback to the districts

Federal EPI Cell

By Monitoring & Evaluation cell: Immediate sharing of VPD data and outbreaks with MoH and concerned EPI partners

Compilation of the weekly reports for onwards submission to the MoH, further analysis and appropriate feedback to the provinces.

Annexure G

Guideline for vaccinating children aged above 1 year

According to childhood immunization schedule in EPI Pakistan, all children should receive all doses of all antigens (except Measles 2nd dose) before his/her 1st birthday. However, for different reasons many children fail to receive all the required doses of the antigens on time and come in contact with the immunization service late. Following guideline is developed according to WHO's recommendation for vaccinating higher age children and to be followed is such situations.

Antigen	Number of doses in primary series	Recommended age of 1st dose	Doses for those who starts vaccination late		
			If ≤1 year	If 1 to 2 years	If >2 years
BCG	1	Soon after birth	1 dose	Not recommended	
tOPV	3	6 weeks (see footnote for birth dose)	3 doses with at least 4 weeks interval in between each dose	3 doses with at least 4 weeks interval in between each dose (for children up to 5 years age)	
Pentavalent (DTP-Hep B-Hib)	3	6 weeks	3 doses with at least 4 weeks interval in between each dose	1st dose: Pentavalent 2nd dose (after 2 months): DTP 3rd dose (after 6 – 12 months): DTP	**2 – 6 years** 1st dose: DTP 2nd dose (after 2 months): DTP 3rd dose (after 6 – 12 months): DTP **6 – 7 years** Use DTaP, 3 doses with interval as above **>7 years** Use Td, 3 doses with interval as above
PCV10	3	6 weeks	3 doses with at least 4 weeks interval in between each dose	2 doses at 4 weeks interval	Only for high risk children up to 5 years: 2 doses at 4 weeks interval
Measles	2	Upon completion of 09 months	1 dose	1 dose (up to 10 years age)	

Note: OPV birth dose: being a polio endemic country, all children in Pakistan should receive a birth dose with tOPV (OPV0) soon after birth. This birth dose is not considered substitute for any of the three doses in the primary series.

Annexure H

Guideline for Standardization of Immunization Supply Chain Refrigeration Equipment in Pakistan

Context

As part of a global initiative to strengthen its immunization supply chain, Pakistan reviewed the diverse selection of cold chain equipment in use for vaccine storage with a view to developing a guideline for future equipment acquisition. The guideline will contribute to the standardization of the types of equipment procured in the future, simplify maintenance and spare parts supply and progressively improve supply chain efficiency through more rational placement of appropriate equipment over the coming 5 year horizon at locations where the storage of vaccines is most needed and investment justified in active cold chain storage equipment.

The country should also review its "freeze risk" policy, as DTP containing and "New" vaccines are damaged by freezing. Freeze indicators are not used in transported vaccines and 30DTR continuous temperature monitoring devices are not used in refrigerators.

Adoption of chilled water packs to transport vaccines other than those with VVM2 or VVM7 indicators during distribution and for outreach activity would reduce the need for vaccine and icepack freezers at the peripheral level of the vaccine supply chain, but would require additional storage space in vaccines refrigerators for chilling water packs and the use of cold boxes and vaccine carriers with an extended "cool life"[3]

Criteria for Standardization

Standardization of supply chain equipment ensures that storage devices are available at all locations in the vaccine supply chain are well matched to storage need. Standardization also ensures that risks to vaccine stocks in the supply chain, and O&M costs are minimized. Standardization is not just having all vaccine refrigerators from a single manufacturer at least cost.

Critical factors of standardisation are:

A program that progressively replaces aging and WHO/PQS non-compliant equipment and eliminates the gap between equipment needed and equipment availability.

Storage devices are used which are adapted to the quality and availability of the energy supply to power the device at the location

Storage devices have sufficient or excess storage capacity to meet all storage needs at least until 2020. The storage device must not have less capacity than needed but may have more.

Maintenance capacity exists or can be created.

Only WHO/PQS pre-qualified devices for use in a hot climate (430C) and have a proven reliable operating history in Pakistan or elsewhere are procured.

All supplied equipment is supported by warranties from well-established, reputed and reliable manufacturers, such that spare parts and contracted service support is assured.

Storage devices are procured which compliment existing brand names where proven reliability and performance is readily apparent.

Cold rooms are used rather than vaccine refrigerators when the target population of a facility requires more than 1500 litres of net storage space.

Vaccines are transported without risks of freezing or heat exposure.

Procured storage devices provide "best value for money" in terms of $/ltr of net storage capacity, quality and performance rather than lowest capital cost.

Approach

The guideline is developed from the following information sources:

WHO/PQS prequalified cold chain refrigeration equipment and passive storage containers[4].

(http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/index.aspx)

The National database of under 5 year old target populations,

A limited amount of data available from the Cold Chain Equipment Management Tool (CCEM2),

The 2014 Effective Management Assessment data from 161 sites assessed,

Data inputted into the vLMIS from the CCEM2 tool,

An equipment inventory database last updated in 2011.

The cMYP's.

How to use passive containers and coolant-packs for vaccine

transport and outreach operations (Module VMH-E7_02.1. Draft: November 2014)

Vaccine storage volumes are estimated at each vaccine storage location with electrically powered cooling equipment from:

The vaccine packed volume in the present national immunization schedule, using the WHO Immunization Supply Chain Sizing Tool (2014)

The packed volume of presently used known new vaccines scheduled to be introduced by 2020,

The projected cumulative increase in birth cohort by 2020,

[3] - Reference WHO draft guideline ((Module VMH-E7_02.1. Draft: November 2014)

[4] - The WHO/PQS catalogue is regularly updated.

An additional 10% storage capacity margin as per the methodology and norms of the EVMA

Provision to store chilled water packs for transport and outreach activities, and

An allowance for the storage of campaign vaccines not exceeding a period of one month.

Determination of Packed Vaccine Volumes per fully immunized child.

Supply Chain Equipment Standards for Pakistan

This standard is developed on the premise that Pakistan will:

Refer to the latest edition of the PQS Devices Catalogue published and regularly updated by WHO. (Reference: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/index.aspx) and

Not revisit its rational for vaccine distribution in the near term. This, however, is a highly desirable exercise and would represent major improvements in vaccine availability and tracking of stocks, major economies of investments required to improve the present cold chain and simplified maintenance and supply chain management.

Supply chain equipment standards for Pakistan require that:

Pakistan equips all functional EPI centres with vaccine refrigerators adapted to accommodate the future needs (2020) rather than present needs of vaccine storage locations. Approximately 3265 vaccine storage devices require immediate replacement. By the year 2020, 5200 vaccine storage devices will be required as replacement or supply to facilities not presently equipped so that all functional EPI centres have vaccine storage devices. All replacement planning should be projected for the need by 2020.

Annex 1: All vaccine storage locations have sufficient or more than sufficient capacity to stock needed vaccine supplies.

Vaccine storage capacity for a given target population at service delivery locations is based upon the estimated maximum volume of routine vaccines projected by 2018 (193.48cc's / FIC). Refrigeration equipment installed should have sufficient capacity to store these volumes and preferably substantially greater capacity, so that vaccines from adjacent facilities can be stored in the event of failure of equipment. It is also important to note:

The cost/ltr of net storage spaces decreases at the size of refrigerators increase.

Available WHO/PQS prequalified equipment is designed for the most part to meet the storage requirements of larger target populations.

A balanced portfolio of equipment categories is required to meet the electrical supply situation nationally.

Solar Direct Drive (SDD) type vaccine refrigerators are required for 18% of locations, AC vaccine refrigerators with extended holdover (more than 5 days) are required for 13% of locations and 59% of locations can be equipped with WHO/PQS prequalified "hot climate" AC systems.

Only WHO/PQS prequalified equipment rated for use in hot climates (430C) is procured.

Equipment procured maintains the balanced portfolio of equipment categories (Refer to Item 39 above), is compliant with the requirement for storage capacity (Ref to Item 37 above) and is procured from approved manufacturers. (Ref to Item 41.)

Available Power Supply

Data sample of 2362 sites in 5 Provinces extracted from CCEM report of February 2014. No data available from remaining provinces. Data from sites assessed in 2014 was not made available.

An average, 17% of the 2362 locations have generating sets. Only 18% of locations with no electricity have generating sets but 23% of locations with more than 16hrs/day also have generating sets. This also suggests that 18% of non-electrified and poorly electrified locations need not depend upon solar energy, however SDD refrigerators require very little maintenance and operating costs are much lower that refrigerators with generators hence the program is encouraged to provide SDD refrigerators at locations having less than 4 hrs/day of electricity on a regular basis rather than supply and maintain generating sets.

Table 3 which summarizes electricity supply by province, assumes that 50% of electrified sites having less than 8hrs/day of electricity have less than 4hr/day hence are only suited to Solar SDD type refrigerators.

Table 3 - Electricity supply by province

Electricity supply situation (hr/day)	Balochistan	Punjab	Sindh	KP	FATA	Province totals	% Distribution by supply quality	Type of Equipment suited
No Electricity or less than 4hrs/day average. Power outages for more than 10 Consecutive days	2	39	27	15	40	123	18%	Solar Direct Drive Refrigerators(No Batteries)
At least 4 hrs of electricity/day average over 6 day periods	82	236	94	84	128	624	13%	Long Autonomy ILRs requiring at least 24 of electricity over a 6 day period.
At least 8 hours of electricity/day on a regular basics. No power outages more than 24 hours	42	670	404	183	55	1,354	57%	Regular AC powered ILR's requiring at least 8 hours of electricity/day
More than 16 hrs/day of electricity every day	34	79	118	26	3	260	11%	
Total # of sites	160	1,024	643	308	226	2,361		

Passive containers (Cold Boxes and Vaccine Carriers) with a long "Cool Life" are used.

This will facilitate the use of chilled water packs rather than ice packs for transported vaccines and eliminate risks of freezing freeze sensitive vaccines during transportation.

All equipment procured includes certain mandatory accessories.

Vaccine Refrigerators

30-DTR WHO/PQS prequalified continuous temperature recording devices. PQS reference: E006/020 or E006/013

1KVA Voltage stabilisers for all AC refrigerators. Preferably integrated in the refrigerator

Replacement parts as per the recommended list in the WHO/PQS catalogue.

Technical specifications, operating instructions and warranties.

Cold Rooms

WHO/PQS prequalified continuous temperature monitoring and data communication system. (PQS reference: E006/019 or E006/025)

Servo stabiliser (15-20KVA/single or 3 phase)

A standby power source (Generating set or Solar Power Pack).

Replacement parts. (15% of equipment cost)

Technical specifications, operating instructions and warranties.

Cold Boxes and Vaccine Carriers.

Freeze Tags. (PQS reference: E006/007 or E006/009). These are no longer required when "cool packs" are used for transporting vaccines.

Equipment (WHO/PQS prequalified) is sourced only from proven reputed manufacturers.

Qualifying refrigeration equipment manufacturers are:

Those already having substantial quantities of cold chain equipment in use in the immunisation supply chain in Pakistan (Vestfrost 68% and Dometic 11.5% of vaccine refrigerators, and Huurre (Porke) 75% of cold rooms/freezer rooms at the central store).

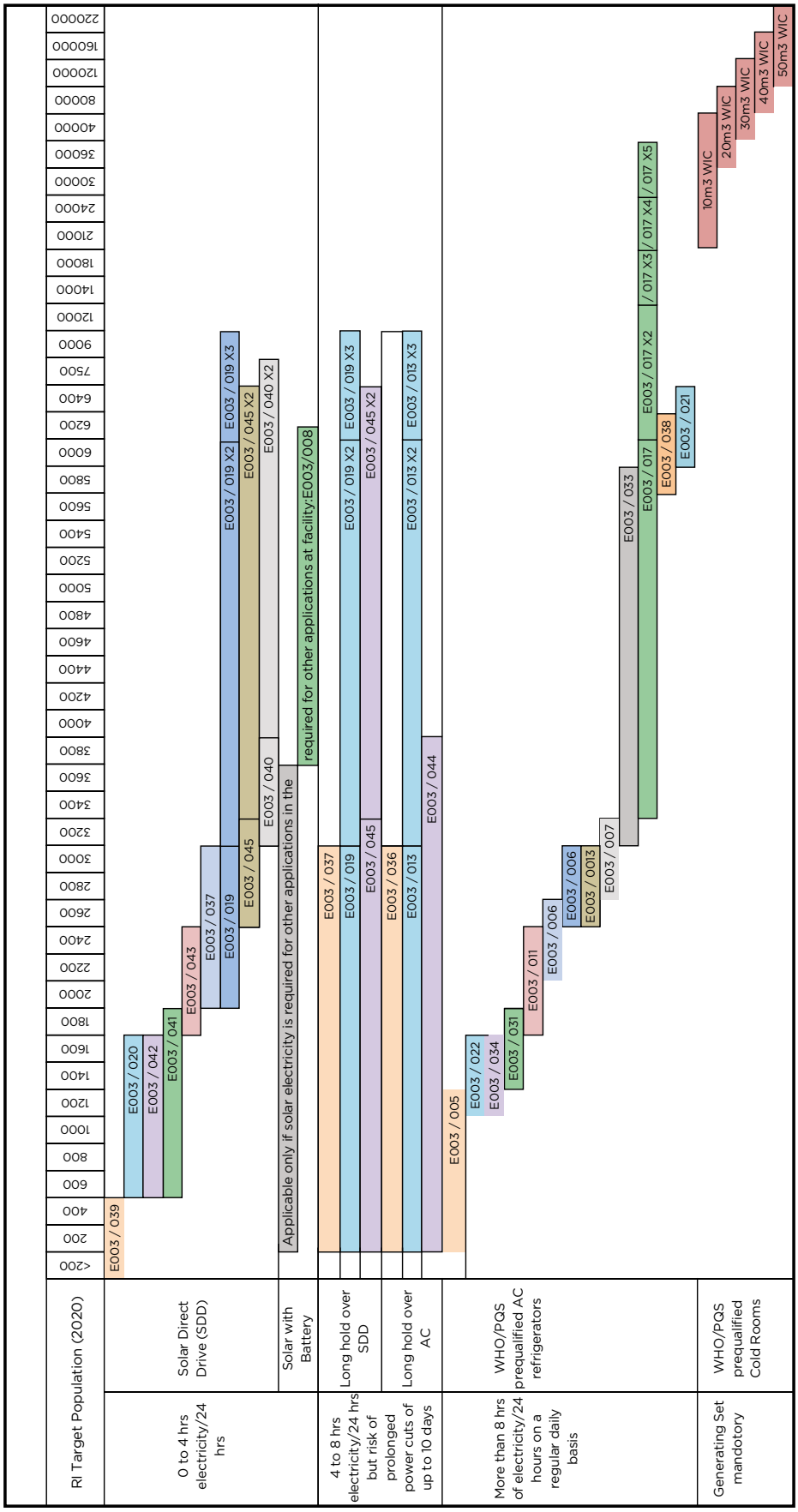
Those offering refrigerator products with superior proven technical specifications or products in a category not available from existing suppliers offering WHO/PQS prequalified equipment. (Surechill (UK),

Godrej (India) and Zero Appliances (SA). These manufacturers offer AC and SDD refrigeration systems with holdover of 5-12 days in the event of electrical supply failure or absence. (Reference: E003/013, E003/019, E003/036, E003/037, E003/044, E003/047, E003/046),

Procured storage devices provide "best value for money" in terms of $/ltr of net storage capacity, quality and performance rather than lowest capital cost.

Future supply patterns

An indicative chart (Chart 7) for future supply patterns corresponding to target population sizes offers a guideline for equipment selection based upon the WHO/PQS prequalified devices catalog.


RI Target Population (2020)
0 to 4 hrs electricity/24 hrs
Solar Direct Drive (SDD)
Solar with Battery
4 to 8 hrs electricity/24 hrs but risk of prolonged power cuts of up to 10 days
Long hold over SDD
Long hold over AC
More than 8 hrs of electricity/24 hours on a regular daily basis
WHO/PQS prequalified AC refrigerators
Generating Set mandotory
WHO/PQS prequalified Cold Rooms
<200
200
400
600
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1200
1400
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1800
2000
2200
2400
2600
2800
3000
3200
3400
3600
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30000
36000
40000
80000
120000
160000
220000
E003 / 039
E003 / 020
E003 / 042
E003 / 041
E003 / 043
E003 / 037
E003 / 019
E003 / 045
E003 / 040
E003 / 019 X2
E003 / 045 X2
E003 / 040 X2
E003 / 019 X3
Applicable only if solar electricity is required for other applications in the
required for other applications at facility:E003/008
E003 / 037
E003 / 019
E003 / 045
E003 / 036
E003 / 013
E003 / 044
E003 / 019 X2
E003 / 045 X2
E003 / 013 X2
E003 / 019 X3
E003 / 013 X3
E003 / 005
E003 / 022
E003 / 034
E003 / 031
E003 / 011
E003 / 006
E003 / 0013
E003 / 007
E003 / 033
E003 / 017
E003 / 017 X2
/ 017 X3
/ 017 X4
/ 017 X5
E003 / 038
E003 / 021
10m3 WIC
20m3 WIC
30m3 WIC
40m3 WIC
50m3 WIC

All vaccine refrigerators are installed, maintained, monitored and used correctly by adequately trained personnel.

20% of installed refrigeration equipment is non functional.

All vaccine refrigerators are installed, maintained, monitored and used correctly by adequately trained personnel.

Appropriately sized and WHO/PQS prequalified cold rooms are supplied and used rather than vaccine refrigerators at locations when the under 1 year target population (catchment) of a facility requires more than 1500 litres of net storage space.

Annex 1: Pakistan equips all functional EPI centres with vaccine refrigerators adapted to the future needs (2020) rather than present needs of vaccine storage locations

EPI Centres

7499 UC's in the target population database of 2013 indicates an under 5-year target population of 36,749,394 . 13% of UC's do not have EPI centres hence 6979 were registered as functional EPI Centres in 2012. 81% of these (5684) are assessed as having adequate numbers of appropriate and functioning cold chain equipment.

Matching vaccine storage needs to vaccine storage devices

Vaccine storage needs in Pakistan is linked to the target population serviced directly by a health facility through fixed, mobile or outreach activity, and the frequency and volume of vaccine supply to that facility in the case of service delivery points.

In the case of vaccine storage and distribution locations, vaccine storage needs are directly related to the frequency and volumes of vaccine supply to that facility and the frequency and volumes of vaccines distributes to other facilities.

Quantities of Supply chain equipment

81% (5684) of the functional UC centers are registered in 2013 are assessed as having adequate numbers of appropriate and functioning equipment. CCEM2 data in 2013 from 3704 pieces of equipment at 2360 sites indicates 74.3% of equipment is functioning well, 6.2% functions but requires attention and 19.5% of equipment is out of order.

59% of refrigerators are more than 5 years old and 34% more than 10 years old.

3265 vaccine storage devices require immediate replacement and by 2020, 5200 vaccine storage devices will require replacement assuming systems less than 5 years which are currently working continue to do so and that all functional EPI centers are equipped with vaccine storage devices.

68% of the UC facilities regularly have more than 8hr/day of electricity, 13% are estimated to have an average of 4-8Hrs of electricity/day, and 18% require solar installations. 17% of sites are equipped with generators regardless of whether they have regular AC power or not. The replacement program should thus envisage

Replacement Schedule (yr)	Total Quantity to Replace	# of AC powered WHO/PQS pre-qualified refrigerators	# of AC Powered WHO/PQS prequalified refrigerators with more than 5 days of autonomy in the event of power failure	Solar Direct Drive (SDD) refrigerators
2014	3265	2,220	424	588
2020	5200	3,536	676	936

Annex 2: All vaccine storage locations will have sufficient or more than sufficient capacity to stock needed vaccine supplies.

Vaccine Volumes per fully immunised child (FIC)

Routine Immunization

The surviving infant population in 2013 and 2020 is projected from cMYP (2014-2018) data. The 2013 and 2020 surviving infant populations are 5,903,175 and 6,775,383 surviving infants respectively.

A factor is thus used to convert the under 5 year target population available for each UC (Polio campaign) to the under 1-year target population (Routine immunization). Source data is shown in Table 1

[5] - Pakistan Demographic and Household Survey 2012-13

[6] - Source cMYP 2014-2018

Data Source	2012	2013	2014	2015	2016
Total pop (CMYP)	178,341,451		185,423,671		
Extrapolated Total Pop CMYP				189,186,106	192,948,540
Surviving infant (CMYP	5,778,564		6,027,786		
Extrapolated Target CMYP		5,903,175		6,152,384	6,276,982
Under 5 Surviving infants(Nat Pop Survey		36,749,394	37,525,081	38,300,768	39,076,454
Under 5 to Under 1 factor		6.23			
Adjustment Factor including population growth			6.11	6.00	5.88

Data Source	2017	2018	2019	2020
Total pop (CMYP)		200,473,409		
Extrapolated Total Pop CMYP	196,710,975		204,235,844	207,850,728
Surviving infant (CMYP		6,526,178		
Extrapolated Target CMYP	6,401,580		6,650,776	6,775,383
Under 5 Surviving infants(Nat Pop	39,852,141	40,627,828	41,403,515	42,179,201
Under 5 to Under 1 factor				
Adjustment Factor including pop	5.77	5.65	5.54	5.42

New vaccines planned or anticipated for inclusion in the future immunization schedule are: Rotarix, IPV, HPV and MR. Based upon WHO data for maximum packed volumes Fully immunized child volumes will need to be 193.8cc/FIC at service delivery level and 174.3cc/FIC for vaccines stored at 2-80C at the central store and provincial cold rooms . Ref: Table 2

Volumes of vaccines to store in the supply chain are determined from the 2014 edition of the WHO Immunization Supply Chain Sizing Tool. Maximum and Average Routine Immunization volumes are based upon the immunization schedule indicated below

Characteristis of vaccines selected for use

Vaccine	Presentation (dose/vial)	Packed volume, based on national data		Maxi packed volume from data base		Storage temperatures rances of vaccines	Price of vaccines
choose from dropdown list	choose from dropdown list	Vaccines (Cm3/dose)	Diluents (Cm3/dose)	Vaccines (Cm3/dose)	Diluents (Cm3/dose)	+2°C to +8°C or -25°C to -15 C	(SUS/dose)
BCG	20			1.3		at +5°C	
DTP-HepB-Hib	1			26.1			
IPV	10			2.5			
Measles	10			2.6	4.0	at +5°C	
HPV	1			15.0			
MR	10					at +5°C	
Rota_liq	1			17.1			
TT	20			2.9			
tOPV	20			1.1			
bOPV	20			1.1			
PCV-10	2			4.8			

[7] - Source: cMYP 2014-2018

Estimated volumes to store vaccines based upon maximum or average packed volumes at the respective tiers of the supply chain are summarised below.

The 3 steps of program expansion comprise:

1 Current immunization schedule,

2 The introduction of IPV and with the tOPV to bOPV swap, and

3 The introduction of HepB birth dose, with the introduction Rotarix (2 dose liquid) in 2018, the introduction of MR, and the eventual introduction of HPV (2 doses)

Packed Volume Scenarios	Max Volume/FIC			Average Volume/ FIC		
Stage of Program Expansion	1	2	3	1	2	3
Net volume of OPV at -20°C in higher level stores, per FIC	5.2	5.3	5.3	3.3	3.9	3.9
Net volume of lyophized vaccines to be stored at -20°C in higher level stores, per FIC	0.0	0.0	0.0	0.0	0.0	0.0
Net volume of vaccines w/o lyo & OPV stored at +5°C in higher level stores, per FIC	117.0	142.7	174.3	85.9	110.7	136.1
Net volume of vaccines w/o OPV stored at +5°C in higher level stores, per FIC	117.0	142.7	174.3	85.9	110.7	136.1
Net volume of all vaccines stored at +5°C in lower level stores, per FIC	122.2	148.1	179.6	89.3	114.6	140.0
Net volume of all vaccines & diluents, stored at +5°C at service delivery, per FIC	136.3	162.2	193.8	101.3	126.7	152.1
No. of vaccine doses per FIC	15.0	18.0	20.0	15.0	18.0	20.0

These scenarios do NOT include provision for:

- Polio campaigns
- Measles campaigns
- TT administered to women of childbearing age.

For purposes of estimating supply chain volume the "Maximum" volume scenario rather than the "Average" volume is adopted since this allows 27% capacity over and above the average packed volumes of RI vaccines. A further 10% margin on required capacity is also included as per the methodology used to estimate required vaccine storage capacity in the EVM assessment tool. This cumulative margin of 37% is sufficient to accommodate the volumes of vaccines required for a measles campaign with a target population of 9 months to 10 years OR Polio campaign vaccines and TT supplement for women of child bearing age (15-45 years) This includes provision for 22% of the population, with a wastage rate of 50%.

The maximum volume of products/FIC to be held in dry store (syringes, safety boxes and diluents is summarised below. This amounts to 0.9ltr of materials/ FIC. Dry store requirements inclusive of a grossing factor are based upon these volumes.

In dry storage		
diluents	syringes	safety boxes
14.1	802.2	91.9

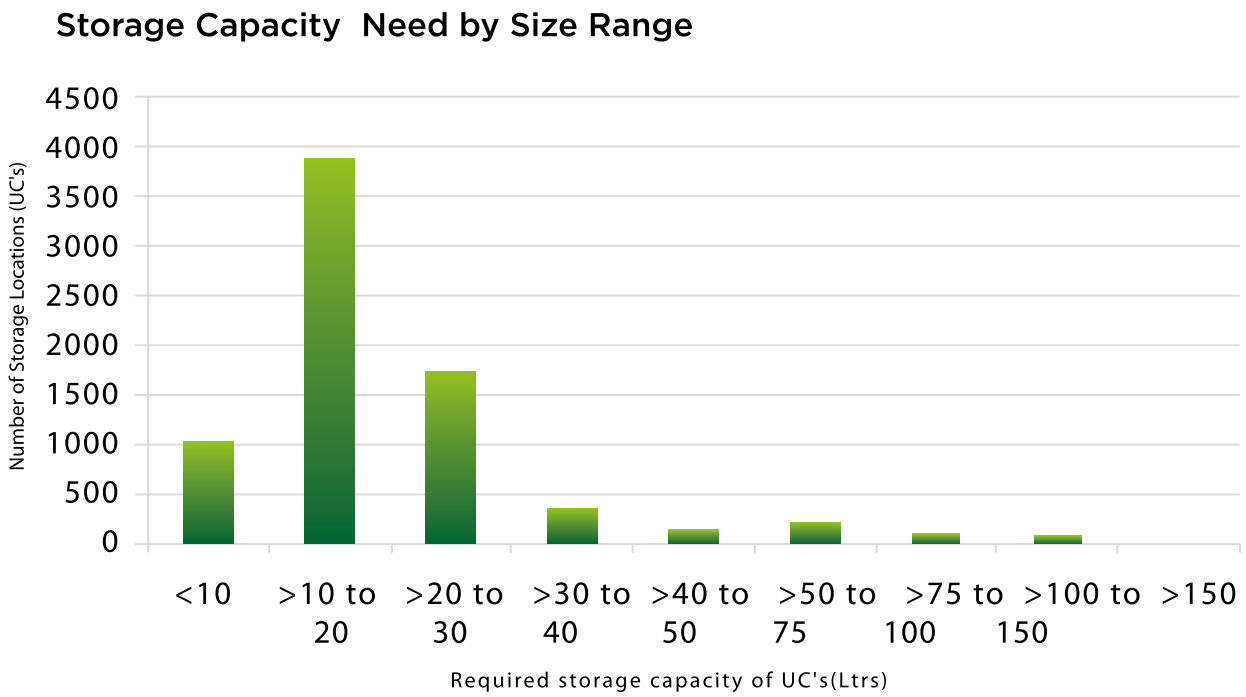
No space provision is required for OPV campaign vaccines, (NID's, SNID's or Case response) and for HPV demo programs since volumes required will be less than the volume for measles campaigns.

Cool Packs

National policy for vaccinators at Union Communes includes provision for up to 2-outreach sessions/day. Chilled water packs for 2 vaccine carriers will occupy 3.2 ltr of refrigerator space at UC storage facilities.

Storage Capacity Required.

Binned distribution of storage capacity required, based upon 7443 UC locations drawn from the National Population database is shown in Error! Reference source not found..



Annex 3: A balanced portfolio of equipment categories is required to meet the electrical supply situation nationally

Classifying devices by power source and holdover time

Vaccine storage devices may be categorized by:

Devices suitable for use in a "hot" climate where AC electricity supply is consistently more than 8 hours per day and power outages do not exceed 1-5 days.

Devices suitable for use in a "hot" climate where AC electricity supply is frequently available for at least 4 hours per day and power outages may occur for up to 10 days

Solar powered devices suitable for "hot "climate which do not use batteries. Suitable for locations where AC electricity cannot be assured for at least 4 hours/day on a reasonably regular basis (At least 24 hours of supply over a 6 day period).

Solar powered devices suitable for "hot "climate which use batteries. Use of equipment in this category is not encouraged in Pakistan, due in part to high investment costs and weak maintenance standards.

24 of the 31 WHO/PQS devices pre-qualified for use in a "hot" climate operate for more than 1 day in the absence of a power source (AC or Solar), 7 devices operate for more than 5 days whereas only 3 devices operate for more than 10 days. Ref to Chart 1. 5 of the devices have capacity to freeze icepacks.

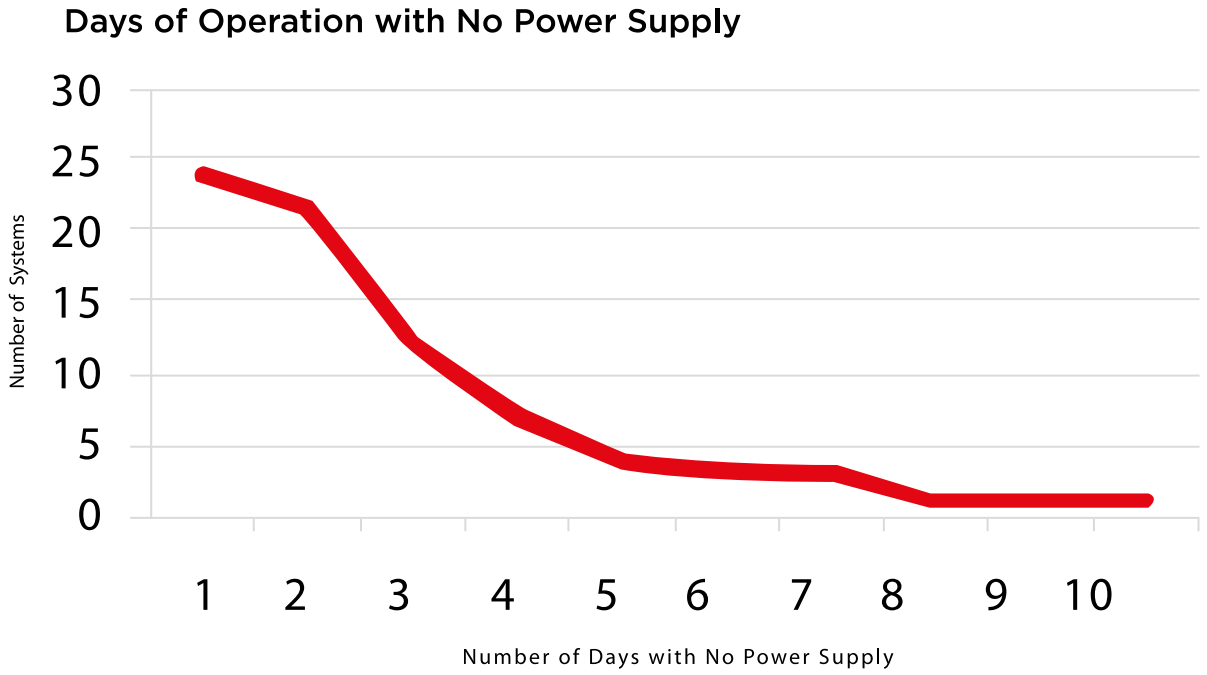
Available Power Supply

Data sample of 2362 sites in 5 Provinces

extracted from CCEM report of February 2014. No data available from remaining provinces. Data from sites assessed in 2014 was not made available.

An average, 17% of the 2362 locations have generating sets. Only 18% of locations with no electricity have generating sets but 23% of locations with more than 16hrs/day also have generating sets. This also suggests that 18% of non-electrified and poorly electrified locations need not depend upon solar energy, however SDD refrigerators require very little maintenance and operating costs are much lower that refrigerators with generators hence the program is encouraged to provide SDD refrigerators at locations having less than 4 hrs/day of electricity on a regular basis rather than supply and maintain generating sets.

Table 3 which summarizes electricity supply by province, assumes that 50% of electrified sites having less than 8hrs/day of electricity have less than 4hr/day hence are only suited to Solar SDD type refrigerators.



Electricity supply situation (hr/day)	Balochistan	Punjab	Sindh	KP	FATA	Province totals	% Distribution by supply quality	Type of Equipment suited
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Total # of sites	160	1,024	643	308	226	2,361		

Annex 4: Only WHO/PQS prequalified equipment rated for use in hot climates (430C) is procured.

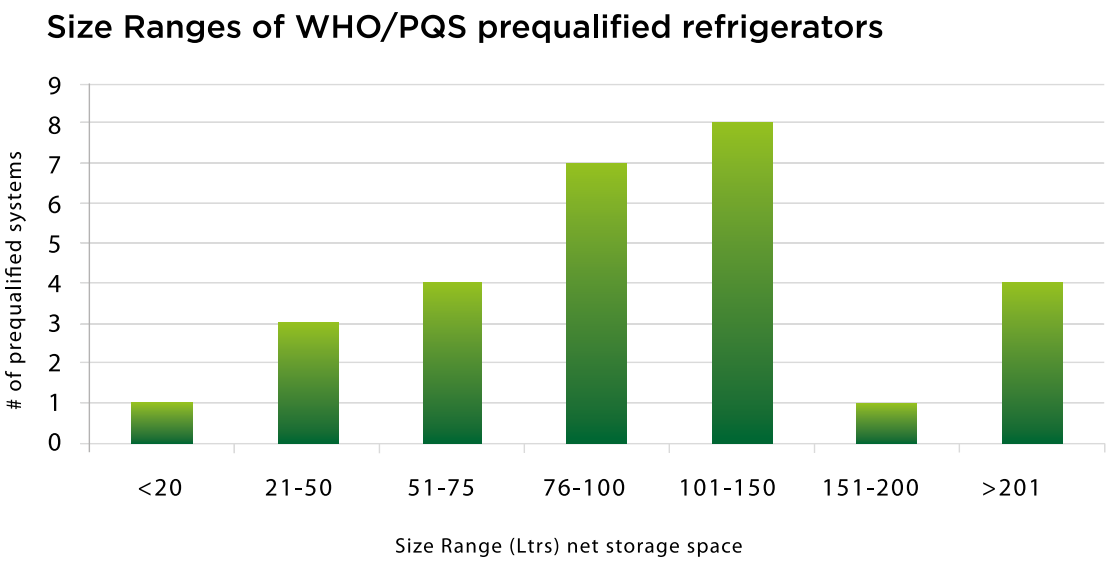
WHO/PQS prequalified refrigeration devices

WHO/PQS prequalified vaccine storage devices (Active) are tabulated below :

WHO/PQS code	Refrigrator Net Capicity (Ltr)	Model Reference	Prequalified Climate	Type of refrigrente	Power source	Autunomy (hrs)	Ice Pack storage capicity (Ltr)	PQS indicative cost/unit ($)	Remarks
E003 / 039	**15**	**BFRV15**	**Hot**	**R134a**	**SDD**	**101**	**0**	**2450**	
E003 / 005	45	HBC70	Hot	R134a	AC	27	0	510	
E003 / 042	46.6	TCW40SDD	Hot	R600a	SDD	82	9.7	4424	
E003 / 022	48	MK144	Hot	R134a	AC	43	0	599	
E003 / 034	52.5	HBC-110	Hot	R134a	AC	36	0	590	
E003 / 020	54.5	BRFV55	Hot	R134a	SDD	83	0	3725	
E003 / 041	55.5	VLSO54	Hot	R600a	SDD	72	0	1495	
E003 / 011	75	MK204	Hot	R134a	AC	75	0	695	
E003 / 043	79	TCW2043 SDD	Hot	R600a	SDD	73	42	7266	
E003 / 006	90	HBC-200	Hot	R134a	AC	31	0	688	
E003 / 013	99	BLF100AC	MultiZone	R134a	AC	249	0	2795	
E003 / 036	99	ZLF100AC	Hot	R134a	AC	113	0	2518	
E003 / 019	99	BLF100DC	Hot	R600a	SDD	170	0	3825	
E003 / 037	99	ZLF100DC	Hot	R600a	SDD	170	0	3799	
E003 / 007	105	MK304	MultiZone	R134a	AC	25	0	774	
E003 / 045	111	TCW3043SDD	Hot	R600a	SDD	116	0	5188	
E003 / 031	59.5	VLS200	Hot	R600a	AC	24	39	568	
E003 / 014	118	TCW200AC	Hot	R134a	AC	39	42	2361	
E003 / 001	118	TCW200DC	Hot	R134a	Solar	13	42	2606	
E003 / 044	128	ZLF150AC	Hot	R134a	AC	128	0	3036	
E003 / 040	132	VC200SDD	Hot	R600a	SDD	79	0	3800	
E003 / 012	135	MK404	Hot	R134a	AC	23	0	879	
E003 / 032	148	VLS300	Hot	R600a	AC	23	0	669	
E003 / 033	196	VLS350	Hot	R600a	AC	31	0	751	
E003 / 017	204	TCW3000AC	Hot	R134a	AC	53	(278)	2461	**Fridge or Freezer**
E003 / 008	204	TCW3000DC	Hot	R134a	Solar	23	(278)	2558	**Fridge or Freezer**
E003 / 038	211	HBC-340	Hot	R134a	AC	45	0	1250	
E003 / 021	216	VLS400	Hot	R600a	AC	30	0	796	

Refrigerator Sizes (Net storage Volume);

More than 50% of prequalified vaccine refrigerators are between 75-150Ltr net capacities, and only 14% have less than 50Ltr storage capacity. There are 4 models (14% with more than 200Ltr capacity. Ref: Chart 2.



[8] - Updated 2 October 2014. Latest version of the WHO/PQS Catalogue for Prequalified devices should be referred to at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/index.aspx

Updated 2 October 2014. Latest version of the WHO/PQS Catalogue for Prequalified devices should be referred to at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/index.aspx

Grouping Devices by Categories

The tables below (Table 4, Table 5, Table 6, Table 7, and Table 8) provide details of WHO/PQS prequalified refrigerators grouped by category of power supply, net storage volume and ice pack freezing capacity.

AC Power systems without Icepack Freezing and less than 5 days autonomy without electricity

	PQS code	Capacity	Ref	Climate	Refrigerant	Power	Autonomy (hr)	IP cap	PQS cost	Manufactured
<50 Ltrs Vaccines	E003/005	45	HBC70	Hot	R 134a	AC	27	0	510	China
	E003/022	48	MK144	Hot	R 134a	AC	43	0	705	Denmark
50-100 Ltrs Vaccine	E003/034	52.5	HBC-110	Hot	R 134a	AC	36	0	590	China
	E003/011	75	MK204	Hot	R 134a	AC	75	0	820	Denmark
	E003/006	90	HBC-200	Hot	R 134a	AC	31	0	688	China
100-150 Ltrs Vaccine	E003/007	105	MK304	MultiZone	R 134a	AC	25	0	973	Denmark
	E003/012	135	MK304	Hot	R 134a	AC	23	0	879	Denmark
	E003/032	148	VLS350	Hot	R 600a	AC	23	0	669	Denmark
>150 Ltr Vaccine	E003/033	196	VLS350	Hot	R 600a	AC	31	0	751	Denmark
	E003/017	204	TCW300DAC	Hot	R 134a	AC	53	0	2461	Luxembourg
	E003/038	211	HBC-340	Hot	R 134a	AC	45	0	1250	China
	E003/021	216	VLS400	Hot	R 600a	AC	30	0	796	Denmark

Table 4

AC Powered systems with more than 5 days autonomy with no electricity

	PQS code	Capacity	Ref	Climate	Refrigerant	Power	Autonomy (hr)	IP cap	PQS cost	Manufactured
50-100 Ltrs Vaccine	E003/013	99	BLF100AC	Multizone	R 134a	AC	249	0	2535	UK
100-150 Ltrs Vaccine	E003/044	128	ZLF150AC	Hot	R 134a	AC	128	0	3036	South Africa

Table 5

AC Powered Refrigerators with icepack freezing capacity

PQS code	Capacity	Ref	Climate	Refrigerant	Power	Autonomy (hr)	IP cap	PQS cost	Manufactured
E003/031	59.5	VLS200	Hot	R 600a	AC	24	39	568	Vestfrost
E003/014	118	TCW2000AC	Hot	R 134a	AC	39	42	2361	Dometic

Table 6

Solar Without Battery Systems (SDD)

	PQS code	Capacity	Ref	Climate	Refrigerant	Power	Autonomy (hr)	IP cap	PQS cost	
<50 Ltrs Vaccines	E003/039	15	BFRV15	Hot	R 134a	SD D	101	0	2450	USA
	E003/042	46.6	TCW40SDD	Hot	R 600a	SD D	82	9.7	6139	Luxembourg
50-100 Ltrs Vaccine	E003/020	54.5	BRFV55	Hot	R 134a	SD D	83	0	3725	USA
	E003/041	55.5	VLS054	Hot	R 600a	SD D	72	0	1495	Denmark
	E003/043	79	TCW2043SDD	Hot	R 600a	SD D	73	42	10500	Luxembourg
	E003/019	99	BLF100DC	Hot	R 600a	SD D	170	0	3825	UK
100-150 Ltrs Vaccine	E003/037	99	ZLF100DC	Hot	R 600a	SD D	170	0	3799	South Africa
	E003/045	111	TCW3043SDD	Hot	R 600a	SD D	116	0	7523	Luxembourg
	E003/040	132	VC200SDD	Hot	R 600a	SD D	79	0	3800	UK

Table 7

Solar SDD Systems with Ice pack freezing capacity

PQS code	Capacity	Ref	Climate	Refrigerant	Power	Autonomy (hr)	IP cap	PQS cost	Manufactured
E003/042	46.6	TCW40SDD	Hot	R 600a	SDD	82	9.7	6139	Luxembourg
E003/043	79	TCW2043SDD	Hot	R 600	SDD	73	42	10500	Luxembourg

Table 8

The match between the size range required in Pakistan and the range of available WHO/PQS prequalified refrigerators is poor even if energy sources are not taken into account.

Active Vaccine Storage Devices

Matching minimum storage capacity requirements to the size ranges of available prequalified refrigerator systems, Refrigerator size ranges can be grouped as indicated in Chart 3. This comprises:

10-20 Ltr range (only 1 prequalified product. SDD type)

20-50 Ltr range (3 prequalified products: 2 AC systems with 1-2 days of autonomy and 1 SDD type)

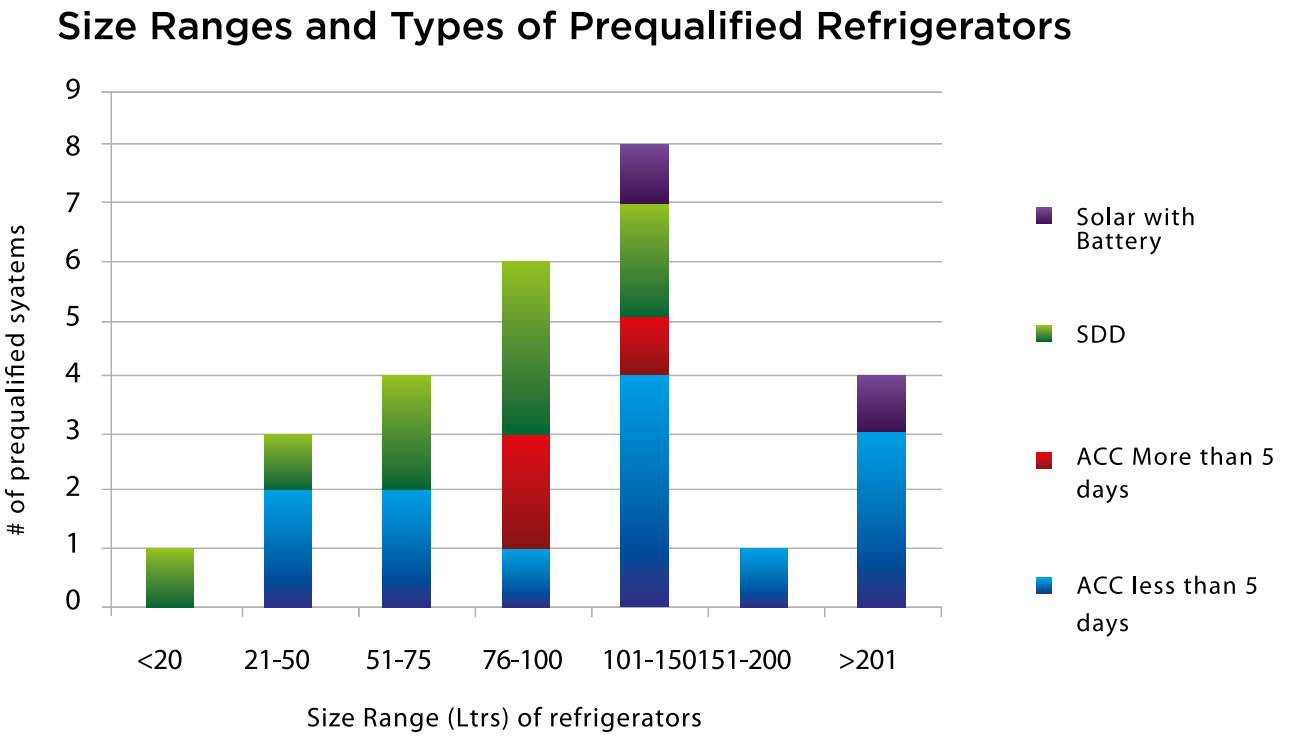
51-75 Ltr range. (4 prequalified products: 2 AC systems with 1.5 to 3 days autonomy, and 2 SDD type)

76-100Ltr range: (6 prequalified systems: 1 AC systems with 1.5 to 3 days autonomy, 2 AC systems with more than 5 days autonomy, and 3 SDD Type)

100-150 Ltr Range: (8 prequalified systems: 4 AC systems with 1 day of autonomy, 1 AC system with more than 5 days of autonomy, 2 SDD types and 2 solar type with batteries.

151-200 Ltr range: 1 prequalified system: AC systems with 1 day autonomy)

More than 200 Ltr range: (4 prequalified systems: 3 AC systems with 1-2 days of autonomy, and 1 solar type with battery.)



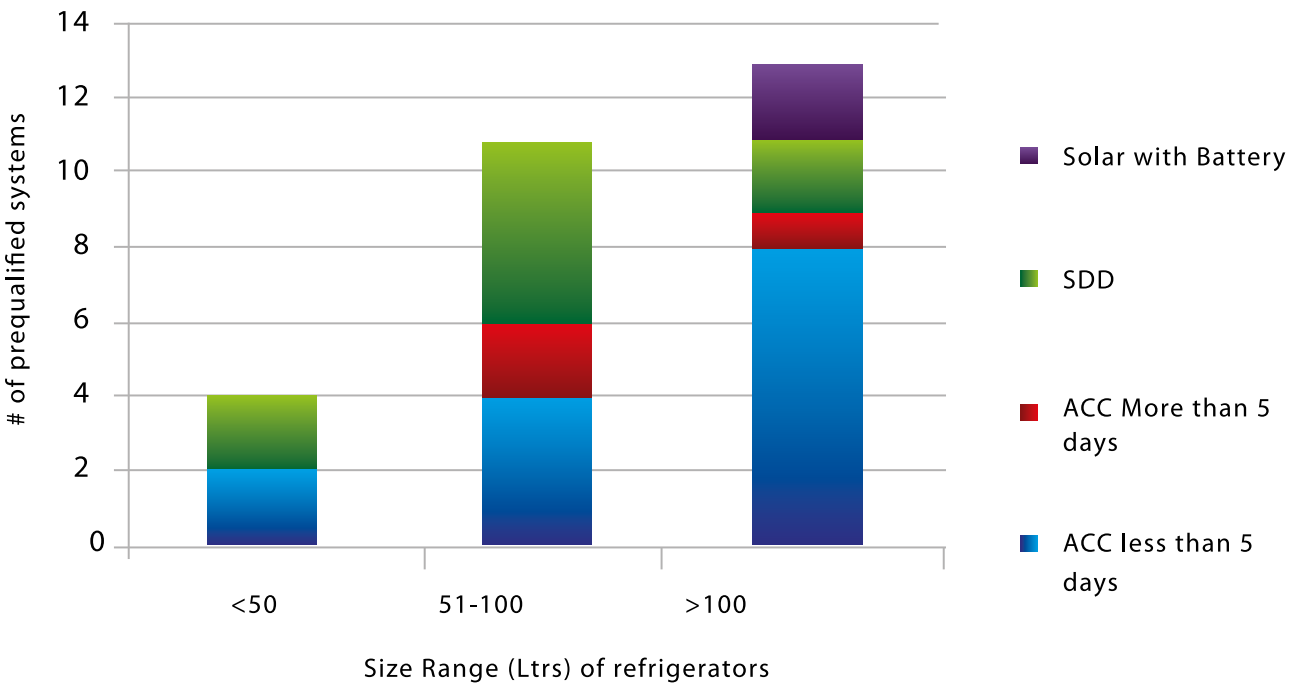
The arrangement above does not offer a sufficient range of product types in each size category; hence a broader categorization is required as indicated below in Chart 4.

1. Vaccine storage devices with a net storage volume of refrigerator compartment of less than 50Ltr

2. Vaccine storage devices with a net storage volume of refrigerator compartment of 51-100 Ltr, and

3. Vaccine storage devices with a net storage volume of refrigerator compartment of more than 100Ltr

Ranges and types of prequalified refrigerators



Annex 5: Passive containers (Cold Boxes and Vaccine Carriers) with a long "Cool Life" are used

Passive Storage Devices.

Passive storage devices are pre-qualified by WHO/PQS.

Certain passive containers retain their cold life or cool life longer than other of similar net storage capacity and also weigh more or less than others. Pakistan is encouraged to procure vaccine carriers and cold boxes which have long cold/cool life and which are not excessively heavy. This is most important as the country progresses towards using cool packs during transportation of vaccines to avoid freeze risk.

Passive storage devices may be categorized by size and Cool Life or Cold Life. Below are listed WHO/PQS prequalified passive containers (Cold Boxes and vaccine Carriers) categories by size, and highlighted by longest cool life. Ref: Table 9

Small (<3 Ltr) Passive Containers with COOL Life >9 and <14hrs.

Manufacturer	PQS	Model	(X)cm	(Y)cm	(Z)cm	Gross volume (litres)	Gross vaccine storage (liters)	Empty weight	Loaded weight	Cold life	Cool life (hrs)	Weight/ gross vol	Weight/ vacci vol
Xinxiang Dengke cold chain equipment Co., Ltd	Ecc4/033	DENCO LCX-6L	34	23.4	27.5	21.9	18	2.4	4.7	39:24:00	10:50:00	0.11	1.35
Nilkamal Limited	Ecc4/029	BCVC 43	28	28	31.5	24.7	15	2.6	4.9	41:02:00	9:30:00	0.11	1.69
SAVSU Technologies	Ecc4/039	PHD-9	27.5	27.5	31.7	28.5	21	2.56	5.57	44:30:00	11:34:00	1.09	1.22
AOV International	Ecc4/009	AVC 46	27	27	32	23.3	25	2.98	6.36	50:12:.00	9:47:00	0.13	1.21
Nilkamal Limited	Ecc4/040	BCVC46	27	27	32	23.3	27	2.32	6.4	46:23:00	13:43:00	0.10	0.85

International Vaccine Carries/Cold Boxes(>6 and <20 Ltr net Volume) with COOL life >24 hrs.

Manufacturer	PQS	Model	(X)cm	(Y)cm	(Z)cm	Gross volume (litres)	Gross vaccine storage (liters)	Empty weight	Loaded weight	Cold life	Cool life (hrs)	Weight/ gross vol	Weight/ vacci vol
Nilkamal Limited	E004/034	RCB 264 SI	65	53	46	158.5	6.7	13.25	27.34	106:00:00	30:00:00	0.08	1.97
AOV International	E004/023	ACB 264 SL	62.4	50.2	42.6	133.4	12.0	12.82	25.4	132:18:00	29:47:00	0.10	1.07
Blowing	E004/018	CB-12-CF	61	60	56	205.0	13.9	20.4	45	156:00:00	33:00:00	0.10	1.47
Nilkamal Limited	E004/025	RCB 246 LS	65	65	37	156.3	17.6	14.2	34.8	73:32:00	26:06:00	0.09	1.81

Large Cold Boxes (>20 Ltrs) with COOL life of >24 hours up to 52 hours.

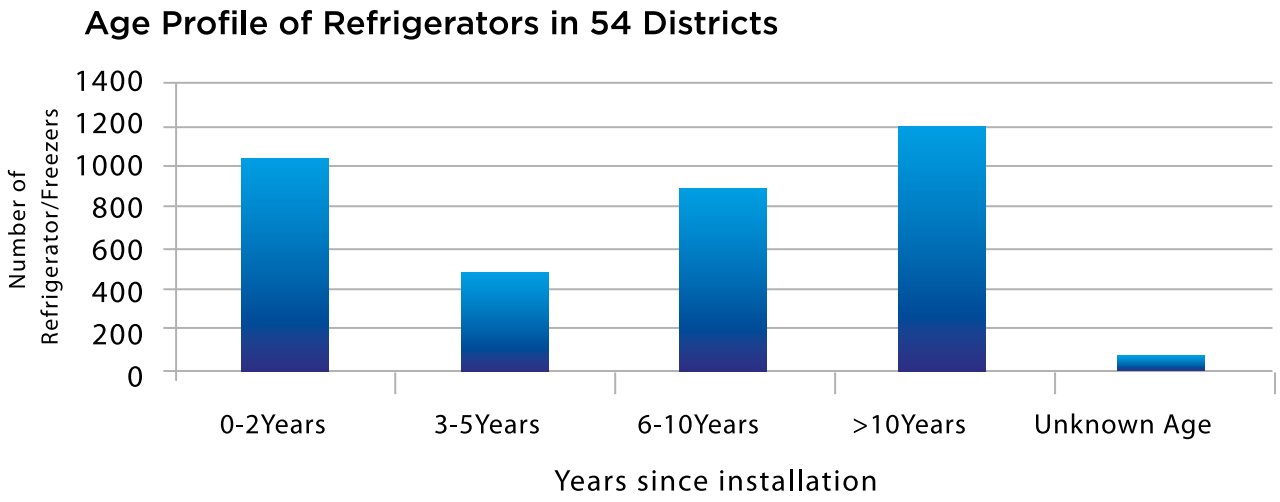
Manufacturer	PQS	Model	(X)cm	(Y)cm	(Z)cm	Gross volume (litres)	Gross vaccine storage (liters)	Empty weight	Loaded weight	Cold life	Cool life (hrs)	Weight/ gross vol	Weight/ vacci vol
Nilkamal Limited	E004/036	RCB 444L-A	77	62	53.5	255.4	20.3	20.525	49.7	152:28:00	51:17:00	0.08	1.01
AOV International	E004/014	ACB 444-L	77	61	51	239.5	22.0	21.34	46.14	147:14:00	30:39:00	0.09	0.97
Apex International	E004/010	AICB 444 L	76.1	61.1	51.3	238.5	22.5	19.93	48.87	140:00:00	25:00:00	0.08	0.89
AOV International	E004/015	ACB 503 L	77	61	51	239.5	22.5	21.78	45.86	126:30:00	28:05:00	0.09	0.97
Apex International	E004/031	AICB 503 L	76.5	61.2	51.5	241.5	22.6	19.73	48.02	127:16:00	31:08:00	0.08	0.87
Nilkamal Limited	E004/013	RIB 444 L 23	77.4	61.6	53	252.7	23.0	17	38	130:08:00	26:57:00	0.07	0.74
Aov International	E004/024	ACB 316 L	77	61.8	51.3	244.1	24.0	20.78	47.86	145:51:00	34:35:00	0.09	0.87
Blowkings	E004/025	CB-20-CF	79.5	56.2	56.5	252.4	24.4	22	49.5	138:00:00	46:00:00	0.09	0.90

Annex 6: Equipment (WHO/PQS prequalified) is sourced only from proven reputed manufacturers

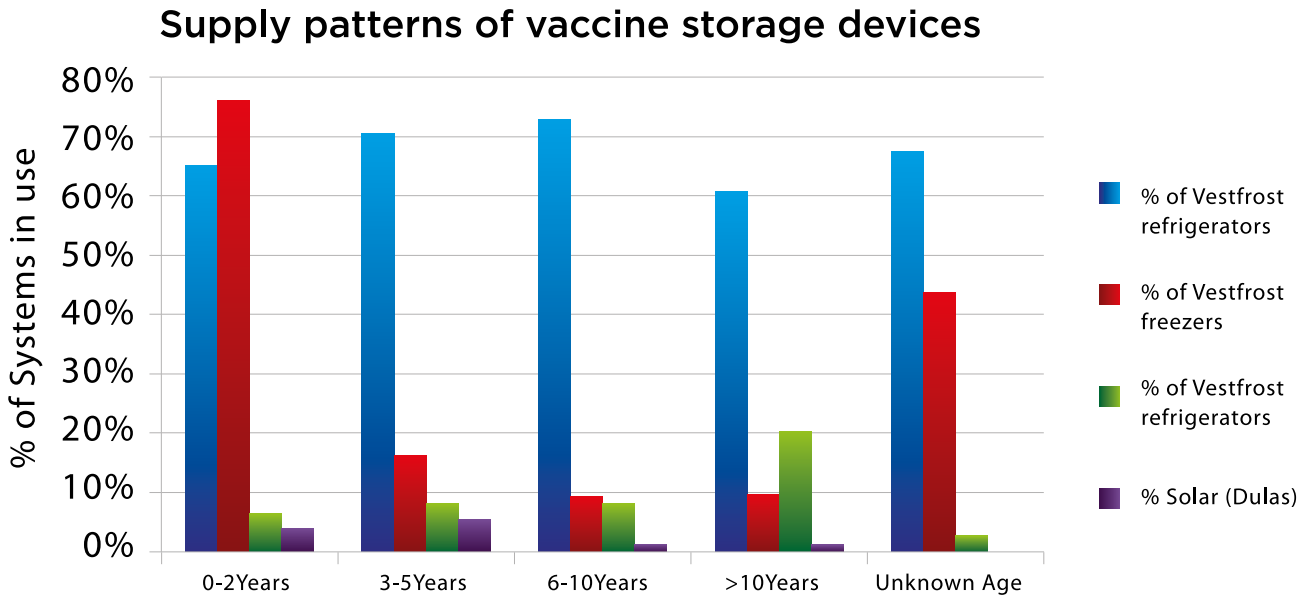
Vaccine storage devices in use in Pakistan.

88% of the 3707 vaccine storage devices inventoried in UC's of 54 districts within the CCEM survey of 2013 are categorized. The balance of 12% is from unidentified sources or erroneously classified in the inventory. 69% of the 3707 systems are identified as refrigerators used for vaccine storage and 19% as freezers. 81% of the refrigerators identified are WHO/PIS or WHO/PQS prequalified at the time of purchase, and 66% (1964 devices) were sourced from Vestfrost and 11% from Dometic. 2.6% are solar powered with batteries sourced from Dulas. Procurement patterns are consistent over the years except for the recent (<2 yr) period when more than 225 vaccine freezers have been procured.

The age profile of equipment (3707 devices) is shown in Chart 5. 34% of systems are more than 10 years old and 59% more than 5 years old.

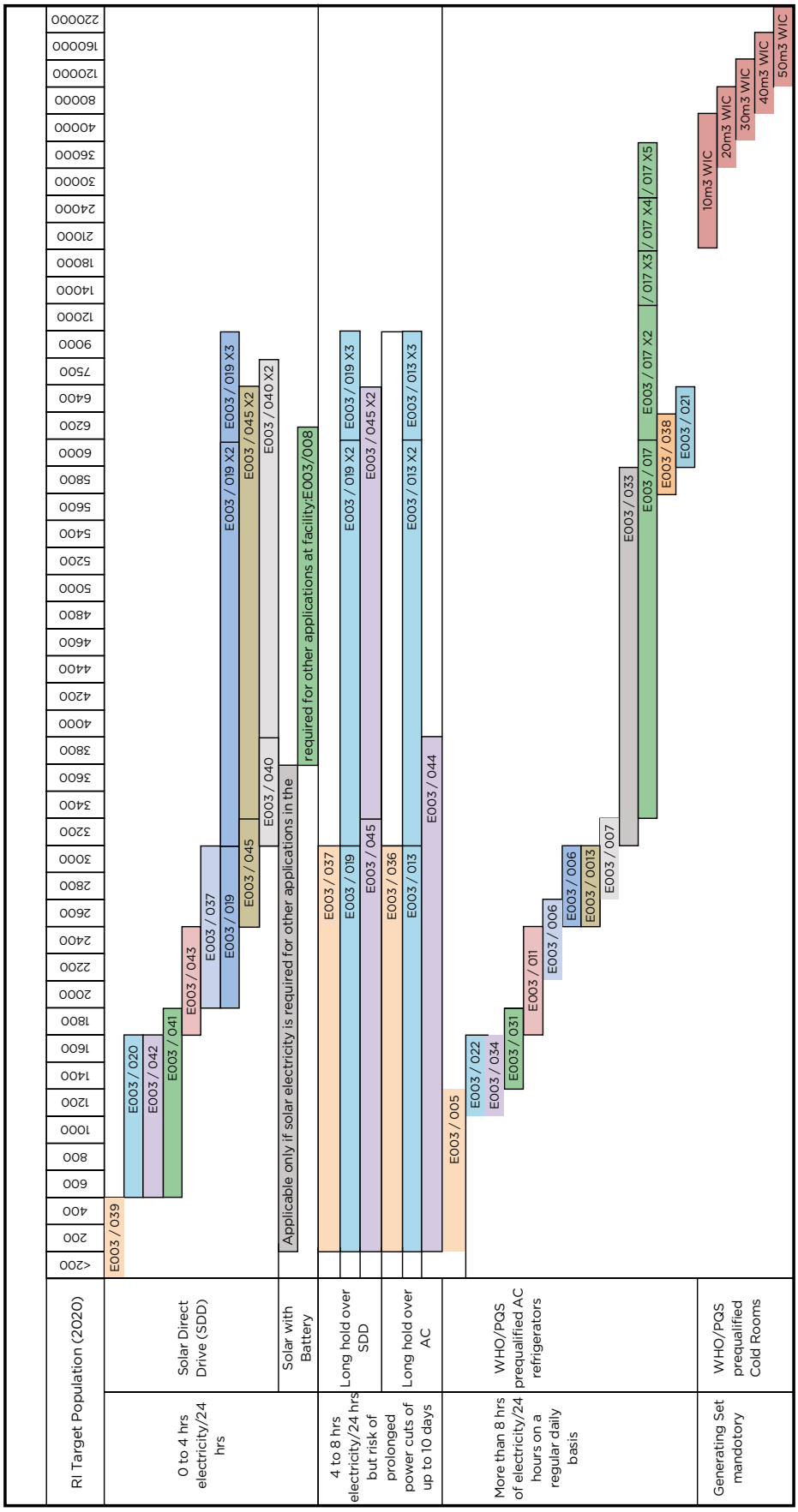


Supply patterns in terms of manufacturer and age are summarized in Chart 6.



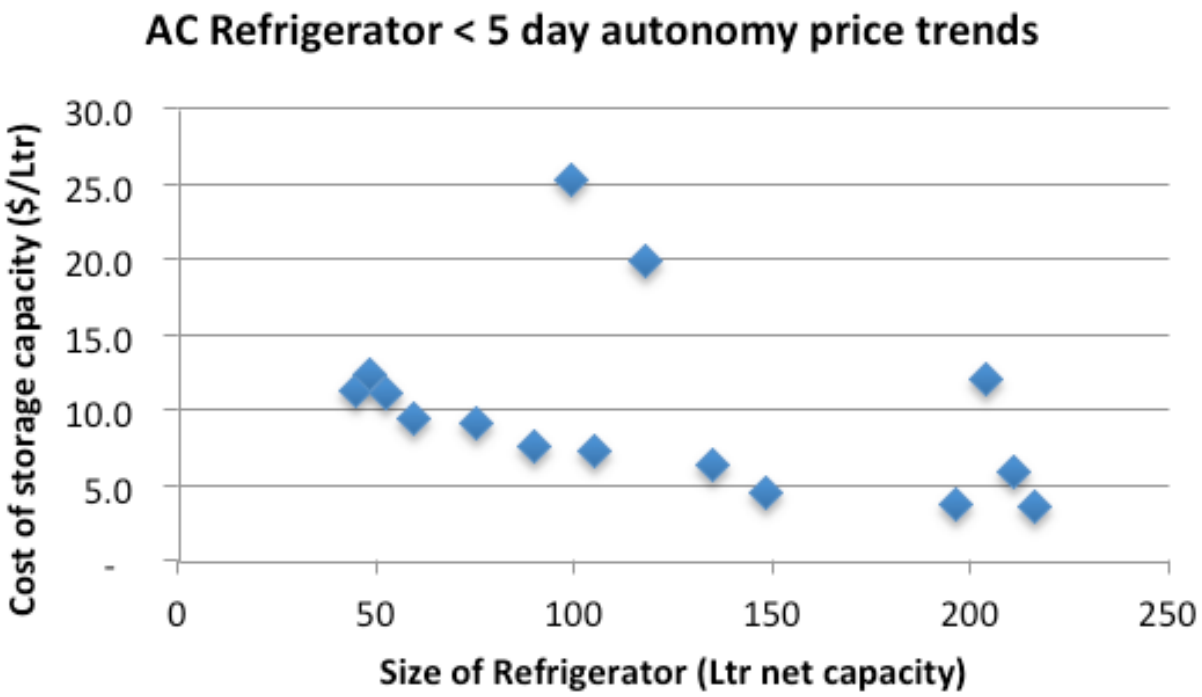
Future supply patterns

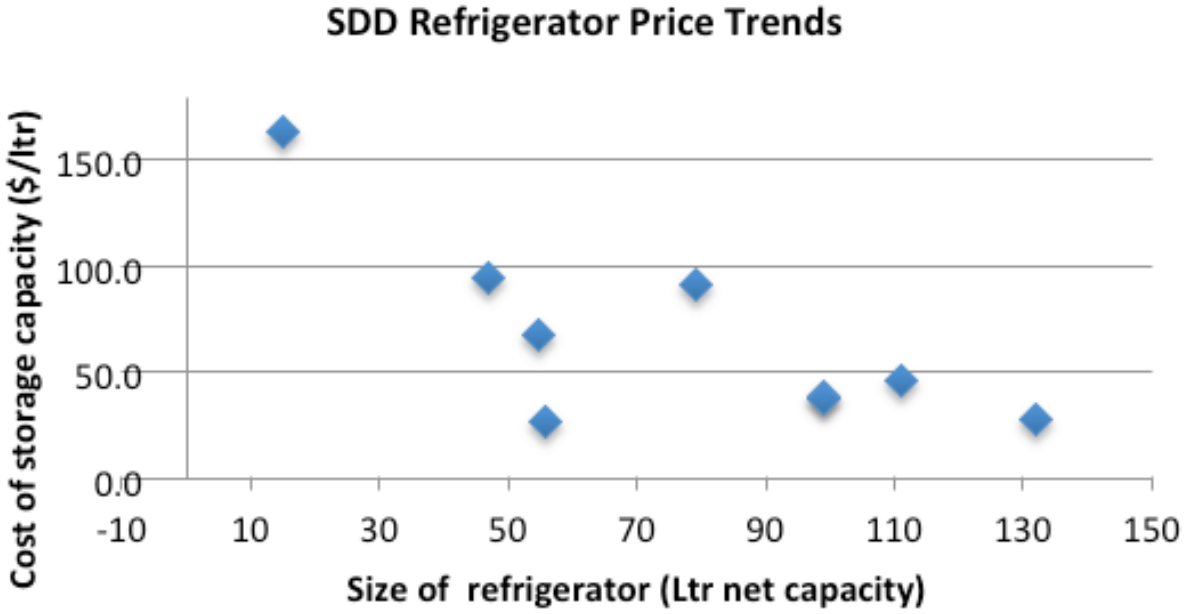
An indicative chart (Chart 7) for future supply patterns corresponding to target population sizes offers a guideline for equipment selection based upon the WHO/PQS prequalified devices catalog.


RI Target Population (2020)
0 to 4 hrs electricity/24 hrs
Solar Direct Drive (SDD)
Solar with Battery
4 to 8 hrs electricity/24 hrs but risk of prolonged power cuts of up to 10 days
Long hold over SDD
Long hold over AC
More than 8 hrs of electricity/24 hours on a regular daily basis
WHO/PQS prequalified AC refrigerators
Generating Set mandotory
WHO/PQS prequalified Cold Rooms
<200
200
400
600
800
1000
1200
1400
1600
1800
2000
2200
2400
2600
2800
3000
3200
3400
3600
3800
4000
4200
4400
4600
4800
5000
5200
5400
5600
5800
6000
6200
6400
7500
9000
12000
14000
18000
21000
24000
30000
36000
40000
80000
120000
160000
220000
E003 / 039
E003 / 020
E003 / 042
E003 / 041
E003 / 043
E003 / 037
E003 / 019
E003 / 045
E003 / 040
Applicable only if solar electricity is required for other applications in the
E003 / 019 X2
E003 / 019 X3
E003 / 045 X2
E003 / 040 X2
required for other applications at facility:E003/008
E003 / 037
E003 / 019
E003 / 045
E003 / 036
E003 / 013
E003 / 044
E003 / 019 X2
E003 / 019 X3
E003 / 045 X2
E003 / 013 X2
E003 / 013 X3
E003 / 005
E003 / 022
E003 / 034
E003 / 031
E003 / 011
E003 / 006
E003 / 0013
E003 / 007
E003 / 033
E003 / 017
E003 / 017 X2
/ 017 X3
/ 017 X4
/ 017 X5
E003 / 038
E003 / 021
10m3 WIC
20m3 WIC
30m3 WIC
40m3 WIC
50m3 WIC

Annex 7: Procured storage devices provide “best value for money” in terms of $/ltr of net storage capacity, quality and performance rather than lowest capital cost.

There are strong economic reasons to supply refrigerators to locations that are larger than the minimum net volume requirement. As refrigerators increase in size, the cost/ltr of net storage space tends to reduce. In the case of AC refrigerators a four fold increase in storage capacity results in a 3 fold reduction of cost/litre of storage capacity. Similar and even more exaggerated trends apply to SDD refrigerators. Ref





Annex 8: All vaccine refrigerators are installed, maintained, monitored and used correctly by adequately trained personnel.

Training

The Effective Vaccine Management (EVM) assessment conducted in April/May 2014 concluded that:

50% of the staff working in the SN stores did not receive any kind of training during the review period.

39% of health workers from 54 facilities received formal or on the job training within the review period and documentary evidence supports this in 90% of the cases.

Province specific rollout training plans have been developed for training of >900 federal, provincial, district and UC levels officials (5 Provinces/FATA + 54 districts + 423 Lead UCs) on WMS and Vaccine Data Entry in the 1st half of 2014.

Training is required for all health workers on proper vaccine management practices and new practices related to temperature monitoring.

Maintenance

The EVM also concluded that maintenance standards and knowledge was notably weak at all levels of the vaccine supply chain except at the central store. Performance ratings are indicated in Error! Reference source not found.

Indicator	Primary Store (PR)	Provincial Stores (SN1, SN2, SN3)	Districts (LD)	Health Facilities (SP)	National Average
Maintenance and Repair (E5)	99%	53%	51%	50%	51%

In most of the provincial and district sites visited, there was no preventive maintenance planned (PPM) program neither for the buildings nor for refrigeration equipment. Only 2 (3%) of assessed locations had a written planned preventive maintenance (PPM) program for buildings and refrigeration equipment.

The performance of the maintenance criteria for the 61-service delivery points assessed was 51%, ranging from a minimum of 0% to a max of 98%.

From a sample of 53 sites, 21 displayed evidence of a facility maintenance program, however there are no written plans or maintenance record except for perhaps 1 isolated case. A similar situation exists for refrigerator maintenance except that 18 facilities have designated responsible persons. Regardless of this apparently inadequate maintenance framework, refrigeration equipment was functional at almost all service delivery facilities and more than 50% of systems were recently defrosted and cleaned.

Functional refrigeration equipment was identified at 59 facilities; status of equipment at the other 2 service delivery facilities is unknown and 29 facilities have icepack freezers all of which function.

In some situations maintenance is not managed directly by EPI hence procedures, manuals, records etc are not maintained at service delivery facilities.

Recommendations for improvement of the maintenance system comprised:

- Develop a comprehensive multi-year or annual preventive maintenance plan for buildings, cold chain equipment and vehicle;
- Routine maintenance should be carried out regularly with well documentation at all levels.
- Data generated from CCEM should be incorporated in the module of vLMIS and ensure up to date equipment status is available and maintenance performed.
- Achieve poliomyelitis free status (as spelled out in cMYP 2014 – 18)
- By 2015, interrupt indigenous wild poliovirus transmission nationally.
- By 2018, certification of poliomyelitis eradication.
- Meet global and regional elimination targets
- 2018: Neonatal tetanus elimination achieved (as spelled out in cMYP 2014 – 18)
- 2015: Measles elimination achieved (This is regional goal. In cMYP the goal is set for 50% reduction in mortality and morbidity due to measles by 2018 in comparison to 2012)
- Meet vaccination coverage targets in every region, country and community (DOV goal)
- 2015: Reach 90% national coverage and 80% in

every district or equivalent administrative unit with three doses of diphtheria-tetanus-pertussis containing vaccines

- 2020: Reach 90% national coverage and 80% in every district or equivalent administrative unit with all vaccines in national EPI programmes
- Introduce new and improved vaccines and technologies (modified from DOV goals as country already achieved the DOV goals)
- 2015: At least two or more new or underutilized vaccines are introduced in the routine immunization schedule
- 2020: At least three or more new or underutilized vaccines are introduced in the routine immunization schedule

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